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Abstracts from the 2024 EAHP Congress

National poster winner abstracts

NP-001 EXTEMPORANEOUS FLUCYTOSINE 15.5% INTRAVAGINAL GEL TO TREAT REFRACTORY *CANDIDA GLABRATA* VULVOVAGINTIS – CASE REPORT

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10.1136/ejhpharm-2024-eahp.1

Background and Importance *Candida glabrata (C. glabrata)* is the second leading cause of vulvovaginal candidiasis (8% of cases).[1–5]

Recommendations to treat azole resistance (AR) *Candida glabrata* (*C. glabrata*) vulvovaginal candidiasis (VVC) are intravaginal boric acid capsules (first-line), intravaginal nystatin suppositories (second-line) and, as third-line, flucytosine cream (17% or 15.5%) or amphotericin B cream.[1–4]

Vaginal flucytosine and amphotericin are not commercially available, so an extemporaneous formulation has to be developed.

Aim and Objectives To compound flucytosine 15.5% intravaginal gel and to evaluate the effectiveness and safety in an AR C. *glabrata* VVC patient.

Materials and Methods Literature review to investigate the above-mentioned compounding magistral formulations.

Effectiveness and safety were assessed by clinical monitoring, analytical monitoring and patient interview.

Results A 47-year-old woman with recurrent VVC since March 2020 was treated with oral fluconazole, oral lactobacillus/lingonberry and multiple intravaginal drugs (clotrimazole, nifurantel, nystatin, benzydamine, estriol + lactobacillus and boric acid). In March 2022, a *C. glabrata* strain was isolated, exhibiting antifungal sensitivity only to caspofungin, flucytosine and micafungin.

Four flucytosine formulations for vaginal application were identified in literature.[5–8] We compounded flucytosine 15.5% gel by reducing fourteen 500 mg flucytosine tablets to a fine powder in a mortar. The powder was then moistened with 5 mL of glycerin to form a smooth paste, which was then added to 40 g of a lubricating vaginal gel base. Shelf-life of was given for 14 days, stored at room temperature. Vaginal applicators were used to apply the gel intravaginally at bedtime for 19 days.

During this period, three active pharmacovigilance interviews were carried out to verify tolerability and side effects. The patient reported only vaginal discharge, no pain, pruritus or rash.

Analytical evaluation (blood count, renal and hepatic function) was performed, without revealing any change. Vaginal culture was negative at week 2, 4 and 6 after treatment. The patient remained asymptomatic until the last evaluation in August 2022.

Conclusion and Relevance The flucytosine 15.5% intravaginal gel formulation fulfilled an unmet need, enabling the effective resolution of AR C. glabrata VVC.

The active monitoring of its use allowed us to collect real context data on safety, verifying the absence of adverse effects and good tolerance.

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NP-002 ABSTRACT WITHDRAWN

NP-003 PATIENT MEDICINE GUIDES SUPPORT SAFE MEDICATION TREATMENT AND DISCHARGE FROM THE HOSPITAL IN PAEDIATRIC SPECIALISED MEDICAL CARE

AS Anna Santamäki*, SF Sanni Fagerroth, VT Venla Töyräs, SK Sini Kuitunen. *HUS Pharmacy Helsinki, Finland*

10.1136/ejhpharm-2024-eahp.3

Background and Importance Children are susceptible to medication deviations and adverse drug events. Several high-risk medicines are used both in hospitals and at home with paediatric patients. Written medication instructions play a key role in ensuring medication safety during the hospital period and after discharge, as many medications are unlicensed or used off-label in paediatrics.
Aim and Objectives The goal was to produce uniform and reliable medication guides for both clinical and home use.
Materials and Methods Pharmacist prepared the guide using the department's previous instructions, manufacturer's product summaries and national databases as a background. The content and structure were based on the needs and questions raised during the patient guidance and were evaluated multiprofessionally.
Results The paediatric organ transplant drug guide was developed first and contains information on the practical instructions for medication treatment at home. The medication guide is given to each family and is also available to other hospital districts and pharmacies through the national database. Warfarin and enoxaparin patient instructions have later been developed using the same ideology. Pictorial instructions provide support and certainty for the use of high-alert medicines at home by, for example, reducing errors in dose calculations. The most recent paediatric cancer medication guide also includes pictorial instructions on the safe handling of chemotherapy drugs at home. As a result of the medication guides, hazardous situations and contacts to the hospital after discharge have decreased.
Conclusion and Relevance Patient medicine guides enable reliable drug information for families and practitioners. With the help of the materials, the family can practice handling medicines safely already in the department. Written material and medication counselling should be given well in advance before discharge, so that the families have time to adopt given information and ask follow-up questions.

NP-004 PALL-OLU.DE: A NEW DATABASE ON THE OFF-LABEL USE OF DRUGS IN PALLIATIVE MEDICINE

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10.1136/ejhpharm-2024-eahp.4

Background and Importance The main focus of palliative care (PC) is the relief of distressing symptoms. Up to 50% of drugs are used off-label (OLU); yet only a limited part of these uses is supported by official recommendations such as guidelines.

The efficient search for evidence-based information is therefore particularly important for treatment planning. However, in everyday clinical practice, health care professionals often lack the time and resources for such research.
Aim and Objectives The aim is to provide healthcare professionals with evidence-based therapy recommendations for OLU in palliative care through the database pall-olu.de.
Materials and Methods Relevant drugs and their OLU in PC are identified using a systematic approach. Treatment recommendations are subsequently developed based on the best available evidence and agreed through a web-based, two-round Delphi panel process with international PC experts. The final off-label treatment recommendations are presented in drug monographs and include additional information, e.g. on monitoring or alternative medical and non-medical treatment options.
Results The first 38 treatment recommendations were agreed upon in 2022. 70 experts participated in each round (response rate: first round 72.9%/second round 67.9%). Since 2023 recommendations are accessible free of charge on pall-olu.de. In total, the aim is to publish around 400 treatment recommendations for around 80 drugs. A smartphone app is under development.
Conclusion and Relevance pall-OLU.de provides easy access to evidence-based information. The database fills an information gap and makes an important contribution to safe and effective pharmacotherapy in PC.

Funding German cancer aid (Fördernr. 70113910).

NP-005 UNAUTHORISED MEDICATION USE IN ESTONIAN HOSPITALS

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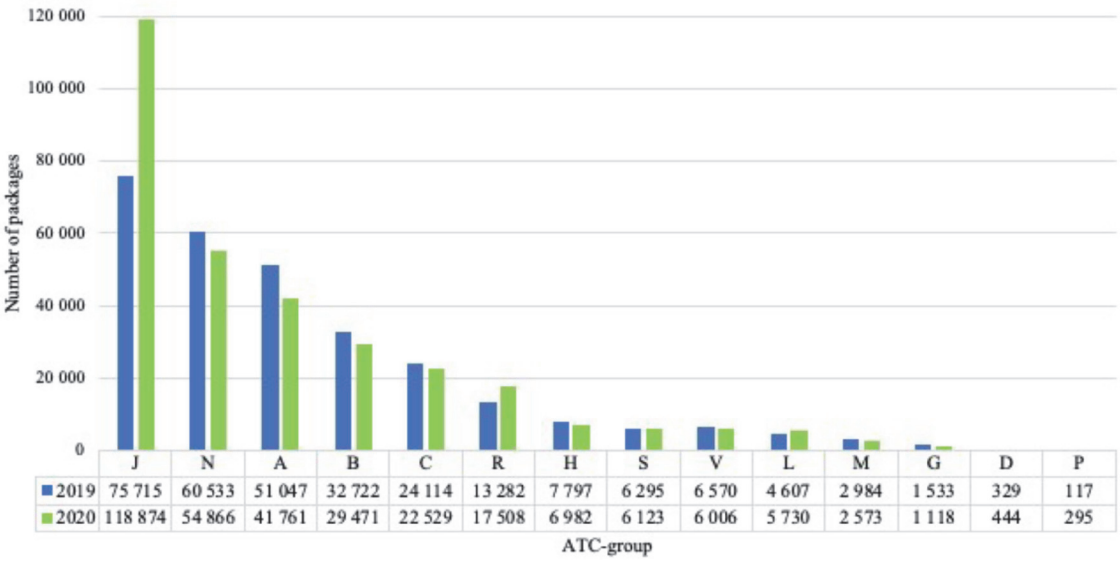
10.1136/ejhpharm-2024-eahp.5

Background and Importance Unauthorised medication use is often inevitable in Estonia owing to the small local pharmaceutical market, supply difficulties etc. Due to the absence of Summary of Product Characteristics in Estonian language and foreign language package of unauthorised medications, several problems related to the use of these medications may arise. However, no research on this topic has been carried out in Estonia.
Aim and Objectives The aim of this study was to find out how much and which unauthorised medications were used in Estonian hospitals in 2019–2020. The objective was to find out: 1) How many packages of unauthorised medications were used; 2) Which were the most used Anatomical Therapeutic Chemical (ATC) groups; 3) What was the most used active ingredient; 4) What were the most used administration routes and dosage forms.
Materials and Methods Data regarding the use of unauthorised medications in Estonian hospitals in 2019–2020 were obtained from the Estonian State Agency of Medicines and was analysed by the number of packages using Microsoft Excel software.
Results 286 719 and 313 793 packages of unauthorised medicines were used in 2019 and 2020, respectively, which



Abstract NP-005 Figure 1 The number of packages of unauthorised medications issued to hospital pharmacies in 2019–2020, arranged by ATC-groups

constitutes approximately 12% of all imported medications in Estonian hospitals in both years. The most used ATC-groups in 2019–2020 were anti-infectives for systemic use, nervous system and alimentary tract and metabolism. The most used active pharmaceutical ingredient was oxacillin in both years. Unauthorised medications in hospitals were administered mainly parentally (approximately 75% of all packages) and the most used dosage form was solution for injection.

Conclusion and Relevance The importance of this work lies in studying the use of unauthorised medications use for the first time in Estonia, similar studies in other countries were not found. As a result of this study, we have information on which unauthorised medications are used the most in Estonian hospitals. Therefore it is possible to improve handling of these medications, for example using labels on packages with the most important information about the specific medication in Estonian language.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

NP-006 DRUGHOST, THE FIRST DATABASE OF UNAVAILABLE DRUGS IN EUROPE – AN ITALIAN MODEL: DATA 1 YEAR AFTER THE START OF THE PLATFORM

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10.1136/ejhpharm-2024-eahp.6

Background and Importance Drug shortages are a global problem; all types of drugs are liable for shortages with multifactorial causes such as supply, demand, and sometimes regulatory issues. Regulatory agencies, associations, and governments have developed various policies, programmes, research studies, and guidelines to address the issue. However, the phenomenon is growing, representing a problem for access to therapies. Our team was the first in Europe to develop a web platform called DruGhost for monitoring unavailable drugs, distinguished for the first time from shortages, proving to be a valid tool for monitoring the phenomenon and related management.

Aim and Objectives The web-based platform, integrated into a national portal for Italian pharmacists (SIFO), collects all reports of unavailable medicines to map their progress and take actions.

Materials and Methods All hospital pharmacists have access to the platform to submit reports, which are published if the necessary conditions are met. These conditions include that the medicine cannot be on the list of shortages, the order date cannot be older than 15 days, and the company must have received one prompt. Concurrently with the validation and publication of the report, the company receives an alert. The data is shared with the national regulatory agency, Agenzia italiana del farmaco (AIFA), with the aim of providing timely information for the possible adoption of rapid measures, especially for orphan, innovative, and life-saving drugs.

Results In the first year following the platform's introduction in Italy in 2022, 17,563 reports were received. Out of the total number of reports, 1,214 were effective reports of unavailable drugs, the remaining, in fact, referred to shortage of drugs already published by AIFA, duplicate reports and, some, were considered non-compliant. 90 reports of unavailability referred to orphan drugs, and 92 others to drugs we have witnessed the transition from unavailable to shortage. Analysing the data for first-level of ATC, it appears as follows: 25% nervous system (N), 15% antineoplastic and immunomodulators (L), and 4% blood drugs and haematopoietic organs (L), followed by lower percentages for the other classes.

The reports are growing exponentially. Our team's aims, among others, is to identify early alerts and adopt preventive measures to guarantee constant access to treatment.

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NP-007 VALIDATION OF ANTIMICROBIAL DEFINED DAILY DOSE FOR THE PAEDIATRIC POPULATION: FINAL RESULTS OF KIDDDS PROJECT

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10.1136/ejhpharm-2024-eahp.7

Background Antimicrobial stewardship programmes (ASPs) optimise antimicrobial use, improve patient outcomes, and reduce resistance. To assess the effectiveness of ASPs, it is necessary to have indicators that can be widely used. Defined daily dose (DDD) was designed by the World Health Organization for the adult population as a consumption indicator.
Objectives Validate the tool designed in phase I of the KiDDDs project to establish the most appropriate DDD values in the paediatric population.
Material and Methods This is an observational, retrospective, multicentre study consisting of two phases. The first phase was aimed at the theoretical calculation of paediatric DDD. The second phase constitutes the validation of the study.

Antimicrobial prescriptions were collected from the wards of seven Spanish hospitals during 2017 and 2018. Studied variables were age, gender, weight, antimicrobial dose, frequency and route of administration. Those antimicrobials included in the first stage were considered.

From the data collected, the total dose of antibiotic received per patient (mg/day) was calculated, subsequently, the median of the resulting DDD per antibiotic (g/day) was obtained (DDD-Phase II) and were compared with the theoretical DDD (DDD-Phase I).

Abstract NP-007 Table 1

The selection criteria of the optimal DDD value are shown in table 1. **POWER VALUE**	**PHASE-DDD I SELECTED**	**PHASE-DDD II SELECTED**
>80%	No significant differences (p>0.01)+Clinical difference magnitude (<10%)	Statistically significant differences (p<0.01)+Clinical difference magnitude (>10%)
Statistically significant differences (p<0.01)+Clinical difference magnitude (<10%)		
No significant differences (p>0.01) +Clinical difference magnitude (>10%)+Degree of agreement (>75%)		
≤80%	Degree of agreement (>75%)	Not apply

NP-008 CASE REPORT: SINGLE-USE CRANIAL DRILLS, HIGH-RISK DEVICES!

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10.1136/ejhpharm-2024-eahp.8

Background and Importance Single-use cranial drills are used in neurosurgery to perforate cranial bones. From June 2018 to October 2020, 18 adverse events (AEs) were recorded in our hospital, seven of which resulted in a material safety (MS) declaration to the *Agence Nationale de Sécurité du Médicament et des produits de santé* (ANSM) for risk of cerebral damage.
Aims and Objectives We aimed to analyse the causes of these AEs in order to propose corrective and preventive measures.
Materials and Methods MS data were analysed chronologically, and the various people involved in the circuit were contacted. Other healthcare establishments were questioned in order to obtain feedback on the management of this type of AE. At the same time, a search of MS data via the American MAUDE database was carried out for the period, targeting the devices used in our centre. We then performed a causal analysis using the 5M method and an Ishikawa diagram.
Results We identified several modes of possible failure: (i) connection between chuck and motor may be loose; (ii) different types of material for the connection tip may influence the behaviour of the device; (iii) an added manual rotation movement during the surgical gesture; (iv) non-perpendicular placement of the device; (v) inappropriate rotation speed, and the thickness of the cranial bone.

Research via MAUDE showed 13 notifications of incidents of non-disengagement over the period.
Conclusion and Relevance Single-use cranial drills require careful handling for optimum disengagement. The material causes have been identified, but the human component cannot be ruled out. Corrective measures have been implemented to reduce the risk of these AEs, including a change of supplier and training for the medical team. Preventive measures also need to be developed such as revised selection criteria for the next call for tenders, or best practices audits in the operating room.

The impact of these corrective and preventive measures will be assessed though AEs monitoring.

NP-009 BARRIERS AND FACILITATORS TO PHARMACY PROFESSIONALS' SPECIALIST PUBLIC HEALTH SKILLS: A MIXED METHODS UK-WIDE PHARMACEUTICAL PUBLIC HEALTH EVIDENCE REVIEW

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10.1136/ejhpharm-2024-eahp.9

Background and Importance In the UK and globally pharmacy professionals (PPs) contribute to the delivery of local and national public/population health (PH) interventions.[1] However, there is paucity of information to what extent PPs have specialist/advanced skills/roles within PH practice.
Aim The mixed methods review, commissioned by the UK Chief Pharmaceutical Officers in 2020, aimed to explore PPs' specialist PH contributions including barriers and opportunities.
Methods Databases available through PubMed were searched to retrieve articles published in English (2011- 2021) on seven topics including: emergency preparedness resilience and response (EPRR); integrating pharmacy to better support

public health protection and improvement goals; public health skills and mitigating health inequalities.

Two independent electronic surveys were developed, piloted and deployed for pharmacy and public health specialists via email cascade and social media. The surveys explored the extent to which PPs are involved in PH roles including the barriers and opportunities.

Descriptive statistics summarised the data, and open-ended responses were themed. UK Health Research Authority tool identified ethics approval was not required; questionnaire included consent request.

Results Rapid Evidence reviews: Following assessment of 2,542 articles, 448 evidence statements were extracted from 135 relevant articles. They were predominantly from the USA (39%) and the UK (29%), with fewer high-quality reviews (17) or guidance (12), than moderate/low-quality reviews (42), single studies (33), or quantitative research (33).

Pharmacy and PH professionals Surveys: There were UK-wide responses from 128 PPs and 37 PH specialists. Responding pharmacists were from primary-care (34%, 43), secondary-care (26%, 33), community pharmacy (13%, 16), and PH bodies (13%, 16). Opportunities identified by PPs included: PH areas they directly contribute to (45%); qualifications, knowledge and skills (27%); strategic position in the community (19%), recent changing health landscape (4%). Barriers included lack of defined career pathway (20%); poor professional recognition (18%); limited resources (16%); lack of training and support (15%) and organisational and structural barriers (10%). Majority of the PHPs stated that it would be beneficial or very beneficial to have PPs specialising in PH (83%).

Conclusion and Relevance Pharmacy professionals make specialist contributions to PH despite barriers. Dedicated Pharmaceutical PH training and system-wide leadership are required to fully realise population-level benefits. Low responses to the surveys present a study limitation, however, there was consensus from the themes emerging from both surveys and rapid evidence reviews findings. Further investigation is required to identify how best to deploy advanced PPH resources. Future qualitative studies should be considered.

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NP-010 COMPATIBILITY OF LOCAL ANAESTHETIC AND CORTICOSTEROID MIXTURES IN TRANSFORAMINAL EPIDURAL STEROID INJECTIONS

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Background and Importance CT-guided transforaminal epidural steroid injection (TFESI) has become increasingly used in the treatment of radicular pain. Choice of pharmacologic agents for this procedure faces several issues, one of them is compatibility of local anaesthetic and corticosteroid mixture.

Aim and Objectives We aimed to assess the compatibility of local anaesthetic and corticosteroid mixtures that are used in TFESI.

Materials and Methods First, we conducted a literature search. In the experimental part of our study, local anaesthetics (lidocaine, bupivacaine, levobupivacaine, trimecaine) and corticosteroids (particulate: betamethasone, methylprednisolone acetate; non-particulate: dexamethasone) for injection available in Slovakia were used. Each local anaesthetic was mixed with each corticosteroid in the syringe using 1:1 and 1:3 volume ratio at room temperature. Formation of crystals in the mixture was observed visually and was confirmed with a microscope. The size of the crystals was determined using a microscope slide with a micrometre scale.

Results Based on a literature search alone we could only identify incompatibility between betamethasone and levobupivacaine and compatibility of mixtures of lidocaine and dexamethasone. *In vitro* we observed a turbidity after mixing lidocaine with dexamethasone in 1:1 ratio, but it was only transient. Precipitation of crystals was observed after mixing dexamethasone with bupivacaine, levobupivacaine and trimecaine. After mixing particulate corticosteroids (betamethasone and methylprednisolone acetate) with local anaesthetic suspension, particles formed big clusters (>> 100 μm).

Conclusion and Relevance In our *in vitro* experiment we confirmed compatibility of the mixture of lidocaine and dexamethasone as described in literature. Incompatibility between dexamethasone and bupivacaine, levobupivacaine and trimecaine was identified *in vitro*, although not reported in literature. Mixtures of local anaesthetic and corticosteroid are potentially unsafe due to possible incompatibilities. Caution is warranted during their use in TFESI. Separate administration of these two drug classes as recommended by some experts would overcome the issues of possible incompatibility of the mixture.

NP-011 LINEZOLID THERAPEUTIC DRUG MONITORING AMONG CRITICALLY ILL ADULT PATIENTS AFTER CARDIOVASCULAR SURGERY

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10.1136/ejhpharm-2024-eahp.11

Background and Importance Sepsis-induced pathophysiological changes can result in serious alterations in the pharmacokinetic parameters of antibiotics. Drug exposure is consequently difficult to predict in critically ill septic patients. The latest *Surviving Sepsis Campaign* guidelines recommend routine therapeutic drug monitoring (TDM) to optimise antibiotic therapy in this patient population. Linezolid is an oxazolidinone antibiotic used to treat infections caused by gram-positive bacteria. The prevalence of its adverse effects is associated with higher exposure, while suboptimal concentrations can lead to treatment failure and an increased risk of clonal evolution of resistant strains.

Aim and Objectives Our aim was to determine optimal dosing strategies among critically ill septic patients after high-risk cardiovascular surgery treated at the intensive care units of a national cardiovascular surgery centre based on TDM results.

Materials and Methods We retrospectively analysed the data of patients treated at our centre from April 2022 to August 2023. A total of 15 patients (11 men, four women) receiving empiric or targeted linezolid therapy guided by TDM were included. Blood samples were centrifuged immediately after being collected, and serum linezolid levels were measured within 24 hours. Trough levels were evaluated when using an intermittent dosing regimen, while blood was taken at random times after reaching the steady state when a continuous infusion was applied.

Results Dose adjustments were performed in 11 patients based on TDM results. Optimal linezolid exposure was only achieved when higher doses (1800–2400 mg/24h) were administered by continuous infusion. This regimen, which was subsequently introduced into routine care, led to linezolid overexposure in a single patient. Dose reduction with clinical improvement was accomplished in three patients. Serum linezolid levels showed no correlation with kidney function, age, or gender.

Conclusion and Relevance Optimal linezolid exposure often cannot be achieved with standard dosing regimens in critically ill patients after high-risk cardiovascular surgery. Higher doses and continuous infusion regimes may be required in this population. TDM is an important tool for guiding therapy.

NP-012 IMPROVING THE CLINICAL PHARMACIST HANDOVER PROCESS USING AN ADAPTED ISBAR COMMUNICATION TOOL WHEN TRANSFERRING PATIENTS FROM CORK UNIVERSITY MATERNITY HOSPITAL (CUMH) TO AN INTENSIVE CARE UNIT (ICU) WITHIN CORK UNIVERSITY HOSPITAL (CUH)

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Introduction Clinical handover has been identified, both nationally and internationally, as a high-risk step in a patient's hospital journey. Barriers such as poor communication can contribute to variations in practice.[1]

The use of different electronic healthcare records between CUMH and the ICU in CUH can lead to timely and ineffective handover. In order to ensure clinical handover of critical patients from CUMH to CUH is not jeopardised, an ISBAR tool was adapted to standardise the patient handover process between clinical pharmacists.

Aims

- To implement a communication handover tool for pharmacists, to optimise patient safety and reduce risk of error or miscommunication between electronic healthcare records, when critically unwell patients are transferred from CUMH to the CUH ICU.
- To determine the benefit of this tool by assessing pharmacist responses.

Method The National Clinical Guideline ISBAR communication tool[2] was adapted for pharmacist use in CUMH for safer transfer of obstetrics and gynaecology patients and their identified requirements.

To evaluate the benefit of the tool, a survey questionnaire was distributed to ICU pharmacists for feedback.

Conclusion At time of abstract submission, the ISBAR tool was newly implemented. Feedback from users was limited but positive.

Since implementation in January 2023, the ISBAR tool was completed for 100% of patients transferring to ICU.

Pharmacist feedback reported satisfaction with the communication method, usability of the tool, accuracy and efficiency of the handover.

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Conflict of Interest No conflict of interest.

1ISG-001 ANALYSIS OF THE USE OF ORAL ONCOLOGY TARGETED THERAPIES IN A REGION OF SPAIN

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Background and Importance Individualised treatments are the most important oncology pharmacotherapeutic innovation nowadays. The high cost of such treatments may hinder their incorporation into clinical practice.

Aim and Objectives To analyse the impact of the incorporation of oral oncology targeted therapies (OOTT) into routine clinical practice in a region.

Material and Methods Retrospective, descriptive study of the uptake and economic impact of OOTT between 2012 and 2022.

Analysis of incorporation and economic impact included OOTT for six molecular targets, which were dispensed in Hospital Pharmacy Services. ALK/ROS1 mutations were analysed together because the indication of OOTT could not be identified.

Regional consumption registers were used as a source of data.

Results Available OOTT options increased by 500%, with 18 authorised drugs at the end of the study. In 2012–2013, only ALK/ROS1 and EGFR drugs were available. BRAF and MEK drugs were added in 2014 and BRCA drugs in 2015.

The percentage of treatments used (greater than 10%) by mutation are shown in table 1.

Abstract 1ISG-001 Table 1

Mutation	Beginning of the study	End of the study
ALK/ROS1	Crizotinib (100%)	Alectinib (44%), lorlatinib (26%), crizotinib (15%)
EGFR	Erlotinib (100%)	Osimertinib (84%), afatinib (7%), erlotinib (6%)
BRAF	Vemurafenib (72%), dabrafenib (28%)	Dabrafenib (54%), encorafenib (41%)
MEK	Trametinib (100%)	Trametinib (60%), binimetinib (38%)
BRCA	Olaparib (100%)	Niraparib (49%), olaparib (47%)

In 2012, EGFR drugs had the greatest impact on both treated patients (99.8%) and pharmaceutical expenditure

(100%). In 2022, BRCA drugs had the greatest impact on treated patients (34%), while the highest pharmaceutical expenditure (34%) was still on EGFR drugs.

By the end of the study, OOTT treatments had increased by 179% and pharmaceutical expenditure by 494%. Drug distribution by mutation was 34% BRCA, 28% EGFR, 15% ALK/ROS1, 13% BRAF, and 11% MEK. The economic impact was 108,138,186€ accumulated over the entire study period.

Conclusion and Relevance Targeted therapies have had a relevant impact in recent years, with new drugs and diagnostic techniques increasing the eligible population. Stringent evaluation and adequate selection of these drugs are necessary in order to optimise the incorporation of innovative therapies while guaranteeing the sustainability of the public healthcare system in Spain.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

1ISG-002 PHARMACIST RISK STRATIFICATION: A CHARACTERISATION OF PATIENTS WITH LOW SOLUBLE UROKINASE PLASMINOGEN ACTIVATOR RECEPTOR WHO DIED WITHIN 90 DAYS OF HOSPITAL DISCHARGE

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Background and Importance Soluble urokinase plasminogen activator receptor (suPAR) is a marker of systemic chronic inflammation thought to reflect overall disease burden. suPAR has been suggested as a prognostic marker in clinical settings, since elevated suPAR levels are strongly associated with mortality. Researchers have suggested using a suPAR level <3 ng/mL for safe and early discharge from the emergency department (ED). However, a subset of patients with low suPAR dies within 90 days of hospital discharge, and the risk is significantly associated with an increased medication use.

Aim and Objectives The aim of the present study was to characterise patients with low suPAR (<3 ng/mL) who died within 90 days of hospital discharge by exploring factors other than suPAR that may explain this contradictory finding of mortality among patients with low suPAR.

Material and Methods This observational registry-based study included consecutively admitted medical patients to the ED at our hospital from November 2013 to March 2017. We used validated databases and national registries to describe patients' characteristics (age, medication use, diagnoses, frailty index).

Results Compared to patients with low suPAR who survived (n=15,122), those who died within 90 days (n=87) had higher age (75.4 years), medication use (7.0; 71.3% with polypharmacy), more blood tests outside reference intervals (5.0) (including C-reactive protein, neutrophils, albumin), and the most common diagnoses were chronic pulmonary disease (27.6%), cerebrovascular disease (18.4%), and dementia (11.5%). The most common medications were antithrombotic agents (44.8%), lipid modifying agents (plain) (39.1%), and other analgesics and antipyretics (33.3%).

Conclusion and Relevance Patients with low suPAR who died had other risk factors explaining their morbidity and mortality risk than what was reflected by their suPAR level. Using suPAR as a proxy for disease burden in clinical settings may be challenging in situations, where patients receive a high number of medications. We suggest including medication use, routine blood tests, and selected diagnosis codes in combination with suPAR when stratifying patients based on their risk of adverse clinical outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

1ISG-003 ABSTRACT WITHDRAWN

1ISG-004 **ABSTRACT WITHDRAWN**

1ISG-005 **ASSESSMENT OF A MANAGEMENT TOOL REGARDING MEDICAL DEVICE VIGILANCE**

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Background and Importance Legislation regarding medical device vigilance requires the reporting of any incident involving medical devices. Within our hospital, the adverse event's declaration (AED) process has been entirely computerised since July 2019. Each adverse event (AE) reported is addressed to the dedicated vigilance officers.
Aim and Objectives The objective of this work is to carry out an assessment of the AED activity before and after the software rollout.
Material and Methods The reporting of AEs was initially processed through paper format in 2019 and after with the AE reporting software from January 2020 to December 2022. Each declaration of AE was analysed by a pharmacist and categorised based on its severity and preventability.
Results Over 212 AEDs were reported: 32 in 2019, 31 in 2020, 60 in 2021 and 89 in 2022. The main reporting departments are the: intensive care cardiac unit, surgery unit and haemodialysis unit with respectively 51%, 13% and 9% of the AED. Damage or visual defect of the medical device represents about 40% of the AED while product failure during use represents 45% of the reports. Following analysis, 16% of the AED have been classified as 'almost accident', 81% as 'undesirable events', 2% as 'serious adverse event with low impact' and 1% as 'serious adverse event'. All AEDs were declared to the French Agency for Medicines and Health Products Safety. Regarding their avoidability, the AEDs were classified as 'preventable', 'likely preventable', 'unavoidable' and 'likely unavoidable' with respectively 79%, 13%, 5% and 3% of the AEDs. The AEDs made in 2019, 2020 and 2021 are all treated and closed, for 38 AEDs we are still awaiting a response from the manufacturers.
Conclusion and Relevance In 4 years, the number of AEDs has nearly quadrupled. This increase is likely the result of accessibility and user friendliness of the software, as well as the implementation of local awareness campaigns regarding AEDs. A new overview of the AED should be scheduled.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

1ISG-006 **ECONOMIC SAVING OF THE PREPARATION OF SUBCUTANEOUS FORMULATIONS COMPARED TO INTRAVENOUS: FOCUS ON DARATUMUMAB IN THREE HEALTHCARE COMPANIES**

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Background and Importance The new onco-haematological formulations are moving more towards subcutaneous administration which represents a technological innovation compared to

intravenous formulations and allows for a greater number of accesses to therapies given the reduced administration times.

Aim and Objectives The objective of this work is to calculate the direct costs of the medical devices necessary for infusion therapy and the indirect costs of the nursing staff responsible for setting up intravenous therapies for daratumumab.

We studied the 2022 data of three local healthcare companies.

Material and Methods With company software we determined the cost of the devices used in intravenous and subcutaneous preparation and the number of patients receiving daratumumab therapy in 2022, considering for each patient 24 cycles of therapy as indicated in the dosage schedules.

Results The cost calculated for a single intravenous preparation is € 12.01, considering the following devices necessary for administration:

Two vial-spikes € 2.84, two syringes with connectors € 2.48, clave-valve € 2.76, bag € 0.60, syring-luerlock for diluent € 0.50, secondary infusion set € 2.20, cap-cap € 0.25, UV-protector bag € 0.25.

The cost for subcutaneous administration is different, equal to € 3.29 for vial-spike, syringe and connector, UV-protector bag and cap-cap.

The indirect cost calculated on the average hourly nursing cost of € 27.83 and considering a 10-minute set-up commitment for two nursing units is € 9.28.

In 2022, 55 patients in healthcare company 1, 69 patients in healthcare company 2, and 12 patients in healthcare company 3 were treated with daratumumab.

Conclusion and Relevance The total cost of the devices and the healthcare staff responsible for preparing the infusion is equal to € 21.66 compared to € 3.29 for the cost of preparing the subcutaneous injection. The subcutaneous administration is more convenient than intravenous, with a saving of € 18.55 per administration. Since the prices of the two formulations of daratumumab are equal, this corresponds to an actual saving.

This saving for the entire year 2022 and for the 24 planned administration cycles would produce a reduction in spending, accounted for in the set-up costs, equal to € 24,486 for healthcare company 1, € 35,885 for healthcare company 2, and € 6,241 for healthcare company 3.

To this we must add an increase in the safety of the operators who prepare and administer, greater patient compliance and a decrease in the social costs of the patient undergoing therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

1ISG-007 HTA ANALYSIS FOR THE INCLUSION OF ANDEXANET ALFA (AA) WITHIN THE HOSPITAL THERAPEUTIC HANDBOOK (HTH) – THE EXPERIENCE OF AN ITALIAN CENTRE SPECIALISING IN CARDIOVASCULAR DISEASES

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Background and Importance The drug Andexanet Alfa (AA), an anti-haemorrhagic antidote capable of rapidly reversing the effect of factor Xa inhibitor DOACS (Apixaban, Rivaroxaban), was recently introduced on the market. The 4-factor prothrombin complex (CPP4), already in use at our centre, also has the same indication.

Aim and Objectives In collaboration with a haematologist and a cardiologist-anaesthetist, an HTA analysis was conducted with the aim of evaluating the real need for the inclusion of AA within the Hospital Therapeutic Handbook (HTH) and its use in cardiac surgery emergency situations and cardiovascular emergency.

Material and Methods A brief review of the literature currently available on various search engines (PubMed, clinicaltrials.gov) was conducted by the hospital pharmacy, looking in particular for comparison studies between AA and CPP4. In parallel, a search was conducted for poison control centres (PCC) and hospital centres close to the facility that had the drug available, an economic evaluation and an analysis of the Summary of Product Characteristics (SmPC).

Results From the retrospective studies analysed (eight, of which only three meta-analyses), data were collected and summarised in terms of efficacy/haemostasis rate (AA: 77.88% vs CPP4: 76.47%, average data) and safety/incidence of post-treatment thromboembolic events (AA: 10.47% vs CPP4: 5.98% average figure).

From the parallel research, the following results emerged: availability of the antidote (one PCC and two hospital centres); treatment costs (AA: Euro 52,666.52 vs CPP4: Euro 3795.90); reimbursement (non-reimbursable drug); AA preparation/infusion times (approximately 2h 30).

Conclusion and Relevance The analysed studies, subject to bias due to the variability of the analysed sample, were mainly focused on intracranial haemorrhage events and not on cardiac surgical complications. From these, it also emerged that AA promotes a refractoriness to the anticoagulant effect of unfractionated heparin, making the use of AA incompatible in patient candidates for a cardiac surgical procedure that requires pre-heparinisation.

Therefore, by virtue of the poor and unfavourable quality of the trials and the unfavourable cost-effectiveness and risk-benefit ratios, it was not considered necessary to introduce the drug within the HTH.

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Web reference (https://pubmed.ncbi.nlm.nih.gov)

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1) https://doi.org/10.1016/j.jacc.2021.04.061;
2) https://doi.org/10.1016/j.ajem.2022.02.029;
3) https://doi.org/10.1177/10760296211039020;
4) DOI: 10.1097/CCM.0000000000005059;
5) https://doi.org/10.1182/hematology.2019000074;
6) DOI: 10.7759/cureus.20632;
7) https://doi.org/10.1002/rth2.12518;
8) DOI: 10.1213/XAA.000000000000163;
9) https://doi.org/10.1007/s12028-022-01573-5;
10) DOI: 10.1213/XAA.0000000000001636

Conflict of Interest No conflict of interest.

1ISG-008 USABILITY EVALUATION OF AN INSULIN MANAGEMENT SOLUTION WITHIN AN ELECTRONIC PATIENT RECORD

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Background and Importance There is evidence to suggest that poor usability of health information systems is associated with negative outcomes including low efficiency and increased risk of medical error. Standardised usability questionnaires have been developed to evaluate usability and recently a novel tool was developed to measure the usability of clinical decision support systems in healthcare environments.[1] A customised insulin management solution was developed and implemented in our hospital to migrate insulin prescribing, administration and review from paper to our electronic patient record (EPR). Assessing the usability of the solution was identified as a way of determining potential areas for optimisation and training post-implementation and of informing future design decisions.

Aim and Objectives

- To assess usability of the insulin management solution
- Compare usability scores across the clinical disciplines

Material and Methods The Healthcare Systems Usability Scale (HSUS) was used to assess usability among system users from the medical, nursing, pharmacy and clinical nutrition professions. [1] HSUS assessed usability in four subscales; patient safety and decision effectiveness, workflow integration/ease of use, work effectiveness and user control. An Independent-Samples Kruskal-Wallis Test was used for statistical analysis.

Results 226 users from medical, nursing, pharmacy and clinical nutrition disciplines completed the HSUS assessment. The average usability score was 81%. There was no significant difference in overall usability scores based on the respondents' discipline. Concerning subscales, the only significant difference between disciplines was in the workflow integration/ease of use domain between the pharmacist and nursing groups (70.8% vs 79.6% $p = 0.020$).

Conclusion and Relevance The insulin management solution implemented into the EPR was regarded as highly usable based on the results of the HSUS in comparison to another study where the usability score was only 64%.[1] The variability between the pharmacy and nursing result warrants further investigation and will inform engagement requirements for future project work. Finally, this study adds to the evidence base in this important area where real-world data is still limited.

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Conflict of Interest No conflict of interest.

1ISG-009 PHARMACOECONOMIC ANALYSIS OF AN ALTERNATIVE DOSAGE REGIMEN FOR PALIVIZUMAB

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Background and Importance According to the Summary of Product Characteristics (SmPC)[1] of palivizumab, the usual regimen consists of five doses of 15 mg/kg/dose, intramuscularly, every 28 days.

For the 2022–2023 campaign, we established a novel regimen based on the Reuter et al.,[2] pharmacokinetic model whereby the dosage per kg decreases as the season progresses, and the initial dosage is defined based on postmenstrual age (PAGE) which is described as gestational age plus chronological age, both measured in weeks (Table 1).

Aim and Objectives To assess the effectiveness of a novel pavilizumab regimen as well as to determine the cost savings derived from the implementation of this regime.

Material and Methods Patients were classified according to their PAGE. The total dosage received per child with the novel protocol was compared with the dosage that they would have received had they been given the dosage as specified in the SmPC.

The effectiveness of the novel protocol was assessed showing no hospital admissions nor emergency department visits in patients undertaking the novel regimen.

The total expenditure on palivizumab during the 2022–2023 season was analysed comparing the expenditure on the PAGE-defined regimen to the theoretical expenditure of SPC-defined regimen.

Results

Abstract 1ISG-009 Table 1 Shows the alternative dosage regimen based on the PAGE system

PAGE (gestational +postnatal age, weeks)	1st dose (mg/kg)	2nd dose (mg/kg)	3rd dose (mg/kg)	4th dose (mg/kg)	5th dose (mg/kg)
<40	20	17,5	15	12,5	10
40–65	17,5	15	12,5	10	7,5
>65	15	12,5	10	7,5	5

Abstract 1ISG-009 Table 2 Shows the cost savings derived from the use of the novel dosage regimen

PAGE (gestational postnatal age, weeks)	Patients (n)	Average Weight (kg)	Total dose administered (mg)	Total theoretical dose as defined by SPC (mg)	Cost savings (mg)	Cost savings (€)	Average patient savings (€)
<40	18	4,3	4270,9	4480,6	209,7	1.514,39 €	84,13 €
40–65	13	6,4	4479,4	5060,6	581,2	4.197,21 €	322,86 €
>65	16	9,5	5897,5	8119,1	2221,6	16.044,26 €	1.002,77 €
Total	47	6,5	14647,8	17660,2	3012,5	21755,85 €	462,89 €

Conclusion and Relevance The PAGE-defined regimen results in significant cost savings compared with the conventional SmPC-defined regimen.

The pharmacist's intervention contributes to the optimisation of health resources, further increasing the sustainability of the health system.

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Conflict of Interest No conflict of interest.

1ISG-010 ECONOMIC IMPACT OF THE CLINICAL PHARMACIST ON THE REDUCTION OF DRUG-RELATED PROBLEMS BEFORE THE INITIATION OF AN ANTI-TUMOUR TREATMENT – A PROSPECTIVE MULTICENTRE TRIAL

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Background and Importance Multiple studies have shown a high rate of drug-related problems (DRP) in patients with cancer. To reduce this risk, several oncology departments have set up multidisciplinary assessment programmes that include pharmaceutical consultation.

Aim and Objectives In a context of limited resources allocation, our study aims to evaluate the economic impact of clinical pharmacists' interventions (PIs) on DRP detection from a hospital perspective.

Material and Methods A French prospective non-interventional double-centre study was set up in 2020. Patients treated for solid tumours were included between February 2020 and March 2021.

First, we calculated the pharmaceutical time based on consultations and analysis times. The time spent has been valued (i) to an average annual full-time equivalent (FTE) and (ii) by the grade of the contributor (2022 salary scales). Two scenarios have been established (low/high salary grades).

Second, we selected PIs regarding clinically significant drug-drug interactions related to drug toxicity (evaluation made by an expert panel). We sought to estimate the cost based on the avoided clinical consequences. We valued the likely 'diagnosis related groups' of the avoided event thanks to the 2019 national survey on hospital costs. Costs were weighted by an occurrence probability based on the level of evidence: p=0.01 for very low; p=0.1 for low; p=0.4 for moderate; and p=0.6 for high.

Results 438 cancer patients were included: 62% of males, mean age of 65+/-13 years.

Per patient, the pharmacist average time was 39+/-15 minutes: 23+/-7 minutes of interview and 16+/-11 minutes of analysis. Total time was 283 hours, and the estimated annual FTE was 0.13. The total cost was estimated between € 4,199 (low salaries) and € 5,250 (high salaries) per year. Cost was estimated between € 11.4 and € 14.3 per patient and between € 18.42 and € 23.02 per drug-drug interaction.

122/266 PIs were evaluated to be clinically significant drug-drug interactions related to drug toxicity that could have caused a hospitalisation. Cost of hospitalisation for these serious avoidable adverse events was estimated on average at € 4,869. Avoided hospitalisation costs were estimated at € 180,633.

Conclusion and Relevance Clinical pharmacists are an indispensable and legitimate member of therapeutic assessment programmes for cancer patients. They help in reducing DRP in a cost-effective manner.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

1ISG-011 OPPORTUNITY FOR DAILY HOME-BASED MANAGEMENT OF CHRONIC PATIENTS FROM THE SAME AREA USING AN INTERPROFESSIONAL NETWORK MODEL DEVISED, SET UP AND IMPLEMENTED FOR THE COVID-19

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Background and Importance The Coronavirus SARS-CoV-2 pandemic highlighted the fragility of National Health Service based on a too specialised and hospital-centred approach. In the pandemic context, the need to reverse the model by focusing on the needs of the community became clear.

Aim and Objectives The main aim of promoting home-based management as much as possible for both chronic and acute conditions, can be achieved through the utilisation of a model of an integrated network involving all stakeholders in the care and assistance process, utilising new technologies and telemedicine systems as done during the pandemic period with an ad hoc interprofessional network within a local health authority.

Material and Methods The model utilised interconnected and functionally integrated structures and nodes, with defined pathways and operational procedures based on dedicated telemedicine platforms. These platforms facilitate the comprehensive management and care of Covid-19 patients by all network stakeholders. Results were monitored using specific and dedicated indicators, collecting and analysing data from the period when the care of positive Covid patients began (November 2020), whose management did not require hospitalisation.

Results From November 2020 to December 2021, the number of patients living in the territory under home management in Home Health Care Units, non-ambulatory residential facilities undergoing non-pharmacological therapy, non-ambulatory vaccinated individuals receiving home vaccination, and vaccinated individuals in residential facilities, amounted to 38,223. Among these, 37.8% tested positive for Covid. The total number of accesses during this period was approximately 94,000. The shift has been significant, transitioning from managing the entirety of patients in hospitals to slightly over 4.5% of the total managed in that period.

Conclusion and Relevance The reproducibility of this system assures the possibility of further network implementation, not only in emergencies but also for the daily management of chronic patients. Moreover, in a time when, among other things, Mission 6 of the PNRR has allocated resources

amounting to 15.63 billion euros to be invested in the healthcare sector, most of which are dedicated to revolutionising our SSN and ensuring its greater efficiency and effectiveness in the territory.

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Conflict of Interest No conflict of interest.

1ISG-012 BALANCING CLINICAL BENEFITS AND COST SAVINGS: COMPASSIONATE DRUG USE AT AN ITALIAN UNIVERSITY HOSPITAL – EVIDENCE AND INSIGHTS

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Background and Importance Compassionate use of drugs (CU) allows patients with serious diseases and no further treatment options to access treatments not yet approved. Specialist referral centres provide a reference point for access to these medicines, with significant benefits both for patient health and for avoided costs to the healthcare system.[1]

Aim and Objectives The aim of this study is to describe the impact, in terms of clinical outcomes and saved costs, of CU at a University Hospital.

Material and Methods An 18-month retrospective analysis of approved CU at the Azienda Ospedale-Università Padova (AOUP) was conducted. A monitoring activity was implemented by the AOUP's Clinical Research Unit through creation of follow-up forms submitted to corporate Operational Units' physicians, which made it possible to track the number of patients involved in CU programmes, their clinical outcomes and duration of therapy. The economic impact was assessed by calculating cost-therapy for each patient based on drug dosage, duration of treatment, and ex-factory price published in the Official Gazette of Italian Republic, for drugs available on the market.

Results In the analysed period, a CU regimen was approved for 84 patients mainly in the haematology (17 patients) and paediatric (24) settings. Of the total, five patients did not start therapy due to death, clinical deterioration, or personal reasons. The remaining 79 underwent treatment. In 81% of cases, this resulted in a partial or complete improvement in the clinical status or, when degenerative diseases occurred, a stabilisation of the disease. On the economic side, avoided costs amounted to € 7,130,668, 62% of which resulted from CU of burosumab in patients with X-linked hypophosphatemic osteomalacia.

Conclusion and Relevance CU in a University Hospital brings both clinical benefits and potentially significant economic savings. Early access to experimental therapies both enhances patients' life expectancy and quality and facilitates the gathering of valuable clinical data on promising investigational drugs. Cost savings generated from this approach can be reinvested to expand, enhance, and make the national healthcare system more sustainable. Collaboration between teaching hospitals, pharmaceutical companies and regulatory authorities is essential to optimise CU programmes and ensure equitable access to potentially lifesaving treatments.

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Conflict of Interest No conflict of interest.

1ISG-013 REAL-LIFE DATA OF CDK4/6 INHIBITORS PALBOCICLIB, RIBOCICLIB AND ABEMACICLIB IN LOCALLY ADVANCED OR METASTATIC BREAST CANCER: EFFECTIVENESS EVALUATION

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Background and Importance Breast cancer is the world's most prevalent cancer. There are approximately 55000 new diagnosed cases per year in Italy. CDK4/6 inhibitors are targeted orally available cancer drugs. These are highly selective inhibitors of CDK4 and CDK6, serine-threonine kinases that regulate the cell cycle progression. CDK4/6 inhibitors are indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer, in combination with an aromatase inhibitor or with fulvestrant in women who have received prior endocrine therapy.

Aim and Objectives To provide real-world evidence of CDK4/6 inhibitors, to analyse drug effectiveness in our hospital.

Material and Methods We included all patients diagnosed with locally advanced or metastatic breast cancer who received CDK4/6 inhibitors (palbociclib, ribociclib and abemaciclib) from national marketing authorisation to 15 September 2023. Patients were stratified by drug, age, line of therapy, Eastern Cooperative Oncology Group (ECOG) performance status (PS) and cancer staging. We assessed progression-free survival (PFS) with the Kaplan-Meier method.

Results Sixty-three patients received CDK4/6 inhibitors. 63% were treated with palbociclib, 24% with ribociclib and 13% with abemaciclib. The mean age was 65. Median PFS was 22.4 months. There was no statistically significant difference between cases treated with palbociclib and ribociclib. Median PFS in the abemaciclib group was not reached. Age older than 65 was a significant predictor for PFS benefit (median PFS 27 months). 51% were first-line treatments (median PFS 22.4 months). Beyond first-line therapy median PFS was 27 months. 49% had baseline PS of 0. PS was identified as an important prognostic factor for PFS: PS0 median PFS 22.4 months versus PS1 median PFS 15.9 months. Locally advanced breast cancer cases had worse prognosis (median PFS 13 months). We recorded 10 cases of dose reduction due to toxicity, but only one patient discontinued therapy due to treatment-limiting toxicity.

Conclusion and Relevance All CDK4/6 inhibitors are beneficial in terms of PFS: we found no significant differences among the three drugs. Toxicities were managed by dose reductions. CDK4/6 inhibitors confer PFS benefit in elderly patients with metastatic disease. We can confirm that these drugs have radically changed the treatment for metastatic breast cancer with increased rates of treatment response and PFS.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

1ISG-014 SUSTAINABLE HEALTHCARE: AN EXAMPLE OF PHARMACEUTICAL INTERVENTION

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Background and Importance Our health facility conducts approximately 400 annual carpal tunnel (CT) surgeries using three distinct ambulatory methods: (1) ultrasound-guided in the operating room (OR), (2) ultrasound-guided office surgery in the consultation room, and (3) endoscopy-assisted in the OR.

Aim and Objectives The study's objective was to assess the environmental footprint of each care pathway and to eco-design the care pathway with the lowest possible impact.

Material and Methods A mixed multidisciplinary team (pharmacist, surgeon, sustainable development engineer) was established. The pharmacist was defined as the pilot of the study. Three life cycle assessments (LCA) were conducted using SimaPro software. The functional unit was 'Performing an outpatient CT surgery, from planning to post-op care'. Ten impact categories were considered including for example global warming (kg CO2e), terrestrial; freshwater and marine ecotoxicity (kg 1.4-DCB), assuming equal patient-to-health-facility distance and surgical efficiency.

Results Care pathway (2) has a 20 kg CO2e carbon footprint, which is half of (1) at 43 kg CO2e, and a third of (3) at 75 kg CO2e. The most significant impacts are patient transport and electricity: for (2) 74% from patient transport and 1% from electricity; for (1) 26% from patient transport and 54% from electricity; for (3) 40% from patient transport and 36% from electricity. Healthcare products (HP) represent an average of 25% of the total impact. The stages with the highest HP impacts were: draping and sterile dressing (0.28kg CO2e (2), 2.7kg CO2e (1) and 6.7kg CO2e (3)); skin preparation of the operating area (0.5kg CO2e (2), 0.9kg CO2e (1) and (3)); and anaesthesia (0.3kg CO2e (1) and (2), 1kg CO2e (3)). In anaesthesia, drugs (acetaminophen, lidocaine, mepivacaine) had minimal impact (10%), whereas for skin preparation, drugs (alcoholic betadine) had a greater impact (70% to 100%) than sterile medical devices. Modelling the implementation of teleconsultation showed a potential savings of 6kg CO2e for (1) and (2) and 12kg CO2e for (3).

Conclusion and Relevance Office surgery, with its minimal impact and equivalent clinical effectiveness, should be promoted. Further reducing its environmental footprint requires essential steps, such as promoting teleconsultation. Pharmacists can also make a significant impact by optimising HP utilisation (e.g., right-sized drapes, no reinforced gowns for non-invasive procedures, controlled betadine use, efficient neurostimulation needle cable recycling).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

1ISG-015 ASSESSMENT OF PREPARATORY STAFF'S KNOWLEDGE OF CARCINOGENIC, MUTAGENIC AND REPROTOXIC (CMR) RISKS

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Background and Importance Context: The preparation of pharmaceutical products is governed by Good Preparation Practices (GPP). Guideline 2: 'Preparation of medicinal products containing substances that may present a risk to health and the environment' states that personnel must be trained and informed.

Aim and Objectives

Objectives To assess the initial knowledge of the preparation team on carcinogenic, mutagenic and reprotoxic (CMR) risks and to establish appropriate training.

Material and Methods

Method A SPHINX® questionnaire was developed based on bibliographical data with methodological support from COMEDIMS, risk preventionists and occupational medicine. The 12-question questionnaire covered not only basic knowledge of the risk, but also the practical application of CMR risk management in the unit. It was submitted to all staff over a 1-month period. The analysis of the results led to the implementation of a training programme adapted to all staff.

Results

Results 28 people completed the questionnaire with a mean score of 12.5/20 [5.8–17.9]. Staff seniority seemed to contribute to a better knowledge of risk (Student, $p = 0.06$), with a mean of 14.7 for those working in our department for more than 5 years compared to 12.1 for new staff. In terms of knowledge, the basic concepts of CMRs and personal protective equipment were acquired (64% and 79% of workers answered these questions correctly). On the other hand, collective protection equipment, guidelines and what to do in case of exposure were less well understood (39%, 7% and 11% respectively).

Conclusion and Relevance

Discussion Based on the results of the questionnaire, CMR risk concepts are not fully understood by all staff, although seniority in the department seems to increase their knowledge. The responses have enabled us to identify the gaps in the team's knowledge and to propose a targeted training course for all, combined with situational exercises. The effectiveness of the training is then evaluated using a questionnaire combined with a satisfaction survey.

Conclusion This assessment enables us to meet the initial training requirements of Guideline 2. The training and assessment materials will form the basis for maintaining skills as part of the unit's ongoing training.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

1ISG-016 OCRELIZUMAB FOR THE TREATMENT OF RELAPSING AND PRIMARY PROGRESSIVE MULTIPLE SCLEROSIS IN A NATIONAL HEALTH SYSTEM: A COST EFFECTIVENESS ANALYSIS

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Background and Importance Ocrelizumab has demonstrated significant clinical benefit for the treatment of relapsing multiple sclerosis (MS) and primary progressive multiple sclerosis (PPMS), a disease characterised by disability.
Aim and Objectives The aim of the study is to evaluate the clinical and economic impact of ocrelizumab compared to current clinical practice, including other disease-modifying therapies (DMTs).
Material and Methods In the literature, the short- and long-term cost-effectiveness implications of DMTs for MS have been estimated through Markov modelling (MM) using the EDSS score (0–9) to define health states and model disease progression and the progression of relapses over time. The cost and effectiveness of ocrelizumab were estimated using MMs for three populations: naive RMS, previously treated RMS, and PPMS. Efficacy was expressed in quality-adjusted life years (QALYs). A systematic review and meta-analysis were used to obtain efficacy data. For RMS, interferon beta1a, dimethyl fumarate, glatiramer, teriflunomide, fingolimod and natalizumab were selected as comparators. For PPMS, supportive care was considered the best.
Results The estimated time (years) before progression to SPMS of ocrelizumab was calculated for patients treated with RMS from 2020 to 2022 compared to the other drugs under analysis. The results expressed in QALYs show that ocrelizumab has gains of 0.3 compared to natalizumab, 0.93 compared to dimethyl fumarate, 1.06 compared to teriflunomide, 1.07 compared to fingolimod, 1.11 compared to interferon beta1a and 1.2 compared to glatiramer. Calculating the incremental cost-effectiveness ratio (ICER) of ocrelizumab compared to interferon-beta-1a, the lowest cost drug among its competitors, we obtained a cost of 16,720 euros per QALY. For patients with PPMS, the ICER of ocrelizumab compared to best supportive care was estimated at 78,858/QALY.
Conclusion and Relevance Ocrelizumab provides important health benefits, and it has been shown to be more cost-effective in RMS or to have costs per QALY likely to be lower than commonly accepted cost-effectiveness thresholds. In PPMS, ocrelizumab fills a clinical gap in clinical practice, but its costs per QALY are likely to have a more significant impact on public spending.

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1ISG-017 THE THREE HORIZONS METHOD AS A TOOL FOR DEFINING THE HOSPITAL PHARMACY RESIDENT OF THE FUTURE (HPRF)

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Background and Importance Based on Bill Sharpe's theory the 'Three Horizons' method serves as a forge for shaping future reality. Through creative discourse on future approaches/scenarios, in fact, a team, composed of a visionary (that paints the futuristic reality), a manager (who in the present ensures correct system management) and an entrepreneur (glue between the other two that invests in realisation of innovation), defines strategies for an identifiable future.
Aim and Objectives Through intersection of three different horizons (3H), from H1 (present's reflection and starting point of discussion) to H3 (projection of a dreamlike reality with respect to nowadays), by means of H2 (bridge for the realisation of strategy), HPRF's figure has been painted, using the most vivid imagination as a means to wish for a 'renewed' affirmation in our country.
Material and Methods The exercise involved the definition of 'Three Horizons', thinking about an HPRF operating in the year 2038, and was divided into two phases. On the one hand, a team has mapped horizons (putting different coloured Post-its for each one on a white wall), strictly following order H1-H3-H2. On the other hand, the team asked itself a series of questions to draw up the 'action plan'.
Results From the exercise emerged an image of the current resident as 'behind the scenes', not fully aware of his/her potential/educational role and not totally included in hospital tissue, without real possibility of gaining experience in all sectors, unpaid and therefore not incentivised to learn deeply from internship, dissatisfied. Conversely HPRF will be fully paid/active on ward by questionnaires production for patients-medical team, raising awareness, supporting pharmacovigilance's importance and promoting fight against antimicrobial resistance, sharing knowledge/entertaining interactions with patients, especially in difficult areas (for example Clinical Trials). A bridge (H2) is represented by a Study Plain organisation finalised to catapult resident into wards from beginning to grasp needs of all healthcare system players.
Conclusion and Relevance '3H' has been a strategic framework useful to define actions to be taken for realising future scenarios. It has been adapted to pharmaceutical practice that is evolving from simple medicines distribution to education especially in the perspective of patients that are increasingly active players that acquire knowledge from both disease experience and the healthcare system, in a mutual exchange of information about pathophysiology/treatment/supply chain.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

1ISG-018 TEN-YEAR DRUG SURVIVAL ANALYSIS IN MODERATE TO SEVERE PLAQUE PSORIASIS FIRST-LINE TREATMENT

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Background and Importance Drug survival is defined as the time interval between treatment initiation and discontinuation. Several factors may influence drug survival such as efficacy, tolerability, and treatment adherence. Thus, drug survival can be used as a surrogate for treatment effectiveness. Biologics have changed the treatment paradigm in moderate to severe plaque psoriasis improving efficacy and tolerability.
Aim and Objectives We aimed to determine the 10-year drug survival for the biologics used in the treatment of moderate to severe plaque psoriasis where possible, in order to estimate real-world effectiveness and improve initial treatment decision making, considering biosimilar's favourable costs.
Material and Methods All adult patients (aged 18–65 years) with a diagnosis of moderate to severe plaque psoriasis who initiated treatment with the following biologics between 28 February 2012 and 28 February 2022 (10 years) were included: adalimumab, brodalumab, certolizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, and ustekinumab. Data were collected from pharmacy dispensing records and included a 6-month wash-out period before inclusion and a 1-year minimum follow-up for the last patient included. Data were censored, considering treatment discontinuation if no records were found in the last 3months of the follow-up period. Data were analysed using R statistical software.
Results A total of 1,353 patients were included (41.3% females, median-age 44 years). Only patients who initiated first-line adalimumab (n=124), etanercept (n=56) and ustekinumab (n=861) reached a 10-year treatment period. The 10-year drug survival (%, 95% confidence interval, n at risk) were: adalimumab (17.0, 10.2–28.3, n=5), etanercept (14.5, 6.74–31.1, n=2), ustekinumab (21.8, 18.1–26.3, n=29). Using adalimumab as reference, the Cox proportional hazard ratios for etanercept and ustekinumab were respectively: 0.90 (0.63–1.28, p=0.557) and 0.58 (0.46–0.72, p<0.001). Treating a patient for a 10-year period with biosimilar etanercept or ustekinumab cost an additional € 46,033 or € 84,504, respectively, comparing to biosimilar adalimumab.
Conclusion and Relevance A 10-year drug survival analysis was only available for adalimumab, etanercept and ustekinumab. Comparing to adalimumab, ustekinumab showed a significant higher 10-year drug survival (21.8 *vs* 17.0%, p<0.001). A strategy of switching from adalimumab to ustekinumab as soon as a biosimilar is available should be evaluated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

1ISG-019 DO ALL SURGICAL SPECIALTIES HAVE AN IDENTICAL CARBON FOOTPRINT WITHIN AN AMBULATORY UNIT?

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Background and Importance Operating theatres produce 30% of the healthcare system's greenhouse gas (GHGs) emissions. As part of its sustainable development strategy, our hospital has decided to assess the greenhouse gases emitted by an Ambulatory Surgery Unit (ASU). Opened in April 2018, the ASU has five operating theatres where eight surgical specialties can operate 22 patients a day.
Aim and Objectives The aim is to assess the carbon footprint of surgical specialties in order to identify the most GHG emitting sources.
Material and Methods Thanks to the hospital's Sustainable Development Commission (SDC), the carbon footprint of the surgical specialties was assessed by two community service students, one extern and one pharmacy resident. The GHG emissions generated in 2022 by water, electricity and energy consumption, equipment, drugs, gas, single-use medical devices (SUMDs) and re-sterilisable medical devices (RSMDs) procurement, Regulated Medical Waste (RMW) and Municipal Solid Waste (MSW), patient and staff movements were estimated based on ADEME factors. Emissions associated with the acquisition of Sterile Medical Devices, known as 'specific emissions', vary according to surgical specialty. The remaining emissions sources are called 'common emissions'.
Results In 2022, the ASU emitted 634 tonnes of eCO2. Common emissions reached 292 t eCO2: equipment (9%), energy (9%), travel (7%), RSMD (6%), drugs (4%), waste (1%) and gas (1%). Specific emissions account for 54% (342 tonnes eCO2). Orthopaedic surgery emits 166 t eCO2 per year, including 59 t eCO2 from common emissions. Orthopaedic, urological, dermatological, gynaecological, gastrointestinal and plastic surgery account for 171, 117, 84, 93, 93 and 85 kg eCO2 per patient respectively.
Conclusion and Relevance This study highlights the most GHG emitting positions (SMD procurement) and specialties (Orthopaedic surgery) in the ASU. Several actions have been taken towards sustainable development. Environmentally, the air-conditioning output is reduced when the operating theatre is closed, waste is distributed in paper or plastic garbage bins, and sevoflurane is the only gas administered. Economically, hospital stays are shorter than those for conventional surgery. Socially, the unit offers patients a peaceful environment. These findings were presented to the SDC. Suggestions were made to refine RSMD compositions with input from surgeons and replace SMD with RSMD whenever possible.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

1ISG-020 DRUG DAY THERAPY APPLIED TO LUSPATERCEPT: RESULTS OBTAINED IN AN ITALIAN ANTIBLASTIC DRUG UNIT

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Background and Importance Luspatercept is an erythroid maturation agent, indicated for myelodysplastic syndrome and β-thalassaemia, reimbursed by the Italian National Health Service as of 09/12/2021. Luspatercept binds to ligands of the transforming growth factor β family by blocking the Smad2/3 signalling pathway that induces maturation of late erythroid

precursors. Patients receive luspatercept every 3 weeks at a per-kilo dose (three steps of incremental doses in myelodysplastic syndromes, and two steps in b-thalassemia). A drug day was set up together with the clinicians.
Aim and Objectives The objective of this study was to assess whether the establishment of drug day could lead to significant savings for the preparation of luspatercept in 2022.
Material and Methods All prescriptions and preparations made at our Unit from 1 January to 31 December 2022 were analysed by means of data extraction from the internal management system for onco-haematologic therapies. The milligrams and vials that hypothetically should have been used were calculated and valued with those actually used.
Results In 2022, 21 patients were treated for a total of 155 treatments (average of 7.38 doses per patient). A total of 16,658 mg of luspatercept was prescribed. 177 bottles of 75 mg and 61 bottles of 25 mg were used for a total of 14,800 mg. The difference of 1,858 mg between hypothetical and actual data shows the presence of an overfill of average powder equal to 3,139 mg for the packaging of 25 mg and 9,417 mg for the packaging of 75 mg (12,56% of nominal filling). The VAT costs included for the individual bottles were: 2421,02€ for the 75 mg bottle and 807,01€ for the 25 mg bottle (exactly 1/3 of the higher dosage). The total expenditure incurred was € 477,748.15 against the hypothetical expenditure of € 538,275.61, with a net saving of € 60,527.52 (11.24% of the theoretical expenditure).
Conclusion and Relevance The administration of luspatarcept organised in drug day has led to a saving due to better management of waste and overfill. These results show how well-established pharmaceutical management and management strategies in clinical practice such as the drug day turn out to be an excellent method of minimising processing residues and controlling expenditure.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

1ISG-021 1 YEAR-REVIEW OF THE EKOSONIC® ENDOVASCULAR SYSTEM (BOSTON SCIENTIFIC) IN THE MANAGEMENT OF PULMONARY EMBOLISM IN AN INTERVENTIONAL CARDIOLOGY DEPARTMENT

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Background and Importance Since September 2022, the EkoS (Boston Scientific) percutaneously inserted thrombolysis catheter has been used in interventional cardiology at the Orléans Regional Hospital Centre for the treatment of intermediate-risk or severe pulmonary embolisms (PE). This medical device (MD) enables in situ administration of actilyse, whose diffusion within the thrombus is promoted by the application of ultrasound. It is an expensive medical device that is not currently reimbursed.
Aim and Objectives The aim of this work is to collect the indications of patients treated, the therapeutic protocol (TP) used and to assess the financial impact of Ekos on their stays.
Material and Methods Over the period from September 2022 to August 2023, indications, clinical contexts and TPs were collected from patient records. A literature review was carried out on the recommended TP. A cost analysis was carried out, taking into account the EKOS and associated actilyse, and the medical information department (MID) was contacted for all PMSI data.
Results Six patients were treated, with a sex ratio M/F = 4/2 and a median age of 69. The indication of high-intermediate-risk bilateral pulmonary embolism was found in all patients, with two catheters used for each; no complications following their use were found. The TPs used indicate an administration of 6mg during 6h per catheter. With regard to financial data, the cost of the technique was € 6,300 excluding VAT (€ 3,000/catheter and € 150/actilysis vial). The coded main diagnosis was PE for all patients. Fibrinolysis procedures and the associated diagnosis of heart failure (always present when fibrinolysis is indicated) were found for only two patients. An intensive care package is associated with each patient. In total, the average amount received was € 6,453 per stay. A simulation was carried out with the MID in order to improve the coding: the value of the stay could then amount to € 12,898.00 i.e. double the initial amount.
Conclusion and Relevance EKOS is used for the indications specified by the manufacturer. The TP may evolve in line with new publications. At present, the amount allocated per stay does not cover the technique used. In the context of healthcare cost control, optimised coding will enable us to continue using EKOS at this hospital in the future.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

1ISG-022 HOSPITAL PHARMACISTS' PERCEPTIONS OF THEIR PROFESSION IN TWO EUROPEAN COUNTRIES

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Background and Importance While 5 years of training are necessary to become a hospital pharmacist (HP) in the United-Kingdom, 9 years are required in France. The UK system allows HPs to acquire an independent prescribing qualification which is not possible for French HPs who tend to practice a wider range of non-prescribing roles.
Aim and Objectives The aim of this study is to compare French and UK HPs' perceptions about their roles and identify the challenges they are facing.
Material and Methods Results were gathered through an electronic survey distributed via emails and social networks. It was produced in English and French and encompassed 26 questions; 17 mandatory and six open. Statistical analysis was performed with a Z test and analysis to open questions was performed with ChatGPT.
Results After 6 weeks, 164 responses were collected: 94 from France, 70 from the UK.

Answers highlight that both groups share similar values such as feeling useful in the patients' care. Perceived workload and stress are higher in the UK ($p<0.015$, $p<0.001$). Patients and medical teams value the pharmacists' role to a higher level in the UK than they do in France ($p<10^{-4}$, $p<10^{-5}$). The levels of personal and job satisfaction are equivalent. Similar issues are raised such as workload, staffing and a need for more training. To tackle these challenges both groups would prioritise improvement of the IT systems, pharmacy technicians' recruitment, and administrative workload reduction. In

Abstract 1ISG-022 Table 1 Percentage of positive responses by pharmacists

Description	UK	France
Running clinical activities:	86%	56%
- Less than 25% of total activity	20%	59%
- Satisfied with clinical share of duties	82%	47%
Doing out of hours duties	24%	52%
Having done additional training	89%	82%
Happy to prescribe drugs	99%	52%
Happy to prescribe follow-ups tests	90%	72%
Wishing to continue working in their current field	84%	82%

the UK, pharmacists also wish to reallocate tasks within the team ($p<0.005$).

Conclusion and Relevance This study shows that HPs enjoy their profession despite issues that require a reorganisation at a national level. Results suggest that UK pharmacists are more confident with being a prescriber than the French, who worry about responsibility and overwork.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

1ISG-023 ECONOMIC IMPACT DERIVED FROM PARTICIPATION ON ANTIRETROVIRAL THERAPY CLINICAL TRIALS IN A THIRD-LEVEL HOSPITAL

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Background and Importance Antiretroviral therapy (ART) cost is an important expense in the annual Hospital Pharmacy Service (PS) investment. Clinical trials (CT) for ART development represent a high percentage of the CT carried out in a PS, being an opportunity for the hospital in terms of cost savings for these medications.

Aim and Objectives To analyse the avoided cost of ART medications because of patient participation in CT.

Material and Methods Retrospective observational study carried out from January 2021 to March 2023. All patients who were participating in CT against human immunodeficiency virus (HIV) treated with ART were included. Variables collected were: number of patients, investigational drugs, visits and dispensations performed, treatment that the patient would have received if they had not participated in the CT and its cost. Patient's treatment before enrolling in CT and standard therapies according GESIDA guidelines at the time of inclusion in CT were considered for that purpose. Information was obtained from Fundanet® and OrionClinic.®

Avoided cost was calculated as the difference between the cost of the treatment that the patient would have received if they had not participated in the CT and the CT treatment cost paid by the hospital.

Results 13 CTs were analysed and 89 patients were included with a median age of 44±12 years old and an 87% (77) of male prevalence. The average time participating in the CT was 16 months, having recorded 1,075 clinical visits (12 visits/patient) and 2,997 dispensations (26 dispensations/patient).

ART for intramuscular and oral administration were studied in three and 10 CTs respectively, with a median of two investigational drugs per CT. The alternative therapeutic combinations to CT participation were: dolutegravir +abacavir+lamivudine (32.6%), bictegravir+emtricitabine +tenofovir alafenamide (14.6%), dolutegravir+lamivudine (14.6%), darunavir+cobicistat+emtricitabine+tenofovir alafenamide (13.5%).

The theoretical total cost of treating patients outside of CT would have been € 734,432. The hospital provided part of the medication of one CT. Therefore, the total cost avoided was € 721,796, being a hospital saving of € 333,136.60 annually; € 8,110.10 per patient and € 3,743.10 per year/patient.

Conclusion and Relevance Patients' inclusion in HIV CT considerably reduces the pharmaceutical expenses related to ART medications since investigational drugs are provided free of charge by the sponsor. Therefore, CTs represent important economic savings for hospitals, contribute to the Spanish Health System sustainability and allow access to new therapies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

1ISG-024 SINGLE-USE MEDICAL DEVICES IN THE TREATMENT OF CHRONIC DISEASES: WHAT IS THE ENVIRONMENTAL IMPACT?

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Background and Importance Single-use medical devices are a common practice in biological drugs administration, potentially improving compliance, reducing the risk of contamination and the need for recharge and sterilisation of used devices.

Rising prevalence of autoimmune diseases and therapeutic innovation promote their usage. However, there is limited literature regarding environmental impact resulting from increased plastic consumption, a component of these devices.

Aim and Objectives To assess the amount of plastic used in biological treatments with pre-filled pen/syringe single-dose format.

Material and Methods Descriptive study consisting in weighing devices for ambulatory dispensing, followed by calculation of expected annual plastic consumption, per drug and dosage.

Extrapolation of results considering the total number of patients undergoing treatment with these drugs as of September 2023.

Comparison of annual plastic consumption for these patients, assuming as alternative, one reusable pen/device annually.

Results Twenty-two drugs available in the institution were selected. Weight values ranged from 5.65g (anakinra) to 74.25g (golimumab), with an average weight of 36.37g per device.

Regarding the number of devices needed for annual maintenance, the lower and upper limits were four pens (ustekinumab, risankizumab, tildrakizumab) and 365 syringes (anakinra).

This corresponded to an annual use of 215.8g, 268g, 191g and 2062.3g of plastic, per patient, respectively.

By analysing the cumulative annual plastic consumption of patients undergoing treatment in the institution (n=948), we obtained the value of 1980.1kg (32972 devices).

Assuming the hypothesis of using only one pen/device per year, with refills that may weigh about 9.4g (using the example of interferon beta-1a), we obtained a value of 345.4kg, leading to an annual reduction of 1634.7 kg of plastic.

Conclusion and Relevance These systems, maintaining safety, efficacy, and therapeutic adherence, could represent significant savings in environmental impact and production costs. The use of existing technology, such as refillable cartridges, could address this issue. Despite the aforementioned advantages, the significant amount of wasted plastic is clear.

A national extrapolation based on relative weight of drug consumption in our institution may indicate that it could be possible to avoid as much as 65 tons per year.

An environmental impact of this magnitude should prompt a reflection on the alternatives that can be employed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

1ISG-025 ANALYSIS OF THE COMPLEXITY OF THE CLINICAL TRIALS CARRIED OUT IN A THIRD-LEVEL HOSPITAL

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Background and Importance Clinical trials (CTs) involve different procedures in which Pharmacy Service (PS) participates. Difficulty evaluation of these activities is important to analyse global CTs complexity, which could be used as a measure of resources needed in each CT by PS.

Aim and Objectives To assess the complexity of the CTs in which PS participates, depending on the CTs' characteristics.

Material and Methods Observational retrospective study which includes CTs started from 2014 to August 2023 when CTs unit was founded as an independent area in PS. CTs' characteristics were collected: medical service involved, pathology, uni/multicentric and phase. Complexity scale from Calvin-Lamas et al., 2012 was used. Complexity punctuation was assessed according to the procedures where PS is involved (investigational products (IP) receipt, conservation, assignment, preparation, conditioning and dispensation; randomisation and blinding). Complexity levels were established: low (until 10 points), moderate (11–19 points) and high (more than 19 points). Complexity analysis was calculated for global, medical service, pathology and CTs' phase. Information was obtained from Fundanet®.

Results 101 CTs started during the studied period. Distribution between medical services was: 48.5% (49) oncology, 21.8% (22) infectious diseases, 20.8% (21) neurology, 5.9% (6) rheumatology, 2.0% (2) surgery and 1.0 (1) psychiatry service. Pathologies more investigated were related to human immunodeficiency virus 16.8% (17), breast cancer 12.9% (13), Parkinson's disease 12.9% (13), colorectal cancer 7.9% (8), Alzheimer's disease 6.9% (7), lung cancer 5.0% (5), gastric cancer 5.0% (5) and rheumatoid arthritis 5.0% (5). According to CTs' phase, 1.0%; 25.7%; 67.3% and 5.9% corresponded to phases I; II; III and IV, respectively. 99.0% were multicentric and 52.5% (53) were unblinded.

CTs which required two pharmacists represented 37.6% (38). Aseptic preparation was needed in 47.5% (48) and dispensation to the research team was needed in 74.3% (75).

Overall average complexity was moderate (15.1±4.0). 16.8% (17) presented low complexity, 70.3% (71) moderate complexity and 11.9% (12) high complexity. The higher complexity corresponds to neurology CTs. Pathologies with higher complexity were gastric cancer (20.2±2.6), Alzheimer's disease (18.1±2.2) and lung cancer (18.0±3.3). Average complexity was moderate for all CTs' phases, being the punctuation higher in phase II CTs (16.6±2.3), followed by phases I (16.0±0), III (15.1±4.2) and IV (12.2±4.8).Classifying by triennium, median CTs complexity has gradually increased:11.0±1.0 for 2014–2016,13.7±8.9 for 2017–2019 and 15.3±5.2 for 2020–2022. In 2023, complexity remained at 16.8±2.4.

Conclusion and Relevance The complexity of CTs has increased over the years, although most CTs have a moderate complexity regardless of their phase. The most complex CTs correspond to oncological and neurological pathologies. Carrying out this type of evaluation is important to optimise resources and to know in which PS procedures it is necessary to invest new resources.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

2SPD-001 CLINICAL IMPACT AND COST SAVINGS OF AN OUTPATIENT ANTIMICROBIAL THERAPY PROGRAMME: A FOCUS ON SELF-ADMINISTRATION

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Background and Importance Outpatient antimicrobial therapy (OPAT) programmes are increasingly used to reduce hospitalisation costs in health care facilities.

Aim and Objectives To analyse the clinical impact and cost savings of an OPAT programme focused on self-administration by the patients of antibiotic elastomeric pumps (AEP) prepared in the pharmacy service.

Material and Methods Observational, retrospective study. It included all patients who received OPAT from 1 May 2022 to 31 July 2023, using 30-minute or 24-hour AEP depending on the antimicrobial. Self-administration was offered to all patients with previous training.

Number of patients, episodes and AEP prepared, demographic variables (sex and gender), start and end of treatment (either in the hospital or at home) and hospital-at-home stay, self-administration episodes and source of infection were registered.

The resolution of the infectious syndrome and hospital readmissions at 30 days were evaluated to analyse the clinical impact.

To analyse cost savings, the time needed by pharmacy technicians to prepare AEP and avoided visits (physicians and nurses) for those patients using self-administration were compiled. Costs associated with daily hospital-at-home stay, AEP used and pharmacy technicians´ preparation were compared with costs of hospital stay and physician and nurse visits.

Results 161 patients (172 episodes and 1,442 AEP prepared) were included. 57.7% were men, with a median age of 68 years (IQR 54–81). The median duration of treatment was 9 days (IQR 6–14), and hospital-at-home stay was 8 days (IQR 6–14). 64 patients (39.8%) were included for self-administration. The most common sources were respiratory (25.5%), intra-abdominal (24.8%) and urinary (18.0%).

Resolution and readmission at 30 days were registered in 91.8% and 13.5% of episodes, respectively.

The time needed by pharmacy technicians was 0.2 hours for 30-minutes and 0.3 hours for 24-hour AEP, having a cost of € 4,952.20. A total of 590 avoided visits were registered, saving € 41,890. Total expenditure of OPAT and hospital-at-home stay was € 386,344.60 compared to € 1,583,109 for hospital stay and additional visits resulting in € 1,196,764.4 of cost savings.

Conclusion and Relevance OPAT programmes pose significant advantages in terms of clinical and economic impact, for managing patients needing longer antimicrobial treatments. Self-administration of AEP is a promising option to optimise their results in clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

2SPD-002 EVALUATION OF THE EFFECTIVENESS AND RELATED COST OF ONCOLOGY DRUGS USED IN SPECIAL SITUATIONS, IN A THIRD-LEVEL UNIVERSITY HOSPITAL

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Background and Importance Some oncological treatments are used in special conditions due to the lack of therapeutic alternatives. The use of drugs in exceptional circumstances or special situations (compassionate use (CU), off-label use (OLU), EMA approved drugs without a refund price in the country, and drugs not included in the hospital's pharmacotherapeutic guide (non-HPG)) is frequent. These treatments must be approved by an internal committee at the hospital level according to Spanish legislation.

Aim and Objectives To analyse the requests and effectiveness of drugs in special situations in oncology patients at a third-level university hospital.

Material and Methods An observational, single-centre, retrospective study was performed to analyse the prescription of special situation drugs in oncology patients between January 2021 and December 2022. Data were collected regarding the nature of the special situation, cancer type, treatment setting (curative or palliative), ESMO clinical benefit, treatment acceptance, clinical response, discontinuation reasons, number of administered cycles, and associated cost, which was calculated based on the treatment cycles administered until the end of the study.

Results 1045 requests were submitted to the hospital committee: 204 (19.52%) belonged to the oncology field (solid tumours). Among these, the types of special drug petitions were: CU (n=46, 22.55%), OLU (n=102, 50%), without a refund price in the country (n=44, 21.57%), and non-HPG (n=12, 5.88%).

Curative setting (n=30): ESMO benefit categories A (n=25, 83.33%), B (n=0, 0%), C (n=4, 13.33%) and not applicable (n=1, 3.33%). Metastatic disease (n=174) ESMO benefit scale 1 (n=32, 18.39%), 2 (n=12, 6.90%), 3 (n=58, 33.33%), 4 (n=55, 31.61%), 5 (n=0, 0%), and not applicable (n=17, 9.77%).

Abstract 2SPD-002 Table 2

Approved treatment (94.12%, N=192)	N(%)
Not initiated	16 (8.33)
Completed/continued	
Ongoing	51 (26.56)
Completed adjuvant therapy	12 (6.25)
Discontinued	
Disease progression	76 (39.58)
Adverse effects	22 (11.46)
Deceased	14 (7.29)
Hospital transfer	1 (0.53)
Denied treatment by Catalan Health Service (5.88%, N=12)	

Patients who did not start the treatment (8.33%) were those with no further therapeutic alternatives who progressed and did not have time to initiate this therapeutic approach.

Abstract 2SPD-002 Table 1

Cancer type	N(%)	Curative N(%)	Metastatic N(%)
Breast	34(16.67)	5(2.45)	29(14.22)
Lung	33(16.18)	8(3.93)	25(12.25)
Central nervous system	33(16.18)	1(0.49)	32(15.69)
Digestive	33(16.18)	3(1.47)	30(14.71)
Skin	26(12.74)	6(2.94)	20(9.80)
Gynaecologic	24(11.76)	5(2.45)	19(9.31)
Genitourinary	16(7.84)	2(0.98)	14(6.86)
Head and neck	5(2.45)	0(0)	5(2.45)
Total	204(100)	30(14.71)	174(85.29)

The average ± SD of administered cycles was 5.89 (±5.74), amounting to a total cost of € 2.597.220.

Conclusion and Relevance There is a high percentage of medication requests in special situations in the oncology field, most of them in the palliative setting (85.29%), with significant economic impact. It is crucial to regulate special-use medications to ensure equal treatment opportunities among cancer patients of different country hospitals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

2SPD-003 PROPER MANAGEMENT AND ECONOMIC BURDEN OF UNUSED MEDICATIONS DISPOSAL IN A SUSTAINABLE LATIN AMERICAN HOSPITAL: A RETROSPECTIVE STUDY

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Background and Importance The remarkable progress made in healthcare has led to a simultaneous surge in pharmaceutical waste generation, driven by the increasing number of patients, prescriptions, medication consumption, and overproduction. Approximately two-thirds of prescription medications go unused. Environmental contamination with medications, if not disposed of correctly, can have far-reaching implications.

For this reason, conducting a thorough assessment of pharmaceutical waste, considering both quantity and quality, is crucial.

Aim and Objectives The goal of this study is to illustrate the correct medication disposal practices and their economic repercussions within a sustainable Latin American hospital. Additionally, it seeks to comprehend the linked indirect costs and identify which medications are at a higher risk of becoming waste.

Material and Methods In this study, we conducted a retrospective analysis of medication disposal records spanning the years 2020 to 2023. The records pertained to routine medication disposal, necessitated primarily by reasons such as expiration, damage, or recalls.

The methodology involved a systematic categorisation of pharmaceutical products earmarked for disposal. For each medication, we meticulously recorded the quantity that was discarded, the specific reason behind its disposal, the original source of the medication, and its corresponding category.

Additionally, we gathered comprehensive data on the procedures employed for the controlled, responsible, and safe disposal of medications, providing insights into the methods utilised to ensure the proper management of pharmaceutical waste.

Results Table 1 shows the discarded units of preparations according to their classification by therapeutic groups, where it is noteworthy that food products, cardiovascular system drugs, and nervous system drugs take the top positions.

On the other hand, when estimating the cost in US dollars. (USD) associated with this waste, it was found that during the study period, the costs of discarded medications amount to approximately 300,000 USD. This is led by anti-infective drugs, antineoplastics, and immunomodulators.

Abstract 2SPD-003 Table 1

Analysis of expired medicine units according to the therapeutic group

Therapeutic Group	Units	% of total units	% expired
Alimentary tract and metabolism	**9839**	**9.20%**	**15.10%**
Drugs used in diabetes	2815	2.63%	3.95%
Drugs for acid related disorders	1387	1.30%	2.64%
Antidiarrheals, intestinal anti/inflammatory/antiinfective agents	2591	2.42%	2.13%
Others	3046	2.85%	6.38%
Cardiovascular system	**9902**	**8.58%**	**13.07%**
Agents acting on the reninangiotensin system	3248	3.50%	5.93%
Lipid modifying agents	1250	1.17%	2.52%
Beta blocking agents	3451	3.23%	2.34%
Others	1303	1.22%	2.31%
Nervous system	**8536**	**7.98%**	**12.54%**
Antiepileptics	1845	1.73%	3.15%
psycholeptics	2089	1.95%	2.91%
Psychoanaleptics	1732	1.62%	2.70%
Others	2870	2.68%	3.77%
Antiinfectives for systemic use	**7975**	**7.46%**	**9.44%**
Antibacterials for systemic use	2160	2.02%	5.36%
Vaccines	819	0.77%	2.10%
Antimycotics for systemic use	134	0.13%	0.66%
Others	4862	4.55%	1.32%
Musculoskeletal system	**4406**	**4.12%**	**7.40%**
Antiinflamatory and antirheumatic products	3969	3.71%	5.90%
Muscle relaxants	360	0.34%	1.20%
Antigout preparations	68	0.06%	0.18%
Others	12	0.01%	0.12%
Respiratory system	**3478**	**3.25%**	**6.41%**
Drugs for obstructive airway diseases	1704	1.59%	2.49%
Cough and cold preparations	619	0.58%	1.89%
Antihistamines for systemic use	755	0.71%	1.29%
Others	400	0.37%	0.75%
Blood and blood forming organs	**2620**	**2.45%**	**5.81%**
Blood substitutes and perfusion solutions	1745	1.63%	3.48%
Antithrombotic agents	650	0.61%	1.56%
Antianemic preparations	171	0.16%	0.45%
Antihemorrhagics	54	0.05%	0.33%
Antineoplastic and immunomodulating agents	**3266**	**3.05%**	**5.39%**
Cardiac therapy	1880	1.76%	3.62%
Immunosuppressants	787	0.74%	0.66%
Antineoplastic agents	172	0.16%	0.60%
Others	427	0.40%	0.51%
Genitourinary system and reproductive hormones	**1419**	**1.33%**	**3.65%**
Urologicals	746	0.70%	1.71%
Sex hormones and modulators of the genital system	487	0.46%	0.87%
Gynecological antiinfectives and antiseptics	75	0.07%	0.60%
Other gynecologicals	111	0.10%	0.48%
Systemic hormonal preparations, excluding reproductive hormones and insulins	**1303**	**1.22%**	**2.70%**
Corticosteroids for systemic use	472	0.44%	1.38%
Thyroid therapy	745	0.70%	1.05%
Pituitary and hypothalamic hormones and analogues	56	0.05%	0.21%
Calcium homeostasis	30	0.03%	0.06%
Sensory organs	**144**	**0.13%**	**1.14%**
Dermatological drugs	**382**	**0.37%**	**3.14%**
Antiparasitic products, insecticides and repellents	**1467**	**1.37%**	**0.90%**
Various ATC Structures	**52702**	**49.28%**	**15.21%**
Total	**106939**	**100.00%**	**100.00%**

Conclusion and Relevance When analysing the outcome of the medication disposal process, it is important to emphasise that these data were collected thanks to a successful protocol for managing such waste. Their analysis highlights a significant monetary wastage and also poses a risk to the environment and public health, as improper disposal of products such as anti-infective drugs, antineoplastics, and immunomodulators could pose a threat.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

2SPD-004 BUDGETARY IMPACT OF THE INTRODUCTION OF CABOTEGRAVIR PLUS RILPIVIRINE LONG-ACTING IN A THIRD-LEVEL HOSPITAL

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Background and Importance To analyse the potential budgetary impact of the introduction of cabotegravir (CAB) plus rilpivirine (RPV) long-acting in a third-level hospital.

Aim and Objectives To analyse the possible budgetary impact on our cohort of human immunodeficiency virus (HIV) patients.

Material and Methods Inclusion criteria: All active HIV-positive (HIV+) patients ≥18 years old (with adherence ≥95% and undetectable viral load (<50 copies/mL) in the last 6 months) and with prescription and dispensing of combination oral antiretroviral therapy (ARTs) in our hospital. Study period: January to December 2022. Exclusion criteria: history of previous failure to non-nucleoside analogues or intolerance; HIV subtype A1-A6; body mass index (BMI) ≥30.

Variables collected Number of patients who meet the inclusion criteria, cost of active ARTs in 2022 and CAB 600 mg IM +RPV 900 mg IM long-acting (and CAB and RPV (oral lead-in)). Only direct pharmacological costs have been taken into account.

A Scenario 1 (CAB+RPV long-acting is not used) vs Scenario 2 (with the introduction of CAB+RPV long-acting throughout the year 2023).

Results Of the total of 2,065 HIV+ active patients in our hospital 1,882 patients have been included. 91% of the most prescribed ARTs: BIC/TAF/FTC in 32.74% (n=676); DTG/3TC in 32.15% (n=664); TAF/FTC/RVP in 8.09% (n=167); DRV/c/FTC in 7.94% (n=164); DTG/ABC/3TC in 5.33% (n=110) and DTG/RVP in 4.89% (n=101). 14% (n=268/1,882) already have RPV in their oral ARTs and would not have to do oral lead-in with CABO+RPV the previous month. Only 90% (n=1,694) met all the inclusion criteria. It has been estimated that only 10% of patients would change oral ARTs for long-acting therapy (n=169).

The cost of scenario 1 for the 169 patients would be € 1,808,525.11/year. In scenario 2, 87% of the patients (n=147/169) would switch to long-acting ART after oral lead-in with CAB+RPV the previous month at a cost of € 1,659,737.31/year; and 13% (N=22/169) would go directly to ART long-acting with a cost of € 265,228.04/year. The overall value of scenario 2 would be € 1,924,965.35/year. The difference in costs would be +€ 116,440.24/year.

Conclusion and Relevance Without taking into account other types of costs, the introduction of CAB+RPV long-acting in a third-level hospital would imply a higher cost vs using oral ARTs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

2SPD-005 ALTERNATIVE TO THE TREATMENT OF POOR GRAFT FUNCTION AFTER HAEMATOPOIETIC STEM CELL TRANSPLANTATION: ELTROMBOPAG

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Background and Importance Poor graft function is a rare and serious complication in patients who have undergone haematopoietic stem cell transplantation (HSCT).

It is characterised by moderate to severe cytopenias (haemoglobin less than 10 g/dl, platelets less than 20* 10^9/L, neutrophils less than 1 * 10^9/L) requiring transfusion support or G-CSF, in patients with complete chimerism.

Currently, treatment options are very limited and not without complications.

Aim and Objectives Our aim is to evaluate the effectiveness of eltrombopag as an off-label indication in patients with poor graft function who have undergone HSCT.

Material and Methods Observational, retrospective, longitudinal study in which the effectiveness and safety of eltrombopag was evaluated in patients with poor graft function who received HSCT between January 2018 to January 2023. Patients were analysed from the start of eltrombopag until recovery of function and/or death.

Poor graft function was defined as the presence of sustained thrombopenia (<20 x10^9/L) despite transfusion support.

Effectiveness was assessed by the overall haematological response rate: platelet recovery (platelets >50 x10^9/L for >4 weeks).

Data analysis was performed using SPSS 21.0 statistical software. Variables were analysed using descriptive statistics.

Results 37 patients (56.8% male), mean age 50.9 years (SD=13.03) were analysed. The most prevalent diagnosis was acute myeloid leukaemia (43.2%), followed by myelodysplastic syndrome (13.5%) and non-Hodgkin's lymphoma (10.8%). The most frequent type of transplant was haploidentical (78.4%).

The median start of treatment since HSCT was 76 days. Most patients started with an eltrombopag dose of 50 mg (56.8%).

The mean platelet count before the start of treatment was 25.378/µL, while at the end of treatment the mean platelet count was 73.162/µL.

Platelet recovery was achieved in 59.5% of patients. The median duration of treatment was 4.1 months.

Conclusion and Relevance Among the few existing therapeutic alternatives for thrombopenia resulting from poor graft function, the use of eltrombopag shows response rates close to 60%, so it appears to be an effective alternative.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

2SPD-006 IMPACT AND CONSEQUENCES OF THE USE OF HUMAN POLYVALENT IMMUNOGLOBULIN DURING THE COVID-19 PANDEMIC (2019–2022)

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Background and Importance The use of human polyvalent immunoglobulin, intravenous or subcutaneous -Ig IV/SC- has suffered a notable increase in recent years – over 10% per year – given the high number of complex pathologies candidates for treatment, and due to the erroneous perception of its safety: the benefit-risk balance is often not considered, nor is the cost-benefit. However, the COVID-19 pandemic has limited patient flows, on the one hand, and donations and, consequently, the availability of the drug, on the other.

Aim and Objectives To evaluate the use – consumption and indications – of Ig IV/SC, during the years 2019–2022, in adult and paediatric patients, in a tertiary hospital.

Material and Methods Analytical, observational, cross-sectional, retrospective study, carried out during the years 2019–2022. Data collected from the prescription and medication administration records were patient, medication, indication, dispensing date, amount dispensed, and department.

The relevance of the therapeutic indications was evaluated according to the classification proposed in the Clinical Guidelines for Immunoglobulin Use of the British Health Department (2nd Edition, 2008, and Updates 2011, 2018), and their Spanish adaptation.

Results Ig IV/SC consumption is shown in the following table 1.

Abstract 2SPD-006 Table 1

	2019	2020	2021	2022
Route of administration				
Intravenous (kg)	169	160	151	143
Subcutaneous (kg)	16	19	16	23
Type of patient				
Adult (kg)	171	164	153	151
Paediatric (kg)	13	15	15	15
Total	**184**	**179**	**167**	**166**

The analysis of the indication for treatment – year 2022 – shows that 364 patients received at least one dose of Ig IV/SC in the Day Hospital or at Home, with a degree of adequacy to the recommendations in 339/364 patients (95.1%); in hospitalisation, counting 207 patients, the degree of adequacy was 160/207 patients (77.0%).

Conclusion and Relevance The global use of Ig IV/SC has been reduced by 9.8% in the context of the COVID-19 pandemic (2019–2022) due to problems of availability and the prioritisation of the indications with the greatest evidence, existing a very high adequacy adaptation to indication recommendations, especially in outpatients (95.1%). However, the use of Ig IV/SC in paediatric patients has increased (17.3%) and the use of Ig SC has also increased globally (40.4%).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

2SPD-007 USE AND COST EVOLUTION OF ADALIMUMAB OVER 8 YEARS IN A LOCAL HOSPITAL

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Background and Importance The ongoing rise in healthcare costs makes it necessary to establish containment strategies, in parallel with the commitment to improve access to the most effective and safest treatments. The introduction of biosimilar medicines is an opportunity for health systems (HS) and patients.

Aim and Objectives The aim of the study was to evaluate the use and cost evolution and adalimumab in a local hospital over the last 8 years. Biosimilar adalimumab was incorporated in 2019.

Material and Methods Data were collected based on consumed units of adalimumab between January 2016 and July 2023. We have multiplied the number of 80 mg adalimumab syringes by two to be able to add them to the 40 mg presentation. Consumption until June 2023 was extrapolated until December 2023 to be able to compare the values with complete years. Also, we grouped the different presentations of original brand and biosimilar molecules available, and the cost associated at the time it was consumed.

Results Adalimumab consumption (brand name and biosimilar adalimumab) has gradually increased over the past 8 years, from 2,424 in 2016 to 4,254 units in 2023 (+75.5%). Consumption, between 2016 and 2018, rose from 2,424 to 2,558 units (+5,5%), and their cost dropped slightly at the same period, from 1,070,460 to 1,053,300 euros (-1.66%). Adalimumab biosimilar was not introduced in the hospital until 2019 (penetration of biosimilars in 2019 was 17.9%, reaching 99.6% in 2023). Between 2019 and 2023, consumption increased from 3,317 to 4,254 units (+28.3%) with an absolute cost reduction of 752,553 euros (-78.3%). Overall, adalimumab spending has decreased by 81.6% over the 8 years despite the increase in consumption (75.5%).

Conclusion and Relevance Innovation in biological therapies, as well as the increase in candidates to receive them, has grown significantly. Involvement of different clinical services with the biosimilar molecules has led to significant savings **(-81.6%)**, despite the increase in consumption **(75.5%).** The commercialisation of biosimilar molecules, promotes the system's sustainability, enables access to a greater number of patients, while allowing for the continued incorporation of innovative molecules.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

2SPD-008 SWITCHING TO A BIOSIMILAR ADALIMUMAB IN DUTCH UNIVERSITY MEDICAL CENTRES: IT IS NOT THAT HARD!

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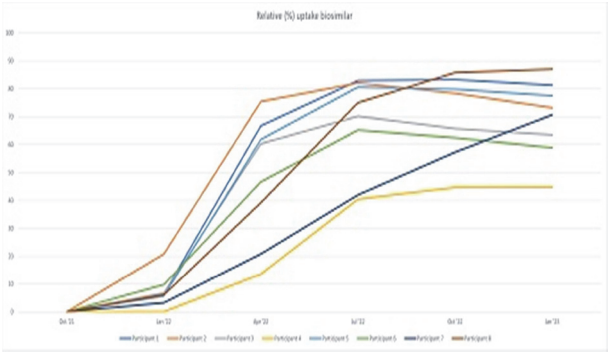
Background and Importance Monoclonal antibodies have extended pharmacotherapeutic treatment options for patients but are also greatly increasing the cost of expensive drugs. Biosimilars are equivalent to the original reference product in terms of efficacy and safety and can significantly attenuate the cost increase. In the Netherlands, University Medical Centres (UMCs) makes joint purchasing agreements for as many drugs as possible. The 2021 procurement of adalimumab, a tumour necrosis factor (TNF) alpha blocker for treatment of rheumatoid arthritis, Crohn's disease, psoriasis and uveitis, among others, resulted in the designation of a biosimilar (Hyrimoz®) as the most effective choice.

Aim and Objectives In this study the quantitative and qualitative aspects of the implementation of the biosimilar for adalimumab in all Dutch UMCs is analysed and we have sought successful strategies.

Material and Methods The analysis took place over the period from October 2021 to January 2023. The proportion of biosimilars was calculated as a percentage of the total number of adalimumab users at t = -3, 0, 3, 6, 9 and 12 months after introduction of the biosimilar. The quantitative study used a Pharma Insights® software tool, which collected add-on drug claims data for each of the eight UMCs.

Pharmacists in each UMC were interviewed about the implementation process and success factors, focusing on preparation, division of tasks, content of communication, instruction letters/materials, monitoring and evaluation of the switch.

Results The relative uptake of the biosimilar adalimumab is shown in figure 1 and differed between medical specialties. Interviews with (hospital) pharmacists revealed that the design



Abstract 2SPD-008 Figure 1

of the implementation process differed among UMCs and a good relationship and communication between the pharmacy and the outpatient clinics also proved essential for a successful switch.

Conclusion and Relevance In this field study in 6,000 Dutch patients, we observed that the pace and success of implementation varied by UMC, and our findings offer opportunities to improve this process by sharing best practices within UMCs and, for example, paying more attention to 'smaller' specialties such as Ophthalmology.

The use of biosimilars contributes to the efficient use of medicines and can save millions of euros on an annual basis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Members of the drug purchasing group of the Dutch UMC's (iZAAZ).

Conflict of Interest No conflict of interest.

2SPD-009 A 5-YEAR RETROSPECTIVE REPORT ON COMPREHENSIVE MEDICINE PROCUREMENT WITHIN A PUBLIC GROUP PROCUREMENT ORGANISATION

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Background and Importance Centralised procurement bodies play a critical role in the efficient procurement of essential medicines. However, in recent years there has been a growing recognition of the need to go beyond the traditional approach and integrate comprehensive approaches into central procurement processes. This shift is driven by the increasing complexity of healthcare systems, rising costs, and the desire to optimise resource utilisation.

Aim and Objectives The objective of this study is to evaluate the implementation of a comprehensive framework for medicine procurement within a regional group procurement organisation (GPO).

Material and Methods A retrospective study was conducted to quantify and assess the outcomes resulting from the comprehensive framework implementation of medicine procurement spanning from 2018 to 2023. The study aimed to determine the extent of the introduced procurement activities' value and the financial as well as non-financial benefits for hospitals and other healthcare organisations.

The comprehensive medicine procurement framework was established in 2018 and introduced new services and approaches to the procurement and tender activities of the GPO. This novel framework encompassed the following components: a) Standardisation of pre-tender activities: needs analysis, horizon scanning, market consultations, benchmarking with other GPOs, standardisation of purchasing criteria, opportunity cost and cost-effectiveness and development of innovative procurement models; b) The establishment of a technical office to coordinate the operational execution; c) Implementation of a contracting process derived from Framework Agreements; d) Ongoing monitoring of the results of awarded tenders, with feedback mechanisms; e) Alignment with the drug policies of public insurance.

Results A total of 127 tenders were conducted across 2018–2023. With an increasing number of tenders though the years. By incorporating services such as demand forecasting, market consultations, and clinical input, times were reduced for purchasing decisions. This optimisation on the procurement performance led to reduced costs, and enhanced supply chain resilience. However, no significant differences were found in the price reduction achieved through the aggregation of purchasing power by the GPO.

Conclusion and Relevance The Comprehensive Medicine Procurement of our GPO represents a transformative approach that aligns with the evolving healthcare landscape. By optimising resource utilisation, enhancing supply chain efficiency, and improving procurement performance, this approach ensures effective resource use for hospital pharmacies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

2SPD-010 IDENTIFYING AND QUANTIFYING DRUG-RELATED WASTE IN A HEALTHCARE ESTABLISHMENT

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Background and Importance In France, 8% of CO2 emissions come from the healthcare system, 20% of which are attributable to the medicines and medical devices used in healthcare establishments. A number of sustainable development initiatives are beginning to be implemented in hospitals, including the management of waste associated with medicines.

Aim and Objectives The aim of the study is to identify and quantify the sources of medicinal waste in order to implement virtuous sustainable development actions.

Material and Methods We targeted two clinical departments (Follow-up and Rehabilitation care (FRC) for spinal cord injuries (Department A) and FRC for geriatrics (Department B)) and the pharmacy. We chose these wards for the patient typology, average length of stay (ALOS), number of beds, dispensing method and type of storage.

Medicines-related waste was quantified over 2023 by recording the number of bins, the fill rate and the weight. Waste qualification was based on a sample of nine bins for which the type of waste they contained was recorded.

Results Department A with 25 beds and twice-weekly nominative dispensing, the ALOS is 186 days, with 140,274 dose units dispensed for 377 references. Medication waste represented 138 kg divided into 25% glass bottles, 23% tubular bags, 20% flexible blisters, 13% lids and 19% other, with a bin fill rate of 67%.

Department B which has 45 beds and is dispensed on a weekly basis, the ALOS is 48 days, with 185,990 dose units dispensed for 1,019 references. Medication waste represented 47.9 kg divided into 42% tubular bags, 31.5% lids, 14% glass bottles and 12.5% other, with a bin fill rate of 85%.

For the pharmacy, waste represented 177.4 kg divided into 34.5% glass bottles, 31.3% lids, 10.5% glass ampoules and 23.7% other, with a bin fill rate of 79%.

Conclusion and Relevance The pharmacy is the backbone of the hospital's medication circuit and must therefore take steps to eliminate medicinal waste in an ecologically responsible way. To do this, it is essential to know the amount of waste and the specific characteristics of each department. The main areas for improvement in reducing our waste are optimising the filling of bins, developing specific sorting channels and starting work on wasting medicines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

2SPD-011 AVAILABILITY OF LIQUID ANTIMICROBIALS – A NATIONAL ANALYSIS OF THE CURRENT SUPPLY SITUATION

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Background and Importance Oral liquid dosage forms of various antimicrobials represent the mainstay of therapy for paediatric infections, especially in infants and young children. However, shortages of such preparations have dramatically increased over the past year, challenging adequate therapy, especially in the community setting.

Aim and Objectives The aim of this study was to assess the supply situation of various antimicrobials in liquid dosage forms in Austria.

Material and Methods The availability of antimicrobials in liquid dosage forms was examined over a period of 27 weeks (February to August 2023). Actual supply data were extracted once weekly from a major Austrian full-service pharmaceutical wholesaler database and the availability of all liquid antimicrobials authorised in Austria was analysed.

Results A total of 42 products containing 15 different antimicrobials in liquid dosage forms are authorised in Austria. During the time period investigated, 34 products (81.0%) were not available for over 50% of the time; eight of those (19.0%) experienced complete unavailability. Only four products (9.5%) demonstrated continuous availability (i.e. preparations containing fluconazole, oseltamivir, and voriconazole).

Availability of cephalosporin antibiotics was specifically limited, with first-generation cephalosporins, being unavailable for prescription in 74.1% of the observation period (20 weeks). Cefpodoxime remained inaccessible for 96.3% of the investigated period (26 weeks), cefaclor and cefalexin for 85.2% (23 weeks) and 74.1% (20 weeks), respectively. Cefixime showed better availability, experiencing stockouts for only 44.4% of the time (12 weeks).

Regarding penicillin antibiotics, amoxicillin was not available for 77.8% of the time (21 weeks) and amoxicillin/clavulanic acid for 59.3% (16 weeks). Penicillin V showed better availability, being out of stock only for 37.0% of the time (10 weeks). Regarding macrolide antibiotics, azithromycin was not available for 63.0% of the time (17 weeks), while clarithromycin experienced 37.0% unavailability (10 weeks).

Conclusion and Relevance Medicines shortages, especially involving antibiotics, pose a global public health dilemma that can lead to adverse health outcomes. Regular monitoring of availability status can help mitigate this issue; however, cross-national strategies are urgently needed to guarantee a constant supply in the future.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

2SPD-012 APPLICATION OF FAILURE MODE AND EFFECTS ANALYSIS TO IMPROVE AUTOMATED DISPENSING CABINETS' DRUG STOCK MANAGEMENT PROCESSES

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Background and Importance Logistics processes for drug stock management are critical in the organisation of pharmacy services. Automated dispensing cabinets (ADCs) allow for better control of these processes, increasing patient safety, optimising drug consumption and costs. However, the use of these devices is not always the most appropriate, compromising its advantages.

Aim and Objectives To carry out a failure mode and effects analysis (FMEA) to optimise the use of ADCs by all stakeholders (pharmacists, pharmacy technicians and nurses).

Material and Methods A multidisciplinary team was established to perform an analysis using FMEA methodology (pharmacists, nurses, and pharmacy technicians). They defined all related failure modes that could occur, indicating causes and consequences through brainstorming meetings. Five risk maps were performed on the following processes: Resupply of ADCs, in floor return of drugs to ADCs, restock of temporary transfer cabinets, review of drugs expiration date, and drug dispensing through ADCs. The risk priority number (RPN) was calculated according to the following indices: Severity x Frequency x Detectability, assigning values from 1 to 10 to each index. Median RPN values were used to prioritise. Preventive and corrective actions were proposed.

Results A total of 27 failure modes were defined, accumulating 3,553 points of RPN (values ranged 9–300). The process 'drug dispensing through ADCs' obtained the highest median RPN value (192, 126–246). The number of failure modes with a RPN >200 was 6. After prioritisation, an action plan consisting of several activities, based on good practices guidelines from the Institute for Safe Medication Practices (ISMP) was proposed. A training programme for nurses on the use of ADCs was designed and implemented to ensure correct use on the hospitalisation floor. A reception plan for new pharmacy technicians, consisting of training documents, was elaborated. Finally, a plan for ADCs' setup and regular stock review by specialist pharmacists was designed. After 6 months, a new analysis was performed, and all the failure modes evaluated scored a RPN value <200.

Conclusion and Relevance The FMEA methodology allowed us to detect and evaluate failure modes and its effects, implementing an action plan to optimise the use of ADCs. In the

future, a survey among sanitary professionals will be carried out to analyse the impact of these actions.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

2SPD-013 A COMPARATIVE LIFE CYCLE ASSESSMENT OF DIFFERENT PACKAGING OPTIONS FOR ALBUMIN DISTRIBUTION

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Background and Importance Traditionally, albumin has been presented in glass vial packaging, but is it the optimal choice for its distribution?

In recent times, many pharmaceutical companies have shifted from glass vials to plastic bags to deliver their hospital products. Plastic bags have demonstrated clear advantages for both nurses (as glass carries a higher risk of breakage) and patients (since the bag does not require air inlet, so there is less risk of contamination). However, plastic bags are often perceived as harmful to ecosystems.

Life Cycle Assessment (LCA) provides the scientific evidence on the actual impact of the entire process. Therefore, when comparing glass and plastic packaging for the same product under LCA methodology, the scientific proof regarding environmental impacts is stablished.

Aim and Objectives The goal of this study is to compare the environmental performance of glass and plastic packaging options for delivering albumin 100 ml doses in the European market, considering all their life cycle stages.

Material and Methods A cradle-to-grave LCA has been performed, considering the distribution of 10.000 units of albumin (20%) served in 100 ml doses to hospitals as a reference or functional unit.

The Product Environmental Footprint method (E.F. 3.0) has been used for the environmental assessment of the alternatives. However, only the more 9 relevant impact categories after normalising the results plus water scarcity indicator have been analysed in further detail.

The study has been conducted following ISO 14.044 standard, using LCA for Experts software Gabi (until very recently known as GaBi) and their relative databases (2023_1 update).

Results Plastic bags perform better than glass vials in all the impact categories analysed. Regarding climate change total (CC) the improvement is 23%. Also noteworthy is the 55% reduction in water scarcity impact.

Conclusion and Relevance Although plastics are popularly considered harmful to ecosystems, plastic bags have less environmental impact than glass vials. So, for 10.000 units of albumin (20%) served in 100ml dose with plastic bag instead glass vial, the emission of 655 kg of CO2eq and the consume of 355 m^3 of water are avoided. This is equivalent to travelling about 3.930 km in an average car and to take 3.500 five-minute showers, respectively.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

2SPD-014 ECO-CONSCIOUS HEALTHCARE PRODUCTS SUPPLY: INVESTIGATING THE EFFECTS OF FEWER ORDERS

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Background and Importance Healthcare sector contributes 8% of the country's carbon footprint, with 50% attributed to healthcare product supply. Plasma-Derived Medicinal Products (PDMP) represent a significant portion of this product supply. An improvement project was initiated in early 2023 in our University Hospital (UH) to reduce the frequency of weekly orders to monthly orders.

Aim and Objectives Evaluate the Environmental Impact (EI) of a 6-month reduction in PDMP orders.

Material and Methods A query of the number of all PDMP orders was carried out using *Pharma*® software (*Computer-engineering*, V5.9). The results from February to July in 2022 and 2023 were compared. Suppliers' ability to communicate the EI of orders is compared to an estimate on literature data and the *Empreinte*® database of the Environment and Energy Management Agency (ADEME). Results are in CO_2 equivalents (eq. CO_2).

Results Among the 189 listed PDMPs from 17 suppliers, reductions were applied to three major suppliers (32% of 2022 orders). Their orders dropped from 99 (2022) to 73 (2023), representing a 26% decrease. The number remained stable for others and PDMP consumption were comparable between two periods. Suppliers could not estimate the orders' EI. Using the *Empreinte*® database, transporting products in fully loaded vehicles is ecologically favourable. According to the Shift Project, a 20–30% truck load increase saves 14% to 21% fuel. The average 400km distance to suppliers and a 20m^3 truck using 10L/100km of diesel B7 would save 5.6L of fuel per round trip. One litre emits 3.10kg.eq.CO_2, saving 451.kg.eq.CO_2 over 6-months. However, the number of PDMPs receipts has not decreased as much as the number of orders. The calculated CO_2 savings are estimates, if the ratio orders/receipts tend towards 1.

Conclusion and Relevance Reducing orders can optimise vehicle filling and lower delivery-related fuel consumption. Coordinating routes with other centres could further reduce EI. Route sharing could be considered by cohabitating flows with other centres. Larger orders require additional storage space, but it is not a concern in our establishment. Fewer orders also ease the workload for logistics staff. However, tensions in healthcare supply can lead to sporadic receptions independent of our reduction policy, making an exact order-receipt match challenging.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

2SPD-015 INTEGRATED HEALTHCARE LOGISTICS: KANBAN SOLUTION FOR MANAGEMENT OF DIALYSIS WAREHOUSES PILOT CASE

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Background and Importance The outsourcing of the integrated healthcare logistics service and the centralisation of the public healthcare company warehouses represent a response to technical and logistical-management critical issues typical of a decentralised system (Hub & Spoke warehouses) characterised by obsolete technologies and IT systems for warehouse stock management. The project (a 9-year contract that started in June 2022) involves the centralisation of all peripheral warehouses in a single warehouse HUB and the installation of a Warehouse Management System (WMS) required for the management of Drugs, Medical Devices (stock, transits) and various material useful for daily hospital activity.
Aim and Objectives This abstract focuses on micrologistics and, in particular, on the reorganisation of a dialysis warehouse based on a Lean Management perspective with the aim of optimising logistics and procurement processes.
Material and Methods The preparatory phase of the project involves the visual reorganisation of the department warehouse, identifying a unique, dedicated and marked location for each product and defining the department stocks (3 days of autonomy) and the mechanism and frequency of resupply (daily).

The key tool is the Kanban method: after taking each product from the department warehouse, the department operator places an 'X' on a dedicated Kanban board. Every day, a warehouse dedicated operator ('spider') collects the board and takes the consumed quantities from the central hospital warehouse to resupply dialysis warehouse stocks. The restored quantities are placed in the previously established spaces in the department locker.
Results The department is able to monitor stocks available on site, allowing a more accurate planning and reduction in waste due to expired goods. Department spaces defined for dialysis material storage are optimised (from 50 m^2 to 15 m^2). The methodology adopted allows us to guarantee a standardised and non-operator-dependent stock resupply method. The time spent by the Unit Coordinator on non-value activities for the reorganisation of the material is reduced (about 7 hours/week).
Conclusion and Relevance
Results are relevant This pilot case, whose main objective is to guarantee operational efficiency for dialysis material resupply through standardised management, provides a solid model that can be applied in the future to other business units in order to improve department efficiency and logistics service quality.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

2SPD-016 DATA-DRIVEN SELECTION OF A MEDICATION MANAGEMENT MODEL IN HOSPITALISATION WARDS

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Background and Importance Optimal dispensing and distribution management model of drugs reduces inefficiencies and increase drug safety.
Aim and Objectives To select best medication management model (centralised in pharmacy vs decentralised in hospitalisation wards (HW)) based on medication consumption pattern of different HW, in context of the redesign of medication management system in a high-complexity hospital.
Material and Methods Applying Pareto principles, an ABC-XYZ matrix was designed using medication consumption data from HW in January 2022. This data, obtained from the hospital's management system, included medications not listed in a pharmacotherapeutic guide (PTG). Information analysed included medication, guide inclusion situation, dispensed quantities, and HW. Within each HW, medications were categorised according to quantity (ABC) and variability (XYZ), with 'A' denoting highest consumption and 'Z' signifying maximum variability in consumption.

ABC:

- A. $x \leq 80{,}0\%$ (x medications ordered from maximum to lowest consumption)
- B. $80{,}0\% < x \leq 95{,}0\%$
- C. $95{,}0\% < x \leq 100{,}0\%$

XYZ:

- X. $CV < 0{,}3$
- Y. $0{,}3 \leq CV \leq 0{,}75$
- Z. $CV > 0{,}75$

Coefficient of variability (CV) was obtained by dividing standard deviation by the mean. Outliers were removed. ABC-XYZ combination defined consumption pattern of each medication for each HW, associated with a management system.

- GROUP 1: AX, AY, BX, CX – High consumption, low variability. Decentralisation and replenishment based on standard minimums.
- GROUP 2: BY, AZ – Moderate volume and variability. Decentralised with replenishment based on criticality or consumption peaks.
- GROUP 3: BZ, CY, CZ – High variability, regardless of consumption. Centralised in pharmacy or decentralised with systematic monitoring of expiration dates.
- GROUP 4: zero consumption.

Results 13 units and 826 references were analysed, 37 not included in PTG. Consumption pattern was similar across HW. In HW, 'A' account for 56–75 medications, 'B' for 63–99 and C for 105–151. A 39–96 [18%-32%] of the references belonged to Group 1, 54–62 [19%-24%] to Group 2, and 116–182 [48%-58%] to Group 3. Each HW only consumed 25%-36% of total references used in the hospital.
Conclusion and Relevance Optimal medication management model was determined by consumption pattern of each reference in each HW, rather than one-size-fits-all approach for entire hospital. However, data supports decentralising medications with monitoring of specific references.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

2SPD-017 RISK IDENTIFICATION IN ANTIDOTE AND EMERGENCY PREPAREDNESS

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Background and Importance Globally, antidote preparedness has been identified as a major challenge (Antoniello et al, 2023). The healthcare system must be able to ensure antidote availability and effective management for both individual poison cases and for mass casualties, whilst weighing in the financial burden. This study recognised a gap in literature on the local situation of emergency preparedness with regards to antidotes and the risks in local antidote availability and accessibility. Identification of risks is crucial for the development of risk management strategies to ensure no disruptions in the antidote supply chain.
Aim and Objectives The aim of this study was to identify risks in the availability and accessibility of antidotes in a small nation.
Material and Methods Vertical audits of eight antidotes (pralidoxime, atropine sulphate 600 mcg/ml injections, hydroxocobalamin kit, sodium thiosulphate, sodium nitrite, digoxin immune fab, activated charcoal and, acetylcysteine) were performed at the procurement unit and two acute general hospitals, to identify risks starting from the sourcing to the dispensing of antidotes for patient use. A clinical expert focus group was established for validation and prioritisation of identified risks.
Results Five of the antidotes were noted to have problematic sourcing due to restricted availability on the open market. Logistics and costs of antidotes had a major influence on antidote availability and accessibility. Other identified risks include inadequate stocking of antidotes, lack of periodic review of procurement specifications, delay of antidote release from quarantine due to regulatory barriers, insufficient training, lack of guidelines and national contingency plan, unreliable suppliers and bureaucratic procurement processes.
Conclusion and Relevance This is the first study of this nature to take place in this small nation. Findings indicate critical need for healthcare system optimisation in emergency preparedness. Risks associated with availability can be mitigated through the establishment of international cooperation agreements at European and global levels. The risks identified will be utilised in the development of guidelines and recommendations on the optimisation of emergency preparedness based on risk management principles.

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Conflict of Interest No conflict of interest.

2SPD-018 IMPACT OF INHALERS ON CO2 EMISSION IN A HEALTH AREA

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Background and Importance There are several types of devices for inhaled therapy, being the most used ones: pressurised metered-dose inhalers (pMDIs), dry-powder inhalers (DPIs) and soft mist inhalers (SMIs). All the types have some environmental impact due to their effect on CO_2 emissions, although very low compared to total CO_2 emissions, pMDIs have proven to exert higher CO_2 emissions than DPIs and SMIs.
Aim and Objectives The main objective is to estimate the impact of pMDIs, DPIs and SMIs, prescribed for any indication, on CO_2 emissions in our health care area during 1 year.
Material and Methods Number of inhalers consumed in our health care area with a population of 550086 inhabitants during 2022 was extracted from the Pharmacy Benefit Management Data.

The inhalers' carbon footprint values were extracted from the publication Montoro et al. The estimated mean value of Kg CO_2-eq/year/pack was 16.69 for pMDIs, 1.02 for DPIs and 0.59 for SMIs.
Results Of the total amount of inhalers consumed during 2022, 39.21% were pMDIs, 54.47% were DPIs and only 6.33% were SMIs.

Considering the estimated correction value, the carbon footprint was 2297846 kg CO_2-eq for pMDIs (91.69% of the total carbon footprint of all the inhalers), 195104 kg CO_2-eq for DPIs (7.79%) and 13105 kg CO_2-eq for SMIs (0.52%).
Conclusion and Relevance The carbon footprint of the pMDIs represented more than 90% of the total carbon footprint of all the inhalers, even when consumption of pMDIs represented less than the 40%. This put in evidence the considerable higher environmental impact of pMDIs compared to DPIs.

However, this does not go in line with several societies and organisms which keep defending that efficacy, safety and patient suitability must continue to be the main factors when choosing a type of inhaler for each patient.

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Conflict of Interest No conflict of interest.

2SPD-019 TOWARDS A SUSTAINABLE OPERATING ROOM: FEEDBACK ON ACTIONS CARRIED OUT AROUND MEDICAL DEVICES

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Background and Importance Since 2022 within our healthcare establishment, a multi-professional think tank has been engaged in the implementation of a sustainable development approach with three objectives: reduction of the volume of waste, energy saving and fight against pollution in the operating room (OR).
Aim and Objectives Rationalise Medical Device (MD) references and move some defined as uncritical in terms of infectious

risk, sterile single-use double packaging, towards reusable 'resterilisable'. The approach was applied to skin preparation sets, electric and cold scalpel handles.

Material and Methods A working group was created, made up of pharmacists, pharmacy technicians, OR managers, OR nurses, sterilisation and hygiene service. The number of references, quantities ordered, and the annual budget spent in 2022 were evaluated. For the skin preparation sets, an audit among OR nurses was carried out to assess usage practices and to find out if switching to re-sterilisable MDs for the skin preparation stage was possible. The organisational, economic and environmental impact was assessed.

Results In 2022, 15,690 skin preparation sets (€ 70,547), 15,455 single-use electric scalpel handles (€ 24,092) and 12,310 single-use cold scalpel handles (€ 2,050) were used. For the skin preparation sets, two of the three available references include a detersion set. The working group decided to remove them, to reference a double-packaged sponge stick and to integrate re-sterilisable cups into the instrumentation boxes (75% were in favour). An update of the procedures concerning skin preparation for the operation has been carried out. To integrate: one cup, one electric scalpel handle and two cold resterilisable scalpel handles, 684 instrumentation boxes were identified. The cost of purchasing MDs represents an investment of € 27,600. That of sterilisation remains zero since these boxes are already in circulation. Finally, the estimated gain for the BO at the end of the first year is € 43,000, i.e. a reduction in CO2 emissions of 13,545 kg.

Conclusion and Relevance This approach has been validated and has been in place since June 2023 with evaluation planned for the end of 2023. Other actions related to the reduction of waste at the OR are in progress, with a reflection on the double packaging of certain MDs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

2SPD-020 DESIGN AND EVALUATION OF AN INNOVATIVE AIRBORNE TRANSPORT SYSTEM FOR BLOOD-DERIVED DRUGS UNDER EMERGENCY CONDITIONS

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Background and Importance Blood-derived medicines are administered especially in response to traumatic events. Since their use is linked to the occurrence of accidents, their need is unpredictable. Consequently, it is difficult to apply traditional management logic of warehouses.

Aim and Objectives The present research aims to compare different strategies of transporting blood-derived drugs under emergency conditions. Specifically, current land transportation is compared to innovative Electric manned Take-Off and Landing aircrafts (EVTOL) and drones. Different aspects are analysed including safety, as well as cost-effectiveness. Furthermore, the analysis includes the identification of the best location of a possible drug distribution hub within the Piedmont region.

Material and Methods Firstly, an assessment of the safety of air overflight is conducted by constructing a risk map. Each cell contains the probability that a catastrophic failure for the vehicle will lead to a fatal impact with a person. The spatial distribution of population density is obtained from a dataset of 'Meta', while the presence of buildings is estimated using 'OpenStreetMap'. Secondly, Dijkstra's algorithm is used to determine the minimum-risk aerial trajectory; instead, for cars, 'NetworkX' is used.

Results An index of merit is constructed to compare transportation means. The EVTOL is the best means of transportation for making delivery between hospitals in densely populated areas, while the drone does not sufficiently meet the safety requirements. The latter is valid for joining non-densely populated areas. Finally, within the same city and for small distances land transportation is the most suitable. As for the delivery hub, it is strategic to place it in the vicinity of hospital centres where the demand for blood-derived drugs is greatest. Also, it would reduce the major risks correlated to proper medicine storage. For land delivery, it is more suitable outside Turin.

Conclusion and Relevance The study demonstrates that manned EVTOLs are the optimal way of transportation for drug delivery under emergency conditions. At the same time, the drone represents a viable solution if the areas to be flown over are not densely populated, also, they would bring reduction in costs compared to land transportation. The hub location study would represent a significant step forward in connecting hospitals and improving the logistics of drugs administered-as-needed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-001 TOPICAL COMPOUNDED CLINDAMYCIN SOLUTION MADE FROM ORAL DOSAGE FORMS, CONTROL AND STABILITY STUDY

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Background and Importance Difficulties in drug supply makes pharmacists find alternative ways to provide functional therapy. API from available pharmaceutical forms can be used as a substance for compounding medicine. Drug effectiveness needs be considered as well as compatibility with excipients and primary packing material. Variable temperature, humidity, light can stimulate changes in all pharmaceutical forms, especially in solutions. Primary packing material should provide protection of dosage forms and compatibility with the medicine.

Aim and Objectives Aim of this study was to examine compounding clindamycin topical solution made from available clindamycin hydrochloride oral dosage forms. Effect of excipients and filtration process was evaluated. Drug stability determine not only effectiveness of drug, but also its safety. Patients may store solution in places that may be inadequate. The study compared glass and plastic bottles for storing the solution.

Material and Methods Method for assay determination was HPLC reversed phase with UV detector. Assay and peaks of related substances and impurities were evaluated. Solution was divided in glass and plastic bottles and stored at light exposure, elevated, decreased and room temperature. Sampling was according to free judgment.

Results Sample solution meets the assay requirements with assay 92% acceptance criteria is 90–110%. No significant API degradation and related substances were noticed. Samples stored in plastic bottles showed assay increase up to 26% compared to samples in glass bottles where reported growth is up to 5%.

Conclusion and Relevance Clindamycin hydrochloride solution for topical use can be made from oral pharmaceutical forms. Compounding process did not have relevant impact to assay of API. Molecule is stable at least 112 days under mentioned conditions. However, assay increase was noticed in plastic HDPE bottles due to vehiculum evaporation which is more expressed in samples conditioned in elevated temperatures. Container closure system should enable adequate closing between cap and bottle which is a key parameter to be considered.

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Conflict of Interest No conflict of interest.

3PC-002 STABILITY OF TENECTEPLASE SYRINGES AFTER FRACTIONATION

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Background and Importance Tenecteplase is a recombinant plasminogen activator protein indicated in adults for the thrombolytic treatment of suspected myocardial infarction within 6 hours of symptom onset. The Spanish Agency of Medicines and Health Products reported a shortage of tenecteplase. Therefore, a tenecteplase fractionation protocol was developed in our pharmacy service based on a study that analysed the stability and bioactivity of frozen syringes (-20°C or -70°C) for 1-month[1], admitting up to six freeze/thaw cycles. No studies exploring stability and bioactivity beyond this have been performed.

Aim and Objectives To evaluate the physical and chemical stability of frozen syringes of reconstituted tenecteplase over a 2-month period using proton nuclear magnetic resonance (1H-NMR).

Material and Methods Tenecteplase was reconstituted and fractionated in 5mg/1mL syringes. They were stored at -20°C and evaluated at days 0, 30, 45 and 60. Physical parameters were monitored: turbidity and colour. Chemical stability was evaluated by 1H-NMR spectroscopy. The spectroscopic signals were interpreted and assigned to the chemical structure of tenecteplase and subsequently compared with the spectra at days 30, 45 and 60. All spectra were acquired using a Bruker Avance DRX 500 MHz spectrometer.

Results In terms of physical parameters there appears to be no difference between the syringe at day 0 and at days 30, 45 and 60. Regarding chemical stability, the spectrum resulting from the syringe at day 30 does not show significant differences compared to the reference spectrum. However, when comparing the spectrum of the syringe at day 45 with the reference spectrum, there do appear to be significant changes that call into question the stability and bioactivity of the fractionated reconstituted tenecteplase. Therefore, the study was stopped and the spectrum at day 60 was not compared with the reference spectrum.

Conclusion and Relevance This study seems to confirm the stability (physical and chemical) and bioactivity of tenecteplase syringes frozen at -20°C for a month. However, it does not seem to maintain chemical stability at 45 days, so it is assumed that at 2 months it has no stability.

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Conflict of Interest No conflict of interest.

3PC-003 SUITABILITY OF ELASTOMERIC PUMPS FOR DRUG STORAGE

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Background and Importance Elastomeric pumps (EP) are self-sufficient delivery systems for the continuous intravenous administration of drugs and are mainly used in outpatient settings (e.g. oncology, infectiology).

The product-contacting materials of EP consist of various polymers and additives. In contrast to sterile plastic syringes, data on leachables for EP are only available in individual cases.[1]

Aim and Objectives In order to assess the suitability of the EP for the storage of drug solutions, a transfer of substances from the pump material into the drug solution was investigated.

Furthermore, the weight loss of the pump contents due to the water vapour permeability of the plastic layers was determined, which can lead to an increased concentration of active substances.

Material and Methods Seven different EP devices were examined: 5 to 10 pumps of each device were filled with isotonic sodium chloride solution. At day 1, 7, 28, 90 and 180 the pump contents were quantified to determine the water vapour permeability as well as according to Ph. Eur. 3.3.8 in terms of absorption, acidic or alkaline reacting and reducing substances.

By means of HPLC-MS leachables were identified from a database of 200 substances and recorded semi-quantitatively.[2]

Results Six of seven EP showed weight loss <8% after 180 days (upper limit: 9.0%). One device showed weight loss ≤7.0% at 90 days and ≥11.4% at 180 days.

All seven EP devices met the requirements according to the monograph Ph. Eur. 3.3.8 regarding absorption, acidic or alkaline reacting and reducing substances.

The transfer of up to five antioxidants and plasticisers into the contained isotonic sodium chloride solutions was detected by HPLC-MS for all seven EP devices from day 1.

Conclusion and Relevance Regarding water vapour permeability and the adapted requirements from Ph. Eur. 3.3.8 six EP devices are suitable for 180 days and one for 90 days for the storage of drug solutions.

The effects of the identified leachables on the human organism are the subject of current investigations and cannot be assessed conclusively at present.[3]

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Conflict of Interest No conflict of interest.

3PC-004 DRUG WASTE OF READY-TO-ADMINISTER SYRINGES IN THE INTENSIVE CARE UNIT: ASEPTICALLY PREPARED SYRINGES VERSUS PREFILLED STERILISED SYRINGES

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Background and Importance The availability of ready-to-administer (RTA) syringes for intravenous drugs facilitates rapid and safe administration in emergency and intensive care situations. However, the preparation of these syringes in hospital pharmacies via aseptic batchwise filling results in significant drug waste due to excess production and their limited microbiological shelf-life of 31 days, which contributes to considerable environmental pollution. RTA sterilised syringes have much longer shelf-lives (up to 36 months) than aseptically prepared RTA syringes and might contribute to reducing drug waste.
Aim and Objectives This study aimed to evaluate the difference in drug waste between RTA syringes that were prepared through aseptic batchwise filling in the hospital pharmacy and RTA sterilised syringes (produced in a large-scale compounding pharmacy) in the Intensive Care Unit (ICU).
Material and Methods In a 32-bed mixed medical-surgical ICU, drug waste of RTA syringes was measured over an 8-year period from August 2015 to May 2023. An intervention group of three drug products that were replaced by RTA sterilised syringes (potassium chloride 60 mmol = 60 ml, midazolam 50 mg = 50 ml and morphine 50 mg = 50 ml) was compared to a control group of five drug products that were not replaced by sterilised syringes during the study period. Statistical analysis included a Kruskall-Wallis test along with two interrupted time series (ITS) analyses to assess and visualise the effect of different study periods on waste percentages.
Results A total of 319,621 RTA syringes were dispensed by our hospital pharmacy during the study period. Introduction of RTA sterilised syringes significantly decreased drug waste of RTA syringes irrespective of drug type in the intervention group, from 31% before introduction to only 5% after introduction ($p<0.001$). The control group showed no significant decrease in drug waste over the same time periods (from 20% to 16%; $p = 0.726$). The ITS model of the intervention group showed a direct decrease of 17.7% in waste percentage after the introduction of the RTA sterilised syringes ($p = 0.083$).
Conclusion and Relevance RTA sterilised syringes can significantly reduce drug waste in the ICU, supporting hospitals to enhance environmental sustainability.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

Conflict of Interest No conflict of interest.

3PC-005 PREPARATION OF EPICUTANEOUS TESTS WITH MINOXIDIL AT 2% AND 5%

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Background and Importance Topical minoxidil solution is a safe and effective treatment for alopecia. However, some patients present pruritus and scalping. Patients suffering from allergic contact dermatitis may benefit from patch testing to determine the causative allergen. In the few reported cases of suspected hypersensitivity to topical minoxidil, propyleneglycol triggered the allergic response in the majority of cases.
Aim and Objectives Describe the design, preparation and results of patch tests and prick tests for minoxidil.
Material and Methods The allergology department requested to perform minoxidil patch tests and prick tests for a patient with suspected type IV hypersensitivity.

The pharmacy department proposed carrying out a battery of epicutaneous tests, both for minoxidil and the excipients present in the commercial drug the patient used.

For patch tests two different vehicles were used in the compounding: Vaseline (usual excipient for patch tests) and dimethyl sulfoxide (DMSO) since it has been described for its involvement in increasing the skin penetration of the accompanying active ingredient.
Results As the commercial drug the patient used had alcohol and propyleneglycol as excipients, the following battery of epicutaneous syringe tests for minoxidil patch test was designed:

- Minoxidil 2 and 5% in liquid Vaseline (compounded as 20 mg and 50 mg in 1 mL).
- Minoxidil 2 and 5% in DMSO (compounded as 20 mg and 50 mg in 1 mL).
- 1 mL of liquid Vaseline.
- 1 mL of DMSO.
- 1 mL of propyleneglycol 10, 50 and 100%.
- 1 mL 70° alcohol.

Additionally, the pharmacy prepared the following syringes for prick tests:

- Sterile minoxidil 2 and 5% in sodium chloride 0.9% (compounded as 20 mg and 50 mg in 1 mL).
- Propyleneglycol prick test was obtained commercially.

The compounding was prepared ready to use.

Results after exposure were negative in the immediate readings, as well as at 48 and 96 hours, ruling out this drug and its excipients as causing the hypersensitivity.
Conclusion and Relevance The design and preparation of patch tests and prick tests are key when it comes to dismiss

hypersensitivity to a specific drug. Excipients must be taken into account to rule out their involvement.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-006 STABILITY STUDY OF CLOBAZAM LIQUID ORAL FORMS FOR PAEDIATRIC PATIENTS

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Background and Importance Clobazam is a benzodiazepine used as an anti-epileptic drug for paediatric patients.

In our hospital, we faced several supply difficulties and even stock-outs of the oral suspension speciality for paediatric use. This treatment cannot be interrupted during a supply disruption and it is not possible to stop treatment initiation for this indication. As paediatric doses are weight-adjusted, the development of a liquid formulation was necessary to handle this supply issue.

Aim and Objectives The study aimed was to determine the stability of Clobazam drinkable forms in two different commercial compounding excipients.

Material and Methods A stability-indicating High Performance Liquid Chromatography method, with UV detection, was developed. Forced degradation of clobazam was studied under several conditions (acid and alkaline hydrolysis, oxidative, thermal stress).

Two formulations of clobazam at 2 mg/mL were produced: with Inorpha® and with Syrspend® SF PH4 liquid.

To assess physical-chemical stability, three batches of each formulation were prepared and packaged in amber glass vials, stored at 25°C ± 2°C with relative humidity at 60% ± 5%.

Visual appearance, clobazam concentration, pH and osmolality were evaluated throughout the study period (84 days).

Results The chromatographic method allowed good separation of clobazam and the degradation products. Its validation was performed in accordance with ICH Q2 guidelines over three days, by two different operators. The method showed good injection repeatability, specificity, precision, accuracy, linearity and no matrix effect from excipients.

At day 84, the clobazam concentration of both formulations remained above 95% of the initial concentration (101.4% in Inorpha® and 99.6% in Syrspend®).

PH (4.8 at D0, 4.7 at D84 in Inorpha® and 4.2 at D0, 4.1 at D84 in Syrspend®) and osmolality (169 mosmol/kg at D0, 170 mosmol/kg at D84 in Inorpha® and 52 mosmol/kg at D0, 53 mosmol/kg at D84 in Syrspend®) also remained stable in both batches.

Visual appearance remained unchanged A sedimentation with Inorpha® was observed, which explains interdays variability.

Conclusion and Relevance A liquid form of clobazam can therefore be produced in either Inorpha® or Syrspend® SF PH4 and stored for 84 days at 25°C, protected from light in case of supply shortage. The formulation with Syrspend® seems to guarantee a better homogeneity due to viscosity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-007 CONTAINMENT PERFORMANCE ASSESSMENT OF CHEMFORT® (ONGUARD®2) CLOSED SYSTEM TRANSFER DEVICE ACCORDING TO 2016 DRAFT NIOSH PROTOCOL AT FIRST AND TENTH ACTIVATIONS END OF SHELF LIFE

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Background and Importance The National Institute of Occupational Safety and Health (NIOSH) defines a CSTD as a device that mechanically prohibits the transfer of environmental contaminants into and escape of hazardous drug or vapour outside of the system. After several connection/disconnection cycles (activations) and extended storage the containment performance of a CSTD may deteriorate risking exposure. The Chemfort® CSTD is approved for 10 activations.

In 2016, NIOSH issued a draft performance test protocol for CSTDs. The protocol recommends nine potential surrogates for hazardous drugs including 2-phenoxyethanol which was recommended by the UK Health and Safety Executive.

Aim and Objectives The study aim was to evaluate the containment performance of Chemfort® at first and tenth activations and the end of its 3-year shelf-life in accordance with the 2016 draft NIOSH protocol and instructions for use.

Material and Methods NIOSH Tasks 1 (reconstitution) and 2 (administration) were performed using 3-year aged Chemfort® following the 2016 NIOSH protocol, using 2.5% v/v 2-phenoxyethanol as surrogate. Devices were assessed in replicate (n=4), on first and tenth activation. Surrogate release was quantified using a qualified thermal desorption-GC/MS method. Positive control tasks were performed with needle and syringe. Limits of detection (LOD) and quantitation (LOQ) were determined based on chamber blank measurement.

Results The LOD and LOQ for 2-phenoxyethanol were determined at 0.36±0.013 ppb and 0.62±0.013 ppb (n=33) respectively. Mean surrogate releases for Chemfort® from both tasks were below the LOD at end of shelf-life at both one and ten activations. Positive controls gave mean releases of 7.79 ppb and 1.82 ppb for tasks 1 and 2, respectively.

Conclusion and Relevance No difference in containment performance was observed for Chemfort® components used at first vs tenth activation at end of shelf-life according to 2016 draft NIOSH protocol. All devices demonstrated containment of 2-phenoxyethanol surrogate. Positive controls demonstrated >LOQ releases of 7.79 ppb and 1.82 ppb for tasks 1 and 2, respectively for an open system. This is the first time CSTD performance has been evaluated at end of shelf-life and tenth activation.

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3PC-008 STABILITY OF PARENTERAL NUTRITION ADMIXTURES: FOCUS ON PRECIPITATION

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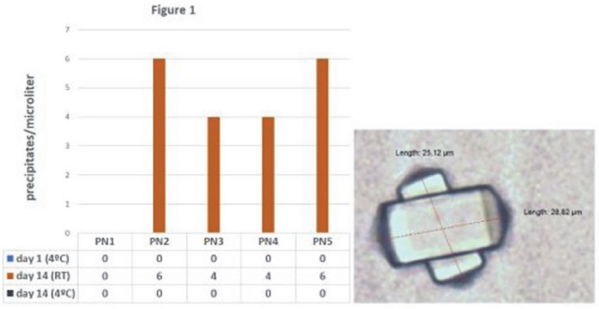
Background and Importance Parenteral nutrition (PN) has a complex composition, so interactions between components lead to instability compromising its safety. Large precipitates can cause thromboembolisms and death. Low concentrations of lipids and amino acids and high concentrations of cations correlate with poorer stability (higher risk of precipitate formation).

Aim and Objectives To analyse the stability of PN samples attending to the appearance of precipitates using optical microscopy measurements.

To evaluate the influence of temperature and time on stability.

Material and Methods We studied 5 PN samples (all-in-one). From a baseline formulation (standard macronutrient ratios), we decreased the lipid concentrations from sample 1 to 5. Micronutrients amounts were greater than those recommended, and vitamins (hydrosoluble and lyposolubles) and zinc were also added. 500mL per sample were prepared according to the centre's protocols. On day 0, a single stock sample was prepared from which 2 aliquots of 250 mL were separated and stored at room temperature (RT) and in a refrigerator (4°C) for 14 days. In order to determine the physical stability of the samples, precipitate formation was assessed using a Fast Read Biosigma® counting camera on a Nikon Eclipse 50i microscope®. Images were taken with a 40X magnification objective. Measurements were taken on the sample on day 1 (4°C) and day 14 (RT and 4°C). Only precipitates larger than 5 microns and with a clearly crystalline form were counted in this analysis. Results are expressed in precipitates per microlitre (according to chamber manufacturer's recommendations).

Results Precipitates were observed in 4/5 samples. All precipitates corresponded to samples analysed after 14 days of storage at RT, none in those stored in the refrigerator. Figure 1 represents the data obtained and an example of the type of precipitates found.



Abstract 3PC-008 Figure 1

Conclusion and Relevance Prolonged storage at room temperature clearly influences the appearance of precipitates.

The observed form of the precipitates may correspond to calcium oxalate crystals, formed by the reaction between calcium and vitamin C degradation products.

The importance of the use of filters in the administration of PN is emphasised.

To establish the overall stability of the PN, more complete studies should be carried out, which analyse more stability-dependent processes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-009 THE EFFECT OF ACCELERATED LIGHT (STRESS) AND NATURAL SUNLIGHT EXPOSURES ON CETUXIMAB (ERBITUX®): EVALUATION OF AGGREGATE FORMATION AND FUNCTIONALITY

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Background and Importance Cetuximab (CTX) is a monoclonal antibody indicated for treatment of metastatic colorectal cancer and squamous cell cancer of head and neck. These kinds of proteins are susceptible to degrade during long-term storage and/or during exposure to environmental conditions (high temperature, agitation, light exposure, etc) when handled in hospitals. Therefore, it is essential to detect critical degradation points before the administration to patients to ensure the efficacy and safety of the medicine.

Aim and Objectives To assess the impact of accelerated light (stress) and natural sunlight exposures on CTX (Erbitux®, 5 mg/mL) safety and efficacy through the study of aggregation formation and functionality when mishandling in real hospital conditions.

Material and Methods CTX (Erbitux®, 5 mg/mL) fresh opened vials were used to carry out the study. Light stress was performed in an accelerated stress test chamber to simulate sunlight (250 W/m^2, 24h, 25°C), while another sample of CTX was exposed to natural sunlight for 24h. Aggregate formation was evaluated by Size-Exclusion Ultra-High-Performance Liquid Chromatography (SE/UHPLC-UV) and functionality was assessed by Enzyme-Linked Immunosorbent Assay (ELISA).

Results SE/UHPLC-UV chromatograms of CTX control sample (5 mg/mL) showed a main chromatographic peak assigned to CTX monomers. The sample subjected to light stress revealed the appearance of three new chromatographic peaks assigned to high molecular weight species (HMWS). However, exposure to natural sunlight only revealed the appearance of one small new peak assigned to HMWS with a low relative abundance. ELISA showed a significant loss of functionality of CTX medicine in both stressful conditions: light stressed sample revealed a loss of biological activity (BA) of around 20%, while the sample exposed to natural sunlight showed a loss of BA of 10%.

Conclusion and Relevance Exposure to light promotes aggregate formation in CTX (Erbitux®), this effect being more noticeable in accelerated light exposure. Moreover, CTX functionality was also affected after the exposure to both stressful conditions, revealing a loss of biological activity. Thus, we recommend preventing CTX from light exposure when handled in hospitals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

3PC-010 DEVELOPMENT OF A STABLE PARENTERAL SOLUTION OF TOPIRAMATE FOR EMERGENCY TREATMENT OF STATUS EPILEPTICUS

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Background and Importance Status epilepticus requires an emergent treatment as continuous epileptic activity results in increased pharmacoresistance, morbidity and mortality. Topiramate leads to a control of status epilepticus in 70% of the patients who showed no response to first-line treatments. As there are no parenteral formulations available, topiramate tablets are administered via enteral feeding tube. This is problematic in an emergency setting because pharmacokinetics are unpredictable and rapid therapeutic drug levels are essential.

Aim and Objectives The aim of this work is the development of a parenteral formulation of topiramate of 200 mg with a stability of at least 3 months to allow the production in a hospital pharmacy for a stock at the intensive care unit (ICU).

Material and Methods Due to poor solubility, different intravenous (IV) formulations were developed for stability and practicability testing: 4 mg/ml and 8 mg/ml with 0.025 M phosphate buffer as ready to use solutions and 20 mg/ml single dose vials with meglumine, a solubility enhancer. A stability study was conducted at time points 0 and 3 months evaluating the concentration of topiramate of three different batches with LC-MS, the pH, the clarity and colouring of the solution according to the European pharmacopoeia. The different formulations were tested during storage at room temperature and at 2–8°C.

Results All three formulations of topiramate (4 mg/ml, 8 mg/ml and 20 mg/ml) passed the stability requirements and exhibited a concentration of 100.7%, 101.2%, and 104.4% respectively after 3 months at room temperature and 106.3%, 101.7% and 99.5% respectively at 2–8 °C. There were no significant pH changes and the colour and clarity of the solution remained clear and colourless.

Conclusion and Relevance Our results are in line with Cloyd's extrapolated stability data, that topiramate 7 mg/ml with 0.1M phosphate buffer is stable for 1.5 years at 5°C with a concentration of at least 90% topiramate. We demonstrated that topiramate parenteral solution is stable at room temperature for at least 3 months, which is favoured in a hospital setting. Therefore, the hospital pharmacy's production unit can provide the ICU with a stock of an IV formulation of topiramate and the stability study will be continued.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-011 MUCOSECTOMY: FEASIBILITY STUDY OF THE AUTOMATED PREPARATION OF A STERILE SOLUTION OF 5/10% FRUCTOSE GLYCEROL

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Background and Importance The digestive endoscopy department sought the expertise of pharmaco-technology to develop a sterile hospital preparation aimed at facilitating mucosectomies. This hyperosmolar solution assists in separating digestive mucus and submucus layers, facilitating polyp removal during endoscopy.

Aim and Objectives The study aims to assess producing a 5% fructose, 10% glycerol solution, and methodically preparing and controlling 30 bags of 100 mL using a sterile isolator and automated filling.

Material and Methods The study entailed literature review, European Pharmacopoeia evaluation, Rennes Hospital Centre procedure analysis, and Civil Hospices of Lyon stability study. Protocols were drafted, followed by test productions. Concentrated solution with 150 g fructose, 240 mL non-sterile glycerol, and 250 mL sterile 0.9% sodium chloride (NaCl) was prepared in a safety cabinet, transferred to an isolator in a sealed Erlenmeyer flask, then filtered into an empty 3 L bag. 0.9% NaCl was added via peristaltic pump, and solution was distributed into 100 mL bags. Sterility was ensured through aseptic processing and 0.22 µm filtration. Controls included osmolality, pH, sodium via inductively coupled plasma optical emission spectrometry, gravimetric checks, and sterility testing.

Results Results validated solution feasibility, process efficacy, and quality controls. Mean osmolality was 1698.11 [±33.70] mOsmol/L, pH 5.64 [±0.11], and sodium 134.37 [±4.39] mM within 10% range around theoretical 137.06 mM. Average weight was 103.42 g, density 1.06, confirming volume per 100 mL. Sterility test passed on Day 14.

Conclusion and Relevance Discussion highlighted challenges like non-sterile raw materials, peristaltic pump use in isolator, batch size, consumable volume, and 0.22 µm filter integration. Fructose and glycerol measurements posed difficulties. Sodium measurements were lower due to fructose's impact on added 0.9% NaCl volume. Bag quantity variation stemmed from NaCl pouch overfilling variability. Preparation feasibility and controls were validated. In conclusion, this study successfully demonstrated the feasibility of producing the hyperosmolar solution, outlined effective preparation processes, and established stringent quality controls for its hospital-scale implementation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-012 CONTENT UNIFORMITY OF SODIUM BENZOATE CAPSULES: VALIDATION OF A METHOD USING QCPREP®

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Background and Importance In response to the lack of paediatric formulation of sodium benzoate in the market, we have

been producing 250mg capsules of pure active ingredient (AI), without excipients, intended for patients with urea cycle disorders. The AI content is verified via high-performance liquid chromatography spectrometry, but this method has limitations (high cost and limited availability).

Aim and Objectives The objective of this study was to develop and validate a dosage method of AI to perform routine capsule content testing using UV/Raman spectrophotometry.

Material and Methods After opening the capsule and dissolving the powder in sterile water, we used the QcPrep® automated system UV/Raman spectrophotometry for AI measurement and identification. The method validation was conducted according to ICH-Q2-R1 criteria. This consisted of six steps. 1) Search for the most relevant spectral band (maximum correlation between absorbance and linearity). 2) Linearity of the calibration curve was assessed between 2.5 and 50.0mg/mL through linear regression and validated if the correlation coefficient (r2) is > 0.999. 3) Repeatability was determined by repeating the analysis (n=6) for the routine dosage concentration (RDC: 25.0mg/mL) and validated if the coefficient of variation (CV) < 2%. 4) Intermediate precision was evaluated by repeating the analysis (n=3) on three different days for the RDC and validated if CV < 5%. 5) Accuracy was assessed at three concentrations, 75%, 100%, and 125% of the RDC (n=3 per concentration) and validated if the deviation was < 5% of the expected value. 6) Specificity was not assessed due to the exclusive composition of the capsules with the AI.

Results The obtained results are as follows:

1. The most relevant spectral band: 279 nm.
2. Linearity: r2 was equal to 0.99993.
3. Repeatability: CV=1.94%.
4. Intermediate precision: CV=0,99%.
5. Accuracy for 75%, 100%, and 125% of the RDC are 0.7%, 0.5%, and 1.1%, respectively.

All criteria met the specified requirements.

Conclusion and Relevance The method is validated: it has demonstrated linearity, repeatability, intermediate precision, and accuracy. The Qc-Prep® is user-friendly, fast, and reliable for the routine content uniformity control of our preparations. The implementation of this pre-release control will be continued for other preparations intended for multiple patients, thereby ensuring the safety of our preparations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-013 RADIOPHARMACEUTICAL SINGLE-VIAL COLD KIT FORMULATION OF FAPI-04, AN EXPERIMENTAL VECTOR FOR GALLIUM-68 PET IMAGING IN ONCOLOGY

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Background and Importance Targeting the tumour microenvironment recently gained interest in oncology, as evidenced by the use of fibroblasts activation protein inhibitors (FAPI) for cancer-associated fibroblasts imaging. Among these derivatives, FAPI-04 radiolabeled with gallium-68 emerged as a promising PET diagnostic agent. To date, [^{68}Ga] Ga-FAPI-04 is considered an experimental radiopharmaceutical, with a tedious and intricate radiolabeling process. Thus, the development of a single-vial cold kit (SVCK) formulation of FAPI-04 to simplify the preparation of [^{68}Ga] Ga-FAPI-04 would be of particular interest.

Aim and Objectives Various parameters involved in the formulation of FAPI-04 as a SVCK were investigated. Then, optimal conditions for successful radiolabeling of [^{68}Ga] Ga-FAPI-04 were identified.

Material and Methods Kit vials were conditioned to contain several bulk agents (five tested), buffers (six tested), anti-radiolysis compound (three tested) and FAPI-04. Mixtures were solubilised in water for injection and then lyophilised. The influence of each component on the radiolabeling process was studied, as well as the amount of vector (30, 45 or 60 µg). [^{68}Ga] $GaCl_3$ was eluted from a GalliAD® generator directly into the kit vials, subsequently heated for 10 minutes at 97°C. Radiochemical purity (RCP) of each reaction was assessed by radio-TLC and radio- HPLC. The pH was checked by pH strips during the kit's conditioning and after each reaction, aiming at an optimal value of 3.4 (ideal for ^{68}Ga radiolabeling).

Results Mannitol (50 mg) was the bulk agent with the best appearance after freeze-drying and was retained in subsequent assays. As expected, the pH of the reaction medium was critical to the success of radiolabeling. HEPES buffer 0.3 M pH 4 allowed RCP of 83.3% by TLC and 78.9% by HPLC, compared with extremely poor results obtained with the five other buffers. Anti-radiolysis agents showed a moderate improvement in RCP (~10% increase with ascorbic acid) which persisted over a period of 4 hours, confirming radiocomplex stability. Using 45 µg FAPI-04 instead of 30 µg in the reaction slightly increased RCP (>96% in TLC, >91% in HPLC).

Conclusion and Relevance The importance of carefully selecting the ingredients of a radiopharmaceutical SVCK was demonstrated, resulting in excellent RCP values for [^{68}Ga] Ga-FAPI-04. A terminal purification step would remove HEPES buffer to comply with European Pharmacopoeia requirements.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-014 PHYSICOCHEMICAL STABILITY OF BEVACIZUMAB 25 MG/ML CONCENTRATE (VEGZELMA®) IN ORIGINAL GLASS VIALS AFTER FIRST OPENING

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Background and Importance Several bevacizumab biosimilars are EMA-approved for the treatment of cancer. For each bevacizumab biosimilar, product-specific stability data regarding the concentrated solution and diluted infusion solutions are to be regarded by health care professionals. To our best knowledge, stability information is missing for the concentrated solution of the bevacizumab biosimilar Vegzelma® (Celltrion) after first opening and prolonged storage.

Aim and Objectives The aim of the study was to investigate the physicochemical stability of bevacizumab 25 mg/mL concentrate (Vegzelma®) punctured and stored in the original glass

vial at two different storage temperatures over a 28-day period.

Material and Methods Three bevacizumab 25 mg/mL vials (Vegelzma®) each were stored after first opening either light protected at 2–8 °C or at 25 °C for 28 days. Samples were withdrawn on day 0, 1, 7, 14, 21, 28 and analysed with size exclusion chromatography (SEC), ion exchange chromatography (IEC), and dynamic light scattering (DLS). The pH values were measured, and the test vials were visually inspected for visible particles and colour changes at each measuring point.

Results After a 14-day storage period, the quantitative SEC analysis indicated bevacizumab concentrations above 95% of the initial concentration in each test vial. DLS measurements showed no significant variation of the mean hydrodynamic diameter and no appearance of small sized aggregates. IEC analysis revealed no signs of instability. pH values of all samples remained constant, and no visible particles or colour changes were observed.

Conclusion and Relevance Bevacizumab 25 mg/mL concentrate (Vegzelma®) revealed to be physicochemically stable in the original glass vial after first opening for at least 14 days when stored light protected at 2–8 °C or at 25 °C. Investigations are ongoing until day 28 and presented.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest Conflict of interest.

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3PC-015 MICROBIOLOGICAL PERFORMANCE QUALIFICATION OF THE ROBOTIC SYSTEMS APOTECASYRINGE AND APOTECAUNIT

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Background and Importance Fully automated aseptic preparation of cytotoxic ready-to-administer (RTA) and ready-to-use (RTU) parenterals is already well established. More recently, innovative robotic systems for the preparation of non-cytotoxic parenterals were brought to the market.

Aim and Objectives The objective of the study was the microbiological performance qualification of the fully automated robotic systems APOTECAsyringe and APOTECAunit (Loccioni, Italy) by media-fill tests and supplemental environmental monitoring in the critical zones.

Material and Methods During the performance qualification phase of the APOTECAsyringe over a 5-day period 500 syringes (10 mL volume) were automatically filled from a bag reservoir containing single-strength tryptic soy broth, capped and labelled. With the APOTECAunit (designed for individual/in series preparation of bags, syringes) over a 10-day period 250 bags and 250 syringes were prepared. Syringes were prepared by dilution of 25 mL of double strength tryptic soy broth with 25 mL of water for injection in 50 mL syringes. Bags were prepared by injection of 50 mL double strength tryptic soy broth into infusion bags prefilled with 50 mL 0.9% sodium chloride solution. Test solutions were incubated at room temperature and visually inspected after 7 and 14 days. Supplemental environmental controls encompassed particle counting, active air sampling (only APOTECAunit), settle plates, contact plates for critical surfaces, and fingerprints. Plates were incubated and colony forming units (cfu) counted.

Results None of the 500 media-fill products prepared by the APOTECAsyringe and 500 products prepared by the APOTECAunit showed turbidity when inspected after 7 and 14 days of incubation, thereby indicating no growth of microorganisms. Particle numbers were below the maximum limits set for cleanroom Grade A, EU-GMP Guide, Annex 1 and cfu counts of the plates met the acceptance criteria.

Conclusion and Relevance APOTECAsyringe and APOTECAunit passed the microbiological performance qualification and allow safe fully automated aseptic preparation of non-cytotoxic RTA and RTU parenterals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-016 PHYSICOCHEMICAL STABILITY OF MOXIFLOXACIN 1 MG/0.2 ML SYRINGES FOR INTRACAMERAL ADMINISTRATION

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Background and Importance Moxifloxacin syringes for intracameral injection are a compounding formula prepared in the Pharmacy Department to prevent endophthalmitis in cataract surgeries.[1] According to the Spanish Good Practice Guides for the preparation of medications in hospital Pharmacy Departments, this compounded formula would have a shelf life of 9 days in the refrigerator (2 °C – 8 °C).[2] This physicochemical stability study is proposed to improve the efficiency in our Pharmacy Service.

Aim and Objectives To characterise the physicochemical stability of intracameral moxifloxacin 1 mg/0.2 ml syringes stored in refrigeration (2 °C – 8 °C) and protected from light for 90 days.

Material and Methods Three 50 ml batches of moxifloxacin were prepared at different concentrations (1, 2, 4, 5, and 7 µg/ml) in a horizontal laminar flow cabinet using water for injection as a solvent, starting from the commercial eye drop Vigamox 5 mg/ml®.

Concentration measurements of moxifloxacin were carried out on days 1, 3, 7, 15, 22, 30, 60, and 90 using a Perkin Elmmer model Lambda 40 UV/visible spectrophotometer at a wavelength of 290 nm (maximum wavelength of moxifloxacin).

Results Throughout the entire analysis period, the moxifloxacin concentrations determined by the spectrophotometer remained constant and within the values accepted by the United States Pharmacopeia that ensure its physicochemical stability (± 10%). In addition, linearity was met in all measurements with a determination coefficient (R^2) > 0.999, indicating that the prepared concentrations of moxifloxacin remained stable over time.

Conclusion and Relevance The formulations of intracameral moxifloxacin 1mg/0.2 ml in water for injection are physicochemically stable at least for 3 months when stored in the refrigerator (2 °C – 8 °C) and protected from light. Further investigation would be advisable to continue with the study in order to extend their shelf life.

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Conflict of Interest No conflict of interest.

3PC-017 ELABORATION OF DEFEROXAMINE EMULSION 0.5% FOR HYPERPIGMENTATION DUE TO INTRAVENOUS IRON EXTRAVASATION

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Background and Importance Cutaneous hyperpigmentation due to iron extravasation is a described adverse effect of its intravenous administration.

Aim and Objectives To describe the components and method of preparation of a 0.5% deferoxamine emulsion for the treatment of hyperpigmentation caused by iron extravasation. To describe the efficacy and tolerance of the pharmaceutical compound on a hospitalised patient.

Material and Methods Literature research was carried out in different databases to determine the clinical evidence and experience. (Google Scholar, PubMed, SEFH formulary, Acofarma website).

In order to assess efficacy and tolerance, direct observation of the stain was performed twice a week for 30 days. Possible colour change, and skin irritation were compared with photographs and interviewing the patient.

Results Composition: deferoxamine 0.5g (commercially available lyophilised powder), propylene glycol 20g; NeoPCL self-emulsifier O/W 25g and purified water in sufficient quantity for 100g. In contrast to the available evidence, Beeler base was not used. Instead, NeoPCL was chosen, which allowed the formation of an aqueous external phase emulsion, not very oily, dense, but easy to apply topically.

Methodology

- Deferoxamine-liophilised was reconstituted with purified water.
- Water, propylene glycol and NeoPCL were weighed separately and placed in a waterbath at 60°C.
- NeoPCL was stirred to facilitate the fusion and propylene glycol was gradually added while stirring to form the oleo-aqueous emulsion.
- Deferoxamine solution was added over the previous mixture, stirring constantly until obtaining the oleo-aqueous emulsion.
- It was stirred for 2–3 minutes with an emulsifier.

The final appearance of PhC was a homogeneous white emulsion with no lumps and no characteristic odour. According to the local Guide of Good Practices, a 30-day expiration period was assigned as well as storage conditions of room temperature and proception from light. Galenic validation was performed, and the emulsion did not lose the characteristics described.

Fifteen days after the extravasation, the emulsion was applied every 12 hours for four weeks. A slight improvement was observed. However, there was complete tolerance to emulsion with no adverse reactions reported.

Conclusion and Relevance The development of the emulsion with a self-emulsifying O/W base ensured that the emulsion remained stable throughout the shelf life.

The results did not match with those described in the literature. Time was a limiting factor to have observed better results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-018 GLASS AMPOULE HANDLING PRACTICES IN DUTCH HEALTHCARE: A COMPREHENSIVE ASSESSMENT

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Background and Importance Glass ampoules are extensively used for intravenous administration, pulmonary nebulisation, and oral preparations such as caffeine. Dutch guidelines recommend filter needles or straws when handling glass ampoules,[1] but compliance remains uncertain.

Aim and Objectives This study aimed to evaluate the utilisation of filter needles/straws, the observation of glass particles, and the disposal of ampoules among pharmacy technicians and nurses. Additionally, we examined the handling of glass ampoules during medication procurement in hospital pharmacies.

Material and Methods We employed an observational approach with a questionnaire developed by Utrecht University's UPPER pharmacy practice research section. The questionnaire covered glass particle management and procurement policies. Pharmacy students conducted interviews with pharmacy technicians (both in the pharmacy and on hospital wards) nurses and pharmacists, during their internships from September to November 2022. Descriptive data analysis was used.

Results Data were gathered from 31 Dutch hospitals, comprising six academic, 15 top clinical, and 10 peripheral institutions. Interviews were conducted with 50 pharmacy technicians in the pharmacy, 51 on the wards, and 50 nurses.

Concerning compounding, 14% of hospitals did not employ filtering techniques, except for intrathecal preparations. On hospital wards, 23% of pharmacy technicians did not employ filtering techniques, rising to 50% for nurses (irregular use).

The results revealed that 82% of pharmacy technicians in the pharmacy encountered glass particles during compounding, rising to 92% on wards and 45% for nurses. In terms of ampoule disposal, approximately 16% of pharmacy technicians in the pharmacy reported discarding ampoules due to the presence of glass particles, compared to 19% on wards and 20% among nurses. Only nine hospital pharmacies had established policies aimed at reducing the procurement of glass ampoules.

Conclusion and Relevance The study highlights the variability in the adoption of filtering techniques for glass ampoules across different hospitals, with hospital pharmacies demonstrating better compliance. Both pharmacy technicians and nurses observed glass particles, leading to ampoule disposal. Future studies should investigate the causes of disparities between pharmacy departments and hospital wards. Additionally, further research is needed to assess potential health consequences of glass particle exposure.

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Conflict of Interest No conflict of interest.

3PC-019 DEVELOPMENT OF A TOPICAL EMULSION FOR THE TREATMENT OF THIRD-DEGREE BURN PATIENT CANDIDATES FOR SKIN GRAFT

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Background and Importance A third-degree burn (TDB) destroys the epidermis and dermis presenting a high risk of infection. These lesions are treated with skin grafts (SK) in the absence of infection.

Aim and Objectives The hospital pharmacist was asked to develop a non-irritating, antibacterial, easily spreadable and removable topical emulsion formula specific to prepare the burned tissue for SK.

The aim is to describe effectiveness and tolerance of topical magistral formula emulsion.

Material and Methods A scientific literature search was conducted.

Galenic development and validation of the formula were described in the monograph 'Semi-solid preparations for cutaneous application' of the Official Pharmacopoeia of the Italian Republic.

The efficacy of the formulation was evaluated by the physician.

A retrospective observational analysis was performed. Patients with TDB who were eligible for SK in 2022–2023 are being evaluated. The variables collected were: duration of treatment, dosage, clinical response and adverse effects.

Results We have formulated Oil-in-water emulsions. The main components are:

- C15–20–acid-PEG-8–ester-12%, hydrophilic-lipophilic balance 12, emulsifier, non-toxic for skin enzymes, suitable for the most sensitive skin, and the most histophilic of known emulsifiers.
- Squalane-7%, a texturiser, creates a film that protects the skin by delaying the loss of trans- epidermal water and improves the spreadability of the product.
- Sebopessina –2%, active principle for sebaceous secretion problems because burned skin has blisters.
- Silicone oil improves –0.3% the application and absorption of creams. The favourable environment, created by occlusion-hydration, the formation of hypertrophic scars is prevented.
- Cerium nitrate –2% combined with silver sulfadiazine-0.3% to provide broad antibacterial activity, forms a temporary barrier and promotes re-epithelialisation.

A shelf life of 30 days has been established, based on the critical skin lesion. Odour, colour and phase separation remained stable over the month. Spreadability and emulsion removal were excellent. Fifteen patients were treated; 100% responded well to treatment after an average of 2 weeks and a dosing frequency of 3 times a day. The physician confirmed good delimitation and absence of infections in the burnt areas that will receive the SK. No adverse reactions were reported.

Conclusion and Relevance The galenic emulsion described is a good therapeutic solution in patients with TDB who are candidates for SK.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-020 PREVENTION OF INFECTIOUS RISK IN PATIENTS TREATED WITH TUMOUR NECROSIS FACTOR ALPHA INHIBITORS (ANTI-TNFα)

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Background and Importance Tumour necrosis factor alpha inhibitors (anti-TNFα) have become a common treatment in many diseases, but they can increase susceptibility to infectious diseases, including tuberculosis.

Aim and Objectives Evaluate the analysis record and vaccination schedules in patients with anti-TNFα treatment in our hospital.

Material and Methods We have reviewed clinic history of all outpatients of the Pharmacy Service in a regional hospital who are currently administering subcutaneous anti-TNF (adalimumab, certolizumab, golimumab and etanercept). The informatics programs Farho and HCl are used to review if tuberculin test or Quantiferon assay, recommended vaccination schedule by the Prevention Service of the hospital and hepatitis serology have been requested (hepatitis B virus (HBV), hepatitis C virus (HCV) and hepatitis A (HAV)).

Results 147 patients with anti-TNFα have been analysed, with a mean age of 49 years (14–84), of which 53% (n=78) are men. 18.37% (n=27) had rheumatoid arthritis, 15.65% (n=23) psoriasis, 14.97% (n=22) psoriatic arthritis, 10.20% (n=15) ankylosing spondylitis, 19.05% (n=28) other spondyloarthropathies, 1.36% (n=2) juvenile idiopathic arthritis, 17.01% (n=25) inflammatory bowel disease, and 3.40% (n=5) others. Tuberculin/quantiferon testing was completed in 87.07% of patients; 12.50% of them were positive and received isoniazid for 9 months. Serological markers have been recorded in 93.20% and 91.16% of patients for HBV and HCV respectively, all of which were negative. 41.50% of the patients received four doses of HBV vaccine, because they presented anti-HBs <10 mUl/ml. 10.88% of the total patients received two doses of the HAV vaccine with an interval of 6 months. 81.63% of patients were vaccinated with the pneumococcal vaccine. 51.02% of patients have received the flu vaccine annually.

Conclusion and Relevance Regarding the safety guidelines, the recommended screening and vaccination schedules are completed and recorded in the majority of patients (>85% patients). Nevertheless, it would be necessary to reconcile the way of registering data in order to simplify the recording of tests performed and the monitoring of administered vaccines.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

3PC-021 FORMULATION OF VORICONAZOLE OVULES AND EFFICACY IN VULVOVAGINAL CCANDIDIASIS BY CANDIDA GLABRATA: A CASE REPORT

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Background and Importance *Candida glabrata* is a vaginal coloniser causing vulvovaginal candidiasis (VVC), usually asymptomatic. Typical first-line therapies, boric acid or nystatin ovules, are not effective due to their inherent resistance. Flucytosine, amphotericin B or voriconazole would be the treatment of choice.
Aim and Objectives To formulate voriconazole ovules (VO) and describe our clinical experience in the treatment of VVC by *C.glabrata*.
Material and Methods The patient was a 52-year-old woman with VVC by *C.glabrata* who presented vulvar pain, irritation, and burning. She was treated with oral fluconazole, oral voriconazole, topical amphotericin B, boric acid ovules and combined therapy by fluconazole-amphotericin B, but her symptoms did not resolve and the culture remained positive.

A bibliographic search was carried out (Pharmacopoeia, UpToDate and PubMed) about VO formulation and its solubility in polyethylene glycol (PEG) was confirmed. Other magistral formulations of ovules containing PEG as an excipient were used as a reference for formulation design. Galenic validation included organoleptic controls and physical tests, mass uniformity and dissolution time.

Finally, treatment efficacy was assessed by symptom resolution and negativisation of the vaginal exudate culture.
Results Modus operandi for 30 units VO 15 mg with an excess of 20%:

1. Melt: 81.36 g PEG 400 and 54.72 g PEG 4.000.
2. Crush 11 tablets of voriconazole 50 mg in a mortar and pestle. Work in biological safety cabinet type I if there is reproductive risk, otherwise Personal Protective Equipment (PPE).
3. Add powder to the melted mass and homogenise.
4. Pour mixture into 3 g ovule moulds and allow to cool.
5. Unmould, package and label.

Regarding galenic validation, the surface of VO was shiny, smooth and without cracks. All were within the weight range (±5) and took 34 minutes to dissolve. The given expiry date was 6 months.

The patient started treatment with daily VO and after 3 months of treatment, complete resolution of symptoms and negative cultures were achieved. The frequency of administration increased to every 48 hours and then every 72 hours until 6 months of treatment, without reactivation of the infection.
Conclusion and Relevance The magistral formulation was validated and proved to be effective in the treatment of VVC by *C.glabrata*.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

3PC-022 DESIGN AND STABILITY STUDY OF AN ISONIAZID AND PYRIDOXINE ORAL LIQUID FORMULATION

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Background and Importance Infant tuberculosis treatment is a combined therapy, which entails two main issues: commercialised paediatric presentations scarcity and inadequate adherence. Isoniazid is indicated as a front-line treatment. In order to prevent isoniazid's induced peripheral neuropathy, pyridoxine should be supplemented.
Aim and Objectives The aim of this study was to develop and study the physicochemical and microbiological stability of a combined isoniazid+pyridoxine oral liquid formulation.
Material and Methods Literature search was performed to study isoniazid + pyridoxine formulation stability. As there were no published data in this field, the active pharmaceutical ingredients physicochemical proprieties and quality conditions were checked in Pharmacopeia and scientific literature. Stability-indicating methods were conducted and validated according to the Methodological Guidelines for non-sterile products.

- Physical study: organoleptic characters (colour, odour, flavour); clarity and degree of opalescence; and pH. The pH-goal of combined doses to avoid any possible active ingredient degradation was settled at 5.
- Microbiological study: total aerobic microbial count <103 UFC/ml; total combined yeasts/moulds count <102 UFC/ml; and absence of Escherichia coli/ml.
- Chemical study: high-performance liquid chromatography (HPLC) analysis and method validation to quantify isoniazid +pyridoxine recommended acceptable purity limit (90–110%).

Results Isoniazid 50 mg/ml + pyridoxine 8,3 mg/ml oral liquid formulation was compounded using aqua conservans and 70% liquid sorbitol. Samples were stored at aliquots, light and non-light-exposed, at room and refrigerated temperature, for 28 days. Each sample was analysed at 0, 7, 14, 21 and 28 days.

Refrigerated samples stayed physically stable and pH measure was 4,8±0,15. Room temperature samples got darker, bitter and slightly acidified. The concentration of isoniazid and pyridoxine was found to be at day-28 50,6±0,6 + 8,2±0,2 at room temperature and 51,3±0,6 + 8,3±0,1 at refrigerated temperature, respectively. Moreover, all samples maintained microbiological stability.

The validated method proved to be selective and linear. It exhibited an adequate repeatability and intermediate precision with variation coefficient lower than 2%, and a recovery higher than 98%.

Conclusion and Relevance

- Isoniazid+pyridoxine oral liquid formulation was physicochemical and microbiologically stable stored at refrigerated conditions for 28 days.
- The proposed analytical method was viable to simultaneously determine two different active ingredients.
- It provides a reliable solution to enhance therapeutic adherence of children.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-023 NEW ACTIVITIES WITHIN A CLINICAL TRIAL MANAGEMENT UNIT: WHAT NEW RISKS FOR THE STAFF?

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Background and Importance Pharmaceutical personnel continually face occupational risks (OR) during clinical research, necessitating regular updates to address evolving activities like Advanced Therapy Medicinal Products (ATMPs) and direct patient dispensation.

Aim and Objectives Our goal was to comprehensively assess these risks, utilising a risk mapping approach and implementing tailored preventive measures (PM) for effective mitigation.

Material and Methods In collaboration with pharmacists, managers, and risk assessors, we conducted a thorough risk mapping, evaluating ORs based on severity, frequency, and control mechanisms. Criticality levels were established, leading to categories of very significant, significant, to be monitored, or tolerable risks. Subsequently, PMs were developed, and an action plan was created. Reassessment using the same parameters resulted in residual risk identification, culminating in a comprehensive risk assessment document.

Results Our assessment revealed nine novel ORs in three categories: travel associated with experimental treatment delivery, biological risks linked to ATMPs, and workplace hazards like burns from nitrogen handling. Five were deemed significant, three required monitoring, and one was tolerable. Post-risk mapping, seven PMs were identified, including individual oximeters and respiratory isolation equipment to address hypoxia risk during ATMP handling. Residual risk evaluation indicated three significant risks, five requiring monitoring, and one tolerable, with no risks considered very significant after PM implementation.

Conclusion and Relevance In conclusion, the assessment and targeted implementation of PMs significantly reduced risk criticality within our unit. This approach enhances staff protection during new assignments and activities. Further evaluations will gauge PM effectiveness in maintaining a safe environment for pharmaceutical personnel involved in cutting-edge clinical research and ATMP management.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-024 IMPLEMENTATION OF A STRATEGY TO OVERCOME THE POTENTIAL TOXIC EFFECTS OF PROPYLENE GLYCOL IN NEONATES

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Background and Importance Available evidence on the safety of excipients in compounded formulations is somewhat limited. Contributing to a higher level of evidence seems relevant, particularly regarding compounded formulations for use in neonatology. In a previous study on the presence of problematic excipients in oral compounded formulations, intake above the recommended limits was reported, mainly of propylene glycol (PG), in neonates under 28 days of age.[1]

Aim and Objectives To implement a strategy aimed at overcoming the potential toxic effects due to the exposure of neonates to PG present in oral compounded formulations.

Material and Methods Evaluation of the composition of compounded formulations regularly used in a neonatal intensive care unit to identify the source of PG.

Assessment of alternatives, considering their preservative power, by calculating the concentration of parabens, and analysing the solubility of the chemical forms of parabens used.

Results The source of the PG in the formulations was the preservative solution used – Paraben Concentrate (B.8).[2] As an alternative to B.8, we evaluated three paraben solutions described in the literature, taking into account the respective parabens concentrations, the nature of the solvent and the reported stability. Since the parabens concentrations were at least 100 times lower than that of the B.8, we decided not to adopt any of the solutions described, since this could compromise the preservation of the formulations and, at the time, we were unable to test it.

In an alternative approach, the preparation of a 10% paraben concentrate in water, instead of PG, was implemented. To promote the dissolution of methylparaben and propylparaben (7:3) in water, the respective sodium salts were used. The solution was prepared after calculating the respective equivalent concentrations and ensuring compliance with the solubility data.[3]

Conclusion and Relevance A water-based, PG-free paraben solution has been developed, suitable for preserving oral compounded formulations. This strategy makes it possible to overcome the potential toxic effects of PG in neonates, thereby increasing the safety of the formulations.

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Conflict of Interest No conflict of interest.

3PC-025 STABILITY STUDY OF STANDARDISED FLUID THERAPY PREPARED BY THE PHARMACY DEPARTMENT TO TREAT PAEDIATRIC DIABETIC KETOACIDOSIS

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Background and Importance The Pharmacy Department prepares and distributes fluid therapy (2 bags-system) for the treatment of diabetic ketoacidosis (DKA) in the paediatric emergency unit.

The implementation of this procedure has improved patient safety, since standardised preparations are used only the rhythm being modified according to the patient's needs.

The two bags system consists in sets of two bags of maintenance electrolytes in 1 litre of 10% dextrose or isotonic saline. Unfortunately, their expiration date was only 7 days due to the lack of data on stability.

In order to improve the convenience and reduce wastage, we designed and carried out a physical-chemical stability study of these solutions.

Aim and Objectives The objective of this study was to evaluate the physical and chemical stability of these solutions prepared in the Pharmacy Department to manage paediatric DKA.

Material and Methods

1. The two bags system contains:
   - Solution 1: Potassium (k) 38meq/l, phosphate (P) 59 mg/dl, magnesium (Mg) 5mg/dl and Sodium (Na)143meq/l in isotonic saline.
   - Solution 2: The same electrolytes concentration in dextrose 10%.
2. We prepared 8 units of each solution, half of them were stored at room temperature (23ªC), and half of them in the refrigerator (4°C).
3. We analysed the electrolytes concentration and made visual inspection for physical changes on the following days: 0 (d0), 14 (d14), 28 (d28), 49 (d49) and 92 (d92).

The chemical analysis was performed by the Laboratory Department through the following techniques: sodium and potassium by indirect potentiometry with selective electrode, phosphate by phosphomolybdate reaction; magnesium and glucose by enzymatic technique.

The physical analysis was determined in pharmacy through visual inspection searching for changes in colour and matter particles against a white and a black background.

The results were expressed in mean+/-SD. It was accepted a deviation <5%.

Results The electrolytes concentration remained stable during the study period. The visual inspection showed physical stability. Table 1 summarises the results.

Conclusion and Relevance The results show the stability of solutions in the period of study. Nevertheless, the beyond-use-date will be re-evaluated when a validated sterility test is performed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-026 COST SAVINGS ASSOCIATED WITH ROMIPLOSTIM REPACKAGING IN A PATIENT WITH IDIOPATHIC THROMBOCYTOPENIC PURPURA

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Background and Importance

Background Romiplostim is indicated for the treatment of primary immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (corticosteroids, immunoglobulins). This drug has an important economic impact, in this sense it has been decided to start a protocol for the use of romiplostim which has been established to group patients or dispense two repackaged romiplostim pre-filled syringes for each patient fractionating vials according to the patient´s dose in syringes as a saving strategy.

Aim and Objectives

Objective Evaluating and quantifying the cost saving of the optimisation of the use of romiplostim vials through repackaging into syringe under aseptic conditions.

Material and Methods Retrospective study from January to June 2023 and patients diagnosed from ITP and treated with romiplostim were included. A protocol is being implemented, which consists of dispensing two repackaged romiplostim prefilled syringes (7 days expiration according to Good Practice Guide of preparation of medications in hospital Pharmacy Service) for each patient or grouping the patients receiving treatment with romiplostim and fractionating the vial in syringes to adjust to the recommended dose according to the Summary of Product Characteristics in a flow laminar cabinet. Variables collected: demographics (sex/age), number of patients, and economic (price of romiplostim vial). Data were collected from pharmacy electronic dispensing records.

Abstract 3PC-025 Table 1

Solution 1		(Mean ± SD)										Diff (%)
		T0		T14		T28		T42		T92		
	Theoric range	23ºC	4ºC	23ºC	4ºC	23ºC	4ºC	23ºC	4ºC	23ºC	4ºC	
Sodium(meq/l)	136,1-150,4	144,2 ± 2,7	143,8 ± 2,6	137,3 ± 2,7	137,0 ± 2,6	142,3 ± 2,7	142,0 ± 2,6	143,8± 2,7	143 ± 2,6	141,5± 2,7	141,5± 2,6	NS
Potassium(meq/l)	36,2- 40,0	37,3 ± 1,4	41,4 ± 2,9	37,8 ± 1,4	37,7 ± 2,9	37,3 ± 1,4	38,3 ± 2,9	38,6 ± 1,4	38,6 ± 2,9	38,3 ± 1,4	38,3 ± 2,9	NS
Phosphate (mg/dl)	56,06-62	56,3 ± 2,1	62,4 ± 4,9	57,3 ± 2,1	58,5 ± 4,9	57,5 ± 4,9	56,5 ± 4,9	58,5 ± 2,1	58,5 ± 2,1	55,6 ± 2,1	55,6 ± 2,1	NS
Magnesium (mg/dl	5,4-5,9	5,9 ± 0,4	7,5 ± 1,4	5,2 ± 0,4	5,3 ± 1,4	5,1 ± 0,4	5,0 ± 1,4	5,8 ± 0,4	5,7 ± 1,4	5,6 ± 0,4	5,5 ± 1,4	NS
Solution 2		**(Mean ± SD)**										
		T0		T14		T28		T42		T92		
	Theoric range	23ºC	4ºC	23ºC	4ºC	23ºC	4ºC	23ºC	4ºC	23ºC	4ºC	
Sodium(meq/l)	136,1-150,4	149,25 ± 4,6	149 ± 3,5	141,5 ± 4,6	140,3 ± 3,5	146 ± 4,6	144,5 ± 3,5	146,75 ± 4,6	145 ± 3,5	145,7 ± 4,6	144,3 ± 3,5	NS
Potassium(meq/l)	36,2- 40,0	40,8 ± 1,4	42,3 ± 2,2	38,6 ± 1,4	37,9 ± 2,2	38,8 ± 1,4	37,9 ± 2,2	39,2 ± 1,4	38,5 ± 2,2	39,1 ± 1,4	38,4 ± 2,2	NS
Phosphate (mg/dl)	56,06-62	59,9 ± 3,2	65,8 ± 4,7	58,7 ± 3,2	58,6 ± 4,7	57,5 ± 3,2	57,2 ± 4,7	59,7 ± 3,2	58,9 ± 4,7	56,6 ± 3,2	56,1 ± 4,7	NS
Magnesium (mg/dl	5,4-5,9	5,8 ± 0,3	6,13 ± 0,4	5,4 ± 0,3	5,6 ± 0,4	5,2 ± 0,3	5,2 ± 0,4	5,8 ± 0,3	5,6 ± 0,4	5,7 ± 0,3	5,6 ± 0,4	NS
Dextrose			10,8± 1,5%	-	10,9± 1,5%	9,6± 3,4%	11,0± 1,5%	9,4 ± 3,4%	10,0± 1,5%	9,4 ± 3,4%	9,5± 1,5%	NS

Results A total of 16 patients suffering from ITP are being treated in our hospital with romiplostim, 50% of them are men, and median age 54 years old (21–90). This treatment has cost a total of € 240,561.95 for these 6 months (January to June), however, if patients had been dispensed two repackaged romiplostim pre-filled syringes or had been grouped and given appointment on the same of the week and romiplostim repackaging had been performed under aseptic conditions, the total cost had been € 158191,48 therefore the cost saving there would been € 82.370,47 (€ 164.740,94/year).

Conclusion and Relevance The dispensing of two romiplostim pre-filled syringes or the grouping of patients and the fractionation of romiplostim vials would suppose a saving of € 164.740,94 (saving of 86.342,21 mcg romiplostim, 345 vials of 250 mcg) every year. The repackaging could represent a significant economic saving in the treatment of idiopathic thrombocytopenic purpura, while contributing to maintaining the sustainability of the national health system.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No-conflict-of-interest

Conflict of Interest No conflict of interest.

3PC-027 USE OF AUTOMATED COMPOUNDING DEVICES IN PAEDIATRIC PARENTERAL NUTRITION: A GOOD WAY TO ENSURE SAFETY

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Background and Importance Parenteral nutrition (PN), particularly in paediatric patients, is a complex and high-risk therapy due to small volumes and high susceptibility. Expert recommendations advocate the use of automated compounding devices (ACD) to enhance the safety and quality of paediatric parenteral nutrition (PPN).

Aim and Objectives To evaluate the implementation of an ACD, taking into account criteria related to complexity of the task, safety and workload, as well as the quality and safety of the PN.

Material and Methods Observational and retrospective study from January to June 2023 in a tertiary care hospital. The number, volume, weight and composition of the PPNs prepared during this period were evaluated. Quality and safety of the admixtures were evaluated through the alerts observed (weight deviation). The weight limit deviation accepted was set in +/-5% for PPN over 100 mL and +/-3% for PPN with a volume of 100 mL or less. The impact on the workload will be assessed based on production times.

Results During the study period, 2.483 units were prepared, consisting of individualised PPN for 190 patients and stock preparations.

The breakdown below offers detailed information about the PNs, patient characteristics and the time needed for the whole compounding process, in paediatrics with the ACD and adults, where a vacuum filling machine is used:

An average of 27 nutrients were used to prepare the PPNs (minimum: 4, maximum: 33). In 2.133 units (86%) heparin was manually added after the completion of the compounding.

The range of weight deviation was [4,14%,-2,43%]. The median was 0,85%. No deviation >5% has been recorded in PPNs with a volume >100 mL. In PPNs with a volume <100 mL all deviations observed were <3%.

Conclusion and Relevance The use of an ACD has ensured process quality and safety, as no significant weight deviations were observed despite the diversity of volumes. Furthermore, it reduces the operator's handling, simplifying the task, minimising the risk of microbiological contamination and the likelihood of errors, without increasing the processing times compared to less precise methods.

Given the complexity of preparations and the achieved results, automating PPN preparation processes proves to be an

Volume of PN (mL)	Number of PN
< 50	50
50-100	274
100-250	730
250-500	354
> 500	1075
Total (units)	2483

Weight of the patient (kg)	Total
< 10	443
10-20	236
20-30	112
30-40	86
> 40	134
Total	1011

	Adult PN	Vacuum filling machine set up	Preparation of components	Total time
Mean time (min:sec)	4:03	9:07	43:55	57:05

	Pediatric PN	ACD set up	Preparation of components	Total time
Mean time (min:sec)	3:47	33:54	22:40	60:21

efficient, safe, and precise method for compounding admixtures

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

3PC-028 FOR A MORE ECONOMICAL AND ECOLOGICAL CENTRAL STERILE SERVICES DEPARTMENT (CSSD): BACK TO THE CONTAINER

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Background and Importance The central sterilisation department is conducting a campaign to reduce the costs and carbon footprint of sterilisation and operating theatres.
Aim and Objectives The aim of this work is to reduce the polypropylene sheets packaging.
Material and Methods In May 2023, a container maintenance operation was carried out at the hospital, recovering those not used in the operating theatres.

Surgical trays (ST) wrapped in polypropylene envelopes (PE) were identified using T-Doc traceability software (Getinge). An inventory was carried out in the operating theatre to validate the feasibility of replacing PE with containers.

The economic dimensions in euros (€) take into account staff work, maintenance, consumables, waste treatment, as well as water, steam and energy consumption.
Results The maintenance work carried out in May 2023 resulted in the recovery of 203 containers of various sizes. 245 PE wraps were identified, 78 of which could not be packaged in containers. The cost of consumables and time spent on washing and packaging amounted to € 1.74 for a container and € 2.15 for a PE. Other re-sterilisation costs are equivalent for both packaging systems. The PE wraps identified by T-Doc represent 5,186 re-sterilisations per year, and the economic gain from replacing packaging with containers corresponds to a profit of € 2,126/year. However, the complete replacement project requires the purchase of 48 additional containers at an initial cost of € 13,200. This purchase will pay for itself in 6 years.

The carbon footprint of a container is smaller than a PE because it generates less waste in operating theatres. The PE consists of a sterile barrier and protective packaging, both made of polypropylene. These are disposed of each time they are used in the operating theatre, compared with two filters and two clips for a container.
Conclusion and Relevance This operation offers economic and ecological advantages after a short return on investment, thus meeting the requirements of the ecological transition for our hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

3PC-029 PH MEASUREMENT: NOT AS SIMPLE AS WE THINK? A CASE OF SODIUM PERCHLORATE INJECTIONS

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Background and Importance Ampoules with sodium perchlorate 100 mg/ml for injection are manufactured at the Hospital Pharmacy for use as a premedication before certain nuclear imaging procedures. The Quality Control department recently became aware that pH measurements during quality control were varying more than expected between batches, resulting in out of trend/specification results as well as greater variation between in-process and release values. No data explaining these variations could be found in the literature.
Aim and Objectives To determine factors which could cause unstable pH measurements of sodium perchlorate solutions, and if changing the pH electrode could solve the problem.

Material and Methods pH-meter: Mettler Toledo SevenExcellence S400-Bio, pH-electrodes: (A) InLab Routine Pro-ISM (Reference electrolyte: potassium chloride (KCl) 3M); (B) InLab Science Pro-ISM (Reference electrolyte: KCl 3M); (C) InLab Expert Pro-ISM (Reference electrolyte: XEROLYT®-polymer).

To establish the influence of external factors, pH was measured over time in different types of vials (glass/plastic) and with extended exposure of solution to air. Comparison of electrodes: pH was measured uninterrupted at regular intervals for 420 seconds (n=3). Raman spectra of the precipitates were acquired by using a WITec Alpha300 Apyron Confocal Raman Microscope.
Results Different types of vials as well as extended air exposure of solution did not result in significant change of pH values. Initial testing with electrode A resulted in a characteristic trend where the pH increased, stabilised, and then decreased, while electrode C remained stable. For electrode B the same trend was observed as for electrode A, but testing was aborted due to visible precipitation in the sample. The precipitates were identified as Potassium perchlorate by Raman spectroscopy. Results from subsequent comparison is shown in table 1 (mean±SD).

Abstract 3PC-029 Table 1

pH measurement	60 seconds	240 seconds	420 seconds
Electrode A	5.22±0.39	5.30±0.40	5.09±0.02
Electrode C	5.70±0.07	5.73±0.08	5.75±0.08

Conclusion and Relevance The unreliable results could be attributed to an interaction between sodium perchlorate and KCl reference electrolyte. This also created a precipitation, more clearly visible in electrode B due to higher flow of reference electrolyte to the sample than electrode A. Electrode C with polymer electrolyte was the most stable, without the characteristic decrease in pH after the initial stabilisation, and no precipitation.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

3PC-030 STABILITY STUDY OF AN EPIDURAL ANALGESIC CONCENTRATE FOR INFUSION USED DURING CHILDBIRTH

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Background and Importance Infusions for epidural analgesia are frequently used in maternity wards to ease pain during childbirth. A standardised concentrate for infusion containing bupivacaine, fentanyl and adrenaline used for general epidural analgesia is produced at the Hospital Pharmacy[1] and diluted in infusion bags by an external compounding unit. Recently, a maternity ward asked the Hospital Pharmacy to prepare a concentrate for infusion more suitable for their patients containing only bupivacaine (in a reduced concentration) and fentanyl, reducing the need for in-house compounded alternatives.
Aim and Objectives To confirm the long-term stability of the newer, more suitable concentrate for infusion through an ongoing stability study.
Material and Methods The concentrate was filled in 50 ml vials and stored at 5°C ± 3°C, protected from light. Samples were assayed by UHPLC as previously described elsewhere,[1] and pH and conductivity were measured. The analytical method is validated for linearity, precision, and specificity. Sterility was tested according to Ph.Eur. 2.6.1.
Results Chemical and microbiological test results during the stability study (mean ±SD, n=3) are summarised in table 1. Concentration of bupivacaine and fentanyl is reported as a percent of release concentration.

Abstract 3PC-029 Table 1

Test	Release	9 months	24 months
Bupivacaine (%)	100.00 (±0.31)	100.88 (±0.09)	101.39 (±0.33)
Fentanyl (%)	100.00 (±0.39)	99.68 (±0.51)	100.68 (±0.53)
pH	4.03 (±0.02)	4.14 (±0.01)	4.30 (±0.04)
Conductivity (mS/cm)	1.696 (±0.001)	1.698 (±0.000)	1.711 (±0.002)
Sterility	No growth	No growth	N/A

Conclusion and Relevance The concentrate for infusion was found stable in terms of drug concentration, conductivity, and sterility. There was a slight increase in pH over time, insignificant to overall stability. Based on the current data, it could be concluded that removing adrenaline from the formulation did not decrease stability, and the shelf life could be set to 9 months similar to the older formulation. Furthermore, the study showed that it might be possible to extend the shelf life to 24 months. Providing the hospital with a ready-to-use product adapted to their needs saves the hospital costs, time, and resources, while increasing quality and patient safety.

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3PC-031 USABILITY OF SEMI-SOLID EXTRUSION 3D PRINTING IN HOSPITAL PHARMACY SETTINGS TO PRODUCE PERSONALISED ORAL MEDICATIONS FOR PAEDIATRIC PATIENTS

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Background and Importance In paediatric hospitals, the lack of age-appropriate licensed medicines for oral use has traditionally been solved by extemporaneous manufacturing of oral liquids, suspensions, dose powders and capsules in hospital pharmacies, and manual drug manipulation at hospital wards. However, there is still a need for new alternatives to provide personalised child-friendly drug formulations and novel printing technologies may present a solution. Despite the recent progress in the development of 3D printers for pharmaceutical applications, there is a lack of research on their usability in extemporaneous manufacturing in hospital pharmacy settings.
Aim and Objectives The aim of this study was to evaluate the perspectives of hospital pharmacy personnel on the usability of semi-solid extrusion printing.
Material and Methods This qualitative study was conducted as focus group discussions in two university hospitals in two Nordic countries. Pharmacists and pharmacy technicians (n=43) from the hospital pharmacies, working within drug manufacturing, compounding, or quality control, participated. Participants did not have previous experience in using 3D printing. Prior to attending the focus groups, they received a demonstration on a semi-solid extrusion 3D printer (Curify MiniLab, CurifyLabs, Finland) and performed the steps in the manufacturing process. A semi-structured interview guide was used to moderate the discussions, which were audio-recorded and transcribed verbatim. In addition, observations were made during the demonstrations as well as the focus group discussions.
Results Many participants perceived the equipment as easy to use. Suggestions for equipment specific development and process optimisation were brought up in the conversations, such as, use of auxiliary tools, disposable cartridges and nozzles, and printing directly into blisters. Benefits and risks associated with quality perspectives, such as drug accuracy and stability, occupational safety, patient safety, and drug administration were recognised. For example, the 3D printed doses had a pleasant aroma and texture and were easier to produce than dose powders.
Conclusion and Relevance To our knowledge, this is the first study to evaluate the perspectives of hospital pharmacy staff on the usability of semi-solid extrusion printing in drug manufacturing in a hospital environment. Our results show that, despite identified further development needs, the manufacturing process shows great potential.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-032 OPTIMISATION OF AN INSULIN 1 IU/ML EYE DROP FORMULATION FOR THE TREATMENT OF CORNEAL ULCERS

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Background and Importance According to literature, a formulation of regular human insulin (Actrapid®) 1 IU/mL eye drops was elaborated using a solution of artificial tears (Systane Ultra®), in sterile amber glass dropper bottles for the treatment of corneal ulcers. To test the stability, a 30-day galenic

validation was performed, storing the eyedrops in refrigeration. The samples prepared at the Pharmacy Department presented turbidity from day 0, therefore it was decided to formulate it in 0.9% sodium chloride (normal saline).

Aim and Objectives Optimise and study the stability through galenic validation of 1 IU/mL insulin eye drops formulated using normal saline in sterile amber glass dropper bottles and in low density polyethylene (LDPE) dropper bottles.

Material and Methods We elaborated a 1 IU/mL regular human insulin eye drops using normal saline stored in refrigeration (2–8°C) in amber glass dropper bottles (IN1) and LPDE dropper bottles (IN2). All samples were prepared in a horizontal laminar-flow cabinet following the Good Practice Guidelines for sterile drug preparation. A 30-day galenic validation was carried out monitoring clarity, colour, pH, osmolality and sterility on days 0, 1, 2, 7, 15, 22, 30 testing three units per sampling point and analysed property. The pH value at which insulin commercial presentations are buffered is 6.9–7.8; and the pH value of normal saline is 6.0.

Results IN1: at day 0, the samples presented a pH around 8.5. After analysing this pH value, it is obtained that it was due to the sterilisation process of the amber glass dropper bottles, which uses buffered formol. The formulation is, therefore, rejected.

IN2: all samples presented, during the whole galenic validation, a transparent and homogeneous appearance, with absence of particulates, pH values of 6–6.3, an osmolality of 282–286 mOsm/kg and no microbiological growth.

Conclusion and Relevance The 1 IU/mL insulin eye drops packaged in LPDE dropper bottles showed no changes in the parameters studied throughout the 30-day galenic validation. They also remained within the eye pH range of maximum tolerability (3.5–10.5). It is required more physicochemical and microbiological stability studies to confirm the stability of the formulation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-033 KIRO ISOLATOR®: A NEW, RELIABLE, ROBOTIC DEVICE FOR THE COMPOUNDING OF INJECTABLE ANTICANCER DRUGS

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Background and Importance The compounding of injectable anticancer drugs in hospital pharmacies is in constant growth and requires innovation and development of flexible preparation methods while reducing the risk of exposure to hazardous drugs for healthcare workers. To this purpose, a robotic system implemented inside an isolator, Kiro Isolator® (Grifols, Spain), was designed.

Aim and Objectives We report the qualification of the first Kiro Isolator® from a microbiological and preparation robustness point of view.

Material and Methods Dose accuracy and precision were assessed for sampling volumes from 1 to 48 mL for three drugs used in our hospital: paclitaxel (viscous solution), vincristine (aqueous solution) and cyclophosphamide (aqueous solution with reconstitution). For each volume tested (1, 5, 10, 20 and 48 mL), five bags of paclitaxel and cyclophosphamide were produced. A volume of 2 mL was tested with vincristine only (n=10 bags). Tests were repeated over three days. All preparations were checked by gravimetric control using the scales of the robot with a weighing tolerance threshold set at 5%. For paclitaxel and cyclophosphamide preparations, an analytical control was performed to confirm the reliability of the robot's gravimetric control using an LC-MS. Deviation from the theoretical concentration was expected to be within +/-15%. Microbiological qualification was carried out by performing Media Fill tests (MFT) over three days.

Results Overall, 75 bags of paclitaxel, 75 bags of cyclophosphamide and 30 bags of vincristine were produced. With the exception of the 1 mL volume, accuracy was validated with gravimetric control for all volumes tested. Analytical controls were compliant with the specifications except for three bags (two cyclophosphamide and one paclitaxel). We assume these results are false negatives due to an issue of homogenisation. Excepted the lowest volume of 1 mL, ANOVAs tests showed that for paclitaxel and cyclophosphamide the concentrations were not different from the theoretical concentrations. No growth was observed during a 15-day incubation of the MFT.

Conclusion and Relevance Accuracy was validated for sampling volumes from 2 to 48 mL with a reliable gravimetric control. The robot's confinement ensures technician safety and environmental protection without affecting its performance. Since its qualification, nearly 20% of our total production is now carried out with this innovative robot.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-034 FORMULATION OF KETAMINE 1% AND AMITRIPTYLINE 1% GEL IN PRURITIC EPIDERMOLYSIS BULLOSA: A CASE REPORT

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Background and Importance Epidermolysis bullosa (EB) is a group of rare genetic diseases characterised by fragility of the skin, resulting in painful and itchy blisters. Although there is no curative treatment for EB, some measures may help to relieve symptoms.

Aim and Objectives To describe a clinical case of a patient with EB and evaluate the effectiveness and tolerance of a ketamine and amitriptyline formula.

To develop and validate a topical gel of ketamine and amitriptyline.

Material and Methods A 29-year-old woman with dystrophic pruritic EB in her lower extremities since she was 3 years old. She was previously treated with methotrexate, oral and topical corticosteroids and cyclosporine. Due to the adverse effects of oral therapy, Dermatology requested a topical formulation of ketamine and amitriptyline.

A literature search on the efficacy, safety and composition of the formula was conducted. A 1% ketamine with 1% amitriptyline gel was developed and the physical and organoleptic characteristics were analysed at 0, 14, 28 and 42 days.

Clinical follow-up was carried out during Pharmacy and Dermatology visits to assess the response to the treatment.
Results The literature reported several cases of ketamine and amitriptyline gel (KAG) at different concentrations for treating chronic pruritus and EB. The off-label use was approved by the medicines-in-special-situations local committee.

Procedure for 400 grams: In phase 1, dissolve 0.6g of sodium methylparaben in 280mL of water and heat it up to 60–70°C. In phase 2, heat 4g of amitriptyline and 40g of glycerol in a second beaker. Add gradually 4g of carboxymethylcellulose at phase 2 until a homogeneous suspension is obtained. Mix both phases at 70°C and stir vigorously until a whitish gel is obtained. After cooling, add 80g of ketamine vial (50mg/mL) and homogenise it. The gel is homogeneous, fluid, whitish, odourless and has good extensibility.

From the treatment's beginning, the patient showed improvement of the pruritus, good tolerance and satisfaction. After 6 weeks, she was ongoing with KAG and applies it every 3 hours instead.
Conclusion and Relevance In our patient, topical KAG is an effective and safe alternative to consider in the EB treatment. The medium long-term effects will be assessed through follow-up. During the studied period, the formula developed maintains stability.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

3PC-035 PATCH TESTS WITH HAZARDOUS DRUGS: IS IT POSSIBLE TO ENSURE SAFETY DURING PRODUCTION?

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Background and Importance Epicutaneous Patch Tests (EPTs) are the first type of skin tests performed by Allergology Department to diagnose Type IV hypersensitivity allergic reactions (IVHAR) to drugs. They involve application of ointments for epicutaneous patches containing the active ingredient, prepared by the Pharmacy Department, followed by reading results 48 and 72 hours later. When there is suspicion of an IVHAR to hazardous drugs, compounding process must be adapted to protect the handler.
Aim and Objectives The aim of this study is to describe the design and formulation of EPT with Imatinib and Nilotinib, classified as Hazardous Drugs Group 1 by the National Institute for Occupational Safety and Health (NIOSH).
Material and Methods A request was made to the Pharmacy Department for an EPT for a patient suspected of IVHAR after treatment with Imatinib in order to confirm the diagnosis and consider switching to Nilotinib.

A literature search was conducted to determine the optimal concentration of both drugs within each EPT, as well as the best vehicle. A galenic control was established to evaluate the extensibility and organoleptic properties of the formula. The stability of the formula was determined in accordance with the risk matrix included in the Good Practices Guide for the preparation of medications in Hospital Pharmacy Services.

The handling of these drugs was always performed in a fume hood with HEPA-H14 filter, wearing a cap, glasses, FFP3 mask, gloves, disposable gown, and shoe covers.
Results Imatinib 5% petrolatum (pet.):

- Imatinib tablet 0.4 g
- Liquid pet. 2 g
- Petroleum Jelly q.s. 8 g
- Nilotinib 5% pet.:
- Nilotinib capsule 0.2 g
- Liquid pet. 1 g
- Petroleum Jelly q.s. 4 g

For the preparation of both ointments, the commercial pharmaceutical form was placed in a ZIP-type resealable bag with an ENFit connection. The active ingredients were pulverised using a specific roller-shaped device. Subsequently, liquid Vaseline was introduced using an ENFit syringe through the bag's connection. After homogenisation, Vaseline filante was introduced in the same manner and homogenised again. Finally, it was dosed into individualised 1 mL ENFit syringes.
Conclusion and Relevance The preparation of EPT with hazardous drugs in the Hospital Pharmacy Department is totally feasible as long as the appropriate procedures and equipment are available.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

3PC-036 RISK ANALYSIS OF THE PHARMACEUTICAL CIRCUIT FOR INJECTABLE CHEMOTHERAPIES AFTER IMPLEMENTATION OF DRUGLOG®

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Background and Importance As part of a quality assurance approach, a UV-visible spectrophotometer has been installed in 2021 in the cytotoxic reconstitution unit (CRU), enabling pre-release analytical control of cytotoxic preparations. This new step has led to a new risk analysis using the FMECA method (Failure Modes, Effects and Criticality Analysis).
Aim and Objectives The aim was to evaluate the entire injectable chemotherapy process compared to an initial FMECA carried out in 2016 in order to assess the added value of the DrugLog® tool.
Material and Methods The FMECA was carried out between June and September 2023. Six multidisciplinary working meetings were held, attended by two pharmacists, one intern and one pharmacy technician. The failure modes (FM) identified in 2016 were reassessed for a total of 97 FM in 2023, divided into 10 themes. For each FM, a criticality index (CI) based on frequency (F), severity (S) and detectability (D) was calculated using the formula: $CI=F\times S\times D$. The CIs were divided into three categories: mild ($CI<25$), moderate ($25<CI<50$) and severe ($CI>75$).
Results Of the 97 FMs identified, 94 were of mild criticality (97%), three moderate (3%) and 0 severe. In 2016 and 2023, 70 items were common. The cumulative CIs were similar (806 in 2016 compared with 809 in 2023). A decrease in cumulative CI was observed in the personnel (-58%), validation (-69%) and release (-46%) themes. However, a sharp increase was observed in the premises (+55%), equipment

(+31%), tray preparation (+48%), and transports (+41%) areas.

The FMECA was used to assess DrugLog®: 18 FM were selected: 100% were of mild criticality, for a cumulative CI of 163.

Conclusion and Relevance FMECA's comparison confirms the added value of DrugLog®. Its implementation secures the release process. All the FM specific to DrugLog® are of mild criticality and make it a useful tool for the CRU process.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-037 ALUMINIUM IN PAEDIATRIC PARENTERAL NUTRITION: ARE MULTICHAMBER BAGS THE SAFER CHOICE?

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Background and Importance Paediatric patients receiving parenteral nutrition (PN) are particularly vulnerable to aluminum exposure, a known contaminant in PN formulations.

Aim and Objectives This study aimed to quantify the aluminum concentrations in paediatric PN admixtures prepared using commercially available multichamber bags (MCBs) for paediatrics and compare them with the aluminium content in compounded PN (CPN) with an equivalent composition of ingredients.

Material and Methods We conducted aluminium content testing on the three commercially available MCB formulations (Numeta® G13, G16, and G19). Simultaneously, we analysed CPN preparations with identical compositions. For the MCB preparations, we utilised two batches of each MCB presentation, both with and without lipids. For CPN, we created three distinct formulations for each MCB presentation: one utilising Primene® as the amino acid source, another using Aminoven-Infant®, and a third modifying the source of electrolytes (using either Aminoven-Infant® or Primene®). CPN was prepared using iv electrolytes compounded by an external pharmacy and commercially available electrolytes. The macronutrients employed for CPN included Aminoven-Infant® or Primene® for amino acids, Glucose 70% for carbohydrates, and Smoflipid® 20% for the lipid source. Aluminium content was quantified using spectrometry. Mann-Whitney tests were employed to compare means.

Abstract 3PC-037 Table 1 Aluminium content in PN preparations

Preparation	Multichamber bag	Compounded PN	P value
Numeta®	9.83 [2.20] (n=12)	20.68 [4.19](n=18)	<0.01
Numeta ®No Lipid	9.85 [2.61] (n=6)	20.79 [4.00] (n=9)	<0.01
Numeta® with Lipid	9.81 [1.94] (n=6)	20.57 [4.62] (n=9)	<0.01
Numeta® G13	11.94 [2.68] (n= 4)	23.00 [5.34] (n=6)	<0.05
Numeta® G16	9.11 [1.06] (n= 4)	20.88 [2.76] (n=6)	<0.05
Numeta® G19	8.44 [0.43] (n= 4)	18.16 [3.08] (n=6)	<0.05
Primene®	-	18.76 [3.00] (n= 11)	0.07
Aminoven-Infant®	-	23.70 [4.17] (n=7)	

Results Overall, we tested 30 PN preparations (12 MCB and 18 CPN). The mean aluminium content was significantly higher in the CPN preparations compared to MCB, measuring 20.68 and 9.83 µg/L, respectively (see table 1).

Data expressed as µg/L[SD]

Conclusion and Relevance This study underscores significant differences in aluminium content between commercially available MCBs and CPN preparations, emphasising safety concerns in neonatal and paediatric patients. The findings underscore the need for efforts to harmonise discrepancies across manufacturers and sources of contamination, ultimately enhancing the quality and safety of paediatric PN formulations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-038 AUTOLOGOUS SERUM EYE DROPS PREPARATION: APPROACH TO THE FILTRATION STEP IMPACT ON THE CONCENTRATION OF ACTIVE MOLECULES

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Background and Importance Autologous serum eye drops (ASEDs) are pharmaceutical preparations used in severe dry eye disease. Sterility is a specification for eye drops, which can be obtained by filtration. Any molecule with a mean diameter greater than the filter porosity is then retained. EGF (Epidermal Growth Factor) is one of the active molecules (AMs) in ASEDs. With an intermediate molecular mass (MM) (180 kDa), its investigation makes possible to predict the impact of filtration on the concentration of other molecules.

Aim and Objectives To evaluate the impact of this sterilisation method on AM by measuring EGF concentrations before/after filtration of collected sera.

Material and Methods Four 4 mL tubes of human serum (P1-P4) were used, all from a hospital biological collection. Each serum underwent the following operations: zero filtration, clarifying filtration (CF, at 0.45 µm porosity) and sterilising filtration (SF, at 0.20 µm). The assay was performed in duplicate using the ELISA technique (Quantikine® Human EGF Immunoassay kit, R&D System, USA). The impact of filtration is considered significant if the relative difference in concentrations after the process exceeds 7.5%.

Results The EGF concentration (pg/mL) in each unfiltered serum represents the maximum concentration (100%), allowing the impact of filtrations to be expressed as relative percentages of this maximum. Under CF, these percentages were respectively, for P1 to P4: 96.2%, 97.2%, 92.8% and 97.1%, representing a reduction in concentrations between 2.8% and 7.2%. Under SF, the percentages were: 94.8%, 93.4%, 91.1%

and 95.9% respectively, representing a reduction of 4.1% to 8.9%.

Conclusion and Relevance As expected, EGF concentrations decrease after filtration, especially when the porosity of the filter used is low. Moreover, the significance threshold is reached for P3 under SF. We may suppose that smaller AMs (ie IGF-1, MM 7.6 kDa; TGF-β1, MM 25 kDa) will be less retained. For larger AMs such as fibronectin (MM around 450kDa), the decrease in concentration is likely to have an impact on the ASEDs efficacy, justifying a more specific study. Other methods of ensuring the microbiological safety of ASEDs should probably also be considered.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

3PC-039 EARLY DE-RISKING OF THE STABILITY OF A PERSONALISED, STERILE BACTERIOPHAGE SUSPENSION ON THE BASIS OF ADVANCED KINETIC MODELLING

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Background and Importance Bacteriophages, natural viruses of bacteria, are a promising therapy against multidrug-resistant bacteria. The use of therapeutic bacteriophages (TBP) requires the selection of the most active ones and their individual formulations (hospital or magistral preparations) by a hospital pharmacy for a personalised medicine. The risk of TBP instability must be managed at the earliest stages of development.

Aim and Objectives Advanced Kinetic Modelling reliability assessment to de-risk the instability of BPT formulations.

Material and Methods A purified anti-staphylococcal BP (*Silviavirus*) formulated in two solutions (A and B) was tested. The main critical quality attribute to assess their stability was the biological activity, determined by numeration of Plaque Forming Unit (PFU) (Spot Test), with a target set at $(10 \pm 9).10^8$ PFU/mL. The following study designs were performed: (i) an accelerated degradation with seven temperature conditions (from -80 °C to +50 °C) during 3 months (analysis at D0, D7, D14, D28, D60, and D90), the data generated being used for AKM with PREDISTAB method; (ii) a prospective stability study based on spot test performed (n=3) at 5 and 25 °C during 12 months for A and 6 months for B.

Results The results (expressed in PFU/mL) of the prospective vs predicted stability studies were as follows:

- for solution A
- ^{8} vs $2.43x10^8$ (D_{LOG}=0.66%) and $1.04x10^5$ vs $2.65x10^5$ (D_{LOG}=8.1%)
- ^{8} vs $1.46\ x10^8$ (D_{LOG}=2.05%) and $3.56x10^2$ vs $4.76x10^2$ (D_{LOG}=4.94%)
- for solution B at 5° and 25°C after 6 months: $2.56x10^8$ vs $5.60x10^8$ (D_{LOG}=4.04%) and $1.67x10^4$ vs $2.69x10^3$(D_{LOG}=18.78%)

Conclusion and Relevance Our data suggest that AKM allows rapid assessment of the risk of instability for both formulations. Comparison of the results of the predictive vs prospective stability studies showed a good precision at 5 °C and 25 °C during 12 months for formulation A and 6 months for formulation B. The prospective study is still ongoing for both formulations to be compared with predictions at 24 months. The PREDISTAB method by identifying the risk of instability at the earliest stage of development should allow the early selection of the best TBP formulation and predict the expiry date.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

3PC-040 RADIOCHEMICAL PURITY DETERMINATION OF 177LU-PSMA-617: DEVELOPMENT AND VALIDATION OF A HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY ANALYTICAL METHOD

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Background and Importance ^{177}Lu-PSMA-617 is a treatment of progressive, metastatic, castration-resistant prostate cancers expressing PSMA receptors, previously treated with taxane and at least one second-generation hormone therapy. ^{177}Lu-PSMA-617 is a radiopharmaceutical drug with a marketing authorisation and is manufactured industrially (PLUVICTO®, Novartis). However, it can also be prepared in-house, especially for preclinical applications. Thus, quality control procedures are required to determine radiochemical purity (RCP).

Aim and Objectives To develop and validate a radio-high-performance liquid chromatography (HPLC) analysis method to measure RCP of ^{177}Lu-PSMA-617.

Material and Methods Radio-HPLC analyses were carried out on an apparatus equipped with a C_{18} column and a radioactivity detector. Three commercial ^{177}Lu-PSMA-617 batches were used as samples. The parameters considered for method validation were specificity, linearity, accuracy, precision, robustness, limits of detection (LOD) and limits of quantification (LOQ). Means, standard deviations and coefficient of variation (CV) for RCP, retention time (tr) and recovery were calculated. Linear regression coefficient R^2 was computed for linearity.

Results Radiochemical identification of ^{177}Lu-PSMA-617 consisted in 10 analyses of each three commercial batches and showed a consistent tr of 10.07 min (CV% < 0.1). Recovery was excellent, with 12.87 ± 0.06 MBq recovered at column outlet for a 12.2 MBq injected activity. The addition of radio-impurities in known quantities validated the accuracy of the method (differences between measured RCP and theoretical RCP ranging from 101.57% to 105.52%). CV% of RCP and tr values over 12 measures of a single batch were respectively <0.11% and <0.12%, which confirmed the repeatability of the method. Forced degradation conditions in the presence of

acid, base, oxidative stress or heating led to the formation in situ of impurities with a tr largely different from the analyte, confirming the specificity of the method. LOQ and LOD were 0.68 and 0.21 MBq/mL, respectively, and the radiodetector response was linear from 2 to 300 MBq/mL (R^2 = 0.9977). Robustness was found to be limited as the mean tr values varied by -4.8% when the column was heated to 50 °C instead of 25 °C.

Conclusion and Relevance A radio-HPLC method for the quality control of ^{177}Lu-PSMA-617 was validated and can be used for in-house preparations for preclinical purposes of this radioactive drug.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

3PC-041 PUBLIC PRODUCTION OF THERAPEUTIC BACTERIOPHAGES

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Background and Importance To stern antibiotic resistance -the death toll of which is predicted to reach 10 million deaths per year by 2050- new strategies are explored such as phage therapy. It takes advantage of the ability of bacteriophages or phages – viruses of bacteria – to infect, replicate and lyse their host.

Aim and Objectives PHAG-ONE project (20-PAMR-0009) allowed the creation of an Etablissement Français des Phages Thérapeutiques (EFPT) working with French hospitals to treat patients who reached therapeutic dead ends. This work details the future approach for hospital production of phage suspensions.

Material and Methods Selection of production host: An *in-silico* approach, based on a bioinformatics pipeline, was developed to select the bacterial strains the most free of virulence factors and resistances.

Selection of high therapeutic potential phages: Phages were sampled from their natural environment, identified by genetic sequencing; their activity range was tested on a bacterial panel representative of the clinical and genetic diversity of the pathogen. Phages with broad activity spectrum and complementary activities were selected for further pharmaceutical development.

Results

Production After amplification on the selected hosts, phages were purified by tangential flow filtration and ultrafiltration. The output was qualified as an active pharmaceutical ingredient (API) authorised by the French regulatory health agency (ANSM). This API can enter hospital preparations.

Formulation and quality control The excipients for the hospital preparations were selected to (i) enhance the phage suspension stability and (ii) be suitable for clinical use. The quality controls target (i) the phage identity and activity; (ii) the risks associated with the administration route; (iii) the risks associated with the production process. The hospital preparation's stability is explored following both ICH and predictive approaches.

Conclusion and Relevance The authorisations to produce phage API and hospital preparations of phage suspensions will be asked according respectively to the fabrication (part 2 and appendix 2) and preparation good practices and to the future general chapter 'Phage therapy active substances and medicinal products for human and veterinary use (5.31)'. Inspired by the French blood establishment, EFPT's purpose will be to offer phage suspensions against multi resistant bacteria or to treat patients with infectious recurrences and other bacterial therapeutic dead ends in a personalised approach.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

3PC-042 STERILE AND NON-STERILE COMPOUNDING: RISK ANALYSIS AND IMPROVEMENT MEASURES

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Background and Importance Drug compounding errors can result in patient harm. Hence, the importance of reviewing formulations to ensure their quality and safety.

Aim and Objectives To analyse the risk derived from our current process of sterile and non-sterile compounding, through error records registered for 1 year, and to list and prioritise measures to solve them.

Material and Methods A descriptive study, including errors related to sterile and non-sterile compounding (non-parenteral nutrition, non-chemotherapy) registered from October 2022 to September 2023, was conducted. Errors were classified according to their causes. Error's severity was determined subjectively by the pharmaceutical team.

A brainstorming session was organised, with technicians and the pharmacist leading safety, to discuss the critical points of the entire process. An Ishikawa diagram was created to visually capture the critical points. Improvement measures to reduce risk of errors were listed and prioritised by feasibility and effectiveness.

Our current process consists of: – Organisation: Outlook schedule, email requests, electronic and paper prescriptions – Non-sterile compounding: managed through Magisfor® software – Sterile compounding: managed through processing forms.

Results Sixty-four errors were detected: seven (10.9%) due to organisational causes, six (9.4%) derived from software/processing forms, eight (12.5%) compounding process, five (7.8%) quality control, five (7.8%) packaging, 23 (35.9%) labelling, seven (10.9%) storage, and three (4.7%) due to validation causes.

Twenty-five (39%) errors were considered severe. Errors were mainly detected by pharmacists during the validation process (n=54, 84%), others by technicians/nurses.

In total, 25 main critical points were detected through the Ishikawa diagram.

Improvement measures that could be implemented are:

- Outpatient scheduling
- Training in our actual software, good clinical practice and the compounding process
- Evaluate other programmes that include sterile compounding
- Periodic revision of the processing forms
- Strategic placement or marking active ingredients/excipients susceptible to cause confusion
- More microbiological controls
- Periodic revalidation of technicians
- Reduce technician turnover and less multitasking
- Measures we could prioritise would be those related to technicians training and revalidation.

Conclusion and Relevance Several critical points were detected in our process of sterile and non-sterile compounding. We found some measures that could help us to reduce risk of errors, but we think that we should prioritise those related to technicians training and revalidation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-043 INTRAVITREAL PREPARATION OF LIPOSOMAL B AMPHOTERICIN: FROM FORMULATION STUDY TO PREPARATION

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Background and Importance Fungal vitreit is a vitreous body infection that falls within the broader field of endophthalmitis. The therapy for this pathology is the intravitreal injection of antifungal drugs that can be accompanied by topical or intravenous administration of the same antifungal drug. The pharmacy had to respond to a request for intravitreal preparation of liposomal b amphotericin 0.01mg/0.1ml. The rational use of the liposomal formulation has been the elective toxicity in the eye compared to the non-liposomal formulation of which are reported in the literature possible adverse events.

Aim and Objectives The purpose of this paper is to describe the process which led to the formulation and compounding of the intravitreal preparation.

Material and Methods The existing scientific literature has been analysed in order to identify the correct procedure for setting up the required galenic preparation. The compounding has been studied from bibliographical data and discussed internally by our team of pharmacists, laboratory technicians and nurses.

Results For the preparation, carried out with aseptic technique, amphotericin b liposomiale 50 mg powder for parenteral use was used. The drug was reconstituted with 12 ml of water for injectable preparation (APPI) to obtain a concentration of 4 mg/ml. The preparation had to be carefully shaken for about 30 seconds to ensure complete dissolution. 2,5 ml of reconstituted solution were taken and then a 5-micron filter was applied and injected into a 100 ml APPI bottle previously emptied of the same ml. A 0,1 mg/ml concentration solution was obtained. 0,3 ml of the final solution was then transferred to a 1 ml luer lock syringe and closed with a self-sealing device. A second syringe has been prepared for microbiological control.

Conclusion and Relevance Clinical galenics has been instrumental in ensuring therapeutic opportunities not available with commercially available medicines for the personalised treatment of a patient with fungal vitreit associated with chorioretinitis. The pharmacist is essential for the particular knowledge of the drug in the field of formulation of galenic prescriptions magistral and laboratory technicians and nurses for the implementation of the same.

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Conflict of Interest No conflict of interest.

3PC-044 A PHYSICO-CHEMICAL STABILITY STUDY OF VANCOMYCIN EYE DROPS AFTER DIFFERENT THAWING TIMES

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Background and Importance In our establishment, an excursion temperature occurred on our freezer containing the hospital preparation including vancomycin eye drops 25 mg/mL. Due to the lack of data, a quarantine of the eye drops was necessary, resulting in a time interval without eye drops preparation. It was necessary to quickly obtain vancomycin eye drops from the other hospitals. Remember that vancomycin eye drops are indicated for the treatment of bacterial keratitis and corneal abscesses.

Aim and Objectives We would like to create four scenarios with different thawing times (0.5h, 2h, 6h and 12h) to imagine different situations can meet users of eye drops to check the stability of the eye drop after 7 days.

Material and Methods After total defrosting the eye drop have been put back to the freezer. After an interval time of at least 48h at -20°C the eye drop was thawed and stored in the fridge condition between 2 and 8°C for 7 days to mimic a normal use. The assay of vancomycin and degradation products has been determined by HPLC at the end of the first thawing time (J0) and at day 0, 3 and 7 of the fridge storage for each batch (D0, D3 and D7). One batch per scenario was tested, each batch contained three samples and each sample was assayed in triplicate.

Detection of the analyte was performed by UV and mass spectrometry (λ=280nm and 725 Da). Likewise, detection of degradation products was carried out by diode array UV and mass spectrometer detector (210 nm to 400 nm and 50–1500 Da).

Results With all these scenarios, we demonstrated that vancomycin eye drops is stable at D7 after 12 hours of thawing. The average variation in vancomycin concentration is less than 5%. No degradation products were observed.

Conclusion and Relevance This physico-chemical study could be reproduced for our other hospital eye drop preparation (ceftazidime and amikacine) which are also used for corneal infections. Then, a microbiological study could be done in the same condition to prove sterility of eye drops after a thawing cycle. These first promising results will permit to avoid quarantine after unintentionally thawing of frozen eye drop preparations.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

3PC-045 RETROSPECTIVE STUDY OVER 6 YEARS OF THE TREND IN FUNGAL CONTAMINATION OF CONTROLLED ATMOSPHERE AREAS WITHIN A CELL THERAPY UNIT

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Background and Importance Moulds are aerobic eukaryotic organisms naturally present in the environment. According to regulations, no mould should be present in a controlled-atmosphere zone (ZAC).

According to the literature, fungal spores can reach significant quantities, up to several 10, 000's of particles/m^3 of ambient air. The highest concentrations are found during the summer-autumn period in Europe. *Cladosporium spp* is the predominant species in most studies, with concentrations of over 4,000 CFU/m^3 of ambient air.

The trend in outdoor air contamination is well known, but few articles deal with the trend in fungal contamination in ZACs.

Aim and Objectives The primary objective of this study was to determine whether there is a seasonal trend in contamination in ZACs. The secondary objectives were to determine the most frequent moulds and the effect of factors such as air conditioning, hygrometry and temperature on fungal contamination in ZACs.

Material and Methods Based on microbiological surveillance register of the ZACs at the Saint-Ismier cell therapy and engineering unit, we collected the contaminated samples without counting the number of CFUs contained in this contamination. When available, identification was provided. The variables of temperature, hygrometry and air conditioning were collected using centralised technical management software for equipment and premises. All the data collected was recorded manually in a Microsoft Excel spreadsheet, with data double-checked at the time of collection. Statistical tests were performed on this table.

Results The results of the trend analysis showed a significant difference between fungal contamination frequencies in ZACs depending on the season. Autumn and summer are the seasons with the highest risk of fungal contamination. The main species in our study were *Cladosporium, spp and Penicillium, spp*.

Conclusion and Relevance These results show that the evolution of fungal contamination in ZACs reflects that of external environment. Indeed, although ZAC air treatment systems are capable of filtering large quantities of fungal spores, factors such as personnel, materials and consumables are potential vectors for microbial transfer.

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Conflict of Interest No conflict of interest.

3PC-046 RISK OF PERSONNEL EXPOSURE TO HAZARDOUS DRUGS IN ROBOTIC COMPOUNDING

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Background and Importance Continuous occupational exposure to hazardous drugs (HD) poses significant risks to healthcare personnel. Robotic compounding systems have been introduced in pharmacies to enhance patient and staff safety. These systems operate within enclosed ISO Class 5 environments with negative pressure, which effectively minimising personnel exposure to HD during critical operations. However, there is a concern that surfaces in the compounding area may get contaminated, potentially exposing hospital personnel to these hazardous substances.

Aim and Objectives The primary objective of this study was to evaluate the risk of occupational exposure to HD when utilising robotic compounding systems for the preparation of antineoplastic sterile medications. Specifically, we aim to assess the levels of HDs present on the surfaces of ready-to-use preparations and on the gloves worn by personnel involved in the compounding process.

Material and Methods This study was conducted over a period of 3 days during routine production at KIRO Oncology (Kiro Grifols, Mondragon, Spain). Each day, we collected wipe samples from the surfaces of 20 HD preparations and from the gloves of the operator engaged in the compounding process using Cytoxlab sampling kits (CYTOXLab, Geneva, Switzerland). Our analysis included the detection and quantification of 25 anticancer molecules commonly used in hospital pharmacies.

Results Throughout the study, 19 different drugs were compounded by the robot, including 5-fluorouracil, bevacizumab, carboplatin, cisplatin, cyclophosphamide, docetaxel, doxorubicin, eribulin, etoposide, gemcitabine, irinotecan, nivolumab, oxaliplatin, paclitaxel, panitumumab, pembrolizumab, pemetrexed, trastuzumab, and vinorelbine. We observed only a negligible amount of gemcitabine, which fell below the quantification limit (<0.005 ng/cm^2), on the surfaces of two out of the 20 bags and on two of the operator's gloves.

Conclusion and Relevance The results of this study demonstrate that levels of HD surface contamination in robotic compounding are exceedingly low and, in most cases, undetectable. Occupational exposure to HD remains consistently below 0.1 ng/cm^2, a threshold deemed 'safe' according to certain studies. This finding assures the safety of the compounding personnel and other hospital staff members involved in cancer treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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Conflict of Interest No conflict of interest.

3PC-047 PAEDIATRIC IV ANTIFUNGAL ADMIXTURES: CENTRALISATION'S ECONOMIC CONSEQUENCES

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Background and Importance Most intravenous admixtures (IVA) are prepared on the wards just before their administration to the patient, discarding the spare volume left in vials afterwards. This wasted volume is especially significant in injectables used in paediatrics. To avoid this, hospital pharmacy Central Intravenous Additive Services (CIVAS) centralise the preparation of IVAs, reducing waste and saving costs.

Aim and Objectives To evaluate the economic impact of centralising injectable paediatric antifungal drugs in a tertiary hospital CIVAS from January to December 2021.

Material and Methods The cost incurred by the preparation of paediatric antifungals on the wards versus CIVAS was estimated. To do this, data were collected from the electronic prescribing system and the centralised preparation costs were calculated considering the number of vials, diluting agents, extra personnel time (0.90€/preparation) and clothing (0,11€ and 0,16€ in a non-hazardous cabin and hazardous cabin, respectively). Expenses on the ward were calculated based on what it would have cost were they not centralised. These calculations were based on the maximum ex-factory price plus VAT minus a national discount.

Results Three drugs were selected for centralisation, namely liposomal amphotericin B (LAB), micafungin and vorizonazol. Stock solutions were prepared for these drugs at a concentration of 1 mg/mL for LAB and micafungin, and 5 mg/mL for voriconazole, which were then used to prepare different patient specific IVAs. During the time period, a total of 2,423 paediatric antifungals were centralised, which comprised 863 LAB, 1531 micafungin, and only 29 voriconazol IVAs. Saving costs between the ward and the CIVAS were just above 26000€ for LAB, about 72000€ for micafungin, and 250€ for voriconazole, which accounted for a total of 96500€ approximately, considering personnel and clothing costs.

Conclusion and Relevance Centralising antifungal drugs into CIVAS in hospital pharmacies is an efficient measure to reduce waste and costs. This is especially important for highly prescribed paediatric IVAs such as LAB and micafungin, and less so for voriconazole which is far less commonly prescribed in paediatrics, being mainly prepared in CIVAS for safety reasons[1].

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Conflict of Interest No conflict of interest.

4CPS-001 COMPARATIVE ANALYSIS OF TWO PHARMACOKINETIC PROGRAMS FOR LITHIUM ADJUSTMENT

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Background and Importance Therapeutic drug monitoring (TDM) is the clinical practice of measuring drugs to maintain a constant concentration in the patient's blood, thereby individualising dosage regimens. TDM is mainly used to monitor drugs with a narrow therapeutic range, drugs with high pharmacokinetic variability, and drugs with a high incidence of adverse effects.

The narrow therapeutic window of lithium (0.6 – 0.8 mmol/L) requires accurate monitoring of its serum concentrations to achieve a safe and effective therapy.

Aim and Objectives To compare two pharmacokinetic programmes and analyse the precision and accuracy of lithium serum concentration adjustment.

Material and Methods Retrospective observational study including admitted patients with at least one determination of serum lithium concentration between January and December 2020 at a secondary hospital.

Electronic medical records were used to obtain the following data: lithium dosage, serum lithium concentrations, date of blood analysis, serum creatinine, renal function (calculated using the Cockcroft-Gault equation), date of birth, sex and weight.

Serum lithium concentrations were estimated using two pharmacokinetic software programs: MwPharm++ and PKS.

Accuracy and precision were evaluated using Sheiner and Beal's prediction error theory. Accuracy was estimated with the mean prediction error (MPE) and precision with the mean absolute prediction error (MAPE) and the square root of the root mean square prediction error (RMSE). These results are accompanied by 95% confidence intervals.

The statistical significance was determined using a t-student test for comparing means.

Results A total of 79 plasma lithium levels from 18 patients were analysed, 55.6% were male, with a median age of 52.4 years [IQI: 41.7–55.4], and a median weight of 70.5 kg [IQI: 66.8–82.15]. Three patients (16.7%) had a creatinine clearance less than 60 ml/min, and 17 (94.4%) had multiple serum lithium determinations. The median number of determinations per patient were 3 IQI [2–4.5].

The following results were obtained:

Accuracy: MPE 0.02 (-0.025–0.065) and -0.02 (-0.064–0.024) for MwPharm++ and PKS, respectively.

Precision: MAPE 0.14 (0.11–0.18) and 0.12 (0.08–0.16), and RMSE 0.20 and 0.20 for MwPharm++ and PKS, respectively.

No statistically significant differences were found for MPE ($p=0.22$) or MAPE ($p=0.40$).

Conclusion and Relevance MwPharm++ and PKS showed satisfactory predictive capabilities, with no significant statistical differences. Both programs seem to be valid options, but larger studies are needed for confirmation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-002 PHARMACEUTICAL CARE IN POSTOPERATIVE PAIN MANAGEMENT AT ADMISSION AND DISCHARGE

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Background and Importance The prevalence of pain in postoperative patients is 88.2%, with moderate to severe pain in 19.6% of cases.
Aim and Objectives The objective was to describe pharmaceutical interventions in pain management and the impact on patient-reported pain on admission and discharge and patient satisfaction.
Material and Methods A prospective interventional study (March-May 2023) in hospitalised adult patients admitted in general or trauma surgery was carried out.
Outcome measures patient-perceived pain (VAS) and patient satisfaction.
Pharmaceutical interventions were made 48 and 96 hours after surgery (at bedside) and 48 hours after discharge (by telephone):

1. Admission:

1.1. Reminding nurses of recording VAS (one per nursing shift).

1.2. If VAS≥4, interventions in analgesia prescription and/or in nurse's administration

1.3 Patient education on VAS scale, therapeutic options and the importance of asking for analgesia if pain.

2. Discharge:

2.1. If VAS>2 patients were reminded how to take analgesia. If no analgesia prescribed, the patient was referred to a primary care physician (PCP).

2.2. If they took the prescribed medication and VAS=4–6, they were referred to PCP and if VAS≥7, to the emergency department.

A descriptive analysis was used.
Results Sixty patients were included, mean age of 66.7 (±16.4) years

On admission, 94 interventions were made (92.3% accepted): to encourage VAS recording (n=26), administer analgesia (n=18), prescribe analgesia (n=18), increase therapeutic step (n=17) and patient education (n=15).

An increase in VAS recording was observed (56.7% vs 76.3%). There was a progressive decrease in current patient-reported pain (2.1 vs 1.9 vs 1.4) and maximum pain in last 24 hours (3.2 vs 2.7 vs 2.3) and in the number of patients with VAS ≥4.

At discharge, 39 interventions were performed: 23 patients were reminded how to take the prescribed analgesia, 15 were referred to PCP for lack of analgesia prescription or moderate pain, and one was referred to the emergency department.

Satisfaction with postoperative pain management and the pharmaceutical care was 7.9 (±2.1) and 9.7(±0.5), respectively.
Conclusion and Relevance Pharmaceutical interventions on education, recording, administration and prescription of analgesics might have contributed to a gradual reduction in patient-reported pain. The pharmacist plays a role in the management of postoperative pain during admission and at discharge with high patient satisfaction.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-003 EVALUATION OF CLINICAL VARIABLES IMPACT ON ENOXAPARIN DOSING AND ANTIXA CONCENTRATION

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Background and Importance Monitoring enoxaparin is not routine as per guidelines but is recommended in renal insufficiency and debated for extreme body weights and pregnancy.
Aim and Objectives This study aims to assess enoxaparin monitoring in hospitalised patients and identify variables that correlate with its efficacy.
Material and Methods A descriptive, single-centre, retrospective study was conducted. Hospitalised patients receiving therapeutic enoxaparin doses were included, with measurement of peak anti-Xa concentration between December 2021 and January 2023. Patients undergoing renal replacement therapies were excluded.

Demographic data, laboratory and clinical parameters, and enoxaparin-related details were collected. Obesity was defined as body mass index ≥30 kg/m^2. Multiple linear regression was used to analyse the relationship between anti-Xa concentration and different variables including enoxaparin dose, obesity, renal impairment (ClCr < 30mL/min), and critical status. Suggested peak target range for anti-Xa is 0.5–1.1 IU/mL. STATA/BE was used to assess their correlation with Pearson coefficient and determine the best predictor.
Results A total of 147 patients were included, with a mean ±SD age of 68 years (±12.29), weight of 85.03 kg (±22.92), and a BMI of 29.64 kg/m^2 (±0.61). Among the study population, 64 patients (43.5%) were obese, 15 (10.2%) had renal impairment, and 78 (53.1%) were critical patients. Mean±SD enoxaparin dose was 0.93 mg/kg (±0.13), and no significant differences were observed between obese (0.91±0.15mg/kg) and non-obese (0.95±0.02 mg/kg) populations (p=0.104). Seventy-nine patients (53.7%) presented anti-Xa concentrations out of range; 36 of them (45.6%) were obese.

In the multiple regression analysis, we observed a statistically significant effect of enoxaparin dose (p<0.001) and obesity (p=0.007) in anti-Xa concentrations.

Using the final model, we found a good correlation between anti-Xa concentration and enoxaparin dose (p<0.001). Pearson coefficient of 0.56 was obtained for the non-obese population, while it was of 0.16 in the obese population.
Conclusion and Relevance In our study, we identified obesity as a variable that showed a significant effect on anti-Xa concentration. We confirmed the existence of a linear association between anti-Xa concentration and enoxaparin dose for the non-obese population. For the obese population, a poor correlation between anti-Xa concentration and enoxaparin was found suggesting the need for monitoring due to less predictable pharmacokinetics.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-004 IMPACT OF INADEQUATE EMPIRICAL THERAPY ON THE MORTALITY RATE IN PSEUDOMONAS AERUGINOSA INFECTIONS

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Background and Importance The appropriate use of antibiotics and their clinical impact is a necessary field of study to address the high incidence of resistance.

Aim and Objectives To analyse the impact of inadequate empirical therapy (IAT) on mortality in patients with Pseudomonas aeruginosa (PA) infection in a tertiary hospital.
Material and Methods Observational, retrospective study of patients with PA infection and treated with previous empirical antipseudomonal antibiotics from 1 January 2021 to 31 October 2021. Variables: gender, age, place of admission, dosing regimen, primary focus of infection and mortality during admission or 30 days after discharge. Definition of IAT: non-adherence to the local guidelines that establish the new EUCAST 2021 dosing criteria to achieve sufficient levels of antibiotics reported as 'sensitive with increased exposure' and which, based on the prevalence of multi-resistance in PA, recommends empirical use with biotherapy until the antibiogram is available. Data source: pharmacotherapeutic management softplante (Farmatools®) and electronic medical records. Analysis with SPSS Statistics21®
Results 92 patients were admitted to ICU and 126 to non-ICU (men 67.4% and 69.8% respectively) with a mean age of 62.9±12.5 years in ICU and 71.4±15.3 in non-ICU.

In the ICU the main source of infection was the lung (48.9%), while in the non-ICU the lung and urinary tract were at the same level (29.4% each).

In both groups the use of β-lactams (76.8% ICU and 65.7% non-ICU), followed by aminoglycosides in the ICU (13.5%) and quinolones in the non-ICU (22.5%). The use of monotherapy was higher in the non-ICU than in the ICU (66.9% vs. 49.2%, p<0.001).

The IAT was higher in the non-ICU (67.5% vs. 47.8% ICU p=0.041). In non-ICU, the mortality rate during admission or at 30 days in patients with IAT was 22.4% vs 7.3% with adequate empirical therapy (OR: 3.64; 95% CI 1.01–13.13), this difference being statistically significant. In ICU there were also higher mortality rates in the IAT group (50.0% vs 39.6%), but without statistically significant differences (OR:1.53; 95% CI 0.67–3.49).
Conclusion and Relevance The higher mortality observed in cases of IAT implies the need to work on the adequacy of dosage according to EUCAST criteria and to promote bitherapy until the antibiogram is available.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-005 DRUG PERSISTENCE OF JAK INHIBITORS COMPARED TO BIOLOGIC DRUGS IN REAL-WORLD PRACTICE IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background and Importance JAK-inhibitors (JAKi) represent an effective choice for patients diagnosed with rheumatoid arthritis (RA). There is limited data available on real use of JAKi.
Aim and Objectives To compare persistence of JAKi, TNF-α inhibitor(TNFi) and non-TNF-α inhibitor(non-TNFi) drugs in patients with RA and reasons for treatment discontinuation.
Material and Methods An ambispective, observational study conducted at a tertiary hospital. Patients diagnosed with RA evaluated at the Rheumatology Interdisciplinary Committee of Biological Drugs from 1 January 2018 to 7 January 2022 that started or switched treatment with JAKi, TNFi and non-TNFi were included. Treatments previously received were included. Follow-up was carried out until 7 January 2023.

Variables collected were age, sex, type of drug, prior biologics (naïve, second-line and third- or higher line), patient's chronicity level according to the Chronicity Strategy of Valencian Community (0 =healthy individual to 4 = chronic patient of high complexity), length of treatment and reasons for discontinuation.

Outcome variable was percentage of treatments that reached 12 months persistence estimated from the first to the last drug dispensation.

Data were collected from the electronic health and pharmacy dispensing records.

Continuous variables were expressed as mean (SD), and categorical variables as absolute and relative frequency. Chi-square test and logistic regression were used to identify variables associated with persistence. Statistical significance was set at p<0.05. Analysis was carried out with R-4.3.1.
Results There were a total of 303 patients (75% women), mean age was 53 (16) years. We recorded 623 treatments: JAKi 156 (25.0%), TNFi 326 (52.4%) and non-TNFi 156 (22.6%).

Chronicity level (n=177 (58.4%) patients) was: '0' 40 (11.7%), '1' 143 (41.7%), '2' 109 (31.8%), '3' 51 (14.8%). Treatment line: first 284 (45.6%), second 146 (23.4%) and third or higher 193 (31.0%).

No difference in persistence was found among JAKi 108 (69.2%), TNFi 215 (66%) and non-TNFi 80 (56.7%) treatments (p=0.06). Treatment line showed persistence differences: naïve 213 (75%), second-line 81 (55.5%) and third -or higher 109 (56.5%) (p<0.01). No difference was found in persistence according to sex, age or chronicity level. Multivariate analysis confirmed these results.

At the end of follow-up 460 (73.8%) treatments had finished due to: 199 (43.3%) secondary failures; 100 (21.7%) adverse effects; 74 (16.1%) primary failures and others 50 (18.9%). No differences were found among according to type of therapy (p=0,48).
Conclusion and Relevance In our hospital 12-months' persistence and reasons for discontinuation among JAKi, TNFi and non-TNFi in patients with RA showed no difference.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-006 ADHERENCE TO NEBULISED ANTIBIOTICS IN CYSTIC FIBROSIS PATIENTS AFTER STARTING ELEXACAFTOR/TEZACAFTOR/IVACAFTOR

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Background and Importance Elexacaftor/tezacaftor/ivacaftor (ETI) are bringing about a major change in the treatment of cystic fibrosis (CF) patients. However, continuing with other treatments such as nebulised antibiotics is necessary.
Aim and Objectives To assess the adherence to inhaled antibiotics before and after starting ETI. Secondary objectives: To assess effectiveness of ETI.

Material and Methods Observational, retrospective study carried out between March 2023 and September 2023, including patients who started with ETI before September 2022, 12 years of age or older when they started, and treated with at least one nebulised antibiotic.

Variables: age, sex, change from baseline in percentage of predicted forced expiratory volume in 1 second (FEV1) at month 12, difference in rate of pulmonary exacerbations 1 year before and after starting ETI, difference in Medication Possession Ratio (MPR) to nebulised antibiotics 1 year before and after starting ETI and MPR to ETI for 12 months.

Data were collected from electronic medical records and pharmacy dispensing programs.

A statistical analysis was performed using dependent samples t-test with IBM SPSS Statistics v21.0.

The study was approved by Ethics Committee of the hospital.

Results In total, 33 patients were included, 21/33 (63.6%) were female. The mean age was 28.1 (±12.5). 14/33 (42.4%) patients had been previously treated with tezacaftor/ivacaftor.

Percentage of predicted FEV1 was 17.8% higher (95% CI 11.8–23.7) at 12 months. Rate of pulmonary exacerbations was 70.2% lower (95% CI 43.3–97.2) and rate of severe pulmonary exacerbations was 86.1% lower (95% CI 43,2–128,9) 12 months after starting ETI. MPR to nebulised antibiotics was 22% lower (95% IC 7,5–36,5) 12 months after starting ETI. (P<0,001 for all comparisons). MPR to ETI was 89,7% (±18,5).

Conclusion and Relevance The introduction of ETI to CF treatment has been a hopeful advance. ETI has shown a good efficacy in our population. However, the adherence to nebulised antibiotics decreased significantly. More studies are needed to evaluate the safety of withdrawing nebulised therapies post-ETI. A strategy to improve adherence in patients with CF has been initiated in collaboration with the CF unit of our hospital.

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Conflict of Interest No conflict of interest.

4CPS-007 ADALIMUMAB IN THE TREATMENT OF RECALCITRANT SWEET SYNDROME: A CASE REPORT

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Background and Importance Sweet syndrome (SS) is a rare febrile neutrophilic dermatosis characterised by edematous and erythematous papules, plaques or nodules on the skin, and fever. SS is associated with infection, malignancy, pregnancy and drug exposure. High doses of systemic glucocorticoids are the first-line treatment. Colchicine, dapsone, and potassium iodide are additional therapies, reserved for refractory cases. In addition, classic immunosuppressants have been effective. Newer case reports suggest benefit from biological therapies in recalcitrant cases.

We have found two other refractory SS cases in the literature.

Aim and Objectives To assess the effectiveness of adalimumab in a 50-year-old patient diagnosed with refractory idiopathic SS in a tertiary hospital.

Material and Methods In 2019, a man presented with fever, episcleritis, joint pain, and elevation of acute phase reactants (RFA) (C-reactive protein level (PCR), 35 mg/L; erythrocyte sedimentation rate (VSG), 48 mm; ferritin 416 ng/L). Early detection of autoimmune and infectious diseases was negative. Finally, he was diagnosed with idiopathic SS in 2022. Initially, colchicine was started without clinical response. Therefore, systemic glucocorticoids were initiated. The response was excellent, but he developed a central serous choroidopathy secondary to glucocorticoids, which contraindicated its use at high doses. Prednisone 5 mg daily was maintained. Later, dapsone was commenced but it was ineffective and caused haematological toxicity (anaemia). After dapsone withdrawal, anaemia blood markers improved. In April 2023, methotrexate 15 mg weekly and prednisone 10 mg daily were commenced. After two months, he presented skin lesions, fever, asthenia, arthralgia and elevated RFA (PCR, 46 mg/L; VSG, 84 mm; ferritin 603 ng/L). Considering it was a refractory SS, adalimumab off-label was requested.

Results On 5 July adalimumab 40 mg biweekly was initiated. Previously, informed consent was signed. Methotrexate and prednisone in descending doses were continued. After two injections, the disease had eased (no fever, skin lesions or inflammation) and without adverse effects. On 28 September, he started treatment with prednisone 5 mg daily, methotrexate 10 mg weekly and adalimumab 40 mg biweekly, and RFA are normal (PCR, <1 mg/L; VSG, 16 mm).

Conclusion and Relevance - Adalimumab is effective in the treatment of recalcitrant SS.

- A longer follow-up is needed to assess the effectiveness in the long term.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-008 ANALYSIS OF PHARMACEUTICAL INTERVENTIONS RELATED TO ANTITHROMBOTIC DRUGS IN EMERGENCY DEPARTMENT

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Background and Importance Antithrombotic Drugs (AD) belong to a therapeutic group considered as high-risk medication and they are a high priority in patient safety strategies.

Aim and Objectives To analyse pharmaceutical interventions according to ADs at the Emergency Department (ED), and to evaluate the factors that could influence the acceptance of pharmaceutical recommendations.

Material and Methods Prospective, longitudinal, observational study was conducted over a 9-month period. We selected pharmaceutical interventions performed by emergency medicine pharmacists in patients receiving ADs during the ED journey. A complete pharmacotherapeutic review was performed for each patient in order to detect drug-related problems (DRP) and a recommendation was issued to the responsible physician.

Collected data sex, age, number of chronic medications, polymedication (simple polymedication 5–9 drugs; extreme polymedication >9 drugs), patient clinical complexity level (low, moderate, high), drug involved.

We analysed type of interventions and DRPs severity according to the National Coordinating Council for Medication Error Reporting and Prevention (NCC-MERP) that classifies the error according to the severity of the outcome (Category A: no error, Category B-D: error without harm, E-H: error with harm, I: death). Severity was not evaluated in patients whose clinical situation changed before considering intervention.

A Chi-squared test was applied for categorical variables. For quantitative variables, t-Student-test or the equivalent non-parametric Mann-Whitney U-test was used. Statistical analysis was performed using SPSS®V22.

Results In total, 809 patients with antithrombotic medications (AD) were assessed. A total of 237 interventions were performed in 227 patients (28.05): 59.9% men, 79±12.4 years, 59% had a medium-high complexity level and 60.8% had extreme polymedication.

Regarding the interventions performed, 75.9% related to indication (57.7% start new medication and 13.3% discontinuing medication) and 20.2% to posology. According to the DRP severity assessment, 206 interventions were classified following NCC-MERP:117C, 48B, 27A, 7D, 5F, 1G and 1I.

Concerning pharmaceutical interventions,72.6% were accepted,14.35% were rejected and 13.1% were related to patients whose clinical situation had changed, and the intervention performed was no longer considered appropriate. Regarding influencing factors, there was a non-significance trend for type C error severity to be accepted more frequently (OR2.03 CI 95% 0.91- 4.52) p=0.07.

Conclusion and Relevance Acceptance rate of pharmaceutical interventions was high. Most of the interventions were related to drug indication. More than a half of the DRPs were errors that reached the patient without causing harm. No factors had an influence on acceptance ratio

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-009 NEONATAL DIAGNOSIS AND TREATMENT OF STIFF BABY SYNDROME: A CASE REPORT

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Background and Importance STIFF syndrome is a rare disease with genetic mutation Cr 5 GLRA1. It is characterised by a neurological disorder with stiffness and muscle spasms, which affects the quality of life of these patients.

Aim and Objectives Describe the diagnostic and therapeutic management of a neonatal patient with Stiff syndrome.

Material and Methods Literature review of cases described with similar clinical features by the pharmacy and neonatology service of a tertiary hospital. Tests were requested for differential and confirmatory diagnosis (whole genome sequencing). The Pharmacy Service collaborated in the search for a possible effective treatment and in adapting it to a paediatric patient.

Results Premature patient (41+2) hospitalised the 16 of August 2022 in a tertiary hospital due to respiratory distress and abnormal neurological signs, followed by a hypertonic seizure with generalised rigidity. A bolus of midazolam 0.1 mg/kg was administered without improvement, followed by phenobarbital 3 mg/kg/24h without clinical response. After negative tests, the genetic study detected an alteration of the GLRA1 gene in the patient, and a heterozygous mutation in the mother. A metabolic study was performed, detecting elevated levels of glutamic acid.[1] A therapeutic trial was started the 28 of August with oral Clonazepam at 0.1 mg/kg every 8 hours.[1] As this was a compounding preparation, the pharmacy prepared the suspension at a concentration of 0.1 mg/ml from 2 mg tablets.[2] Due to the improvement in stiffness and hyperplexia since the start of treatment, clonazepam was maintained at discharge, and continues being active at 0.3 mg/kg/8 hours. At follow-up at 11 months of age, the patient was in good general condition. The condition had attenuated, with less startle and reflexes.

Conclusion and Relevance Stiff syndrome is a disease that is difficult to diagnose and to treat due to its low prevalence. The favourable clinical response after starting treatment with clonazepam should be highlighted. The preparation of a pharmaceutical formulation from the Pharmacy Service allowed to individualise the dose according to the patient's weight and clinical evolution.

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Conflict of Interest No conflict of interest.

4CPS-010 CAN ERENUMAB IMPROVE QUALITY OF LIFE PERCEIVED BY PATIENTS?

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Background and Importance Migraine is a highly disabling chronic disease. Erenumab is a preventive treatment to reduce frequency, intensity and duration of migraine crises, to improve the quality of life, reducing the impact of the disease on the functionality of the patient.

Aim and Objectives The aim was to evaluate the quality of life perceived by the patient before starting treatment with erenumab and after 12 months.

Material and Methods Prospective observational study which includes patients with chronic or episodic high-frequency migraine treated with erenumab (August 2020 to December 2022), who had completed 12 months of treatment.

Demographic data (sex; age), clinical data (type of migraine; monthly migraine days and intensity at the beginning of treatment and 12 months after) were collected and EuroQol-Questionnaire was performed to assess quality of life at the beginning and 12 months after.

With EQ-5D-5L-Questionnaire, patients evaluate his own health status. Crosswalk Index Value Calculator and SPSS-Statistics v28.0.1.1 were used for the health status calculation.

Results We analysed 32 patients with a median age of 52 years (IQR: 46.45–59.4) being 27 women. Twenty-eight of them were diagnosed with chronic migraine and four with high frequency episodic migraine. Two patients stopped treatment before 12 months due to lack of response (excluded from the analysis).

Average reduction in monthly migraines was 10.75 days (7.07–14.42). Mean migraines intensity before treatment was 8.6 (7.97–9.3); and 5.28 (4.18–6.37) after. Number of patients who report not having problems related to mobility, personal care, daily activities, pain/discomfort and anxiety/depression has increased and/or maintained after 12 months of treatment compared to baseline: 18 vs 21; 23 vs 23; 9 vs 18; 3 vs 12; and 6 vs 11, respectively. Mean according to EQ-5D-questionnaire before erenumab was 0.5694 (-0.008–1) and 0.7198 (-0.096–1) after. Improvement of quality life was considered statistically significant ($p<0.01$). Mean value of EVA scale before treatment was 50% (10–95%) and 68.5% (15–100%) after. Improvement in quality of life is considered statistically significant ($p=0.008$).

Conclusion and Relevance It is important to carry out studies that include greater sample, but in our experience treatment with erenumab has been a great improvement in quality life of patients with migraine, thus reducing the impact of their disease in their day to day.

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Conflict of Interest No conflict of interest.

4CPS-011 REAL-WORLD EFFECTIVENESS AND SURVIVAL OF GUSELKUMAB IN PATIENTS WITH PSORIASIS AND PSORIATIC ARTHRITIS: MULTICENTRE ANALYSIS IN DAILY CLINICAL PRACTICE BY THE VALENCIAN COMMUNITY PSORIASIS GROUP

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Background and Importance Guselkumab is approved for the treatment of psoriasis and psoriatic arthritis. Nonetheless, patients who participate in clinical trials are quite different from those seen in daily clinical practice.

Aim and Objectives The objective of our study was to assess the effectiveness and drug survival in patients who suffer from psoriasis and psoriatic arthritis in real-life settings treated with guselkumab in eight hospitals in Valencian Community (Spain).

Material and Methods This was a multicentric retrospective study, adult patients with psoriasis and psoriatic arthritis and was approved by the Drug Research Ethics Committee (CEIm). We included patients who had previous exposure to one or more biologic drugs and received guselkumab (April 2019 to October 2022 (42 months)).

Results A total number of 184 patients with plaque psoriasis (81.5% n=150) or psoriatic arthritis (18.5% n=34) were enrolled in this study, with a predominance of male patients (52.2%; n = 88). Mean (± SD) age at the initiation of guselkumab therapy was 37,3 ± 17.0 for psoriasis patients and 47,1 ± 14,1 for psoriatic arthritis patients ($p< 0.05$).

About the previous lines of treatment they had been received: 91.8% (n=169) received one, 62.5% (n=115) received two and 44.0% (n=81) had received more than three previous lines. As first-line of treatment, 65.7% (n=111) had been treated with tumour necrosis factor (TNF) inhibitor, 17.2% (n=29) with IL-12/23 inhibitor, 8.3% (n=14) with IL17 inhibitors, 3.0% (n=5) with IL23 inhibitors, and 3.0% (n=5) with apremilast.

The mean (± SD) PASI score decreased from 7.6 ± 5.8 at baseline to 1.5 ± 6.8 after 24 weeks of therapy ($p< 0.05$), and to 0.0 ± 1.2 after 52 weeks ($p<0.05$). These results are similar to those observed in pivotal trials VOYAGE 1, VOYAGE 2 and NAVIGATE (1, 2, 3) Reason for discontinuation: loss of effectiveness 14 (7.6%), lost follow-up two (1.1%), security issues two (1.1%), and others six (3.3%). Overall cumulative drug survival was 87.0% at 42 months.

Conclusion and Relevance This multicentre retrospective study analysed data from eight hospitals, demonstrating effectiveness and drug survival of guselkumab in a real-world setting, similar to those observed in pivotal trials.

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Conflict of Interest No conflict of interest.

4CPS-012 IMPROVING PARENTAL MEDICATION LITERACY BY PHARMACIST-LED DISCHARGE COUNSELLING IN PAEDIATRIC HAEMATOPOIETIC STEM CELL TRANSPLANTATION

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Background and Importance Children undergoing allogeneic haematopoietic stem cell transplantation (HSCT) require a broad spectrum of pharmacotherapy. After discharge, parents are liable for safe and effective drug use. As dosage depends on body weight and paediatric formulations are commonly lacking, children are prone to medication errors. Therefore, parents and children require a sufficient level of medication literacy (ML).

Aim and Objectives To evaluate the impact of a pharmacist-led discharge counselling for parents on a paediatric transplant unit at a tertiary care children's hospital.

Material and Methods A pharmacy-led discharge counselling program was developed based on the findings of a literature review and on the results of a status quo analysis of the actual medication education process. Service delivery was implemented as a preplanned counselling session with parents

of newly transplanted children prior to discharge. To evaluate the impact of the service, a peer-reviewed knowledge test (11 points equaling highest knowledge) was performed before and after counselling. Results were compared using a two-sample t-test for dependent samples. Parents were encouraged to ask questions regarding their medication. A written medication plan containing relevant drug information was furthermore provided.

Results Between November 2022 and May 2023, 10 parents received counselling. The median age of children [male n=8 female n=2] was 4.5 years (range 2–15). Children took 8.9 ±2.0 different drugs and duration of counselling was 41±17 minutes. The parents scored 6.2±1.3 and 9.7±0.8 of 11 points on the knowledge test before and after counselling, respectively ($p<0.001$).

Conclusion and Relevance In general, pharmacist-led discharge counselling was highly appreciated by parents and the involved health care team. Counselling might substantially improve the parents' knowledge on questions regarding drug therapy and will help parents make informed decisions after discharge.

Based on Vaillancourt et al., [1] it can be hypothesised that higher medication literacy translates into improved clinical outcomes. However, evaluation in our project was limited to a single session and a written medication plan. To document a sustained impact on medication literacy, it would be necessary to follow up with parents and children during aftercare.

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Conflict of Interest No conflict of interest.

4CPS-013 INTRAVENOUS LEVETIRACETAM SUPPLETION DURING HAEMODIALYSIS PRESERVED STABLE THERAPEUTIC SERUM CONCENTRATIONS: A CASE REPORT

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Background and Importance Levetiracetam is a widely used antiepileptic drug. Due to its pharmacokinetic properties including low molecular weight, low volume of distribution and small protein binding, it is a highly dialyzed during haemodialysis (HD).[1] Therefore, it is difficult to preserve stable plasma levels during dialysis and patients starting with HD are often switched to other antiepileptic drugs. Information about levetiracetam concentrations in this group of patients are rarely described and show conflicting data. We describe a case report in which levetiracetam was supplemented during HD and where multiple levetiracetam levels were measured during HD sessions.

Aim and Objectives To determine whether stable levetiracetam plasma concentrations can be preserved during HD by intravenous suppletion. We report a case of a 63-year-old woman who started intermittent HD because of renal failure due to diabetic nephropathy. She was treated with levetiracetam 250 mg b.i.d. for therapy-resistant focal epilepsy. Levels <10 mg/L resulted in frequent seizures, therefore the target values in this patient were set at 10–25 mg/L.

Material and Methods HD sessions lasted 4 hours. Additional intravenous doses of levetiracetam were administered during bypass pre-HD, after 2 hours HD and post-HD (see table 1). Levetiracetam concentrations were measured 30 minutes after levetiracetam supplementation. Pre-HD samples were measured before the first supplementation dose was given.

Results

Abstract 4CPS-013 Table 1 Levetiracetam supplemental dose and serum concentrations pre-HD, during HD and post-HD

HD session	1	2	3	4	5	6	7
Supplemental intravenous dose (mg) of levetiracetam							
Pre-HD	250	250	250	250	250	250	500
2 hours HD	250	250	250	250	250	250	250
Post-HD				250	250	250	250
Levetiracetam plasma concentrations (mg/L)							
Pre-HD	18	20	19	18	20	10	19
2,5 hours HD	8	10	10	13	12	17	15
Post-HD	8	8	17	11	10	9	13

Plasma concentrations remained most stable with suppletion doses of 500–250-250mg and did not result in seizures following HD.

Conclusion and Relevance HD showed to eliminate levetiracetam significantly. In this case report, intravenous levetiracetam suppletion during HD safely preserved stable levetiracetam plasma concentrations preventing seizures. Close monitoring of plasma concentrations is recommended to determine the appropriate supplemental dose to maintain therapeutic levels.

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Conflict of Interest No conflict of interest.

4CPS-014 REAL WORLD DATA ON THE USE OF PCSK9 INHIBITOR TREATMENTS IN HYPERCHOLESTEROLEMIA

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Background and Importance LDL levels have been considered a surrogate marker of cardiovascular risk, which has taken on greater relevance in recent years.

Aim and Objectives To analyse the use and effectiveness of PCSK9 inhibitors (PCSK9i) in real world data

Material and Methods Retrospective study that includes patients treated >3 months with iPCSK9 from 1/1/2016 to 12/31/2022 in the Murcia Health Service. The parameters collected were age, sex, indication, LDL, iPCSK9 used, use of previous statins and mortality.

Data collection/analysis was carried out with Access® and PowerBi®. The drug consumption data was obtained from the Business Intelligence Portal and the clinical parameters of analysis/clinical history application

Results A total of 266 patients (61% men) with a median age of 58 years were included. The indication was, 59% familial hypercholesterolemia (FH) and 41% with established cardiovascular disease (CD).

The median LDL before treatment was 138 mg/dl, being 172 for FH and 117 for CD.

The 93% of patients had received a statin (73% high-intensity statin therapy: rosuvastatin ≥20 mg or atorvastatin 80 mg). The PCSK9 i drugs used were evolocumab in 58% of patients and alirocumab in 42%.

The median LDL at 3 months was 79 mg/ml and 68 mg/dl in the last year of tratament (reduction of 74 mg/dl compared to baseline) and was 92 for those on FH and 65 for patients with CD.

The 72% of patients reduced >30% their baseline LDL, 52% reached levels <70 mg/dl and 74.5% reached levels <100 mg/dl.

The percentage of patients who reached levels <100 mg/dl was higher in the CV group 78% compared to HF 62% ($p<0.04$).

Regarding (any cause) mortality, there was a total of 7 deaths (2.6%) distributed evenly in the two indications, with a probability of survival of 90% at 5 years.

Conclusion and Relevance The median LDL at the beginning of treatment was greater than 100 mg/dl, and 93% had received statins prior to treatment.

The effectiveness of the treatments regarding LDL reduction is similar to those published in pivotal clinical trials. The 5-year mortality published in this real-world data study is somewhat lower than that published in the FOURIER and ODYSSEY trials (2.6% vs 4.7% and 5%)

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-015 ASSESSMENT OF IN-HOSPITAL ANTIBIOTICS CONSUMPTION PATTERN ACCORDING TO THE WHO AWARE CLASSIFICATION IN A LOCAL HEALTH AUTHORITY

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Background and Importance Antimicrobial resistance (AMR) is a recognised global health concern. For this reason, in 2017, the World Health Organization (WHO) developed the AWaRe classification of antibiotics, which grouped them into three main groups: *Access*, *Watch* and *Reserve*. WHO AWaRe classification is a helpful tool to promote the appropriate and responsible use of antibacterials, reduce AMR, monitor antibiotics consumption and assess the effectiveness of stewardship programs.

Aim and Objectives We aimed to evaluate the antibiotic consumption pattern of the seven suburban hospitals of our Local Health Authority, comparing a 6-month period in 2023 to a 6-month period in 2022. The main goal of the analysis was to assess the performance of stewardship initiatives.

Material and Methods First, antibiotic consumption data regarding in-hospital settings from January 1, 2022, to June 30, 2023, were extracted from the National Health System (NHS) dispensing database. The total Defined Daily Dose (DDD) as a percentage and the DDD per 100 bed days were used as measures of antibiotic consumption. Second, the Anatomical Therapeutic Chemical (ATC) 4th level code was used to categorise antimicrobials within the different AWaRe groups.

Results The comparative analysis of the time period considered showed a similar overall DDD consumption of antibiotics. Noteworthy, among the different AWaRe groups, an increase in consumption in the Watch group antibiotics equal to plus 10.5% (2023 75% vs. 2022 64.5%) and a reduction in the Access group equal to minus 10% (2023 23% vs. 2022 33%) were observed. The DDD consumption of Reserve group antibacterials was quite similar among the two periods (2023 2% vs. 2022 2.3%). Within the Watch group, the most consumed antimicrobials according to ATC 4th level were J01DD with 29.6 DDD/100 bed-days, J01MA 22.5, J01FA 11.7, J01CR 10.3, J01DH 9 and J01XA 5.3 respectively.

Conclusion and Relevance In contrast with WHO indications (at least 60% of total antibiotics in the *Access* group), our findings show that in our Local Health Authority the majority of antimicrobials consumed belong to the *Watch* group. The results of our investigation highlight the need for further efforts by the Antimicrobial Stewardship Team in order to improve the appropriate use of antibiotics in the hospital setting and fight AMR.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-016 EXPERIENCES, VIEWS AND ATTITUDES OF HOSPITAL NURSING STAFF TOWARDS THE IMPLEMENTATION OF THE UNIT DOSE DISPENSING SYSTEM FOR INPATIENTS: A QUALITATIVE INTERVIEW STUDY

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Background and Importance Medication errors pose a major economic problem and, more importantly, a major cause of avoidable harm in medical care. With the Global 'Patient safety action plan 2021–2023' the World Health Organisation (WHO) calls for a rethink of processes and structures within the healthcare system to ensure optimal patient safety. One such optimisation measure could be the introduction of the Unit dose dispensing system (UDDS), which is thought to have multiple benefits from avoidance of medication errors to improved patient autonomy.

Aim and Objectives To determine hospital nurses' attitudes towards the UDDS, examine their perceptions of opportunities and barriers in everyday practice and explore their experiences with its implementation.

Material and Methods A prospective qualitative interview study with 23 nurses from the Barmherzige Brüder Hospital Linz, Austria was conducted. The validated and piloted semi-structured interview guide was based on existing literature, best practice guidelines for qualitative interview studies and the constructs of the Consolidated Framework for Implementation Research (CFIR). Interviews were transcribed verbatim and mapped against the Framework of Implementation of Services in Pharmacy (FISpH) by two researchers independently.

Results Nurses' satisfaction with the UDDS was high as it affords them a considerable time saving, ease of use in daily practice and reduced workload. Furthermore, UDDS is

considered to reduce medication errors and improve patient safety. However, the study also revealed challenges mainly concerning medication changes and non-blistered medication – often resulting in re-dispensing the UDDS blisters into individual patient dosette boxes – as well as mechanical handling of the blisters. Nurses are concerned about the decline in their personal medication knowledge. Reduced stock levels on the wards save time and resources but can pose inconveniences for nursing staff. Several possibilities for improvement of the workflow, training and communication between ward staff and pharmacy could be identified.

Conclusion and Relevance Results show that the UDDS provides several significant benefits to nursing staff. In addition patient safety is thought to have improved. Cooperation of all hospital stakeholders with ward nurses is of immense importance to further advance the UDDS. These results may be of interest. to any hospital/pharmacy management planning to implement a UDDS.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-017 COMPARATIVE STUDY BETWEEN TIXAGEVIMAB/CILGAVIMAB AND SOTROVIMAB IN PATIENTS WITH COVID-19: A MONOCENTRIC EXPERIENCE AT UNIVERSITY HOSPITAL

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Background and Importance Tixagevimab/cilgavimab and sotrovimab are only monoclonal antibodies (Mabs) recommended against recent variants neutralising SARS-CoV-2. These Mabs have been effective in reducing hospitalisation and mortality rates in outpatients diagnosed with mild to moderate COVID-19. However, the emergence of new SARS-CoV-2 subvariants (BA.2.75; BA.5; XBB.1.5) may change their efficacy.

Aim and Objectives The objective of this study was to evaluate the effectiviness of both Mabs against recent variants of Covid-19 in terms of reduction of duration of virological clearance, worsening of symptoms and mortality.

Material and Methods An observational, retrospective study was conducted, which included all eligible patients who received tixagevimab/cilgavimab 600mg and sotrovimab 500mg from September 2022 to May 2023. Clinical data were recorded through an electronic prescription system. Univariate and multivariate analyses were carried out to evaluate the impact of the Mabs on study outcomes. R software was used for statistical analyses.

Results A total of 284 patients were examined, 150 (53%) have received sotrovimab and 134 (47%) had received tixagevimab/cilgavimab. Sotrovimab group had a median age of 62 years (range,18–99), while tixagevimab/cilgavimab group had a median age of 69 years (range,26–97). In sotrovimab group, 82% of patients were vaccinated (69% of these within 120 days) and comorbidity was 91%. In tixagevimab/cilgavimab group, 97% of patients were vaccinated (16% of these within 120 days) and comorbidity was 69%. Data showed that the patients administrated with tixagevimab/cilgavimab exhibited a significant reduction in clearance time compared to those patients received sotrovimab (Beta=-4.8days,95% CI:-7.0,-2.7, p<0.001). Furthermore, virological clearance's time was increased by comorbidities (Beta=3.0days,95%CI:0.67,5.3, p=0.01) and it was decreased in patients who had received the vaccine within the last 120 days (Beta=-2.3days,95%CI:-4.4,-0.21,p=0.032). It was observed that 2.2% of patients in sotrovimab group experienced a worsening of symptoms with no recorded deaths, whereas tixagevimab/cilgavimab group showed a worsening in 9.9% of patients, resulting in 3.4% deaths. However, logistic multivariate analysis was not statistically significant.

Conclusion and Relevance Our findings suggest that the administration of tixagevimab/cilgavimab, may be more effective than sotrovimab in reducing the clearance time in the patients affected of COVID-19. However, there was no marked reduction between two Mabs concerning worsening and mortality rates.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-018 SWITCHING BETWEEN CALCITONIN GENE RELATED PEPTIDE MONOCLONAL ANTIBODIES IN THE PROPHYLAXIS OF MIGRAINE

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Background and Importance Therapeutic options for migraine prevention in non-responder patients to monoclonal antibodies (mAbs) targeting Calcitonin Gene-Related Peptide (CGRP) and its receptor are often limited. There are no recommendations of switching between mAbs classes.

Aim and Objectives To assess the effectiveness and safety of mAb switching in non-responder migraine patients.

Material and Methods Retrospective observational study in a tertiary hospital (1-January-2021 to 31-July-2023). We included patients who received a first mAb for ≥3 months, were non-responders and switched to another mAb class. Patients were excluded if they switched due to side effects. Monthly headache days (MHD) were collected to assess the ≥50% responder rates and the absolute reduction of MHD at

Abstract 4CPS-018 Table 1

	Switched from ligand mAb to receptor mAb (n=23)	Switched from receptor mAb to ligand mAb (n=28)
Female,n(%)	21(91,3)	27(96,4)
Age in years,mean(SD)	44,9(11)	46,5(12,6)
Disease duration in years,median (IQR)	13(8,3–18,5)	12(8–23,3)
Diagnosis,n(%)	2(8,7)21(91,3)	10(35,7)18(64,3)
High-frequency episodic migraine		
Chronic migraine		
Aura,n(%)	2(8,7)	4(14,3)
Comorbidities,n(%)	4(17,4)2(8,7)	10(35,7)1(3,6)
Anxious-depressive syndrome		
Fibromyalgia		
Concomitant prophylaxis,n(%)	8(34,8)	13(46,4)
Treatment duration in months, median(IQR)	5(3,75–7)	9(5–11)

3 months, as well as the absolute reduction of monthly acute medication days (AMD). Data were recorded from electronic medical records and patient interviews. The study was approved by the Ethics Committee. Informed consent was obtained.

Results We identified 110 patients who had received galcanezumab (n=57) and fremanezumab (n=53) as their first mAb. Of these, 24 (21,8%) switched to the CGRP-receptor mAb, erenumab. Of 105 patients treated with erenumab, 30 (28,6%) switched to a CGRP-ligand mAb. Three patients switched because of side effects, so 51 patients were included.

The ≥50% responder rate was 40% and 61,9% at 3 months with erenumab and CGRP-ligand mAb, respectively. MHD reduction: 17±7,4 to 13,8±8,7 and 16±7,7 to 8,4 ±6,1, respectively. AMD reduction: 16,1±9,9 to 15,4±10,2 and 11,7±9,2 to 7,6±7,3. Seven patients (35%) changed to a third mAb in patients that switched from ligand mAb to receptor mAb, 23,8% in the other group.

Conclusion and Relevance Switching seems to be a promising treatment option especially in migraine patients that switched from CGRP-receptor mAb to CGRP-ligand mAb. However, some of them need to switch to a third mAb. More studies are needed to describe which patients will respond to CGRP-mAb switching.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-019 DIFFERENCES IN MEROPENEM DOSE ADJUSTMENT WITH CALCULATION OF GLOMERULAR FILTRATION RATETHROUGH DIFFERENT FORMULAS

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Background and Importance Meropenem is a carbapenemic antibiotic that is mainly eliminated by renal route. Therefore, an alteration of the glomerular filtration rate (GFR) may affect the elimination of the drug. GFR can be calculated using several validated formulas using different parameters.

Aim and Objectives The aim of the study was to analyse the discrepancies between the results of the different GFR equations and the dosage adjustment.

Material and Methods A descriptive, retrospective and cross-sectional study that included patients treated with meropenem for 3 months was performed. The standard dose was 1g every 8 hours. Dose adjustments were made according to a data sheet (TFG <50mL/min and <25mL/min).

Age, sex, weight, creatinine (mg/dl), urea (mg/dl), albumin (g/dl)) and meropenem doses were recorded. With these data, the GFR was calculated: Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) (ml/min/1.73m2); Modification of Diet in Renal Disease Study Equation (MDRD) (ml/min/1.73m2); and Cockcroft-Gault (CG) (ml/min).

Results A total of 136 patients were included. The mean age was 76.84 + 12.7 years. The calculation of mean GFR according to the different equations was as follows: 60.46 ± 49.0 ml/min/1.73m2 (MDRD); 72.12 ± 49.6 ml/min (Cockroft-Gault) and 86.17 ± 63.1 ml/min/1.73m2 (CKD-EPI).

Dose adjustment was carried out In 19.12% (26) of the patients meropenem dose adjustment was performed with GFR <50ml/min and in 12.5% (17) GFR <25ml/min was adjusted.

The dose adjustment of meropenem should have been with MDRD: 39.8% (54) of the patients had a GFR lower than 50ml/min and 23.53% (32) had a GFR lower than 25ml/min. According to Cockroft-Gault: 38.23% (52) of the patients had GFR <50ml/min and 16.17% (22) had GFR <25ml/min. Finally, according to CKD-EPI, 36.03% (49) had GFR <51ml/min and 12.5% (17) had GFR <25ml/min.

Finally, it was observed that 2.2% (3) of the patients had no dose adjustment for GFR <50ml/min when any of the equations indicated this; and that in 14.0% (19), dose adjustment by GFR <25ml/min was not performed when required it.

Conclusion and Relevance There are significant discrepancies in the calculation of GFR with different equations, which affects the dose adjustment of meropenem. Taking into account the values of several equations would improve both the efficacy and safety of meropenem treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-020 EVALUATION OF THE EFFECTIVENESS OF MONOCLONAL ANTIBODIES AGAINST MIGRAINE HEADACHE

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Background and Importance Erenumab and galcanezumab are monoclonal antibodies that act at the level of the calcitonin gene-related peptide, elevated in patients with migraine.

Aim and Objectives To establish the effectiveness of erenumab and galcanezumab in the treatment of migraine.

Material and Methods Observational, single-centre, retrospective study. All adult patients who initiated treatment between February 2020 to March 2023 were included.

Demographic data were collected (age and sex), drug discontinuation and its reason (primary, secondary failure or adverse effects [AE]) and duration of treatment.

According to our centre's protocol, these treatments are intended to be withdrawn after one year, as they are prophylactic treatments, not continuation treatments. Thus, the main endpoint to determine the drug's effectiveness was the response at 1 year of treatment and the evolution after withdrawal (resumption of treatment vs no treatment).

Statistical analysis was performed using Pearson's Chi-square test (SPSS v. 26.0).

Results We included 273 patients (59% erenumab, 41% galcanezumab), of whom 82% were women. Median age: 52 years [19 – 83].

With erenumab, 9% of patients achieved complete response at 1 year and were able to withdraw treatment. However, 21% of patients had a partial response, 11% were secondary failures and 10% continued without withdrawing the drug. 43% discontinued; after primary failure (37%) or AE (6%), mainly constipation.

With galcanezumab, 10% of the patients achieved a complete response at one year and were able to withdraw the

drug. Nevertheless, 22% of patients had a partial response, 3% were secondary failures and 19% were still unable to withdraw the drug. 34% discontinued; after primary failure (29%) or AE (5%), mainly constipation.

At the end of the study, 27% of patients treated with erenumab did not complete 1 year of treatment due to lack of time, and the same was true for 34% of patients with galcanezumab.

Patients who reached the primary endpoint were still without any treatment after a mean of 4 months.

Conclusion and Relevance Results obtained do not demonstrate a high effectiveness after one year of treatment with these drugs or differences between erenumab and galcanezumab, so more studies are necessary to continue evaluating effectiveness.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-021 PERFORMANCE OF MULTIPLE TRIGGER TOOLS IN IDENTIFYING MEDICATION-RELATED HOSPITAL READMISSIONS

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Background and Importance The Dutch polypharmacy guideline recommends using a trigger tool to identify medication-related hospital (re)admissions. Many trigger tools exist for this purpose. Yet, the effectiveness of these trigger tools and clinical applicability remains uncertain.

Aim and Objectives The aim of this study is to evaluate the performance of trigger tools in identifying medication-related readmissions (MRRs).

Material and Methods In a single-centre cross-sectional study, data was analysed from a previous study assessing 1120 readmissions. In this prior study, a panel of physicians and pharmacists retrospectively assessed readmissions as medication-related (n=181), including preventability.

This current study employed four trigger tools (START-STOPP criteria, OPERAM, ADR-tool, and QUADRAT*) on clinically adjudicated MRRs. The START-STOPP criteria focus on under- and overtreatment, OPERAM on multiple causes, while ADR and QUADRAT tools focus on side effects. The tools include explicit triggers (medication + symptom, e.g., diuretics and dehydration) and implicit triggers (general triggers requiring extensive reviewer knowledge, e.g., avoiding overtreatment). The trigger tools were applied to clinically adjudicated MRRs in duplicate. The primary outcome was each tool's performance in identifying MRRs. Secondary outcomes included assessing the performances of these tools in identifying MRRs based on the potential preventability and age of patients (most tools are developed for patients $\geq$70 years). Descriptive data-analysis was used.

Results Of 181 MRRs, 159 (88%) were regarded potentially preventable by the panel. Among the 181 MRRs, the OPERAM trigger tool identified 92% of MRRs (62% explicit and 30% implicit triggers), while the QUADRAT, ADR and START-STOPP criteria respectively identified 76%, 51% and 7% of MRRs. The tools were more effective in identifying non-preventable MRRs. The tools missed triggers regarding transition in care errors, non-adherence or sick day rules. The trigger tools identified an equal proportion of MRRs for patients below and above 70 years.

Conclusion and Relevance Multiple trigger tools were applied to real-life patient data. START-STOPP criteria, ADR-tool, and QUADRAT were unsuccessful in identifying MRRs in this study. OPERAM performed the best but included many implicit triggers necessitating substantial reviewer knowledge to assess MRRs. Consequently, in daily clinical practice, OPERAM is not easy to apply as a quick screening tool but could be a good tool for research purposes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-022 THE EFFECT OF DIGITAL CLINICAL DECISION SUPPORT ON PHARMACOTHERAPY IN HOSPITALISED (MORBIDLY) OBESE PATIENTS: A PROSPECTIVE INTERVENTION STUDY

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Background and Importance The pharmacokinetics and dynamics of medication can be altered in (morbidly) obese patients. Standard medication doses may be suboptimal in these patients and adjustments based on body mass index (BMI) or body weight (BW) may be needed. Digital clinical decision support (eCDS) may help optimise pharmacotherapy in these patients.

Aim and Objectives The aim of this study was to assess the effect of eCDS on adjustments in pharmacotherapy based on BMI or BW in hospitalised (morbidly) obese patients.

Material and Methods This prospective intervention study with retrospective baseline measurement included hospitalised patients $\geq$ 18 years with BMI $\geq$ 30 kg/m^2 and/or BW $\geq$ 90 kg from 1 January 2022to 30 September 2022 (pre-eCDS group) and from 10 October 2022 to 25 November 2022 (post-eCDS group). In the intervention period, hospital pharmacy recommended pharmacotherapy adjustments to prescribers based on eCDS. eCDS is a tool, integrated in the hospital's electronic health record system, that detected patients whose medication order(s) needed to be adjusted to BMI or BW. Study outcomes were (i) prevalence of medication orders adjusted to BMI or BW pre-eCDS versus post-eCDS, (ii) prevalence of post-eCDS patients with $\geq$1 medication orders resulting in a recommendation for adjustment, including medication details, (iii) number and percentage of recommendations that actually led to an adjustment in pharmacotherapy, including reasons for rejecting a recommendation.

Results In the post-eCDS group pharmacotherapy was significantly more often adjusted to BMI or BW: 77.7% (912 of 1,173 medication orders) post-eCDS vs 58.2% (3,519 of 6,049 medication orders) pre-eCDS ($p<0.0001$). Post-eCDS 328 patients had $\geq$1 medication order(s) resulting in a recommendation for adjustment. The majority of recommendations and adjustments were for nadroparin, 93% (324/349) and 89% (163/186) respectively. 186 of 349 (53.3%)

recommendations actually led to an adjustment in pharmacotherapy. The main reason for not accepting a recommendation by a physician was near discharge from hospital: 90.8% (148 of 163 recommendations).

Conclusion and Relevance Implementation of eCDS in hospital pharmacy led to a significant increase in medication orders adjusted to BMI or BW, in (morbidly) obese patients. It is important to implement and evaluate such interventions to optimise treatment for this growing population.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-023 OPTIMISING BIOLOGIC THERAPY IN SEVERE UNCONTROLLED ASTHMA PATIENTS ON OMALIZUMAB TREATMENT

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Background and Importance Severe uncontrolled asthma (SUA) is a chronic pathology that requires close monitoring of the effectiveness of biological drugs and an assessment of the safety and economic implications to individualise therapeutic goals.

Aim and Objectives Evaluate the effectiveness and safety of omalizumab, propose a switch to biologic treatment to optimise therapy and evaluate the economic impact after intervention.

Material and Methods Prospective study from January 2021 to April 2023. All patients on treatment with omalizumab for SUA were included. Patients with allergic asthma phenotype were excluded. Candidates for optimisation were patients well-controlled or those who had exacerbations in the last 12 months, Asthma Control Test (ACT) score < 20, forced expiratory volume in 1 second (FEV1) <80%, need for oral corticosteroids and the pharmacy dispensing record. To assess the effectiveness of the intervention, data were collected on biological treatment, FEV1, ACT, IgE and eosinophil values before and after the treatment switch or discontinuation. The exacerbations or treatment with oral corticosteroids were also recorded. Clinical variables were obtained using electronic medical records.

Results Sixty-one patients with mixed or eosinophilic phenotype SUA on treatment with omalizumab. Of these, 30 patients met criteria for well-controlled disease and 31 (50.8%) were candidates for optimisation of therapy. 55.5% women with a median age of 51 years (IQR 66 – 42). The median pre-test IgE value was 459 UI/mL (734.7–239.1), eosinophils 300/µL (445–140), ACT 17 (23–12) and FEV1 78% (100–65). Eight patients switched to benralizumab, seven to mepolizumab and six to dupilumab. Seven patients were discontinued due to well-controlled SUA, two patients were expected to switch due to the need for previous complementary tests, one patient died of another cause. After optimisation the eosinophil value at week 16 and 32 dropped to 80 and 50 respectively. Median ACT 18 (20–16) and FEV1 83.5 (98.5–59.5). Five patients had exacerbations and six patients required oral corticosteroids. Two of the patients with mepolizumab returned to omalizumab. Optimisation of therapy for SUA resulted in a 38.2% cost saving.

Conclusion and Relevance Optimisation of pharmacotherapy allows for individualisation of treatment and dosage, which has an impact on effectiveness and safety while minimising costs in the health system.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-024 ANALYSIS OF POLYMEDICATION AND ADEQUACY TREATMENT RECOMMENDATIONS IN PATIENTS WITH MULTIPLE SCLEROSIS IN A TERTIARY LEVEL HOSPITAL

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Background and Importance Multiple sclerosis (MS) population has been aging in parallel to the increasing life expectancy of the general population. This could be related to potentially inappropriate medication prescriptions, drug-drug interactions and therapeutic non-adherence.

Aim and Objectives Determine the prevalence of polymedication in an MS population aged 55 years or more and provide therapeutic recommendations to adjust treatment of the patient.

Material and Methods Observational, cross-sectional, study that included patients over 55 years of age with MS at a tertiary level hospital between December 2022-February 2023. Demographic variables: age, sex, date of MS diagnosis, type of MS and the Expanded Disability Status Scale (EDSS). Medication, polypharmacy (five or more drugs), major polypharmacy (10 or more drugs), anticholinergic burden, potentially inappropriate medication, drug-drug interactions (Lexicomp® database) and non-adherence to concomitant medication were collected. Statistical analysis was carried out with R Commander® software. Data was obtained from electronic prescription (Prisma®) and medical records (Diraya®) applications.

Results 95 MS patients aged 55 years or older were included. 68.4% were women. The median age was 61 years (IQR 58–65). Median age at the diagnosis 45.2 years (IQR 38.5–50.2). Type MS: recurrent remitting (71.6%), secondary progressive (19%) and primary progressive (9.4%). Median EDSS scale 2 (IQR 1–3). The most frequent disease-modulating drugs (MSD) were: interferon (23.1%), fampridine (16.8%), teriflunomide (14.7%), fingolimod (8.4%) and glatiramer acetate (7.4%). Median number of drugs concomitant with MSD 6 (IQR 3–9). Polypharmacy 68.4%. High treatment complexity index 40%. Non-adherence to concomitant medication was identified in 84.4% of patients and drug-drug interactions in 56.2% (category D 83.8% and X 16.2%). Anticholinergic load: no risk 20%, moderate risk 22.1% and high risk 57.9%. A total of 20 pharmaceutical interventions were carried out in 17 patients (17.9%), the potentially inappropriate medication criterion was responsible for 11 interventions, non-adherence for seven and interactions for two. Of the 11 interventions on inappropriate medication criteria, nine (81.8%) were accepted, resulting in the discontinuation of 15 drugs that were appropriately prescribed.

Conclusion and Relevance Polypharmacy plays a very important role in adult MS patients as it is associated with a higher prevalence of inappropriate medication prescriptions, drug-drug interactions and therapeutic non-adherence.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-025 MANAGEMENT OF COVID-19 WITH NIRMATRELVIR/RITONAVIR AND TACROLIMUS MONITORING IN RENAL TRANSPLANTATION: A CASE REPORT

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Background and Importance Nirmatrelvir/ritonavir (N/R) is an oral treatment for COVID-19 that reduces the risk of developing severe disease. Renal transplant patients are treated with immunosuppressants such as tacrolimus, that is metabolised by CYP43A as well as N/R. Co-administration with the irreversible CYP3A4 inhibitor ritonavir, is associated with serious interactions and toxicity in patients.
Aim and Objectives To describe the management of COVID-19 treatment with N/R and tacrolimus in renal transplant patients.
Material and Methods A 49-year-old woman with chronic kidney disease who underwent kidney transplantation in February 2019. She was on treatment with prednisone, mycophenolate and tacrolimus, presenting chronic rejection in April 2023 for which she received rituximab.

In June 2023 she was admitted to a tertiary hospital with a diagnosis of COVID-19 and severe pneumonia, requiring supplemental oxygen. She had received four doses of the COVID-19 vaccine and was on tacrolimus 5 mg/day, with a creatinine of 1.7 mg/dl. Due to the interaction of tacrolimus with N/R, she was first treated with remdesivir.
Results Due to the lack of clinical improvement, the Infectious Diseases, Nephrology, and Pharmacy units decided to initiate N/R adjusted to renal function (eGRF 30–60 ml/min) at a dosage of 150/100 mg/12 hours for 5 days. Tacrolimus was suspended during the treatment, with diligent therapeutic drug monitoring (TDM).

Tacrolimus concentration was measured prior to commencing N/R therapy. Because of the somewhat elevated tacrolimus concentration (16.4 ng/mL), it was determined to postpone the initiation of N/R for 48 hours. During N/R treatment, tacrolimus concentration remained around 6–7 ng/ml (target: 5–15 ng/ml). Four days after the end of N/R, the plasma level was 2.2 ng/mL, leading to the decision to reintroduce tacrolimus at a reduced daily dose of 2.5 mg.

The infectious condition was successfully resolved following N/R, without any transplant rejection. However, the patient experienced a slight deterioration of creatinine levels, which returned to baseline values after restarting tacrolimus.
Conclusion and Relevance Our experience contributes additional evidence indicating that this interaction should not be considered a contraindication for N/R treatment in COVID-19 pneumonia patients and can be effectively managed through TDM of tacrolimus. Nevertheless, further studies involving a larger patient population are necessary to establish more precise conclusions.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-026 ACCEPTABILITY AND WILLINGNESS TO SWITCH ANTIRETROVIRAL TREATMENT IN PATIENTS WITH LONG-ACTING INJECTABLE THERAPY CRITERIA

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Background and Importance The development of long-acting injectable treatment has become a new treatment strategy that could change the handling of patients with antiretroviral therapy (ART) for HIV infection.

Cabotegravir/rilpivirine represents the first long-acting drug combination approved by the Food and Drug Administration (FDA) and the Spanish Agency for Medicines and Health Products (AEMPS) for this indication.
Aim and Objectives To know the acceptability and willingness of patients with HIV infection to switch their oral antiretroviral treatment to a long-acting injectable.
Material and Methods Qualitative descriptive population study carried out at a third-level hospital. All adult patients with an indication for cabotegravir/rilpivirine treatment attended at the pharmacy consult were included.

A questionnaire was prepared where the patient's data were collected and the degree of satisfaction with their treatment and the acceptance of the therapy with long-acting injectables were evaluated.
Results A total of 57 patients [70.2% (n=40) men and 29.8% (n=17) women] with a median age of 54 years [range: 28 – 78] completed the questionnaire. The ART they received were: Dovato®, Triumeq®, Juluca®, Biktarvy®, Odefsey®, Genvoya® or Symtuza®.

Patients expressed being satisfied [33,3% (n=19)] or very satisfied [66,7% (n=38)] with their usual ART and that it was not an inconvenience to take the medication orally every day [75,4% (n=43)]. The majority stated that they were willing [54,4% (n=31)] or very willing [31,6% (n=18)] to continue with their treatment.

Furthermore, most of the patients had prior knowledge of long-acting injectable therapy [71.9% (n=41)] and expressed that they did not mind receiving two intramuscular injections every 2 months [86.0% (n=49)] and that they were not worried about the secondary pain [57.9% (n=33)]. The majority stated that they were willing [52.6% (n=30)] or very willing [35.1% (n=20)] to switch treatment.

The main reasons for switching treatment were to remove the stigma, to avoid forgetting to take the medication and the worry about running out of medication.
Conclusion and Relevance Results reflected a great acceptability and willingness of our patients to receive long-acting antiretrovirals, showing agreement with previously conducted studies.

In addition, the patients also appreciated being asked their opinion about the treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-027 ANALYSIS OF CARDIOVASCULAR RISK ASSOCIATED WITH IRREVERSIBLE INHIBITOR OF BRUTON'S TYROSINE KINASE TREATMENT IN PATIENTS WITH CHRONIC LYMPHOID LEUKAEMIA

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Background and Importance Side effects of inhibitors of Bruton's tyrosine kinase (BTK) include hypertension, arrhythmias and cardiac events. The cardiovascular risks associated with ibrutinib and acalabrutinib may vary depending on individual patient factors.

Aim and Objectives Outcome analysis of the occurrence of cardiovascular adverse events and cardiovascular risk in chronic lymphoid leukaemia (CLL) patients on treatment with BTK.

Material and Methods Observational retrospective study from January 2017 to May 2023. Clinical variables: sex, age, obesity, smoking, Eastern Cooperative Oncology Group (ECOG) scale, TP53 mutation, date of diagnosis, treatment, duration, adverse effects or dose modifications. Cardiovascular risk at baseline was obtained with the SCORE 2 (healthy patients), SCORE 2-OP (over 70 years of age), ADVANCE (diabetics) and SMART (previous cardiovascular disease) calculator. Data was obtained from oncology electronic prescription and electronic medical records. R commander was used for the statistical analysis.

Results Fifty-six patients with BTK treatment were included. 55.3% male, median age 73 (IQR 66–79). 51.7% TP53 mutation positive. Median years of diagnosis was 2014 (IQR 2010–2018). 30.3% obesity, 21.4% smokers and 16 ex-smokers. The median 10-year risk of cardiovascular events was 8.3% (IQR 4–11). At the start of treatment: 53.5% arterial hypertension, 26.7% dyslipidemia, 23.2% diabetes, 16% ischemic heart disease, 5.3% atrial fibrillation and 3.5% pulmonary embolism. 49 patients received treatment with ibrutinib (26.5% first- line) and 7 patients with acalabrutinib (85.7% first-line). The median treatment duration is 30 months (IQR 12–46). 23.2% reduced the dose and 42% discontinued treatment (25% remained in therapeutic abstinence). 24% developed some cardiovascular pathology during the course of treatment (14.2% developed major adverse cardiovascular events (MACE) with hospitalisation). The median year of treatment at which MACE developed was the second year (IQR 1–3). Statistically significant differences were found between the occurrence of MACE and sex ($p=0.04$), duration of treatment ($p=0.02$) and hypertension before starting BTK ($p=0.009$). 28.5% died (two patients due to MACE and one patient due to CLL progression).

Conclusion and Relevance The occurrence of MACE occurs in a modest number of patients with a low associated mortality. A statistically significant association was found with sex, duration of treatment and hypertension at the start of BTK.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-028 ANALYSIS OF INTERACTIONS DETECTED IN THE CONCOMITANT USE OF ANTINEOPLASTIC AGENTS AND PHYTOTHERAPY IN ONCO-HAEMATOLOGY PRACTICE AND INTERVENTIONS CARRIED OUT

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Background and Importance The use of phytotherapy is very widespread. Onco-haematology patients are particularly at risk of drug or phytotherapeutic interactions that may compromise the efficacy and safety of chemotherapy treatment.

Aim and Objectives To detect patients who consume phytotherapeutic products as well as their interactions with anticancer agents in onco-haematology patients and to provide pharmaceutical interventions to optimise treatment.

Material and Methods Prospective observational study of onco-haematology patients in a tertiary hospital from January 2023 to August 2023. Demographic variables (age, sex, pathology) were collected. To identify the type of intervention performed, a database was created using an Excel® spreadsheet to record and categorise it. Interactions were detected using the applications Drugs®, Lexicomp® and About Herb®. The pharmacological intervention was recorded in electronic medical records.

Results Sixty-three patients were found to be taking herbal medicine concomitantly with onco-haematologic treatment. 57% of patients were women. The median age was 62 [61.5–65.4] years. The patients belonged to two clinical services, 39.6% to Haematology and 60.4% to Oncology. The most frequent onco-haematologic pathologies: Prostate Cancer (33%), Colon Cancer (23%), Chronic Lymphocytic Leukaemia (12%), Multiple Myeloma (11%), Ovarian Cancer (8%), Brain Tumours (5%), Lung Cancer (6%) and Breast Cancer (2%). The main supplements with a potential risk of interactions were echinacea (39%), magnesium (32%), green tea (21%), soy (5%), capsaicin (4%), ashwagandha (1%) and devil's claw (1%). The potential consequences were an increase or a decrease in the concentration of the anticancer agents (82%), an increase in the risk of bleeding (13%), hepatotoxicity (3%), and hypokalaemia (2%). The consumption of phytotherapy was unknown by a health professional for 48% of the patients. 100% of the pharmaceutical interventions were entered in the patient's clinical history as a clinical report. 95% were accepted and prevented errors of medication errors in patients.

Conclusion and Relevance The risk of interactions between plants and antineoplastic agents is frequently observed in clinical practice and due to its increasing popularity, healthcare professionals need to be alert. Multidisciplinary teams working together can detect this problem and avoid loss of effectiveness or toxicity of chemotherapy treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-029 USE OF TOPICAL 1% CIDOFOVIR ON SKIN LESIONS IN A PATIENT WITH MONKEYPOX

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Background and Importance Monkeypox (MPX) is a zoonosis caused by an orthopoxvirus transmitted by droplets, direct contact or fomites. Different signs and symptoms are caused, including a variety of skin lesions.
Aim and Objectives The aim is to evaluate the response of vesiculo-pustular lesions to treatment with a topical magistral formulation (MF) of cidofovir.
Material and Methods On a second-level hospital, during September-November 2022, a MF of topical 1% cidofovir in Base Beeler was developed by the pharmacotechnical area for the treatment of papillomatous lesions in the facial region, perianal area and extremities associated to the MPX diagnosis.

The patient's evolution was monitored for 4 months, variables were collected, based on the electronic medical records and the centre's prescription records.
Results A 31-year-old male was admitted in July 2022 after 7–10 days of uncontrolled pain in the perianal area and skin lesions on the face and torso of 3–4 days of evolution. Suspicion of MPX led to a request for Orthopoxvirus real-time PCR. Diagnosis was confirmed with complete serology and positive detection for HIV (stage C3) and coronavirus.

Initially, the lesions were treated with 1/1000 zinc sulfate and topical fusidic acid every 12 hours. Given the poor response, fusidic acid was modified for topical Liade® (antibiotic ointment: polymyxin B sulfate, neomycin and bacitracin). It was also added Apodrex®, sterile dressing applied to the perianal lesion for the absorption of exudate.

Due to lack of response the Pharmacy service was requested to develop a topical 1% Cidofovir MF; Zinc sulfate was discontinued and Liade® was maintained.

The regimen was one application to each lesion twice a day, as well as Liade®.

Vesiculo-pustular lesions in necrotic phase evolved to crusty phase and then to lesions with granulation tissue and some of them even to healing process.

Four months later, due to lack of response and without achieving the complete disappearance of the lesions, it was returned to the initial treatment.
Conclusion and Relevance In the absence of consensus on the treatment of lesions caused by MPX, the application of topical 1% cidofovir improves these lesions partially, some of them up to the scarring phase. It can be considered as an alternative to zinc sulfate treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-030 ANALYSIS OF ADHERENCE TO GROWTH HORMONE TREATMENT IN PAEDIATRIC PATIENTS

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Background and Importance Adherence to growth hormone treatment is critical as it is associated with increased growth velocity and improved adult height. However, because it requires daily injections, adherence may decline in paediatric patients.
Aim and Objectives The objectives of this study are to measure patient adherence to growth hormone treatment, evaluate the influence of age on adherence, and identify patient groups needing close pharmacist monitoring.
Material and Methods A retrospective and descriptive study included all patients undergoing growth hormone (somatostatin) treatment from 1 January 2017, to 31 December 2022. Variables considered included age (calculated from the last dispensation), gender, dispensation dates, and dispensed quantities.

Adherence was estimated using the indirect method of measuring medication dispensed over an interval (CSA: Continuous Single Interval Measure of Medication Acquisition); percentage of days covered relative to the total days in the interval, using the computer software Farmatools® (Dominion).
Results The study included 160 patients (52.5% girls, 47.5% boys), aged 4–18 years, with an average age of 12.5 years and a mean treatment duration of 3.2 years. Age groups comprised 4–6 years (10 patients), 7–9 years (21 patients), 10–12 years (39 patients), 13–15 years (53 patients), and 16–18 years (37 patients).

Regardless of age, 80.63% of the patients had an adherence rate of over 90% (68.13% over 95% adherence).

When analysing adherence within these age ranges, 30% (three patients) had adherence below 90% in the group aged 4–6 years, 4.76% (one patient) aged 7–9 years, 15.38% (six patients) aged 10–12 years, 13.21% (seven patients) aged 13–15 years and 37.84% (14 patients) aged 16–18 years.

Only one patient (10%) in the group aged 4–6 years had adherence below 85%, 0% in the group aged 7–9 years, 5.13% (two patients) in the group aged 10–12 years, 7.55% (four patients) in the group aged 13–15 years and 16.22% (six patients) in the group aged 16–18 years.
Conclusion and Relevance Most patients had optimal adherence, with the worst adherence in the extreme age groups. In younger children this may be due to fear of injections and in adolescents due to relaxation over time and lack of family supervision.

These age groups could benefit from closer pharmaceutical care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-031 A POPULATION PHARMACOKINETIC MODEL OF VEDOLIZUMAB IN ADULT PATIENTS WITH INFLAMMATORY BOWEL DISEASE: A PRELIMINARY ANALYSIS

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Background and Importance Understanding determinants of vedolizumab clearance may enhance treatment optimisation as there are limited data on therapeutic drug monitoring (TDM) in patients with inflammatory bowel disease (IBD).

Aim and Objectives The objective of this study was to perform a preliminary pharmacokinetic (PK) model of vedolizumab in real-life to evaluate covariates potentially responsible for the PK variability in adult patients with IBD.
Material and Methods A 5-year retrospective unicentre study was performed including adults (>18 years) diagnosed with IBD and treated with intravenous vedolizumab. Demographic and clinical data were collected, including serum albumin, C reactive protein (CRP) and faecal calprotectin (FCal). Vedolizumab trough levels (VTL) were obtained before administrations. Vedolizumab concentrations and anti-vedolizumab antibodies (AVA) were determined by ELISA. The model was developed in NONMEM v7.4 by approximating the non-linear mixed effects models. The first order conditional estimation method with interaction (FOCEI) was used for model building. Body weight (WGT) was included in PK parameters following an allometric relationship.
Results Sixty-one patients (27 women) were included, 34 (56%) were diagnosed with ulcerative colitis and 27 (44%) with Crohn's disease. Median age (range) was 43 (IQR:35–59) years and weight 70.9 (CI 95%: 67.2–74.7) kg. A total of 101 concentrations were determined, with a median concentration of 25.9 (IQR:10.4–47.1) µg/mL. Median serum albumin, CRP and FCal levels were: 4.5 (IQR: 4.2–4.7)g/dL, 3.6 (IQR:1.3–8.0) mg/dL and 404.2 (IQR:105.3–1329) µg/g, respectively. Any patient has developed AVA. Population PK model (PopPK): a one compartment with first order elimination described adequately the VTL. Among the clinical variables analysed, none was found significant on clearance (CL) and distribution volume (Vd). The final PopPK model in the absence of AVA was as defined as: V=4.55L and CL(L/day) $=0.15\ (WGT/70kg)^{0.75}$. Interindividual variability associated with CL (IIVCL) from 14.2%. Proportional residual error estimated was 15.1%.
Conclusion and Relevance Vedolizumab PK in adult patients with IBD was best described by a one compartment model with first order elimination. WGT was included in CL, following an allometric relationship. Further investigation is required in order to find possible covariates and validate this PK model.

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Conflict of Interest No conflict of interest.

4CPS-032 PHARMACEUTICAL INTERVENTIONS FOR MEDICATION RECONCILIATION IN COMPLEX CHRONICALLY ILL PATIENTS

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Background and Importance Elderly patients who receive chronic medication for multiple pathologies have a high risk of suffering from medication discrepancies and adverse drug events. The role of pharmacists is vital to improve health outcomes by avoiding these medication errors.
Aim and Objectives To analyse the pharmaceutical interventions (PIs) of medication reconciliation in hospitalised multipathological patients over 65 years of age and to evaluate the degree of acceptance by the physicians.
Material and Methods A prospective observational study was conducted between 1 March 2023 and 15 April 2023. We analysed the PIs on therapeutic conciliation performed in multipathological patients admitted to the hospitalisation ward where the pharmacist has recently been integrated in collaboration with an internist and a nurse.
The following variables were collected number of patients admitted to the ward and those on whom PIs were performed, pathologies involved according to the drugs used, number and type of PIs identified. In addition, the degree of acceptance of the PIs was measured and PIs were identified with drugs considered high-risk in chronic patients according to the MARC list.
Results Eighty-three patients were admitted to the Internal Medicine hospitalisation ward. Of the total number of patients, 52 PIs were performed in 33 patients. The nature of the diseases associated with PIs were cardiovascular (n=16.48%), metabolic-renal (n= 9.28%), neurological (n= 5.15%) and respiratory (n=3.9%).

The recommendations made in the PIs were: discontinuation of medication (n=16), dosage adjustment (n=14), prescription of medication (n=11), substitution of the drug for a more effective one (n=7), exchange of the drug for a therapeutic equivalent (n=3) and change of the route of administration (n=1).

The degree of acceptance was 86.54%.

Of the PIs performed, 27% (n=14) involved a high-risk drug. Specifically, loop diuretics (4), anticoagulants (4), antiplatelet agents (1), beta-blockers (2), NSAIDs (1), hypoglycaemic agents (1) and insulins (1).
Conclusion and Relevance Most of the PIs were related to the addition or discontinuation of a drug, as well as to the dose adjustment of a drug. The degree of acceptance of the PIs was very high, which reinforces the role of the pharmacist within a multidisciplinary team.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-033 REAL-WORLD TREATMENT PATTERNS AND OUTCOMES OF SELECTIVE CYCLIN-DEPENDENT KINASE (CDK) 4/6 INHIBITORS UTILISATION IN METASTATIC BREAST CANCER – REVEAL STUDY

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Background and Importance Active involvement of hospital pharmacists in real-world effectiveness studies is paramount to generate evidence about the value of innovative

medicines in clinical practice. The REVEAL study was designed and implemented by a cooperative research group of hospital pharmacists to assess the therapeutic value of current standard of care with CDKi4/6 in HER2-negative, hormone receptor-positive metastatic breast cancer (MBC: HR+;HER2(-)).

Aim and Objectives To characterise treatment patterns of CDK4/6 inhibitors palbociclib and ribociclib use in women with MBC. To quantify dose adjustments until 6 months of CDKi4/6 treatment. To estimate persistence on treatment with ribociclib at 12 and 24 months.

Material and Methods Retrospective observational cohort study, including adult women with MBC: HR+;HER2(-) who used CDKi4/6 (ribociclib or palbociclib) in addition to hormone therapy, between March and December 2019. Data was from records of the Hospital Pharmaceutical Services. The study comprised two follow-ups: until June 2020 to quantify dose adjustments; until 24 months to assess persistence on treatment with ribociclib (last observation 31 December 2021). Study protocol was approved by hospitals' Ethics Committees. Persistence on treatment with ribociclib was calculated using the Kaplan-Meier estimator. A significance level of 5% was adopted.

Results We included 121 women from seven public hospitals: palbociclib (n=86;71.1%); ribociclib (n=35; 28.9%). The average age (min; max) was 58 (27; 92) years. Most patients started CDKi4/6 treatment in postmenopause (n=85; 70.2%) and as second-line therapy (n=87; 71.9%). Combination with hormonal therapy was aromatase inhibitors 97% in ribociclib and 71% in palbociclib patients (p-value=0.003); fulvestrant in 6.1% ribociclib and 33.9% palbociclib patients (p-value=0.003). The majority (76%) of patients had no dose adjustment in the first 6 months. There were no significant differences in the proportion of patients with dose modifications according to CDK4/6 inhibitor, patient's age, type of hormonotherapy or therapy line. The median persistence on treatment with ribociclib was 16.3 months (95% CI= [10; NA]). Persistence [95% CI] on treatment with ribociclib at 12 months was 57% [40%;81%] and at 24 months 43% [26%; 73%].

Conclusion and Relevance The REVEAL study confirmed the effectiveness of CDKi4/6 in real-world settings, including dose adjustments and persistence on treatment. Leadership in real-world effectiveness studies is paramount to elevate the role of pharmacists in establishing the therapeutic value of innovative medicines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest Conflict of interest.

Corporate sponsored research or other substantive relationships:

This project was developed within the framework of a clinical research collaboration protocol established between Novartis Farma, Produtos Farmacêuticos S.A., Exigo Consultores and a group of Portuguese hospitals.

4CPS-034 REAL-WORLD SAFETY AND TOLERABILITY IN PATIENTS TREATED WITH ABEMACICLIB AND ENDOCRINE THERAPY: A RETROSPECTIVE OBSERVATIONAL STUDY

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Background and Importance Abemaciclib is a selective CDK4/6 inhibitor and it is authorised in combination with endocrine therapy (ET). Its use was associated with superior outcomes compared to ET alone in women with HR+/HER2- metastatic breast cancer (mBC), providing a new standard of care for this patient population.

Aim and Objectives The aim of the study was to evaluate the safety profile of abemaciclib, the severity and types of toxicities and the factors leading to discontinuation of treatment.

Material and Methods A retrospective, observational, descriptive study was carried out at a tertiary care hospital. Women aged >18 years with HR+/HER2- mBC receiving abemaciclib in combination with ET between June 2019 and July 2022 were included. Variables: age, hormonal therapy in combination, concomitant therapies, duration of treatments, adverse events (AEs), dose adjustment and treatment discontinuation. AEs were classified according to CTCAE. Clinical and analytical data were collected from electronic clinical records.

Results 39 patients were included, median age was 68(56–76) years. Abemaciclib was administered in combination with tamoxifen (39%), letrozole (18%), anastrozole (26%) and exemestane (17%). 67% of patients reported at least one comorbidity. 45% of patients used 3–5 drugs and 18% used 6–10 drugs as concomitant therapy. 74.4% followed for the whole duration of the study, while 25.6% discontinued therapy due to toxicity. Disease progression was experienced by 15.4% of patients and dose reduction was achieved in 33% of cases. AEs occurred in 89.7% of patients, of these 74% were mild to moderate (G1-G2) and 26% were severe (G3-G4).The most common AEs reported were neutropenia in 23% of patients (55.5% G3-G4), anaemia 38.5%, diarrhoea 74.3% (only one severe), nausea 10.2%, asthenia 51.3% (10% G4), liver dysfunction 15.4% (33.3% G3-G4), renal dysfunction 15.4%. Multivariate regression analysis showed an increase of serious AEs associated with the use of abemaciclib in combination with 3–5 concomitant therapies (p<0.001) and 6–10 concomitant treatments (p=0.018).

Conclusion and Relevance Our data showed that the concomitant use of polytherapy is associated with higher toxicity in patients affected by mBC treated with abemaciclib+ET. However, this combination demonstrated an acceptable, safe and tolerable profile. Most AEs were reversible and well controlled with concomitant medications and/or dose modifications, according to the reported toxicity data from the clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-035 IMPACT OF ANTIBIOTIC STEWARDSHIP PROGRAMME (ASP) ON ANTIBIOTIC USE AND CLINICAL OUTCOMES IN PATIENTS HOSPITALISED WITH COMMUNITY-ACQUIRED PNEUMONIA (CAP): RETROSPECTIVE OBSERVATIONAL BEFORE-AFTER STUDY

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Background and Importance Community-acquired pneumonia (CAP) is still one of the leading causes of death worldwide. In our previous studies, the guideline adherence to national and international CAP guidelines in terms of agent choice was found to be poor. Implementation of the Antibiotic Stewardship Programme (ASP) aimed to improve the correct and responsible antibiotic use by encouraging guideline adherence.
Aim and Objectives This retrospective observational before-after study aimed to evaluate whether the ASP may improve guideline adherence, antibiotic exposure and clinical outcomes in patients hospitalised with CAP in Hungary.
Material and Methods The study was conducted at a Pulmonology Department of a tertiary care medical centre in Hungary. The ASP implementation consisted of written and published guidelines available to all professionals, continuous supervision and counselling service on antibiotic therapies. The intervention was performed by a multidisciplinary antibiotic stewardship team (AST) at an individual level, with the aim to ensure compliance with CAP guidelines. Overall guideline adherence (agent selection, route of administration, dose), clinical outcomes (length of stay-LOS, 30-day mortality), and antibiotic exposure were compared between the pre-intervention and ASP periods (both retrospective observational). Fisher's exact test and t-test were applied to compare categorical and continuous variables, respectively. Significant p values were defined as below 0.05.
Results Significant improvement in overall CAP guideline adherence (by 30.2%, from 46.6% to 76.8%, p=0.017) and significant reduction in the total duration of antibiotic therapy (by 13.5%, 7.58±3.83 vs. 6.15±3.72 days, p=0.002) were observed. Guideline non-adherent combination therapies with metronidazole decreased significantly by 28.1% (from 31.1% to 3.0%, p<0.001). Antibiotic exposure decreased by 7.2% (from 17.9±10.64 to 15.47±11.03 DDD/patient, p=0.061) and sequential therapy increased significantly by 10.5% (from 3.9% to 14.14%, p=0.01). Moreover, ASP had benefits on clinical outcomes (LOS: decreased by 13.5%, from 8.85±6.1 to 7.09±5.84 days, p=0.016; 30-day survival: increased by 5.9%, from 72.5% to 78.4%, p=0.711).
Conclusion and Relevance Availability of written protocols on the ward and the continuous counselling service is crucial in optimising antibiotic use. Implementation of ASP led to a significant improvement in CAP guideline adherence and sequential therapy, that also entailed the significant reduction of total duration of antibiotic therapy, and length of stay.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-036 EVALUATION OF THE DIAGNOSIS AND ANTIBIOTIC PRESCRIPTION PATTERN IN PATIENTS HOSPITALISED WITH URINARY TRACT INFECTIONS (UTIS)

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Background and Importance Urinary Tract Infections (UTIs) are common bacterial infections with non-negligible hospitalisation rate. The diagnosis of UTIs remains a challenge for prescribers and common source for misdiagnosis.
Aim and Objectives This retrospective observational study aimed to evaluate whether recorded diagnosis by clinicians and empirical antibiotic therapy met the European Association of Urology (EAU) guideline in patients hospitalised with a UTI.
Material and Methods The study was conducted at an internal medicine unit of a tertiary care medical centre in Hungary. Diagnosis was assessed based on the clinical presentation, physical examination, and laboratory (inclusive microbiological) results considering risk factors. Diagnosis was considered misdiagnosis when was not confirmed by clinical presentation or clinical signs and symptoms. Analyses for empirical antibiotic therapy were performed only for confirmed UTIs. Empirical treatment was considered guideline adherent when complying with the recommendations. Fisher's exact test and t-test were applied to compare categorical and continuous variables between groups. Significant p values were defined as below 0.05.
Results Out of 185 patients 41.6% (n=77) have not met EAU diagnosis criteria, of which 27.6% (n=51) were misdiagnosis and 14.1% (n=26) were ABU (asymptomatic bacteriuria). The diagnosis of urosepsis recorded at admission (9.7%) was not supported in any cases neither by clinical nor by microbiological tests. The initial empirical therapies for UTI showed a relatively low rate (45.4%, 49/108) of guideline adherence regarding to agent selection. The most common guideline non-adherent therapies were combinations with metronidazole (16,7%, 18/108). Although dosage appropriateness assessments showed a higher guideline adherence rate (36.1%, 39/108), underdosing due to the higher body weight was relatively high (9.3%, 10/108). Overall (agent, route of administration, dose, duration) guideline adherence was found to be substantially low (10.2%, 11/108).
Conclusion and Relevance We found a relatively high rate of misdiagnosed UTIs. Written protocols on the ward may be crucial in reducing misdiagnosis and in optimising antibiotic use.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-037 INTEGRATION OF THE PHARMACIST IN THE MULTIDISCIPLINARY COMMITTEE OF URO-ONCOLOGICAL PATHOLOGY

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Background and Importance The figure of the pharmacist was incorporated into the Multidisciplinary Committee Uro-Oncological Pathology (MCUP): Oncology, Radiation Oncology, Urology, Pathological Anatomy, Nuclear Medicine, Radiology), for the evaluation of patients with locally advanced or metastatic prostate cancer (PC), participating in the selection of the most appropriate treatment (effectiveness, safety, efficiency, comorbidities and interactions) and appropriateness of prescription (financing criteria of Ministry of Health and Multidisciplinary Commission Rational Use of Medicines).

Aim and Objectives To describe the integration of the pharmacist in the MCUP, participating in the selection of treatment, adequacy of the prescription and concomitant medication. Degree of acceptance (GA) of the recommendations.

Material and Methods Observational, retrospective study of patients with prostate cancer reviewed at MCUP between January 2022 and June 2023.

Variables collected from electronic medical record Diraya®: age, functional status (ECOG), Gleason, comorbidities, diagnosis, previous treatment, proposed treatment at MCUP, home medication and allergies.

Interactions with Micromedex®, Cancer Drug Interactions, drug labels and patient interview were verified.

Registration of medication in the outpatient dispensing programme (Athos Prisma®,) or Farmis Oncofarm.®

Continuous variables were expressed as median [(Interquartile Range (IQR)].

Results 69 treatments were reevaluated. 72 years (IQR:66–78). Median of associated comorbidities: 4 (IQR: 2.75–5) among them:

Arterial hypertension (n=60), dyslipidaemia (n=35), cardiovascular disease (n=30) and diabetes mellitus (n=29). Median number of medications prescribed: 8.5 (IQR:5–10.25;

527 medications were reviewed, 85 interactions detected. Selection of best treatment according to comorbidities/interactions (n=20, GA:85%) and modification/monitoring of concomitant medication (n=65, GA:87%).

Previous treatment androgen deprivation therapy (n=45), radiotherapy (n=39), radical prostatectomy (n=36), chemotherapy (n=16), new antiandrogens (n=14).

The following requests to start treatment were evaluated and agreed upon: 10 requests to start apalutamide [(nine metastatic hormone-sensitive (mHSPC), one non-metastatic castration-resistant (CRPC0)], 13 abiraterone (nine metastatic castration-resistant (mCRPC), four mCSPC), 14 enzalutamide (12 mCRPC, two CRPC), nine docetaxel (six mCRPC, three mCPHS), seven darolutamide (CPHSM0), 12 abiraterone in combination with docetaxel (CPHSM new high-risk diagnosis, off-label use), four cabazitaxel (mCRPC).

Conclusion and Relevance The integration of the pharmacist into MCUP for assessment of PC treatment improves the quality of care, guaranteeing patient safety, compliance with protocols, individualisation of therapy, improving access to drugs, favouring the innovation and the sustainability of the health system. Degree of acceptance of recommendations was high.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Thanks MCUP

Conflict of Interest No conflict of interest.

4CPS-038 CASE REPORT ON AUTONOMIC NEUROPATHY INDUCED BY BORTEZOMIB

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Background and Importance Peripheral neuropathy is one of the most common adverse reactions to bortezomib. However, bortezomib can much less frequently produce other nervous system alterations. We present the case of a patient undergoing bortezomib treatment for multiple myeloma (MM), who developed toxicity in the form of autonomic neuropathy.

Aim and Objectives A 68-year-old patient with a history of hypertension, dyslipidaemia and depressive syndrome. In May 2023, MM was diagnosed, and induction treatment with daratumumab/bortezomib/lenalidomide/dexamethasone (D-VRd) was initiated.

During the first cycle of treatment, tolerance was excellent. The patient was included in the home chemotherapy administration programme for the second cycle. On the 8th day of the second cycle, the patient reported significant diarrhoea in the previous days. Hygienic-dietary recommendations were provided. After seven doses of bortezomib (cumulative dose: 16.8 mg), on the 11th day of the second cycle, when the nurse visited the patient at home, she found the patient hyporeactive, having difficulty speaking and standing, non-reactive pupils, and skin pallor.

Material and Methods During hospitalisation, the patient experienced significant hypotension (76/52mm Hg), and dizziness, along with intolerance to standing and diarrhoea (grade 2). After ruling out cardiac causes (echocardiography), structural brain abnormalities (CT scan), amyloidosis and infectious origin, it was suspected to be vasovagal episodes secondary to autonomic neurological toxicity due to bortezomib. Intensive fluid therapy was administered. Progressive improvement was observed and the patient was discharged on the sixth day of admission with the ability to walk without recurrence of symptoms.

Results The treatment for MM was resumed after 15 days without bortezomib. Bortezomib was not administered again, and the symptoms did not recur. The reaction was classified as 'probable' according to the Naranjo algorithm.

Conclusion and Relevance There are few reported cases of autonomic neurological toxicity due to bortezomib.[1–4] Similar to our case, Suyani et al. and Stratogianni et al. reported two cases of patients who required hospitalisation due to dizziness and orthostatic hypotension, ultimately associated with bortezomib. In conclusion, autonomic neuropathic toxicity caused by bortezomib should be considered in the differential diagnosis of orthostatic hypotension in haematological patients. Home chemotherapy administration allows for early detection of toxicities and streamlines healthcare processes.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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Conflict of Interest No conflict of interest.

4CPS-039 ABSTRACT WITHDRAWN

4CPS-040 ADHERENCE TO GUIDELINES AND PRESCRIBING TRENDS OF STATINS IN PATIENTS WITH ACUTE CORONARY SYNDROME

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Background and Importance Early use of statins in patients with Acute Coronary Syndrome (ACS) was associated with a reduced in-hospital mortality rate. Furthermore, there is evidence that apart from LDL-C lowering, statin therapy provides other clinical benefits, referred as pleiotropic effects, which can be beneficial early after an ACS, including enhancement of plaque stabilisation, improvement of endothelial function, anti-inflammatory effects and decreased thrombogenicity. Despite this, epidemiological studies in USA suggest that a large proportion of patients with ACS did not receive high intensity statins.

Aim and Objectives The goal of the current study is to evaluate the prescribing trends of high intensity statin treatment early in the post-ACS course in hospitalised patients in Greece.

Material and Methods We conducted a multicentre retrospective study of patients who had experienced an ACS event during the period between January 2012 and December 2016 in four hospitals in Greece. The International Statistical Classification of Diseases and Related Health Problems – Tenth Revision – Clinical Modification (ICD-10-CM) was used to identify ACS events in the electronic inpatient medical records. Demographics, baseline lipid levels, statin dosage regimens, days of hospitalisation and in-hospital mortality were recorded.

Results Among 2,708 patients meeting the inclusion criteria, 41.8% received high-, 37.2% moderate-, and only 0.2% low-intensity therapy, while 19.8% did not receive any statins. Out of the high-intensity regimens, atorvastatin 40 mg was the most common regimen prescribed followed by rosuvastatin 20 mg. Only 29.9% of patients aged >75 received intensive regimens, while the percentage for patients aged ≤75 was 46.9%. A significant correlation ($p<0.05$) was found between the decision to prescribe a statin and the mean baseline LDL-cholesterol level.

Conclusion and Relevance The majority of ACS patients in the four Greek Hospitals included in the study did not receive high-intensity statins, but the percentage who did receive these drugs was higher than that reported in other similar studies in the USA. Adherence to recommended guidelines for statins should be encouraged within the health system in order to optimise the utilisation of these lipid-lowering agents and reduce the risk of recurrent cardiovascular events in ACS patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-041 SILENCE SPEAKS LOUDER THAN WORDS: OMISSION OF PRESCRIPTION IN THE EMERGENCY ROOM

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Background and Importance Medicines reconciliation is the process of accurately listing a person's current medicines. This is recommended when admitted into a service or treatment changes. The Emergency Room (ER) is one way from primary health care to secondary and tertiary; as such, medicine reconciliation plays a critical role. Electronic prescription allows the tracking of prescriptions during the admission of patients to the ER.

Aim and Objectives This project aimed to assess the current situation regarding medicines reconciliation during ER admission and to estimate the degree of electronic prescription omission in the ER.

Material and Methods

One hundred patients were registered The exclusion criteria was discharge time inferior to 4 hours after admission.

Over 10 consecutive work days, 10 patients were chosen every day in the following manner: The five most recent patients admitted to the ER during the night shift (0–8 am) and the first five patients admitted during the morning shift (8 am to 3 pm).

Current medicines for each patient were obtained from electronic records prior to admission, current medical visit and, in case of doubt, direct patient interview.

Sex, age and omission between electronic prescription in the ER and each patient's current medicines were registered.

Omissions were considered justified when omitted medicine was the reason to visit the ER, acute clinical situations made the medicine contraindicated, and there was a significant interaction (level D or X) between the omitted medicine and any medicine or process indicated during the admission.

Omitted medicines were sorted out by ATC group of active principle.

Results Among the 100 patients, 47 were women, and 53 were men. Age was 66.5 ± 21.4 years.

Out of 100 patients, 71 had errors in their electronic prescriptions, resulting in 121 omissions. Of these omissions, 61 (50.4%) were classified as unjustified. Medicines fell into ATC groups by C (41%, 25), N (27.9%, 17), B (11.5%, 7), S (9.8%, 6), R (4.9%, 3), A (3.3%, 2) and J (1.6%, 1).

Conclusion and Relevance Omissions of prescriptions, particularly for cardiovascular and nervous system medications, are common in our hospital's ER. This issue must be addressed as it may result in negative clinical outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-042 OVERDOSE OF DARBEPOETIN IN PATIENTS WITH CHRONIC KIDNEY FAILURE. ROOM FOR IMPROVEMENT WITH PHARMACIST INTERVENTIONS

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Background and Importance Darbepoetin is used to treat symptomatic anaemia associated with chronic kidney failure (CKD) and to increase haemoglobin concentration to a level no higher than 12 g/dl.

Patients should be closely monitored to ensure that the lowest authorised effective dose of darbepoetin adequately controls the anemia-related symptoms while maintaining a haemoglobin concentration below or equal to 12 g/dl.

Aim and Objectives To improve the safety of darbepoetin treatment, this study aimed to identify patients with CKD and haemoglobin levels exceeding 12g/dl.

Material and Methods An observational, descriptive, and retrospective study was conducted to analyse CKD patients who received treatment with darbepoetin from January 2022 to August 2023.

Data collected included gender, date of birth, darbepoetin dosage in mcg, and haemoglobin value in g/dl.

For this study, we retrieve the data from Electronic Health Records (HER).

Results During the analysed period, darbepoetin treatment was administered to 567 CKD patients, 56% were man with a median age of 72, and 129/567 (22.7%) had haemoglobin levels above 12 g/dl.

Among these 129 patients, 86 (66.7%) had a haemoglobin value between 12 and 13.9 g/dl, 15 (11.6%) patients between 14 and 15.9 g/dl, and 2 (1.5%) patients had a haemoglobin value higher than 16 g/dl.

Furthermore, 5 (3.8%) patients with high haemoglobin values still received a dose of darbepoetin higher than 100 mcg.

Conclusion and Relevance According to the product information document, there is room to improve the safety of darbepoetin treatments as many patients continue treatment with darbepoetin even when the target haemoglobin level has been reached.

It is crucial to closely monitor patients starting darbepoetin treatment and adjust doses to achieve the desired haemoglobin level safely.

When patients pick up their medication from the hospital pharmacy, analytical haemoglobin values must be checked, and the attending pharmacists can communicate with nephrologists if patients do not fulfill the treatment criteria for darbepoetin.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-043 EFFICACY AND SAFETY OF ANTI-CALCITONIN GENE-RELATED PEPTIDE MONOCLONAL ANTIBODIES FOR MIGRAINE PROPHYLAXIS: ONE-YEAR REAL-LIFE EXPERIENCE

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Background and Importance Clinical manifestations of migraine compromise patient's quality of life (QoL). Randomised studies showed monoclonal antibodies against calcitonin gene-related peptide (AM-anti-CGRP) reduce frequency and intensity of migraine episodes but there is still lack of real-life effectiveness and safety data in some clinical scenarios.

Aim and Objectives Assess the one-year efficacy and safety of AM-anti-CGRP in those patients' refractory to other prophylactic treatments through clinical pharmacist assessment.

Material and Methods Observational and retrospective study including patients with chronic migraine (CM) or episodic migraine (EM) who started treatment with AM-anti-CGRP between March 2020 and March 2022 completing one-year treatment.

Pharmacotherapeutic follow-up was performed together with the Neurology team. Sex, age, type of migraine and number of previous treatments were collected. Migraine days per month (MDM) and QoL scale (HIT-6) was assessed at baseline, 6- and 12-months follow-up. Treatment response was considered if there was an improvement of 50% MDM at 6 months or ≥30% of HIT-6 at one year. Drug adverse effects that conditioned treatment continuation were assessed.

Results 42 patients were included (CM=29; EM=13), 69% female, mean age 44.6±9.9 years. 51 treatments were recorded (22 erenumab, 23 galcanezumab, 6 fremanezumab). Patients received a mean of 6±1.6 (erenumab group), 5.4±1.4 (galcanezumab group) and 6.2±1.5 (fremanezumab group) prior treatments.

Mean±SD baseline MDM and median (range) HIT-6 values were: 17.6±8.0 and 67(52–74) (erenumab group), 20.7±7.7 and 68(53–78) (galcanezumab group) and 20.8± 8.7 and 70 (52–72) (fremanezumab group) days.

Mean±SD MDM values at 6- and 12-month follow-up were: 6.4±4.6 and 6.2±4.5 (erenumab), 10.7±8.2 and 10.3 ±7.7 (galcanezumab) and 6.7±0.6 and 7.5±2.1 (fremanezumab).

Median (range) HIT-6 values at 6- and 12-month follow-up were: 58.5(44–78) and 53(44–74) (erenumab), 62(46–78) and 65(54–76) (galcanezumab) and 62(46–78) and 65(54–76) (fremanezumab).

14 (63.6%), 15 (65.2%) and 3 (50%) of patients, responded to erenumab, galcanezumab and fremanezumab, respectively.

3 patients discontinued treatment due to adverse effects (n=2 erenumab-group, n=1 fremanezumab-group).

Conclusion and Relevance High responses rates ≥50% were observed in the three groups, higher in the galcanezumab group although conclusions limited due to small sample. Results show treatments were safe and well-tolerated, with only 5.88% treatment discontinuations due to adverse effects. Multidisciplinary follow-up including clinical pharmacist assessment could help optimising treatment response and safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-044 PRE-EXPOSURE PROPHYLAXIS DROP-OUT: FOLLOW-UP AND RELINKING THROUGH TELEPHONE CONTACT

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Background and Importance Pre-exposure prophylaxis (PrEP) is an effective HIV prevention strategy for people at high risk of infection. Long-term adherence to PrEP program in our health care setting is unknown.

Aim and Objectives To identify users who dropped out PrEP and to evaluate the usefulness of telephone contact for recapturing, through a multidisciplinary strategy (Infectious Diseases-Pharmacy).

Material and Methods Transversal study on a cohort of PrEP users (April 2022-July 2023). Potential users without drug dispensing in the last three-months were identified. Clinical histories were reviewed to determine 'true treatment discontinuations' (TTD). Those patients were contacted by telephone to offer relinking. Statistical analysis: values were expressed as medians (interquartile range-IQR) and patients (percentages).

Results Follow-up in 292 users: 47 (16%) potential dropouts, 23 (7.9%) TTD. The remaining 24: 15 cases were suitable discontinuations, 1 unsuitable discontinuation, 3 used PrEP on demand without requiring standard dispensing, 1 was transferred to another hospital and 4 were awaiting dispensation.

Abstract 4CPS-044 Table 1 Characteristics of 23 TTD

		N (%)/median (IQR)
Gender	Cis man	23 (100)
Age		33.6 (29.5–39.7)
Origin	Spain Latin-America Europe/Western	12 (52.2) 8 (34.8) 3 (12)
Medical history	Psychiatrists Smoker Alcohol Non-sexual drugs Chemsex Three-month sessions Slamsex	6 (26.1) 11 (47.8) 16 (69.6) 16 (69.6) 6 (26.1) 2.5 (5) 2 (8.7)
Previous sexually transmitted infection (STI)	Syphilis MonkeyPox	8 (34.8) 1 (4.3)
% preservative		65 (52)
Couples/month		6.5 (4.3–11.5)
Previous PrEP		6 (26.1)
Previous post-exposure prophylaxis (PEP) Number of PEPs		13 (56.5) 1 (0–2)
Baseline tests	VIH Hepatitis B virus Hepatitis C virus *Neisseria gonorrhoeae Chlamydia trachomatis* Lymphogranuloma venereum *Mycoplasma genitalium* Syphilis	0 0 0 1 (4.3) 0 0 2 (8.7) 0
N° users/month		3.9 (2.8–6.0)
Medical revisions		1 (0–2)
Reason for loss of tracking	Discontinuation Ending risky behaviour Transfer Missed appointment Others	14 (60.9) 1 (4.3) 3 (13) 4 (17.4) 1 (1)
Relinked patients		8 (34.8)

Conclusion and Relevance Adherence to PrEP program is a healthcare challenge. Users showed high risk of HIV and STI transmission, and PrEP drop-out could lead to new avoidable HIV infections. Telephone contact could be insufficient to guarantee continuity in this program. The collaboration of Infectious Diseases and Pharmacy Department ensures communication with these users and retention in this program.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-045 OPTIMISATION OF OMALIZUMAB FOR SEVERE ALLERGIC ASTHMA IN PAEDIATRIC POPULATION

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Background and Importance Omalizumab is indicated in children aged 6 years and older as adjunctive therapy to improve the control of uncontrolled severe allergic asthma (SAA).

Aim and Objectives To assess the effectiveness of omalizumab optimisation in paediatric patients with SAA.

Material and Methods Retrospective descriptive study including all paediatric patients who received omalizumab for the treatment of SAA. The initial dose of omalizumab was determined according to IgE levels (IU/mL) and body weight (Kg). Optimisation strategies: reduction of the dose received while maintaining the administration interval or maintaining the dose and increasing the administration interval, until discontinuation if possible. The following variables were recorded: sex, age, initial dose, optimisations, treatment time to optimisation and treatment discontinuation. Effectiveness was measured as the maintenance of stable disease after optimisation. Safety was assessed by adverse reactions (AR).

Results Thirty-eight patients, 25 males, with a median age of 10 (6–13) years were included. 22 patients started treatment every 4 weeks (Q4W) and 16 patients every 2 weeks (Q2W). The median duration of treatment with omalizumab was 59 (3–96) months. Thirty-six patients underwent treatment optimisations. The median time from omalizumab initiation to optimisation was 36 (12–84) months. The number of optimisations performed were: 1 (n=14), 2 (n=5), ≥3 (n=8). 26 patients achieved treatment discontinuation due to disease stability, 9 of them without prior optimisation. Since treatment optimisation, 10 patients experienced loss of asthma stability due to exacerbation of the disease, 3 of them resumed the previously used regimen. All of them subsequently achieved asthma stabilisation. Six patients had some AR: four had headaches, one had weight gain and one had flu-like syndrome.

Conclusion and Relevance Omalizumab optimisation guidelines in patients with allergic asthma with stable disease have been effective in most patients, achieving drug withdrawal in more than half of the patients. This omalizumab optimisation strategy could reduce the risk of AR of omalizumab in children and helps to decrease the costs associated with the drug.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-046 EVALUATION OF HEALTH IMPACT IN INFLIXIMAB-TREATED PATIENTS WITH INFLAMMATORY BOWEL DISEASE: INCORPORATION OF PATIENT REPORTED OUTCOME MEASURES (PROMS)

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Background and Importance Anti-TNF-alpha therapy, such as infliximab, is the initial choice among biologic treatments for inflammatory bowel disease (IBD) when conventional therapies fail. IBD can impacts patient's life quality. Therefore, integrate Patient Reported Outcome Measures (PROMs) offers a valuable approach to monitor ttreatment from the patient's perspective.

Aim and Objectives Assess disease impact in infliximab-treated patients affected with IBDs using PROMs.

Material and Methods Cross-sectional study. Patients were included if they were outpatients treated with infliximab for ulcerative colitis(UC) and Crohn's disease(CD), ≥18 years. Socio-demographic and clinical characteristics were collected from clinical records: age, gender, type of IBD, starting date of biological treatment, health status, previous biological treatment, concomitant immunosuppressive treatment. To determine health status, we used Harvey-Bradshaw Index (HBI) for CD and Partial Mayo Score Index (PMSI) for UC. Clinical pharmacists performed 2 questionnaires to evaluate PROMs at outpatient facilties: IBDControl (IBD-Control-8-score plus visual analogue scale (VAS), that range from 0–16 and 0–100, respectively, higher scores representing better disease control) and IBD-Disk (that ranges from 0–100, higher score representing higher IBD daily-life burden).

Results 51 patients with CD and 20 with UC were included (mean age 44.4±13.5, 63.4% men).

The mean number of patients previously treated with biologic agents in CD and UC was 13.7% and 35%, respectively. In both groups the majority of patients were treated >6 months with their current biological agent (CD: 50, UC:19). Patients took concomitant treatment with oral immunosuppressants in 80.4% in CD and 65% in UC.

Health status by HBI in CD-group was: 43 remission-state, 5 mild-disease, 2 moderate-disease and 1 severe-disease. According to questionnaires: mean IBD-Control-8-score and VAS-score was 11.9±4.2 and 82±21.4, respectively. Mean IBD-Disk score was 33.6±27.4 (70.6% of patients <50 points).

Health status according to PMSI in UC-group was: 16 remission-state, 2 mild-disease and 2 moderate-disease. According to questionnaires: mean IBD-Control-8-score and VAS-scores was 12.6±4 and 90.1±20.3, respectively. Mean IBD-Disk score was 37.3±27.5 (60% of patients <50 points).

Conclusion and Relevance The results show that most patients in both groups were in remission as reflected in the IBD-Control-8 and VAS scores. IBD-DISK shows moderate daily life impact, with ≥60% scoring <50. Therefore, PROMs are useful tools and could be included within pharmaceutical practice strategies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-047 EVALUATION OF ANTIRESORPTIVE AGENT-RELATED OSTEONECROSIS THERAPY BY MEASURING CONCENTRATIONS OF PENICILLIN G IN JAWBONE

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Background and Importance Antiresorptive agent-related osteonecrosis of the jawbone (ARONJ) is a severe complication after therapy with bisphosphonates or denosumab. The current ARONJ guideline by the German Dental and German Oral and Maxillofacial Associations states the administration of systemic antibiotics intended as an adjunct to surgery to be obligatory in all operative ARONJ treatment. Penicillin-based antibiotics (alone or in combination with beta-lactamase inhibitors or metronidazole) are the agents administered most frequently. Knowledge of the achievable antibiotic concentrations is important specially as the efficacy of antibiotic treatment depends significantly on the penetration to the infection site.

Aim and Objectives The aim of this study was to obtain qualitative and quantitative data on penicillin G concentrations in bone affected by ARONJ following intravenous administration and get comparable results to other concentrations measured with the same extraction method.

Material and Methods Samples of necrotic bone and pre- and intraoperative blood samples were obtained at 18 to 72 min after completion of a single perioperative infusion with 10 million IU (6000 mg) of penicillin G from a total of 19 patients meeting all inclusion criteria. The bone samples were extracted with phosphate buffer solution in a proportion of 1:10 as in the comparative studies. After deproteinisation with acetonitrile, we used LC-MS (q-TOF) to analyse the bone extracts and the serum samples. To evaluate minimum inhibitory concentrations in µg/ml the bone concentrations (µg/g) were multiplied by 1.5.

Results As expected, the values of the bone concentrations were lower than comparable results reported for healthy jawbone (median concentrations 2.7µg/g vs. 17.4µg/g). The calculated bone concentrations in µg/ml were: 14 samples > 1µg/mL, 2 samples > 0,1µg/mL and 3 samples < 0,1µg/mL. With regard to bacteria commonly found in bone affected by ARONJ, the minimum inhibitory concentrations (MIC/MIC90) values for penicillin G were mostly exceeded. The median intraoperative serum concentration was 116µg/mL.

Conclusion and Relevance The conventional analytical method, developed in the hospital pharmacy led to comparable results and was relevant to evaluate the preoperative infusion of penicillin G. As oral administration of antibiotics is common in clinical practice, a similar study might be carried out focusing on antibiotics administered orally.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-048 A COMPLEX, ADHERENCE-IMPROVING PHARMACIST INTERVENTION TO REDUCE HYPERPHOSPHATEMIA IN HEMODIALYSIS PATIENTS

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Background and Importance Suboptimal treatment adherence to phosphate-binding drugs frequently occurs in hemodialysis patients, mostly because of a high pill burden and a complex treatment schedule. Several pharmacist interventions have been developed to improve adherence to phosphate-binding drugs, often with minor effects on adherence and phosphate concentrations.

Aim and Objectives We designed a complex, adherence-improving pharmacist intervention in which barriers to adherence are discussed, combined with a dose reduction of phosphate-binding drugs with the aim to increase adherence and thereby reduce phosphate concentrations.

Material and Methods We performed a prospective, single-centre intervention study in 69 hemodialysis patients with hyperphosphatemia and a high pill burden of phosphate-binding drugs. The complex, adherence-improving intervention consisted of three pharmacist-patient consultations at baseline, at 1–2 weeks, and at 3 months. At baseline the Quick Barrier Scan (QBS), to investigate barriers to adherence, and MARS-5 (Medication Adherence Report Scale 5, patient-reported adherence), were administered. At 1–2 weeks, the pharmacist provided patient recommendations based on the QBS, plus a dose reduction for phosphate-binding drugs. After three months, patient experiences were discussed, and MARS-5 was repeated. The primary outcome parameter was the mean phosphate concentration in the three months after start of the intervention versus the three months before. Secondary outcome parameters were pill burden for phosphate-binding drugs and patient-reported adherence (MARS-5) at baseline and after three months. Data were analysed with SPSS version 28.0, a paired T-test was used to compare phosphate concentrations and pill burden, the Wilcoxon signed rank test was used to compare MARS-5.

Results The mean (±SD) phosphate concentration did not change (1.99±0.38 mmol/L before versus 2.04±0.35 mmol/L after, p=0.193). Mean daily phosphate-binder pill burden decreased from 8.6±3.1 to 5.7±2.7 units (p<0.001). Patient-reported adherence increased, although the median adherence did not change (24 IQR 22–25, before, versus 24 IQR 23.25–25 after, p=0.008).

Conclusion and Relevance Although the intervention did not reduce phosphate concentrations, a major reduction in phosphate-binder pill burden was achieved, which implies a more effective use of the phosphate-binding drugs. This complex, adherence-improving intervention seems promising in decreasing pill burden and improving adherence, but our results need to be confirmed in larger, controlled studies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-049 TREATMENT OF ROSAI DORFMAN'S HISTIOCYTOSIS: CASE REPORT

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Background and Importance Rosai Dorfman disease (DRD) is a rare non-Langerhans histiocytosis. There is no established treatment, and if necessary there are few therapeutic options which have limited evidence. DRD has recently been related to the identification of mutations in the mitogenic activation protein kinase (MAPK)-dependent signaling pathway, being an interesting target for its treatment.
Aim and Objectives This report will discuss the case of a patient with DRD who responded adequately to targeted therapy with trametinib, after failure to several lines of treatment.
Material and Methods The episodes in oncohematology day hospital of patients diagnosed in a tertiary University Hospital are reviewed. A bibliographic review of cases described with similar symptoms was carried out. The Pharmacy Service collaborated in the search for a possible effective treatment and justified the need to start treatment with a MEK inhibitor.
Results 45-year-old patient being followed up for gastrointestinal episodes and lymphadenopathy who was diagnosed with histiocytosis compatible with DRD in 2021.It was started treatment with corticosteroids at a dose of 1 mg/kg, which in the event of refractoriness was changed to peginterferon alfa (90 mcg) without response. At the beginning of March 2023, he was admitted to the ward due to deep vein thrombosis and pulmonary thromboembolism. He received a new treatment regimen with anakinra for 13 days without success. The case is consulted and it is decided to change to a MEK inhibitor. Its use is requested outside of indication despite not obtaining any alteration in the MAPK pathway. Trametinib was started at a dose of 1 mg/day. After 3 months, she currently has good tolerance with platelet counts of 37,000 and decreased lymphadenopathy. As toxicity to trametinib, acneiform rash have been reported.
Conclusion and Relevance There is no well-defined protocol for the treatment of DRD and therefore they represent a diagnostic and therapeutic challenge. This case contributes to the limited data published on targeted therapy with MEK inhibitors in DRD when cases are refractory to traditional therapies.

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Conflict of Interest No conflict of interest.

4CPS-050 PRE-EXPOSURE PROPHYLAXIS FOR HIV INFECTION: PREVALENCE OF SEXUALLY TRANSMITTED INFECTIONS (STIS) AND ADHERENCE DURING THE PROGRAMME

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Background and Importance Pre-exposure prophylaxis (PrEP) is a preventive measure to avoid HIV infection. The European Medicines Agency approved the guideline of an already marketed antiretroviral drug, Emtricitabine + Tenofovir disoproxil fumarate, for once-daily use, which, combined with other prevention and education measures, aims to decrease the transmission of this disease. This programme was implemented in our hospital in November 2021.
Aim and Objectives To analyse adherence to treatment and the occurrence of STIs in patients included in PrEP.
Material and Methods Observational, prospective, single-centre study. Inclusion criteria: subjects who met the criteria for PrEP program funding, from January 2022 to March 2023 in a tertiary level hospital. The variables collected were adherence and STI occurrence before subjects' inclusion in the program and those detected during programme participation. Adherence to treatment was estimated through the Simplified Medication Adherence Questionnaire (SMAQ) and dispensing records (DR).
Results 50 candidates were included in the study with a mean age of 39 years (range: 23–68). At the beginning, 18 subjects (36%) showed at least one sexually transmitted infection: 6/18 (33%) *Ureaplasma urealyticum*, 3/18 (17%), *Neisseria gonorrhoeae*, 3/18 (17%), *Chlamydia trachomatis*, 3/18 (17%) *Mycoplasma genitalium*, 2/18 (11%) *Haemophilus* and 1/18 (5%) *Treponema Pallidum*, while at quarterly control at least one STI was detected in 22 (44%) of subjects: 6/22 (27%) *Chlamydia trachomatis*, 4/22 (18%) *Neisseria gonorrhoeae*, 4/22 (18%) *Haemophilus*, 3/22 (14%) *Streptococcus agalactiae*, 2/22 (9%) *Ureaplasma urealyticum*,2/22 (9%) *Mycoplasma genitalium* and 1/22 (5%) *Treponema Pallidum*. Adherence to treatment by evaluation with the SMAQ and RD questionnaire was 96% and 92% respectively.
Conclusion and Relevance In our study we observed an increase in STIs after the inclusion of subjects in this programme, due to sexual risk compensation. However, this programme has boosted the increase of STI screening tests and more STIs can be diagnosed and treated. Regarding adherence, in our study we obtained high adherence rates measured by two methods (SMAQ and DR).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-051 COST SAVING IMPACT OF BIOSIMILAR TRASTUZUMAB FOR THE TREATMENT OF HER-2 POSITIVE BREAST CANCER IN A HOSPITAL

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Background and Importance The ongoing rise in healthcare costs makes it necessary to establish containment strategies, in parallel with the commitment to improve access to the most effective andsafest treatments. In this sense, it is postulated that the availability of the biosimilar trastuzumab offers cost savings compared to the innovator, which could lead patients to switch drugs, maintaining efficacy while decreasing the cost of HER-2 positive breast cancer treatment.
Aim and Objectives The aim of this study was to evaluate the cost saving impact of the introduction of biosimilar trastuzumab in the treatment of HER-2 positive breast cancer in a tertiary hospital.
Material and Methods Observational, retrospective study of patients treated with biosimilar trastuzumab between January 2022 and December 2022 in a tertiary hospital.
Variables collected demographics (sex and age), number of patients, stage (early stage, locally advanced or metastatic) and economic (price of original trastuzumab and biosimilar trastuzumab).
Variables analysed economic savings, estimated number of patients who could benefit from treatment based on the savings achieved.
Results 59 patients included between January and December 2022 with a median age of 54.7+/-12.27. 42.4% (n=25) had an early stage, 23.7% (n=14) locally advanced and 33.9% (n=20) metastatic.

In our hospital, the price of one biosimilar-trastuzumab-420mg vial is € 130 (0.31 €/mg) and € 414.4 for 1 original-trastuzumab-150mg vial (2.76 €/mg). Treatment of our patients with biosimilar trastuzumab cost a total of € 66,011.4. If these patients had been treated with the original trastuzumab, the cost would have been € 587,714.4, a saving of 88.7% (€ 521,703).

If the average weight of a 54-year-old woman in Spain is about 70–75 kg according to the Statistics National Institute, the saving of € 587,714.4 (1,895,852.9mg) would allow the 18-cycle finite treatment between 229 and 246 women with early-stage breast cancer.
Conclusion and Relevance Innovation in biological therapies, as well as the increase in candidates to receive them, has grown significantly. It is associated with an increase in costs that may become unaffordable for public Health Service. The inclusion of biosimilar drugs in breast cancer represents a significant economic saving in the treatment of breast cancer, while contributing to maintaining the sustainability of the national health system.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.
Conflict of Interest No conflict of interest.

4CPS-052 EVALUATION OF USTEKINUMAB USE IN INFLAMMATORY BOWEL DISEASES

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Background and Importance Ustekinumab is a monoclonal antibody used in inflammatory diseases like Crohn´s disease(CD) and ulcerative colitis(UC). Sometimes, an intensification of its dosage is necessary to achieve the goal.
Aim and Objectives The objective is to know the dosage usually used in our patients compared to that indicated in the label, and the economic impact when an intensified dosage is used.
Material and Methods Retrospective, observational study. Patients with inflammatory bowel disease(IBD) treated with Ustekinumab from January 2022 to March 2023. The variables collected were age, sex, weight, indication, dosage(induction and maintenance regimen) and prior biological treatments. The data was obtained through Orion Clinic® and FarmisOncofarm®. The economic data were obtained using Orion Logis®.
Results 39 patients treated with Ustekinumab were analysed, being 59%(23) men. The median age was 54 years and the average weight was 67 kg. The indication for which Ustekinumab was prescribed: CD in 82%(32) and UC in 18%(7). Regarding previous treatments with biological drugs, 82%(32) had been treated with a single biological drug, while 18%(7) had used two previous lines of treatment. In all cases, the intravenous induction regimen was in accordance with the label according to weight range: 9 patients were 260 mg(≤ 55 kg), 24 received 390 mg(>55 kg to ≤ 85 kg), and 6 patients 520 mg(>85 kg). Regarding the maintenance regimen, 49% (19) of the patients continued with the dosage established in the label(90 mg subcutaneous (sc) every 8 weeks). In the remainder, corresponding to 51%(20), the dosage regimen was intensified mainly due to clinical criteria: 3%(1) continued with 90 mg sc/6 weeks, 3%(1) with 40 mg sc/4 weeks, 41% (16) in treatment with 130 mg IV/monthly, and 5%(2) with 130 mg IV/15 days. The average cost of the treatment the first year in patients who use the dosage of the label is 20148€, whereas the average cost in intensified dosage is 38533€.
Conclusion and Relevance In half of the patients, the maintenance dosage was off label, requiring changes in both the dosage regimen and the route of administration to achieve the clinical objectives, highlighting the need of individualisation. In addition, the intensification dosage involves a financial cost of almost twice as much.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-053 OUTCOMES OF INFRADOSED ANTIMICROBIALS PATIENTS WITH BACTEREMIA IN THE EMERGENCY DEPARTMENT

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Background and Importance Bacteremia is a major cause of sepsis and is associated with high morbidity and mortality. Suboptimal antibiotic dosing in the bacteraemic population has previously been associated with poorer outcomes in the Emergency departments (ED).

Aim and Objectives This study has been designed to analyse clinical outcomes in patients with bacteraemia when receiving suboptimal antibiotic dosing (SAD).

Material and Methods Observational, retrospective cohort study performed in a third-level hospital in Spain. The population studied included patients admitted in an ED with positive blood cultures for true pathogenic microorganisms (November 2021 to June 2022). SAD was defined according to Stanford Severe Sepsis and Septic Shock Antibiotic Guide (2020), except for ceftriaxone, in which we used the recommendation of *Aaron J. Heffernan et al, 2020* (2g/24h). Data were collected on demographics, microorganisms responsible for the infection, focus of infection, antibiotics and doses used and outcomes in terms of 30-day mortality.

Results A total of 442 patients with bacteremia caused by a microorganism susceptible to the antibiotic prescribed in the ED were evaluated (Mean age: 73±15 years, 54% male), being 54 (12%) considered as SAD. From these patients, 24 infections (44%) were caused by *E.coli,* being the main focus the urinary tract (n=29, 54%). The most frequently SAD treatments were beta-lactams (n=35, 65%), followed by carbapenems (n=17, 32%), vancomycin (n=8, 15%) and aminoglycosides (n=5, 9%). Among beta-lactams, ceftriaxone was prescribed in SAD (1g/24h) in 8 patients (22%); within carbapenems, meropenem was usually prescribed (without loading dose) adjusted to kidney impairment in the moment of admission. Patients who received SAD presented a higher 30-mortality than those who received an appropriate dosing (22% vs 7%; p=0.001).

Conclusion and Relevance SAD in bacteraemic patients in the ED is 12%, being associated with higher risk of mortality. Beta-lactams and carbapenems are the most prescribed antibiotics in bacteraemia to cover gram-negative spectrum. A possible explanation for SAD in the ED might be that antibiotics are adjusted according to renal function in the moment of admission. We don't recommend adjusting doses of antibiotics during the first 24–48h of treatment in order to reduce the risk of SAD.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-054 ABSTRACT WITHDRAWN

4CPS-055 PHARMACOGENETICS AND ITS APPLICATIONS IN PERSONALISED MEDICINE: A SYSTEMATIC REVIEW

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Background and Importance Pharmacogenetics evaluates how genetic variations influence drug responses. Nowadays, genetic tests have advanced, become more affordable, and its integration are supported by stronger clinical evidence. Guidelines such as those from CPIC and resources like PharmGKB facilitate genotype-based prescribing. Organisations like the FDA promote genetic testing before initiating certain medications. Preventive pharmacogenetic panels seems promising, but further research on biomarkers and diverse populations is needed.

Aim and Objectives This review examines recent evidence on the genotype-drug response relationship and its application in clinical practice.

Material and Methods A systematic search was conducted on PubMed to identify articles investigating the genotype-drug response relationship. The search strategy included terms such as 'pharmacogenetics,' 'personalised treatment,' 'precision medicine,' 'dose adjustment,' 'individualised dosing,' 'clinical routine,' and 'clinical practice.' Studies such as clinical trials, observational studies, and meta-analyses were included. The initial search yielded a total of 136 articles published between 2013 and 2023 for analysis.

Results 49 articles were included for the final analysis. The characteristics of the articles are explained in table 1.

A relationship between genetic polymorphisms and drug response or toxicity was found for drugs such as opioids, GLP-1 agonists, tacrolimus, oral anticoagulants, oral antineoplastics, atypical antipsychotics, efavirenz, clopidogrel, lamotrigine, anti-TNFα agents, voriconazole, SSRIs, or statins, among others. However, for drugs like metformin, quetiapine, irinotecan, bisoprolol, and anti-VEGF agents, no statistically significant association between genotype and response was found.

Conclusion and Relevance The studies analysed in this review suggest a strong correlation between genetic variability and individual drug responses, supporting the use of pharmacogenetics for treatment optimisation. However, for certain drugs like metformin, quetiapine, etc., the influence of genotype on their response remains unclear. More studies with larger sample sizes, greater ethnic diversity, and consideration of non-genetic factors are needed. Lack of standardisation in analysis methods and accessibility to genetic testing are significant challenges in this field. In summary, pharmacogenetics shows immense potential in personalised medicine, but further research is required.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

Abstract 4CPS-055 Table 1

Table 1. Characteristics of studies

Study	Drug prescribed	Genotype(s) used	Primary outcome result	Study	Drug prescribed	Genotype (s) used	Primary outcome result
Abdelhady *et al.*	Efavirenz	CYP2B6*6*6	↑QTcF interval in *6/*6 carriers. CYP2B6*6*6 ↑EFV exposure.	Lee *et al.* (2018)	Clopidogrel	CYP2C19	Risk for adverse CV events was ↑ in LOF carriers.
Casajus *et al.*	Azathioprine	TPMT NUDT15	NUDT15 PMs/IMs ↑ risk of leukopenia.	Lee *et al.* (2021)	Clopidogrel	CYP2C19	PMs/IMs without *17 ↑risk of major atherothrombotic events.
Castaño-Amores *et al.*	Bisoprolol	ADRB1	ADRB1 Arg389Gly affect response to bisoprolol. Not confirmed with meta-analysis.	Limviphuvadh *et al.*	Gemcitabine	ABCG2 SLC29A3	ABCG2 Q141K CA/AA ↑ PFS and toxicity vs. CC. SLC29A3 S158F CT/TT ↑ OS vs. CC.
Cavallari *et al.* (2018)	Clopidogrel	CYP2C19	↑risk for adverse CV events in CYP2C19 IMs/PMs.	Linares *et al.*	Oxycodone	CYP2D6	Oxycodone concentrations: PM > EM > UM.
Cavallari *et al.* (2022)	Opioids	CYP2D6	CYP2D6 PMs/IMs may attain no relief from some opioids.	Lu *et al.*	Antipsychotics	CYP2D6	UMs and PMs are at increased risk for tardive dyskinesia.
Danese *et al.*	Coumarins	CYP4F2*3	CYP4F2 T allele variation needed ↑coumarin doses	Maagdenberg *et al.*	Acenocouma	VKORC1 CYP2C9 CYP4F2	VKORC1, CYP2C9*2/CYP2C9*3 and CYP3A4*22 ↓ stable dose.
Dapía *et al.*	Voriconazole	CYP2C19 POR CYP2C9	Contribution to interindividual variability of voriconazole AUC: CYP2C19>POR>CYP2C9.	Miroshnichenko *et al.*	Olanzapine	CYP2D6 CYP1A2	Differences were found in olanzapine concentrations in CYP2D6 PMs (G/A) and EMs (G/G).
Davis *et al.*	Cannabidiol	ADK1 SLC15A1	↑ response: ADK1 rs6729738 CC. ↓ response: SLC15A1 rs1339067 TT	Neary *et al.* (2017)	Efavirenz	CYP2B6	CYP2B6 516G>T TT ↑ EFV concentration than GG.
Dawed *et al.*	GLP-1 agonis	ARRB1 GLPR1	GLP1R Gly168Ser and ARRB1 Thr370Met ↓ HbA1c after treatment with GLP-1 agonist.	Neary *et al.* (2019)	Efavirenz	CYP2B6	Efavirenz concentration ↑ in CYP2B6 983 T>C CT vs. TT.
Degorter *et al.*	Statins	SLCO1B1 ABCG2	Rosuvastatin concentration ↑ in SLCO1B1 c.521C and ABCG2 c.421A. Atorvastatin concentrations ↑ with SLCO1B1 c.521C, ↓ with SLCO1B1 c.388G.	Ovejero-Benito *et al.* (2017)	Etanercept	HLA-B MAP3K1 PTTG1	PTTG1 rs2431697 C, HLA-B/MICA rs13437088 T ↑non-responders. MAP3K1 rs96844 C ↑ responders.
Dias *et al.*	Irinotecan	UGT1A1*28	Difference in OS, PFS between UGT1A1*28 genotypes was not statistically significant.	Ovejero-Benito *et al.* (2018)	Infliximab Adalimumab	IVL IL-12B NFKBIA	IVL rs6661932 T and NF-κB G ↑ no response. IL-12B rs2546890 A ↑ response.
Díaz-Villamarín *et al.*	Anti-VEGF	ARMS2 A69S	No statistically significant association between efficacy and ARMS2 A69S.	Packiasabapathy *et al.*	Methadone	CYP2B6	CYP2B6 PMs ↓metabolism vs. NMs. rs4803419 TT ↓ pain scores vs. CC.
Dujic *et al.*	Metformin	SLC22A1 SLC47A1	None of the variants were significantly associated with response.	Peña *et al.*	Imatinib	CYP2B6 CYP3A4	CYP2B6 G516T ↓ imatinib concentration and t1/2. ↓adverse effects in CYP3A4 *22/*22,*1/*20 and *1/*22 vs. *1/*1.
Ebid *et al.*	Tacrolimus	CYP3A4 CYP3A5	Tacrolimus levels ↑ in CYP3A4*22 and CYP3A5*3 than in CYP3A4*1 and CYP3A5*1.	Postmus *et al.*	Pravastatin	OOZ4 DNAJC58	Not significant associations between SNPs and CV event reduction by pravastatin.
El Rouby *et al.*	Warfarin	VKORC1 CYP2C9	CYP2C9 rs4086116 T ↓ weekly warfarin dose vs. CC.	Russman *et al.*	Clopidogrel	CYP2C19	CYP2C19 IMs/PMs associated with ↓ risk of thrombotic events.
Gassó *et al.*	Fluoxetine	TPH2	rs11179002, rs60032326 and rs34517220, associated with ↑ clinical improvement.	Saiz-Rodríguez *et al.*	Clopidogrel	CYP2C19 ABCB1	CYP2C19 IM-PMs ↑ aggregation value. ABCB1 C3435T, C1236T and G2677T/A variants had ↓.
Guillat *et al.*	Apixaban	ABCG2	ABCG2 c.421C > A predictor of ↑ apixaban concentration.	Shilbayeh *et al.*	Quetiapine	CYP3A5 ABCB1	CYP3A5 *1/*1 ↑ clearance vs. *1/*3 y *3/*3.
Guo *et al.*	Warfarin	CYP2C9 VKORC1	CYP4F2*3 associated with ↑warfarin dose requirements.	Soo *et al.*	Capecitabine	TSER	TSER (TYMS enhancer region) 3R/3R ↑ tolerance to capecitabine.
Haas *et al.* (2020)	Efavirenz	CYP2B6	CYP2B6 PMs associated with ↑ plasma efavirenz.	Talamonti *et al.*	Ustekinuma b	HLA-C*6	HLA-C*06 associated with ↑ and faster response.
Haas *et al.* (2021)	Rifapentine Efavirenz	NAT2 CYP2B6	NAT2 PMs ↑rifapentine concentrations. CYP2B6 PMs ↑efavirenz concentration.	Tejpar *et al.*	Irinotecan	UGT1A1	UGT1A*28 7/7 ↑ grade III-IV irinotecan-induced neutropenia.
Ham *et al.*	Benzodiazepi	CYP2C9*2/*3	CYP2C9 *2 or *3 ↑fall risk and non-carriers did not.	Theken *et al.*	NSAIDs	CYP2C9	CYP2C9 IMs/PMs ↑ NSAID exposure and risk of adverse effects.
Kato *et al.*	Fluvoxamine	5-HTTLPR FGF2	5-HTTLPR LA/S' and FGF2 rs1449683C/T associated with HAM-D change.	Thomas *et al.*	Metoprolol	CYP2D6	CYP2D6 AS=1 ↑Cl vs. AS 0. ↑HR reduction with AS 1 vs. AS 2–2.25.
Kim *et al.*	Sunitinib	ABCG2	ABCG2 421 AA associated with toxicity (thrombocytopenia, neutropenia, and HFS).	Wang *et al.*	Azathioprine	TPMT NUDT15	IMs of TPMT have increased risk of azathioprine-induced leukopenia compared with NMs.
Klarica *et al.*	Lamotrigine	ABCG2 421C>A	ABCG2 421C>A ↓ troughs of lamotrigine vs. wild-type.	Xia *et al.*	Warfarin	CYP2C9*3 VKORC1	VKORC1-1639G > A affect the most the initial dose of warfarin. The required stable dose ↑ in GG.
Zhao *et al.*	Tacrolimus	CYP3A5	Tacrolimus Cl ↑ in CYP3A5*1 vs.				

4CPS-056 EFFECTIVENESS AND SAFETY OF ERIBULIN THERAPY IN PATIENTS WITH METASTATIC BREAST CANCER

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Background and Importance Eribulin is one of the therapeutic alternatives for patients with metastatic breast cancer. In clinical practice, its use will depend on the particular characteristics of each patient.

Aim and Objectives To review the treatment used with eribulin in our patients and to analyse the effectiveness and safety achieved.

Material and Methods Retrospective observational study of patients diagnosed with metastatic breast cancer was conducted. Age, dose and eribulin cycles received were recorded. Previous lines of treatment were analysed. Progression-free survival (PFS), overall survival (OS) and safety of eribulin treatment in our patients were evaluated.

Results Forty women diagnosed with her2- metastatic breast cancer during January 2021 until January 2023 were included. The mean age was 60 years (42–80 years). 58% (23/40) received full doses of treatment and 42% (17/40) received reduced doses. The average number of cycles received was 6 cycles (2–19). The mean number of treatments prior to eribulin was 3 treatments(1–6). Eribulin was used in most patients in the fourth line of treatment 58%(23/40),second and third line 20% (8/40), fifth line 15%(6/40),between sixth and eighth lines 20%(8/40).The first line of treatment used was estrogen blockers together with cyclin inhibitors (48%). The second line of treatment was oral capecitabine (45%) and vinorelbine (37%). In the third line capecitabine (18%), vinorelbine (18%), taxol (15%) and liposomal doxorubin (15%).The PFS achieved with eribulin treatment was 6 months(3–20) and the OS was 3 months.(6–2). Eleven (27%) patients were exitus. Grade III adverse reactions described were alopecia (20%), neurotoxicity, neutropenia and pain(2%). Grade II were asthenia, alopecia, mucositis, neurotoxicity and diarrhoea (2%). Grade I bone pain, mucositis, asthenia, increased transaminase levels (10%).

Conclusion and Relevance Eribulin has been able to be used at full doses despite being an advanced line of treatment in multi-treated patients.

Progression-free survival and overall survival achieved is acceptable as a treatment in patients with advanced metastatic disease.

Alopecia is a frequent and important reaction that can condition the choice of treatment in these patients and justifies the use of eribulin in later lines of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-057 EFFECTIVENESS, SAFETY, AND PATIENT-REPORTED OUTCOME OF JANUS KINASE INHIBITORS IN RHEUMATOID ARTHRITIS IN CLINICAL PRACTICE

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Background and Importance Janus kinase inhibitors (iJAK) are emerging as an effective alternative in the treatment of rheumatoid arthritis (AR), with a manageable toxicity profile. Currently, there is a growing emphasis on achieving comprehensive remission that includes patient-reported outcomes (PROs).

Aim and Objectives Assess the effectiveness and safety of iJAK treatment in clinical AR practice.

Analyze the results obtained from specific PROs to AR.

Material and Methods Retrospective descriptive study including patients with AR treated with iJAKs between Febraury 2018-June 2023. Data collected from electronic medical records: sex, age, iJAK treatment, drug persistence, concomitant disease-modifying antirheumatic drugs (DMARDs), treatment regimen, current effectiveness parameters (Disease Activity Score on 28joint counts [DAS28], and Clinical Disease Activity Index [CDAI]), specific PROs (Rheumathoid Arthritis Impact of Disease [RAID] and Routine Assessment of Patient Index Data [RAPID3]), and adverse effects (AE).

Results 34 patients included. Mean age: 58,12 years (SD: 8,21). 91,18% women. 52,94% of patients undergoing treatment with baricitinib, 20,59% upadacitinib, 14,71% filgotinib, 11,76% tofacitinib. Average drug persistence: 26,84 months (SD: 20,00). 32,35% of patients receiving concomitant treatment with DMARDs. Treatment regimen: 35,30% of patients in first-line treatment, 32,35% second/third-line, 32,35% fourth-line/higher. According to DAS28, 44,12% of patients were in remission (DAS28: 2,16; CDAI: 3,21; RAID: 1,62; RAPID3: 4,15), 32,35% low disease activity (DAS28: 2,99; CDAI: 8,09; RAID: 4,24; RAPID3: 10,38), 17,65% moderate activity (DAS28: 3,97; CDAI: 13,42; RAID: 3,93; RAPID3: 11,80), and 5,88% high activity (DAS28: 5,66; CDAI: 20,50; RAID: 5,35; RAPID3: 14,80). 23.52% of patients experienced AE: 8,82% gastrointestinal, 5,88% cardiovascular, 2,94% infectious, 2,94% metabolic disorder, 2,94% headache.

Conclusion and Relevance Nearly half of patients receiving iJAK treatment are in clinical remission, and almost 75% demonstrate favourable outcomes in activity parameters (remission/low activity). Therefore, iJAKs may represent a promising treatment alternative in AR. Parameters of effectiveness align with PROs results. Regarding safety, iJAKs exhibit a manageable and expected safety profile.

Inclusion of PROs in the concept of comprehensive remission in AR provides a more complete perspective of the patient‘s condition. This enables guiding future interventions, such as prioritising patients with poorer AR control or implementing strategies to optimise healthcare management.

The role of the pharmacist is crucial in ensuring treatment efficacy, adherence, and early detection of toxicities.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-058 ANALYSIS OF ANTIFUNGAL CONSUMPTION IN AN INTENSIVE CARE UNIT OVER 5 YEARS

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Background and Importance Fungal infections pose a high cost, both in terms of morbidity and mortality, as well as economically. Antifungal treatments (AF) generally receive less attention and review in Antimicrobial Stewardship Programs (ASP) than antimicrobials. These infections have increased in recent years, primarily due to the rising number of patients with risk factors for invasive fungal infection, such as immunosuppressed patients and those who have received broad-spectrum antibiotic treatments.
Aim and Objectives To analyse the consumption of broad-spectrum antifungals in the Intensive Care Unit (ICU) of our centre over a 5-year period, observe trends, and assess whether the SARS-CoV-2 pandemic has altered their usage.
Material and Methods This is a comparative, retrospective, longitudinal study of the consumption of systemic broad-spectrum antifungals (liposomal amphotericin B, voriconazole, caspofungin, anidulafungin and micafungin) in the ICU of a third-level University Hospital in Spain. DDD and DOT/100 Bed Days were calculated for each AF. Data on treatment duration and the number of episodes with prescribed antifungals were obtained.
Results Over the 5-year study period, a total of 855 admissions were included, generating a cumulative stay of 10,686 days, with AF prescribed in 12 episodes/100 admissions. A consistent distribution pattern was observed, with liposomal amphotericin B (LBL) being the primary prescribed AF (close to 50%), followed by echinocandins (30%), and finally voriconazole (25.3%). The median overall consumption was 39.26 DDD/100B (39.21–65.12) and 9.03 DOT/100B (8.34–10.46). This represented a 42.9% decrease in DDD/100B and a 42.5% decrease in DOT/100B, primarily due to reduced LBL usage, which decreased by 54.3%. Regarding the average duration of each AF cycle, there was a decreasing trend from 12.65 to 9.4 days.
Conclusion and Relevance The consumption of AF in our centre's ICU has significantly decreased during the study period, coupled with a reduction in the average treatment duration. Concerning the most acute phase of the COVID-19 pandemic (2020), there is an increase in AF consumption related to an increase in the number of episodes with AF and overall ICU activity, which decreases in 2021 and 2022.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-059 SEVENTEEN DRUGS, ONE SAMPLE: ANALYSING MULTIPLE ANTI-TUBERCULOSIS DRUGS SIMULTANEOUSLY USING ONE METHOD

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Background and Importance In 2021, a total of 1.6M people died from tuberculosis (TB), although it is a preventable and curable disease. Depending on susceptibility, TB is treated with a combination of several of 20 anti-TB drugs from the World Health Organization (WHO) treatment guidelines. Interindividual variability may result in toxicity or ineffective treatment. Therapeutic drug monitoring (TDM) can be used to optimise dosing and treatment. However, several analyses may be needed, which is time consuming, expensive, and may result in needing multiple samples from a patient.
Aim and Objectives Therefore, we aimed to develop a simple method to analyse all anti-TB drugs in one analysis.
Material and Methods We developed a liquid chromatography tandem mass spectrometry (LC-MS/MS) method in plasma, serum or saliva, allowing simultaneous analysis of 17 anti-TB drugs and 6 metabolites. The runtime of any combination of these 17 drugs only takes 1.7 minutes. We checked all standard parameters assuring the quality of our analysis and checked the expiry of the samples at different temperatures, allowing extrapolation to low-income countries.
Results With this method, we are able to analyse all first-line and most second-line anti-TB drugs, if processed immediately (e.g. pretomanid, delamanid, levofloxacin, moxifloxacin, gatifloxacin, bedaquiline, linezolid, tedizolid, clofazimine, ethionamide, prothionamide, rifapentine, and rifabutin) using a method that was validated according to the EMA Guidance.
Conclusion and Relevance In conclusion, we developed a method to analyse 17 anti-TB drugs simultaneously in one sample of plasma, serum or saliva: all first-line, BPaLM (bedaquiline, pretomanid, linezolid, and moxifloxacin), and 9m all oral regimen for multidrug-resistant/rifampicin resistant (MDR/RR-TB) drugs, and 63% of the longer MDR-TB regimen drugs. This method will save time and will further optimise therapeutic drug monitoring.

REFERENCES AND/OR ACKNOWLEDGEMENTS
N/A
Conflict of Interest No conflict of interest.

4CPS-060 IMPACT OF OBESITY ON VANCOMYCIN PHARMACOKINETIC PARAMETERS IN ADULT PATIENTS

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Background and Importance Information regarding the impact of obesity on the pharmacokinetics of most drugs is limited. Obesity is associated with physiopathological changes that may affect the pharmacokinetics of vancomycin. Therefore, there is a need for pharmacokinetic models specific to the obese population to optimise dosing schedules in this group of patients.
Aim and Objectives To determine the differences in pharmacokinetic parameters (PKP) in hospitalised obese patients.
Material and Methods Retrospective observational study including adult patients who had a plasmatic concentration of vancomycin between March 2022 and August 2023. Critically ill patients and those with renal failure were excluded. Demographic variables collected were: sex, age, weight, height, body mass index (BMI), PKP (volume of distribution (Vc), stade state volume of distribution (Vss), clearance (Cl), half-life ($t_{1/2}$)), peak (Cmax) and through (Cmin) level, start date of vancomycin treatment and sample collection date. Patients were grouped according to BMI: obese (BMI $\geq$30 kg/m^2) and non-obese (BMI <30 kg/m^2). All data were collected from electronic health records and pharmacokinetic reports. This report includes the PKP calculated using a pharmacokinetic

programme (PKS®), based on a bicompartimental model. Data were analyced by SPSS statistics 21®. Qualitative variables were presented by frecuency and quantitative variables by mean ± standard deviation and median (interquartile range). T-student and U-Mann-Whitney were used to compare parametric and non-parametric variables.

Results 57 patients (63.2% men) with a mean age of 67.3 ±12.8 years. 17.5% were obese. The pharmacokinetic data in the obese group were: Cmin=10±7.7 mg/L, Cmax=39.3± 28.1 mg/L, Vc=19.8 (19–23.4) L, Vss=74.6±19.8 L, Cl=5 ±2.4 L/h, $t_{1/2}$=11.4 (7.5–15.2) h. The pharmacokinetic data in the non-obese group were: Cmin=12 (9–16.7) mg/L, Cmax=24.7±7.2 mg/L, Vc=14.4±2.3 L, Vss=49.1±8.8 L, Clp=4 (3.25–4.59) L/h, $t_{1/2}$=9.6 (8.1–12.1) h. Statistically significant differences were only found between both groups in Vc ($p<0.05$) and Vss ($p<0.05$).

Conclusion and Relevance The volume of distribution (Vc and Vss) in obese patients is higher than in non-obese patients, with significant differences being found. For the rest of pharmacokinetic data, no significant differences were found. It is necessary to carry out studies that allow designing a pharmacokinetic model of vancomycin in obese patients in order to optimise treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-061 SAFETY AND EFFECTIVENESS OF THE OFF-LABEL USE OF CANGRELOR IN PERIOPERATIVE BRIDGING: A CASE SERIES

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Background and Importance Cangrelor has been proposed for the off-label indication of antiplatelet bridging prior to surgery in patients at high risk for thrombotic complications in urgent or non-delayable surgery or procedure, particularly in those who have had recent coronary stenting and are therefore at higher risk for subacute stent thrombosis.

Aim and Objectives To determine the safety and effectiveness of cangrelor bridging therapy for patients undergoing urgent invasive procedures.

Material and Methods Retrospective observational study that included all patients who received cangrelor for off-label bridging purposes from January 2022 and June 2023 in a tertiary hospital.

Demographic, clinical and those variables related with the treatment were captured from pharmacy and medical electronic records.

Related to efficacy, we report in-hospital mortality and thrombotic events, including stroke and myocardial infarction, during 30 days after cangrelor administration. Related to safety, bleeding was only considered associated with cangrelor if it occurred during administration or up to 48 hours after discontinuation according to Bleeding Academic Research Consortium (BARC) 3–5.

Results Seven patients were identified (100% male; median age 71 years (interquartile range: 59–79)). All of them had coronary arterial stenting within the previous 1 month. The rest of patient and treatment characteristics can be found at the table 1.

No patient in the study developed in-stent thrombosis or other thrombotic complication while receiving cangrelor neither withing 30 days of stopping therapy. No patient experienced clinically relevant bleeding according to BARC.

Conclusion and Relevance This study of patients receiving cangrelor as short-term antiplatelet therapy prior to surgical procedures with history of coronary stent placement demonstrated that a low dose of 0,75 mcg/kg/min provided adequate effectiveness and safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-062 POSITIVE IMPACT OF EXTENDING NATALIZUMAB DOSAGE INTERVAL FROM EVERY 4 WEEKS TO EVERY 6 WEEKS IN MULTIPLE SCLEROSIS PATIENTS

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Background and Importance Natalizumab (NTZ) is a monoclonal antibody which targets a protein called α4β1 integrin on white blood cells involved in inflammation that has demonstrated remarkable efficacy in reducing relapse rates and disability progression in relapsing-remitting multiple sclerosis (RRMS). The main risk of treatment with NTZ is the possibility of developing progressive multifocal leukoencephalopathy, which is related to JC virus positivity and the number

Abstract 4CPS-061 Table 1

Patients	Surgical intervention	Hemorrhagic risk (HAS-BLEED)	Previous antiaggregant	Days of antiplatelet withdrawal	Start times of the cangrelor before the procedure (hours)	Anti-aggregant restarted	Anti-aggregation start times after procedure (hours)
1	Catheter implantation	3	Clopidogrel	2	21	Clopidogrel	2
2	Femur fracture	3	Clopidogrel	5	72	Clopidogrel	1
3	Catheterism	4	Ticagrelor	5	72	Clopidogrel	24
4	Femur fracture	3	Ticagrelor	3	72	Ticagrelor	12
5	Catheterism	6	Clopidogrel	5	72	Clopidogrel	120
6	Catheterism	6	Clopidogrel	3	72	Clopidogrel	4
7	Catheterism	5	Ticagrelor	2	12	Clopidogrel	6

of NTZ infusions. This has led us to search an optimal dosing strategy.

Aim and Objectives In this study, we explore the impact of extending the dosing interval of NTZ from every four weeks to every six weeks in RRMS patients.

Material and Methods A retrospective observational study was carried out in a general hospital from January 2023 to September 2023. RRMS patients who had been receiving Natalizumab every four weeks for at least one year and subsequently switched to a six-week dosing interval were included. Clinical data were collected and analysed including relapse rates, disability progression, and adverse events.

Results 11 RRMS patients were included. None of them had new focal neurological symptoms, as evidenced by stable MRI (Magnetic Resonance Imaging) findings and absence of clinical relapses. Importantly, no cases of PML or other serious adverse events were reported during the study period. One patient reported visual worsening in the left eye but this was attributed to other factors unrelated to the dosing interval change.

Conclusion and Relevance In this study, the extension of Natalizumab dosing interval in RRMS patients demonstrated promising results, including stable disease activity and an absence of PML cases.

The absence of PML cases in our cohort is particularly encouraging, suggesting that the risk of PML may not be significantly increased with this extended dosing regimen.

This dosing strategy may offer a balance between maintaining therapeutic efficacy and minimising potential safety concerns. However, more studies are needed to confirm these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-063 CLINICAL PHARMACIST IN THE MULTIDISCIPLINARY TEAM IN THE INTENSIVE CARE UNIT IMPROVE THE QUALITY OF MEDICINE THROUGHOUT THE PATIENT'S HOSPITAL STAY

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Background and Importance Medication errors during a hospital stay can endanger patient safety, prolong the patients hospital stay and even be fatal. The critically ill patients in the intensive care unit (ICU) are particularly vulnerable to errors in medication management, and each care transition increases the risk of medication discrepancies.

Aim and Objectives The aims of the study were 1) to develop a workflow for clinical pharmacist to become an integral part of the multidisciplinary ICU team, 2) to perform a pharmacist-led intervention to improve the documentation of medication lists, optimise medical treatment and avoid drug-related problems (DRPs).

Material and Methods A preintervention retrospective control cohort at the ICU (n=34) was used to assess the effect of pharmacist-led intervention. Clinical pharmacist registered medication information about the patients before admission to ICU, quality score of the medication information in the admission records, medication information when patients were transferred in-hospital, and in the discharge summary. Additional in the pharmacist-led intervention (n=23) medication reconciliation and drug review were performed.

Results Clinical pharmacist found discrepancies in medication information and/or electronic prescribing for 55 different drugs (n=19 patients, 82%), in average 2.4 drugs per patient. Most common discrepancies were drugs missing (n=25, 45%), important information about poor compliance were missing (n=12, 22%) and drugs no longer in use were listed in medication information and/or electronic prescription (n=10, 18%).

Most of the patients (n=20, 87%) had DRPs or potentially DRPs, in total 85 DRPs. Most commonly DRPs included drugs needed monitoring (n= 16, 19%) and drugs were found unnecessary for patient (n=15, 18%). The ATC group N including central nervous agents like anxiolytics, hypnotics and sedatives, antipsychotics and antidepressants were commonly related to the DRPs or potentially DRPs (n=26, 31%).

The average quality score of medication information in discharge summery were higher in the intervention group (n=18, score: 11.5) compared to the control group (n=31, score: 8.3). Maximum score is 21.

Conclusion and Relevance In an ICU multidisciplinary team, clinical pharmacist should be integral part to increase patient safety. The clinical pharmacist contributed to less medication errors and DRPs and improved documentation of the medication lists throughout the hospital stay.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-064 REVIEW OF USE OF IMMUNOGLOBULINS IN TERTIARY HOSPITAL

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Background and Importance Human immunoglobulins (HI) are essential for treatment of primary immunodeficiency (PI). They are also used for other conditions, some of which do not have very high evidence or have therapeutic alternatives other than HI. Given the current shortage of HI, careful consideration of its indications and administration is warranted.

Aim and Objectives I)To describe the use of HI of an adult population treated in a tertiary university hospital (767 beds), which is a reference hospital for PI and other minority pathologies. II)To identify those indications for which the use of HI has a low level of evidence according to the national guidelines.

Material and Methods

Observational retrospective study No intervention. All patients who received HI during 1/1–31/12, 2022 were included. Data was obtained from electronic medical records.

Results A total of 104786g of HI were administered to 432 patients (52.3% women). Median age and weight were 60.0

years (IQR:45.0–71.3) and 68.0kg (IQR:59.0–80.0), respectively. Seventy patients (16.2%) had a BMI >30kg/m^2. Two hundred eleven patients (48.8%) received HI for the first time. There were 209 (48.4%) long-term HI treatments (minimum three-month duration) and 224 (51.6%) short-term treatments.

Only 13200g of HI (12.6%) were administered to 134 inpatients. High number of patients (85.2%) received intravenous HI, consuming 87495g (83.5%). The indications with the highest consumption of HI were immunomodulatory treatment of dermatomyositis and other inflammatory myopathies (4.9% and 4.6% of patients; 19,2% and 10.0% of consumption, respectively) and replacement therapy in common variable immunodeficiency (11.1% of patients, 10.0% of consumption). HI were prescribed from 12 different specialties, with internal medicine, neurology and hematology being the most, with 32.5%, 15.8% and 15.4% of total consumption, respectively.

An 8.3% of total HI consumption was administered to 33 patients (7.6%) with indications with low evidence of HI efficacy. Of these indications, the most common were BK virus nephropathy in kidney transplant patients (n=5), autoimmune dermatological diseases (n=5), severe myocarditis (n=3) and autoimmune haemolytic anaemias (n=3).

Conclusion and Relevance HI are widely used by multiple specialties. HI for low-evidence indications are used in a low, but not minimal, percentage. These uses must be reviewed by a multidisciplinary team in order to optimise the prescription of HI.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-065 EXPERIENCE OF IMMUNOCHEMOTHERAPY VERSUS STANDARD TREATMENT IN SMALL-CELL LUNG CANCER

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Background and Importance Immunotherapy has emerged as a revolutionary approach to the treatment of small-cell lung cancer. This aggressive form of lung cancer presents significant challenges due to limited therapeutic response and even resistance to and even resistance to conventional chemotherapy. However, the strategy of combining immunotherapy with chemotherapy makes it possible to stimulate a patient's own immune system to fight cancer cells, triggering a specific immune response. This novel combination has shown promising results in improving survival and quality of life for survival and quality of life of patients with metastatic MPC in clinical trials.

Aim and Objectives - To evaluate the effectiveness and safety of combination immunochemotherapy in patients with metastatic small cell cancer.

- Compare immunochemotherapy vs standar of care treatment data.

Material and Methods An observational, multicentre, retrospective study was conducted to evaluate the effectiveness and safety of treatments used in patients diagnosed with metastatic MPC. Patient demographics, clinical and treatment variables were collected. Treatment consisted of courses of carboplatin, etoposide and atezolizumab, followed by atezolizumab maintenance. Tumour responses were classified according to RECIST 1.1 response criteria and toxicities were assessed according to common adverse event criteria CTCAE v5.0

Results Data were collected from 63 patients diagnosed with metastatic small cell lung cancer. 50.8% received combination chemotherapy with atezolizumab and carboplatin plus etoposide, while 49.2% received chemotherapy alone.Median overall survival was 7.5 months in the combination arm and 7.3 months in the combination arm. The median progression-free survival was 7.12 months in the combination arm and 3.1 months in the chemotherapy arm. The adverse event rate for the combination was 78.2% vs 75% for chemotherapy. Adverse events in the combination arm were asthenia, neutropenia, anaemia, nausea and nausea, anaemia, nausea and infections

Conclusion and Relevance The combination of atezolizumab with carboplatin and etoposide shows better survival outcomes without increasing toxicity, than standard therapy.

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Conflict of Interest No conflict of interest.

4CPS-066 THERAPEUTIC DRUG MONITORING OF ANTI-TNF THERAPY IN INFLAMMATORY BOWEL DISEASE

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Background and Importance Anti-TNF drugs are often considered the primary treatment for most patients with inflammatory bowel disease. However, there is a significant interindividual variability in the therapeutic response. Approximately 30% of patients do not respond to induction (primary failure) and more than 50% of patients lose response over time (secondary failure). Given that there is a strong correlation between anti-TNF drug levels and its efficacy, pharmacokinetic monitoring of plasma levels has become a useful strategy to optimise the treatments.

Aim and Objectives To analyse the percentage of pharmacokinetic recommendations accepted by the physician to optimise anti-TNF treatment in patients with inflammatory bowel disease

Material and Methods Prospective, observational study, which included patients with inflammatory bowel disease treated with adalimumab and infliximab from february to october 23. Demographic variables (age, sex), diagnosis (Crohn's disease or ulcerative colitis), treatment (adalimumab or infliximab) and type of recommendation (dose intensification, interval intensification or both, regimen maintenance, treatment change, treatment de-intensification or suspension) were collected. The measurement of drug levels was conducted using a rapid determination system (RIDA®Quick System) followed by

interpretation using a computer application based on analysis by Bayesian methods. (PKS® Abbott). The data analysis was based on pharmacokinetic models published in the literature.[1,2] Subsequently, the pharmacokinetic recommendation was provided to the physician, who made the final decision.

Results Twenty-eight patients (50% men and 50% women) with a mean age of 40 years were included. Regarding diagnosis, 53,6% was ulcerative colitis and 46,4% was Crohn's disease. Thirty-three determinations were made (17 adalimumab and 13 infliximab). The total percentage of acceptance of the pharmacokinetic recommendations was 84,8% and was distributed as follows: Maintenance of regimen (33.3%), interval intensification (27.7%), dose intensification (12.12%), dose and interval intensification (12.12%), change of treatment (9.09%), de-intensification (3.03%) and discontinuation of treatment (3.03%).

Conclusion and Relevance The degree of acceptance of the pharmacokinetic recommendations was high. It remains to be determined in the long term whether this type of intervention will yield a positive clinical impact, potentially enhancing treatment persistence.

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Conflict of Interest No conflict of interest.

4CPS-067 EFFECTIVENESS AND SAFETY OF 1 IU/ML TOPICAL INSULIN TO TREAT PERSISTENT CORNEAL ULCERS

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Background and Importance The presence of epithelial corneal ulcers due to various reasons significanttly impacts in plenty of patient's quality of life. Recently, the use of topical insulin has emerged as a potential alternative treatment, with promising preclinical results. However, clinical evidence remains limited.

The presence of insulin and insulin-like growth factor receptors in corneal keratocytes and epithelial cells may explain these findings.

Aim and Objectives These study aims is to assess the effectiveness and safety of insulin 1 IU/mL eye drops for persistent corneal ulcers (PCU).

Material and Methods Observational retrospective study conducted in a tertiary hospital among patients receiving topical insulin 1 IU/mL treatment for PCU between January 2021 and July 2023. Data collected included patient demographics, PCU etiology, treatment duration, prior and concurrent hospital treatments, clinical response (assessed via anterior segment biomicroscopy) and adverse effects.

Pharmacy Hospital prepared insulin eye drops at a concentration of 1 IU/mL, and were administrated 3 or 4 times daily.

Results 54 patients were treated with 1 IU/mL topical insulin for PCU, including 23 (43%) males, with a median age of 70 (58–79) years. The most common PCU etiologies were post-surgical in 11 (20.4%) patients, herpetic in 10 (18.5%), neurotrophic in 9 (16.7%), dry eye in 6 (11.1%) and infectious in 5 (9.3%) patients. 8 (14.8%) patients had diabetes.

12 (22.2%) and 16 (29.6%) patients previously received autologous serum or cyclosporine eye drops, respectively; and 9 (16.7%) and 12 (22.2%) concurrently used autologous serum or cyclosporine eye drops, respectively.

The median duration of treatment was 2,2 (1.4–5.6) months. 17 (31.5%) patients finished treatment due to PCU improvement, 6 (11.1%) due to PCU resolution, 18 (33.3) due to lack of efficacy, 1 (1.9%) due to intolerance and 7 (13.0%) continued in treatment at follow-up ending. Patients with improvement or resolution had a treatment duration of less than 5 months.

Response (PCU improvement or resolution) were better in infectious (60.0%) and post-surgical (54.5%).

Conclusion and Relevance The 1 IU/mL topical insulin eye drops formulation appears to be an effective, safe and rapid option for patients with PCU. However, treatments without effectiveness in the first 5 months do not seem to be effective. Further studies are needed to confirm these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-068 TARGET THERAPY IN NON-SMALL CELL LUNG CANCER (NSCLC): A RETROSPECTIVE ANALYSIS TO GUARANTEE THE APPROPRIATENESS OF THE PRESCRIPTIONS IN OUR HOSPITAL

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Background and Importance During past years several target therapies have been approved for various mutations in non-small cell lung cancer (NSCLC). Target therapy has been shown to be effective in several metastatic cancers with specific gene mutations or molecular biomarkers, and sophisticated molecular diagnostics allow greater personalised treatment selection to prevent treatment failure, avoid unnecessary treatment, and improve survival.

Aim and Objectives The aim of this retrospective analysis is to verify that in the actual clinical practice of our hospital target therapy prescriptions and deliveries for patients diagnosed with NSCLC match with a proper molecular diagnostic testing (human DNA/RNA analysis).

Material and Methods The pharmacist crosses data regarding patients' gene mutations and anti-cancer oral drugs deliveries to patients. Data sources are pathology department software that includes mutations tested with a real-time PCR fully automated and pharmacy software that includes for each patient the name of the anti-cancer drug, the number of confections, the date of delivery.

Results From April 2020 to August 2022, target oral therapies for lung cancer were provided to 90 patients: 53 treated with osimertinib, 16 with alectinib, 3 with gefitinb, 8 with afatinib, 3 patients with trametinib and dabrafenib, 1 with entrectinib, 1 with crizotinib, 2 with erlotinib. 58 patients were transferred from another centre with a prescription yet and for the other 32 patients we performed the molecular test in site. 25 of the 53 patients treated with osimertinib, carried out the

molecular test on site with a diagnosis of deletion of exon 19 of the EGFR gene (17 patients), and one patient also had a T790M resistance mutation. 6 diagnosed with EGFR L858R mutation and 1 with EGFR G719S mutation. Of the 16 patients treated with alectinib, 5 underwent on-site molecular investigations with a positive ALK gene mutation diagnosis. Of the 8 with afatinib, 2 were diagnosed with an EGFR gene mutation.

Conclusion and Relevance This retrospective analysis of real-world data among patients with NSCLC has found that target therapies prescribed in our hospital are linked to an oncogene mutation. Next step is to develop an IT integration between departments' software in order to allow the pharmacist to check the fully appropriateness of prescription before delivery.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-069 OUTPATIENT SATISFACTION IN THE TELEPHARMACY PROGRAM OF A TERTIARY HOSPITAL PHARMACY SERVICE

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Background and Importance Telepharmacy (TPh) consists of telematic pharmaceutical care and delivery of hospital outpatient medication, avoiding patient's displacement to the hospital. There are different TF models depending on the delivery destination: patient's home, pharmacy offices and health or social-health centres. To be included in TF program, patients must meet a series of inclusion criteria, including home distance from the hospital, fragility and functional dependence, among others.

Aim and Objectives To evaluate the opinion of patients included in TPh program and the telematic pharmaceutical care received through a satisfaction survey.

Material and Methods Prospective observational study in which all patients in TPh program who received a medication shipment to a pharmacy office during May 2023 were included. The information was obtained through a telematic anonymous survey. Different aspects about TPh were scored: circuit, delivery destination, pharmacist availability during delivery, shipping planning, medication access through pharmacy office, quantity of dispensed medication, possible financial contribution and pharmaceutical care received. Overall satisfaction level was also rated. The satisfaction patient degree was evaluated with a numerical result from 1 (minimum satisfaction) to 10 (maximum satisfaction).

Results During data collection period, 30 patients answered the survey and 3 refused it. 57% (17) of the participants were female. The most prevalent age group was over 65 years in 57% (17) of survey respondents. The mean satisfaction scores were 10 for circuit, 9.9 for delivery destination, 9.9 for pharmacist availability during delivery, 10 for shipping planning, 10 for medication access, 9.9 for quantity of dispensed medication, 6.7 for possible financial contribution and 10 for pharmaceutical care received. Regarding overall satisfaction, an average score of 10 was obtained.

Conclusion and Relevance The TPh service and telematic pharmaceutical care received are highly satisfactory from the survey respondents' point of view. Even so, trying to adapt the delivery destination and quantity of dispensed medication could be some areas to improve the service.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-070 EVALUATION OF AVOIDED COST IN CLINICAL TRIALS WITH IMMUNOTHERAPY IN LUNG CANCER

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Background and Importance Lung cancer (LC) is the third most common prevalent cancer and the leading cause of cancer-related death. Therapeutic options for LC are limited. A large number of immunotherapy-based clinical trials (CT) are underway due to their promising results. Therefore, it is necessary to evaluate the economic impact of CT in LC patients.

Aim and Objectives To evaluate the economic impact of participating in CT with immunotherapy provided by the sponsor in patients with LC.

Material and Methods Single-centre multidisciplinary study calculating the cost-saving impact of the use of immunotherapy provided by the sponsor in CT in a tertiary hospital between January2019 and December2022.

Inclusion criteria patients diagnosed with LC (small cell and non-small cell) treated with commercialised immunotherapy in CT (amivantamab, atezolizumab, avelumab, durvalumab, ipilimumab, nivolumab and pembrolizumab). Exclusion criteria: CT with placebo-masked immunotherapy.

The information was retrieved from Farmis-Oncofarm®, pkEnsayos® and Orion-Logis®. Baseline characteristics (age and sex), diagnosis, clinical data (trials per phase and drug administered) and consumption data (quantity expressed in mg and costs avoided per CT, per patient and per diagnosis) were analysed.

Statistical analysis calculation of percentages and means with 95% confidence intervals (95%CI). Economic data was expressed in avoided costs.

Results The study included 81 patients (71.6% male) with an average age of 65.7 years (95%CI:63.8–67.6). Most of patients were diagnosed with non-small-cell LC (85.2%, n=69).

A total of 27 CT were included (81.5% for non-small-cell and 18.5% for small-cell): phase I (n=1), phase I/II (n=2), phase II (n=6), phase IIa (n=1), phase III (n=12), phase IIIb (n=2), phase IIIb/IV (n=2) and phase IV (n=1). Nine of them used nivolumab (33.3%); 6 atezolizumab (22.2%); 6 pembrolizumab (22.2%); 3 durvalumab (11.1%); 2 ipilimumab (7.4%); 1 amivantamab (3.7%) and 1 avelumab (3.7%).

The overall avoided cost was 2,178,167€ (1,715,360€ and 462,807€ for non-small cell lung cancer and small cell lung cancer, respectively), per CT 80,673€ and per patient 26,891€ .

Conclusion and Relevance Patient participation in CT with immunotherapy in LC has a great economic impact in terms of direct costs avoided in antineoplastic treatment. The inclusion of patients in these CT contributes to the sustainability of the healthcare system and allows patients access to innovative therapies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-071 ANTIBIOTIC CONSUMPTION MONITORING BY AWARE CLASSIFICATION: A 6-MONTH ANALYSIS

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Background and Importance The AWaRe classification of antibiotics, developed by the World Health Organization, is a useful tool for monitoring antibiotic consumption, defining targets and verifying the effects of stewardship policies that aim to optimise antibiotics use and reduce antimicrobial resistances. Antibiotics are classified into three groups, Access, Watch and Reserve, considering the impact on antimicrobial resistance and emphasising the importance of their appropriate use. The 'Access' group contains antibiotics used in the first- and second-line treatment of infections. The 'Watch' group contains broad-spectrum antibiotics with a higher potential of developing resistance. The 'Reserve' group contains last-resort antibiotics used for multidrug-resistant infections.

Aim and Objectives The aim of this study was to evaluate and monitor the consumption of antibiotics for parenteral use in the hospital wards, considering the AWaRe classification, during a period of 6 months (from January 2023 to June 2023).

Material and Methods From January 2023 to June 2023 all the requests of antibiotics for parenteral use were analysed using an informatic database and classified according to the AWaRe classification and the hospital wards. Moreover, the prescriptions appropriateness was verified by checking the validity of the documentation needed (antibiograms, infectivologist reports).

Results In the period considered 110.662 vials of antibiotics for parenteral use were dispensed. Among these, 68.096 vials (61.53%) were antibiotics from the 'Watch' group. Meropenem and Ceftriaxone resulted the most administered molecules, especially in Respiratory disease and Emergency wards.

26.942 (24.34%) antibiotic vials were dispensed from the 'Access' group and 15.624 (14.11%) from the 'Reserve' one. Cefazolin and Metronidazole ('Access') and Colistimethate ('Reserve') resulted the most used antibiotics in their categories, with higher prevalence in Obstetrics and Gynecology, Surgery and Respiratory disease wards, respectively.

Conclusion and Relevance We found out high antibiotic consumptions, in particular for the 'Watch' category, probably due to antibiotic resistance towards the molecules from the 'Access' group. These data confirm the importance of the role of the hospital pharmacist, who can promote adherence to guidelines and the correct use of antibiotics, actively contributing to the antimicrobial stewardship programme

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Conflict of Interest No conflict of interest.

4CPS-072 SETMELANOTIDE IN MONOGENIC OBESITY: A CASE REPORT

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Background and Importance The melanocortin 4 receptor (MC4R), component of the leptin-melanocortin pathway, plays a part in body weight regulation (hunger, satiety and energy expenditure).

Setmelanotide is a highly potent MC4R-agonist that leads to weight loss in Monogenic Obesity (MO) individuals with complete pro-opiomelanocortin (POMC) deficiency or leptin receptor (LEPR) deficiency.

Aim and Objectives To evaluate the efficacy of setmelanotide in a 3-year-old paediatric patient with MO due to LEPR deficiency (off-label use).

Material and Methods Observational, retrospective and descriptive study of a child with MO in a third-tier hospital for 6 months (April to September 2023).

The information was obtained from the Electronic Clinical History and the Pharmacy Service Managing Software.

Results The child born at 36+2 weeks with a weight appropriate to his gestational age (2.5 kg).

He was admitted in an obesity study in May 2021. He was diagnosed with MO due to LEPR deficiency in September 2021.

The child started with setmelanotide 0.5mg in April 2023 and was increased to a current dose of 1.5mg daily subcutaneous injection.

He has lost weight from 40 to 38 kg in 6 months. He also eats less food and his craving for food has decreased. Analytical levels improved from October 22 to May 23: triglycerides: 99 to 75 mg/mL; cholesterol 217 to 139 mg/dL; LDL 144 to 72 mg/dL. The patient has decreased in adipose component and has increased in muscle mass. Progress in mobility, crawling and kneeling. Sleeps through the night with a daytime nap, not always.

There are no alternative treatments suitable for the patient's age.

Setmelanotide has demonstrated statistically significant weight loss with at least a 5% decrease in body weight after 6 months and decreased appetite, therefore it could reach a 10% after 1 year.

The child has skin rash and skin hyperpigmentation (activity at melanocortin 1-receptors (MC1R) as adverse effects.

Conclusion and Relevance Setmelanotide is the first European Medicines Agency approved medication for the treatment of POMC and LEPR deficiency in patients (children from 6 years old and adults) with MO.

In our case report is an off-label use and the child has been treated efficiently with setmelanotide for 6 months with a reduction in weight, hunger and analytical parameters.

We should evaluate the response after 1-year with setmelanotide to confirm that the treatment objectives are achieved (10%weight loss in 1-year).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-073 ANALYSIS OF THE REASONS FOR CHANGING TREATMENT IN PATIENTS WITH MULTIPLE SCLEROSIS

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Background and Importance Treatment for multiple sclerosis (MS) has changed in the last few years. The introduction of new therapies has led to improved tolerance and new options in the progression of disease.

Aim and Objectives To evaluate the reasons for changing treatment in patients diagnosed with MS and its economic impact.

Material and Methods Descriptive, retrospective and observational study of patients with MS, who changed treatment during 2022.

The variables collected from the clinical history were: age, sex, type of MS, EDSS scale, previous and new treatment and reason for the change. The economic impact associated with treatment changes was also evaluated.

Results During 2022 there was a 12% change in treatments (n=63/535 patients, 67 changes).

68% (n=43) were women with a mean age of 45 years. At the moment of change, mean EDSS was 2.9 (0.0–7.0) and 86% (n=54) had a diagnosis of relapsing-remitting MS and 14% (n=9) of secondary progressive multiple sclerosis (SPMS).

Treatment changes were due to: 46% (n=31) adverse events (AEs), 46% (n=31) progression, 5% (n=3) AEs/progression and 3% (n=2) pregnancy desire.

The AEs were: 50% injection site disorders and/or flu-like symptoms (100% IM/SC drugs), 17% gastrointestinal disorders ± flushing or uncontrolled blood pressure (100% oral drugs), 15% infusion-related reactions, 12% lymphopenia and 3% hepatotoxicity and increased anti-JC titre. 100% SC/IM treatments switched to oral drugs and 100% natalizumab$_{IV}$ was changed to natalizumab$_{sc}$.

Changes for progression (n=34) were: 74% highly effective drugs (12 ocrelizumab, 7 cladribine and 6 natalizumab), 21% progression to SPMS (5 siponimod and 2 rituximab), and 5% dimethyl fumarate.

Previous treatments were 19% dimethyl fumarate, 16% teriflunomide, 15% natalizumab$_{IV}$, 9% glatiramer, 9% fingolimod, 7% interferon beta-1a$_{IM}$, 7% peginterferon$_{SC}$, 6% interferon beta-1b$_{SC}$, 4% interferon beta-1a$_{SC}$, 3% rituximab, 1% siponimod and cladribine.

New treatments were 19% ocrelizumab, 18% teriflunomide, 15% cladribine, 10% dimethyl fumarate, 9% natalizumab$_{SC}$, 7% natalizumab$_{IV}$, 7% siponimod, 6% rituximab, 3% glatiramer, 1% ozanimod, ponesimod and diroximel fumarate.

The mean monthly cost before the changes was 833€ and 1,543€ with the new treatments.

Conclusion and Relevance The introduction of new therapies has led to having more therapeutic alternatives and they are well tolerated in those patients with AEs or progressive MS, but the economic impact is higher.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-074 DRUG CLASSES COMMONLY RELATED TO MEDICATION ERRORS AT TRANSITION OF CARE

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Background and Importance Transitions of care, such as from hospital to community settings, are often associated with changes in medication regimens, and patients are therefore at risk of drug-related problems (DRPs).[1] Medication reconciliation by clinical pharmacists aims to reduce DRPs and thus improve patient safety.

Aim and Objectives We aimed to identify drug classes most susceptible to DRPs and to quantify the proportion of DRPs originating from transition of care (admission or discharge). This could support clinical pharmacists in more targeted medication reconciliation.

Material and Methods Medication reconciliation was performed by clinical pharmacists in a regional hospital for patients discharged from internal medicine, surgical, orthopaedic, and gynaecological wards. For each identified DRP, the involved drug class (ATC code) and its origin (transition of care, or other origin, such as prior to or during hospitalisation) were systematically documented. For this descriptive observational study, we analysed data over 3.5 years to calculate the frequency of DRPs of specific drug classes and their origins.

Results Between January 2019 and June 2023, a total of 25,298 medication reconciliations were performed, DRPs were documented for 3,401 discharges with a prevalence of 13.4%. The five drug classes most often related to DRPs were cardiovascular agents with 836 records (18.2%), gastrointestinal tract drugs with 751 records (16.3%), analgesics with 615 records (13.4%), antithrombotic drugs with 470 records (10.2%), and anti-infectives with 390 records (8.5%). Other drug classes accounted for fewer DRPs.

78.8% of DRPs involving cardiovascular agents originated from a transition of care, along with 56.7% for anti-infectives, 52.3% for antithrombotic agents, 51.9% for gastrointestinal tract drugs and, 49.3% for analgesics.

Conclusion and Relevance We identified a set of drug classes commonly related to DRPs. Furthermore, we observed that most of the DRPs originated from a transition of care. This study emphasises the importance of medication reconciliation during transitions of care and identifies which drug classes should be focused on.

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Conflict of Interest No conflict of interest.

4CPS-075 A SYSTEMATIC REVIEW OF THE TARGET PHARMACOKINETIC/PHARMACODYNAMIC PARAMETERS OF ANTIBIOTICS TREATING GRAM-NEGATIVE INFECTIONS

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Background and Importance Following the introduction of pharmacokinetic/pharmacodynamic (PK/PD) parameters in preclinical development of antibiotics, the application of PK/PD in guiding doses has been highly encouraged. Previous findings remain controversial and vary greatly, causing difficulties in determining the appropriate PK/PD parameters for individuals in practice.

Aim and Objectives This systematic review aims to identify the PK/PD targets of antibiotics treating gram-negative infections in clinical practice, focusing on multi-drug resistant gram-negative infections.

Material and Methods Database from Cochrane Central, Web of Science, PubMed, Embase and Scopus were searched using defined terms. Studies using PK/PD targets to determine dosing regimens of parenteral antibiotics for patients with gram-negative infections in practice were selected. Studies were excluded if examining the PK/PD targets of antibiotics for healthy participants, virtual patients, and gram-positive infections. Study bias was evaluated using the Cochrane risk of bias tool.

Results A total of 41 studies investigating 21 antibiotics and two combinations involving 799 participants were selected. The majority of eligible studies (21 articles, 51.2%) were case studies, which were evaluated as high risk of bias. Three (5.9%) studies were RCTs and 17 (33.3%) were non-RCTs. Only one RCT was evaluated as at low risk of bias. 58% of the investigated population was treated using predefined PK/PD indices derived from preclinical studies. Yet, among them, more than 60% modified the dosing and the duration of administration to attain a higher target value. Cefiderocol and meropenem were the two antibiotics most prescribed for multi-drug resistant bacteria, usually combined with other antibiotics. Extended infusion of meropenem to at least 30 minutes per administration resulted in the achievement of 100% $fT>MIC$ or 100% $fT>4–6$ MIC instead of 40% $fT>MIC$ while the prescription of Cefiderocol followed the labelled instruction of use. Still, about 79% of these cases targeted a higher value of predefined 77% $fT>MIC$ derived from preclinical data.

Conclusion and Relevance The PK/PD target values of antibiotics treating resistant gram-negative bacteria are variable and divergent from preclinical data. A range of PK/PD targets may be more realistic in practice to optimise dosing regimens for the facilitation of clinical outcomes, and PK/PD targets should be used to inform dosing regimens. Further research with standardised patient outcomes is required.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-076 EFFECTIVENESS AND SAFETY OF DUPILUMAB AND TRALOKINUMAB IN ATOPIC DERMATITIS IN CLINICAL PRACTICE

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Background and Importance Dupilumab, an IL-4/IL-13 antagonist, and tralokinumab, an IL-13 antagonist, are approved for the treatment of moderate-to-severe atopic dermatitis (AD). Until now, no published studies have compared these treatments in clinical practice.

Aim and Objectives To evaluate and compare the effectiveness and safety of dupilumab and tralokinumab in AD patients in clinical practice.

Material and Methods We conducted a retrospective study in a tertiary hospital. We included AD patients who initiated dupilumab or tralokinumab as the first targeted treatment between 11/2017 and 5/2023.

We collected the following data from electronic medical and pharmacy records: age, sex, Eczema Area and Severity Index (EASI), Peak Pruritus-Numerical Rate Scale (PP-NRS), and adverse effects (AE). Effectiveness endpoints were EASI and PP-NRS at the first follow-up medical visit. Safety endpoints were the number and type of AE during the study period.

Results In total, 78 patients were included in the study. Mean age (±SD) was 40.8 (±17.4) years. Thirty-nine (50.0%) patients were women. Dupilumab group included 61 patients, whereas tralokinumab, 17.

In dupilumab group, mean initial EASI (±SD) was 32.5 (±9.7) and PP-NRS, 8.2 (±1.3). At first follow-up, the mean EASI was 7.1 (±6.0) and PP-NRS 2.7 (±1.8). In the tralokinumab group, mean initial EASI (±SD) was 26.4 (±8.3) and PP-NRS, 7.3 (±1.7). At first follow-up visit, the mean EASI was 2.4 (±4.8) and PP-NRS 1.9 (±2.7). The reduction in EASI and PP-NRS was statistically significant ($p<0.001$) in both groups. At first follow-up visit, tralokinumab was superior to dupilumab in the reduction of EASI ($p=0.005$), but not in PP-NRS. However, comparing the normalised reductions of EASI and PP-NRS, there were no significant differences between dupilumab and tralokinumab groups.

AE were reported in 23 (37.7%) dupilumab-treated patients and 5 (29.4%) tralokinumab-treated patients, which were mostly ophthalmologic (52.2% and 60.0%, respectively). Eight (13.1%) dupilumab-treated patients and 2 (11.8%) tralokinumab had to discontinue the treatment due to AE.

Conclusion and Relevance In our cohort, dupilumab and tralokinumab were effective. Our study shows a significant improvement in EASI and PP-NRS in the first follow-up visit. AE data show that close ophthalmologic monitoring is recommended in these patients. Further studies are warranted to validate the differences found between both treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-077 PHARMACEUTICAL INTERVENTIONS AFTER DETECTION OF NON-HANDLING MEDICATIONS IN PATIENTS WITH DYSPHAGIA

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Background and Importance Geriatric community is the main group of patients affected by oropharyngeal dysphagia. In these population, numerous pharmaceutical forms need to be handled for subsequent administration. However, this manipulation can compromise the drug´s safety and efficacy.
Aim and Objectives To analyse the interventions for the adaptation of pharmacological treatment in nursing home (NH) patients with dysphagia.
Material and Methods An observational, retrospective and descriptive study was carried out in two NH from June 2023 to September 2023. All patients with medication crushed were identified with the collaboration of the nursing staff. Biodemographic data, prescribed medications and the suggested interventions were recorded. The DEGLUFARM® guide was used for the interventions performed. The prescribing clinicians were notified.
Results 184 NH patients were included in our study. 60 of them (32.61%) had their medication crushed. Of these, 19 were male (31.67%) and 41 female (68.33%) with a median age of 86 years (ages ranging from 38 to 100 years). A total of 509 oral medications were analysed, with a median of 9 drugs per patient. Of all prescribed medications, 23 conflicting drugs prescribed in 20 patients were identified (33.33% of the patients who had their medication crushed).

According to ATC classification, the most common conflicting drugs were: 6 Alpha-adrenoreceptor antagonists (26.09%), 3 drugs for constipation (13.04%) 3 antidepressants (13.04%), and 2 anticholinesterases (8.70%). The pharmaceutical forms that sholud not be crushed were: 8 retard tablets (34.78%), 5 gastroresistant tablets (21.74%), 5 retard capsules (21.74%) 4 coated tablets (17.39%) and 1 capsule containing gastrorresistant pellets (4.43%).

The prescribing physician was notified in all cases, with the following proposals: 12 changes to a different active ingredient (52.17%), 10 changes to a different pharmaceutical form with the same active ingredient (43.48%) and 1 proposal for withdrawing due to a negative benefit-risk balance (4.35%).
Conclusion and Relevance High percentage of pharmaceutical forms that sould not be manipulated is prescribed in NH patients who have their medication crushed due to dysphagia Most of the proposed changes involve changes in active ingredients, so further clinical monitoring can be important. The pharmacists are qualified to carry out this type of intervention, improving the efficacy and safety of pharmacological treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-078 QUALITY OF LIFE AND PATIENT-REPORTED OUTCOMES WITH MULTIPLE MYELOMA TREATEDS WITH DARATUMUMAB

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Background and Importance Multiple myeloma (MM) is an incurable and chronic disease, so the quality of life (QoL) of patients with MM is an important criterion to consider. The patient-reported outcomes (PROs) are a fundamental tool to know the success of a treatment in clinical practice.
Aim and Objectives Assessing QoL as a PROs in adult with MM treated with daratumumab.
Material and Methods Retrospective observational study which included patients with MM treated with daratumumab between 01/2019 and 04/2023 in a second-level Hospital.

The electronic medical record were used to search patients and treatments variables. QoL was analysed using a standardised questionnaire (EORTC QLQ-C30 v3) and the MM-specific questionnaire (QLQ-MY20) to be answered by the patients themselves. The items to be answered were the presence of symptoms classifying as 'not at all', 'a little', 'quite' and 'a lot'. The general health and the QoL were assessed with a score of 1 to 7, being 1 terrible and 7 excellent.
Results Of the 39 patients (58.97% men, median age 70 years) treated with daratumumab in the study period, 11 completed the questionnaires. In 5 of them, the questionnaire was completed on two occasions: before starting and during treatment. In the remaining 6, only during treatment. The average of treatments received at the time of completing the form was 23.25 months (SD:7.39). In active treatment, 58.17% of the responses were symptoms 'not at all'. In 30.29% were 'a little', in 10.10% 'quite a bit' and a 1. 44% 'a lot.' General health was assessed with an average of 4.2 points before treatment and 4.89 points during treatment. The QoL was assessed with 4.4 points before treatment and 5 points during treatment.
Conclusion and Relevance In general, the presence of symptoms or problems related to the disease were mostly considered by the patients themselves as null. In addition, general health and QoL improving in the patients who were given the questionnaire at the beginning and during treatment with daratumumab.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-079 INDIRECT COMPARISON OF IL-13 INHIBITORS PLUS TOPICAL CORTICOSTEROIDS IN MODERATE TO SEVERE ATOPIC DERMATITIS

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Background and Importance Lebrikizumab, tralokinumab and dupilumab are anti-interleukin-13 monoclonal antibody used as therapy in patients with moderate to severe atopic dermatitis (msAD). There are no direct comparisons among them.
Aim and Objectives To establish whether lebrikizumab plus topical corticosteroids (L-TC), tralokinumab plus topical corticosteroids (T-TC) and dupilumab plus topical corticosteroids (D-TC) can be declared equivalent therapeutic alternatives (ETA) in patients with msAD through an adjusted indirect treatment comparison (ITC) using a common comparator.
Material and Methods A bibliographic search was conducted to identify phase III clinical trial (CTs) with L-TC or T-TC or D-TC with similar populations, duration and endpoints. Inclusion criteria were: phase III, randomised, double-blinded, placebo controlled and in patients with msAD. The 90% improvement in Eczema Area and Severity Index (EASI90) at week 16 was used as the main variable. An ITC of L-TC versus T-TC and L-TC vs D-TC was performed using the Bucher method, using the Indirect Treatment Comparisons calculator from the Canadian Agency for Health Technology. Delta value (Δ, maximum difference as a clinical criterion of equivalence) was calculated using half of the ARR in EASI90 obtained in the pivotal CT of dupilumab (pooled ARR=29%; Δ =15%). The results were analysed graphically and the relative position of the 95% CI and the equivalence margin were observed. Positioning was established following the ETA Guide.
Results Included three CTs in the ITC between L-TC (Adhere), T-TC (ECZTRA 3) and D-TC (Liberty ad Chronos). The difference in EASI90 expressed as ARR (IC95%) of L-TC versus T-TC, and L-TC versus D-TC, was: 6.6 (-9–22.2) y -11 (-27–5). Applying the ETA Guide, L-TC, T-TC and D-TC could be considered ETA, being the probability of clinically relevant difference <50% (most of the 95% CI is in the equivalence range), and the failure does not involve serious/irreversible damage.
Conclusion and Relevance The ITC showed no statistically significant and clinically relevant differences in EASI90 between anti-interleukin-13 plus topical corticosteroids. These drugs could be considered ETA in most patients with msDA.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-080 METASTATIC HER2-POSITIVE BREAST CARCINOMA CASE REPORT: ANTI-HER2 TREATMENT MAINTENANCE DESPITE OLIGOPROGRESSION

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Background and Importance The new anti-HER2 conjugated drugs have represented a significant advancement in the treatment and management of metastatic HER2-positive breast cancer patients, enabling the application of local ablative therapy in the case of oligoprogression, with a positive impact on the survival of these patients.
Aim and Objectives The objective of this text is to provide a comprehensive overview of the patient's medical history and treatment progression in managing HER2-positive breast carcinoma. It aims to underscore the importance of pharmaceutical interventions, interdisciplinary cooperation, and adaptability in achieving favourable treatment outcomes for patients with complex oncological conditions.
Material and Methods 51-year-old woman. Diagnosed in May 2005 with infiltrating ductal carcinoma of the left breast, underwent surgery after neoadjuvant chemotherapy + Trastuzumab, luminal B HER2-positive immunophenotype. Subsequently, received adjuvant radiotherapy + trastuzumab + hormone therapy. All treatments concluded in April 2011.
Results In January 2020, she was admitted to the Internal Medicine ward due to dyspnea related to bilateral paraneoplastic pulmonary embolism, prompting an extension study revealing multiple metastatic bone lesions. Bone biopsy confirmed infiltration by HER2-positive breast carcinoma. In February 2020, she commenced first-line systemic treatment with Docetaxel + Trastuzumab + Pertuzumab, with excellent tolerance.

In December 2021, disease progression was observed with the emergence of lung metastases and a pre-sternal nodule, while bone disease remained stable. A request was made to Pharmacy for Trastuzumab-Emtansine treatment, which commenced in January 2022.

In May 2023, there was growth of the pre-sternal lesion while other lesions remained stable. After histologically confirming the same immunophenotype, the case was discussed in a multidisciplinary committee, and it was decided to administer stereotactic body radiation therapy (SBRT) while maintaining systemic treatment for proper local control. The patient continues treatment with a good clinical course.
Conclusion and Relevance This pharmaceutical perspective highlights the patient's treatment journey and the role of various therapies in managing HER2-positive breast carcinoma, emphasising the need for adaptability and interdisciplinary collaboration to optimise outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-081 CONSENSUS ON INDICATORS FOR MEDICATION-RELATED READMISSIONS: A DELPHI STUDY

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Background and Importance Medication-related readmissions (MRRs) represent a significant burden on patients and healthcare systems. Despite the relevance of MRRs, a consensus on the most important risk factors is currently lacking.
Aim and Objectives This study aimed to develop a comprehensive set of indicators for 30-day MRRs through a consensus-based Delphi study. We sought to identify and prioritise key risk factors associated with MRRs.
Material and Methods We assembled an expert panel consisting of clinical pharmacists, physicians, and nursing experts. The potential indicators were developed by conducting a scoping literature review (n = 20). The study team added eleven

indicators not found in the existing literature but considered potentially relevant. The 31 proposed indicators were rated by the experts on a scale of 1 to 9 for relevance. Indicators with a median rating of 7 or higher were considered relevant. Consensus was determined using the RAND/UCLA method. In the second round, experts re-evaluated indicators without consensus and provided specifications for indicators requiring further detail.

Results In the first round, 38 experts participated, leading to the inclusion of 25 indicators and the exclusion of six. All indicators reached consensus, and five new indicators were suggested. In the second round, 34 experts participated, resulting in the inclusion of four out of five newly proposed indicators, all of which reached consensus. The expert panel prioritised the following indicators: (1) insufficient communication between different healthcare providers, (2) polypharmacy (seven or more medications), (3) low medication adherence (forgetting or administer medications wrongly at least twice per week), (4) complex medication regimen that involves taking at least three doses per day, using at least two different dosage forms, and administering them through at least two different routes each day, and (5) multimorbidity (three or more chronic conditions).

Conclusion and Relevance The comprehensive set of MRR indicators developed in this study addresses the need for a standardised MRR risk assessment and offers a tool for pharmacists to prioritise clinical pharmacy services during hospital discharge. This could lead to more efficient resource allocation and potentially improve patient outcomes. Future work will focus on validating the identified indicators.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-082 DESCRIPTIVE STUDY OF POST-SURGERY ANALGESIC PRESCRIPTIONS

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Background and Importance Inadequately treated postoperative pain can compromise the patient's recovery, prolong hospital stay and contribute to chronic pain. In our hospital there are only some surgical services with analgesia protocols. For this reason, it's proposed a study of post-surgical pain treatment.

Aim and Objectives Descriptive study of the management of acute postoperative pain in hospitalised patients after scheduled surgery and the degree of adherence to the analgesia protocols available in the hospital.

Material and Methods Retrospective observational study of hospitalised adults for scheduled surgery during November 2022. Data collection was carried out through the clinical history and Hospiwin2000® electronic prescription program. The collected variables were sex, age, prescribed analgesic regimen, usance or not of analgesia protocol and pain registration according to the numerical scale (NS). The NS classifies types of pain into three ranges: NS 1–3 mild pain, NS 4–6 moderate pain, NS 7–9 severe pain.

Results 125 patients were considered (49.6% male; 50.4% female). Of which the mean age was 57 years (19–89). Out of the 125 cases, there were 22 different analgesia regimens.

The most frequently used intravenous analgesia treatment was dexketoprofen 50 mg/8h + acetaminophen 1 g/8h (19.2%); followed by dexketoprofen 50 mg/8h + acetaminophen 1 g/6h (17.6%). Overall, in only 59% of the cases the prescription of analgesia corresponded to the available protocols in the electronic prescription program. Pain level was recorded in 69% of the patients. All those patients in whom the NS was collected presented different range of pain during the hospital stay: 5% recorded severe pain; 29% moderate pain; and 66% mild pain. 43 prescriptions were detected that did not comply with the technical data sheet recommendations for intravenous analgesic drugs (Metamizole dose > 5 g/day, dexketoprofen > 48 hours).

Conclusion and Relevance A high prevalence of patients with pain and high variability of non-protocolised analgesic guidelines, and even with doses not included in the technical data sheet of the analgesic drugs, were detected.

The analysis of the current situation in our hospital is the starting point for reviewing the existing protocols and developing new ones that unify and optimise the analgesia prescription guidelines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-083 MEDICATION RECONCILIATION INTERVENTIONS IN AN EMERGENCY DEPARTMENT AT ADMISSION

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Background and Importance The Institute for Health care Improvement (IHI) defines Medication Reconciliation as the formal process of obtaining a complete list of the patient's medication prior to admission, comparing it with the one that has been prescribed in the health centre, in transfers and medical discharge.

Reconciliation errors occur in 50% of patients admitted to hospitals and have been identified by organisations such as the WHO or NICE as a priority practice for patient safety.

Aim and Objectives The aim of the study is to describe the pharmaceutical interventions related to medication reconciliation in an Emergency Department at the admission process, the degree of acceptance by clinicians and the most commonly pharmacological groups involved in these interventions.

Material and Methods It was a descriptive and transversal study conducted in the Emergency Department of a Regional Hospital (<150 beds) during February 2021-July 2023.

A review of usual medications of patients admitted during the night was performed daily. Reconciliation interventions were registered in a database (Microsoft Excel (r)) and classified in five types: omission, dose, therapeutic equivalents, drug not necessary and adverse event. Drugs involved were classified according to the Anatomic Therapeutic Classification (ATC).

Results Six hundred and eighty-two pharmaceutical interventions were carried out, of which 59% were of the medication reconciliation type. The degree of acceptance by the clinicians was 75%.

The medication reconciliation interventions were made in 228 patients of whom 55% were male. The mean age of the patients was 75.86 years (range 20–97).

The most frequent reconciliation errors were related to the omission of the drug (46.03%), dosage errors (37.37%) and therapeutic equivalents (6.93%).

Drugs most frequently involved in pharmaceutical interventions belonged to the following ATC groups: cardiovascular system- C (43.06%), nervous system – N (33.41%), blood- B (7.17%) and systemic hormonal preparations-H (5.69%).

Conclusion and Relevance More than a half of the interventions were related to medication reconciliation which shows that this process is important at hospital admission. The high degree of acceptance by clinicians shows that the pharmacist should be part of a multidisciplinary team and can contribute improving patients' safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-084 GENOTYPING ANALYSIS OF POLYMORPHISMS IN THE DIAHYDROPYRHYDROMIDINE DEHYDROGENASE (DPYD) GENE PRIOR TO ADMINISTRATION OF FLUOROPIRMIDINES

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Background and Importance It is highly recommended to genotype DPYD gene polymorphisms before administration. Complete deficiency of DPD activity is very rare, estimated at 0.01% to 0.5% of individuals, partial deficiency has been estimated at 3% to 8%.

Aim and Objectives The aims of the study included the description and frequency of DPYD gene polymorphisms prior to fluoropyrimidine administration in all tumour types and the measures taken.

Material and Methods Retrospective, multidisciplinary study in a tertiary hospital, with the participation of pharmacy, clinical analysis and oncology departments, by reviewing the genotyping of DPYD gene polymorphisms. Oncology patients who were genotyped in the period from June 2020 to December 2021 were included. Four DPYD variants were analysed: DPYD*2A, c.2846A>T, c.1679T>G and c.1236G>A(HapB3) and the genotype of 82 polymorphic regions of the DPYD gene related to the level of enzyme activity. Variables recorded: sex, age, tumour location, variant found and degree of enzyme activity (poor metaboliser(0–0.5), intermediate metaboliser(1–1.5) and normal metaboliser(2).

Results A total of 150 patients, 56.7% female, with a median age of 68.9 years(53.2–84.6) were screened. Tumour sites were: colorectal(48.7%), breast(22.7%), gastric(8.7%), pancreatic(8.7%), cholangiocarcinoma(6%), head and neck(2.7%) and others (2.5%). 15 patients(10%) had some degree of enzyme deficiency. 5(30%) of the patients presented an enzyme activity level of 1.5, 8 (53%) presented 1, 1 (6%) presented 0.5 and 1(6%) presented 0. The variants found were: in 6 patients (40%) c.2846A>T, 3(20%) c.1129–5923C>G, 7 (46.7%) c.1156G>T(*12), 1 (6.7%)c.1777 G>A, 1(6.7%) c.1905+1G>A, 1(6.7%) c.483+18G>A and 1(6.7%) c.1236G>A. 2(13.3%) of the patients had both alleles with mutated variants. 11(73.3%) of the patients had one variant, 3(20%) had 2 variants and 1(6.7%) had 3 variants affected. Intermediate metabolisers had their dose of fluoropyrimidines reduced by 50% and poor metabolisers were spared the use of fluoropyrimidines.

Conclusion and Relevance The main diagnoses were colon and breast cancer. 10% of patients studied had some degree of enzyme deficiency according to the variants analysed, 8.6% with partial deficiency and 1.3% with complete deficiency. Our population showed a high prevalence of deficiencies in relation to the literature described. This determination allowed dose adjustment of these drugs, which represents an advance in terms of safety, allowing personalised treatments, individualising doses and avoiding toxicities.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-085 LONG-TERM PERSISTENCE IN PSORIASIS PATIENTS WITH HIGH RESPONSE TO GUSELKUMAB: A REAL-WORLD RETROSPECTIVE STUDY

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Background and Importance Guselkumab represents an important advancement in the treatment of psoriasis. By targeting the IL-23 pathway, it addresses the underlying immune dysregulation that drives psoriasis, leading to significant improvements in symptoms, quality of life, and long-term disease management for many patients.

Aim and Objectives This study aims to evaluate the real-world persistence of Guselkumab in adult patients with moderate-to-severe psoriasis in a multicentre analysis. Secondary objectives of the study were to analyse the effectiveness and safety of Guselkumab in the same cohort of patients.

Material and Methods This retrospective cohort study used registries and medical records from 2 different hospitals (Apr 2019 to Sept 2023). Adults with moderate-to-severe psoriasis who initiated Guselkumab treatment were identified and followed-up until Sept 2023, or disenrollment. Baseline demographic and clinical characteristics studied included: sex, age at diagnosis, current age, psoriasis area severity index (PASI), previous treatment, and comorbidities. Kaplan-Meier analysis was used to estimate Guselkumab persistence at one, two and three years.

Results A total of 62 patients with moderate-to-severe psoriasis were included (age 49.3 ± 13.7 years; 64.5% men). 29% of included patients were naïve to biological treatment. Baseline PASI score was 8.4 and patients received 1.9 ± 0.9 prior lines of treatment. Most common previous biological treatments included ustekinumab (59.1%), anti-TNFα (52.3%) and IL-17 inhibitor drugs (31.8%). 5 out of 62 patients discontinued Guselkumab treatment due to the following reasons: lack of efficacy (4.8%), transaminase elevation (1.6%) and pregnancy (1.6%). Guselkumab persistence was 21.6 ± [2.0] months for all patients. When performing a subgroup analysis, non-naïve patients obtained a persistence of 23.0 ± [1.5] months followed by 16.6 ± [4.1] months for naïve patients (p=0.250). Guselkumab persistence at 1 year, 2 year and 3 year was 95%, 93% and 91%, respectively.

Conclusion and Relevance Guselkumab demonstrated high persistence during the study period, suggesting patient and healthcare professional satisfaction with efficacy and tolerability over time in patients with moderate to severe psoriasis.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-086 ASSESSMENT OF THE CLINICAL RELEVANCE OF LEVETIRACETAM MONITORING

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Background and Importance Monitoring of levetiractetam is necessary for treatment optimisation due to their wide interindividual pharmacokinetic variability. Age,clinical situation and pregnancy contribute greatly to its pharmacokinetic alterations.
Aim and Objectives To evaluate the impact and usefulness in clinical practice of pharmacokinetic monitoring of levetiracetam in a tertiary university hospital carried out by the pharmacy service.
Material and Methods Retrospective observational study in 53 patients between 02/2016–05/2023. Pharmacokinetic and patient data were obtained from Gestlab® and Orion Clinic® software:sex,age,weight,concomitant antiepileptic,creatinine value and hepatic insufficiency diagnosis.Patients were classified:paediatric(0–14years),pregnant,critical ill or outpatients.The clinical relevance of levetiracetam monitoring was assessed by whether the first levetiracetam level of patients was within or outside the therapeutic range(12–46mcg/mL) and the pharmacokinetic recommendation made by the pharmacy service.
Results
Fifty-three patients were studied 25 men and 28 women with a median of 4(4) years and 18(20)Kg in paediatric and of 42 (32.25) years and 69(34)Kg in adults. There were 33% paediatric,6% pregnant,15% critical ill and 45% outpatients.Two patients had creatinine levels above 1.3mg/dL,two diagnosed with liver failure and 43% had concomitant antiepileptic treatment. 53% of patients had levetiracetam level out of range,79% were below:14% pregnant,41% paediatric,9% critical ill and 36% outpatient. 68% were adjusted according to the pharmacy service of which 100% decided to increase the dosage:100% of pregnant and critical,63% of outpatient and 55% of paediatric. In 32% not adjusted,29% got the treatment suspended,29% was increased by the physician and 14% was not possible to carry out the pharmacokinetic report. The remaining 21% were above the range:17% were critical ill and 83% outpatient,50% percent were adjusted according to the pharmacy service:60% of outpatient in which 100% decided to reduce the dosage. In 50% not adjusted,33% it was not possible to carry out the pharmacokinetic report. Treatment was adjusted in 2 patients despite they were within range due to poor renal function or by decision of the physician.
Conclusion and Relevance Monitoring of levetiracetam levels has been shown to be clinically relevant for better individualisation of treatment since more than half of the patients were out of range. This has allowed pharmacokinetic adjustment in most cases to maintain the drug in therapeutic range and optimise treatment,especially in pregnant,critical ill and paediatric patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-087 ADALIMUMAB PERSISTENCE IN CLINICAL PRACTICE AT A REGIONAL HOSPITAL

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Background and Importance Currently, biosimilar drugs are a great cost-effective alternative to maintain the public health system sustainable.
Aim and Objectives To analyse persistence between biosimilar and originator adalimumab, as well as predictors associated with a higher risk of discontinuation.
Material and Methods Retrospective study conducted in a regional hospital with a reference area of 133,734 inhabitants.

All patients who have been treated in our hospital with originator or biosimilar adalimumab were included. Patients switching were excluded.
Variables studied sex, age, treatment, indication, starting and ending date, previous treatments and reason for interruption.

Kaplan-Meier method was used to analyse the 48 month retention rate and compared by a stratified log rank test. A Cox proportional hazards regression analysis stratified by age, sex, indication, year of prescription and reason for interruption was done.

Statistical analysis was performed using SPSS Statistics v22. Categorical variables are shown with percentages and quantitative variables with median and interquartile range.
Results The study included 401 patients, 222 women (55.4%), median age 54.0 (43.0–63.0) years. Adalimumab biosimilar was indicated in 185 (46.1%) patients. Treatment duration for the originator vs biosimilar was 21.9 (5.7–61.8) vs 9.3 (5.0–20.7) months.
Indication distribution 137 (34.2%) rheumatoid arthritis, 74 (18.5%) psoriasis, 63 (15.7%) Chron disease, 50 (12.5%) psoriatic arthritis, 50 (12.5%) spondyloarthitis, 21 (5.2%) hidradenitis suppurativa, 3 (0.7%) ulcerative colitis, 2 juvenile idiopathic arthritis (0.5%), 1 SAPHO (0.2%).
Main reasons for stopping adalimumab 74 (18.5%) no response, 58 (14.5%) adverse effect, 47 (11.7%) loss of effectiveness and 33 (8.2%) remission.

The overall 48-month retention rate was 17.2%. Estimated proportions of patients maintaining originator and biosimilar were 30.1% vs 2.2% after 48 months. Originator showed a higher survival retention (HR 0.42, 95% CI 0.34–0.53, $p<0.0001$).

The Cox proportional hazard regression showed that the predictors significantly associated with adalimumab discontinuation were age, reason for discontinuation and year of prescription.
Conclusion and Relevance

- Biosimilar persistence was lower than expected. Probable reasons were lack of clinician's confidence and the increasing variability of treatments.
- The duration of treatment with originator was more than twice longer than biosimilar.
- The highest number of discontinuations took place in the first 12 months.

- The high number of discontinuations causes a lot of biological turnover.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-088 FOLIC ACID, FOLINIC ACID AND HEMATOTOXIC TREATMENTS: A REVIEW AT A UNIVERSITY HOSPITAL CENTRE

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Background and Importance Studies have shown that folic acid (FA) and folinic acid (FAi) are equally effective in preventing methotrexate-related haematotoxicity. According to its marketing autorisation (MA), FA is indicated for the treatment of folate deficiency, chronic intestinal absorption disorders and supplementation during pregnancy and FAi for the prevention and correction of haematotoxicity caused by co-trimoxazole (CMX), pyrimethamine (PYM) and methotrexate (MTX).

Aim and Objectives Assessment of the compliance of prescriptions with the indications for FA and FAi at our university hospital centre (UHC).

Material and Methods A retrospective study was carried out on nominative deliveries in 2022 on 2 UHC establishments. The indication (prevention or supplementation), whether it was combined with haematotoxic treatment, and the search for vitamin B9 (VB9) deficiency prior to initiating treatment were sought using the prescription assistance software.

Results 266 patients were included in our study: 56% (n=150) received FA and 44% FAi (n=116). 84% of prescriptions complied with MA indications.

Regarding FA, a VB9 dosage was performed in 42% (n=63) of patients and a deficiency was observed in 57% (n=36) of cases. 90% (n=135) of patients received it for a supplementation and 10% (n=15) to prevent haematotoxicity due to treatment (n=11 on CMX, n=4 on MTX) and are therefore off-label.

Regarding AFi, a VB9 dosage was performed in 20% (n=23) of patients and a deficiency was identified in 22% (n=5). In 77% (n=89) of cases, FAi was used to prevent haematotoxicity during treatment (n=85 on CMX, n=3 on PYM, n=1 on MTX) and 23% (n=27) received it as a supplement and are therefore off-label.

Conclusion and Relevance Some prescriptions don't correspond to the MA indications, and the efficacy of FA has not been demonstrated in the prevention of CMX haematotoxicity. Moreover, the unit cost of FAi is higher: failure to comply with the indications may result in higher treatment costs.

Disagreement between prescribers is observed through the heterogeneity of prescriptions. To reduce the rate of non-compliant prescriptions, consultation between doctors and pharmacists needs to be developed to reach a consensus.

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Conflict of Interest No conflict of interest.

4CPS-089 CLINICAL PHARMACIST EFFECTIVENESS IN HOSPITALISED PATIENTS: ANALYSIS OF THE INTERVENTION RECORD IN A SECONDARY ACUTE HOSPITAL

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Background and Importance Clinical pharmacist activity is fundamental in the hospitalised patient, since it prevents medication errors, participates in the selection of medication and facilitates medication compliance in terms of dispensing and administration.

Aim and Objectives To analyse the profile of the clinical pharmacist's interventions in patients hospitalised in a second-level hospital. Therefore, clinical needs can be discovered and preventive actions promoted.

Material and Methods Retrospective multidisciplinary, interventional study, from 08/2023 to 09/2023. Acute-hospitalised patients from medical and surgical areas were selected.

The variables recorded were intervention/day ratio, medications prevalence and their incidences and reasons for intervention. A descriptive analysis was performed using absolute frequencies and percentages.

Results 1555 pharmaceutical interventions were recorded, with a 12.34 interventions/day ratio and 7.05 implemented interventions/day/100 patients, considering 175 hospital beds.

Medications with more than 10 interventions and their incidence were: non-guide oral medications (183, hospital admission conciliation), intravenous dexketoprofen (33, kidney-failure adjustment), intravenous acetaminophen (31, therapeutic duplicity), piperacillin-tazobactam (31, treatment duration, kidney-failure adjustment), oral allopurinol (30, hospital admission conciliation), non-guide inhaled medications (25, hospital admission conciliation), intravenous potassium chloride (24, improper dosage, frequency not compatible with fluid therapy), intravenous metamizole (22, excessive dose), among others.

Abstract 4CPS-089 Table 1 Shows main reasons for the interventions

Intervention reasons (n=1555)	Absolute frequency	Percentage (%)
Other intervention reasons	283	18.3
Facilitate compliance	258	16,6
Incomplete order	182	11,7
Therapeutic duplication	139	8,9
To promote compliance	114	7,3
Home treatment not prescribed	91	5,9
Overdose	89	5,7
Therapeutic exchange	87	5,6
Allergies not introduced	78	5,1
Excessive duration	70	4,5
More frequent than recommended	66	4,1
Under-dosage	58	3,7
Needs additional treatment	40	2,6

Of the implemented interventions, 50.48% corresponded to surgical areas and 49.52% to medical areas.

Conclusion and Relevance The task carried out by the clinical pharmacist is fundamental in the hospital environment, since it ensures the proper use of medications to maximise their effectiveness, minimise the side effects and prevent medication errors.

This study shows that the registry of interventions is crucial to carry out preventive strategies with a population impact in the most prevalent interventions. Thanks to this, strategies were implemented such as mandatory allergy registration, assisted prescription modification to avoid overdoses (e.g. metamizole, dexketoprofen) or expanding the hospital's pharmacotherapeutic guide.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-090 REAL-WORLD PERSISTENCE WITH FREMANEZUMAB VERSUS ERENUMAB AMONG MIGRAINE PATIENTS

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Background and Importance Migraine therapy is a major challenge. Monoclonal antibodies against calcitonin gene-related peptide (anti-CGRP mAb), as fremanezumab and erenumab, are indicated for migraine prophylaxis in adults.

Little is known about the comparative persistence of fremanezumab and erenumab, two anti-CGRP mAbs commonly used in our clinical practice.

Aim and Objectives To compare the persistence of fremanezumab and erenumab in patients with migraine and to identify factors associated with it.

Material and Methods We conducted a retrospective, non-interventional, longitudinal study. All chronic or episodic migraine naive patients over 18 years treated with fremanezumab or erenumab in our centre were included.

Persistence was defined as the duration of time from initiation to discontinuation of therapy (last dispensing or end of follow-up in August 2023). Permissible gap (days between two prescription fills exceeding the allowable refill period) was 60 days.

Covariates collected from medical record were: age, gender, baseline migraine days per month (MDM) and Medication Possession Ratio (MPR).

We compared qualitative variables using the χ^2 distribution. For quantitative variables, we used either the Mann-Whitney U test or the Student's t-distribution based on normality assessment.

Kaplan-Meier survival analysis was performed and differences were evaluated using the log-rank test. Adjusted risk of discontinuation was assessed with Cox Proportional Hazard models. Significance level was 0.05.

Results Eighty patients were included, 86.3% were female. Age (mean±SD) was 48±10 years. MPR was 98.4±4.1, 61.3% were treated with fremanezumab. Baseline MDM (median) was 17 days (IQ 12–28). There were no statistically significant differences between the groups.

Overall, mean persistence duration was 482 days (CI 95% 404–559). Persistence with fremanezumab was 743 days (CI 95% 638–848) and persistence with erenumab was 548 days (CI 95% 368–729);p=0.001. According to adjusted Cox-model by MDM HR was 3.5 (CI 95% 1.7–6.9;p=0.001) for anti-CGRP mAb and 1.1 (CI 95%, 1.04–1.15 p=0.001) for baseline MDM.

Conclusion and Relevance In our study, naive patients treated with fremanezumab had higher persistence rates than those treated with erenumab. Baseline MDM was also found to influence persistence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-091 REAL-LIFE PERSISTENCE, EFFECTIVENESS AND SAFETY OF FREMANEZUMAB IN PATIENTS WITH CHRONIC MIGRAINE

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Background and Importance Chronic migraine (CM) is a highly disabling disorder characterised by recurrent episodes of moderate to severe headache. Several preventive treatments are available, including monoclonal antibodies against calcitonin gene-related peptide (CGRP), such as fremanezumab.

Aim and Objectives The aim of this study was to evaluate the persistence, effectiveness and safety of fremanezumab in clinical practice in patients with CM.

Material and Methods This is a restrospective and descriptive study conducted at a tertiary teaching hospital. All patients who started fremanezumab as a first-line anti-CGRP therapy between August 2020 and December 2022 were included. Inclusion criteria were: age $\geq$ 18 years, diagnosis of CM and a minimum follow-up of 3 months.

Patients demographic and clinical data were obtained from electronic medical records. These data included age, sex, comorbidities, number and type of previous preventive treatments, and monthly migraine days (MMD) at initiation, 3 months and 6 months. Persistence was calculated as the number of days between treatment initiation and discontinuation or the end of study follow-up, whichever occurred first. Efectiveness was calculated considering a $\geq$50% reduction of mean MMD at 3 and 6 months. Safety was analysed according to the number and type of adverse events that occurred during treatment.

Results A total of 207 patients were included, of whom 190 (92%) were women with a median age of 48 years (18–81 years). The two most frequent comorbidities were depression (23%) and anxiety (20%). Patients had received a mean of 4.6 preventive treatments before anti-CGRP initiation, highlighting the use of antidepressants (72.4%) and onabotulinum toxin (89.3%). At 3 and 6 months of follow-up, persistence were 92.6% and 80.0%, respectively. The percentage of patients who achieved a 50% MMD reduction was 56.8% at 3 months and 54.5% at 6 months. A total of 27 patients (13%) developed side effects during fremanezumab therapy,

being the most common allergic reaction or pruritus (11 patients; 5.3%) constipation (5 patients; 2.4%) and injection site reaction (5 patients; 2.4%).
Conclusion and Relevance Our results show that fremanezumab is an effective and safe treatment for CM, which has demonstrated good persistence data in clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-092 ANALYSIS OF ANTIBIOTICS CONSUMPTION AT AN ITALIAN CARDIOLOGY CENTRE: PHARMACOUSE PROFILE ACCORDING TO THE AWARE CLASSIFICATION

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Background and Importance Resistant bacteria and multidrug-resistant bacteria (MDRO) represent a problem for public health, both for the epidemiological impact and clinical manifestations and for the associated economic consequences.
Aim and Objectives Antimicrobial stewardship includes the use of the AwaRe classification which divides antibiotics into Access, Watch and Reserve categories. An analysis of the DDD (defined daily dose) consumption of antibiotics distributed by the Hospital Pharmacy to the departments between 2018 and 2021 was conducted in order to implement the use of antibiotic drugs as suggested by the World Health Organization Healthcare (WHO).
Material and Methods In order to monitor the use of drugs, the hospital pharmacy extracted the consumption into dosage units using the SAP software and then converting them into DDD. To compare the consumption data with the literature reports, it was necessary to relate the DDDs to the days of hospitalisation. Finally, the drugs were divided into AwaRe categories and the trend in consumption of each molecule in the period considered was calculated.
Results The analysis revealed that the most used category is Watch, whose consumption decreased in 2019 compared to the previous year by -6.31%, and then increased in 2020 by +21.49%. Watch consumption in 2021 is comparable to that of 2019. Access consumption underwent a slight increase in 2019 compared to 2018 of +24.77%, while it decreased in the following two years (-21.19% in 2021 vs 2019). The Reserves showed a growth trend between 2018 and 2020 (+83.90%). Compared to 2020, in 2021 the data relating to the use of these antibiotics decreased slightly (-24.36%). Finally, the Access to Watch indicator was calculated to evaluate the appropriateness of antibiotic consumption. The results emerging from this report does not match to the ideal value recommended by the WHO.[1]
Conclusion and relevance The consumption of antibiotics in the Watch and Reserve categories should decrease in favour of those belonging to the Access category. The use of latest generation antibiotics belonging to the Reserve category should be limited to cases in which antibiotics from other classes are inappropriate.

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Conflict of Interest No conflict of interest.

4CPS-093 ANTIBIOTIC RESISTANCE IN THE HOSPITAL CONTEXT: RETROSPECTIVE ANALYSIS OF ANTIBIOGRAMS, RESISTANCE AND SENSITIVITY PROFILES AT AN ITALIAN HEART CENTRE

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Background and Importance The fight against antibiotic resistance is one of the main challenges of the twenty-first century. Hospital antimicrobial stewardship activities are fundamental for appropriate antibiotic therapies against multi-resistant bacteria (MDRO).
Aim and Objectives A retrospective descriptive analysis of a sample of patients hospitalised to a cardiac centre between 2018 and 2021 and subjected to culture examination was conducted in order to evaluate the resistance and sensitivity profile of MDRO through the evaluation of MICs (minimum inhibitory concentration) expressed in the antibiograms.
Material and Methods The MICs of some antibiotic-MDRO combinations were evaluated compared to the epidemiological cut-off ECOFF. The calculated differences were evaluated using the Student's t test for paired samples. All results are presented as two-sided values and a p value<0.05 is considered significant. analyses were performed with SAS software.
Results The retrospective analysis was conducted on 167 adult subjects. The majority of patients are male (65.27%, n=109) aged between 56 and 75 years (50.9%, n=85). The majority tested positive for gram-negative bacteria throughout the period (55.56% n=30 in 2019, 65.85% n=27 in 2020, 68% n=34 in 2021), with the exception of 2018 in which a prevalence of gram-positive s was detected (55.41%, n=41). The most widespread bacterial species were Escherichia coli and Klebsiella Pneumoniae among gram-negatives and Staphylococcus epidermidis and Staphylococcus aureus among gram-positives.

The MICs of these bacteria are increasing, as in the case of Klebsiella Pneumoniae, for which the MIC value of meropenem exceeds the ECOFF with a frequency of 99.9%. The Staphylococci family expressed MIC values for the antibiotic linezolid equal to the ECOFF with a frequency of 5.38%. The MIC of daptomycin was equal to the ECOFF for 17.58% of the isolates.
Conclusion and Relevance From this work, the need for clinicians to consult antibiograms and evaluate the ECOFF parameter has emerged. The project will be continued in the future in order to monitor the evolution of the resistance profiles of MDROs and to evaluate the prescriptive appropriateness through the analysis of the clinical outcome of treatment efficacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-094 RISK FACTORS FOR EMERGENCY DEPARTMENT RE-VISIT IN ELDERLY PATIENTS WITH GASTROINTESTINAL BLEEDING SECONDARY TO DIRECT ORAL ANTICOAGULANTS

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Background and Importance Gastrointestinal bleeding related to antithrombotic therapy is a main cause of emergency department (ED) consultation. Data regarding the risk factors involved in the onset of new bleeding episodes associated with new anticoagulant treatment after the first episode is scarce.

Aim and Objectives To evaluate the frequency of ED re-visits among elderly patients with gastrointestinal bleeding secondary to direct oral anticoagulant (DOACs) treatment and to identify risk factors associated with an increased risk of ED re-visits.

Material and Methods A four years (2018–2022) retrospective observational study was designed, including adult patients (≥18 years) with atrial fibrillation and undergoing oral anticoagulation therapy who visited the ED for gastrointestinal bleeding. To evaluate the risk factors for 90 days re-visit, a multivariate analysis was designed including patients comorbidities, concomitant treatment, change in anticoagulant treatment and prescription of direct-acting oral anticoagulants.

Results 127 patients (Mean age (SD): 84.7 (7.6) years; 61.4% females) were included. At discharge, anticoagulation therapy was modified in 45 (35.4%) patients; changed from an oral anticoagulant to heparin in 18 (18.9%) patients, to another DOACs in 21 (46.7%) and to a vitamin K antagonist in four (0.9%). Anticoagulant treatment was withdrawn in eleven (9.0%) patients at discharge. 15 (12.2%) patients revisited the ED 90 days after hospital discharge for bleeding or thrombotic episodes. A non-significant decrease in the frequency of ED re-visits was observed in those patients who changed their anticoagulant treatment at discharge (10.1% vs 17.5%; p=0.241). In the multivariate analysis, chronic kidney disease was the only factor significantly associated with revisits at 90 days [OR: 1.58 (1.01–4.05)]

Conclusion and Relevance Elderly patients who experience a first episode of gastrointestinal bleeding have a high risk of re-visiting the ED for a bleeding episode. Those patients with antithrombotic change at discharge may decrease the risk of new emergency visits.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-095 EXPLORATORY ANALYSIS OF CARDIOVASCULAR EVENTS IN AN ASTHMATIC COHORT

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Background and Importance Asthma often accompanies a range of concurrent health conditions. However, there is a scarcity of evidence concerning the cardiovascular consequences in individuals with asthma.

Aim and Objectives The primary objective of the study was to analyse the impact of cardiovascular factors on a group of asthma patients in our hospital.

Material and Methods This was a retrospective, observational study including 206 patients with asthma who were assessed at the Difficult Asthma Control Unit of a tertiary hospital. Patients who had experienced a cardiovascular effect before the diagnosis of asthma were excluded.

We gathered demographic and clinical data, as well as comorbidities, asthma subtypes, biological markers and spirometric measurements using the electronic medical record via the HCIS application. We also documented the patients' cardiovascular event history, specifying the type of event. Furthermore, we recorded information regarding the patients' use of biological therapy, systemic corticosteroids and inhalation therapy

Results The majority of patients were women(65,6%) with an average age of 57±18 years. Among them, 121 patients had allergic asthma. Other comorbidities include: obesity or overweight(98), diabetes(24), hypertension(65), dyslipidemia(52) and sleep apnea (21).

108 patients were treated with omalizumab, 35 with mepolizumab, 18 with benralizumab and 40 werent receiving biological treatment. A total of 125 patients had more than 300 eosinophils and 110 had a total immunoglobulin E (IgE) level greater than 100 kU/L.

114 patients experienced at least one asthma exacerbation per year, while 109 patients had forced expiratory volume (FEV1) values <80% of predicted. 77 patients had a recent fraction of exhaled nitric oxide greater than 40 ppb.

23 patients (11%) suffered a cardiovascular event, including 5 anginas pectoris, 5 myocardial infarction, 6 heart failures, 8 supraventricular arrhythmias, 5 thromboembolisms, 5 strokes, and 1 with lower limb thrombosis.

Conclusion and Relevance Cardiovascular events are more prevalent in our asthmatic patients (11%) compared to the general European population (7%). It is essential to determine whether there is a relationship between cardiovascular processes and asthma, and if so, evaluate the mutual impact of both processes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-096 USE OF COVID-19 ANTIVIRALS IN PATIENTS PREVIOUSLY TREATED WITH TIXAGEVIMAB/CILGAVIMAB PROPHYLAXIS: EXPERIENCE OF AN ITALIAN HOSPITAL

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Background and Importance Some COVID-19 authorised drugs target the entry of SARS CoV-2 into the host cell, such as the combination of monoclonal antibodies tixagevimab/cilgavimab (T/C), while others prevent viral replication, such as the antivirals remdesivir and nirmatrelvir/ritonavir. Pre-exposure prophylaxis with T/C is indicated in frail patients at risk of

developing severe COVID-19. One pivotal study reported a 77% reduction in disease risk compared to placebo, with protection estimated at least six months.

Aim and Objectives To evaluate how many patients have developed COVID-19 that required treatment with a specific antiviral among the ones in prophylaxis with T/C in our hospital.

Material and Methods Through the analysis of AIFA Monitoring Registers it was possible to obtain data of patients in prophylaxis with T/C and subsequently treated with COVID-19 antiviral. The data obtained refers to the period between 10th March 2022 (date of the first administration of prophylaxis in the hospital) and 10th September 2023. Cases of ineffectiveness of T/C have been reported in the National Pharmacovigilance Network.

Results During the considered period, 314 patients were treated with T/C prophylaxis. Of these, 9 (2.9%) received remdesivir, 6 (1.9%) remdesivir early treatment, 4 (1.3%) nirmatrelvir/ritonavir. 1 patient (0.3%) contracted the infection 3 times after prophylaxis (the first within 1 month and the following after 6 months) requiring 3 antiviral treatments: nirmatrelvir/ritonavir, remdesivir early treatment and remdesivir. Overall, 6.4% of patients undergoing prophylaxis were subsequently treated with at least one antiviral, 85% of them within 6 months. The average time between prophylaxis and antiviral treatment was 113 days.

Conclusion and Relevance The AIFA Monitoring Registers have been a useful tool for the clinical evaluation of the therapeutic efficacy of T/C prophylaxis and for pharmacovigilance activities. In the sample considered, 93,6% of patients who received prophylaxis didn't develop COVID-19 that required antiviral treatment in a hospital setting. Our data only refers to inpatients subjects, thus representing a limitation for the analysis; T/C prophylaxis for frail patients has however proved to be a valuable resource in addition to vaccination.

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Conflict of Interest No conflict of interest.

4CPS-097 REAL-WORLD STUDY OF APALUTAMIDE TREATMENT IN PATIENTS WITH METASTATIC HORMONE-SENSITIVE PROSTATE CANCER IN NINE HOSPITALS OF VALENCIAN COMMUNITY

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Background and Importance Systemic involvement of prostate cancer(PC) typically occurs at the bone level (65–85%). Patients with metastatic hormone-sensitive prostate cancer (mHSPC) have survival rates ranging from 1–6 years, depending on high-risk prognostic factors such as:

- Elevated levels of prostate-specific antigen(PSA>20) at diagnosis.
- High Gleason score(8–10).
- Increased volume of metastatic disease.
- Poor functional status.
- Bone symptoms or the presence of visceral metastases.

Apalutamide, abiraterone, and enzalutamide are orally administered treatments financed for use in combination with androgen deprivation therapy. They have demonstrated improvement in overall survival (OS), particularly in high-risk progression populations, and a favourable safety profile.

Aim and Objectives Study to asses the efficacy profile, safety and clinical follow-up of patients with mHSPC undergoing Apalutamide treatment.

Material and Methods A retrospective observational study was conducted on patients with mHSPC who initiated Apalutamide treatment in 9 public hospitals in Valencian Community, Spain. These patients had a minimum clinical follow-up of 6 months as of March 2023. Clinical records, PSA evolution, and toxicity reported by healthcare professionals or the patients themselves were reviewed. A comprehensive descriptive statistical analysis was conducted, both overall and by disease volume.

Results A total of 172 patients(73±8 years) were included, with high disease volume(n=80;46.5%) and low disease volume(n=92;53.5%). 41.3% had received prior local treatment. The median pre-treatment PSA level was 22.2 (3.4–97.9) ng/mL, 69.8% had metastases at diagnosis with predominantly bone metastasis (61.6%), and a median time from diagnosis to the initiation of apalutamide was 4 (2–51) months.

At 3 months, 69.7% of patients achieved >90% reduction in baseline PSA, and an 87.7% reduction >50% in PSA in real-world conditions. After 12 months of treatment, 80% of patients continued with apalutamide, with discontinuation due to toxicity in 4.2% and progression or death in 13.1% of patients.

Conclusion and Relevance We did not observe significant response differences between low and high volume groups. Apalutamide in real-world treatment of men with mHSPC demonstrates a favourable safety profile like data published in clinical trials.

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Conflict of Interest No conflict of interest.

4CPS-098 EFECTIVENESS AND SAFETY OF LONG-ACTING CABOTEGRAVIR/RILPIVIRINE IN REAL-LIFE POPULATION

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Background and Importance Simplification strategies aimed to improve antiretroviral therapy adherence, tolerability and compliance have emerged during recent decades. In this context, long-acting cabotegravir/rilpivirine injectable has been recently

commercialised as a new promising treatment alternative, and pharmacist-led long-term monitoring could be beneficial to ensure treatment effectiveness and safety.

Aim and Objectives Assess the long-term real-life effectiveness and safety of cabotegravir/rilpivirine.

Material and Methods This was an observational, longitudinal and prospective study performed between March and September 2023. Patients were included if they started treatment with either a one-month oral lead-in (OLI) with cabotegravir/rilpivirine followed by long-acting therapy or directly with the long-acting injection regimen (at month 0, 1, 3 and 5) and received at least 4 injectable doses and excluded if participated in FLAIR and ATLAS studies. Sociodemographic (age, sex at birth), anthropometric (body mass index [BMI]) and viral (HIV-RNA viral load at baseline and 5-month follow-up) data were collected. Treatment was considered effective when patients achieved or maintained virological suppression

Drug adverse effects were collected and followed-up through active pharmacist validation, and clinical and nursing-staff monitoring.

Results 30 patients were included (90% male sex at birth, mean age 43.7 years). 1 patient had a BMI>30. At baseline, all patients had undetectable viral load (HIV-RNA<50 copies/mL) and 6(20%) started with OLI.

At 5-months follow-up, 28(93.3%) patients had an undetectable viral load. 2 patients abandoned treatment after 1 month, due to an unknown archived rilpivirine mutation (one patient had a VL of 113,146 copies/mL and the other remained undetectable).

90% of patients reported at least 1 adverse effect, being the most frequent: injection-site reactions (83.3% of patients reported gluteal pain, 13.3% induration), followed-by low-grade fever (10%), fatigue (6.7%) and diarrhoea (6.7%).

Conclusion and Relevance Cabotegravir/rilpivirine effectiveness and safety were favourable in this cohort of baseline virologically suppressed patients. No treatment interruptions due to adverse effects were observed but resistance mutations need to be considered.

Although small sample size, low proportion of female patients and a short-term follow-up due to recent commercialisation, this study could be of help due to lack of studies reporting data on cabotegravir/rilpivirine effectiveness in real-life population and long-term pharmacist treatment monitoring

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-099 CHIMERIC ANTIGEN RECEPTOR-T CELLS (CAR-T CELLS) AND ANTIBIOTICS: A NOT-SO-INNOCENT ASSOCIATION

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Background and Importance According to an American study[1], prior exposure to Piperacillin/tazobactam (P/T), Imipenem/cilastatin (I) and meropenem (M) is correlated with reduced overall survival and a 71% higher risk of death in patients treated with CAR-T cells (Chimeric Antigen Receptor T cells). This exposure is also associated with an increased risk of immune effector cell-associated neurotoxicity syndrome (ICANS).

Aim and Objectives The aim is to demonstrate if the American results apply to our real-life results.

Material and Methods For each patient who received a CAR-T cells injection between January 2019 and August 2023, the 'CAR-T cells' pharmaceutical team checked: antibiotic prescription 4 weeks prior to CAR-T cells injection, post-injection toxicities (ICANS and cytokine release syndrome (CRS)) and death within 6 months of CAR-T cells injection.

To have populations comparable to those in the study, we defined two groups: 'P/T/I/M' is patients who received P/T/I/M antibiotics, and 'Other antibiotics and naive' is patients who received antibiotics other than P/T/I/M or antibiotic naive. we selected all CAR-T cells with marketing authorisation.

Statistical comparisons were made using the Fischer test (risk = 5% bilateral).

Results Two-hundred and five patients received CAR-T cells: 172 'Other ATB and naive' patients (84%) and 33 'P/T/I/M' patients (16%) in the 4 weeks prior to injection.

In the 'P/T/I/M' population, there were 12 CRS (36.5%), 0 ICANS, 12 ICANS+CRS (36.5%) and 9 (27%) without toxicities. Seven (21%) patients died.

In the 'Other antibiotics and naive' population, there were 100 CRS (58%), 2 ICANS (1%), 43 ICANS+CRS (25%) and 27 no toxicities (16%). Twenty-four patients (14%) died.

A higher risk of CRS has been identified in the 'P/T/I/M' group (p=0.02).

No other significant difference was found between the 2 groups on: ICANS+CRS (p=0.2), ICANS (p=1), or death (p=0.29).

Conclusion and Relevance Our study shows a higher risk of CRS for patients exposed to P/T/I/M 4 weeks prior to injection.

Our study also shows no excess risk of ICANS nor toxicities and death for 'P/T/I/M' patients. Our results are therefore not similar to those of the American study.

These differences could be explained by the size of our population and the fact that the American study only selected anti-CD19 CAR-T cells.

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1. https://doi.org/10.1038/s41591-022-01702-9

Conflict of Interest No conflict of interest.

4CPS-100 THE UTILITY OF EARLY PHARMACEUTICAL VALIDATION OF SELECTED HIGH-RISK DRUGS IN A HOSPITAL EMERGENCY DEPARTMENT

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Background and Importance High-risk medication and the associated errors represent a potential source of adverse effects and readmissions for patients.

Aim and Objectives To analyse the utility of early pharmaceutical validation of direct oral anticoagulants (DOACs) and long-acting insulins (LAIs) in a Hospital Emergency Department (ED).

Material and Methods This retrospective study was conducted between May 15, 2023, and September 28, 2023. Two groups of high-risk medications (HRMs) were selected: DOACs

(apixaban/dabigatran/edoxaban/rivaroxaban) and LAIs (degludec/detemir/toujeo (glargine)) due to their high-risk nature, requiring validation by a pharmacist for the early in the morning dispensation. On weekdays, these medications were identified in the ED through the electronic prescription program and subjected to pharmaceutical validation. All locations, appropriateness, and, in cases of inappropriateness, both the underlying reasons and their acceptance were recorded. Recommendations were communicated through the patient's electronic medical record or by telephone to the attending physician. Locations reviewed on previous days were excluded to prevent duplication. The primary variable was the degree of total non-appropriateness, both overall and by therapeutic group. Secondary variables included the reasons for non-appropriateness, the degree of acceptance of pharmaceutical recommendations, and, in cases of non-acceptance, the occurrence of adverse drug events (ADEs) for each therapeutic group. The analysis was performed using Microsoft Excel® for Microsoft 365 MSO (2308 version).

Results During the study period, a total of 338 locations were recorded: 193 DOACs and 145 LAIs. The overall degree of non-appropriateness was 16.6% (56/338), with 13.0% (25/193) for DOACs and 21.4% (31/145) for LAIs. The main reasons for non-appropriateness for DOACs were 52.0% temporary contraindication (13/25), 36.0% inappropriate dosage (9/25), and 12.0% reconciliation (3/25); for LAIs: 58.1% inappropriate dosage (18/31), 32.3% contraindication (10/31), and 9.7% inappropriate presentation (3/31). The overall acceptance rate of recommendations made was 86.0% (49/57), with rates of 100% (13/13) and 88.0% (22/25) for DOACs and LAIs, respectively. No ADEs occurred.

Conclusion and Relevance Early and proactive validation by the pharmacist in the Emergency Department of selected high-risk drugs appears to optimise pharmacotherapy and reduce the occurrence of adverse events associated with these medications.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-101 MONITORING METABOLIC SYNDROME IN OLANZAPINE TREATED PATIENTS

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Background and Importance Neuropsychiatric disorders are associated with significant reduction in life expectancy and increased risk of cardiovascular mortality. Olanzapine, can exacerbate the development of metabolic síndrome (MS), especially at the beggining of treatment

Aim and Objectives Main objetives are to analyse the metabolic monitoring of patients receiving oral olanzapine treatment, to study the association between olanzapine use and the development of metabolic alterations (MA) and to investigate the prescription of specific treatments for MS in patients who develop it

Material and Methods This was an observational, descriptive, and retrospective study that included adult patients admitted to the psychiatric hospital unit and prescribed oral olanzapine between January 2023 and April 2023.

The collected variables included sex, age, risk factors (smoking and substance use) and Body Mass Index (BMI).

It was recorded whether there was an initial blood test and a follow-up test conducted between two and twelve months after the start of treatment, along with the time elapsed until the follow-up test. The following parameters were collected: cholesterol, triglycerides, high-density lipoprotein (HDL), low-density lipoprotein (LDL), and blood glucose.

For patients developing MA, the study examined the prescription of hypoglycemic and lipid-lowering medications.

Results 42 patients were included, 57% women and Mean age (±SD) was 40±15.5 years. Risk factors included substance use in 19.05% of patients and tobacco use in 16.6%. The mean BMI was 24.5±5 kg/m^2.

Only 45% of patients underwent an initial blood test. None of them had hyperglycemia, but 31.6% had lipid abnormalities (LA), with hypertriglyceridemia in 50% of cases followed by high cholesterol and elevated LDL.

Within the first few months of treatment (4.5 ± 2.5), 54.8% had follow-up blood tests. None of these patients had hyperglycemia, but 52.17% showed LA, increased TG in 50% and decreased HDL in 41.6%.

Only one of these received lipid-lowering medication.

Conclusion and Relevance A substantial percentage of patients were not monitored for the potential development of MS associated with olanzapine use. There was an observed increase in LA, possibly linked to it. Importantly, lipid-lowering medication use was limited when LA were present.

The study highlights the need to raise awareness among healthcare professionals about the importance of monitoring MS in these patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-102 AMIODARONE AND LITHIUM-INDUCED THYROID DYSFUNCTION: WHO INITIATES THE PRESCRIBING CASCADE?

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Background and Importance Prescribing cascades occur when an unrecognised adverse drug reaction (ADR) leads to the initiation of additional medication, contributing to polypharmacy. It remains unclear whether prescribing cascades are initiated by physicians from specialties other than the initial prescriber. This study focuses on amiodarone and lithium, two medications exclusively initiated in hospitals, while the ADR thyroid dysfunction occurs in primary care (median: after two years).

Aim and Objectives To assess whether the specialty of the physician initiating amiodarone or lithium differs from the specialty of the physician initiating the thyroid medication.

Material and Methods A retrospective study was conducted (two teaching hospitals and 22 community pharmacies). Patients initiating amiodarone or lithium (index) and subsequently receiving thyroid medication (marker) within 24 months were included. The primary outcome was the

proportion of different specialties initiating the index and marker medication. Secondary outcomes included the recognition of prescribing cascades in hospitals, communication of the ADR to general practitioners (GPs) through discharge letters, and the knowledge of these cascades among community pharmacists, as well as their preferences for addressing them (interviews). Descriptive analysis was used.

Results The study comprised 100 amiodarone and 17 lithium users who subsequently received thyroid medication. Different specialties were involved for amiodarone (62%) and lithium (71%). For amiodarone (initiated by cardiologists), internists initiated 48% of the marker medication, and GPs initiated 11%. For lithium (initiated by psychiatrists), GPs (47%) and internists (24%) initiated the marker medication.

In 75% (n=59) of hospital cases, the medical specialist initiating marker and/or index medication recognised the cascades as such and informed GPs in 89% of these cases. In the remaining 25% of unrecognised cases, the thyroid medication was primarily initiated by another specialty (93%). Interviews with community pharmacists revealed limited awareness of these prescribing cascades and they expressed the need for a clinical decision support system.

Conclusion and Relevance This study demonstrated that various physicians can be involved in prescribing cascades within the continuum of care. GPs are not consistently informed about managing ADRs, and community pharmacists lack awareness of these prescribing cascades. Hospital pharmacists could play a crucial role in recognising and managing these cascades in collaboration with community pharmacists.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-103 ANALYSIS OF PNEUMONIA ASSOCIATED WITH MECHANICAL VENTILATION IN CRITICALLY ILL PATIENTS UNDERGOING SELECTIVE DIGESTIVE DECONTAMINATION

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Background and Importance Pneumonia Zero project is a multifactorial national intervention, based on the concurrent application of measures to prevent ventilator-associated pneumonia (VAP). Within the package of measures, selective digestive decontamination (SDD) is included as an optional but highly recommended measure.

Aim and Objectives SDD was recently implemented in our centre with a paste and solution formulation based on colistin, tobramycin and nystatin. Our aim is analysing incidence and mortality of VAP after SDD implantation and related factors.

Material and Methods Retrospective observational study in second-level hospital including all patients who consumed DDS formula in Intensive Care Unit (ICU) during 2022. Data were collected from digital medical records and FarmaTools® electronic prescription software: age, sex, cause of admission to ICU (medical, surgical or trauma), days of ICU stay, days with mechanical ventilation (MV), presence or absence of VAP during admission, use of intravenous antibiotics during MV, presence or absence of multidrug-resistant microorganism in cultures and deaths.

For data analysis, we calculated incidence of VAP, median days with MV in patients with VAP, multidrug-resistant organisms in patients with VAP, incidence of deaths in patients with and without VAP.

Results

Sample 71 patients (73% male). Median age: 61 [17–85]. Cause of ICU admission; medical: 61 (81%), surgical: 6 (8%), trauma: 4 (7%). Median number of days in ICU: 14 [1–82]. Median days with MV: 10 [1–75]. Patients with VAP: 18 (25%). Use of antibiotics during MV: 57 (80%). Multidrug-resistant microorganisms: 10 (14%). Deaths: 41 (57%)

VAP incidence 25%. Median days of MV in VAP patients: 14 [4–63]. Multidrug-resistant microorganisms in VAP: 9 (50%). Death incidence without VAP: 18%. Death incidence with VAP: 44%.

Conclusion and Relevance Data suggest a significant incidence of VAP and a higher associated mortality compared who have not suffered this complication during admission. As would be expected the incidence increases with the number of days on MV. Most cases, intravenous antibiotics were used as a measure included in the Zero Pneumonia protocol. It should be noted that half of the micro-organisms isolated in patients with VAP are multi-resistant. More data from previous years prior to the introduction of SDD would be needed to compare a real-world effectiveness

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-104 COMORBIDITY PATTERNS IN THE OLDER HIV PATIENT

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Background and Importance The life expectancy of people living with HIV (PLHIV) has risen. However, PLHIV present chronic systemic inflammation, which results in premature ageing and an increased risk of age-associated comorbidities compared to the general population.

Aim and Objectives To determine the prevalence of comorbidities among PLHIV who are 65 years old or above, and to categorise their distribution in multimorbidity patterns according to the study by Prado Torres et al: cardio-metabolic, depressive-geriatric and mechanical-thyroid.

Material and Methods Prospective descriptive study through interviews with 47 PLHIV over 65 years of age on active antiretroviral treatment seen in the outpatient pharmaceutical care clinic. The comorbidities were obtained from the computerised clinical history (Selene®), the primary care health history (Horus®) and the clinical interview with the patient. The comorbidities were classified into comorbidity patterns according to the study by Prado Torres et al, which is included in the 'Model of Selection and Pharmaceutical Care for HIV Patients' by the Hospital Pharmacy Society of our country. A comorbidity pattern is diagnosed in a patient if they present at least two pathologies of the same pattern. Multiple patterns of comorbidity may be present in a patient.

Results The patients had a median of 5 comorbidities (RIQ: 2–6). Out of 47 patients, 28 (60.0%) present a cardio-metabolic pattern, 13 (27.7%) a depressive-geriatric pattern and 18

(38.3%) a mechanical-thyroid pattern. Two patients had up to 7 pathologies of the same pattern. 4 patients (8.5%) had over 10 comorbidities. 57.4% of the patients suffered from arterial hypertension, 53.2% dyslipemia, 31.9% diabetes and 23.4% benign prostatic hypertrophy.

Conclusion and Relevance In conclusion, non-HIV-related comorbidities are increasingly important in older HIV-infected people. It is important to detect and prevent modifiable age-related risks of non-HIV comorbidities. It is necessary to develop a multidisciplinary approach to ensure high-quality clinical care in these patients. Understanding the range of comorbidity patterns facilitates precision in developing forthcoming health interventions in complex elderly PLHIV.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-105 MEDICINES OPTIMISATION FOR PATIENTS IN A NURSING HOME

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Background and Importance Inappropriate prescribing is associated with increased morbidity and mortality, especially in the elderly. It is necessary to find tools to improve the care of these patients.

Aim and Objectives The objective was to evaluate the results of a medication review program in nursing home (NH) patients, analysing the acceptance of pharmacotherapeutic recommendations and identifying the most frequent interventions and the pharmacological groups involved.

Material and Methods Prospective-multidisciplinary intervention study carried out between 03/07/23 and 25/09/23 using a treatment review program for institutionalised patients in NH.

All institutionalised patients were included. Patients who died were excluded. Sex, age, NG-tube, creatinine, blood pressure, main diagnoses, and drugs prescribed were collected. Using the software Checkthemeds®,the pharmacist reviewed treatments, preparing a report that included the problems detected and suggestions: Start drug, stop drug, substitution, dose change, or monitoring. Therefore, the NH doctor could assess the need for treatments modifications.

Number of initial and final drugs, interventions performed and accepted, and type of interventions were analysed.

The descriptive analysis was performed using Microsoft Excel® (percentages, means, standard deviations).

Results A total of 46 patients (28 women), mean age 85.95 years [7.96], were reviewed. Two were excluded due to death. A total of 526 drugs were analysed. Each patient was prescribed an average of 11.95 [4.45]. In 5 patients no recommendation was made. Eighty-nine recommendations were made, 46 (51.7%) were accepted, being the recommendations: 2 new medicines suggestions, none accepted; 75 medication discontinuations, 40 accepted; 5 therapeutic substitutions, 3 accepted; 6 dose modifications, 2 accepted and 1 monitoring, 1 accepted. The final number of drugs was 11.02 [4.21]. Drugs involved were mainly Central Nervous System depressants (34 recommendations); Proton Pump Inhibitors (20); and antianemic preparations (12). The main cause of non-acceptance was the reluctance of relatives to modify antipsychotic therapies.

Conclusion and Relevance The medication review program for NH residents, through the collaboration of a hospital pharmacist and a primary-care physician, optimises the pharmacotherapy of institutionalised patients. The interventions of the multidisciplinary team provide great value in deprescribing, reducing the number of drugs used, and are a valuable tool to improve the safety and effectiveness of treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-106 AUC-SURVIVAL REANALYSIS OF TROPICS-02 TRIAL WITH SACITUZUMAB GOVITECANFOR METASTATIC LUMINAL BREAST CANCER

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Background and Importance Sacituzumab govitecan (SG) was recently approved by European Medicines Agency for heavily treated metastatic breast cancer (mBC) patients positive hormone receptor (HR+) and human epidermal growth factor receptor-2(HER2) negative supported by TROPiCS-02 trial which compare standard chemotherapy (ChT). Pivotal study results in overall survival (OS) was HR=0,78 IC95% (0,65–0,95). OS difference in median survival times was: 3,3 months. Although medians are commonly used in oncology to measure the magnitude of the benefit between different drugs, this is not accurate because only measures the difference in one point of the curves. A visual inspection of Kaplan-Meier's survival functions of TROPiCS-02 suggested that the difference of medians could overestimate the OS benefit, as the curves separate in the central area.

Aim and Objectives The aim of study was to reanalyse the OS benefit of SG from pivotal clinical trial by calculating the difference in mean survival time by area-under curves (AUC)-based methods.

Material and Methods We use WebPoltDigitizer 4.6 to extract survival data at 100 points in each Kaplan-Meier's OS curves. Mean survival times were estimated by AUC with Seruga's method (Ann Oncol 2012). with or without a correction from Fenix's method (Eur J Clin Pharm 2015). The later prevents underestimation by subtracting the areas corresponding to the proportion of the population whose survival is greater than the maximum observation time.

Results The AUC-estimated difference for SG vs. standard ChT were 2,30 by Seruga's AUC method and 2,35 months with the correction from Fenix et al. It was 1 month less than the difference of medians showed the pivotal study.

Conclusion and Relevance European Society Medical Oncology rated this drug-indication with a score of 3 (not substantial benefit) in their Magnitude of Clinical Benefit Scale (0 to 5). Moreover, the difference of medians overestimated the benefit in the pivotal trial, as it was just shown by AUC-methods. These results suggest a modest benefit for SG in mBC HR+/HER2-. Indeed AUC-methods could be a good option when difference of medians are doubtful to estimate the benefit; its use should be extended.

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Conflict of Interest No conflict of interest.

4CPS-107 ADHERENCE TO DAILY ORAL TREATMENT IN MULTIPLE SCLEROSIS

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Background and Importance Several studies conclude that correct adherence of patients with multiple sclerosis (MS) is related to higher efficacy and lower risk of relapses, disease progression, hospitalisations, emergency department visits, and ultimately lower health care costs. Therefore, it is a priority to detect non-adherence in order to optimise therapy.
Aim and Objectives To assess adherence to daily oral treatment in people with MS. To perform a detailed descriptive analysis of non-adherent treatments, identifying reasons, previous treatments received and current status.
Material and Methods Using the Hospital's outpatient module, a record was obtained of the corresponding dispensing dates between December 2017 and September 2023. This information was used to calculate adherence for treatments exceeding 6 months, which was complemented with the electronic medical record and patient interviews. A medication possession rate (MPR) of less than 90% was considered non-adherence. Interruptions due to medical reasons were taken into account.
Results A total of 114 patients were included and 144 treatments were analysed, corresponding to 66 treatments with dimethyl fumarate (9 non-adherent, 13.6%), 63 with teriflunomide (3 non-adherent, 4.8%), 13 with fingolimod (2 non-adherent, 15.4%) and 2 treatments with ponesimod without adherence problems.

There was non-adherence in 14 treatments corresponding to 12 patients, with a median MPR of 84.4% (interquartile range 78.0 – 85.5%). Of these, 7 patients remained on the same treatment despite non-adherence, with no worsening of lesions detected by magnetic resonance imaging. 4 patients switched to another treatment and 1 patient discontinued treatment without switching to another treatment. Of the 12 patients, 7 had previously received other treatments, with glatiramer being the most common, along with interferon and teriflunomide.

Reasons for non-adherence in 14 treatments were adverse effects (4), missed doses (4) and in 6 patients we could not clearly identify the cause.
Conclusion and Relevance We found good adherence in almost all patients. In non-adherent patients the rate of medication possession remains high and did not translate in most cases into clinical worsening.

Adherence assessment and subsequent detection of non-adherent patients in MS is a key strategy for pharmaceutical interventions aimed at achieving better health outcomes and efficiency.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-108 CLINICAL IMPACT OF PHARMACOKINETIC MONITORING OF INFLIXIMAB AND ADALIMUMAB IN INFLAMMATORY BOWEL DISEASE

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Background and Importance Failure of biologic therapy (anti-tumour necrosis factor (TNF) drugs) is a common problem. Pharmacokinetic monitoring can contribute to early identification of therapeutic failure and thus optimise treatment by keeping drug concentrations within the therapeutic interval (TI) where the probability of efficacy is higher and the likelihood of toxicity and development of immunogenicity is minimal.
Aim and Objectives To assess the acceptability of pharmacokinetic recommendations for adalimumab (ADA) and infliximab (IFX) in clinical practice in patients with inflammatory bowel disease (IBD).
Material and Methods Retrospective observational study (June 2023 – September 2023) in patients with IBD treated with anti-TNF drugs. All patients who were requested for ADA or IFX plasma levels were included.
Variables sex, age, type of pathology (Crohn's disease (CD) or Ulcerative Colitis (UC)), anti-TNF regimen, concomitant immunomodulators, type of recommendation (maintenance of regimen, optimisation, intensification) and acceptance of recommendations. The therapeutic interval (TI) was 3–10 mcg/ml (IFX) and 5–12 mcg/ml (ADA).
Data source electronic health record (Mambrino XXI®) and MwPharm++ pharmacokinetic monitoring software.
Results Seventy-two patients (65% male) were included, with a median age of 47 (16–77) years. Of these, 75% had CD and 25% had UC. 53 patients were on ADA and 19 on IFX. Seventy-eight pharmacokinetic monitoring tests were performed. 60% were within the TI, 21% were subtherapeutic and 19% were supratherapeutic. In 3 patients, the concentration was higher than the TI and was not in accordance with the previous ones, so a new control was requested. After this, it was confirmed that they were within the TI and maintenance of the regimen was recommended.
The pharmacokinetic recommendations conducted were maintenance of regimen (73%), intensification (17%) and optimisation (10%). 94% of recommendations were accepted. The recommendations that were not accepted (6%) were due to clinical worsening of the patient and a change of therapeutic target was made.
Conclusion and Relevance Based on the results of our study, the degree of acceptance of pharmacokinetic recommendations was high (94%). Pharmacokinetic monitoring is an important element of support in clinical decision making. Through this practice, the hospital pharmacist contributes to the optimisation of these treatments, helping to ensure that the appropriate adjustment is made for a better response.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-109 SEX-RELATED DIFFERENCES IN THE EFFECTIVENESS OF JANUS KINASE INHIBITORS IN RHEUMATOID ARTHRITIS TREATMENT

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Background and Importance There is evidence on the influence of sex on the effectiveness and safety of drugs, as pharmacokinetics and pharmacodynamics differ between women and men. Women exhibit higher blood drug concentrations and longer drug clearance times compared to men. To date, there is limited real-world data assessing the influence of sex on the effectiveness of Janus kinase inhibitors (JAKi) in rheumatoid arthritis (RA) treatment.

Aim and Objectives (a) To compare the probability of reaching remission in women and men treated with JAKi, and (b) to analyse the potential impact of sex on JAKi treatment discontinuation due to lack of effectiveness.

Material and Methods This observational retrospective study involved the RA patients who were treated with tofacitinib, baricitinib, upadacitinib, or filgotinib at a tertiary hospital, between September 2017 and September 2023.

Logistic regression was applied to compare the odds of reaching remission (defined by the Disease Activity Score 28-joints using Erythrocyte Sedimentation Rate [DAS28-ESR] of <2.6) at 6 months in women versus men. The Cox model was used to analyse sex as a potential predictive factor that could influence JAKi treatment discontinuation due to lack of effectiveness. Statistical analyses were performed utilising STATA software.

Results 184 JAKi treatments were included, corresponding to 123 RA patients (86% women, 63±13 years old).

There were no significant differences in baseline RA disease activities between women (DAS28-ESR: 5.0 [SD 1.3]) and men (DAS28-ESR: 4.7 [SD 1.3]), $p=0.251$. At 6 months of JAKi treatment, women were more likely to reach DAS28-ESR remission in comparison with men (odds ratio [OR]: 2.72, 95%CI: 1.05–7.10; $p=0.040$). Discontinuation rates of JAKi treatment due to lack of effectiveness were not related with sex (hazard ratio [HR]: 1.14, 95%CI: 0.54–2.41; $p=0.732$).

Conclusion and Relevance Women with RA who received treatment with JAKi possessed higher odds of reaching remission at 6 months of treatment than men. Sex was not found to impact on JAKi treatment discontinuation due to lack of effectiveness.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-110 SYSTEMATIC REVIEW AND E-QUESTIONNAIRE ON THE SERVICE CHARACTERISTICS, OPERATIONS AND ACTIVITIES OF CENTRES FOR MEDICINES INFORMATION (CMI)

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Background and Importance Clinical pharmacy is well-developed in our country, but is currently mainly bedside-oriented and driven by pharmacist initiatives. Furthermore, a standardized approach for providing and following-up on clinical pharmacy on demand is lacking. In our centre, only a basic service is foreseen in which recommendations are given in response to telephone inquiries. There is a need to develop and implement a Centre for Medicines Information (CMI

4CPS-111 PHARMACEUTICAL INTERVENTIONS IN PATIENTS UNDER CHRONIC OPIOID TREATMENT ADMITTED TO TRAUMATOLOGY UNITS

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Background and Importance Opioid analgesics are considered high risk medications. Their growing use in patients with non-oncological chronic pain has increased in recent years, making it important to review the appropriateness of the prescriptions in order to minimise the risk of adverse events.

Aim and Objectives The objective of the study was to analyse pharmaceutical interventions carried out in hospitalised trauma patients already receiving chronic treatment with opioids at the time of admission.

Material and Methods Prospective, observational study, carried out between April and July 2023. Pharmacists daily reviewed the chronic therapies that included opioids prescribed to patients admitted to the trauma unit, and recorded the pharmaceutical interventions that were carried out. The following variables were considered: age, sex, diagnosis, indication of chronic therapy with opioids, opioids prescribed, adverse events, type of interventions carried out, and degree of acceptance of the interventions by the clinics. Information was obtained from electronic clinical records for primary care and specialised care, and from the hospital electronic prescription program.

Results During the time of the study, prescriptions were validated for 596 patients and pharmacists intervened in 34 patients (73.5% women) with a mean age [range] of 73.5 [62.5–81.5] years. A total of 45 interventions were carried out, with a degree of acceptance by clinics of 76%. Most interventions (52%) involved patients being treated with fentanyl patches, followed by tapentadol tablets (25%).

The interventions were focused to warn professionals about reconciliation errors with chronic opioid therapy at admission (53.3%), inappropriate prescription of two or more opioids (20%), dosage errors (17.8%) and risk of respiratory depression due to comorbidity and/or concomitant medications (8.9%).

The percentage of patients with adverse events was 21%, and consisted of withdrawal symptoms, dizziness, hypotension, disorientation, and constipation.

Conclusion and Relevance Prescription review by pharmacists allowed us to detect and avoid numerous errors in treating trauma patients who receive chronic opioids to treat non-oncologic pain, leading to safer use of these medications.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-112 ANTIMICROBIAL STEWARDSHIP PROGRAMME INTERVENTIONS IN INTENSIVE CARE UNIT

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Background and Importance The antimicrobial stewardship programmes are essential to achieve appropriate use of antibiotics. The objectives of this multidisciplinary programme (MP) are to optimise the prescription of these drugs to improve patient's prognosis, to minimise adverse effects, to control the emergence of antimicrobial resistance and to ensure the use of cost-effective treatments. The intensive care units are complex ones with a high percentage of patients with antibiotic treatment.[1]

Aim and Objectives To describe the interventions carried out by a MP in terms of antimicrobial stewardship and its acceptance in an intensive care unit (ICU).

Material and Methods A retrospective descriptive study was conducted between January 2023 and September 2023 in a tertiary hospital. Intensivists, pharmacists and microbiologists composed the MP.

Variables included were number of ICU admission, number of patients with antibiotic prescription, number of interventions, type of interventions and acceptance rate. This MP met daily to review antibiotics prescriptions in ICU. The interventions were classified into nine groups: therapeutic indication or addition of another antibiotic, discontinuation, therapeutic window, de-escalating, therapeutic drug monitoring (TDM), dosage adjustment, microbiological cultivation and central venous or urinary catheters replacement.

Results A total of 4770 clinical episodes were reviewed of which 47.2% of cases involved at least one antibiotic. The MP performed 947 interventions. The 17,7% was related with therapeutic indication or addition of another antibiotic, the 16,3% to discontinuation the antibiotic, the 3,3% to therapeutic window, the 20,1% to de-escalating, the 12,0% to TDM, the 12,7% to dose adjustment, the 15,2% to microbiological cultivation, the 0,4% to central venous catheter replacement and the 3,4% to urinary catheter replacement. 98,2% of the suggestions were accepted.

Conclusion and Relevance The antimicrobial stewardship programme interventions obtained an acceptance ratio >98% in that period. This programme has been included in the daily clinical practice in ICU being essential to ensure the appropriate use of antimicrobial therapy. The integration of a clinical pharmacist in this MP increases the optimisation of the antimicrobial treatment particularly in terms of efficacy, medication safety through dose adjustment and TDM, and cost effectiveness.

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Conflict of Interest No conflict of interest.

4CPS-113 THE EFFECTIVENESS OF JANUS KINASE INHIBITORS IN MODERATE TO SEVERE ACTIVE RHEUMATOID ARTHRITIS

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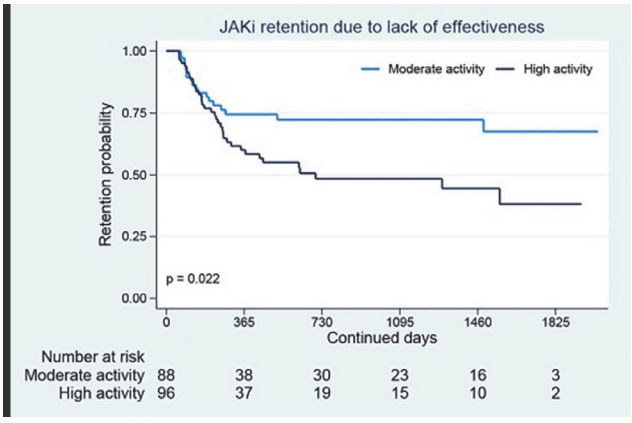
Background and Importance Janus kinase inhibitors (JAKi) are indicated for the treatment of moderate to severe active rheumatoid arthritis (RA). Their mechanism of pharmacological action depends on their competition with adenosine triphosphate (ATP) for the catalytic site of Janus Kinases. ATP levels have been correlated with the systemic cytokine storm induction and inflammation. To date, there is limited real-world data assessing the influence of RA disease activity on the effectiveness of JAKi treatment.

Aim and Objectives To evaluate the influence of RA disease activity on the effectiveness of JAKi treatment, within real-world scenarios.

Material and Methods This was a retrospective study (2017/09–2023/09) that included all RA patients who were treated with tofacitinib, baricitinib, upadacitinib, or filgotinib at a tertiary hospital.

Treatment retentions, for the discontinuation reason of lack of effectiveness, were examined through the Cox model and the Kaplan-Meier estimate. The Cox model was applied to analyse the disease activity as a potential predictive factor that could influence treatment retention. The Disease Activity Score 28-joints using C-Reactive Protein (DAS28-CRP) was considered for measuring disease activity. The Kaplan-Meier estimate was used to evaluate treatment retention curves, with the log-rank test employed for comparison. Statistical analyses were performed utilising STATA software.

Results 184 JAKi treatments were included, corresponding to 123 RA patients (86% women, 63±13 years old). At JAKi treatment initiation, RA disease activities were: moderate activity (47.8%) and high activity (52.2%).



Abstract 4CPS-113 Figure 1

The Cox model's analysis indicated that high activity significantly increased the risk of treatment discontinuation due to lack of effectiveness (HR: 1.91; $p=0.025$). The Kaplan-Meier estimate showed that discontinuation rates due to lack of effectiveness were greater for high activity compared to moderate activity ($p=0.022$; figure 1).

Conclusion and Relevance Our findings suggest statistically significant differences in the influence of high RA disease activity compared to moderate activity on the effectiveness of JAKi treatment. A high activity was significantly linked to an increased risk of treatment discontinuation due to lack of effectiveness.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-114 SUBLINGUAL ADMINISTRATION OF TACROLIMUS IN LIVER TRANSPLANT PATIENT WITH INTESTINAL MALABSORPTION: A CASE REPORT

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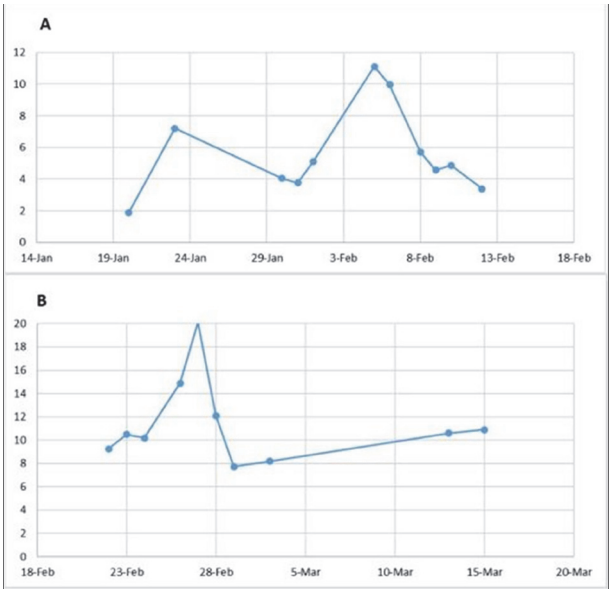
Background and Importance A combination of a calcineurin inhibitor with an antimetabolite and corticosteroids is the standard immunosuppression regime after liver transplant. Therapeutic drug monitoring (TDM) is recommended for tacrolimus due to its narrow therapeutic margin in order to avoid transplant rejection.

Aim and Objectives To report a case of a liver-transplant patient that required sublingual tacrolimus owing to intestinal malabsorption to reach therapeutic levels.

Material and Methods A 37-year-old woman with history of obesity and bariatric surgery (gastric bypass with union of ileum to stomach) was admitted to our centre in January 2023 with the diagnosis of fulminant liver failure and received an emergency transplant. Prolonged-release tacrolimus tablets 0.1 mg/kg/day (with subsequent adjustments according to blood trough concentrations), intravenous mycophenolate mofetil 1000 mg/12 hours, and intravenous methylprednisolone were initiated. During her evolution, she presented sustained sub-therapeutic tacrolimus concentrations (target trough concentrations for the first 4 weeks post-transplant when combined with mycophenolate and corticosteroids: 6–10 ng/mL) (figure 1A), as well as elevated levels of transaminases, which together with a biopsy confirmed a type II acute rejection and was re-transplanted in February 2023. Given the suspicion of tacrolimus malabsorption due to her history of bariatric surgery, alternatives were sought. A systematic review [1] concluded that sublingual administration of immediate-release tacrolimus was an adequate strategy to reach therapeutic levels in lung and kidney transplant patients with a 1:2 sublingual: oral ratio. The Pharmacy Service proposed switching to immediate-release tacrolimus capsules and sublingual administration.

Results 3 mg/12 hours sublingual tacrolimus was started (previous prolonged-release tacrolimus dose: 12 mg/day) with subsequent adjustment according to TDM results. Capsules content was deposited under patient's tongue, avoiding swallowing for 15 minutes and drinking liquids for 30 minutes. Sustained therapeutic levels of tacrolimus were reached (figure 1B) and a progressive decrease in transaminases was observed until reaching normal range values.



Abstract 4CPS-114 Figure 1

Conclusion and Relevance Sublingual administration of tacrolimus could be a feasible strategy to reach therapeutic levels in patients with intestinal malabsorption and avoid possible rejections.

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Conflict of Interest No conflict of interest.

4CPS-115 CHRONIC MIGRAINE REVERSION AND SYMPTOMATIC MEDICATION REDUCTION WITH FREMANEZUMAB

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Background and Importance The diagnosis of chronic migraine (CM) includes headaches for more than 15 days per month for at least three months and suffering this pain with migraine criteria for at least eight days The clinical manifestations of CM have a high impact on the quality of life of patients. Failure to control the pain can lead to a high risk of treatment abuse. Monoclonal antibodies such as fremanezumab are used as prophylactic treatment.

Aim and Objectives The objectives of this real-life study were to analyse the reversion of CM to episodic (EM) and evaluate the benefit on the symptomatology in young patients treated with botulinum toxin-resistant fremanezumab.

Material and Methods Patients aged 18–65 years diagnosed with CM and under neurological follow-up, treated for at least 3 months with fremanezumab as a 225mg monthly inyection were interviewed. The data to assess effectiveness

were before treatment and at the time of the interview: monthly headache days (MHDs), monthly symptomatic medication days (MSMDs) and percentage of patients with symptomatic medication overuse (SMO). Converters were defined as those patients whose number of MHDs decreased to less than 15 days after at least three months of fremanezumab treatment. The criterion for considering strong medication use as abusive was set at taking medication at least 15 days a month.

Results

Fifty-four patients were interviewed The median age of the study population was 51.5 years old (47.4–55.3, 95%CI), with a median treatment duration of 12 months (9.4–15.0, 95%CI). Fourty patients were converters to EM. The median of MHDs decreased from 28.7 (27.1–30.0, 95%CI) to 4.0 (3.9–6.4, 95% CI; p<0.001) in converters. The median of MSMDs fell from 28.9 (27.8–30.0, 95%CI) to 4.0 (3.0–4.6, 95%CI; p<0.001) in converters. The percentage of patients with SMO decreased from 97.5% to 2.5% (p<0.001) in converters.

Conclusion and Relevance The decrease in converters of all the effectiveness variables, shows a high benefit in patients' clinical and quality of life, supporting the outcomes obtained in clinical trials. The large decrease in the percentage of patients with SMO reflects the high ability to combat one of the most interrelated clinical consequences of CM.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-116 REAL-WORLD EFFECTIVENESS AND COSTS OF USTEKINUMAB IN PATIENTS DIAGNOSED WITH INFLAMMATORY BOWEL DISEASE

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Background and Importance Real world use of ustekinumab in inflammatory bowel disease (IBD) influence real costs of treatment.

Aim and Objectives To evaluate the effectiveness of ustekinumab in terms of persistence, doses dispensed and economic annual impact per patient in real-world clinical practice.

Material and Methods Retrospective review of patients diagnosed with IBD that started treatment with ustekinumab from 01/01/2018 to 06/30/2022. Follow-up was carried out until 06/30/2023.

Variables collected sex, weight, height, age, diagnosis, prior biologic or JAK-inhibitor(iJAK) therapies, time in treatment with ustekinumab, reason for discontinuation and cumulative dose dispensed during the follow-up period.

Outcome variables: persistence defined as percentage of patients that reached 12months treatment and median annual cost of treatment with ustekinumab. As dosing of ustekinumab in real-world practice is dynamic, cost of treatment on maintenance was evaluated using the number of doses dispensed. Theoretical cost was obtained from the dose provided in the drug file.

Data were collected from the electronic health and pharmacy dispensing record.

Statistical analysis Continuous variables were expressed as mean(SD) or median(Q1-Q3), and categorical variables as absolute and relative frequency. Statistical analysis was performed with R-commander_v.2.9.

Results Fifty-nine patients were included, 30(50.8%) men, 50 (84.7%) Crohn`s disease, mean age 46(14.3) years, mean weight 67(14) kg and mean height 168(8.9) cm.

Patients treated with ustekinumab in first line were 10 (17.0%), second line 24(40.6%) and 25(42.4%) other treatment lines.

Twelve months persistence of ustekinumab was 79.6% (n=47 patients). Reasons for discontinuation were 6(42.8%) secondary failure, 4(28.6%) primary failure, 2(14.4%) side effects, 2(14.2%) others. Median time on treatment was 16 (RIC 31) months.

Median annual cumulative dose per patient was 783.5 mg (RIC 429), while theoretical annual dose was 585mg (dosage of 90mg/8weeks) and 387mg (dosage of 90mg/12weeks) representing a dose-escalation of 33% and 102% compared with the theorical dose respectively. Median annual cost per patient was 18102.€, while theoretical annual cost was 15027.3€ (90mg/8weks) and 9941€ (90mg/12weeks), which represents an increase of 20.4% and 82.1% respectively.

Conclusion and Relevance Ustekinumab was associated with a 12months persistence of 66%. Doses-escalation is common clinical practice in IBD with ustekinumab. Consequently, this has important implications for real costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-117 UPDATE OF STOPP/START CRITERIA IN 2023: WHAT ARE THE IMPACTS ON OUR PHARMACEUTICAL INTERVENTIONS?

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Background and Importance Since their first versions[1], the STOPP/START criteria have demonstrated their interest in clinical pharmacy practices. In 2023, these criteria were updated in line with advances in clinical research. This new version requires us to update our knowledge and practices.

Aim and Objectives Assess the impact of the 3rd version of the STOPP/START criteria on our pharmaceutical interventions (PI) in both geriatric and non-geriatric services.

Material and Methods Prospective analysis of 75 prescriptions: 50 from geriatric services (acute care and nursing homes) and 25 from non-geriatric medical services with patients over 65 years old. The number of PIs concerning the common to versions 2 and 3 was recorded and the number of PIs related to the new criteria in 2023 (version 3).

Results The average age was 84.2 and 83.7 years for non-geriatric and geriatric services, respectively. The average number of prescription lines was 11.5 and 12.2.

The prevalence of prescriptions containing at least one inappropriate medication according to the new version was 84% and 72% (1.24 and 1.7 criteria per patient).

Common criteria between the two versions resulted in 51 PIs, 19 and 32 PIs, respectively, equating to 0.76 and 0.64 criteria per patient. The most commonly encountered common criteria (8) was benzodiazepines for anxiety for $\geq$ 4 weeks.

New criteria in version 3 represented 31 PIs, 10 and 21 PIs, respectively, representing 0.16 and 0.42 criteria per patient. The most commonly encountered new criteria (13) was benzodiazepines for insomnia for $\geq$ 2 weeks.

Conclusion and Relevance The third version of the STOPP/START criteria impacts our clinical pharmacy practices, leading to an increase in the number of PIs in prescriptions analysed within our institution, across all sectors. This new version will affect the medication management of these polypharmacy elderly patients.

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Conflict of Interest No conflict of interest.

4CPS-118 ABSTRACT WITHDRAWN

4CPS-119 A REAL-LIFE STUDY OF PHARMACOKINETIC MONITORING: NEPHROTOXIC IMPACT OF AMINOGLYCOSIDES AND VANCOMYCIN

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Background and Importance Therapeutic drug monitoring (TDM) is essential to achieve the pharmacokinetic/pharmacodynamic target avoiding toxicities.

Aim and Objectives To evaluate the impact of renal damage of aminoglycosides and vancomycin in patients making a proactive TDM in a tertiary-hospital.

Material and Methods Retrospective observational analysis from January to December 2022.

Nephrotoxicity variables: shift of final-serum creatinine and initial-serum creatinine (fCr-iCr) and variation of glomerular filtration rate (GFR), estimated according to the CKD-EPI (2009) formula at the end of TDM respect to the baseline. Impact kidney damage: increase of serum creatinine above 0.5

mg/dl or ≥50% the initial value. Pharmacokinetic Bayesian estimation was performed with PKS-Abbott®.
Variables collected demographic (age, sex), clinical (GFR, fCR-iCr, plasma drug level) and hospitalisation unit.
Results We included 123 patients in the study (81 men, mean age 66.6 ± 16.6 years) receiving vancomycin (57/123) and aminoglycosides (66/123). The pharmacist assessed 367 TDM and 255 dosage recommendation.

All patients presented a mean iCr of 1,02 g/dl (±0,69) and fCr of 1,02 g/dl (±0,72): no renal worsening was observed. 7 patients(12.3%) aggravated their GFR with vancomycin, and 10(15,2%) with aminoglycosides.

At the beginning of TDM: 53/123 patients(43,1%) presented a GFR>90ml/min, finding that, at the end of treatment, 48 of them maintained the same GFR and 5 deteriorated it. 34/123 patients(27,6%) showed a moderate GFR(60–89ml/min) before extracting drug levels; only 4 patients(11,8%) exceeded the established damage limit. 36/123 patients(29,3%) presented worst GFR(29–45ml/min), registering 7 patients(19.4%) with associated nephrotoxicity to these drugs.

Looking at the critical-care units: 64/123 patients presented an iCr of 0.93 g/dl (±0.67) and fCr of 0.98g/dl (±0.81). We saw 9(14.1%) patients with renal deterioring despite TDM.
Conclusion and Relevance Patients with a slightly decreased GFR at the baseline showed a higher risk of nephrotoxicity associated to the use of these nephrotoxic drugs. Kidney damage is more evident in critically-care patients. Our sample registered a nephrotoxicity results lower than those published in the studies by Mañez Sevilla M et al.(2015) and the meta-analysis by S J van Hal et al.(2013). Just 17 patients(13.8%) worsened their kidney function after its use.

Strategies such as TDM are necessary to optimise doses and avoid harm. Even so, it is necessary to continue collecting data to expand other possible causes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-120 EFFICACY OF PEMBROLIZUMAB FOR NON-SMALL CELL LUNG CANCER (NSCLC): PRELIMINARY REAL-WORLD ANALYSIS AND COMPARISON WITH THE PIVOTAL STUDY (PS)

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Background and Importance Pembrolizumab (P) is a monoclonal antibody used in immunotherapy, indicated for NSCLC.
Aim and Objectives Evaluate the effectiveness of P in terms of progression free survival (PFS) in patients affected by NSCLC in an Italian Hospital (IH), and comparing it with the PS. The Italian regulatory agency (AIFA) authorised P at 2 mg per kg dose, subsequently at a flat dose of 200 mg. [1] Therefore, a secondary aim is to verify whether there was a difference in terms of PFS between flat dose and per kg dose.
Material and Methods The death and progression data were taken from the AIFA monitoring registers (RA) and compared with the company management system. PFS is the time from the first prescription to the date of end of treatment due to death or progression. The period considered is 2017–2023. The PS is Keynote024[2]. Patients were divided into two homogeneous groups: the first at <3mg/kg(group1) and the second ≥ 3mg/kg(group2). We calculated OS and PFS for each group.
Results Patients evaluated were 165, 71.6% male, median age 71 years. All administrations were recorded in the RAs. Median PFS IH 218 days (0.95CI 114;230) *vs* PS 288 (0.95CI 187.6;nr). At 182 days, 57% of patients progressed (IH) *vs* 62.1% (PS). 52% of patients took a dose < 3 mg/kg, 48% ≥ 3 mg/kg. Median PFS is 258 days for the group1 (0.95CI 186;456) and 218 for the group2 (0.95CI 158;393). At 182 days: 30 patients had an event (group1) *vs* 29 patients (group2).
Conclusion and Relevance PFS data resembles PS data. There is no significant difference in using a dose > 3 mg/kg compared to a lower one, this means that a dose per kg would lead to a reduction in drug consumption and in costs. The future goal is to reach significant numbers and to investigate adverse reactions from immunotherapy, related to different doses.

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Conflict of Interest No conflict of interest.

4CPS-121 OPTIMISING ANTIDIABETIC TREATMENT FOR ELDERLY PATIENTS ACCORDING TO THEIR FUNCTIONAL STATUS

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Background and Importance Treatments for elderly patients with diabetes mellitus (DM) prioritise improving the quality of life, preserving their functional status, and avoiding hypoglycemia, which is associated with an increased risk of falling, morbidity and mortality.
Aim and Objectives The aim of this work is to determine the DM prevalence in hospitalised patients at the Acute Geriatric Unit (AGU) and to assess the adherence to the recommendations stablished by the American Diabetes Association (ADA). These recommendations include having an adequate antidiabetic treatment based on patients' functional status and an updated glycated haemoglobin (HbA1c) value.
Material and Methods This observational, retrospective study includes hospitalised patients admitted to the AGU and discharged between January and February 2023.

We collected HbA1c values and functional status (Barthel Index) of AGU DM patients. The HbA1c was consider as updated if the measure was done during the hospitalisation or the last three months.

The antidiabetic treatment adequation was evaluated based on HbA1c and patient functionality. The HbA1c ADA recommendations are 7–7.5%(functionally independent patients), 7.5–8%(functionally dependent patients), and prevent symptomatic hyperglycemia (end-of-life). The patients were categorised as controlled (complies with ADA´s recommendations),

over-controlled (lower HbA1c levels) and inadequately controlled (higher HbA1c levels).

Modifications to antidiabetic treatment at discharge were documented including the drugs involved and the type of modification applied (treatment or dose initiation/increase, discontinuation/reduction).

Results This study includes 300 patients with a 33%prevalence of DM at the AGU (107 patients). From the diabetic patients, 90%(n=96) had an updated mean value of HbA1c of 7.4 ±1.5%. Among these 96 patients, 46%achieved appropriate control, 41%were over-controlled and 13%were inadequately controlled. Thus, 52 patients(54%) had an inadequate disease control either excessive or insufficient.

From these 52 patients with inadequate control, 75%had guideline-based antidiabetic treatment modifications. The main drug groups involved were insulins(46%), biguanides(27%), and DPP-4 inhibitors(13%). The treatment modifications applied were 75%discontinuation/reduction and 25%initiation/increase.

Conclusion and Relevance Approximately one-third of AGU patients have diabetes and, in most the cases, an updated HbA1c values were available.

On hospital admission, over half of the patients did not follow ADA recommendations for metabolic control, leading to over-control. Most patients with inadequate control had discharge changes ADA recommendations based. Main modification were discontinuation or dose reduction in antidiabetic treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-122 ANALYSIS OF THE USE AND EFFECTIVENESS OF FIDAXOMICIN IN CLOSTRIDIOIDES DIFFICILE INFECTION

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Background and Importance Clostridioides difficile infection (CDI) is the main cause of infectious diarrhoea in the hospital setting.

Aim and Objectives The aim of this study is to analyse the use and effectiveness of fidaxomicin in CDI.

Material and Methods An observational, descriptive and retrospective study was conducted in patients treated with fidaxomicin between April 2018-August 2023. Variables, collected through the electronic medical record, were: sex, age, patient location, immunosuppression, severity and type of episode, previous antibiotic treatment, indication, dose and duration, time to clinical cure (days between fidaxomicin started and diarrhoea resolution) and recurrence (presence of diarrhoea or positive toxin in stool within 4 weeks after treatment). Effectiveness was assessed by clinical cure rate, recurrence rate and overall cure rate (absence of stool-positive toxin and diarrhoea within 4 weeks after treatment). Outpatients were excluded from the clinical cure analysis. Continuous variables are expressed as median and interquartile range while categorical variables as frequency and percentage.

Results A total of 37 patients were included, 17 (46%) male, aged 73 [62–80] years, 25 (67.6%) were inpatients and 14 (37.8%) immunocompromised. Most of them were severe cases with high risk of recurrence (20 (54.1%)).

Most patients received fidaxomicin during the first (13 (35.1%)) or higher (16 (40,5%)) recurrence episode and only 8 (21.6%) during the first CDI episode. Previously, 28 (75,7%) patients had received oral vancomycin and 22 (59.5%) metronidazole. Vancomycin refractoriness (35 (94.6%)) was the main indication. The dose used in all cases was 200mg/12h for 10 days [10–15].

The effectiveness analysis was conducted in 35 patients (2 died during the study period) (table 1).

Abstract 4CPS-122 Table 1 Effectiveness analysis

	All patients (n=35)	First Episode CDI (n=8)	Recurrence CDI (n=27)
Clinical Cure (days)	5 [3–6]	5 [3–6]	5 [3–6,8]
Recurrence Rate (N(%))	12(34,3)	2(25)	10(37)
Days to Recurrence (days)	14 [13,3–16,8]	18,5 [17,2–19,8]	14 [12,3–14,8]
Overall Cure Rate (N(%))	23(65,7)	6(75)	17(63)

Conclusion and Relevance In this study, fidaxomicin has been shown to be effective in resolving CDI diarrhoea , although with a less favourable clinical cure, recurrence and overall cure rate than obtained in pivotal trials. Due to the small sample size further research is needed to support the results obtained here.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-123 SARGRAMOSTIM AND LIPOSOMAL AMPHOTERICIN B FOR THE TREATMENT OF CHRONIC VISCERAL LEISHMANIASIS IN HIV CO-INFECTED PATIENT: A CASE REPORT

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Background and Importance In Spain, leishmaniasis is caused by *Leishmania infantum*, whose main reservoirs are dogs or small mammals, transmitted through the bite of dipterian insects of the genus *Phlebotomus*. *Leishmania* infection causes disease ranging from localised cutaneous to visceral leishmaniasis (VL), the most severe form, affecting frequently to profoundly immunocompromised individuals, such as late-stage HIV-infected patients, with high rates of treatment failure, relapses, and mortality.

Liposomal amphotericin B (LAB) is the VL treatment of choice, with an induction regimen followed by maintenance (3–5mg/kg/monthly). Published data[1] suggests that sargramostim, a recombinant human granulocyte-macrophage colony-stimulating factor, has potential as co-adjuvant treatment to LAB in VL-HIV to augment immune responses and clinical control.

Aim and Objectives To report a case of VL-HIV co-infection successfully treated with monthly LAB and sargramostim for 12 weeks.

Material and Methods A 47-year-old male, diagnosed with HIV infection in 2017 (CD4 T cell count: 14/µl; viral load: 1380000 copies/mL. *Pneumocystis jirovecii* pneumonia and esophageal candidiasis). Despite a continuous undetectable viral load with antiretroviral treatment, CD4 count remained ≤75–100/µL. In December 2020, he presented a mixed cryoglobulinemic membranoproliferative glomerulonephritis secondary to VL. Despite having received a complete induction regimen with LAB, febricula, systemic symptoms and positive *Leishmania* PCR persisted, therefore monthly LAB 3mg/kg were administered until March 2023.

Off-label use of sargramostim 150 mcg subcutaneously every two weeks for 3 months was requested as co-adjuvant treatment to LAB 3mg/kg/monthly, was approved by the off-label Pharmacy committee and authorised by national spanish drug regulator (AEMPS). Success of the treatment was defined as the discontinuation of LAB without clinical relapse.

Results After having completed 3 months of sargramostim plus LAB, the patient was asymptomatic, HIV viral load was undetectable and *Leishmania* PCR in bone marrow was still positive, but microscopically negative. LAB and sargramostim were discontinued and the patient was monthly evaluated. Four months later, the patient remained completely asymptomatic, awaiting further evaluation.

Regarding sargramostim safety, the patient presented fever after two doses, requiring a dose reduction by half. Treatment was afterwards well tolerated and completed with full sargramostim dose.

Conclusion and Relevance Sagramostim co-adjuvant treatment with LAB may be effective for the treatment of VL-HIV co-infected patients, although further long-term revaluation is needed.

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Conflict of Interest No conflict of interest.

4CPS-124 MONITORING OF HIGH-COST ANTIBIOTIC'S PRESCRIPTIONS IN ORDER TO ENSURE PRESCRIPTIVE APPROPRIATENESS, PATIENT SAFETY AND CONTAINING EXPENDITURE

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Background and Importance Inappropriate/unnecessary high-cost antibiotics prescription (such as cefiderecol, ceftazidime/avibactam, meropenem/aborbactam) can lead to development of resistant germs, patient toxicity and increased healthcare-costs. For these antibiotics, Regulatory Authority of our country has decided that, together with request of hospital ward, an official paper form must be sent obligatorily to pharmacy, in which, for each patient, diagnosis, dosage, antibiogram (where applicable) is reported. Hospital pharmacist has the duty of checking exhaustiveness and accuracy of the documentation received, in order to obtain appropriate/complete prescriptions, to ensure success of the clinical purpose, patient safety and containing expenditure.

Aim and Objectives The aim of study is to quantify the pharmacist's interventions in requesting clarifications and/or integrations to the documentation provided by ward, in the period between 01/05/2022–30/04/2023. Without such measures, unnecessary antibiotics would have been dispensed: this would have had negative impact on patient safety and healthcare-costs.

Material and Methods The analysis was conducted on prescriptions received in hospital pharmacy unit. The data obtained were divided by: active substance, hospital ward, request/not request for clarifications/integrations by pharmacist to ward, type of clarification/integration requested.

Results Among 258 requests received (146/258 of ceftazidime/avibactam, 61/258 of cefiderecol, 51/258 of meropenem/vaborbactam) 97/258 were appropriate and complete; 161/258 instead needed to request the ward for clarification and/or integrations. Among the latter, in 48.7% of cases the quantity of vials required didn't comply with the prescribed dosage; 21.5% didn't report attached antibiogram, where instead it was mandatory; in 14.8% of cases the official paper form was completely missing and, in 11,4% of cases, it was not complete due to lack of diagnosis and/or duration of therapy. Finally, in 3,6% of cases, the prescription wasn't performed by the infectious specialist, where necessary.

Conclusion and Relevance The analysis has revealed a large number of irregular prescriptions: implementations requested by hospital pharmacist were essential to obtain valid requests, to the benefit of both patient safety and the expense for hospital. In fact, through an accurate analysis of the dosage units required and the completeness of attached information, it has been possible to reduce not only economic waste, but also the onset of toxicity and/or antibiotic-resistance deriving from inappropriate prescriptions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-125 PHARMACEUTICAL CONSULTATIONS DEDICATED TO DIRECT ORAL ANTICOAGULANTS FOR CANCER PATIENTS: A SINGLE-CENTRE PROSPECTIVE STUDY

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Background and Importance The use of direct oral anticoagulants (DOACs) in cancer patients is complex with frequent drug-drug interactions (DDIs) and suboptimal adherence. We therefore set up hospital-based pharmaceutical consultations dedicated to DOACs in an oncology department.

Aim and Objectives To (i) characterise the prevalence and nature of DDIs and drug-related problems, (ii) assess patients' adherence rates, and (iii) detect occurrence of overdosing clinical signs among cancer outpatients treated with DOACs.

Material and Methods An observational prospective cohort included cancer patients treated with apixaban or rivaroxaban. Two pharmacist standardised interviews at six months interval were used to assess (a) drug-related problems, (b) patient adherence (Girerd score and medication possession ratio [MPR]) and (c) the occurrence of overdosing clinical signs. Antitumor treatment change between the interviews was an exclusion criterion. Results are presented as mean [minimum-

maximum]. Statistical analyses (Paired t-test, McNemar's Chi-squared test) were performed with R software.

Results 56 cancer patients (28 women, 28 men, mean age: 70 years) were included: 34 outpatients receiving an antitumor treatment and 22 outpatients before their antitumor treatment initiation (mainly chemotherapy (27) and immunotherapy (15)). Their number of medications was 6[0–15]; 15/56 used complementary medicines. They were treated with apixaban (77%) or rivaroxaban (23%) for venous thromboembolism (69%) or atrial fibrillation (27%). 36 patients (64%) were concerned by drug-related problems: side-effects (2/36), underdosing (2/36), and DDI (32/36), that frequently lead to DOAC monitoring (58%). Of note, 37/56 patients knew no DDI with their DOACs (aspirin…). MPR was 102[40–162]% and Girerd score was 1.2[0–6]. Adherence was optimal (MPR >80% and GIRERD score of 0–1) for 36/56 patients (64%). 24 patients have reported 0.7[0–4] clinical signs typical of overdosing. The second interview was assessed in 18/56 patients (31 excluded patients). There was no statistical difference between the two interviews in patient adherence ($p>0.05$), knowledge about DDI or signs of DOACs over- or under-dosing ($p>0.05$).

Conclusion and Relevance Adherence to DOACs seemed optimal in our single-centre cancer patients' cohort. Pharmaceutical consultations may help to optimise DOACs use with DDI detection in 56% cancer patients and clinical toxicities management. Unfortunately, pharmacist interviews didn't improve patient knowledge about DOACs. A 'cancer and thrombosis' therapeutic education program could be evaluated.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-126 ADHERENCE, PERSISTENCE, AND SWITCHING MEDICATION IN PATIENTS WITH MULTIPLE SCLEROSIS INITIATING ORAL DISEASE MODIFYING THERAPIES: A RETROSPECTIVE REAL-WORLD STUDY

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Background and Importance Therapeutic efficacy of disease modifying therapies (DMTs) for multiple sclerosis (MS) is often hindered by poor persistence and adherence, impacted by patient-perceived efficacy concerns, adverse effects and forgetfulness. Real-world studies have shown that nonpersistence and nonadherence to DMTs can lead to negative clinical outcomes, including higher rates of relapse and disease progression.

Aim and Objectives This study measured persistence, adherence, and time to switching to other therapy among patients with MS initiating teriflunomide or dimethyl fumarate treatment.

Material and Methods This retrospective study used data from patients with MS newly initiated oral DMTs teriflunomide, dimethyl fumarate within the qualifying time period (January 1, 2019 through December 31, 2019). Patient demographics were collected for each patient and included age, sex, and treatment history. Patients were followed from the start of the initial treatment until December 2021. Persistence was defined as the duration a patient continued their medication. Kaplan-Meier curves assessed persistence. Adherence was measured using medication possession ratio (MPR); patients with MPR>80% were considered adherent. Switching was measured by comparing number of patients switching and mean time to switch to other therapies.

Results The baseline characteristics of the 201 patients included in this study were collected. The majority of patients were on dimethyl fumarate (72,6%; n = 146), followed by teriflunomide (27,3%; n = 55). The majority of patients were female (75,1%).Teriflunomide and dimethyl fumarate patients had a high persistence rates, 74,5% and 68,4%, respectively, after 12 months. The proportion of patients adherent (MPR> 80%) to teriflunomide and dimethyl fumarate were 90% and 72%, respectively. Patients newly initiated on dimethyl fumarate had the highest rate of switching to other therapy (32,1%; n = 47), followed by patients on teriflunomide (21,8%; n = 12). The mean time to switching ranged from 277 days for teriflunomide to 342 days for dimethyl fumarate.

Conclusion and Relevance This real-world claims data study demonstrates that patients with MS newly initiated on teriflunomide and dimethyl fumarate had high persistence and adherence at 12 months.

Given the importance of treatment persistence, adherence, and time to switching on clinical outcomes for patients with MS, our findings can be used to inform treatment decision-making by healthcare providers.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-127 PERSISTENCE OF BIOLOGICAL DISEASE-MODIFYING DRUGS AND PHOSPHODIESTERASE-4- INHIBITORS IN PATIENTS WITH PSORIATIC ARTHRITHIS

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Background and Importance Persistence provides information on treatment effectiveness, durability, and tolerance in real-world patient populations. Little is known about the persistence of treatments used in Psoriatic Arthritis (PsA).

Aim and Objectives This work compares the persistence of biological disease-modifying drugs (bDMARDs) and phosphodiesterase-4-inhibitors (PD-4-Is) in PsA patients and investigate the reasons for treatment discontinuation.

Material and Methods Longitudinal, retrospective, and observational study. It included PsA patients who initiated bDMARDs (anti-TNF, anti-IL12/23, anti-IL17 and anti-IL23) and PD-4-Is treatment between January 2014 and June 2022, with follow-up until December 2023.

Persistence is the period from initiation to discontinuation. Persistence was also calculated as a dichotomous variable at 6 months from the treatment initiation. The permissible gap (threshold of a period without treatment) was 60 days.

The variables analysed include age, gender, treatment line, treatment start and end dates, reasons for discontinuation, treatment-naive and adherence (medication possession ratio >90%).

Persistence after six months was compared using the χ^2 test. Kaplan-Meier survival analysis was performed, and differences were evaluated using the log-rank test. Adjusted risk of

discontinuation was assessed with Cox Proportional Hazard models. Statistical analysis was conducted with SPSS®V27.0.

Results 206 patients were included, 47.6% were men. The mean age±SD was 53.2±11.6 years. A total of 354 treatment lines were recorded (37.3% anti-TNF; 25.2% PD-4-Is; 20.3% anti-IL17; 9.0% anti-IL12/23; 8.2% anti-IL23).

Overall treatment persistence rate at 6 months was 86.4% (96.8% anti-IL12/23; 95.2% anti-IL23; 91.2% anti-TNF; 83.8% anti-IL17; 75.9% PD-4-Is).

Mean overall persistence duration was 1542 days (CI 95% 1376–1707). According to Cox regression, the mean persistence was 1626 (CI 95% 1436–1815) days for bDMARDs and 1086 days (CI95% 863–1310) for PD-4-Is. Men were more persistent [HR 1.41 (CI95% 1.04–1.93), $p<0.05$]. bDMARDs were more persistent [HR 1.11 (CI95% 1.02–1.21) $p<0.05$].

13.6% (n=46) PsA patients treated with bDMARDs or PD-4-Is discontinued treatment before 6 months. The reasons were: 55.5% lack of effectiveness (37.5% anti-TNF; 37.5% anti-IL17; 20.8% PD-4-Is; 4.2% anti-IL12/23); 39.5% adverse effects associated with PD-4-Is and 5.0% unknown reason.

Conclusion and Relevance Patients with greater treatment persistence are those treated with bDMARDs and are predominantly male. Lack of effectiveness were the main reason for early discontinuation of treatment. All patients who discontinued treatment for adverse effects were treated with PD-4-Is.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-128 POTENTIAL DRUG-DRUG INTERACTIONS IN HYPERTENSIVE PATIENTS

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Background and Importance Hypertension is among the most frequently diagnosed chronic medical condition in adults. Treatment of hypertension requires one or more drugs (usually thiazide, angiotensin converting enzyme inhibitor (ACEI), angiotensin-II-receptor blocker (ARB), calcium channel blocker (CCB) and/or beta-blockers). Potential drug-drug interactions (pDDIs) are highly prevalent in hypertensive patients receiving multidrug therapy. Knowledge about pDDIs may help physicians minimise adverse effects by careful choice of drugs.

Aim and Objectives To analyse pDDIs among hypertensive patients and evaluate the mechanism and severity of potential outcomes of such interactions.

Material and Methods We conducted a cross-sectional study during a two months period, which included 350 patients with hypertension, treated in university hospita, who had ≥2 medications prescribed. Approval was granted by the Ethics Committee of the hospital. Medication prescriptions were analysed for clinically relevant pDDIs using Lexi-Interact database (Lexi-Comp, Inc, Hudson, Ohio. Statistical analyis was performed using the software PASW Statistics (PASW Inc., Chicago, IL, USA) version 22 and Microsoft Excel® 2010. An expert group, consisting of two clinical pharmacists and two hospital pharmacists, assessed the benefits and risks of each prescribed drug by using the Medication Appropriateness Index. Discontinuation or substitution with another drug with less interacting potential was suggested.

Results A total of 350 patients were included in this study, with average age 77 (36–98) years and 6.1 (2.5) medications. The majority of patients (86.0%) had at least one clinically significant pDDI, average was 3.78 (range 1–25). Suggestions for treatment change aimed mainly at eliminating drug duplications, reducing the use of thiazide diuretics, sulfonylureas, alpha-lipoic acid and pentoxiphylline and increasing the use of calcium-channel blockers, when appropriate. pDDIs would have decreased to 2.10, $p<0.001$, yet male gender, ≥ 6 medications, cardiovascular diseases, diabetes, benign prostatic hyperplasia, would be predictive of ≥2 pDDIs. The main potential adverse outcomes of pDDIs were hypotension, renal failure, hypoglycemia, bradycardia and lactic acidosis.

Conclusion and Relevance Careful choice of drugs can reduce, but not eliminate pDDIs in hypertensive patients. Close monitoring for hypotension, renal failure, hypoglycemia, bradycardia and lactic acidosis is necessary.

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4CPS-129 EVALUATION OF THE BENEFIT OF CAROB FLOUR ON NINTEDANIB DIARRHOEA IN THE TREATMENT OF DIFFUSE INTERSTITIAL LUNG DISEASE

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Background and Importance Nintedanib is a tyrosine kinase inhibitor drug indicated for idiopathic pulmonary fibrosis and other chronic progressive phenotype fibrosis. However, it is difficult to maintain the full dose due to its most frequent adverse effect: diarrhoea.

Because of the complexity of these patients, multidisciplinary care between nursing and pharmacy is performed. Before starting treatment, oral intake of carob flour is indicated to prevent and treat diarrhoea.

Carob is a plant with medicinal use in gastrointestinal disorders as it has anti-inflammatory, anti-diarrhoeal and anti-ulcer properties. We recommend, according to bibliography, the intake of 20 grams once or twice a day.

Aim and Objectives To evaluate the benefit of daily intake of carob flour on diarrhoea caused by the antifibrotic drug nintedanib in a tertiary level hospital.

Material and Methods All patients dispensed nintedanib from March 2022 to July 2023 were included. Information regarding nintedanib initiation date, duration of treatment, indication, dosing at cut-off and co-medications was collected from medical history. Carob flour intakes and incidence of diarrhoea were registered by nursing and pharmacy on follow-up.

Results Forty-seven patients were included, highlighting two groups:

Patients who took carob flour 48.9% (n=23), of whom 20 did not have diarrhoea. The other three patients had diarrhoea,

suspecting that they took less than recommended, in two of them it was necessary to reduce the dose.

Patients who did not take flour: 51.1% (n=24), of whom 16 did not have diarrhoea. The remaining eight patients had diarrhoea, decreasing the dose in four of them.

Most of the patients who did not take flour started treatment more than 12 months ago (62.5%), when this dietary recommendation was not made.

Conclusion and Relevance Carob flour is useful in preventing diarrhoea caused by nintedanib due to its anti-diarrhoeal properties because it is rich in starch and fibre, which leads to a decrease in stool production and diarrhoea. In addition, the proteins present utilise separate glucose and amino acid cotransporters that promote glucose absorption. By improving stool consistency, it contributes to better tolerance of nintedanib.

More exhaustive studies should be performed to confirm these results, bearing in mind the carob flour intake varies from patient to patient, making results difficult to assess.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-130 RISK OF HYPOKALAEMIA IN HOSPITALISED PATIENTS ASSOCIATED WITH THE COMBINATION OF DIURETICS

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Background and Importance Loop diuretics and thiazides are commonly known to cause hypokalaemia. Several cases of hypokalaemia were discovered in patients undergoing diuretic treatment during pharmaceutical validation.

Aim and Objectives Main objective was to study the risk of hypokalaemia in hospitalised patients receiving ≥2 diuretics.

Material and Methods A descriptive and retrospective study was designed. The number of admissions treated with diuretics from August 2022 to July 2023 were extracted from electronic prescription software (Dominion FarmaTools®) and potassium blood levels from laboratory software (Modulab®).

The outcome was the proportion of included patients with hypokalaemia. Inclusion criteria: ≥2 diuretics for ≥2 consecutive days with ≥2 serum potassium levels. Assessed diuretics were: furosemide (F), hydrochlorothiazide (H), eplerenone (E) and spironolactone (S). Assessed potassium supplement (PS) were: potassium hydrogencarbonate and potassium chloride.

'Diuretic-associated hypokalaemia' was defined as potassium level <3.5mEq/dL at least two days after initiating treatment with ≥2 diuretics. Additionally, PS were also collected from admissions with hypokalaemia.

Results A total of 4,127 registers of patients admitted with diuretic treatment were initially reviewed, 988 had ≥2 concomitant diuretics and 517 of them were prescribed for ≥2 days.

Hypokalaemia was identified in 40.8% of patients admitted. Loop diuretic combined with either S or E had similar hypokalemic rates (42,7%; 41,4% respectively) but not as high as when combined with H(59.4%).

In addition, PS had to be added to 124(58.8%) of patients that developed hypokalaemia.

Abstract 4CPS-130 Table 1

	Total	Hypokalemia n(%)
Admissions	517	211(40.8;IC95 36.6–45.0)
F + H	138	82(59.4;IC95 51.2–67.6)
F + S	131	56(42.7;IC95 34.3–51.2)
F + E	140	58(41.4;IC95 33.3–49.6)
F + H + S	42	7(16.7;IC 95 5.4–27.9)
Other associations	66	8(12.1;IC95 4.2–20)

Conclusion and Relevance Almost half of admissions with combination of diuretics developed hypokalaemia due to these drug combination.

F was involved in every treatment. F + H was the combination more commonly associated with hypokalaemia (risk difference 25.4%;IC95 15.9–34.9 vs the rest of associations).

The combination of loop and potassium-sparing diuretics also leads to hypokalaemia despite S or E.

More than half of admissions required the addition of PS. Potassium levels should be monitored regularly in all patients receiving diuretic treatment with ≥2 drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-131 ABSTRACT WITHDRAWN

4CPS-132 RIBOCICLIB IN METASTASIC BREAST CANCER TREATMENT: FRECUENCY AND ANALYSIS OF DIFFERENTS ADVERSE EFFECTS WHICH REQUIRED INTERVENTION

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Background and Importance Ribociclib is a selective cyclin-dependent kinase 4/6 (CDK4/6) inhibitor approved for the treatment of hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2−) locally advanced or metastatic breast cancer (LA/MBC) in combination with an aromatase inhibitor or fulvestrant as initial hormonal treatment. Multiple adverse effects were advertised in clinical trials which led to modifications such as dose reductions or drug change.

Aim and Objectives The aim of this study was to evaluate the side effects due to ribociclib and to analyse how modifications in treatments are made in clinical practice.

Material and Methods We conducted a descriptive, observational and retrospective study of patients treated with Ribociclib from 2017 to present in a third-level hospital. The data were obtained from the electronic medical records of the patients and the Farmatools Management program. The parameters analysed were: demographic information, time from first dose to first event noticed (dose reduction/drug change), doses reductions, changes to other CDK4/6 inhibitor, frecuency and description of adverse effects and discontinuation treatment. Data were processed by Microsoft Excel software.

Results A total of 81 women with HR+/HER2− MBC were studied. Median age was 62 years. 62% (50/81) had to undergo some modification with respect the original treatment due to adverse effects. 40% (32/81) required some dose reduction [35% (28/81) only one reduction; 5% (4/81) needed two reductions]. 22% (18/81) had to switch drug. Main signs involved were hematological toxicity -neutropenia- (24 cases), dermal toxicity (8), liver toxicity (5), gastrointestinal toxicity (3), heart toxicity -long QT syndrome- (2). Average time to first dose reduction was 83 days. Average time to drug change was 117 days. Average cycles until first event was 2,5. Average cycles until end of study or event was 6,9. To the end of study, 64% (32/50) continue treatment with ribociclib, 26% (13/50) changed to other cycline inhibitor and 10% (5/50) changed to another drugs. Rest of them was suspended by cancer progression.

Conclusion and Relevance The frequency of dose reductions and interruptions of treatment in our population was similar to clinical trials (MONALEESA). The kind of adverse effects observed was similar too, although we focused on those which supposed dose reduction or drug change.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-133 EFFECTIVENESS AND SAFETY OF ANTI IL-5 DRUGS BENRALIZUMAB AND MEPOLIZUMAB IN SEVERE UNCONTROLLED EOSINOPHILIC ASTHMA PATIENTS

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Background and Importance Severe uncontrolled eosinophilic asthma (EA) is defined by pulmonary inflammation caused by eosinophilic cells. It is associated with an increased-on cytokine IL-5. Patients diagnosed with this phenotype of asthma are corticoids resistant. Among the new treatments, biological therapy with monoclonal antibodies against IL-5 seems to be a suitable option.

Aim and Objectives Analyze the effectiveness and safety in daily life routine practice with anti IL-5 biological drugs, benralizumab and mepolizumab, used by severe uncontrolled EA patients.

Material and Methods Retrospective observational study in a daily life clinical practice of a third-level hospital. Patients selected diagnosed with EA treated with benralizumab and mepolizumab for at least 12 months from January 2018 to March 2023.

Data was collected from electronic medical records and drug dispensing program: sex, age, Forced Expiratory Volume in 1 second (FEV1), comorbidities, blood eosinophilic count (EOS), Asthma Control Test (ACT), exacerbation's number, oral glucocorticoid (OCS) based on equivalent doses of prednisone, inhaled treatment. Effectiveness was assessed by the reduction of EOS, OCS and exacerbations; and by the improvement of FEV1 and ACT. Safety profile was demonstrated based on adverse effects (AE) described. The software used for data collection was Microsoft Excel and for statistical analysis JAMOVI.

Results 45 patients were included, 31 women (68.9%), mean age 65.6 years (42–81). 26 patients (57.8%) were treated with benralizumab and 19 (42.2%) with mepolizumab. Most frequent comorbidities presented by patients were: 21 nasal polyposis (46.7%), eight rhinosinusitis (17.8%) and seven Samster's triad (15.6%). Two patients were smokers (4.4%). After 12 months of treatment FEV1 increased by 20.4% (-18.0–45.5; n=32). 13 patients did not complete the test due to COVID pandemic situation. EOS blood test was reduced by 96.7% (81.8–100.0) from basal level concentrations. Exacerbations' number presented on the previous year were reduced from 3.75 (0.0–9.0) to 0.5 (0.0–6.0). ACT improved 6.5 points (-6.0–16.0). Only 21 patients (46.7%) required diary OCS, and their dose was reduced to 4.67 mg per day (0.0–30.0). All patients continued inhaled therapy. Any AE were described.

Conclusion and Relevance The use of anti-IL5, benralizumab and mepolizumab, in severe uncontrolled EA patients has shown to be effective and safe on daily life clinical practice, experiencing greater control of asthma.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-134 REAL-WORLD EVIDENCE OF CEFIDEROCOL IN CLINICAL PRACTICE

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Background and Importance Antimicrobial resistance is a serious health threat. In Italy there are 56,600 total cases of resistant infections. Cefiderocol is an antibacterial for systemic use belonging to the class of siderophore cephalosporins. It is indicated for the treatment of serious infections caused by aerobic gram – (g-) organisms in adults with limited therapeutic options.

Aim and Objectives Describe the use of cefiderocol in real clinical practice and compare its effectiveness data with those present in the literature.

Material and Methods A single-centre retrospective observational study was conducted taking into account cefiderocol prescriptions in the period from April-22 to September-23. The data were extrapolated from a computerised personalised prescription system and from a computerised laboratory test data collection system. Personal data (age and sex), etiological agent, antibiogram, average daily dose, duration of therapy, cause of hospitalisation and hospitalisation department were analysed. The effectiveness of the therapy was obtained from the outcome of the microbiological examination at the end of administration.

Results 48 patients were enrolled with an average age of 72.5 years (26–95) of which 62% were male. 96% of patients had a g- infection, of which 35% also showed positivity for gram+ (g+). The most isolated bacterial strains were respectively: Acinetobacter baumanii (87%), Stenotrophomonas maltophilia (17%) and Klebsiella pneumoniae (17%). 69% of patients showed susceptibility to colistin antibiogram testing. On average patients received a daily dose of 4.5g (1–8). The average duration of therapy was 6 days (1–39) with 71% of patients receiving therapy in a period of 5> days <21. 17% of patients received therapy for <5 days and 12% >21 days. The causes of hospitalisation were 71% infections, 13% surgical, 12% organ failure. The greatest number of prescriptions comes from the departments of: infectious diseases (25%), resuscitation (21%) and geriatrics (17%). After cefiderocol administration, 52% of patients tested negative for g- culture.

Conclusion and Relevance Cefiderocol showed effectiveness comparable to that reported in the CREDIBLE-CR and APEKS-NP phase III clinical trials (58.3%).[1] No treatments were suspended due to toxicity. It is useful to evaluate the follow-up of patients particularly those who showed sensitivity to colistin.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

4CPS-135 EVALUATION AND MANAGEMENT OF CONSTIPATION IN THE CRITICALLY ILL PATIENT

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Background and Importance Constipation (CIN) is a prevalent concern in critically ill patients (CIP) within intensive care units (ICU), potentially exacerbating their condition.

Aim and Objectives Evaluate the management of CIN in CIP, discern its causes and consequences, and propose prophylactic and therapeutic measures.

Material and Methods A descriptive observational study was conducted in a tertiary-level hospital's ICU. Demographic data, medical history, enteral nutrition (EN) type, factors influencing constipation (treatment regimens, clinical status, and devices), stool history in the last week, and interventions were collected through a cross-sectional approach. CIN was defined as 'absence of stool after 3 days from the start of the EN/oral diet'. Sixty-three patients were reviewed, and 20 were excluded. Exclusion criteria: admission less than 3 days and no oral/NE tolerance.

Results Forty-three patients were included, with a mean age of 57±13.4 years and an average stay of 23±16.7 days. 58% suffered CIN. The patients showed a mean of 2.93±2.61 days since the last stool and 3.98±2.13 days without stool in the last 7 days. Mobility grades 0 and 2 were predominant (37.21%; 25.58%), with 81.40% requiring mechanical ventilation; of these, 62.8% suffered CIN. The most prevalent diseases were respiratory (46.51%), septic shock (25.58%), and neurological (23.26%). Opioids (53.49%) were the most common pharmacological treatment; 73% suffered CIN. Non-fibre diets (48.9%) were the most commonly used EN; 57% of these patients suffered CIN. Only 39.5% received a fibre-rich diet, with a 64.7% constipation incidence. Laxatives (25.6%), followed by enemas (16.3%), were the most used. CIN was elevated in both groups (72%; 71%). Prokinetics were used in 13.9% of patients and in combination with laxatives in 6.9%. No intervention was applied to 46.5% of patients, 50% of whom had CIN. Lactulose (50%), followed by magnesium hydroxide (37.5%), were the most commonly used laxatives. The most common enema used was Casen® in 85% of patients.

Conclusion and Relevance This study's implications are significant, highlighting the necessity for vigilant monitoring of CIN-inducing medications in critically ill patients, early implementation of high-fibre diets, and the proactive use of laxatives and prokinetics, possibly in combination. Furthermore, the study underscores the urgency of creating a standardised protocol for CIN prophylaxis and management in ICU settings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-136 ANALYSIS OF THE SITUATION OF PHARMACEUTICAL CARE FOR PATIENTS WITH IMMUNE-MEDIATED INFLAMMATORY DISEASES BEFORE AND AFTER THE COVID-19 PANDEMIC

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Background and Importance Pharmaceutical care in patients with immune-mediated inflammatory diseases is essential for the correct management of pharmacotherapy. However, the arrival of the severe acute respiratory syndrome coronavirus 2 has required the adaptation of consultations to preserve the health of patients.

Aim and Objectives To describe, analyse and compare the situation of pharmaceutical care consultations for outpatients with immune-mediated inflammatory diseases of the Pharmacy Services of Spain at two different times.

Material and Methods Longitudinal, multicentre and unidisciplinary descriptive observational study, carried out by the Immune-mediated Inflammatory Diseases Working Group of the Spanish Society of Hospital Pharmacy through a virtual survey in 2019 and 2021. Variables were collected regarding coordination, resources, biosimilars, unmet needs and telepharmacy. Numerical results were presented in absolute value and percentage and free text responses were grouped by topic areas. To compare the results between the two collection times, the Chi-Square test was used with a significance level of $p<0.05$.

Results The level of participation was 70 pharmacists in 2019 and 53 in 2021. The main significant findings obtained were an increase in participation in asthma biologic committees ($p=0.044$) and care coordination in dermatology ($p=0.003$) and digestive system ($p=0.022$). The wide use of biosimilar biological medicines stood out, with a 15% increase in the exchange of the reference biological to the biosimilar. The lack of research in the field and insufficient human resources, among other unmet needs, were revealed. In the outpatient units, the use of the stratification model of the strategic map of outpatient pharmaceutical care was a minority and an increase in the use of information and communication technologies was promoted. Motivated by the pandemic derived from coronavirus disease 2019, telepharmacy was established for the first time in 85% of the centres, maintaining the service at 66% at the time of the second survey.

Conclusion and Relevance Outpatient units are undergoing constant change to adapt to new times, for which institutional support is needed to invest more resources to promote the development of strategies to reduce unmet needs. We must continue working to achieve a pharmaceutical practice that provides efficiency, safety, quality of life and access to innovative drugs in patients with immune-mediated inflammatory diseases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-137 CEFIDEROCOL: UTILISATION PROFILE IN THE TREATMENT OF MULTIDRUG-RESISTANT BACTERIA, A RETROSPECTIVE OVERVIEW

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Background and Importance Gram-negative bacterial multidrug-resistance has reached alarming levels worldwide. Cefiderocol is a novel siderophore-cephalosporin conjugate, with activity against carbapenem-resistant and multidrug-resistant gram-negative bacilli.

Aim and Objectives To describe the utilisation profile of cefiderocol in the treatment of multidrug-resistant gram-negative infections.

Material and Methods Retrospective study including all patients treated with cefiderocol during March 2021 to July 2023. Patient demographics (age, sex, hospital stay, intensive care unit (ICU)) stay, and clinical and infectious variables (infection/colonisation site, isolated gram-negative bacteria, and mechanisms of resistance) were collected. Statistical analysis: values were expressed as medians (interquartile range) and patients (percentages).

Results Fifty-three patients started treatment with cefiderocol: 10/53 (18.9%) colonisations and 43/53 (81.1%) active infections. 34/53 (64.2%) were male with a median age of 65.6 (56.6–72.3) years. The median hospital stay was 57.3 (31.5–82.2) days, 31/53 patients (58.5%) required admission to the ICU, with a median stay of 40.0 (25.0–76.5) days. The main focus of infection was respiratory (16/53, 30.2%), followed by urinary (10/53, 18.9%), intra-abdominal (5/53, 9.4%), skin and soft tissue (5/53, 9.4%), endovascular (4/53, 7.5%) and osteoarticular (3/53, 5.7%); and 10/53 (18.9%) were colonisation samples (rectal exudates). 7/53 (13.2%) patients had another focus and 11/53 (20.8%) had sepsis. A total of 73 isolates of multidrug-resistant gram-negative bacteria were obtained. Microorganisms with more than one isolation were: 18/73 (24.7%) IMP carbapenemase-producing *Pseudomonas aeruginosa*, 7/73 (9.6%) VIM carbapenemase-producing *Pseudomonas putida*, 6/73 (8.2%) multidrug-resistant *Stenotrophomonas maltophilia*, 5/73 (6.8%) Carbapenem-resistant *Acinetobacter baumannii*, 4/73 (5.5%) VIM carbapenemase-producing *Pseudomonas aeruginosa*, 3/73 (4.1%) IMP carbapenemase-producing *Klebsiella oxytoca*, 3/73 (4.1%) VIM carbapenemase-producing *Klebsiella oxytoca*, 3/73 (4.1%) VIM carbapenemase-producing *Serratia marcescens*, 2/73 (2.7%) multidrug-resistant *Proteus mirabilis* and 2/73 (2.7%) multidrug-resistant *Pseudomonas aeruginosa*. Just 4/57 isolates with resistance to cefiderocol were recorded. In 5/43 (11.6%) patients treatment was empirical. The median duration of treatment was 9.0 (6.0–15.0) days.

Conclusion and Relevance Cefiderocol was mainly used as a targeted treatment of respiratory and urinary tract infections in a population with long hospital stays and a high rate of ICU admission. Most of the isolated bacteria presented carbapenemases, especially VIM and IMP, with a low resistance ratio to cefiderocol. Therefore, cefiderocol was well utilised, being restricted to patients with severe infections caused by pathogens with carbapenemases.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-138 CEFIDEROCOL: EFFECTIVENESS AND MORTALITY OF MULTIDRUG-RESISTANT BACTERIA INFECTIONS, A RETROSPECTIVE OVERVIEW

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Background and Importance Cefiderocol is a novel siderophore-cephalosporin conjugate, with activity against carbapenem-resistant and multidrug-resistant gram-negative bacilli. The novelty of and need for cefiderocol are clear but available real-setting clinical data are limited.
Aim and Objectives To determine the effectiveness of cefiderocol (microbiological eradication, clinical cure, and recurrence), and mortality of treated infections.
Material and Methods Retrospective study that included all patients with active infection and treatment with cefiderocol during March 2021 to July 2023. Demographic, clinical, infection, and treatment variables were collected. Patients with microbiological eradication (negative culture), clinical cure, recurrence of infection (positive culture), early (7–10 days from initiation of cefiderocol), and 30-day mortality were calculated. Statistical analysis: values were expressed as medians (interquartile range) and patients (percentages).
Results Forty-three patients initiated treatment with cefiderocol, 27/43 (62.8%) were male with a median age of 66.0 (57.7–73.5) years. The median hospital stay was 64.1 (29.9–89.3) days, 29/43 (67.4%) patients required intensive care unit (ICU) admission, with a median stay of 42.0 (25.0–83.0) days. The main focus of infection was respiratory (16/43, 37.2%), followed by urinary (10/43, 23.3%), intra-abdominal (5/43, 11.6%), skin and soft tissue (5/43, 11.6%), endovascular (4/43, 9.3%) and osteoarticular (3/43, 7.0%). 5/43 (11.6%) patients presented another focus and 11/43 (25.6%) had sepsis. A total of 57 multidrug-resistant gram-negative and 14 gram-positive bacteria were isolated. In 19/43 (44.2%) patients more than one microorganism were isolated. Resistance to cefiderocol was recorded in 3/43 (7.0%) patients. The median treatment was 9.0 (6.0–17.5) days. In 36/43 (83.7%) patients more than one antibiotic was used, and 18/43 (41.9%) of them, with synergistic action.

In 31/43 (72.2%) patients microbiological eradication was achieved, in 4/43 (9.3%) it was indeterminate, and in 35/43 (81.4%) patients achieved a clinical cure. Mortality rates: early 2/43 (4.7%), at 30 days 7/43 (16.3%) and intra-hospital 13/43 (30.2%). The recurrence rate was 8/43 (18.6%).
Conclusion and Relevance Cefiderocol was effective in the treatment of multidrug-resistant gram-negative bacteria infections in our cohort, with a high rate of admission to the ICU, and large hospital stay. Microbiological eradication was lower than clinical cure, influenced by loss of values. Mortality rates were low in this clinical stage, with intra-hospital mortality being the highest.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-139 VORICONAZOLE SERUM CONCENTRATIONS MONITORING

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Background and Importance Invasive aspergillosis is on the rise due to factors like increased oncological therapies, corticoid treatments, and viral infections. Managing this infection is challenging, especially with the drug voriconazole, which has a narrow therapeutic range and variable effects between individuals.
Aim and Objectives To describe serum levels of voriconazole in a cohort of patients in two tertiary-level hospitals.
Material and Methods Descriptive observational retrospective multicentre study enrolling patients who received antifungal treatment with voriconazole for the diagnosis or high suspicion of invasive aspergillosis in the period between 1January to 31 August 2023. Patients received 6mg/kg on the first day and a maintenance dose 4mg/kg/12 h. Serum levels were measured using the HPLC method at steady state, considering 1.5–5.5 mg/L as the therapeutic range. The following variables were collected: age, gender, weight.
Results 53 patients were evaluated (36, 67.9% male), all adults with a mean age ± SD 62.7 ± 9.8 years and mean weight ± SD 68.6 ± 17.3 kg, and a total of 90 determinations were carried out.

42.2% of the cases were in the therapeutic range, but the 57.8% not. Of them, 61.5% had subtherapeutic levels and 38.5% supratherapeutic.

In case of levels in therapeutic range, the same dose was maintained.

In case of levels in subtherapeutic range (mean levels ± SD 0.7 ± 2.7), doses were increased by 25–50% until therapeutic levels were achieved. If they were not reached, a switch to isavuconazole was made.

In case of levels in supratherapeutic range (7.2 ± 2.7) doses were decreased by 25–50%. In some cases, monitoring was repeated due to improper sample collection.
Conclusion and Relevance The high interindividual variability of voriconazole brings to light the need of monitoring serum levels, to adjust the dose to reach effective levels and avoid toxicity.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-140 EXPERIENCE OF USING PALBOCICLIB, RIBOCICLIB AND ABEMACICLIB IN A TERTIARY HOSPITAL

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Background and Importance The cyclin-dependent kinase 4 and 6 (CPKi) inhibitor drugs palbociclib, ribociclib and abemaciclib, in combination with hormone therapy have been shown to improve progression-free survival, and in some cases, overall survival, in women with HER2-positive, hormone receptor-positive or locally advanced breast cancer.

Aim and Objectives Evaluate dose adjustment due to safety data in routine clinical practice in women with metastatic breast cancer.

Material and Methods Observational, descriptive and retrospective study including women treated with palbociclib, ribociclib and abemaciclib in combination with hormone therapy between January 2018 and December 2021.

Patients with active CPKi treatment were selected. Data collected by reviewing digital medical records. These data were: age, initial dose, whether they received CPKi as the first line of treatment, dose reduction, treatment interruption, and months of treatment during the study follow-up period.

Results

Patients (N total = 114)	Mean age in years	Average treatment duration in months	CPKi as first line	Average initial dose	N,% patients keeping initial dose	% patients reducing initial dose	N,% patients ceasing treatment
Palbociclib (69)	61.3	12		62.3%	123.5 mg	36, 52.2%	47.8%
40, 57.9%							
Ribociclib (32)	53	7		93.7%	600 mg	18, 56.25%	43.75%
15, 46.88%							
							Abemaciclib (13)
50.1	7	53.8%	284.6 mg	8, 61.54%	38.46%	8, 61.54%	

Conclusion and Relevance Ribociclib is the CPKi most commonly prescribed as the first-line. In the abemaciclib group, more patients maintained initial dose, and fewer patients reduced the starting dose compared to palbociclib and ribociclib groups, but the small population of our cohort does not allow to assume this results. However, there were more interruptions of treatments in this group.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-141 REAL-LIFE IMPACT OF INCLUDING MONTELUKAST AS PREMEDICATION ON THE INCIDENCE OF INFUSION-RELATED REACTIONS TO ISATUXIMAB AND DESCRIPTION OF RISK FACTORS

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Background and Importance Infusion-related reactions (IRR) are one of isatuximab's most frequent and significant adverse reactions that may lead to treatment discontinuation despite premedicating with dexamethasone, paracetamol, and anti-H1 antihistamines. Similarly to daratumumab, adding montelukast as premedication could improve its tolerability. Additionally, there are no studies to date describing which risk factors (RF) may affect the likeliness of an isatuximab IRR.

Aim and Objectives The primary objective was to assess the impact of including montelukast as premedication on the incidence of IRR (iIRR) associated with the administration of isatuximab.

Secondary objectives included describing the iIRR in a real-life setting and evaluating possible risk factors: food, environmental or medicine allergies; previous IRR; and infusion bag concentration.

Material and Methods Multicentric retrospective study conducted in one secondary and three tertiary hospitals. Eligibility criteria included adults having started isatuximab and excluded patients receiving off-label corticosteroid doses and those enrolled in clinical trials. Follow-up was carried out until September 2023, treatment discontinuation or death.

Baseline characteristics were sex, age, treatment regimen, premedication regimen, number of isatuximab doses and occurrence of IRR. These numerical and categorical variables were expressed as number of observations and medians respectively.

Odds ratios (OR) and Mann-Whitney U tests were calculated to evaluate qualitative and quantitative RF, respectively. Absolute risk reduction (ARR) and number needed to treat (NNT) were used to assess the impact of montelukast as premedication. 95% confidence intervals (95%CI) were applied.

Results 40 patients were included, with a median age of 66 (54 – 72) years, 60.0% being men. The median number of isatuximab doses per patient was 8 (4–18).

The iIRR for cycle-one-day-one was 7.7% for the group premedicated with montelukast and 29.6% without. OR was 0.20 (95% CI 0.02 – 1.79), ARR was 0.22 (95% CI -0.01 – 0.44) and NNT was 5. No IRR were found for second or further doses in any patient and no risk factors were found.

Conclusion and Relevance In our experience, iIRR observed for isatuximab was lower compared to pivotal clinical trials. The inclusion of montelukast as premedication might reduce IRR, which should be confirmed in subsequent studies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-142 COMMUNITY PHARMACY-BASED HBA1C SCREENING FOR EARLY DETECTION OF DIABETES AND PRE-DIABETES

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Background and Importance Diabetes continues to affect an increasing number of Canadians each year and threatens the sustainability of our healthcare system. Early detection is key to improved health outcomes, yet access to testing was limited during the global pandemic. Point-of-care HbA1C screening technology allows for detection of diabetes and pre-diabetes in the community pharmacy setting.

Aim and Objectives To evaluate the effectiveness of a standardised community pharmacist-directed point-of-care HbA1C screening program and to identify the prevalence of diabetes and pre-diabetes in previously undiagnosed patients.

Material and Methods Patients 40 years or older with no diabetes diagnosis or HbA1C result in the last 6 months were

offered a complimentary HbA1C test across 40 community pharmacies in Alberta (15) and Ontario (25). They provided a sample of peripheral blood via finger-prick and HbA1C and lipids were reported by a point-of-care testing device (Abbott Affinion 2™ analyser). Once results were available, the pharmacist conducted a comprehensive review with the patient and recommended certain follow-up actions if appropriate.

Results 9041 participants were screened over a 13-week period between 18 June and 15 September 2023. 6% of patients were identified with undiagnosed diabetes (HbA1C value equal to or greater than 6.5%) while 13% presented with HbA1C values consistent with pre-diabetes (HbA1C value between 6.0% – 6.4%). Pharmacist conducted Framingham® risk assessments revealed 24% of patients at moderate to high risk of a cardiovascular event over the next 10 years. Of those screened, 62% were attached to a regular primary care physician and 38% were unattached. The detection rate for pre-diabetes and diabetes was 18.2% in attached patients and 18.5% in unattached patients.

Conclusion and Relevance These results illustrate the prevalence of abnormal glycaemic control among undiagnosed-community pharmacy patients. Pharmacists, as the most accessible healthcare practitioners, are ideally positioned to utilise novel point-of care technologies to improve access to HbA1C screening and increase awareness around the importance of early detection of diabetes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-143 A DESCRIPTION OF PHARMACISTS' INTERVENTIONS TO OPTIMISE THE TREATMENT OF ADULTS WITH ORALLY AVAILABLE COVID-DRUG PAXLOVID®

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Background and Importance Ritonavir is one of the main components of Paxlovid® an oral COVID-drug with numerous clinically significant interactions. This, results in increased numbers of adverse events, raising concerns for patient safety.

Aim and Objectives The aim was to describe the frequency, type, and severity of detected drug-drug interactions in Paxlovid® recipients identified during pharmacy screening. This service was introduced since numerous instances of inappropriate prescribing, particularly with co-medications, were noted at the pharmacy despite prescriber consideration at the point of prescribing.

Material and Methods A retrospective monocentric quantitative data analysis was performed after ethical approval in an Austrian clinic in Vienna. All patients prescribed Paxlovid® were included and data collected from the patients' electronic records. A data collection tool was developed and piloted to ensure inter-rater reliability. Drug-drug interactions including prescribing recommendations were determined using the COVID-19 Drug Interactions checker developed by the University of Liverpool.

Results 122 of 140 (87.1%) included patients required dose reduction, alternative COVID medication, or interventions to prevent interactions or overdosing. In 33 cases the necessary action was performed by the doctors at the point of prescribing. However, in 89 (63.6%) cases the required action was not identified at the point of prescribing but identified during the pharmaceutical medication analysis after Paxlovid® was ordered in the pharmacy. Since interventions were made prior to the patient receiving the supply, all patients in this group benefitted from the pharmaceutical service leading to enhancement of patient safety.

Conclusion and Relevance This study demonstrated that many drug-drug interactions were identified through the pharmaceutical intervention. This shows that pharmacist involvement in prescribing highly interacting drugs such as Paxlovid® is beneficial to enhance patient safety and mitigate risks.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-144 ABSTRACT WITHDRAWN

4CPS-145 COLLABORATIVE IMPLEMENTATION OF 'WALANT' (LOCAL ANAESTHETIC) TECHNIQUE IN A HAND SURGERY WARD

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Background and Importance The Wide-Awake Local Anaesthesia No Tourniquet (WALANT) technique is an alternative approach in certain hand- and upper extremity surgery procedures, that utilises a combination of local anaesthetic and haemostatic agent to replace traditional general anaesthesia and tourniquet application, making procedures time-saving, cost-effective and also enables faster recovery. To meet these expectations, a request for developing an adapted formulation of WALANT solution arrived from Hand Surgery Department.

Aim and Objectives Our aim was to designate the obtainable and suitable pharmaceutical products serving as the basis of the WALANT solution. Also, we aimed to design a practical and visually comprehensible dosage guide (in table form), as well as to reply to various professional questions that may arise (duration of action, shelf life, side effects, etc.).

Material and Methods An adapted formulation was developed, relying on international recommendations and extensive literature research, considering professional and economic issues, harmonising different measurement units. The dosage guide was compiled in accordance with the instructions provided by SPCs, in two effective concentrations of various commercially available products.

Results The local concentration of haemostatic adrenaline solution was determined to be 0.005% (1:200,000 ratio for adults). For children and cardiology patients, exceeding a 0.0025% (1:400,000) local adrenaline concentration is not recommended; therefore, our dosage table includes the formula of diluted solution as well. As for the local anaesthetic, lidocaine was used in 1% concentration. Chemical stability of the solution was ensured by adding sodium bicarbonate (0.84%). The appropriate amount of normal (0.9%) saline solution was used for dilution, depending on the desired total volume (5, 10 or 20 ml). After 'in situ' preparation of WALANT solution by physicians, opened ampules were advised to be discarded, due to concerns of microbiological stability, labelling and storage safety. Hand Surgery Department specialists were educated on potential adverse drug reactions and management. The workload of the anaesthetic team has been considerably reduced by approximately 30–40%, which has had good impact on human resource capacities and cost-effectivity.

Conclusion and Relevance The introduction of WALANT technique has had a beneficial effect on cost-effectivity while maintaining patient safety. This successful collaboration strengthened the professional relationship and trust between the Hand Surgery Department and Hospital Pharmacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-146 ECONOMIC IMPACT ON MULTIPLE MYELOMA CLINICAL TRIALS IN THE PHARMACY SERVICE

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Background and Importance Clinical trials (CTs) offer a chance to use innovative therapies, discover new treatments, and expand options for specific diseases. According to current legislation (RD1090/2015), sponsors are required to provide all investigational medication, except for certain exceptions.

Aim and Objectives Given the increase in clinical trials of multiple myeloma (MM) in our centre, we focused on determining the economic savings this entailed. This is because the medication for patients included in the trial was provided by the sponsor, resulting in zero cost for the centre.

Material and Methods Retrospective, single-centre observational study encompassed all MM CTs conducted at the hospital from 2018 to 2022. Exclusion criteria: CTs that did not enrol patients during the study period or did not dispense medication.

The calculation of medication cost savings took into account medications provided by CT sponsors, leading to reduced treatment expenses for patients since the hospital would have covered these costs if patients had not participated in the clinical trial. Medications not available on the market during the study period were not considered in the analysis. Cost calculations were based on PVL-DISCOUNT (discount agreed with the laboratories) +VAT at the time of the trial.

The main study variable was the avoided medication cost over 5 years, while secondary variables included the average cost saved per CT and the average cost saved per patient. The analysis did not take into account the cost of materials used in CT development, personnel, other medications, day hospital costs, etc.

Results Currently, there are 298 active CTs related to MM in Europe, of which 123 are in Spain, and 19 are in our region. Out of these 19 active CTs, 14 are active in our Health Area. However, one was excluded because no dispensations were made within the analysis period, resulting in a total of 13 included CTs (Phase I:0%; Phase II:33.3%; Phase III:66.6%), which recruited only 67 patients during the study period, due to the pandemic (average 5.15 patients/CT; range 1–22).

The direct cost saved over 5 years amounted to € 2,920,608.28, average savings per CT € 224,662.17.

Conclusion and Relevance In conclusion, the development of CTs in the study centre generated significant economic savings in MM treatment.This cost provided by sponsors should be reinvested in the creation of well-equipped clinical trial units.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-147 OSIMERTINIB: A PROMISING TREATMENT FOR EGFR MUTATION-POSITIVE NON-SMALL-CELL LUNG CANCER

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Background and Importance A total of 10–40% of non-small-cell lung cancer (NSCLC) tumours harbour EGFR-sensitising mutations. EGFR tyrosine-kinase inhibitors (TKIs) inhibit the proliferation of tumour cells via binding to EGFR specifically and show favourable therapeutic effects on advanced EGFR-mutated NSCLC. The presence of the T790M variant reduces the ability of the reversible EGFR-TKIs. Osimertinib is an orally taken third-generation EGFR-TKI which can form an irreversible covalent bond via the cysteine 797 residue and T790M or other EGFR mutations. Osimertinib has showed an impressive antitumour activity in treatment-naïve advanced NSCLC harbouring EGFR-TKI-sensitising mutations.

Aim and Objectives The aim of the study was to evaluate the effectiveness and safety of osimertinib in patients with EGFR mutation positive NSCLC.

Material and Methods

Observational retrospective study All patients with NSCLC undergoing treatment with osimertinib were included (July 2017 to August 2022). Demographic variables: age and sex. Clinical variables: diagnosis, stage, performance status (PS) according ECOG scale, line of treatment, and dose; and other variables: smoking. Overall survival (OS) and progression-free survival (PFS) were analysed using Kaplan-Meier. Adverse events (AE) were also assessed.

Results 39 patients were included with activating EGFR mutations (25.6% T790M), average age was 64.6±11.1 years, 76.9% were women. NSCLC stage was IV in 100% of patients, 23.1% suffered from brain metastases, and 79.5% had ECOG-PS 0–1. Patients started treatment with osimertinib as first-line therapy in 66.6%, 23.1% as second-line and 10.2% as third-line. Previous therapies received: erlotinib (n=3), gefitinib (n=5), afatinib (n=5), chemotherapy (n=4). 17.9% underwent osimertinib dose-reduction mainly due to pneumonitis. 38.5% were past smokers and 17.9% smokers. Median PFS was 10 months (95% CI 4.0–16.0) and OS 28 months (95% CI 14.1–41.8).84.6% of patient had at least one AE of any grade. Most frequent AE were G1–2 asthenia (46.1%), G1–2 cutaneous (35.9%), and G1–2 diarrhoea (30.8%).

Conclusion and Relevance Osimertinib demonstrates a PFS similar to that observed in the second-line AURA-3 trial, although it is lower than the survival outcomes reported in the first-line FLAURA trial. These findings are reasonable when considering our comprehensive dataset, which encompasses both pretreated and brain metastatic populations. Additionally, osimertinib exhibits a favourable toxicity profile. Given the limited sample size, further investigations are needed to validate these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-148 EAVLUATION OF DAILY DOSE MANUAL DRUG DISPENSING ACCURACY

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Background and Importance Medication errors (MEs) associated with drug therapy pose a direct risk to patient safety and negatively affect therapeutic success. Identifying drug dispensing-related MEs allows for root cause analysis and the implementation of preventive measures. Clinical pharmacy service is one applicable resource of minimising MEs.

Aim and Objectives Prior to extending clinical pharmacy control on daily dose manual drug dispensing (MDD) in new hospital settings, our study aims to assess the accuracy and appropriateness of this method, as well as to communicate findings to relevant departments and to develop strategies to rectify identified errors.

Material and Methods Unannounced point prevalence studies were conducted in September 2023, on two different occasions. Data were collected in eight inpatient care units (30 beds each) using camera-equipped mobile phones. Photographic comparison of MDD boxes has been made visually by clinical pharmacists (CP), comparing box content with relevant medication charts. In departments under clinical pharmacy control (=control group) drug dispensing was performed by pharmacy assistants under CP supervision, while in departments with no clinical pharmacy control (=case group) MDD was accomplished by nurses without double-check or supervision. Classification of MEs (using PCNE categories, Pharmaceutical Care Network Europe, version 9.1.) and prescribed drugs on ATC 7 level were recorded and analysed in an Excel table (MS Office 2021).

Results Drug dispensing errors were frequent in the case group: 38 false boxes out of 95 (40% failure rate). Overall, 59 mistakes were identified. Inappropriate dosing intervals (PCNE C.6.1.) happened in 5.0% of all mistakes, wrong drug was administered (C.6.5.) in 13.6%, deviation from the prescribed dosage (C.6.2. and C.6.3.) occurred in 17.0%, drug administration was missed (C.6.4.) in 64.4%. Omitted medications were mainly drugs acting on the cardiovascular system. In the control group, out of 103 boxes one error (<1%) was identified during the study period.

Conclusion and Relevance Identifying drug dispensing-related MEs enables the introduction of targeted interventions that minimise mistakes, enhance patient safety and promote accuracy in practice. Additive safety controls implemented in units with CP supervision can significantly reduce the occurrence of MEs in daily dose manual drug dispensing systems (failure prevalence approaching zero).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-149 CENTRAL VENOUS CATHETER-RELATED BLOODSTREAM INFECTIONS IN PATIENTS ON TOTAL PARENTERAL NUTRITION

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Background and Importance Current evidence shows that the central line-associated bloodstream infections (CLABSI) frequency is between 15–30% and there are related risk factors, such as the insertion line and its duration. CLABSI is associated with high mortality and economic costs increased.
Aim and Objectives Analysing the CLABSI frequency and characteristics in patients on total parenteral nutrition (TPN) and to compare with the current data.
Material and Methods Retrospective observational study, carried out since January to April 2023 in a regional university hospital. Selected patients: all adult patients on under the care of Intensive Care Unit (ICU) and General Surgery (GS). Collected data: demographic data (sex, age),TNP duration, central venous catheter (CVC)-related data (insertion place, insertion line) and patients CLABSI diagnosed, days until the infection development and microbiological culture. Search sources: medical histories database, electronic prescription and nutrition program (CLINUS).
Results 64 patients were enrolled, 70% men, average age 60 years (SD±16). 67.19% were surgical patients and 32.81% were ICU patients. The average TPN duration was 14.7days (SD±11.43). CVC insertion places: 64% operating room and 36% ICU. The most frequent line insertion was the jugular vein (68.75%). There was 15% CLABSI diagnosed patients. The average number of days until bacteremia development was 25.4 days (SD±18.41). The most isolated microorganism was S.epidermidis (60%).
Conclusion and Relevance The CLABSI frequency in our hospital coincides with the current data. Although the subclavian vein is the most recommended because of its lower risk of infection, the jugular line has been the most frequently used in this hospital. None of the CVC were inserted on the hospital ward, which reduces the risk of infection. However, we do not have data on the lines nursing care and this is another risk factor that should be considered. The results show that CLABSI is still a common complication in patients on TPN and it is needed to increase the healthcare efforts to reduce its frequency.

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Conflict of Interest No conflict of interest.

4CPS-150 PHARMACEUTICAL INTERVENTIONS IN OBESE PATIENTS IN HAEMATOPOIETIC STEM CELL TRANSPLANTATION

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Background and Importance Although obesity is a risk factor of inferior health, it has not been conclusively proven to be associated with worse outcomes in haematopoietic stem cell transplantation (HSCT). Despite the insufficient scientific evidence, the American Society for Blood and Marrow Transplantation (ASBMT) consider that some drugs used in conditioning therapy before HSCT may need dose adjustment in obese patients in order to reduce toxicities, such as gastrointestinal and haematologic toxicities.
Aim and Objectives The objective of this study is to assess pharmaceutical interventions of dose drug adjustment in obese patients during hospital admission following the ASBMT recommendations.
Material and Methods Prospective observational study of obese patients receiving HSCT from January 2021 to August 2023. Drugs that required weight dose adjustment were busulfan, etoposide, cyclophosphamide, thiotepa and carmustine. Patients were categorised by body mass index (BMI): normal (<25kg/m2), overweight (25–29.9kg/m2), obese (30–39.9kg/m2) or severely obese (BMI>40kg/m2). Dose adjustment was made when real weight >120% of ideal weight and BMI ≥27kg/m2. Pharmaceutical interventions were carried out for a correct drug dosage.
Results 154 adult patients received HSCT in the study period (87 autologous, 67 allogeneic) for haematological diseases. In 77 (50%) patients had been prescribed a chemotherapy drug that required weight dose adjustment, 31.2% (24/77) patients were overweight or obese, so they needed a prescription, pharmaceutical review. Median BMI of these patients were 31 kg/m2 (28–32). Out of these 24 obese patients, 17 (70.8%) medical prescriptions were reviewed and 23 drug doses were modified after pharmaceutical intervention to get an appropriate dose in obese (10 busulfan, 6 thiotepa, 5 carmustine, 2 cyclophosphamide).
Conclusion and Relevance Selecting the optimal dose of conditioning chemotherapy in obese patients is complicated, but the role of the pharmacist is essential to optimise chemotherapy in obese patients receiving HSCT, working with the haematologist in a multidisciplinary team. Further research is necessary to corroborate whether these dose adjustments provide real benefit in reducing toxicity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-151 ANALYSIS OF ANTIBIOTIC TREATMENT IN PATIENTS WITH VENTILATOR ASSOCIATED PNEUMONIA

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Background and Importance Pneumonia is the main infectious complication in patients with mechanical ventilation. Early adequate empirical therapy is an important determinant of clinical outcome. Once the pathogen has been identified, empirical treatment must be adjusted to the drugs with the narrowest spectrum and for the shortest time.

Aim and Objectives To describe the antibiotic treatment of patients with ventilator-associated pneumonia (VAP) and evaluate whether it was appropriate according to the hospital protocols (choice of empirical treatment and duration).

Material and Methods An observational, retrospective and multidisciplinary analysis in a tertiary hospital was performed. All patients with VAP during a year (January-December 2022) were included. Variables collected were: demographics, treatment, duration and clinical outcome (exitus or not). Appropriate treatment was considered when piperacillin/tazobactam, cefepime or meropenem (+/- amikacin) were prescribed for 7–15 days, according to hospital protocols.

A descriptive statistical analysis was done with measures of central tendency and dispersion.

Results Antibiotic treatments of 32 patients with VAP were analysed (81% men, mean age: 61 years old). Empirical treatments were piperacillin/tazobactam (n=23), cefepime (n=2) and meropenem (n=7), in many cases associated to amikacin, according to hospital protocols.

All patients received appropriate treatment considering the identified pathogen. *Staphylococcus aureus* (n=6), *Klebsiella pneumoniae* (n=6), *Pseudomonas aeruginosa* (n=5) and *Serratia marcescens* (n=4) were the most frequent microorganisms.

The average duration in this study was 14 days (SD:9, median:11), which is within the range established for VAP in the hospital protocols.

Most patients (n=23, 72%) were treated for 15 or fewer days. Three patients died in the first five days of treatment and five patients received antibiotic treatment for 7–9 days. In some cases (n=9, 28%) treatments were prolonged for more than 15 days. Six of them received antibiotics for 16–21 days and in the remaining three cases antimicrobials were prescribed for 26, 40 and 50 days due to clinical complications and the presence of extremely resistant microorganisms.

Conclusion and Relevance Empirical treatments for VAP were appropriated according to hospital protocols. Although in general length of treatment ranged between 7–15 days there were some exceptions in which this duration needed to be prolonged. An effort should be made to establish shorter duration when possible.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-152 THE INCLUSION OF TRAMADOL FOR PARENTERAL ADMINISTRATION IN THE NARCOTIC TABLE OF PHARMACOPOEIA: ANALYSIS OF EFFECTS AND CONSUMPTION IN A GENERAL HOSPITAL SETTING

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Background and Importance Tramadol is an opioid analgesic drug for moderate pain. From 8 November 2022 the Minister of Health of a European country ordered the inclusion of tramadol (only for parenteral administration (Inj.)) in the narcotic table of Pharmacopoeia. The drug was inserted on a narcotic register, allowing consumption to be controlled like other narcotics. This measure reflects the concerns by the World Health Organization regarding the potential abuse of tramadol (Inj.), whose dependence is comparable to morphine and methadone.

Aim and Objectives The objective of the study was to evaluate the effects of the decree on the consumption of tramadol (Inj.) on the wards of a general hospital, compared to other painkillers.

Material and Methods The analysis of the consumption of tramadol (100mg/2ml) compared to ketorolac (30mg/ml), diclofenac (75mg/3ml) and paracetamol (10mg/ml) was carried out in the period between 8 May 2022 and 8 May 2023, considering the 13 wards with the highest tramadol consumption. We compared the quantity of tramadol requested to the pharmacy 6 months before and 6 months after the decree was issued.

Results All the analysed wards reduced use of tramadol (Inj.) (Δ%:90.2; 2150 vs 210 vials, before and after the decree, respectively). The wards with a total reduction of consumption resulted orthopedic (Δ%:100; 760 vs 0) and emergency room (Δ%:100(555 vs 0). These wards simultaneously recorded an increase of 26.6% respectively (2,970 vs 2,346) in requests of non-steroidal anti-inflamatory drugs (NSAID) (diclofenac and ketorolac) and a 39.1% increase (1,476 vs 2,054) in diclofenac. In general, paracetamol underwent the most significant increase in 92.8% of the wards (12/13) with a Δ%:110.6% (2810 vs 5918). The wards with the most significant increases were vascular surgery (Δ%:233.3;90 vs 300), thoracic surgery (Δ%:167.7;270 vs 723) and trauma centre (Δ %:173;150 vs 410).

Conclusion and Relevance The decree limited the use of tramadol (Inj.). Before the drug was delivered upon simple wards request without supervision. The inclusion in the narcotics register has instead allowed the pharmacist to supervise their consumption by the wards who now have to submit a request on a specific form. This led to a discussion with the clinical on the choice of an alternative therapy in the treatment of moderate pain, moving to NSAIDs and paracetamol when possible.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-153 ECONOMIC BENEFIT ANALYSIS ON LUNG CANCER CLINICAL TRIALS: MEDICATION AND MEDICAL TESTS

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Background and Importance Clinical trials are the main source of information to establish new treatments' efficacy and safety. Patients' enrolment in these studies may result in economic benefits for the participating sites since usually the costs derived from their inclusion are funded by sponsors. However, these economic benefits are rarely quantified.

Aim and Objectives The primary object of this study was to calculate the economic benefit obtained from patients' inclusion in lung cancer clinical trials in two scopes: medication and medical tests. The secondary object was to determine whether avoided costs in medication were significantly different from those in medical tests.

Material and Methods An observational retrospective study was conducted in all patients enrolled in lung cancer clinical trials from 2017 to 2021 at our hospital.

The avoided costs in medication were calculated considering the medication which would have been given to the patient in the standard of care taking into account their specific data.

The avoided costs in medical tests per patient were calculated from the prices published and the total number of each test performed on each patient from their first treatment visit until the end of the treatment visit.

The homogeneity of the two groups was analysed using a univariate analysis by applying the chi-square test for qualitative variables and the t test or Mann-Whitney test to compare quantitative variables. A p value of <0.05 was considered statistically significant.

Results The economic benefit generated from sponsor-provided drugs in the 35 clinical trials was 3,778,393.93€ .

A total of 642 medical tests were performed in the 117 patients under study. Specifically, 546 were CTs, 58 were MRs, 6 PETs and 32 were gamma graphics. The total economic benefit generated in five years by the sponsor financing these tests was 128,448€ .

The results from the statistical analysis revealed that the economic differences between sponsors providing the medication and financing the medical tests were significantly different with $p<0.05$ ($p=0.0482$).

Conclusion and Relevance In the 5 years studied, over 3.9 million euros were saved by including patients in lung cancer trials in one site, being 96.7% derived from avoided costs in medication. Thus, the participation of patients in clinical trials is economically beneficial for them and society.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-154 THERAPEUTIC DRUG MONITORING OF AMIKACIN IN NEONATES: ABOUT A NEW PROTOCOL

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Background and Importance Amikacin is a widely used antibiotic in neonates. An adequate dosing regimen is essential for effective and safe therapy; however, many patients do not achieve adequate plasma concentrations due to high interindividual variability in this population.

Aim and Objectives To compare the amikacin plasma concentrations in neonates according to the administered 15mg/kg/24h dosing regimen (15-DR), a previously established protocol, versus the amikacin 12mg/kg/24h (12-DR) new protocol, with the aim of establishing best initial dosing regimen (DR) that guarantees an effective and safe treatment, as well as analysing differences between subpopulations (preterm or term).

Material and Methods

Retrospective observational study All patients admitted to neonatal unit or neonatal intensive care unit under amikacin treatment and with 12-DR or 15-DR between January-July 2023 were included. Patients with different DR were excluded.

The following variables were collected from the patients' clinical histories (Orion Clínic®): gender, age, weight, preterm (<37 gestation weeks)/term, DR, minimum (Cmin) and maximum (Cmax) plasma concentrations. The optimal levels established were: Cmin <5 μg/mL and Cmax 20–30μg/mL.

Quantitative variables are expressed as mean and standard deviation (SD) and qualitative variables as number and percentage (%). The Chi-square test was used to compare qualitative variables. Statistical significance was considered when $p \leq 0.05$. Statistical analysis was performed with SPSS version 23.0.

Results A total of 88 patients were identified, 11 were excluded because they were not neonates and 27 patients because they presented a different DR. Finally, 50 patients were included, 26 (52.0%) were male, mean age at level time was 7.6 (1.7) days, weight 2.9 (1.0) kg, and 35 (70.0%) were at term.

Regarding treatment, 24 (48.0%) patients were treated with 12-DR and 26 (52.0%) with 15-DR. The mean Cmin was 1.4 (0.2) μg/mL and 2.3 (0.3), respectively, and mean Cmax was 26.0 (0.9) μg/mL for 12-DR group and 33.5 (1.3) μg/mL for 15-DR group. A total of 18 (75.0%) patients with 12-DR achieved target plasma concentrations compared to 7 (26.9%) in the 15-DR group, statistically significant differences were observed. When comparing between premature and term patients, no statistically significant differences were observed.

Conclusion and Relevance This study demonstrates that amikacin 12mg/kg/24h dosing regimen guarantees better results in terms of optimal plasma concentrations in neonatal patients, which allows us to establish this dosage regimen as the initial dose in our patients. Clinical pharmacokinetics is essential for improving outcomes in neonates.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-155 PERCEPTION OF HOSPITAL PHARMACIES ABOUT TELEPHARMACY IN THE PROVISION OF HEALTHCARE FOR PEOPLE LIVING WITH HIV

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Background and Importance The aim of telepharmacy (TF) is to maximise the potential of telehealth and transform remote

monitoring by hospital pharmacies (HP) into added value to society. This service should be made available preferably to the most vulnerable patients in terms of mobility, geographic distance, economic capacity or work constraints.

Aim and Objectives To evaluate the knowledge of HP about TF in Portugal with regards to possible benefits and barriers for the implementation of a regulated and funded model for antiretroviral therapy (ART) delivery proximity programme for people living with the Human Immunodeficiency Virus (PLHIV).

Material and Methods A quantitative, cross-sectional and analytical study was carried out through application of a previously validated questionnaire to 32 HP in Portugal that provide ART. Outpatient care for HP and their perception of follow-up using TF was characterised. It was assessed whether there was a statistical correlation between medicines delivery proximity programme and remote follow-up of PLHIV.

Results Our data shows that more than two thirds of the HP have opening hours outside regular hours and >90% are opened during lunchtime. More than half of PLHIV live close to the hospital, >80% have outreach programmes that are close to PLHIV, and around 60% have long-distance follow-up for this pathology. More than 60% of HPs believe that TF is useful in the absence of face-to-face contacts. There is a consensus about the advantages of TF for patients, HP and health systems. All HP have considered an elaboration of a TF regulation manual and its inclusion in hospital funding. We have found correlation between the existence of ART delivery proximity programme to PLHIV and high rurality ($p<0.05$) and low population density ($p<0.05$). The existence of ART delivery proximity programme to PLHIV has also been associated with adherence to this service ($p<0.05$).

Conclusion and Relevance The results of this study suggest that medicines delivery proximity programme and the follow-up of patients through TF enhance the adherence of PLHIV, thus avoiding unnecessary trips to the hospital. Distance or time constraints are minimised and health outcomes are maximised.

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Conflict of Interest No conflict of interest.

4CPS-156 ANALYSIS OF THE PRESCRIPTION PATTERN AND DAYS OF HOSPITALISATION AVOIDED BY OUTPATIENT INTRAVENOUS ANTIBIOTIC THERAPY AND THE SAFETY OF THIS PRACTICE

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Background and Importance The use of intravenous anti-infective therapy for non-hospitalised patients is an increasingly common practice that allows prescribers to treat patients with intravenous therapy without lengthening hospital stay.

Aim and Objectives To assess the prescription pattern and days of admission avoided with outpatient intravenous antibiotic therapy (OPAT). Also, to analyse the safety of this practice.

Material and Methods We made a retrospective observational study including patients who received out-of-hospital intravenous anti-infective treatment in a tertiary-level hospital in Madrid between 1 August 2021, to 31 August 2022. We collected from the electronic prescription indication, etiologic agent, prescribing physician as well as days of hospitalisation avoided, understood as total days of hospitalisation avoided by the number of days of intravenous treatment duration. Also, we recalled adverse reactions that occurred during the therapy period.

Sociodemographic, clinical and pharmacological variables were collected from the electronic medical record.

Results We included 85 patients (52.9% women) in the study, with a median age of 75 years (62–86).

Among the most frequently prescribed anti-infectives we found ertapenem (32.6%), dalbavancin (15.3%), amoxicillin/clavulanic acid (9.2%), ceftriaxone (7.1%) and piperaziline/tazobactam (7.1%). The most frequent indications were urinary tract infections (26.5%), skin and soft tissue infections (18.4%) and respiratory infections (14.3%). As for those infections caused by bacteria (64.7%), 44.6% were gram-negative multi-resistant. Fungi accounted for 4% of the causative agents, protozoa for 1% and viruses for 1%.

Infectious diseases department was responsible of 61.2% of the prescriptions. In 68.4% of cases, there was a complete antibiogram at the time of prescription.

The median of hospitalisation days avoided was 7 (19–6). The highest amount of days avoided was 365 days for three patients, treated for visceral leishmaniasis, mycobacteria infection and infection of sanitary material.

Only 1 patient (1%) presented adverse events (renal toxicity due to amphotericin) that did not require hospitalisation, only suspension of treatment.

Conclusion and Relevance OAPAT receivers in our hospital are mostly elderly patients with bacterial infections. Prescribers made prescriptions based on the results of an antibiogram on more than half of the occasions . The out-of-hospital administration of these drugs saves a median of 7 days for patient, being a practice with low appearance of adverse effects during treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-157 PERSPECTIVES OF PATIENTS AND MEDICAL PROVIDERS ON MULTIDISCIPLINARY MEDICATION RECONCILIATIONS SERVICE IN ADULT PATIENTS UNDERGOING THORACIC AND CARDIOVASCULAR SURGERY (MERITS STUDY)

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Background and Importance The implementation of medication reconciliation (MR) services is a global endeavour, but still faces technological and data-related barriers. To promote widespread adoption, understanding the perspectives of patients and medical providers on MR services is crucial.

Aim and Objectives This study aimed to investigate the satisfaction levels and perceptions of patients who have experienced MR services, as well as the satisfaction, perceived needs, and expectations of medical providers.
Material and Methods This research is a part of the prospective study evaluating of multidisciplinary medication reconciliation service in adult patients undergoing thoracic and cardiovascular surgery (MERITS study). The protocol of the study was approved by Institutional Review Board of Seoul National University Hospital (IRB No. 2109–135-1257). Patients' feedback was collected through surveys using 5-point Likert-scales, encompassing their awareness of services, improvement in medication behaviours, perception about pharmacists, and overall satisfaction with services. In parallel, healthcare providers were surveyed addressing their perceptions, satisfaction level, needs, and expectations concerning MR services.
Results Among 216 patients enrolled in MERITS study, 208 patients completed the questionnaires. These patients expressed a high degree of satisfaction with MR services (average score 4.67). The aspect receiving the highest rating (4.79) pertained to the professionalism exhibited by pharmacists, whereas the lowest score (4.61) was attributed to the need for revisiting the service. Average score of 4.63 were rated for improvement in medication behaviours. Medical staff (12 out of 22, response rate 54.5%) expressed satisfaction, with nine rating the overall services as 'very satisfied'. They showed the highest satisfaction in 'comprehensive medication review and resolving drug-related problems' and 'discharge counselling'. In terms of the need for services, eight respondents answered 'very much in need' while four considered they 'needed', with the greatest demand for 'providing the best possible medication history'. Additionally, the services' overall expectations were also positive, especially for identifying and improving discrepancies during transitions.
Conclusion and Relevance The findings of this study underscore a positive reception of MR services from both patients and medical staff. These findings emphasise the need to further promote and enhance MR services in Korea.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-158 RELAPSED/REFRACTORY MULTIPLE MYELOMA AND NEW THERAPEUTIC OPTIONS: EXPERIENCE IN A PHASE 1 CLINICAL TRIALS UNIT

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Background and Importance Treatment landscape for relapsed/refractory Multiple Myeloma (RRMM) has changed significantly due to the availability and good results of new drugs such as immunotherapy agents.

Phase I clinical trials (CTs) allow patients to access new drugs prematurely, but the high complexity of these CTs makes essential the integration of a pharmacist in the Phase I team to ensure the safe preparation and dispensation of investigational drugs.

Aim and Objectives To know RRMM patient's profile treated in a Phase I Unit, describe overall results in terms of efficacy and adverse effects, and analyse the pharmaceutical interventions (PIs) carried out and the medication-related problems (MRPs) detected.
Material and Methods Observational, retrospective study, with RRMM patients treated with investigational drugs in a Phase I CT Unit. Main data collected were demographics; number of previous treatment lines; ECOG at inclusion in CT; type of investigational treatment received; treatment effectiveness: type of response, overall survival (OS), progression-free survival (PFS); adverse effects (AEs); PIs and detection of MRPs.
Results 42 patients were analysed, average age was 67.6 years, 71.4% women, average previous lines 5, ECOG 1 and types of investigational treatments received were mostly Bispecific Antibody(Ab) (antiGPRC5D-CD3) +Bispecific Ab (antiBCMA-CD3) (26.2%) and Bispecific Ab (antiBCMA-CD3) + anti-CD38 Ab (26.2%).

54.8% of patients obtained partial or greater response. Median PFS was 11.5 months. Median OS was 25.3 months. 93% of patients experienced some AEs, most common were haematological, including neutropenia (29%), anaemia (21%), and platetopenia (12%).

36 PIs were carried out, mainly related to prescription errors (44%) and detection of drug interactions (33%). A PI was performed for each MRP detected, preventing negative results in all cases.
Conclusion and Relevance Patients with RRMM in Phase I CT Unit are middle-old age, highly pretreated and with acceptable functional status. Overall efficacy and safety results are positive, which reinforces participation in Phase I CT as an option to be evaluated.

The detection of prescription errors and drug interactions were high in number and with potential impact. Bispecific Abs seem to be a promising treatment for patients with RRMM and due to their complexity, the figure of the pharmacist proves to be essential within the healthcare team of Phase I CT Units.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-159 ANALYSIS OF THE INTERVENTIONS CARRIED OUT IN THE GERIATRIC SERVICE IN COLLABORATION WITH THE INTERNAL MEDICINE AND MICROBIOLOGY SERVICES

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Background and Importance Controlling the prescription of antibiotics is important for better patient care and reducing the emergence of resistance.
Aim and Objectives Analysing the interventions carried out on patients admitted to the geriatric service from the antimicrobial use optimisation programme (PROA) of our hospital and evaluating the degree of acceptance.
Material and Methods Observational, descriptive and prospective study of the interventions carried out by the PROA team (pharmacists, internists and microbiologists) to patients

admitted to the Geriatrics service in the period between January 2022 and March 2023.

All patients with any prescribed antimicrobial were included, reviewing their daily clinical evolution during the duration of treatment. The data collected were: sex, age, analytical values, antimicrobials prescribed, interventions performed and acceptance of them. The types of interventions were classified as empirical treatment adjustment, targeted treatment adjustment, end of treatment and renal function adjustment.

Data were obtained from the inpatient electronic prescribing programme and the electronic health record. Data were processed by Microsoft Excel software.

Results During the study period, a total of 840 patients with a mean age of 90 years (±4 SD) were admitted to the geriatrics service and they started antimicrobial treatment.

A total of 180 interventions were carried out, 158 (87.78%) were accepted. Empirical treatment adjustment was suggested in 8.34% (15/180), targeted treatment adjustment in 28.33% (51/180), treatment completion in 30% (54/180) and a dosage adjustment based on renal function in 33.33 (60/180).

Among the most notable interventions would be meropenem, with 24 interventions carried out, 83.33% were accepted; and piperacillin-tazobactam, with 24 interventions and with an acceptance rate of 79.17%. Although in a lower percentage, we also found other high-impact antimicrobials, such as linezolid, with nine interventions and an acceptance rate of 77.78%; and ceftazidime-avibactam, with six interventions performed and all of them were accepted.

Conclusion and Relevance With such prominent data regarding acceptance, the training and value of the pharmacist's role within the multidisciplinary team formed in collaboration with Internal Medicine and Microbiology is demonstrated. Furthermore, the importance of the existence of antimicrobial use optimisation programmes in the hospital setting is highlighted, showing how the inappropriate use of certain high-impact medications is reduced, achieving a decrease in the appearance of resistance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-160 LONG-TERM EFFECTIVENESS AND SAFETY RESULTS OF GALCANEZUMAB IN REAL-WORLD DATA IN MIGRAINE PROPHYLAXIS

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Background and Importance Galcanezumab is a monoclonal antibody (MAB) for migraine prophylaxis. MAB has been shown to be safe and effective in reducing the number of migraine days per month in short-duration clinical trials. However, the optimal duration of therapy remains unresolved. Clinical practice guidelines recommend maintaining treatment for 12 months.

Drug is dispensed in the hospital pharmacy service, where pharmacists follow-up the effectiveness, safety and adherence of MAB.

Aim and Objectives To assess the long-term effectiveness and safety of galcanezumab in episodic migraine (EM) and chronic migraine (CM).

Material and Methods Retrospective observational study in a second-level hospital. Study period: September 2020– July 2023.

Migraine patients treated with galcanezumab were evaluated for at least a 12-month follow-up period from the start of treatment.

According to hospital protocol, after 12 months of MAB, neurologists decide whether to continue or discontinue it and re-assess 3 months later and restart MAB if migraine worsens.

Data were collected from the electronic medical record. The database included demographic variables, migraine-related variables, treatment-related variables, and adverse events (AE).

Results 64 patients, 54 CM and 10 EM, median age 48 years (76–21), women 84%. Mean of days of migraine previous to galcanezumab: 20.46±6.55 (CM) and 12±1.48 (EM).

The median duration of galcanezumab was 18.4 (1.9–34.9) months.

48 patients (n=64) completed the first 12-month of treatment. 32 patients (n=45) continued at 18 months, 19 (n=26) at 24 months, 14 (n=18) at 30 months and 8 (n=8) at 34 months. They were chronically maintained galcanezumab to prevent worsening if MAB was discontinued.

24 patients discontinued galcanezumab: lack of response (20), injection site rash (2), pregnancy (1), excellent treatment response (1). 17 patients were switched to another MAB (15: rebound; 2: injection site rash).

2 patients restart galcanezumab: after pregnancy (1) and for rebound 10 months after stop galcanezumab (1).

AE: constipation (12), injection site pain (3), dizziness (3), rhinitis (3), diarrhoea (2), injection site rash (2).

Conclusion and Relevance In our study, galcanezumab remained long-term effectiveness, safe, and well tolerated with few adverse events for more than 12 months in patients with episodic and chronic migraine. It was only discontinued in case of great improvement or therapeutic failure. Studies with larger samples are required to establish whether it could be used as a chronic treatment in patients with a high probability of worsening if treatment is discontinued.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-161 VANCOMYCIN PHARMACOKINETIC MONITORING IN CRITICALLY ILL NEONATAL PATIENTS

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Background and Importance Vancomycin is a bactericidal glycopeptide antibiotic with activity against aerobic and anaerobic gram-positive bacteria. Its use in neonatal critically ill patients is widespread, as it provides treatment for typical pathogens affecting this population, which presents an increased risk of infection. Dose in these patients is adjusted according to gestational weeks and pharmacokinetic monitoring is essential due to its potential nephrotoxicity.

Aim and Objectives Assessing possible under-exposure to vancomycin in critically ill neonatal patients after dosing, as recommended by standard guidelines.
Material and Methods A retrospective observational study in a tertiary hospital was conducted from March 2021 to June 2023. Critically ill patients who received vancomycin with <1 month of life at baseline were included. The following data were collected from medical records: demographics, diagnosis, microbiological culture results, renal function, vancomycin dosing regimen, plasma concentration (PC), antimicrobial treatment duration and occurrence of nephrotoxicity (determined as 50% increase in creatinine value versus baseline). PC is considered therapeutic for vancomycin at 10–20mg/dL and the first pharmacokinetic determination was performed before dose 4.
Results During the study period, 79 pharmacokinetic determinations were performed in 34 patients, corresponding to 45 treatments with a median duration of 6 days (4, 14), of which 31 (68.9%) were empirical. Pathogens were isolated in 28 (62.2%) of the microbiological cultures, the main ones being: *S.epidermidis* 11 (28.2%), *E.faecalis* 4 (10.3%) and *K. pneumoniae* 4 (10.3%). Most frequent diagnoses were: catheter infection 17 (37.8%), sepsis 8 (17.8%) and necrotising enterocolitis 8 (17.8%). 48 (60.8%) PC were sub-therapeutic, 29 (36.7%) within range and 2 (2.5%) supratherapeutic. 13 (26%) of the out-of-range PC achieved the desired targets thanks to the pharmacokinetic recommendations. Finally, nephrotoxicity was observed in 9 (13.3%) patients.
Conclusion and Relevance 48 (60.8%) critically ill neonates were under-treated and 9 (13.3%) had nephrotoxicity with the dosing regimens recommended by standard guidelines. It is therefore necessary to review the recommended dosing regimens in this group of patients to achieve therapeutic PC of vancomycin from the start of treatment guided by pharmacokinetic monitoring.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-162 'TO ERR IS HUMAN' – PRESENTING CASES OF MEDICATION ERRORS FROM REAL CLINICAL PRACTICE

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Background and Importance Medication errors (ME) are preventable mistakes or incidents that can occur at any stage of the medication use process, which can cause patient harm and significant morbidity and mortality.
Aim and Objectives Identification of the nature, incidence, and potential preventative measures of DRPs. To evaluate the role of the pharmacist in ME risk reduction process and to identify critical points and outline strategies to reduce iatrogenic ME.
Material and Methods The current prospective direct clinical observation was carried out in the period June- December 2022 by analysing the electronic records of 1625 patients in a specialised gynaecological hospital with national coverage. Participants were also interviewed by a clinical pharmacist to verify the information extracted from the electronic records.
Results The average number of medications per person was five, and the median age of the cohort was 36 years. In 1/3 of the cases, the therapy consisted of both drugs and supplements. The desired therapeutic outcome was achieved in 320 of the records, while treatment was discontinued in 569. The highest number of ME was observed in the age group >40 years, followed by 31–40 years. Parenteral products accounted for 68% of the errors. Categories of ME identified were: administration, prescribing, dispensing, drug interactions, patient error, and other. Inadequate recording of prescription details in the electronic hospital system accounted for most of the identified errors. Misuse, followed by inappropriate choice of drug/dose or duration of treatment, and inappropriate route of administration are among the most common DRPs identified. In only 12% of cases was the error identified and the associated harm prevented as a result of a physician-initiated consultation with the hospital pharmacist. The physician's acceptance of the pharmacist's suggestions was >80%.
Conclusion and Relevance Although hospital e-prescribing systems are seen as a tool to reduce prescribing errors, the above cases demonstrate that these systems alone are not sufficient to significantly reduce the risk of inappropriate prescribing. Hospital pharmacists can be considered as a valid checkpoint to effectively reduce DRP.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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Conflict of Interest No conflict of interest.

4CPS-163 EFFECTIVENESS OF SODIUM ZIRCONIUM CYCLOSILICATE IN HOSPITALISED PATIENTS WITH HYPERKALAEMIA

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Background and Importance Sodium zirconium cyclosilicate (SZC) is used to correct hyperkalaemia (K>5.1 mEq/L). SZC should be administered to patients who have not responded well or have become intolerant to alternative treatments, such as resins, using an initial dose of 10mg/8h followed by a maintenance dose of either 5 mg or 10mg every 24h. Real clinical data of use might be required to optimise this treatment.
Aim and Objectives To describe effectiveness and use of SZC for the treatment of hyperkalaemia in hospitalised patients with an initial or maintenance starting dose.
Material and Methods Retrospective descriptive study was designed in hospitalised patients who started treatment with SZC between July 2021 and July 2023. Outcomes were collected from medical records and electronic prescription software: gender, age, initial dose and/or maintenance dose, serum potassium concentrations (at 0, 48 and 72 hours after starting SZC treatment) and previous use of exchange resins like calcium polystyrene sulfonate (CPS). The effectiveness endpoint was described as: percentage of patients who achieved a normal serum potassium level (3.5–5 mEq/L) at 48 and 72 h, with either initial or maintenance starting dose.

Results There were 35 patients (62.2% male and 37.8% female) that presented a mean age of 69 (34–96) years. Initial dose of 10 mg/8h were used in 29.7% of patients. Maintenance dose of 5 mg/24h were used as starting dose in 64.9% of patients and 10 mg/24h in 35.1%. Starting serum potassium concentration mean was 6.3 mEq/L (5.2–9.8). In terms of use, CPS were previously used in 43.2% of patients. About effectiveness results at 48h, 60% of patients reached normal potassium concentrations, 72.7% received the initial starting dose while 54.2% did not received the initial starting dose. At 72h, 80% of patients reached normal potassium concentrations, 90.9% received the initial starting dose while 75% did not receive the initial starting dose.

Conclusion and Relevance SZC therapy displayed that more than 50% of patients achieved normal potassium levels at 48 and 72h with both regimens. Starting SZC therapy with the initial starting dose showed better and faster effectiveness. More than half of the patients had not previously tried CPS, the most cost-effectiveness option.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-164 ANALYSIS OF USTEKINUMAB INTENSIFICATION IN INFLAMMATORY BOWEL DISEASE ACCORDING TO LINE OF TREATMENT

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Background and Importance Ustekinumab has been shown to be effective and safe in the long term in inflammatory bowel disease. However, its use in advanced treatment stages is associated with a loss of effectiveness, leading to intensified usage and an associated additional cost.

Aim and Objectives The objective is to analyse the posological intensification of ustekinumab in ulcerative colitis (UC) and Crohn's disease (CD) in real clinical practice according to the line of treatment used.

Material and Methods Retrospective observational study in which all patients treated with ustekinumab in a tertiary hospital were included during the period January 2017, to September 15, 2023.

The analysed variables included age, sex, previous anti-TNF therapy, intensified patients, months from the start of Ustekinumab until needing intensification to 6 weeks and 4 weeks, causes of Ustekinumab use in first line treatment. The sources used to obtain data were the electronic prescription application Prisma® and the computerised medical record system Diraya®.

Results A total of 177 patients were included (48.1% women), with a mean age of 48 years (range 19–85). Among them, 37.3% (n=66) had been previously treated with two anti-tnf, either exclusively with Adalimumab (n=71. 40.1%), exclusively with Infliximab (n=20. 11.3%) or had no prior anti-tnf treatment (n=20, 11.3%).

Intensification of the regimen with ustekinumab was necessary in 54.5% of those previously treated with two anti-tnf, 49.3% only adalimumab, 50% only infliximab, 45% no previous anti-TNF.

The initial posology of ustekinumab was 8 weeks. The median number of months for the intensification of ustekinumab to 6 weeks and 4 weeks was 10.5 months and 19.9 months (two anti-TNF), 11.4 months and 20.6 months (adalimumab), 12.3 months and 20.6 months (infliximab) and 19.7 months and 26.5 months (non anti-TNF).

In our hospital, patients who had not previously undergone any anti-TNF treatment did so due to neoplasia (46.6%), infections (20%), HLA-DQA1*05 (13.3%) or multiple sclerosis (13.3%).

Conclusion and Relevance The percentage of patients intensified with ustekinumab is higher in those treated with anti-TNF than in those not treated.

In addition, patients treated with one anti-TNF or no anti-TNF required more time to intensify than patients treated with two anti-TNFs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-165 DETERMINATION OF PREDICTIVE FACTORS FOR IMMUNE-RELATED TOXICITY IN LUNG CANCER PATIENTS TREATED WITH IMMUNOTHERAPY

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Background and Importance Immunotherapy has provided better responses and tolerance in the treatment of lung cancer than intravenous chemotherapy. However, it can also induce autoimmune adverse effects that could lead to hospital admission or death of the patient.

Aim and Objectives To analyse possible factors associated with the incidence of immune-related adverse events (iRAEs) in lung cancer (LC) patients treated with immune checkpoint inhibitors (ICI).

Material and Methods Retrospective analysis of patients with LC treated with ICI between 2015 and 2023 in a tertiary hospital. The variables collected from the clinical history were: age, sex, performance status, history of allergy/autoimmune disease, treatment with corticosteroids or antibiotics prior to the ICI, occurrence of iRAEs, type of toxicity and severity, laboratory variables (haemoglobin, neutrophil count, platelet count, LDH), date of progression and death. The association was determined using Chi-square tests and Fisher's exact test. Progression-free survival (PFS) and overall survival (OS) were calculated using the Kaplan-Meier method

Results A total of 67 patients (74.6% men; mean age 68.6 ±9.4 years) treated with ICI were analysed. Of these, 49 developed at least one iRAE (73.1%), 37.3% from grade≥3. Statistically significant associations were found between appearance of skin toxicity and altered LDH levels (p=0.048), and musculoskeletal toxicity and ECOG≥2 (p=0.037). History of allergy/autoimmune disease and treatment with corticosteroids or antibiotics in the 3 months prior to the start of immunotherapy were associated with the appearance of liver toxicity (p=0.015 in all cases), asthenia (p=0.027; p=0.021; p=0.032) and musculoskeletal toxicity (p=0.006; p=0.006); p=0.005). Patients with iRAEs had longer PFS (14.8 vs. 3.3 months) and longer OS (19.2 vs. 2.9 months).

Conclusion and Relevance No association was found between the proposed variables and the appearance of immune-related toxicity in general but a significant relation was found between altered LDH and skin toxicity, and between ECOG≥2 and musculoskeletal toxicity. Correlation was also found between a history of allergy or autoimmune disease and the consumption of antibiotics or corticosteroids with the appearance of hepatic, general or musculoskeletal toxicity.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-166 COMPREHENSIVE ASSESSMENT OF PHARMACOTHERAPY IN THE COMPLEX CHRONIC PATIENT: COLLABORATION BETWEEN DIFFERENT LEVELS OF CARE

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Background and Importance Complex chronic patients (CCP) have changing needs that require continuous reassessment and effective coordination of different levels of care.
Aim and Objectives To analyse a comprehensive pharmacotherapy assessment programme (CPAP) in the CCP regarding health resources utilisation, optimisation of pharmacotherapy, pharmacotherapeutic and patient satisfaction.
Material and Methods Prospective intervention study in a tertiary hospital´s emergency department (ED) between 9 January 2023 to 31 August 2023. Inclusion criteria: CCP who consulted the ED, signed informed consent, and were not seriously ill or institutionalised.

A CPAP in <24 h/48h in the ED included: conciliation, review of pharmacotherapy and prescriptions and issue of a pharmacotherapeutic recommendations report. The report was sent to primary care (PC) professionals at discharge. To assess patient's satisfaction, a follow-up phone call was made 30 days after discharge (score 0–10).

Collected variables were age, sex, Charlson index, admission service, length of stay, 30-day post-discharge ED visits, mortality, number of drugs, number of recommendations issued and accepted.
Results One hundred and ten CCPs were included in the ED, 56 males (50.9%), median age 86(35–101), median Charlson Index: 7(2–14).

103 (94%) patients were polymedicated and 74(67.3%) hyperpolymedicated. Median number of chronic drugs per patient was 11 (3–21).

Eighty-five (77.3%) were admitted, mean stay 8 days, at Internal Medicine 37 (43.5%).

Seventy-six (83.6%) completed the follow-up period, of which 17 (15.8%) returned to the ED and 6 (7.9%) were readmitted. Losses: Exitus:18; Palliative:8 ; Other: 8.

In the ED, 376 recommendations were made (mean 3.4/patients) and 91(24.2%) were accepted. At discharge 168 (mean 2.2/patient) and 54 (32.1%) were accepted. 95 errors were detected between the electronic prescription and the discharge report, 55 (57.9%) in the first evaluation.

Patient satisfaction with the project was 9.4 (7–10).

Conclusion and Relevance A high percentage of CCPs attending the ED were admitted. A quarter of the CCPs were readmitted or returned to the ED during the month of follow-up.

There is a decrease in the number of recommendations issued after the CCP's stay in the hospital, but there is greater acceptance of the discharge recommendations.

In more than half of the patients there are discrepancies between the treatment described in the discharge report and their electronic prescription, which is a safety problem.

Patients reported a high satisfaction level with the project.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-167 USE OF STANDARD- AND HIGH-DOSE LIPOSOMAL AMPHOTERICIN B AND ITS RELATIONSHIP WITH HYPOMAGNESAEMIA

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Background and Importance Magnesium deficiency is mainly manifested in cardiac and neuromuscular disorders. Hypomagnesaemia has been described as a frequent adverse reaction associated with the intravenous administration of liposomal amphotericin B.
Aim and Objectives To compare associated hypomagnesaemia in patients with fungal infection receiving standard- versus high-dose of liposomal amphotericin B.
Material and Methods One-year retrospective observational study including patients who received liposomal amphotericin B for at least 5 days. The variables collected were age, sex, mean dose, duration of treatment, serum magnesium and need for magnesium supplementation. Patients were divided into two groups: standard doses (≤ 3 mg/kg/day) and high doses (> 3 mg/kg/day). The change in magnesium at the beginning and the end of the period studied in each of the groups was analysed.
Results A total of 31 patients (38% women) with a mean age of 60±13 years were included. The baseline magnesium value of the patients who started treatment was 1.95±0.34 mg/dl, with only two patients being below the physiological range (1.6–2.4 mg/dl).

In the standard dose group, 11 patients (35%) were included with a mean dose of 1.63±0.84 mg/kg/day and a mean duration of 22±10 days. At five days, no patient was below the physiological range, although magnesium decreased by an average of 0.076 mg/dl (4% with respect to baseline). This meant that 45% of the patients had to be supplemented with intravenous magnesium. In the high-dose group, 20 patients (64%) were included, who received a mean dose of 4.88±0.91 mg/kg/day for a mean of 17±10 days. On the fifth day, 20% of the patients showed levels below the physiological range of magnesium. Furthermore, the mean decrease in this group was 0.195 mg/dl (10%), with 65% requiring exogenous supplementation. There are statistically significant differences ($p<0.05$) showing that a greater decrease in serum magnesium levels is associated with high-dose amphotericin.
Conclusion and Relevance Real-life data show a greater decrease in serum magnesium with high doses of liposomal

amphotericin B. Therefore, monitoring and follow-up of these patients -who will require more frequent magnesium supplementation- is a priority.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-168 EFFECTIVENESS, SAFETY AND ADHERENCE TO EVOLOCUMAB IN REAL CLINICAL PRACTICE

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Background and Importance Evolocumab, an inhibitor of proprotein convertase subtilin-kexin type 9, represents an alternative therapeutic option for individuals who exhibit intolerance to standard low-density lipoprotein cholesterol (LDL-C) treatments or fail to attain desired LDL-C levels.
Aim and Objectives This study aims to assess the effectiveness, safety and adherence to evolocumab among patients with hypercholesterolemia.
Material and Methods Observational, retrospective, and multidisciplinary study that included patients who started treatment with evolocumab in a tertiary hospital between July 2016 and August 2022. Data variables (clinical history and dispensing program) were sex, age, indication, statins treatment, evolucumab dosage, treatment duration, LDL-C levels at baseline, 3, 6, 12 and 36 months, adverse effects (AEs) and adherence (medication possession rate). SPSS-27 statistical program (Wilcoxon test) was used to compare the decrease in LCL-C levels at different times.
Results The study enrolled 63 patients (52.4% women), with an average age at initiation of 61.8 (SD:11.1) years. The primary diagnoses included familial hypercholesterolemia (57.1%), established cardiovascular disease (33.3%) or both (9.5%). 63.5% of patients were intolerant to statins, 1.6% had contraindications, and 34.9% received statins at maximum tolerated doses without achieving target LDL-C levels. Dosage was 140 mg/14 days, with an average treatment duration of 3.0 (SD:1.6) years and an adherence rate of 91.3 (SD:14.9)%. The average LDL-C levels was 169.9 (SD:57.5) mg/dl, 84.9 (SD: 62.6) mg/dl, 77.2 (SD: 47.5)mg/dl, 75.7 (SD: 39.0) mg/dl and 84.0 (SD: 44.5) mg/dl at basal, 3, 6, 12 and 36 months, respectively. These LDL-C levels were significantly reduced ($p<0.01$) when compared to basal. Currently the majority (85.7%) of patients continue their treatment, 1.6% lost to follow-up, and 12.7% discontinued due to death (4.8%), AEs (6.3%) and lack of response (1.6%). Only four patients had AEs (headache; pseudo catarrhal symptoms, haematomas, spasms; anaphylaxis; skin reaction, diarrhoea and myopathies), and evolocumab was withdrawn in all of them.
Conclusion and Relevance Evolocumab emerges as a compelling therapeutic option for LDL-C reduction and cardiovascular risk mitigation, particularly for patients with statin intolerance or inadequate statin response. The results obtained in our real clinical practice (55.4% decrease in LDL-C levels at 12 months) were similar to those of the pivotal clinical trials. Further research is warranted to ascertain its impact on major cardiovascular events in real-world settings.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-169 EVALUATION OF ANTICHOLINERGIC DRUG PRESCRIPTION USING A CLINICAL DECISION SUPPORT SYSTEM: A PROSPECTIVE STUDY IN A GERIATRIC REHABILITATION CENTRE

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Background and Importance Anticholinergic drugs are considered as potentially inappropriate in older adults. Different scales are available to quantify anticholinergic burden. A score ≥ 3 is considered as increasing the risk of side effects. Clinical pharmacists can play an important role in reducing anticholinergic drug prescription, but resources are limited. A clinical decision support system (CDSS) based on anticholinergic burden scales can help pharmacists to identify patients at higher risk of anticholinergic side effects.
Aim and Objectives The objective of this prospective study was to evaluate the prescription of anticholinergic drugs in a geriatric rehabilitation unit (RU) and the anticholinergic burden for each patient regarding the prescription at home, at discharge of acute care, on admission in RU and at discharge to home.
Material and Methods All patients, aged > 65 years, with at least one anticholinergic drug on admission in RU or during the stay were eligible. The CDSS Pharmaclass® was used to detect patients with anticholinergic drugs, based on the CRIDECO anticholinergic burden scale. When the score was ≥ 3, the pharmacist evaluated the situation and informed the physician. If needed, he suggested pharmaceutical interventions.
Results 132 patients were included between April and May 2023. Average anticholinergic score was 1.83 (+/- 1.6 SD) for the usual home treatment, 2.81 (+/- 1.78 SD), the last day in the acute unit, 2.45 (+/- 1.54 SD) on admission in the RU and 1.81 (+/- 1.54 SD) at discharge. 40% of the patients had an anticholinergic score ≥ 3 on admission and 24% at discharge. Anticholinergic drugs were prescribed 349 times with analgesics being the most prescribed (24%), followed by antidepressants (16%). Pharmacist informed the prescriber about a score ≥ 3 for 58 patients and realised 45 interventions with an acceptance rate of 82%.
Conclusion and Relevance Hospitalisation in acute care led to an increase of anticholinergic drug prescription. A stay in a geriatric rehabilitation unit before discharge helped reducing this burden. Sensitivity of geriatrician regarding inappropriate prescriptions as well as focused pharmaceutical interventions, supported by a CDSS, result in this score reduction. This study reveals the need to deploy the anticholinergic alert of CDSS to other wards in acute care.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-170 CLINICAL PHARMACY PRIORITISATION ALGORITHM FOR PATIENTS IN PSYCHIATRIC LONG-TERM CARE: A PILOT STUDY

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Background and Importance A prioritisation algorithm for long-term psychiatric patients contributes to patient safety by identifying the individual's risk of experiencing drug-related problems (DRPs). To date no such algorithm is applicable to long-term psychiatric care.

Aim and Objectives This pilot study aimed to develop a clinical pharmacist prioritisation algorithm for psychiatric patients in a long-term care facility.

Material and Methods This retrospective, mixed methods study was conducted in three phases. *Phase I:* A narrative literature review to identify a validated methodological approach that guides algorithm development. *Phase II:* Medication reviews for 66 long-term psychiatric inpatients were conducted by a clinical pharmacist (ASH) in a specialist care facility. *Phase III:* An expert panel of three clinical pharmacists (MM/MC/AEW) independently rated a statistically relevant sample size of all identified drug related problems (DRPs) and their intervention on their contribution to patient safety using the classification system by Overhage and Lukes. Based on these findings and non-parametric statistical analysis (Mann-Whitney U test, Kruskal-Wallis test), a pilot algorithm for clinical pharmacists interventions in this patient population was developed. The study received ethical approval from the Medical University Innsbruck [no. 1064/2023].

Results A total of 382 DRPs were identified across 66 patients. The most common types of DRPs were 'drug-interaction' (51,4%/n=196) and 'adverse drug reaction' (39,0%/n=149) with the most frequent interventions being 'controlling for symptoms' (34,6%/n=132) and 'drug switch' (22,6%/n=86). The five drug classes most often associated with DRPs were N05A ANTIPSYCHOTICS (36%/n=272), N06A ANTIDEPRESSANTS (14,7%/n=110), N05B ANXIOLYTICS (13,1%/n=98), N03A ANTIEPILEPTICS (5,9%/n=44) and N02A OPIOIDS (3,5%/n=26). Intervention rating was categorised as avoiding 'significant' or 'major' complications in 33,9% (n=126) and 12,4% (n=46) of cases, respectively. DRPs identified to carry the highest patient risk and included in the prioritisation algorithm were: combination of sedative agents; concomitant use of QT interval prolonging drugs; cumulative anticholinergic burden; combination of acetylsalicylic acid and valproic acid.

Conclusion and Relevance The pilot algorithm proposed in this study provides a means for clinical pharmacists to prioritise patients at greatest risk of DRPs in this unique patient population. While it is the first algorithm for this patient population, further research is needed to ensure internal and external validation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-171 FIXED-DOSE VERSUS WEIGHT-BASED DOSING REGIMEN OF PEMBROLIZUMAB

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Background and Importance Pembrolizumab is a PD-1 antibody, which was first approved with a dosage regimen of 2 mg/kg every 3 weeks. In 2018, marketing authorisation was changed to fixed dosing of 200 mg every 3 weeks.

The Commission of Pharmacy and Therapeutics of our region has taken the stance that based on the available evidence both regimens may be used.

Therefore, our hospital has agreed on a protocol that establishes to use fixed-dose for patients with weight $\geq$ 100 kg and the weigh-based for < 100 kg.

Aim and Objectives Evaluation of the accordance to the protocol establish in our hospital for the dose of Pembrolizumab and to calculate the financial impact of this implementation.

Material and Methods Retrospective observational study in individuals who started pembrolizumab since 1August 2022 for 1 year.

Variables analysed were epidemiological, weigh, cancer type, initial date, fixed-dose or weight-dose protocol used, change of the protocol.

1081.75€ has selected as the vial price of 100 mg of pembrolizumab.

Data was extracted from our prescription software for chemotherapy (Oncofarm®).

Results 131 patients initiated pembrolizumab, 62.60% men, mean age 65 years old. Mean weight was 71.8 kg and four patients weighted >100 kg. Pembrolizumab cancer indications were: melanoma (6.11%), non-small-cell lung (57.25%), head and neck squamous (6.11%), renal (3.05%), colorectal (3.82%), triple-negative breast (9.92%), endometrial (5.34%), cervical (2.29%), gastric (2.29%) and others (3.82%).

74.05% (n=98) of the patients initiated at the fixed-dose and only 25.95% (n=33) with weigh-based dose. There were four patients with weight > 100 kg which initiated with 200 mg.

Of the patients that initiated with fixed-dose, 11.22% (n=11) changed to the weight-based dose. Dose was reduced in a mean of 24.91%, which implied a total cost reduction of 29012€ (mean 2637€ per patient) and represented a 14.86% mean cost reduction in comparison with continuing with the fixed-dose.

Conclusion and Relevance Although it was accorded to use weight-based strategy for the patients < 100 kg, the reality was than less than 26% of the new pembrolizumab treatments were in compliance with it.

However, it is true that approximately 10% of the patients were changed to the weight-based regimen in order to decrease the economical cost.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Keytruda: EPAR – Product information.

Conflict of Interest No conflict of interest.

4CPS-172 IMPROVING POST-OPERATIVE ANALGESIA AND ASSOCIATED PRESCRIBING IN THE ORTHOPAEDIC SETTING

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Background and Importance In January 2022 the HSE issued 'Guidance for opioid prescribing for acute noncancer pain, postoperative pain and post-procedure pain'.

Three Guidance documents were developed by a multidisciplinary team comprising of: senior pharmacist, pain management CNS, consultant ortho-geriatrician and consultant anaesthetist.

Three key documents were developed

- Post-Operative Opioid Conversion Chart
- Analgesia Prescribing Guideline
- Opioid Patient Information Leaflet

Aim and Objectives The aim of the project was to implement the recommendations of the HSE Guidelines to 'improve quality and safety of opioid prescribing in the acute hospital setting and reduce harm from their use'.

The objectives were Avoid use of long-acting opioids in the port-operative setting

Appropriate prescribing of post-operative medicines.

Material and methods A point prevalence baseline audit of post-operative prescribing was undertaken in July 2022 before the introduction of the guidelines.

A2 posters of the guidance documents were printed and displayed on the orthopaedic ward accompanied by intensive education.

Prescribing was reaudited using the same parameters in November 2022.

Results The demographics of the patients for the audit (n=29) and re-audit (n=28) were comparable. Hip related injuries was the most prevalent type of injury for patients in both audits.

The baseline audit found the highest incidence of inappropriate prescribing in the areas of: Opioids, Laxatives and NSAIDs. These three areas were targeted for improvement.

A summary of the key results is depicted in table 1 below:

Abstract 4CPS-172 Table 1 Comparison of prescribing of audit and re-audit

Parameter	July 2022	Nov 2022
No Opioid naïve patient > 65 years to be prescribed a long-acting opioid post-op	15%	0
Patient ≤4 days post-op to be prescribed a regular and PRN short-acting opioid	65%	93%
All patients prescribed an opioid to be prescribed at least one regular laxative	73%	92%

Conclusion and Relevance Post-operative analgesia and associated prescribing can be improved with provision of clear, accessible, evidence based guidelines and information to prescribers and ward staff.

A key learning point was that education provision must be continuous with intensification at the time of team rotations.

Since completion of this initial project, a separate general surgery post-operative prescribing guideline has been developed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

4CPS-173 PRESCRIPTION OF PSYCHOTROPIC DRUGS IN PATIENTS WITH HUMAN IMMUNODEFICIENCY VIRUS INFECTION ON INTEGRASE INHIBITOR-BASED ANTIRETROVIRAL THERAPY

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Background and Importance Neuropsychiatric adverse effects, such as depression, anxiety and sleep disorders, are associated with integrase strand transfer inhibitors (INSTIs). According to a study, the rate of NPAE with bictegravir is higher than first generation INSTIs.

Aim and Objectives To analyse whether the switch of integrase inhibitor in patients with chronic human immunodeficiency virus (HIV) infection on antiretroviral treatment (ART) affects the consumption of psychotropic drugs.

Material and Methods We include patients who in 2019 were being treated with elvitegravir/cobicistat-based ART and as of 2021, they either maintained the same treatment (group 1) or switched to bictegravir-based ART during the next 2 years (group 2).

The primary endpoint was the relative risk of taking psychotropic drugs after changing antiretroviral treatment.

The home treatment of these patients was reviewed and those who had been treated with psychotropic drugs, such as anxiolytics, hypnotics and sedatives, and antidepressants (N05B, N05C and N06A in the ATC classification, respectively) during the study years, were selected.

The data were obtained through the Pharmaceutical Benefit Management program (GAIA®)

Results A total of 122 patients were included: 34 (27.9%) were treated with elvitegravir/cobicistat during the 4 years of the study (group 1) and 88 (72.1%) switched to bictegravir in 2021 and maintained it in 2022. (group 2).

While the percentage of patients treated with psychotropic drugs remained stable in group 1, the percentage of patients taking any psychotropic drug increased by 9% in the group that switched to bictegravir. The antiretroviral treatment change group had a 6.5 times greater risk of taking some type of psychotropic drug than the control group, but this increase in risk was not statistically significant (p=0.19).

In the group of patients who were not taking psychotropic drugs, 15% started taking them after switching to bictegravir compared to 9% in the control group (RR 1.6 p=0.5).

Conclusion and Relevance Almost 40% of patients being treated with integrase inhibitors are being treated with some

psychotropic drug. The change from elvitegravir/cobicistat to bictegravir seems to be accompanied by a slight increase in the taking of psychotropic drugs, although it was not statistically significant.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. doi: 10.1097/COH.0000000000000705. PMID: 34475342.

Conflict of Interest No conflict of interest.

4CPS-174 NASAL ESKETAMINE USE FOR MAYOR DEPRESSIVE DISORDER, FROM A THIRD-LEVEL HOSPITAL TO PERIPHERAL MENTAL CENTRES

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Background and Importance Esketamine was recently commercialised for major depressive disorder and in our community is available through a restricted program due to its characteristics and price. In this study, the patients started the treatment at an acute hospital and when they reach the maintenance were derived to peripheral Mental Health Centres.

Aim and Objectives Study the effectiveness and security of Nasal esketamine in an acute hospital.

Material and Methods All patients starting esketamine treatment from December 2022 to July 2023 were included. Efficacy and adverse effect (AE) data were collected and evaluated at each dose administered, objectively with the MADRS (Montgomery-Albert depression Rating Scale). A psychiatrist and psychiatric nurse evaluate subjectibly and a pharmacist registered it. This data were collected three times: before treatment, during and at the end of the study.

Results 33 patients were included; 20 women, median age 56 years [31–74] and median weight 72 kg [42–110]. Five patients left the treatment, three due to AE and two that were not evaluated by MADRS.

In 28 patients, the difference of the MADRS medians prior to treatment compared to the two times studied was significant (p=0.00). Before treatment the median was 44 (IQR 35–46.75), at the end of induction 25 (IQR 20–31.5) and at the end of the maintenance 23.5 (IQR 11.5–29.75).

Patients went from severe to moderate-mild depression in approximately 12 weeks, two patients obtained remission, MADRS <6 result.

Two patients dropped out due to severe dissociative AEs and another one due to lack of efficacy and AEs. Nevertheless, AEs were generally mild-moderate and tolerance improved as treatment progressed. Most frequent AEs were 73% drowsiness, 53% dizziness, 50% dissociative pictures, 36% transient hypertension, 13% gait instability. These effects generally subside within two hours and in some patients the tolerance improved increasing the time between nebulisation's more than 5–10 min.

Conclusion and Relevance EA profile and effectiveness is similar to the clinical trial. It is possible to manage these patients in peripheral Mental Health Centres due to the tolerance of the AE and the good results of the treatment, permitting discharge the acute hospital.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

4CPS-175 EFFECTIVENESS OF IMMUNOTHERAPY AS A FUNCTION OF AGE: META-ANALYSIS OF THE APPROVED COMBINATIONS IN FIRST-LINE METASTATIC NON-SMALL-CELL LUNG CANCER IN PATIENTS WITHOUT MUTATIONS

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Background and Importance It could be hypothesised that patients older than 65 years old may experience decreased immune function due to the natural aging process, which could lead to a more limited response to immunotherapy compared to those younger than 65 years old.

The forest-plot analysis for age-dependent overall survival from the clinical trial of cemiplimab in combination with chemotherapy in locally advanced or metastatic non-small-cell lung cancer (NSCLC), EMPOWER-Lung 3, showed a borderline interaction between the subgroups younger and older than 65 years old, with a p-interaction=0.0895 (own calculation) and HR 0.53 (0.39–0.72), HR 0.81 (0.55–1.18), respectively.

Aim and Objectives To verify the consistency of the hypothesis of an age-related effectiveness by a meta-analysis considering all approved immunotherapy combinations in first-line NSCLC.

Material and Methods A MEDLINE-PubMed literature search was conducted for phase III randomised clinical trials (RCTs) with similar population and duration of pembrolizumab, atezolizumab ± bevacizumab, nivolumab + ipilimumab, durvalumab + tremelimumab and cemiplimab, in combination with chemotherapy and nivolumab + ipilimumab. A meta-analysis was performed with the MetaSurv calculator. The primary endpoint was overall survival (OS) in patients younger and older than, or equal to, 65 years of age. Age-dependent OS data for immunotherapy combinations versus a common comparator, platinum-based chemotherapy, were compared. Interaction was considered significative if $p<0.05$ and doubtful if $0.05 \leq p < 0.1$.

Results A pooled HR of 0.67 (95% CI 0.58–0.76), $p<0.000001$ was obtained in patients younger than 65 years of age. Heterogeneity among trials estimate values were as follows: Q 14.84, p=0.03812. I2 53% (CI 95% 0–79%).

In those older than 65 years old, the combined HR obtained was 0.77 (95% CI 0.70–0.84), $p<0.000001$. Heterogeneity estimate values were as follows: Q for heterogeneity 0.81 p=0.99733. I2 0% (CI 95% 0–0%).

The calculated p-interaction between the combined HRs of the under-65 and over-65 groups was 0.0551, which is considered a doubtful interaction in a subgroup analysis.

Conclusion and Relevance A significant benefit for immunotherapy-chemotherapy over chemotherapy alone was shown in both age groups. There is some consistency regarding a greater effectiveness of immunotherapy in patients under 65 years of age, but more data would be needed to confirm this possible difference.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-176 USE AND PERSISTENCE OF GUSELKUMAB IN TREATMENT FOR RHEUMATIC AND DERMATOLOGICAL DISEASE

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Background and Importance Guselkumab is anti-interleukin-23 monoclonal antibody used for moderate to severe psoriasis (msPs) and psoriatic arthritis (PsA) in patients refractory to other biological agents in clinical practice.
Aim and Objectives To analyse the profile of use and persistence of guselkumab in patients diagnosed with msPs and PsA.
Material and Methods An observational, descriptive and retrospective study (May 2019 to August 2023) in which we included all patients who initiated treatment with guselkumab. Data of sex, age, diagnostic, comorbidities, previous biological, start date, last dispensation date and the reasons for treatment discontinuation were collected from the medical records and prescription medications program.

Categorical variables were summarised as percentage (N) and as median for continuous variables. The cumulative probability of treatment persistence was analysed by Kaplan-Meier method and log-rank test to compare the survival along diagnostic, line of treatment and comorbidities using SPSS Statistics, considering a p-value <0.05.
Results Guselkumab was initiated by 40 patients, 57.5%(23) with PsA and 42.5%(17) with msPs. Median age was 54 years, and 57.3% (23) were female. All patients had prior exposure to biologic therapy except one, 87.5% (35) anti-TNF-a (adalimumab, infliximab, etanercept), 47.5% (19) anti-IL-17 (ixekizumab, secukinumab) and 30% (12) ustekinumab. The exposed patients 97.5% (39) had used 1–5 biologic therapies before guselkumab initiation, 40% (16) of patients received three or more therapies. 22.5% (9) of patients had no comorbidities, 35% (14) had at least one comorbidity and 42.5% (17) showed two or more.

The cumulative probability of guselkumab treatment persistence was 74.8% at 1 year and 67.3% at 2 years. Median persistence of guselkumab was 31.2 months (95% CI: 21.2–41.2). 32.5% (13) discontinued treatment during the study, the main cause of discontinuation was secondary failure (46.1%). Comparing groups, there were statistical differences in guselkumab's persistence in msPs vs PsA (14–36.7 months, p=0.059), however, patients with or without prior anti-IL-17 therapy, with or without comorbidities, or according to the number of prior biologics did not show any statistical differences.
Conclusion and Relevance Drug survival of guselkumab in this study is acceptable but main limitation is short follow-up time in some of the patients due to their recent coverage by the Spanish health system in PsA. More studies with larger sample sizes are needed to establish the factors that play a key role in the persistence of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-177 LONG-ACTING INTRAMUSCULAR ANTIRETROVIRALS: WHAT REAL-WORLD DATA DO WE HAVE?

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Background and Importance The new intramuscular antiretroviral treatments (IM-ART), cabotegravir-rilpivirine, have represented a breakthrough in reducing stigma and improving adherence among HIV patients. However, it is necessary to understand how their real-world use impacts patient outcomes.
Aim and Objectives To assess the effectiveness and safety of IM-ART in real-world settings and investigate their impact on analytical parameters.
Material and Methods A retrospective observational study conducted from January to September 2023, including all patients treated with LA-ART with at least three doses. Demographic data (age, gender), treatment-related information (previous ART and presence of resistance mutations (RM)), clinical data (LDL-cholesterol, HDL-cholesterol, creatinine, GOT, GPT, alkaline phosphatase, GGT, total bilirubin, calcium, and phosphorus before and after IM-ART), and effectiveness data (HIV-RNA copies (CV), CD4 count, and CD4/CD8 ratio before and after starting IM-ART) were collected. Adverse events (AE) and pain assessed on the Visual Analog Scale (VAS) during the first two administrations were recorded. Paired Student's t-test and Wilcoxon signed-rank test were used for statistical analysis of differences between pre- and post-LA-ART variables, depending on the distribution. Statistical analysis was performed using Stata/IC16.1 software.
Results Sixty-six patients (93.9% men) were analysed. Median age: 42 years (IQR:38–46). 50,0% were receiving triple therapy before the switch, and 27.6% had at least one RM, which did not affect IM-ART. Three patients had CV>30 copies/mL before starting LA-ART. All patients included maintained CV<30 copies/mL during the study period. Statistically significant differences were observed in LDL-cholesterol (p=0.0193) and CD4 (p=0.0035) between pre- and post-IM-ART values.

All patients experienced at least one AE, with injection site reactions being the most frequent (98.5%). The observed AEs included: general malaise (36.7%), asthenia (13.6%), fever (12.1%), diarrhoea (9.1%), headache (7.6%), sleep disturbances (6.1%), nausea (3.0%), and others (4.5%). One patient discontinued IM-ART due to AE.

Differences in pain assessed on the VAS were observed between rilpivirine vs cabotegravir administration [0.9 (95% CI: 0.3–1.5; p=0.0029)] and between the second vs first administration: rilpivirine [1.6 (95% CI: 0.5–2.7; p=0.0042)]; cabotegravir [1.6 (95% CI: 0.6–2.6; p=0.0032)].
Conclusion and Relevance LA-ART has demonstrated effectiveness and acceptable safety in real-world data, consistent with the results of the ATLAS and FLAIR studies. Longer-term studies are needed to evaluate the evolution of CD4 counts, LDL levels and pain.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-178 EFFECT OF PCSK9 INHIBITORS ON HYPERCHOLESTEROLEMIA

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Background and Importance Patients with hypercholesterolaemia are at risk of cardiovascular events. Some patients have to resort to monoclonal antibody treatments to lower their blood cholesterol levels, despite taking statins at full doses.

Aim and Objectives The aim of this study is to determine the reduction of LDL cholesterol (LDL-c) with PCSK9 inhibitors (alirocumab and evolocumab) in patients with mixed dyslipidaemia, atherosclerotic cardiovascular disease or familial hypercholesterolemia.

Material and Methods

Retrospective observational study Adult patients under treatment with ALI or EVO, with at least 12 weeks of follow-up were included. Patients without control laboratory tests after initiation of therapy were excluded.

Primary endpoint of the study was the percentage reduction in LDL-c with respect to baseline.

Retrospective data collection was carried out using electronic medical records (Selene®) and the analysis results software (INFINITY). The Mann-Whitney U test was used to determine whether there were differences in the percentage reduction of LDL-c with respect to baseline between patients treated with alirocumab and evolocumab.

Analyses were performed using SPSS/PC statistical software (version 24.0 for Windows, SPSS, Inc, Chicago, IL).

Results Eighty-eight patients were analysed, of whom 67% were male and the median age 59 ± 9 years.

Of the 88 patients, 61% were diagnosed with mixed dyslipidaemia, 31% with familial hypercholesterolemia, and the remainder with atherosclerotic cardiovascular disease. Eighty-one percent of the patients were treated with alirocumab and the remainder with evolucumab.

The baseline LDL-c level was 156 mg/dL [126–188], total cholesterol 238 mg/dL [202–266], HDL cholesterol 45 mg/dL [37–54] and triglycerides 183 mg/dL [114–250]. At the patients' last blood test, after a minimum of 12 weeks from the start of treatment, LDL-c was 60 mg/dl [37–67], total cholesterol 137 mg/dl [114–170] and HDL cholesterol 48 mg/dl [41–60].

The median percent reduction in LDL-c from baseline in patients on PCSK9 inhibitor treatment was 45%. This percent reduction was 43% while in patients on evolocumab treatment it was 46%, U = 552, z = -0.374, p=0.708.

Conclusion and Relevance Treatment with PCSK9 inhibitors reduces basal LDL-c by 45%. No statistically significant differences were found according to the treatment used (alirocumab or evolocumab), p=0.708. .

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-179 REAL-LIFE ANALYSIS OF THE DEVELOPMENT OF ANTI-DRUG ANTIBODIES IN PATIENTS WITH INFLAMMATORY BOWEL DISEASEAND THERAPEUTIC APPROACH

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Background and Importance Loss of response to infliximab and adalimumab therapy may occur due to development of neutralising anti-drug antibodies (ADA), leading to treatment failure in inflammatory bowel disease (IBD).

Aim and Objectives To assess the immunogenicity of infliximab and adalimumab in adults and paediatric IBD patients, along with therapeutic approach and potential factors contributing ADA development.

Material and Methods Retrospective observational study in adult and paediatric IBD patients treated with infliximab and adalimumab, between January 2019 to June 2023.

Adalimumab, infliximab and ADA concentrations were determined by enzyme immunoassays. Concretely, ADA if patients had infliximab ≤3 mcg/ml and adalimumab ≤5mcg/ml concentrations (drug-sensitive assay). Standard dosage regimen (SD): adalimumab 40 mg/14 days, Infliximab 5 mg/kg/8 weeks; intensified dosage involved either shortening the interval or increasing dose.

Results 659 patients were included. Specifically, 399 (60.5%) received adalimumab: 24 (6.0%) paediatrics and 375 (94.0%) adults; and 260 (39.5%) received infliximab: 36 (13.8%) paediatrics and 224 (86.2%) adults.

Adalimumab antibodies (AAA) were evaluated in 412 samples from 195 (48.9%) patients [10 (5.1%) paediatrics and 185 (94.9%) adults] and infliximab antibodies (ATI) were evaluated in 377 samples from 150 (57.7%) patients [19 (12.7%) paediatrics and 131 (97.3%) adults].

Thirteen (3.3%) patients developed AAA: all were adults with Crohn's disease and mean age of 40.6 (12.9) years, including 7 (53.8%) females. Seven (53.8%) patients had been on adalimumab for <1 year. At the time of AAA detection, five (38.5%) patients had adalimumab SD, and six (46.2%) receiving immunosuppressants. Eleven (84.6%) patients discontinued adalimumab, while two (15.4%) with AAA of 133ng/ml and 107.9ng/ml underwent adalimumab intensification achieved AAA negativisation. Poor adherence was suspected in five (38.5%) patients.

Twenty-two (8.5%) patients developed ATI: 20 (90.9%) adults with 45.2 (12.8) years, including 8 (40%) females; and 2 (9.9%) paediatrics with 15.0 (5.7) years comprising one (50%) female. IBD diagnosed: Crohn's disease in 14 (63.6%) and ulcerative colitis in eight (36.4%) patients. Eleven (50%)

patients had been on infliximab for <1year. At the time of ATI detection, 12 (54.5%) patients had infliximab SD, and 12 (54.5%) receiving immunosuppressants. Thirteen (59.1%) patients discontinued infliximab, while seven (31.8%) with ATI <30ng/ml and two (9.1%) with 100.6ng/ml and 171.7ng/ml underwent infliximab intensification achieved ATI negativisation. Poor adherence was confirmed in six (27.3%) patients.

Adalimumab and infliximab concentrations were <1mg/ml in all patients with ADA.

Conclusion and Relevance A proportion of IBD patients developed ADA, with a higher incidence observed in those receiving infliximab. Enhancing adherence could reduce the risk of ADA development, and intensifying treatment may be effective in achieving ADA negativisation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-180 SACITUZUMAB-GOVITECAN IN METASTATIC TRIPLE-NEGATIVE BREAST CANCER: COMPARISON OF OUR DATA TO THE ASCENT TRIAL AFTER 2 YEARS OF EXPERIENCE

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Background and Importance Sacituzumab-govitecan (SG) is an antibody-drug conjugate used in metastatic triple-negative (TN) breast cancer (BC). Adverse events (AEs) described in the physical desk reference are often based on an over selected population and can be more severe in real-life conditions.

Aim and Objectives After two years of practice, what are the most common AEs in our hospital and what did we do to prevent them?

Material and Methods We did a retrospective study that included all our patients with TNBC from May 2021 to July 2023, and compared our results to the Ascent Trial (AT). We monitored their general state, the number of treatments and metastatic sites they had before the first cycle, the types and grades of AE and how we managed them.

Results Our 25 patients' medium age was 62 (AT = 54). In our study, the median number of lines before SG was four, just like in the AT. 56% of our patients had a performance status (ECOG) 0 (AT = 43%), 32% were ECOG 1 (AT = 57%) and 12% were ECOG 2.

Regarding AEs alone, 21 out of our 25 patients experienced them, mainly after 15,2 weeks of treatment (around the fifth cycle). The average dose-intensity at the time of AEs was 1120 ± 300 mg/21 days. 56% of our patients had neutropenia (AT = 63%) but we had less grade 3 or higher (G3+) neutropenia compared to the AT (24% versus 51%). 68% of our patients received growth factors (AT = 49%). 52% of our patients experienced asthenia (AT = 45%), 44% nausea (AT = 57%) and 52% diarrhoea (AT = 59%) among which 20% were a G3+ (AT = 10%).

Dose reductions were more frequent in our group compared to the AT (60% versus 22%). 28% had to skip at least one cycle and three patients had to change line because of AE.

Conclusion and Relevance Our study's AEs were similar to the ones described in the AT. However, we observed more G3+ diarrhoea and less G3+ neutropenia. Since June 2023, atropine has been used as systematic premedication to prevent severe diarrhoea. Our centre also resorts to growth factor injections more frequently.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-181 ELECTRONIC PRESCRIBING IN THE NEONATAL INTENSIVE CARE UNIT: ANALYSIS OF PRESCRIBING ERRORS AND RISK FACTORS

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Background and Importance Patients admitted to neonatal intensive care units (NICU) are up to eight times more at risk of medication errors than patients admitted to adult intensive care units. Prescribing errors account for up to 74% of medication errors. The implementation of electronic prescribing has been postulated as a useful tool to reduce prescription errors.

Aim and Objectives To analyse the most prevalent prescribing errors with the e-prescribing system and to analyse risk factors.

Material and Methods All patients born during the study period who were admitted to the NICU for at least 24 hours and with active pharmacological treatment were included in the study. The prescriptions were made in the IntelliSpace Critical Care and Anaesthesia (ICCA®) electronic assisted prescription software integrated in the medical record for the critically ill patient. Treatment review was performed by a pharmacist on a daily basis and errors were graded according to the taxonomic criteria of the National Coordinating Council for Medication Error Reporting and Prevention.

Results 240 patients participated (September 2021 to June/2022). A total of 13,876 prescriptions were reviewed in 158 patients; 455 errors were found in 119 patients.

Prescribing errors were concentrated in 40 drugs/nutritions of the total 139 that were prescribed. The most frequent error was the discrepancy between the prescription and the associated free text field (n=96) with more than half of these errors (n=106,54.1%) concentrated in enteral nutrition. The five drugs with the most errors were: lactobacillus acidofilus (n=45,9.89%), caffeine citrate (n=40,8.79%), paracetamol (n=35,7.69%), gentamicin (n=25,5.49%) and cholecalciferol (n=16,3.52%).

In terms of risk factors, patients with a birth weight between 1000–1500 grams were 82% more likely to have an error than those with extremely low birth weight (<1000g) (OR=1.81, CI 95% 1.42–2.89, p<0.05). Prematurity was also associated with an increased risk of prescription errors, the patients at highest risk were those with gestational age between 28–32 weeks, with 29.80% higher risk of prescription error compared to gestational age less than 28 weeks (OR=1.29,CI 95% 1.02–1.65, p<0.05).

Conclusion and Relevance Prescribing errors were more frequent in very low birth weight and very preterm patients. It is important to know which drugs are more susceptible to e-prescribing errors and in which type of patients in order to implement additional safety measures.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-182 DESCRIPTION OF A CLINICAL PHARMACIST INTERVENTION FOCUSED ON MANAGEMENT OF A CHRONIC DISEASE AT HOSPITAL: THE EXAMPLE OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

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Background and Importance COPD is currently the third leading cause of death worldwide with 3.23 million deaths in 2019. Despite recommendations, many care non-conformities are observed in COPD patients.

Aim and Objectives The aim of the study was to describe the intervention of a clinical pharmacist focused on the respect of COPD management recommendations emitted by the French Health Authority.

Material and Methods Our study is an observational study conducted between January and July 2022. Clinical pharmacist included COPD patients and performed a pharmaceutical interview focused on COPD management. This interview assessed medical follow-up by a pneumologist, smoking, vaccination against pneumococcus, COPD medication, medication adherence and proper use of inhalation devices. The number of non-conformities to recommendations and their distribution were collected at the end of the intervention. Propositions emitted by clinical pharmacist were collected and factors that may have an impact on the recommendations non-compliance were identified.

Results A total of 85 patients were included in the study. The mean age was 70.5 years. A total of 173 non-conformities were detected on 79 patients, i.e., two non-conformities per patient. At least one non-conformity was observed in 93% of patients. The most frequent non-conformities were the misuse of inhalation devices (77.2%) and the absence of vaccination against pneumococcus (67.1%). Follow up by a pneumologist concerned 64.7% of patients, 32.9% of patients were active smokers and 31.2% of the prescriptions were considered to be non-compliant. After interview, 89 propositions were emitted and clinical pharmacist intervention allowed to change COPD medication on 14.1% of patients. Follow-up by a pneumologist increases significantly pneumococcal vaccination coverage and proper use of inhaler devices.

Conclusion and Relevance Our study shows that clinical pharmacist can detect non-conformities and make recommendations to optimise COPD management during patient hospitalisation. This kind of intervention could also be used for patients suffering from other chronic disease as heart failure, asthma or diabetes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-183 PHARMACIST LED OPT-OUT CESSATION TREATMENT PROTOCOL FOR COMBUSTIBLE TOBACCO SMOKING

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Background and Importance In hospitals where pharmacists are accountable for obtaining medication histories and completing medication reconciliation and medication related education for all patients, the pharmacist offers a nearly universal access point to address tobacco use and deliver a cessation intervention.

Aim and Objectives This formative study describes the development and refinement of a pharmacist-led intervention through pilot testing to full implementation, with input from pharmacists and others.

Material and Methods A delegation protocol for hospital pharmacy inpatients who smoked cigarettes gave hospital pharmacists the authority to order nicotine replacement therapy (NRT) during hospitalisation and at discharge. The smoking cessation intervention protocol was approved by the hospital's Pharmacy and Therapeutics Committee and Medical Board.

Patients targeted for intervention were adults (age 18 years or older) admitted to a participating inpatient unit and service who were identified via an EHR entry on admission as currently smoking cigarettes (at any level of smoking), with or without other forms of tobacco use.

The programme was pilot tested in phases, with pharmacist feedback between phases, and then implemented hospital-wide. Interviews, surveys, and informal mechanisms identified ways to improve implementation and workflows.

Results Feedback from pharmacists led to changes that improved workflow, training and patient education materials, and enhanced adoption and reach. Refining implementation strategies across pilot phases increased prescribed NRT from 2% to 44%.

Conclusion and Relevance Results of this multi-phased, pharmacist led smoking cessation intervention roll-out suggest that improving implementation strategies can meaningfully increase the rates at which hospitalised patients who smoke receive evidence based smoking cessation treatment.

This programme, developed by a multidisciplinary team of stakeholders, capitalises on the unique role of pharmacists who interact with nearly every inpatient at admission. Iterative input from pharmacists was used to refine implementation strategies and better integrate smoking cessation intervention into existing workflows to enhance the reach of NRT and tobacco quit-line referral among inpatients.

Hospitalisations provide an ideal opportunity for patients to make a tobacco quit attempt, and pharmacists can capitalise on this opportunity by integrating smoking cessation treatment into existing inpatient medication reconciliation workflows. Pharmacist-led implementation strategies developed in this study may be applicable in other inpatient settings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-184 THERAPIES IN ENDOMETRIAL CANCER WITH DNA MISMATCH REPAIR DEFICIENT OR MICROSATELLITE INSTABILITY: A SYSTEMATIC REVIEW

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Background and Importance Standard therapy for advanced endometrial cancer (EC) pre-treated with platinum-based chemotherapy (PCT) showed limited efficacy. DNA mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) neoplasms are associated with increased PD-1 and PD-L1 expression. Thus, immunotherapy could play an important role in EC with dMMR/MSI-H.
Aim and Objectives To conduct a systematic review of scientific evidence on treatments for EC with dMMR/MSI-H in patients who previously received PCT.
Material and Methods A literature search in PubMed® database was performed to August 2023. Filter 'clinical trials' was applied with the following search strategy: [microsatellites instability OR Mismatch Repair Deficient] AND endometrial cancer. Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) methodology was used in bibliographic review. Inclusion criteria: clinical trials (CTs) involving patients with dMMR, or MSI-H diagnosed with advanced and/or metastatic EC who had previously received PCT. Efficacy endpoints assessed were overall survival (OS), progression-free survival (PFS) and objective response rate (ORR). Data collected: publication date, study design, stage, median patient follow-up, sample size, therapies, comparator arm and efficacy data.
Results A total of 30 search results were identified. Thirteen CTs met the inclusion criteria. These studies were published between May 2019 and February 2023. Study design: nine non-randomised phase II, two non-randomised phase I, one randomised phase III and one randomised phase Ib/II. Patients with advanced EC were included in 23.1% of CTs, with metastatic disease in 23.1% and both in 53.8%. Median follow-up ranged from six to 42.6 months. Sample size comprised 11 to 130 patients. Therapies analysed were: pembrolizumab, pembrolizumab plus lenvatinib, durvalumab, durvalumab plus tremelimumab, dostarlimab, nivolumab and avelumab. A total of 11 studies had no comparator arm. Pembrolizumab achieved the highest numerical efficacy [OS= 40.0 months (95% CI 25.3-Not Reached); PFS= 23.5 months (95% CI 10.7-NR); ORR= 58% (95% CI 37–78)]. Dostarlimab [OS= NR; PFS= 12.2 months (95% CI not available); ORR= 43.5% (95% CI 34.5–53.4)] and durvalumab [OS= NR; PFS= 8.3 months (95% CI 2.4-NR); ORR= 47% (95% CI 32–63)] presented the next best numerical efficacy. No CTs compared pembrolizumab with dostarlimab or durvalumab.
Conclusion and Relevance The greatest numerical efficacy data were achieved by pembrolizumab, followed by dostarlimab and durvalumab. Nevertheless, CTs with adequate comparisons are needed for reliable data interpretation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-185 ANALYSIS OF THE USE OF MEDICATION NOT INCLUDED IN THE PHARMACOTHERAPEUTIC GUIDE OF A TERTIARY HOSPITAL

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Background and Importance Interdisciplinary collaboration, particularly involving pharmacists in medication reconciliation, can prevent errors. Medication discrepancies at care transitions are common and linked to adverse events that's why addressing communication barriers before errors happen is crucial.
Aim and Objectives This study aims to analyse the prescription of medication not included in the hospital's pharmacotherapeutic guide (MNIG) and the pharmaceutical interventions (PI) performed.

Additionally, this research evaluates the effectiveness of a quality indicator aimed at reducing MNIG prescriptions in the cardiology service through PI.
Material and Methods A prospective study was conducted from 20 April to 31 August 2023, utilising the Farmatools® program to assess the following variables:

- The percentage of MNIG prescriptions, categorised by therapeutic group (TG) based on ATC codes.
- The cause of MNIG prescriptions, including reconciliation and new treatment.

-Number of substitutions in the therapeutic exchange program (TEP) resulting from PI, including the percentage of MNIG replaced by therapeutic equivalents (TE), discontinued, not substitutable, and included in the hospital guideline.
Results 322 MNIG were prescribed: 13% G04C, 12% B01A, 11% A10BD, 10% C10B, and the remaining 54%, miscellaneous drugs.

As for the cause of prescription: 95% is conciliation and 5% is prescription of a new treatment.

Of the MNIG prescribed, 53.4% had TE in the TEP, 18% were substituted, and the rest were provided by the patient. A total of 26.4% were not substitutable, and 11.18% were included in the hospital pharmacotherapeutic guide (HPG) and 9% were recommended to be suspended on admission, as indicated by the TEP.

The prescription of MNIG is variable during the months studied, with a median of 4%, maximum of 7.5% and minimum of 2%, with concerning the total number of prescriptions, without a linear trend.
Conclusion and Relevance The multidisciplinary team responsible for the patient should be involved in the reduction of MNIG to avoid medication errors, through the use of HPG and TEP.

Regarding the analysis of the indicator, we consider it important to perform PI to raise awareness among physicians of the correct use of NID, although we cannot confirm that the punctual decreases in prescriptions are due to the PI performed. In addition, the pharmacy service should review the HPG and TEP to include the necessary drugs and to disseminate the PET among health professionals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-186 IMPLEMENTATION OF A PATIENT STRATIFICATION MODEL IN OUTPATIENT PHARMACY FOR IMMUNE-MEDIATED DERMATOLOGICAL DISEASES

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Background and Importance Pharmaceutical care (PC) involves pharmacists engaging with patients to achieve safe pharmacotherapeutic goals, improving health outcomes. The Spanish Society of Hospital Pharmacy devised the CMO stratification model (Capacity, Motivation, Opportunity) to determine patient follow-up frequency and target those who benefit most from PC. It assigns patients to priority levels 1, 2, or 3 (normally 10%, 30% and 60% of stratified patients respectively) aiding pharmacists in optimising resources and tailored interventions.

Aim and Objectives To determine the complexity of patients with immunomediated dermatological diseases initiating biological therapy in our hospital, using the CMO model, and compare the results with the expected model outcomes.

Material and Methods A cross-sectional study completed between May and September 2023 at a Spanish Tertiary hospital. Patients diagnosed with immunomediated dermatological diseases, initiating biological therapy were included. To determine the complexity level, the CMO model was applied, encompassing 23 variables in demographic, sociosanitary and cognitive, healthcare service utilisation, and treatment-related categories. The patient's total score was calculated by combining the points assigned to each variable. Data were collected from patient medical records, electronic prescription dispensing records, and clinical interviews in pharmaceutical care consultations. Results were compared with the percentage distribution proposed for each complexity level by the model.

Results A total of 52 patients were stratified, 94% adults and 56% males. Among them, 88% had psoriasis, 8% atopic dermatitis, and 4% hidradenitis. Variables such as active smokers (23%), language barrier (4%), psychiatric history (31%), and reduced quality of life (83%) were identified. Additionally, 29% had $\geq$2 chronic diseases, and 73% exhibited moderate/high disease activity. Regarding treatment, 27% were on polypharmacy, 42% were treatment-naive, 8% had a risk of significant interactions with their existing medication, and 10% of non-adherence.

Upon applying the CMO model, 8% (4) fell into priority 1, 48% (25) priority 2, and 44% (23) priority 3.

Conclusion and Relevance Against expectations from the CMO, most patients were in level 2 instead of level 3, possibly due to stratification timing, occurring during treatment initiation or changes when patients' diseases were most exacerbated.

Through the CMO application, we identified patients most likely to benefit from PC, enabling us to reallocate resources for more regular follow-up, ensuring comprehensive patient support.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-187 DEVELOPMENT OF A POPULATION PHARMACOKINETIC MODEL OF CYCLOSPORINE

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Background and Importance Cyclosporine is an immunosuppressive drug with complex pharmacokinetics, a narrow therapeutic interval and dose-related adverse effects (nephrotoxicity, hepatotoxicity, and neurotoxicity).

Amiodarone, verapamil and macrolides increase cyclosporine serum concentrations (CSC), whereas other drugs such as phenytoin, carbamazepine and rifampin decrease CSC.

Therefore, therapeutic drug monitoring of cyclosporine is of great importance in routine clinical practice.

Aim and Objectives

- Design a population pharmacokinetic model of cyclosporine.
- Analyse the influence of the recorded covariates.

Material and Methods Retrospective observational study that included patients hospitalised at Severo Ochoa University Hospital and treated with cyclosporine between January 2016 and April 2022. Patients hospitalised in the ICU and outpatients were excluded.

Data recorded date, time and value of the CSC, route of administration, doses administered, sex, age, weight, haematocrit, albumin, serum creatinine and concomitant treatment.

We tested the one- and two-compartmental models with four estimations: first order, first order with interaction, first order conditional and first order conditional with interaction. The influence of the recorded covariates was evaluated, selecting those that showed a statistically significant reduction in the objective function (OFV).

Results

Patients included 29 patients, aged 65 years-old (28–92), 66,7% female. Mean weight was 75.1 kg (42.5–125), serum creatinine 1.12 mg/dL (0.33–4.41), serum albumin 3.5 g/dL (2.3–4.6) and haematocrit 32.6% (13.4–48.5). None of the patients received the registered drugs.

The one-compartment model showed a better OFV than the two-compartment model (-663,636 vs -654,430). However, the graphical analysis showed a better correlation between the CSC and those predicted, therefore the analysis of the covariates was continued with the two-compartment model.

The variables were evaluated in the two-compartment model and an influence of age and weight on clearance was observed, with statistically insignificant differences. No covariate showed an effect on the volume of distribution.

Conclusion and Relevance

- The two-compartment model with first order conditional estimation with interactions showed a better goodness of fit.
- The development of a pharmacokinetic model of cyclosporine assists clinicians to establish an effective and safe dosing regimen.
- Further studies are needed to better analyse the population pharmacokinetics of cyclosporine.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-188 IMPLEMENTATION OF THIOPURINE PHARMACOGENETICS TO IMPROVE PAEDIATRIC SAFETY AT A TERTIARY HOSPITAL

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Background and Importance Thiopurines play a crucial role in the treatment of paediatric patients with acute lymphoid leukaemia (ALL). Although these drugs are administered almost continuously for over two years, their main drawback lies in the occurrence of adverse events (AEs), particularly hepatotoxicity and myelotoxicity, which can lead to treatment delays.

Research has established a link between these AEs and the genotypes of two enzymes involved in thiopurine metabolism: thiopurine methyltransferase (TPMT) and nudix 15 hydrolase (NUDT15). Currently, recommendations exist for adjusting the initial dosages based on genotype.

Aim and Objectives

- Determine the prevalence of alleles associated with the most common enzyme activity deficiencies for TPMT and NUDT15 in our region, comparing them with literature data.
- Implement an analysis and information circuit enabling individualised thiopurine dosing based on pharmacogenetics for paediatric ALL patients.

Material and Methods We conducted a literature review to identify alleles linked to intolerance to standard thiopurine doses. Considering the allelic prevalence in different populations, we selected three TPMT alleles and one NUDT15 allele according to ours. These alleles were classified as first-level by various agencies and consortiums. We designed primers for allele screening with Sanger sequencing technique.

Our centre's database contained 2,194 exomes with informed consent, which we analysed to estimate allele prevalence in our population. Techniques, test request procedures, and decision algorithms for initial dosages were protocolised based on current recommendations.

Results In a total of 2,194 exomes, we studied mutations rs1800462, rs1800460, and rs1142345 for TPMT, and rs116855232 for NUDT15. We identified 36, 113, 147, and 48 cases, respectively. Our population exhibited higher frequencies compared to non-Finnish Europeans (NFE) in the Genome Aggregation Database, with rates of 1.64% vs. 0.24%, 5.15% vs. 3.82%, 6.7% vs. 4.23%, and 2.18% vs. 0.29%, respectively.

Conclusion and Relevance Our results support the benefit of genetic testing in our population due to the prevalence of low-activity alleles.

We anticipate performing 10 to 15 genetic studies annually, aligning with the ALL cases we treat each year.

The implementation of an individualised dosing circuit based on pharmacogenetics represents a substantial advancement. This approach will enhance the safety and efficacy of thiopurine treatment.

This model can be replicated in hospitals with genetic determination capabilities through Sanger sequencing.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-189 LOCAL EXPERIENCE ON THE USE OF CANNABIDIOL FOR THE TREATMENT OF REFRACTORY EPILEPSY: SAFETY AND EFFICACY ON A 10 PATIENT COHORT

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Background and Importance Cannabidiol is approved in Europe as adjunctive therapy for preventing seizures associated with Lennox-Gastaut Syndrome (LGS), Dravet Syndrome (DS), and Tuberous Sclerosis Complex (TSC) in patients with previous treatment refractory epilepsy.

Aim and Objectives This study aims to evaluate the efficacy and safety of cannabidiol in a cohort of patients from a medium-sized hospital.

Material and Methods An observational retrospective study was conducted. Patients diagnosed with LGS and DS who began treatment with cannabidiol from October 2019 to September 2023 were included. Data collected were demographics (gender, age), drug therapy (number of concomitant drugs) and clinical outcomes (Reduction > 50% on seizure rate and cannabidiol side effects).

Abstract 4CPS-189 Table 1

Pat	Age (years)	Sex	Indication	Treatment Duration (days)	Epidyolex dose (mg/Kg/day)	Drug AR	Concomitant ASD's	> 50% seizure rate reduction
1	48	M	DS	210	7,24	None	5	Yes
2	23	F	LGS	1432	22,85	None	3	Yes
3	21	M	LGS	1434	17,27	None	7	Yes
4	42	M	LGS	413	5,08	Digestive	7	Yes
5	21	F	LGS	668	13,33	Digestive	5	Yes
6	35	M	LGS	598	5,2	Digestive	4	Yes
7	53	M	LGS	852	16	None	5	Yes
8	23	M	LGS	1049	11,9	None	6	Not
9	38	M	LGS	1158	9,09	Digestive	5	Not
10	24	M	LGS	212	4,33	None	4	Not
	mean= 32,8	8 Male 2 Female	90% SLG 10% TSC	mean= 737,3 median= 633	mean= 11,23 median = 10,49	70% No AR 30% AR (digestive)	mean = 5,1 median = 5	70% responders rate

Results Ten patients were included on the analysed data set, with a mean age of 32.8 years, nine of them had LGS associated epilepsy, and one to DS. With a median treatment duration of 633 days and a cannabidiol median dose of 10,49 mg/Kg/day, 70% of patients reached a seizure reduction > 50%, being the majority of them out of drug related side effects.
Conclusion and Relevance As a real-life experience, our findings confirm that the safety and efficacy profiles of cannabidiol showed by the trials GWPCARE3 and GWPCARE4 (mean age=15 years)[1]are extended to our local adult population with a higher average age of 32.8 years.

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Conflict of Interest No conflict of interest.

4CPS-190 DEVELOPMENT OF TRANSMURAL PHARMACEUTICAL CARE IN A GENERAL HOSPITAL

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Background and Importance The transition between different care settings is vulnerable to medication errors. To avoid these errors, information about new medications must be shared between different care providers.

The PACT project, an integrated care project, proposes to carry out medication reconciliation according to a structured methodology using envelopes. At hospital admission, blue envelopes are used. They contain the patient's medication scheme previously produced by the reference pharmacist in a community pharmacy. At hospital discharge, the new medication scheme and the new prescriptions are placed in a green envelope. This envelope must be given to the reference pharmacist who must explain any changes to the patient.
Aim and objectives • To set up and evaluate the impact of pharmaceutical interventions aiming to implement the PACT medication reconciliation system at hospital discharge.
Material and Methods Two audits, each carried out over a period of 10 days in December 2022, were conducted in three care units on a pre-test group and a test group. The test group was constituted during the period of test which included pharmaceutical interventions (real-time interventions and outreach visits to practitioners).

- We evaluated the similarity between the two groups in terms of demographic and clinical characteristics and in terms of medication characteristics using Student's test and the Chi-Squared test ($\chi 2$ test).
- The impact of the pharmaceutical interventions was then evaluated by comparing between the two groups the rate of green envelopes delivered to the patient. Data were analysed using $\chi 2$ test.

Results

- The two groups were similar in terms of demographic and clinical characteristics. Regarding medication characteristics, the analysis confirmed the similarity between groups, except for the number of newly prescribed medicines ($p = 0.04$) and the number of medicines to be stopped after hospitalisation ($p = 0.03$).
- The rate of green envelopes delivered to the patient at the end of hospitalisation was higher in the test group (78%) compared to the pre-test group (33%) ($p < 0.001$).

Conclusion and Relevance This work highlights the importance of developing the role of integrated care pharmacist coordinator to strengthen the communication on patient medications.

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Conflict of Interest No conflict of interest

4CPS-191 PRE-RADIOIODINE THERAPY SURGICAL MODALITIES: COMPARISON OF POST-OPERATIVE THYROGLOBULIN LEVELS IN PATIENTS UNDERGOING 1- OR 2-STEP THYROIDECTOMY FOR DIFFERENTIATED THYROID CANCER

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Background and Importance Surgical practices in thyroid oncology recently evolved towards de-escalation, with more frequent 2-step surgery (lobectomy then totalisation). Moreover, in non-metastatic thyroid cancers with low risks of recurrence, radioiodine therapy (RIT) to eliminate potential residual cancer cells has become optional, particularly in cases displaying low postoperative thyroglobulin (POTg) values. It is known that plasma thyroglobulin is correlated with the size of the post-thyroidectomy residue, excluding distant metastases. However, it is not known whether this residue is greater in the case of 1- or 2-step surgery. Indeed, the 2-stage approach may provide a more substantial residue, measurable by the POTg value. Clinicians should therefore take this notion into consideration when deciding on adjuvant RIT.
Aim and Objectives To compare POTg values in patients undergoing 1- or 2-step thyroidectomy for low-risk thyroid cancer, based on retrospective collection of biological data from operative and pathological reports in a cohort of RIT patients at our centre.
Material and Methods Inclusion criteria for this study were: non-metastatic patients with a low-risk pathology who had biological tests performed between surgery and RIT consultation, a non-detectable anti-thyroglobulin antibody assay, a period >28 days between surgery and biological tests, and TSH levels <5 µIU/mL. Parameters useful for describing the patient population and comparing POTg values were compiled in a computerised spreadsheet and analysed.
Results Between 15 July 2016 and 24 February 2023, 70 patients from our centre met the inclusion criteria. Mean TSH value was 1.377 ± 1.336 µIU/mL and mean POTg was 0.543 ± 1.067 ng/mL. Mean time between operations for patients treated in 2-steps was 82 ± 55 days and mean time between operation and biological test was 68 ± 54 days. Two groups

were defined, including 49 patients who underwent 1-step surgery and 21 patients who underwent 2-step surgery. Difference between the two groups in mean TSH values and average time between operation and biological test were not statistically significant (p = 0.204 and 0.97, respectively). No statistically significant difference could be demonstrated between the mean POTg in the two groups (p = 0.622).
Conclusion and Relevance Mean POTg appears to be independent of the surgical procedure, which is an important consideration when deciding on postoperative treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-192 ASTHMA AND RISK OF CARDIOVASCULAR EVENTS: A RETROSPECTIVE STUDY

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Background and Importance Asthma is frequently associated with respiratory and non-respiratory comorbidities. Non-respiratory comorbid conditions include cardiovascular disease; indeed, asthma has been linked with increased risk of cardiovascular events, although its prevalence varies between studies and robust evidence of this relationship is limited.
Aim and Objectives The aim of this study was to identify and assess cardiovascular disease risk for asthma patients.
Material and Methods Retrospective cohort study involving patients followed-up by the severe asthma unit of a tertiary care hospital in Spain. Sociodemographic variables included sex and age. The clinical variables were comorbidities (obesity, BMI>30; type 2 diabetes; arterial hypertension; dyslipidaemia and other respiratory conditions), smoking status, asthma phenotype, biomarker concentrations (fractional exhaled nitric oxide [FeNO], total and specific serum IgE and blood eosinophil count [BEC]) and lung function. Treatment with biologics for asthma, systemic and inhaled corticosteroids, inhaled short-acting beta-agonists and antihypertensive medication were also recorded. Patients with a cardiovascular event prior diagnosis of asthma were excluded. History of cardiovascular events was obtained and odds ratios (ORs) for cardiovascular events in asthmatic patients were analysed using a multiple logistic regression model.
Results A total of 206 patients with asthma were included (65.6% female; mean ± SD age 57 ± 18 years). 121 patients had allergic asthma, 98 were obese, 24 had diabetes, 65 had hypertension, 52 had dyslipidaemia and 21 had obstructive sleep apnoea. 23 patients (11%) suffered a cardiovascular event. A higher risk of cardiovascular event was observed in those patients with hypertension (OR=2.717, p=0.026), dyslipidaemia (OR=2.717, p=0.026), and chronic obstructive pulmonary disease (COPD) (OR=5.358, p=0.003). A higher risk was also observed in patients with FEV1>80% prior biologic therapy (OR=3.316, p=0.013).

In contrast, a reduced risk of a cardiovascular event was observed in those patients who had inhaled corticosteroids (OR=0.187, p=0.007) or had a BEC>150 cells/μL (OR=0.225, p=0.025).
Conclusion and Relevance Risks of cardiovascular events were increased in asthma patients with hypertension, dyslipidaemia or COPD. A lower risk of cardiovascular events was observed in patients on inhaled corticosteroids and, unexpectedly, in those with FEV1<80% and BEC>150 cells/μL. Nonetheless, these results must be interpreted with caution as the design of the current study is subject to limitations.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-193 EFFECTIVENESS AND SAFETY OF INTRAVENOUS USTEKINUMAB INTENSIFICATION IN CROHN'S DISEASE WITH LOSS OF RESPONSE OR PARTIAL RESPONSE TO SUBCUTANEOUS THERAPY

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Background and Importance Ustekinumab is approved for adult patients with moderately-severe active Crohn's disease (CD) at a usual dosing schedule of 90 mg every 8 to 12 weeks subcutaneously. Some patients may experience a partial response or secondary loss of response. There is increasing evidence for patient rescue by shortening the subcutaneous administration interval, but very little evidence for intravenous intensification.
Aim and Objectives To evaluate the effectiveness and safety of treatment intensification with intravenous ustekinumab in adults with CD and loss of response to the standard subcutaneous regimen.
Material and Methods Single-centre, descriptive, retrospective study including CD patients who intensified ustekinumab treatment to receive 130 mg intravenously every 4–6 weeks from January 2020 to August 2022.

The clinical remission rate (defined as a Harvey-Bradshaw index (HBI) <5) at 12, 24 and 52 weeks and the early clinical response rate (defined as a reduction in HBI by ≥3 points or by a 30% from baseline) at 12 weeks were analysed. The evolution of inflammatory laboratory parameters such as C-reactive protein (CRP) and faecal calprotectin (FC) was assessed. Adverse effects developed during the follow-up period were collected.
Results Forty-one patients were included; 61.0% were male, with a median age at intensification of 44.9 years (interquartile range (IQR): 37.8–59.6), a median disease progression of 16.6 years (IQR: 8.1–22.3) and a median time to intensification from ustekinumab initiation of 19.6 months (IQR: 10.8–31.3). The most frequent phenotypes were L3 (53.7%) and B2 (43.9%). Perianal involvement was present in 46.3% of patients.

Of the total, 31 (75.6%) patients had a baseline HBI ≥5, of whom 18 (58.1%) achieved early clinical response. Clinical remission was achieved by 39.0% of patients at 12 weeks and by 58.5% at 52 weeks. The persistence rate at 52 weeks was 90.2%. Median laboratory parameter values improved at each time cut-off from baseline.

No serious adverse effects were reported and no patient discontinued treatment due to adverse effects. One episode of urinary tract infection and one episode of nasopharyngitis were documented.

Conclusion and Relevance Intravenous ustekinumab at 130 mg every 4–6 weeks improves CD inflammatory activity in patients with loss of response or partial response to the standard subcutaneous regimen.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-194 EVOLUTION OF HOSPITAL CLINICAL PHARMACY SERVICES IN FINLAND DURING YEARS 2017–2022: A FOLLOW-UP SURVEY

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Background and Importance Pharmacists' involvement in patient care became more common along with system-based medication safety work in Finnish hospitals during 2011–2016. The first national survey was conducted in 2011 and repeated using the same method in 2016. This development is in line with national and international patient safety policy initiatives and European hospital pharmacy statements.

Aim and Objectives The aim of this study was to conduct the third national follow-up survey on hospital clinical pharmacy services in Finland in 2022 and compare the results to the year 2016.

Material and Methods The study was conducted in 2022 as a national online survey targeted to hospital pharmacies (n=22) and medical dispensaries (n=23). The questions were analysed using descriptive statistics and qualitative content analysis.

Results The response rate of the survey was 62% (n=29/45). Clinical pharmacy services were provided in 83% (n=24/29) of the responding units. The number of clinical pharmacy staff increased between 2017 and 2022, and services were provided in more versatile environments. In particular, the services had become more common at admission and in outpatient units, such as first aid, emergency rooms, and outpatient clinics where medication reconciliation is essential. Furthermore, in some units (25%, n=6/24), services were also available in the evenings and during weekends in one responding unit. As in 2016, the system-based medication safety work and the comprehensive development of the medication management system were highlighted also in this survey. The most increased tasks were medication reviews and medication safety audits, whereas in 2016 the most increased task was medication reconciliation. Surprisingly, pharmacists' participation in the patient's discharge had decreased. Despite the increasing prevalence of automation technology and pharmacy assistants, logistic tasks had remained on the same level as in 2016.

Conclusion and Relevance Finnish hospital clinical pharmacy services have expanded in line with national and international guidelines and increasingly concentrate on promoting medication safety. The focus is currently on admission and outpatient units. In the future, more effort should be put into discharge, because it would be particularly cost-effective by decreasing drug-related readmissions.

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Conflict of Interest No conflict of interest.

4CPS-195 CHARACTERISATION OF INJECTABLE FORMULATIONS AND OPTIMISATION OF THEIR DELIVERY BY ENTERAL TUBE: A PHYSICOCHEMICAL AND PHYSIOLOGICAL APPROACH

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Background and Importance Oral administration of injectables is an alternative for patients with difficulties tolerating solid pharmaceutical forms.

Due to their physicochemical characteristics not adapted to oral administration, gastrointestinal adverse effects can occur, especially in patients with transpyloric feeding tube, especially when they have an osmolarity >500 mOsm/L or pH <3.5.

Aim and Objectives The aim of the present work is to characterise the physicochemical properties of injectable formulations commonly used orally and their gastrointestinal absorption site in order to increase safety in their administration by transpyloric feeding tube.

Material and Methods A literature search was conducted to establish the gastrointestinal absorption site of the active principles (AP) analysed.

For each preparation, pH and osmolality were experimentally determined. The pH was measured with a pH meter (Crison 2006, Hach Lange España, S.L.U., Spain). Osmolarity was determined using the Fiske Model 210 Micro Osmometer (John Morris Scientific Pty Ltd., Australia), considering the density of the active principles studied to be equal to 1 mg/ml. All measurements were performed in triplicate.

Results Of the 24 APs analysed, pH values<3.5 were found in 21% of preparations, which discourages transyejunal administration. In addition, 25% of the formulas administered had osmolarity >500 mOsm/L.

- Of the 13 APs that have bioavailability by transpyloric route, only eight are adequately formulated for this, and another three could be diluted prior to administration to avoid high osmolarities.
- Of the five APs that cannot be administered via the transpyloric route, three of them are also not adequately formulated.
- Of the remaining six APs, whose absorption site cannot be objectified, three have good physicochemical characteristics and with another two this could be achieved by diluting with water.

Conclusion and Relevance Most of APs studied, the gastrointestinal absorption of the drug is not sufficiently characterised,

leading to uncertainty when administered by transpyloric feeding tube.

Many of the injectables have a high osmolarity and therefore require prior dilution, while the pH values of some of them can be an added factor for the development of digestive intolerances.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-196 ASSESSMENT OF ORAL DRUG THERAPY REGARDING ABSORPTION DISORDERS IN PATIENTS WITH INTESTINAL OSTOMIES – AN OBSERVATIONAL STUDY

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Background and Importance An insufficient absorption of orally administered drugs may threaten therapy goals. Thus, gastrointestinal alterations associated with ostomy formations may pave the way towards absorption disorders. Although there had been reports, this topic remains not sufficiently studied.[1]

Aim and Objectives The main purpose of this study was to assess oral medication in patients who had newly undergone ileostomy or colostomy formation in order to observe whether surgery led to presence of any drug residuals in the pouches, ineffectiveness of therapy or any other indications of absorption disturbances.

Material and Methods An observational study was conducted between March 2022 and September 2023 at the Division of Visceral Surgery at the hospital. Fifty patients aged 18–80 years, were enrolled. Oral drug therapy of every patient was assessed following ostomy surgery. Prior hospital discharge, an interview was led with the patients to collect additional data regarding clinical status. At earliest, 2–8 weeks after discharge, the patients were interviewed a second time at the ostomy outpatient clinic or by telephone call. Both interviews were led by two pharmacists based on standardised questionnaires.

Results

Sixty-three different agents were administered In the following (table 1), findings regarding drug category are shown. Table 2 presents a drug monitoring carried out to proof impaired absorption of bupropion.

Abstract 4CPS-196 Table 1

Findings	tmax[h] (total number of applied drugs)		
	0,5- 3 (36)	3- 5 (16)	>5 (10)
Impaired disintegration/dissolution	Capecitabine Carvedilol Esomeprazole	Acetylsalicylic acid Aprepitant Bupropion	Pramipexole
Ineffectiveness (based on clinical symptoms and/or laboratory parameters)	Trimethoprim Loperamide	Amlodipine Levothyroxine Tamsulosin	

Abstract 4CPS-196 Table 2

	Value [ng/ml]	Therapeutic range of plasma levels [ng/ml]
Bupropion + Hydroxybupropion	353.0	850–1500
Bupropion	16.0	
Hydroxybupropion	337.0	

Conclusion and Relevance The results of this study confirm that, contrary to assumptions, absorption disorders may also occur in drug therapy which seems to be absorbed rapidly. Therefore, no absolute statements regarding intestinal absorptive capacity can be done. Oral drug therapy of every patient has to be assessed individually based on intestinal condition and applied drug properties.

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Conflict of Interest No conflict of interest.

4CPS-197 THE KTIA-SCORAC STUDY: SECURING THE MEDICATION MANAGEMENT OF ELDERLY PATIENTS BY THE SYSTEMATIC EVALUATION OF ANTICHOLINERGIC LOAD SCORES VIA A CLINICAL DECISION SUPPORT SYSTEM

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Background and Importance The use of anticholinergic drugs and their cumulative effects are highly prevalent in older people and are associated with adverse effects and outcomes. However, pharmaceutical analysis to assess anticholinergic risk, remains a challenge due to constrained human resources, insufficient functionalities of prescription assistance software, non-interoperability of hospital information systems and the lack of awareness on the anticholinergic burden among elderly patients.

Aim and Objectives This study aimed to 1/evaluate and stratify anticholinergic scores based on patient profile, admission unit, and class of drugs, 2/propose guidelines for medication management and 3/secure drug related management by reducing anticholinergic patient's exposure.

Material and Methods We conducted a retrospective study including all patients > 65 years admitted in our hospital from 1 April 2023 to 31 May 2023 using the CRIDECO Anticholinergic Load Scales (CALS) integrated in the Clinical Decision Support (CDSS) PharmaClass software 3.0 ®.[1]

Results 1186 patients (n=1316 admissions) were enrolled with 130 patients re-hospitalised. Around 32% of patients with CALS $\geq$ 0 were admitted to the surgical department, 13% to a geriatric department and cardiology-pneumology each. In

total, throughout their hospital stay, 64% (n=837) of admissions had no change in their CALS (largest group), 36% (n=469) of admissions had an increase and a minority had a decrease in score. For score ≥ 3, ≥ 4 and ≥ 5, increase was observed from admission to discharge of 26%, 16% and 12% respectively. Patients with increase of at least of 1 point of CALS were significantly older ($pval<10^{-4}$) and had increase length of hospital stay ($pval<10^{-15}$). The most common prescribed drugs were analgesics, anti-epileptic and diuretics.

Conclusion and Relevance Following the CRIDECO rule, 30% of patients > 65 years had a risk of anticholinergic burden at admission, and this risk does not decrease during hospitalisations. A threshold of five might be a potential cut-off choice for pharmaceutical interventions in future studies due to its significant increase for a small sample size. This further supports the feasibility and promising benefits of implementing new strategies for physicians with CDSS to improve medication management and to reduce the anticholinergic burden.

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Conflict of Interest No conflict of interest.

4CPS-198 EVALUATION OF PROA TEAM INTERVENTION ACCEPTANCE RATES THROUGH AN AUTOMATED MEASUREMENT SYSTEM

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Background and Importance Programmes to optimise antibiotics use (PROA) are constituted by multidisciplinary teams involving at least one physician, one pharmacist and one microbiologist. Their purpose is to improve clinical outcomes related to antibiotic use, reduce adverse effects and ensure cost-effectiveness treatment through educational clinical interventions.

Aim and Objectives The aim of this study is to evaluate the acceptance of these interventions through an automated system and compare the results with those obtained manually in the previous year.

Material and Methods Descriptive, retrospective and cross-sectional study, conducted between January-September 2023. A software tool was developed to analyse whether PROA interventions were accepted within the following 48 hours.

The system, by means of computer programming, analyses the recorded interventions and assesses whether the prescriptions have been modified. It only focuses on recommendations related to treatment suspension, sequential therapy or antibiotic de-escalation and classifies them as rejected, if prescription continued unaltered, or accepted if changes occurred according with the recommendation. Subsequently, a comparative analysis was conducted between data obtained using this tool and data manually obtained previously from a cross-section study carried out in February 2022. All information was collected from electronic medical records and analysed using the R statistical programme (v.4.2.2). Categorical variables are expressed as frequency and percentage.

Results A total of 859 interventions were analysed with an acceptance rate of 83.5%; 556 involved treatment suspension, 245 antibiotic de-escalation and 58 sequential therapy. Acceptance rates for each were 86%, 80% and 74%, respectively.

Abstract 4CPS-198 Table 1 Acceptance rate of PROA interventions: comparative analysis

Type of intervention	February 2022 N=(154/192)	January-September 2023 N=(717/859)
Treatment suspension%(N)	76% (73/96)	86% (478/556)
Antibiotic de-escalation%(N)	87,2% (68/78)	80% (196/245)
Sequential therapy%(N)	72% (13/18)	74% (43/58)

Conclusion and Relevance The automated system offers a comprehensive view of the acceptance rates of PROA interventions over time, contrasting with the manual approach that only can be afforded for a short period of time. Although it has some limitations because it does not include all intervention types, it allows a quick analysis of the impact of these interventions in clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-199 COMPARATIVE EVALUATION OF ENZYME-LINKED IMMUNOSORBENT ASSAY VERSUS A POINT-OF-CARE TECHNIQUE IN THE DETERMINATION OF ADALIMUMAB LEVELS

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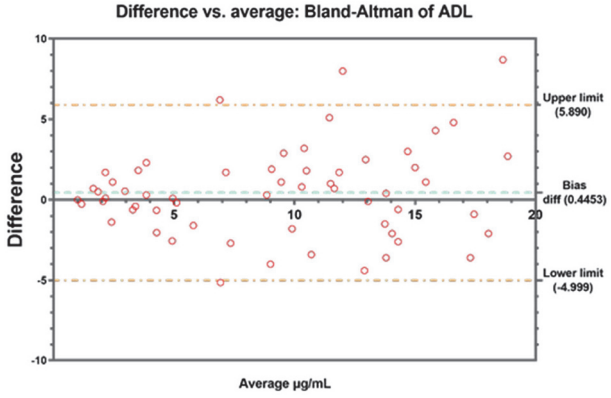
Background and Importance Therapeutic drug monitoring in inflammatory bowel disease (IBD) is a useful tool for optimising biologic therapy. The analysis of adalimumab (ADL) concentrations in blood through enzyme-linked immunosorbent assay (ELISA) requires accumulation of samples to make it a cost-efficient technique, delaying the results for several days. On the other hand, point-of-care (POC) tests facilitate immediate decision making by providing ADL concentration results in less than half an hour. However, it is necessary to demonstrate the equivalence of both methods and their interchangeability.

Aim and Objectives The aim of this study is to compare the reference technique for quantifying ADL levels using ELISA with quantification using POC test.

Material and Methods From our own biobank with serum samples of 200 IBD patients treated with biologics, those with adalimumab levels were selected. Later, a total of 60 patients were randomly selected: 19 for ADL sub-therapeutic range (<5 µg/ml), 21 for ADL therapeutic range (5–12 µg/ml) and 20 for ADL supra-therapeutic range (>12 µg/ml). Quantitative sandwich ELISA assay was performed with Promonitor ADL kit and POC test was performed with Quantum Blue assay. Correlation was evaluated with Spearman's correlation

coefficient (rs). Concordance between the three different therapeutic groups was assessed through weighted Cohen's kappa (κ) and differences in classification for each group was determined using McNemar test.

Results No statistically significant differences in ADL trough levels were observed between ELISA and POC (p= 0.3101). Median values were 10 µg/mL (IQR: 3.87–13.25) for the Promonitor assay and 8.85 µg/ml (IQR: 3.67–13.62) for Quantum Blue assay. A good correlation of ADL trough levels between the two assays (rs = 0.88) and a substantial agreement in stratifying in the different groups of therapeutic ranges (K= 0.751 ± 0.063) were observed. McNemar's test revealed no significant differences among different ranges classification (p-value=1). Bland-Altman's analysis (figure 1) was done to complete the comparison between the methods, revealing a bias difference of 0.4453.



Abstract 4CPS-199 Figure 1

Conclusion and Relevance The Quantum Blue POC test represents an alternative to ELISA in determining ADL concentrations, allowing results to be obtained in less time, which facilitates therapeutic decision-making in patients with IBD.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-200 TRIPLE THERAPY FOR METASTATIC HORMONE-SENSITIVE PROSTATE CANCER PATIENTS BASED ON A PHARMACOLOGICAL TREATMENT ALGORITHM

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Background and Importance Standard treatment for metastatic hormone-sensitive prostate cancer (mHSPC) supplements androgen deprivation therapy (ADT) with docetaxel, second-generation hormonal therapy, or radiotherapy. However, the PEACE-1 study demonstrates that adding abiraterone plus prednisone to ADT and docetaxel improves survival with a moderate increase in toxicity, currently off label.

Aim and Objectives To evaluate eligibility for abiraterone plus ADT and docetaxel in de novo metastatic hormone-sensitive prostate cancer (mHSPC) based on a pharmacological treatment algorithm.

Material and Methods Observational, prospective, multidisciplinary study including all mHSPC patients scheduled for first-line treatment (July 2022/December 2022). The choice of triplet therapy was based on compliance with a pharmacological treatment algorithm, including: age <75 years, geriatric assessment using the Geriatric 8 (G8) scale >14, no fragility impression by the oncologist, ECOG 0–1, absence of comorbidities such as liver disease, coagulation problems, and/or active heart disease in the last 6 months; High Risk (at least two of the following characteristics): Gleason 8–10, ≥ 3 bone metastases and/or ≥ 1 visceral metastasis; High Volume (CHAARTED trial); and Prognostic Grade Group (ISSUP 2014-OMS 2016) 4–5. Other variables: PSA, comorbidities, polypharmacy, treatment. Progression-free survival (PFS) and treatment duration. Adverse reactions (AR).

Results Twenty-nine patients were included, 75.9% were de novo mHSPC, 44.8% had high volume, of which 69.2% met all algorithm criteria. Patients treated with the triplet had a median age of 65 years, 100% had G8>14, 66.6% had ECOG 1, 77.7% had multiple bone metastases, mean PSA at the start was 136.32ng/ml, 77.7% had Gleason 9, 88.8% had ISSUP 5, only one patient had >3 comorbidities, and three patients were on polypharmacy. The median treatment duration was 5.97 months, and PFS has not been reached yet, with only one patient progressing during docetaxel treatment, while the rest completed the proposed six cycles. 77.7% of patients experienced some AR, none of which were G3–4. The most common AR was skin-related (44.4%), followed by edema (33.3%), insomnia (22.2%), digestive toxicity (11.1%), neurotoxicity (11.1%), and elevated transaminases (11.1%).

Conclusion and Relevance Choosing triplet therapy based on a studied algorithm helps identify patients who can benefit more from treatment, focusing on those at higher risk and with worse prognosis, leading to favourable outcomes in efficacy and safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-201 CLINICAL EXPERIENCE OF TYROSINE-KINASE INHIBITORS DISCONTINUATION IN CHRONIC MYELOID LEUKAEMIA

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Background and Importance Tyrosine-kinase inhibitors (TKIs) have shown to be effective in chronic myeloid leukaemia (CML) treatment. Recent clinical trials show selected patients with deep molecular response (DMR) can safely discontinue treatment.

Aim and Objectives Describing clinical experience of discontinuing treatment with TKIs in CML patients.

Material and Methods A retrospective observational study analysed TKIs discontinuation and maintenance of major molecular response (MMR) after discontinuation in all CML patients treated at our centre from the moment they started TKIs until September 2023.

Discontinuation protocol stipulates patients must have been treated for five first generation TKIs) or three (second

generation TKIs) years and must have achieved 2 years of DMR (molecular response (MR) =4 or greater). After discontinuation they have monthly monitoring visits for 6 months (period when most patients lose MMR), afterwards controls are spaced out over time. If patients lose MMR (MR=3) treatment should restart.

Variables age, gender, TKI, start date, response, DMR achieving date, TKI switch before discontinuation and cause, discontinuation and date, withdrawal syndrome (WS), WS treatment, restart date and TKI, last consultation date.

Results Sixty-two CML patients were treated with TKIs and 48.4%(30) discontinued. Median age of patients who discontinued was 57.8 years [interquartile range (IQR): 50.1–67.1], 63.3% were female.

We found 73.3% discontinued with 1st-line TKIs, 26.6% received various TKIs before discontinuation due to: toxicity (60%) and suboptimal response(40%).

For those who discontinued median TKI treatment until discontinuation was 6.2 years [IQR: 4.9–12.1], and median time with DMR was 4.9 years [IQR: 3.3–8.1]. When they discontinued, they were treated with: imatinib (63.3%), nilotinib (23.3%), dasatinib (6.7%), bosutinib (6.7%).

Five patients developed WS: osteomuscular pain (4), panniculitis (1). One patient received corticosteroids and two received analgesics.

63.3% maintained discontinuation, follow-up median of 3.4 years [IQR: 0.9–4.5].

36.7% patients lost MMR, follow-up median until restart was 5.3 months [IQR: 4.2–6.9]. Seven patients restarted with previous TKI, four changed to second generation TKIs. One had a late relapse at 19.4 months. All patients regained MMR after restarting treatment.

Conclusion and Relevance Our results are in line with current literature showing controlled discontinuation is a viable and potentially long-term option. Discontinuation is already part of the standard of care in selected patients since it's cost-effective, representing savings for Healthcare System and improving patient's life quality.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-202 EVALUATION OF THE EXCHANGE OF ANTI-CGRP MONOCLONAL ANTIBODIES FOR THE TREATMENT OF CHRONIC REFRACTORY MIGRAINE

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Background and Importance In clinical practice of chronic migraine treatment, changes between the different anti-CGRP monoclonal antibodies (mABs) on the market are made, but there are still no clinical trials to support the effectiveness of such a switch.

Aim and Objectives To determine the characteristics of the switches made between mABs (fremanezumab, galcanezumab and erenumab) in our hospital, and to evaluate the effectiveness of these changes.

Material and Methods Descriptive observational and retrospective study in a second-level hospital in which patients diagnosed with refractory chronic migraine from June 2020 to September 2023 and who had been on treatment with the three drugs, were included. Inclusion criteria: patients aged >18years, on treatment for at least 3 months with fremanezumab (225 mg/month), galcanezumab (120 mg/month (initial 240 mg) and erenumab (140 mg/month).

Demographic variables (sex, age), efficacy variables: monthly days with headache of at least moderate intensity (HMD) at 0, 3 and 6 months, type of drug used and timing, duration of treatment (DT (months)), and use of concomitant prophylaxis (CP) were collected. Changes with respect to baseline HMD were analysed, establishing as effective a change greater than 30% and 50%.

Results Eighteen patients were included, 71% female (N=13) and a median age of 44.6 (RIQ: 42.6–58.4) years. Patients had a mean and standard deviation (SD) 20.6 (SD 7.8) days of baseline headache. A total of 55 treatments were reviewed: 81% (N=42) received PC together with AcM. The median DT with fremanezumab, galcanezumab and erenumab was 6.7, 10.1 and 7 (SD 4.5, 7 and 5) months respectively. In terms of efficacy, two and three patients (11%/16%) respectively achieved at least a 50% and 30% reduction in headache days at the first change, and none at a second change of treatment, both at 3 and 6 months of treatment (all were on fremanezumab).

Abstract 4CPS-202 Table 1

	1st choice	2nd choice	3rd choice
Erenumab	55%	0%	45%
Galcanezumab	0%	89%	11%
Fremanezumab	45%	11%	44%

Conclusion and Relevance Following the active treatment protocols for chronic migraine with mABs in our centre at any given time, our patient sample shows that only a maximum of 16% of patients could be rescued, taking a 30% decrease in the number of headache days per month as efficacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-203 DEVELOPMENT AND VALIDATION OF A DATA COLLECTION TOOL TO EVALUATE PHARMACEUTICAL INTERVENTIONS IN AN INTENSIVE CARE UNIT

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Background and Importance Clinical pharmacy services have been recently introduced in a local intensive care unit (ICU) and consequently, service evaluation is anticipated. There is the need for a tool to capture pharmaceutical interventions in ICU and assess their impact on specific patient outcomes.

Aim and Objectives To develop and validate a tool to describe and classify drug-related problems (DRPs) and pharmaceutical interventions (PIs) in ICU and evaluate the clinical relevance of the PI in preventing a potential Adverse Drug Event (pADE).

Material and Methods A classification system based on Pharmaceutical Care Network Europe (PCNE) V9.1 was identified

to capture and resolve DRPs identified in ICU. The PCNE V9.1 classification provides extensive categories of DRPs. Evaluation of impact of PIs in preventing a pADE is conducted using an established score[1]. The pADE score reflects the likelihood of an ADE occurring in the absence of a PI. The developed data collection tool was validated by an expert panel made up of three clinical pharmacists practising in ICU and a consultant intensivist. The expert panel assessed the tool for face and content validity and practicality in ICU setting. Subsequently, the tool was piloted in ICU for 10 days.

Results The data collection tool consists of seven sections namely patient demographics with details about pertinent laboratory results, description of DRP and PI, classification of DRP and PI, outcome of PI, and categorisation of medications involved. The final section of the tool relates to evaluation of PI in relation to prevention of a pADE and contains five categories, zero to high, which correspond to the probability of a pADE occurring if the pharmacist had not intervened. Examples from literature are presented for each pADE category to assist with the evaluation of PIs. Following validation and pilot testing, four sections were amended to better adapt the tool to ICU setting.

Conclusion and Relevance The development of such a data collection tool is important to standardise the classification of DRPs and interventions recommended by pharmacists in ICU. The tool contributes to data demonstrating value of pharmacist interventions on patient outcomes.

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Conflict of Interest No conflict of interest.

4CPS-204 MONITORING OF LINEZOLID IN HAEMODIALYSIS: A CLINICAL CASE

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Background and Importance The Antimicrobial Therapy Guidelines recommend the conventional dosage of linezolid (600 mg every 12 hours) for patients on haemodialysis (HD). Linezolid dialyzes 40% by HD.

Aim and Objectives Monitoring plasma concentrations of linezolid in a patient on HD.

Material and Methods A 63-year-old man with a history of bypass with saphenous vein and stage-4 of chronic kidney disease on an HD programme, was admitted to the intensive care unit (ICU) for septic shock due to an ischiorectal abscess.

Enterococcus faecium sensitive to linezolid (MIC 2) was isolated from the abscess culture and linezolid treatment (600 mg every 12 hours) was started. During his stay at the ICU, he underwent daily continuous haemodiafiltration.

After that, he was transferred to the ward where he underwent three conventional high flow HD sessions per week.

Upon arrival at the ward, we were asked to monitor linezolid levels due to probable toxicity associated with a decrease in platelets (196,000/mcl at that moment vs. 441,000/mcl prior to linezolid).

Results After 12 days of linezolid treatment, a trough level of 12.6 mcg/ml was obtained (range 2 – 7 mcg/ml). We recommended to discontinue the linezolid treatment and to measure the trough level again the next day before and after HD. The levels found were 6.71 and 1.26 mcg/ml respectively (HD elimination rate of 81.22%). Thus, we advised to restart with a dosage of 600 mg every 24 hours that same night.

During the following days, we recommended to continue with the same dosage guided by pre- and post-HD levels. The platelet count increased progressively after establishing levels within the therapeutic range.

Abstract 4CPS-204 Table 1

Linezolid days	Pre-HD level (mcg/ml)	Post-HD level (mcg/ml)	HD elimination rate (%)
13	1.26	6.71	81.22
15	1.39	5.95	76.64
23	2.06	7.14	71.15
25	2.04	8.32	75.48

Conclusion and Relevance This clinical case demonstrates that there may be patients undergoing HD who have toxic levels of linezolid with the standard dosage. In these cases, there is a need to monitor and adjust the dose.

We have also observed that the HD elimination in this patient differs from the value reported by the Antimicrobial Therapy Guidelines probably due to the different type of HD membrane.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-205 RESULTS OF ANTIBIOTIC PROPHYLAXIS IN ACUTE BRONCHO ASPIRATION PNEUMONITIS

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Background and Importance The use of antibiotics in acute bronchial aspiration is common, although there is little evidence that it provides benefits, and it exposes patients to increased microbiological resistance and the appearance of side effects from the use of antibiotics.

Aim and Objectives Compare mortality, change of ventilation modality, ICU admission and hospital stay of patients with aspiration who receive prophylactic antibiotic therapy, with patients who do not receive antibiotics.

Material and Methods Retrospective descriptive observational study of patients with acute bronchial aspiration (January 2022 to March/2023). Demographic and clinical data were collected from the patient's medical history; and medication-related information from the electronic prescription software available in the hospital.

Results 267 patients (50.6% women). Average 81.62 years. Services: Emergencies (75.7%), Internal (12.4%). Charlson index 6.10 (SD 2.73). Risk of bronchial aspiration in 71 patients (26.6%). 231 (86.5%) antibiotic, 36 (13.5%)

without antibiotic. Amoxicillin-clavulanic acid was most commonly used (59.2%). Antibiotic treatment duration 6.64 days (SD 4.40). Seven complications secondary to antibiotics. Antibiotic indicated in 28 patients (10.5%). 30 patients (11.2%) changed ventilatory modality, 21 patients (7.9%) were admitted to the ICU. 97 patients (36.3%) died (days until death 5.75 days), of which 75 (77.1%) received antibiotics.

Conclusion and Relevance Prophylactic antibiotics during acute aspiration do not reduce mortality or the need for ICU admission, but rather increase the need to change ventilation modality. The hospital stay in prophylactic antibiotic therapy is longer compared to patients who do not receive antibiotics.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-206 PRE-EXPOSURE PROPHYLAXIS, ARE WE DOING IT RIGHT?

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Background and Importance The United Nations General Assembly established that a fast response was required to end AIDS epidemics by 2030. Pre-exposure prophylaxis (PrEP) involves reducing the risk of acquiring HIV. However, a main apprehension exists with regard to risk compensation, concerning that PrEP decreases the condom use and increases sexually transmitted infections (STI). Similarly, to the aforementioned goal, by 2030, the WHO's proposed a 90% reduction in the syphilis and gonorrhoea incidence. Regarding PrEPs increasing use, it is important to assess our standpoint and how to improve.

Aim and Objectives Characterise and assess the PrEP using population regarding demographics, adherence, STI prevalence and HIV infection.

Material and Methods Retrospective study of PrEP prescribed patients, between 2017–2022 (minimum 6-month period intake). Population characteristics, post-exposure prophylaxis history (PEP), PrEP regimen, adherence, therapeutic suspension and their causes, seroconversion and STIs (chlamydia, syphilis, gonorrhoea, trichomoniasis, Mycoplasma genitallium), were analysed and confronted with our country's latest report of STI notification.

Results We analysed 392 patients (97% male; 91.7% male sex with male), with a medium age of 37 years, mainly from Portugal (52%) and Brazil (33.7%). Only 14.3% did PEP, meaning that 85.7% started PrEP straightaway. The majority (91.6%) were on a daily regimen. The STI prevalence was 73.4% (gonorrhoea 46.2% and chlamydia 38.3%). The Covid-19 pandemic had little effect on adherence, increasing PrEPs use (proportion days covered =82.8%). Only two patients tested positive for HIV. Suspension rate was 28.1% in which 50.5% of causes were traceable (four patients due to adverse effects).

Conclusion and Relevance PrEP demonstrated high tolerability and efficacy but had a big prevalence of STIs among PrEP users. Between 2015–2017 nationwide, 4819 cases of chlamydia, gonorrhoea, and syphilis were reported, comparing to 463 patients of a regional hospital, even acknowledging a wider period. Access difficulties might be the cause of high suspension rate, despite free supply. Hospitals are assuming an increasing burden of costs, leading to monthly supply of increasing patients, investing in HIV prevention but promoting STIs. We can engage with prescribers to start pharmaceutical appointments to promote behavioural changes concerning STIs and to educate for the need of maintaining PReP adherence. Simultaneously, we can give educational materials and health lectures.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-207 EVALUATION OF PROSTATIC SPECIFIC ANTIGEN DEPLETION WITH ABIRATERONE AS A PRONOSTATIVE FACTOR FOR SURVIVAL IN METASTATIC CASTRATION-SENSITIVE PROSTATE CANCER

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Background and Importance In the literature, there is an indicator of response to treatment with enzalutamide and apalutamide, defined as PSA90, for patients with metastatic castration-sensitive prostate cancer (mCSPC). However, no early response marker to abiraterone treatment in the setting of synchronous mCSPC has been described.

Aim and Objectives The aim was to analyse the deep prostatic specific antigen (PSA) response in patients with mCSPC treated with abiraterone.

Material and Methods Retrospective analysis of patients with metastatic mCSPC treated with abiraterone according to the LATITUDE clinical trial criteria (2 of 3 criteria: bone metastases $\geq$3, Gleason score $\geq$8 or presence of visceral metastases), in our centre from September 2017 to January 2023. Data collected for each patient were: age, PSA at baseline (PSA0), percentage of PSA decline after 14±7 days since the start of abiraterone treatment (%PSA), Gleason score at baseline (GS), type of metastases, event (defined as progression or death) and progression-free survival (PFS). Receiver operating characteristic (ROC) curve was used to evaluate the optimal PSA cut-off point to identify a greater possibility of response. Event-time distributions were estimated using Kaplan-Meier methodology. Log-rank tests were used to test for differences in event-time distributions. All p-values are 2-sided and CIs are at the 95% level, with significance pre-defined to be at the 0.05 level.

Results Data from 41 patients were analysed, of which there was no biochemical response in five of them. Table 1 shows the median and standard deviation of the variables analysed.

Abstract 4CPS-207 Table 1

Age	**69 ± 7,5 years**
PSA0	3,67 ± 566,8 ng/mL
%PSA	47,7 ± 24,32%

Fifty percent of patients had a GS=9. The percentage of patients with bone, visceral and lymph node metastases was 50%, 33% and 17%, respectively. A cut-off of 30% for PSA decline was established. Median PFS was 10.1 months (95% CI: 5.3–14.8) in patients with PSA decline <30% and 23.9 months (95%CI: 11.7–36.1) in patients with PSA decline ≥30%(p=0.001).

Conclusion and Relevance This real-life study shows that an early decline in PSA value ≥30% after initiating abiraterone treatment may be an indicator of improved treatment response in patients with mCSPC. Larger studies are needed to confirm this hypothesis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-208 ANALYSIS OF THE IMPLEMENTATION OF A MULTIDISCIPLINARY PHARMACEUTICAL CARE PROJECT FOR GERIATRIC HAEMATO-ONCOLOGY PATIENTS

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Background and Importance The elderly constitute a large percentage of patients with haematologic malignancies. It is estimated that this percentage will grow due to the ageing of the population and the new therapeutic targets that manage to control and chronify the disease. They present cognitive impairment, malnutrition, physical dependence and polymedication, requiring a comprehensive and multidisciplinary approach.

Aim and Objectives To design a pharmaceutical care protocol for geriatric haemato-oncology patients and to evaluate the results.

Material and Methods Prospective observational study conducted from January 2022 to September 2023 in the Pharmaceutical Care Consultation for oncohaematologic patients of a tertiary hospital. The haematologist selected the most fragile patients with the G8 scale and with the highest number of comorbidities evaluated with the CIRS-G scale and sent them to the Pharmacy consultation, where the pharmacist in charge made a previous evaluation of home medication, self-medication, alternative medicine with the aim of detecting drug interactions, therapeutic duplications, inappropriately prescribed drugs using the START-STOPP criteria, assessing the possible deprescription of polymedication, and lack of adherence using the Morisky-Green test. In the event of detecting any errors in medication intake, interactions of interest. or adverse reactions, pharmaceutical interventions were made in the patient's clinical history for consultation by any health professional.

Results With this new protocol, 40 patients were attended, with a median age of 80 years, 68% men and 32% women. Adherence to haemato-oncologic treatment was improved by 90%. Thirty-five pharmaceutical interventions were carried out: 3 related to the dosage and way of taking the treatment, 10 with pharmacological interactions in which it was necessary to substitute a drug in the treatment, five therapeutic duplications, eight with the use of herbal products and multivitamin complexes that interacted with their treatment, four for not attending their medical check-up in 2 years and five had prescribed medication of little therapeutic value and with a high anticholinergic load that was suspended from the treatment.

Conclusion and Relevance The hospital pharmacist has an important role in the pharmaceutical care of geriatric haemato-oncology patients by creating multidisciplinary work protocols offering personalised treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

4CPS-209 COMPARISON OF TWO PHARMACOKINETIC/PHARMACODYNAMIC INDICES IN CRITICALLY ILL PATIENTS TREATED WITH AMIKACIN

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Background and Importance Amikacin is commonly used as an empirical treatment for gram-negative infections in intensive care unit (ICU) patients. The pharmacokinetic/pharmacodynamic (PK/PD) index commonly used is the ratio maximal concentration: minimum inhibitory concentration (Cmax/MIC) and, to a lesser extent, the ratio area under the curve from 0 to 24h:MIC (AUC0– 24/MIC).

Aim and Objectives To evaluate the PK/PD indices Cmax/MIC and AUC0–24/CMI for amikacin in critically ill patients.

Material and Methods Patients admitted to a medical ICU with preserved renal function (CKD-EPI>60 ml/min) treated with empirical amikacin once-daily were included. Therapeutic Drug Monitoring (TDM) was carried out after the first dose (sample timing: Cmax and Cpost-8h, at 30 minutes and 8 hours respectively, after a 30-minute infusion). Targets for PK/PD Cmax/MIC and AUC0–24/MIC were 8–10 and 80, respectively. An empirical MIC of 4 mg/L was established for the calculation. Parametric AUC calculation was performed by empirical Bayesian estimation of pharmacokinetic parameter. Bayesian estimates were performed using PKS® software with a single compartment pharmacokinetic model. Patients were classified according to those who reached the target or not for both indices (Cmax/MIC and AUC0–24/MIC).

Results Results expressed as median and percentile 25–75.

N=48	
Age	63 years
Weight	83 kg
Creatinine	0.6 mg/dL

	Starting dose	After TDM	p>0.05
Total dose (mg)	1225 (1000–1500)	1250 (1200–1500)	
Dose adjusted for total weight (mg/kg)	14.7 (11.8–18.3)	14.7 (12.5–17.1)	
Dose adjusted for ideal weight (mg/kg)	19 (15.3–22.8)	19 (17.6–22.2)	

Cmax (mg/L)	48.3 (45.9–50.9)
Cmin (mg/L)	0.19 (0.03–0.61)
AUC (mg·h/L)	235 (191–271)
Cmax/MIC	12.1 (11.5–12.7)
AUC0–24/MIC	58.7 (47.7–67.9)

Due to TDM, 100% of patients reached the therapeutic objective according to the Cmax/MIC index, although the percentage was reduced to 17% when the PK/PD index of efficacy was AUC0–24/MIC ratio (concordance index kappa=0.275; p≤0.05). To achieve the AUC0–24/MIC target, the required dose was estimated to be 1760 mg (1300–2270) (p=<0.05).

Conclusion and Relevance No correlation between the PK/PD Cmax/CMI and AUC0–24/MIC indices was observed. To achieve the AUC0–24/MIC target, a significant dose increase is necessary compared to the doses required for Cmax/MIC.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-210 HOME INFUSION CHEMOTHERAPY TREATMENT FOR PATIENTS WITH MALIGNANT HAEMATOLOGICAL DISORDERS

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Background and Importance Home-based chemotherapy is becoming a valid alternative to hospital-based treatment for patients with malignant haematological disorders.

Aim and Objectives To evaluate the benefits of implementing a home infusion chemotherapy treatment for patients with malignant haematological disorders.

Material and Methods Prospective observational study from February 2016 to September 2023 in a tertiary hospital. The haematologist selected patients with autonomy for self-care and good family support. The chemotherapy protocols administered at home were: ESHAP: Etoposide 40 mg/m^2 IV over 2 h days 1 to 4 – Cytarabine 2000 mg/m^{2}IV over 2 h on day 5 – Cisplatin 25 mg/m^2 in 22 h continuous IV infusion days 1 to 4 – Prednisone 60 mg/m^2 oral days 1 to 5, DHAOx: Oxaliplatin 130 mg/m^2 IV over 2h day 1- Cytarabine 2000mg/m^2/12h IV in 2h day 2 – Dexamethasone 40mg oral days 1 to 4 and EPOCH: Etoposide 50 mg/m^2+Doxorubicine 10mg/m^2+Vincristine 0, 4 mg/m^2 continuous IV infusion 24h days 1–4, cyclophosphamide 750mg/m^2 IV day 5, Prednisone 60mg/m^2 oral days 1 to 5. Patients were infused at home using an elastomeric infuser. Home treatment was prepared individually by the pharmacist.

Results Home infusion chemotherapy treatment was performed in 46 patients. 43,4% with non-Hodgkin's lymphoma received ESHAP in second-line, with a median age of 51 years, and 32,6% with mantle cell lymphoma received DHAOX in first-line with a median age of 46 years and 23,9% with aggressive non-Hodgkin's lymphoma were treated with EPOCH in first-line with median age 42 years. This allowed an optimisation of waiting lists by 90%, treating more patients requiring admission to the inpatient ward with less delay. Acceptance of the procedure increased in 92% of patients. The risk of infection by nosocomial microorganisms was reduced. A saving of 2500 euros per patient was achieved. 95% of patients said they were very satisfied receiving their chemotherapy treatment, being more comfortable.

Conclusion and Relevance Home Infusion Chemotherapy Treatment for ESHAP, DHAOX and EPOCH has been an effective, safe and feasible process. It has managed to avoid hospitalisation of haemato-oncology patients receiving IV chemotherapy, saving hospital stays, reducing nosocomial infections and improving quality of life.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-211 ANALYSIS OF THE PRESCRIPTION OF VITAMIN D SUPPLEMENTS IN A SOCIAL HEALTH CENTRE

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Background and Importance According to the recommendations for the appropriate use of vitamin D tests and supplements in the general population published in 2021, several bulletins have been published as support tools in routine practice, the analysis carried out being variable.

Aim and Objectives Study of the consumption and prescriptions of vitamin D supplements alone in a social health centre.

Material and Methods Observational, retrospective study of the consumption of vitamin D supplements and cross-sectional analysis of current prescriptions for external intake of vitamin D. All patients institutionalised were included. The variables collected were: age, sex, posology of vitamin D, levels and whether they had: bone, kidney or both pathologies. The data were obtained from the inpatient management program and the computerised clinical history. For the analysis, we used the laboratory analytical parameters as a reference: deficiency (<10ng/dL), insufficiency (10–30 ng/dL), sufficiency (30–100 ng/dL) and toxicity (>100 ng/dL).

Results 300 residents were reviewed, of which 43.67% (131/300) were prescribed vitamin D, 32 men and 99 women, with a mean age of 84.4 years [52–102]. The distribution by posology was: monthly in 70.23% (92/131) residents, biweekly in 25.95% (34/131) residents, with the weekly regimen and every 10 days in 1.53% (2/131) residents, respectively and every 21 days only 0.76% (1/131) residents. According to laboratory data, 12 of them had deficiency (<10 ng/dL), 90 had insufficiency (10 ng/dL-30 ng/dL) and 27 had sufficiency (30

ng/dL-100 ng/dL).Regarding associated pathologies: 62 (47.33%) residents had bone pathology, 17 (12.98%) had kidney pathology, and both pathologies were present in eight (6.11%) of them. 39.69% (52/131) residents did not present any pathology related to vitamin D deficiency. In relation to the consumption of vitamin D:

2018	355	0
2019	618	174,08%
2020	892	251,23%
2021	1321	372,11%
2022	1964	553,24%

Conclusion and Relevance The external supply of vitamin D is necessary in certain pathologies. However, this consumption has increased exponentially for no apparent reason other than the result of the levels of vitamin D in the tests. In view of the results obtained, it would be advisable to carry out periodic reviews of vitamin D supplementation in institutionalised patients, as well as consider deprescribing them if said contribution is unnecessary.

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Conflict of Interest No conflict of interest.

4CPS-212 MANAGEMENT OF POST CAR-T NEUROTOXICITY USING ANAKINRA: A CASE REPORT

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Background and Importance The prognosis for relapsed/refractory(R/R) Mantle cell lymphoma (MCL), a mature B-cell lymphoma, after the failure of Bruton tyrosine kinase inhibitors (BTKi) remains unfavourable. Brexucabtagene autoleucel, an autologous anti-CD19 CAR T-cell therapy, represents the first FDA-EMA approved CAR-T treatment for BTKi-refractory R/R MCL. Here, we describe a challenging case of haematologic toxicity associated with immune effector cell-associated syndrome (ICANS).

Aim and Objectives The patient is a 59-year-old with refractory mantle cell lymphoma, initially treated with six alternating cycles of R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone) and R-DAHP (rituximab, cisplatin, cytarabine, and dexamethasone), followed by autologous stem cell transplantation. In the second-line, the patient received ibrutinib, and in the third-line, Brexucabtagene autoleucel.

Material and Methods The patient experienced grade≥3 cytokine release syndrome (CRS), treated with tocilizumab and steroids, and immune effector cell-associated neurotoxicity syndrome (ICANS), with neurological symptoms such as worsened handwriting, significant attention and orientation decline, necessitating the administration of 20 mg dexamethasone and, for refractoriness, 100 mg anakinra every 6 hours.

Results The combined therapy resulted in rapid improvement of the patient's toxicity, leading to discharge from the intensive care unit. The therapy was definitively discontinued after 5 days. PET and CT scans showed complete remission of the lymphoma. As the adoption of CAR-T therapy in haematology increases, the management of side effects becomes crucial. ICANS is a common toxicity, particularly in patients treated with axicabtagene ciloleucel and brexucabtagene celeucel, with a median onset time of 6–8 days. In this case, ICANS lasted 25 days, but the combination of dexamethasone and anakinra proved effective. The use of anakinra, an IL-1 receptor antagonist approved for rheumatoid arthritis, was first examined for refractory CRS/ICANS in a murine model before entering clinical practice at various CAR-T centres. The administration of anakinra, in conjunction with dexamethasone, has shown benefits in managing severe ICANS. A phase 2 study (NCT4205838) aims to gather solid evidence for its application. Initial results from the study, based on seven patients, show potential in reducing severe ICANS and corticosteroid use.

Conclusion and Relevance In conclusion, CAR T-cell therapy offers innovative treatment for B-cell malignancies but introduces unique toxicity. Careful monitoring and interventions are essential to ensure patient safety. Anakinra shows promise in ICANS management and reducing corticosteroid use.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-213 RESULTS OF ANTIBIOTIC TREATMENT OF AORTIC ENDOPROSTHESIS INFECTIONS IN PATIENTS NOT CANDIDATES FOR SURGERY

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Background and Importance Aortic endoprosthesis infection (AIE) complicate 0.6–3% of these interventions, with surgery being the standard treatment. When surgery is not possible, conservative treatment is a necessity despite the lack of evidence. In this series, clinical data of the patients and survival are provided.

Aim and Objectives To know the etiology of EIA, the antibiotic treatments received and the mortality results of these patients who are candidates for conservative treatment.

Material and Methods Retrospective study of patients admitted for AIE with conservative treatment in our hospital, from January 2014 to July 2023. Clinical (Charlson index, time of first symptom, symptoms, antibiotic type and response, death time), epidemiological (age and sex) and microbiological data were collected from the clinical history.

Results 31 patients were evaluated with a mean age of 72.8 years, 90.9% male, and a mean Charlson index of 7. The mean time from the intervention to the first symptoms was 32.7 months (4–120 months) and from the onset of symptoms to diagnosis of 4.5 weeks (1–16 weeks). The most frequent symptoms were pain (67.3%), fever (54.5%) and constitutional symptoms (45.45%). The causative microorganism was only identified in 38.7% (12) of the patients, the most frequent being: E. avium (5), K. pneumoniae (4), E. coli (1) and E.

faecalis (1). The initial antibiotic treatment included a beta-lactam in 28 cases, associated with vancomycin in 12 cases and daptomycin in another 12. Maintenance treatments included rifampin (n = 9), linezolid (n = 6), and dalbavancin. (n = 3). 15 patients (48.4%) died in the first 2 years: six from a septic process, six from gastrointestinal bleeding due to aortoenteric fistula, and five from unrelated causes (lung neoplasia and cerebral haemorrhage). The median survival time was 18.7 months (1–60 months).

Conclusion and Relevance The identification of the causative microorganism occurred in less than 40% of cases, emphasis is required on said identification to carry out targeted treatment. Half of the patients who suffered AIE died within 2 years.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-214 MONITORING OF TACROLIMUS IN A KIDNEY TRANSPLANTED COHORT

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Background and Importance Tacrolimus (TAC) is the first-choice immunosuppressant for patients undergoing kidney transplantation. However, it has considerable drug interactions likelihood, high inter/intra-patient variability and a narrow therapeutic index. Therefore, constant monitoring is request, to avoid organ rejection or adverse events. From this perspective, a multidisciplinary team of clinicians, hospital pharmacists and nurses, provides to outpatients: recognition and reconciliation of drug therapy, therapeutic drug monitoring(TDM) of TAC concentrations in whole blood, professional counselling to verify therapeutic adherence and correct drug intake.

Aim and Objectives To examine tacrolimus plasma concentration variability in a cohort of transplanted patients in order to identify significant correlation useful for guiding clinician in optimising therapy.

Material and Methods Tacrolimus TDM values were analysed in a cohort of 160 patients (72% male). A total of 5562 tacrolimus measurements over a 4 years period were evaluated. In the descriptive statistics, continuous and non-normal variables were shown as median values. Statistical dispersion of data measured in the interquartile range (IQR, quartile 1-quartile 3). The Mann-Whitney test was used to evaluate the influence of sex (male and female patients) on creatinine levels, eGFR levels and plasma concentrations of tacrolimus (level of statistical significance p-value < 0, 05). All tests were performed with IBM SPSS Statistics 25.0 for Windows.

Results The distribution analysis by sex shows that 73.7% (N=4171) of the 5662 measurements analysed were from male. Considering all the samples, the median TAC concentration(μg/ml) was 6.60(IQR 5,20–8,50). Separately evaluating sexes show that median TAC concentration was 6.60(IQR 5.30–8.50) and 6.50(IQR 4.90–8.60) for males and females respectively. The Mann-Whitney test show that sex influences tacrolimus plasma concentration with statistical significance ($p<0.001$). Sex influence was statistically significant also on creatinine levels (mg/dL)($p=0.007$) and eGFR levels (mL/min) ($p<0.001$).

Conclusion and Relevance Data disaggregation by sex variability can be the key to improve patients' quality of life and better individualise treatment and care. The multidisciplinary approach allows to optimise processes and obtain useful and reliable results. Further analysis is needed to further stratify patients and determine correlations useful to guide clinicians in monitoring drug therapy especially in polypharmacy patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-215 ADJUSTMENT OF ANTIBIOTICS THROUGH THE HEMOFILTER: A CASE REPORT

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Background and Importance

Aim and Objectives In renal support therapies, the amount of drug eliminated will depend on the therapeutic modality used (convection/diffusion) and dosage, the fluid replacement site (prefilter/postfilter), as well as the filter surface and material, but also on intrinsic characteristics of the drug itself: volume of distribution (DV), plasma protein binding (PPB), molecular weight (MW) and patient characteristics.

Material and Methods Our case is a 67-year-old woman admitted to the ICU for septic shock of probable urinary origin. Given the urea levels, metabolic acidosis with severe electrolyte disturbance and acute on chronic renal failure, extrarenal depuration therapy was started with continuous venovenous hemodiafiltration (CVVHDF) and empirical antibiotic treatment with ertapenem 1g/24h. Literature review was made to evaluate the adjustment of antibiotic therapy in hemofiltration until antibiogram results were obtained. The most dialysable drugs are those with low MW, low DV, high renal clearance and low PPB.

Results Among the carbapenems, the most studied is meropenem. It presents low UPP (2%), PM 383.4 Dalton and a VD between 11–27L, resulting in a better alternative to ertapenem. Antibiotherapy was modified to meropenem adjusted to HDFVVC 1g/6h in 3h extended perfusion prior loading dose of 2 g to ensure an MIC >40% of the time to achieve both bacteriostatic and bactericidal effect. After antibiogram, it was downgraded to ceftriaxone, a hydrophilic molecule, with high UPP (85–95%) and a PM 554.58 Dalton. Hydrophilic drugs such as cephalosporins and penicillins generally do not cross cell membranes, so they only diffuse to the extracellular space and their DV is lower than that of lipophilic drugs, in addition to renal elimination. Ceftriaxone, however, despite being a hydrophilic drug, is preferentially eliminated through bile and, since it has such a high affinity to protein, it is hardly dialyzed and therefore does not require adjustment. To ensure correct antibiotic dosage, it was decided to use ceftriaxone 1g/12h prior loading dose of 3g for reaching levels early,

Conclusion and Relevance The prescription of the appropriate dose of antibiotic is fundamental in the critical patient since it allows avoiding the establishment of excessive doses that can

cause toxicity or an insufficient dose causing therapeutic failure or favouring the appearance of multi-resistances.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-216 EFFICACY AND SAFETY ANALYSIS OF OBETICHOLIC ACID IN PRIMARY BILIARY CHOLANGITIS: REAL-LIFE DATA

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Background and Importance Obeticholic acid (OCA) is an orphan drug for patients with primary biliary cholangitis (PBC), a rare autoimmune disease, who do not respond adequately to treatment with ursodeoxycholic acid (UDCA) or do not tolerate it.
Aim and Objectives To evaluate the efficacy and safety of OCA in patients with PBC.
Material and Methods Descriptive and retrospective study. Data from patients who received OCA from January-2021 April-2023 were analysed. Demographic variables (sex and age); previous treatment with UDCA; plasma values of liver markers: alkaline phosphatase (ALP), gamma-glutamyl transferase (GGT), total bilirubin (Bt), aspartate aminotransferase (AST) and alanine aminotransferase (ALT), at the start of treatment with OCA, at 6 months and at 12 months, were collected from the electronic medical records programme. Adverse effects described since the start of treatment were also collected. Treatment response was defined as an ALP value less than 1.67 times the upper limit of normality (ULN), a Bt value within the normal range and a decrease from baseline ALP value of at least 15%, according to the pivotal drug trial.
Results Thirty patients (87% women) were evaluated. The median age was 66 years. All patients except one (3%) were on treatment with UDCA. Median values and percentile 25–75 are shown.

Abstract 4CPS-216 Table 1

	Baseline	6 months	12 months
ALP	333,5 (242–453,5)	295,5 (187–428)	252,5 (162–332,2)
Bt	0,6 (0,5–0,7)	0,7 (0,5–0,8)	0,6 (0,4–0,77)
GGT	136 (84,5–279,5)	82,5 (39,5–187,5)	56 (22,2–113,2)
AST	36,5 (33,5–45,7)	32,5 (29–49,5)	35 (28–45)
ALT	40,5 (28,2–61,5)	30,5 (23–46)	29,5 (23–43,7)

A reduction of ALP>15% was achieved in 15 (50%) and 16 patients (53%) at 6 and 12 months, respectively. 29 patients (97%) had bilirubin in the normal range at 6 months, and all (100%) at 12 months. ALP<1.67xULN was obtained in seven (23%) and 11 (37%) patients at 6 and 12 months, respectively. Overall, four patients (13%) fulfilled the three pivotal trial conditions at 6 months and eight patients (26%) at 12 months. Adverse reactions reported were: pruritus in 14 patients (47%) and fatigue in one (3%).
Conclusion and Relevance Based on clinical trial endpoints, OCA achieved modest results at 6 months, which doubled 1 year after initiation of treatment. Further studies are needed to assess long-term benefit.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-217 A COMPARATIVE EVALUATION OF THE LONG-TERM EFFECTIVENESS OF GUSELKUMAB AND RISANKIZUMAB IN THE CLINICAL MANAGEMENT OF PLAQUE PSORIASIS

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Background and Importance Anti-interleukin 23 drugs were approved in the last 6 years. The absence of long-term comparison between alternatives such as risankizumab or guselkumab needs to be fulfilled.
Aim and Objectives To evaluate the effectiveness through indirect comparisons of risankizumab and guselkumab in plaque psoriasis long-term treatment.
Material and Methods Multicentric, retrospective and observational study. Comparison made with plaque psoriasis patients with active treatment with risankizumab or guselkumab to September 2023 overcoming 52 weeks of treatment. Demographic (sex, age) and clinical (psoriasis area severity index (PASI) at baseline and in subsequent dermatology controls, PASI clearance (PASI 90 and PASI100)) data collected. Comparison made through PASI90/PASI100 and PASI reduction.
Results 110 patients recruited for the study, with 35.5% of them being female and with an average age of 51.7 years. Initial PASI score was 9.46 for the 46 patients treated with guselkumab, and 8.04 for the 64 patients treated with risankizumab. The results are shown in the following tables:

N	PASI	Averaged weeks	PASI90	PASI100
46 (guselkumab)	1,12	62	60,8%	56,5%
64 (risankizumab)	0,88	63	68,75%	62,5%

N	PASI	Averaged weeks	PASI90	PASI100
23 (guselkumab)	0,94	114	69,5%	65,2%
30 (risankizumab)	0,89	110	63,3%	46,6%

N	PASI	Averaged weeks	PASI90	PASI100
15 (guselkumab)	2,61	150	60%	60%
18 (risankizumab)	0,7	136	72,2%	50%

Conclusion and Relevance Both molecules offer highly positive long-term results, particularly valued by patients with plaque psoriasis, although guselkumab seems to maintain a slightly greater full clearance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Artificial intelligence tool utilised to translate texts.

Conflict of Interest No conflict of interest.

4CPS-218 OPIOID PRESCRIBING FOR ACUTE NON-CANCER PAIN, POST-OPERATIVE PAIN AND POST-PROCEDURE PAIN BY SURGICAL TEAMS AT A TERTIARY HOSPITAL: 1-DAY AUDIT

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Background and Importance In Ireland, numbers of prescribed opioids are increasing yearly, out of proportion to population increase1. Acute hospitals are a major source of initial opioid prescriptions into communities 2. The Health Service Executive (HSE) has published opioid prescribing guidelines for the management of acute non-cancer pain, post-operative pain and post-procedure pain, specifically addressing the use of slow-release opioids, duration of prescription and avoidance of diversion following discharge 3.

At our hospital, there is no standardised approach to opioid prescribing in this population. A baseline point prevalence survey (PPS) of opioid prescribing in this population by surgical teams was conducted.

Aim and Objectives • To characterise opioid prescribing for acute non-cancer pain, post-operative pain and post-procedure pain in a tertiary healthcare setting

• To inform local policy development on appropriate opioid use.

Material and Methods The PPS took place on a single day in May 2023. Approval to conduct the survey was sought from the hospital Quality and Patient Safety Dept. All adult patients admitted to our hospital under a surgical team were included. The inpatient medication prescription record and medical notes for each patient were reviewed by a clinical pharmacist. Opioid prescription details were recorded on a data collection form hosted on Microsoft Forms.

Results

- 72% of study population (n=205) were prescribed an opioid; total of 224 opioid prescriptions
- Most common indication, 43%, was acute postoperative pain (97/224)
- 27% (61/224) of prescriptions were for slow-release formulations
- 30% (67/224) of opioid prescriptions were prescribed for > 1 week
- 97% (218/224) of opioid prescriptions were commenced during the current admission
- Figures 1 & 2 respectively, summarise the opioid agent and formulation prescribed.

Conclusion and Relevance This 1-day snapshot audit has presented several areas for improvement at our hospital, specifically the use of slow-release opioids, treatment duration and discharge prescription. Several quality improvement initiatives are being initiated as part of a wider opioid stewardship programme in line with the HSE National Clinical Programme for Anaesthesia.

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Conflict of Interest No conflict of interest.

4CPS-219 BEYOND THE EXPECTED: THE ENHANCED DETECTION OF DRUG RELATED PROBLEMS, THE MOST OF A PHARMACEUTICAL DECISION SUPPORT SYSTEM

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Background and Importance The EAHP statement integrates pharmaceutical analysis into our practices mentioning that all prescriptions should be reviewed and validated as soon as possible by a pharmacist.

However this practice is highly variable. Reviewing all prescriptions as soon as possible by a pharmacist and detecting drug-related problems remains a challenge.

Pharmaceutical decision support systems (PDSS) are associated with the decrease of adverse drug events and the improvement of prescribing practices.

Our PDSS works on the patient's data, modelled situations and Pharmaclass® (Keenturtle – F) in real time.

Aim and objectives This study aims to present pharmacists' ability to detect drug-related problems (DRP) in usual care by using a PDSS.

Material and Methods An observational prospective study has been ongoing from November 2019 to June 2023 in two facilities (1600 beds). PDSS is applied in addition to standard care.

Up to a maximum of 201 modelled situations were integrated in the PDSS.

A DRP resolution strategy structure the pharmaceutical analysis of DRPs. It is the support of the human supervision of the PDSS.

Data collected are the number alerts analysed, DRPs, PIs and accepted PIs.

Data analysis is performed by using Pandas library in Python.

Results The data are collected during 663 non-consecutive days.

On 14331 alerts 3157 were technical false positives (22.0%) and 3821 situations do not correspond to a DRP (26.7%).

DRP detection is performed for 7,353 situations by the pharmacists using the PDSS (51.3% of analysed alerts).

5,062 DRP (68.9% of all DRP detected) required a pharmacist's intervention that analyses the alert.

For 2648 of them a pharmacist had missed the identification of the DRP during his analysis.

In addition, 838 PIs were transmitted for DRPs identified following the overall analysis of the situation. These last two comments constitute the specific added value of using a PDSS.

Another 927 DRPs (12.6% of all DRP detected) had already benefited from a PI by another pharmacist.

For 1364 DRPs (18.5% of all DRP detected) the physician changed the drug management just before analysis of the alert.

Conclusion and Relevance A PDSS is both efficient and offers added value in routine care to secure the patient's medication management.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-220 EVALUATION OF THE IMPLEMENTATION OF A PRE-EXPOSURE PROPHYLAXIS PROGRAMME: 2 YEARS EXPERIENCE IN OUR REGION

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Background and Importance HIV remains a significant social and economic problem. Recently, continuous use of antiretrovirals (mtricitabina/tenofovir) have been used as pre-exposure prophylaxis (PrEP) with positive clinical and economic outcomes. However, the use of drugs in individuals without pathology can be controverted due to the potential exposure to toxic effects.

Aim and Objectives To study the sociodemographic characteristics, effectiveness, and safety of PrEP in the users of our region.

Material and Methods

Retrospective study Period August 2021 to September 2023. Variables: gender, age, risk behaviours, sexually transmitted infections (STI), chemsex, adherence, serology, side effects, discontinuation.

Results 303 users enrolled from August 2021 to September 2023. There are 297 males, four transgender women, one female, and one non-binary. Users' age distribution was: <25 (2%), 25–34 (28%), 35–44 (43%), 45–54 (20%), 55–64 (5%), and >65 (1%).

58% were engaged in three or more risk behaviours. >10 sexual partners during last year (93%), no condom (85%) and a sexually transmitted infection (STI) in the last year (52%). Approximately 37% reported drug use, mostly poppers (80%), cocaine, marijuana, ecstasy and GHB (around 35% each), speed (24%), and ketamine (14%). 326 STIs were diagnosed: 51% gonorrhoea, 32% chlamydia, and 17% syphilis. Only 70% of users reported a perfect adherence. None became infected with HIV.

Regarding safety, 19% experienced adverse effects, almost all of which were mild and self-limiting. Gastrointestinal disorders (13%), nausea (6%), and headache (3%) were the most common adverse effects. 27 users discontinued the programme. 10 of them due to renal impairment, four from adverse effects, and 13 for personal reasons. Average serum creatinine deviation from baseline at 1, 3, 6, 12, 18 and 24 months was 0,02 ± 0,2 mg/dL for every period.

Conclusion and Relevance PrEP is an effective and safe strategy for preventing HIV infection in individuals practising risky behaviors, the majority being young adults with higher education or further and employed. Follow-up programmes allow for the detection and treatment of multiple STIs to reduce their spread, requiring a specialised team to provide the necessary treatment and education. Interestingly, renal function was not affected at least in short term use within two years and despite low adherence, no user was infected by HIV.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-221 EVALUATION OF THE RELEVANCE OF STATINS PRESCRIPTION IN THE ELDERLY: TOWARDS A DEPRESCRIPTION?

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Background and Importance Statins effectiveness in reducing cardiovascular risk has been demonstrated in numerous studies. However, the assessment of the benefit/risk balance can favour deprescription

Aim and Objectives Evaluation of the relevance of deprescribing statins in patients over 75 years old.

Material and Methods This is a prospective observational study lasting 6 weeks in patients over 75 years of age hospitalised in the departments of cardiology, pulmonology and geriatrics. A daily analysis of computerised prescriptions on HopitalManager® software was done. It led to pharmaceutical interventions (PI), oral and written, about dosage reduction or statin discontinuation in cases of misuse or irrelevant prescription. Misuse situations correspond to statins use without indication found or with presence of adverse effects, drug interactions (DI) or contraindication (CI). Statin discontinuation was either gradual or immediate. PI monitoring was controlled at patient discharge.

Results In total, 48 patients were included. Average age was 83 years and sex ratio M/F was 0.92. A statin indication was found and justified for 33 patients (68.7%). PIs were formulated for 15 patients (31.3%). Among these 15 patients, nine (18.8%) did not have an indication for a statin prescription. The proposed PI was a gradual dose reduction (accepted for 7/15 patients). Of 15 patients, six (12.5%) had no statin indication and an increase in Creatine Phospho Kinase (CPK) levels attributable to the statin. Thereby, 5/6 had an increase lower than five times normal (<5N). The proposed PI was a progressive decrease. Only 1/6 had CPK > 5N. It led to immediately stop the statin. PI were accepted for all six. No CI or DI were detected. The total acceptance rate for PIs is 13/15 i.e 86.7%.

Conclusion and Relevance This work confirmed the multidisciplinary interest in the re-evaluation of statin indication and its deprescription when it no longer had its place in patients therapeutic strategy. However, this decision making is more complicated among hospital professionals who are not at the origin of the initiation. Strengthening the city-hospital link could improve it. In existence of protocols is also an obstacle to deprescription. Harmonising practices with the development of a deprescribing algorithm would be an ideal tool to

facilitate patient care. This algorithm is the subject of a parallel work.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-222 THE REAL-LIFE OF BENZODIAZEPINES IN GERIATRIC DEPARTMENTS: CAN THE PHARMACIST HAVE AN IMPACT?

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Background and Importance Benzodiazepines and derivatives (BZD) are anti-anxiety or hypnotic drugs. They are frequently prescribed over a long period of time and are rarely re-evaluated. However, they can cause side effects, especially among the elderly. It is then necessary to reassess the treatment. Through his activities, the pharmacist may participate at a re-evaluation of treatment (pharmaceutical validation, medication reconciliation process).
Aim and Objectives This study assesses the impact of the pharmacist in the re-evaluation of benzodiazepines treatments.
Material and Methods An extraction of prescriptions containing at least one BZD in a geriatric ward was conducted for 4 months. A pharmaceutical analysis of the prescription is carried out, then pharmaceutical interventions are made by message to the prescribers via our prescription software in order to propose substitutions, dosage reductions or stoppage of treatments by BZD.

At the patient's discharge, a comparison of the exit prescription and the prescription during the hospitalisation allows us to know if the pharmaceutical interventions were accepted. Some patients have had a medication reconciliation process during which the same proposals are made to the doctor.
Results A total of 202 BZD were prescribed to the geriatric unit over 4 months, representing 169 patients. Of these, 34.2% were initiated during hospitalisation and 65.8% were home treatments.

A pharmaceutical intervention was performed in 71% of cases: a substitution was proposed in 40%, a dosage decrease in 13.3%, a re-evaluation of exit treatment in 15% and a discontinuation in 31.7%.

A total of 55% of pharmaceutical interventions were accepted at the discharge of patient.

Among the 169 patients, 12.4% received a medication reconciliation process during which pharmaceutical interventions were done: a substitution was proposed in 28.6% of cases, a dosage decrease in 19% and a discontinuation in 52.4%. In 100% of cases, they were accepted.
Conclusion and Relevance Through this study, we analyse that the pharmacist has a positive impact on the re-evaluation of treatments, especially during the medication reconciliation process where a review of BZD drug relevance is carried out with the geriatrician. It would be interesting to analyse if the presence of a pharmacist on the ward may improve the acceptance of pharmaceutical interventions and allow more medication reconciliation processing.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-223 A STUDY ON THE PERCEPTION OF ELDERLY PATIENTS ON THE EXPIRATION DATE AND STORAGE OF PRESCRIBED MEDICATION: A QUESTIONNAIRE STUDY

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Background and Importance Due to the increase in the elderly population in Korea, the number of powdered medicines and long-term repackaging of prescriptions has increased. As a result, the safety of medicines is becoming vulnerable.
Aim and Objectives This study aims to find out how elderly patients perceive the expiration date and storage of prescription drugs and to consider appropriate patient education for the safe use of drugs.
Material and Methods A cross-sectional study was conducted among 221 elderly outpatients from 14 December 2022 to 21 April 2023 at Veterans Health Service (VHS) medical centre in Seoul, South Korea. The questionnaire was divided into five parts. We used a Chi-squared test and Fisher's exact test to compare each group and $p<0.05$ was considered statistically.
Results A survey of 213 people was analysed, excluding eight who dropped out. When asked about the expiration date of the prescribed medicines, the most people responded '3 months'. The main storage place for medicines was the 'living room/bedroom drawer' at 30.52%. The main storage places for powdered medicines were 28.64% for 'refrigerator/kimchi refrigerator' and 26.29% for 'living room/bedroom drawer.' There were 136 people (63.85%) who responded that they would grind 3 months' worth of powdered medicine at once, and the most common reason given by 66 people (30.99%) was 'difficulty in grinding'. Seventy-seven people (36.15%) said they would crush the pill every time they took it, and the most common reason was 'risk of deterioration' at 37 people (17.37%). There was no statistically significant difference when analysing the perception of expiration date and storage of medicines according to drug managers and perception of powdered medicine according to whether or not to prescribe powdered medicine.
Conclusion and Relevance Elderly patients recognised the expiration date of oral medicines was shorter than recommended by the Korean Pharmaceutical Association. There was also a lack of awareness of how to properly store medicines. Therefore, in consideration of drug safety, long-term prescriptions, repackaged prescriptions, and powdered preparations should be avoided if possible. If medical institutions conduct patient education for the safe use of medicines, they will be able to provide proper pharmacist services that consider the safety of medicines.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-224 MEDICATION RECONCILIATION IN A SURGERY DEPARTMENT: 6-MONTHS' EXPERIENCE

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Background and Importance Medication Reconciliation (MR) allows us to reduce medication errors that are very likely to occur in care transitions like admission, transfer and clinical discharge. In our country, a few hospital institutions have MR, although the effectiveness of this method and Pharmaceutical Interventions (PI) in preventing adverse reactions, drug interactions and prescription errors. is known.
Aim and Objectives Establishing MR for patients at a vascular surgery department, in a tertiary care university hospital, to evaluate its impact in prescription error prevention and to characterise PI and its acceptance in our centre.
Material and Methods MR applied in the first 48 hours of patient admissions between April 2023 and September 2023. Inclusion criteria: age $\geq$ 35 years, presence of comorbidities and pharmacotherapy with $\geq$ 3 drugs. Elaboration of Best Possible Medication History (BPMH) taking $\geq$ 3 sources of information into account, comparison with medical prescription for identification and classification of discrepancies. Discussion of PI with prescribers, data recording and analysis using Microsoft Excel.
Results Of 210 patients (77.4% male), 16 were excluded for intervention rescheduling, sudden clinical discharge or transfer between departments. Medium age was 70.7 years [range 35; 92] and we found a medium of 4.7 comorbidities per patient as hypertension, dyslipidaemia and diabetes were the most prevalent. For BPMH gathering, medical records (28.8%), patient interview (25.0%) and drug packaging (20.2%) were the most used sources of information. In 202 MR, 3,010 prescription lines were analysed and 77.5% of them contained discrepancies. Of those, 31.5% were unintentional with potential to cause harm to patients. A total of 761 PI were made with 89.1% acceptance by prescribers, mostly for drugs with cardiovascular (32.5%), central nervous system (18.8%) and endocrine (13.9%) action. Drug omission was the most frequent medication error (62.8%), followed by erroneous dose (16.9%) and erroneous drug (6.1%). It was detected 348 pharmacological interactions and 37 adverse events with independent PI, whenever patient harm was considered.
Conclusion and Relevance MR allowed us to reduce and prevent a major number of medication errors, as almost 90% of PI were accepted by physicians. This method should be implemented in most susceptible hospital departments, as a clinical pharmacist presence benefits all of the healthcare team, the patient and medication safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-225 DEFINING INTERNATIONAL CRITICAL CARE PHARMACIST ASPIRATIONS TO THE MANAGEMENT OF SEPSIS

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Background and Importance Clinical pharmacist input in intensive care unit (ICU) patient care varies greatly among different countries and settings.
Aim and Objectives To identify areas of desired professional contribution and development, whilst exploring variability. This is envisaged to support leadership activities to enhance the clinical pharmacist workforce based on evolving ICU infrastructures.
Material and Methods Clinical pharmacists involved in the management of sepsis in the ICU setting were surveyed using semi-structured interview methods. Institutional ethical approval for the study was obtained, which included a data protection impact assessment. Recruitment via non-probability convenience and snowball sampling of registered pharmacists proficient in the English language occurred between 31 May 2013 and 13 July 2023. Data saturation determined the sample size. Remote interviews were conducted via Zoom. Interviews were transcribed, coded and thematically analysed in line with Braun and Clarke's six-stage process. As this was an exploratory study, no theoretical assumptions were addressed.
Results Twenty participants from 14 countries participated. Reported aspirations varied between pharmacists working in dedicated ICU roles based at the bedside and non-dedicated ICU roles with little/no bedside component. Overcoming multifaceted professional barriers associated with physical, social, financial and training/education themes relative to local/national contexts were consistently reported. As were research aspirations. Physical and social themes were associated with scope of practice and ICU/patient record access. This included sepsis identification, initiating antimicrobials, individualising/altering antimicrobial dosing and ownership of therapeutic drug monitoring (TDM) activities. Improving multidisciplinary team integration, stakeholder perceptions, digital infrastructures and legislation were identified as key vehicles. Improved financial incentives were interlinked with stakeholder perceptions and metric capture associated with pharmacist contributions. Whereas education/training was desired for workforce standardisation, increasing scope of practice and improving research outputs. Including increased/improved TDM practices supplemented by pharmacokinetic/pharmacodynamic expertise, enhanced by point-of-care devices and metagenomics.
Conclusion and Relevance The content and variation in ICU clinical pharmacist aspirations worldwide reflects a broader disparity in ICU clinical pharmacist adoption/contribution worldwide, particularly in Europe. Leadership and research addressing study identified themes is required to enable pharmacists to maximise their impact on the care of septic patients. This must demonstrate the value of ICU clinical pharmacists to different stakeholders to promote adoption, capability enhancement and research outputs.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

4CPS-226 PHARMACEUTICAL INTERVENTION ON THE ADEQUACY OF THE INDICATION OF SEMAGLUTIDE IN DIABETES MELLITUS 2

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Background and Importance Semaglutide is a GLP-1 analogue approved for the treatment of adults with poorly controlled type 2 diabetes mellitus (DMII). It has been shown to reduce blood glucose levels and the risk of health complications. It

also produces weight loss, an effect considered beneficial in this type of patient. This has led to inconsistent prescribing, and it has even been used to reduce weight in obese non-diabetic patients. As a consequence of the increase in inappropriate use, in March 2023 the Spanish Agency for Medicines and Health Products issued a shortage alert.

Aim and Objectives Implementation of a strategy to review the suitability of semaglutide to its therapeutic indication and intervention in inappropriate prescriptions.

Material and Methods Prospective descriptive study including all patients on active treatment with semaglutide. An intervention strategy was implemented by reviewing all medical prescriptions, stratifying patients by hospital services, and drawing up lists of patients who did not comply with the authorised indications. In August 2023, meetings were held with the doctor in charge of each department to communicate the need for review and the suspension of treatment of patients who did not comply with the indication.

Results Sixty patients were reviewed, 62% male, with a median age of 54 years. Active semaglutide prescriptions by hospital services were as follows: 55% Endocrinology, 18.3% Cardiology, 16.7% Internal medicine, 3.3% Nephrology, 3.3% Mental health, 1.7% Dermatology and 1.7% Traumatology. 28.3% of patients had DMII, 46.7% did not and 25% had pre-DMII. Of the patients without DMII, 100% were obese. It was agreed to suspend treatment for all patients who did not comply with the indication.

Conclusion and Relevance The procedure has provided insight into the conditions under which semaglutide is being used. In the context of stock-outs, the suspension of semaglutide in patients with off-label use allowed access for poorly controlled diabetic patients. The adequacy review can be extrapolated to the abuse and/or misuse of any drug as part of the rational medicine use strategy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-227 PHARMACEUTICAL REVIEW AND PHARMACEUTICAL INTERVENTION IN A NURSING HOME TO ENHANCE THE MEDICATION MANAGEMENT OF RESIDENTS

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Background and Importance Geriatrics is particularly concerned by iatrogenic medication accidents, especially in nursing homes (NH) where residents are often polypathological and can spend months without treatment revaluation.

Aim and Objectives Enhance the medication management of residents in NH.

Material and Methods Pharmaceutical review (PR) conducted during multidisciplinary meetings, based on computerised prescriptions, biological and clinical data from the electronic patient record, and then compared to national references. Subsequently, the pharmaceutical interventions (PI) carried out are quantified and analysed.

The anticholinergic score (AS) was calculated for each resident using two assessment scales: the ACB (Anticholinergic Cognitive Burden) and CIA (Cholinergic Drug Burden) scale.

Results Among 71 residents, 142 PIs were carried out, with a 58.5% acceptance rate (n=83) of the physician, averaging two PIs per resident.

Most PIs (33.1%; n=47) concerned unsuitable medication for the elderly, with a 61.7% acceptance rate. Initially, 62 potentially inappropriate medications (PIMs) were identified for 38 residents, averaging 0.87 PIMs per resident. After the PR: only 33 PIMs remaining for 25 residents, averaging 0.47 PIMs per patient.

A high AS was found for 20 residents. Twenty-six PIs (18.3%) with a 42.3% acceptance rate (n=11) were performed in attempts to reduce these AS: which resulted in a decrease from five residents with a significant ACB score to three, and from 15 residents with a high CIA score to 11.

Seventy-four PIs (52.1%) were related to nervous system drugs. After a multidisciplinary discussion with geriatricians and psychiatrists, 43.2% of these PIs (n=32) were accepted. Substitution was the most recommended type of PI (n=38), resulting in a modest reduction in psychotropic drug consumption (9.7%).

Conclusion and Relevance This NH accommodates residents with psychotic disorders, behavioural issues, and intellectual disabilities, which explains the low acceptance rate of PIs related to psychotropic drugs and the difficulty in reducing the AS. Beyond the acceptance of PIs, the PR enables the coordinating physician to re-evaluate the overall therapeutic management of residents, and helps mitigate the underuse, overuse and misuse of medications, which are quite common in geriatrics.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-228 IMPACT AND ACCEPTANCE OF PHARMACEUTICAL INTERVENTIONS FOR EARLY MEDICATION RECONCILIATION IN THE EMERGENCY DEPARTMENT

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Background and Importance Emergency departments (EDs) are characterised by high care load, staff rotation and critical situations that require rapid decisions. Early conciliation in high-risk patients may improve patient safety during care transitions.

Aim and Objectives To establish a protocol of early medication reconciliation process in ED and re-evaluation in patients with complexity criteria (validated by Hohl et al.). Medication review by referent pharmacists in ED and their interventions were evaluated for acceptancy rate and quality.

Material and Methods A protocol of medication reconciliation was developed based on the 'Consensus document of RED-FASTER and SEMES-FARMA group for Medication reconciliation in ED'. Reinitiation priority of each pharmacologic group was evaluated individually, considering the benefit of their reconciliation during ED stay and defining those drugs whose reconciliation is recommended to be done in the first 12 hours.

This protocol was implemented in a third-level hospital with 330 average daily ED assistance and five daily hours of presential pharmaceutical activity.

ED pharmacists made individual recommendations: early reconciliation was performed in all patients reviewed, and remaining conciliation interventions were performed in patients with stays longer than 12 hours and complexity criteria.

Results The chronic medication of 1,645 patients was reviewed over a 2-month period: 475 recommendations of early reconciliations were given in 337 patients and physicians accepted 248 (52.32%). Demographic data: 73 (13,64) average age, 196 (58,16%) men. Mean time of recommendations from arrival to ED was 6.73 hours. Time average of reintroduction by physicians was 10,38h. Within the first 12 hours, 179 drugs (72.18%) were introduced.

Forty pharmacological groups were recommended to be reintroduced: insulin and analogues (A10A) and beta blockers (C07A) were the most recommended (N=236), following others: antithrombotic (B01A) (N=37), Calcium channel blockers (C08C) (N=34), immunosuppressant (L04A) (N=37), antiepileptic (N03A) (N=33), nitrates (C01DA) (N=18).

A total of 402 patients with stays longer than 12 hours and complexity criteria were reviewed, leading to 171 recommendations.

Pharmaceutical interventions were analysed over a period of 2 months comparing before and after protocol application: variety of intervention were similar, but quantity increased after protocol implementation (531 vs 1043 interventions).

Conclusion and relevance Early conciliation led to early reintroduction of priority drugs, ensuring safety and quality across care transitions and with a high rate acceptance among physicians.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

4CPS-229 SUSTAINABILITY: A PERSON-CENTRED, WHOLE SYSTEMS APPROACH TO MEDICINES OPTIMISATION

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Background and Importance Suboptimal medicines use is a challenge for health systems globally, contributing to suboptimal outcomes, inefficiencies and sustainability issues, including waste.

Aim and Objectives The aim was to utilise the Clinical Pharmacy Team to drive medicines optimisation and sustainability in a Health and Social Care Trust through the safe, effective and economic use of medicines.

Material and Methods In 2001, a person-centred, whole systems approach to medicines optimisation was implemented in a Health and Social Care Trust. Central to the model was a ward-based Clinical Pharmacy team delivering a comprehensive clinical pharmacy service including medicines reconciliation, medicine review, patient education, interface communication and extended roles for the Clinical Pharmacy team. Evaluation included length of stay, readmission, medicines appropriateness using the Medicines Appropriateness Index and clinical significance of pharmacist interventions using the Eadon grading tool. The model was further developed and evaluated over two decades to include pharmacist prescribing, post-discharge telephone follow-up and person-centred structured medicine review and was extended to include nursing and intermediate care settings.

Results Initial evaluation demonstrated significantly improved medicines appropriateness, reduced length of stay (2 days) and readmission (number needed to treat =12). Further benefits were achieved through post-discharge telephone follow-up (10% reduction in readmission) and structured medicine reviews (94.7% interventions deemed clinically significant and 92% of medicines stopped remained stopped 1year post-review).

Conclusion and Relevance This work has demonstrated improved medicines optimisation and sustainability and has been scaled and spread to other European countries including Austria and Poland. It has been identified as an example of best practice to inform Clinical Pharmacy Services in Central and Eastern Europe[1] and work is ongoing to innovate and further develop the model.

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Conflict of Interest No conflict of interest.

4CPS-230 IDENTIFICATION OF RARE DPYD VARIANTS ASSOCIATED WITH TOXICITY TO FLUOROPYRIMIDINES IN A CLINICAL PHARMACOGENOMICS PROGRAMME

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Background and Importance Dihydropyrimidine dehydrogenase (DPYD) is a key enzyme in the metabolism of fluoropyrimidines. Patients with deficiency in DPYD are at great risk of severe adverse events when treated with fluoropyrimidines (5-fluorouracil, capecitabine). It is recommended that patients are screened for the most common variants in this gene before initiating chemotherapy. However, some patients still develop early serious toxicities.

Aim and Objectives We report the result of a clinical pharmacogenomics programme targeted to patients who developed toxicity with fluoropyrimidines. The aim was to identify rare variants in the DPYD gene associated with severe toxicity, and to provide patients and clinicians with pharmacogenomic counselling.

Material and Methods Patients who suffered severe toxicities (grade≥3) during their first three cycles of treatment with fluoropyrimidines were identified by their oncologist or oncology pharmacist. They were all negative for the four recommended variants (DPYD*2A, c.2846A>T, c.1679T>G, and c.1236G>A). A methodology for sequencing the 23 exons of DPYD was developed by the Pharmacogenomics Unit, integrated in the Hospital Pharmacy Department. The study was approved by the local Ethics Committee. Patients were informed and gave consent to participate in the programme.

Results Since 2017, 91 patients have been included in the programme and 32 variants in DPYD were identified. Nine of

these 32 variants were associated with the development of severe toxicity in these patients (c.257C>T, c.704G>A, c.775A>G, c.851G>T, c.1977–1984-CTCCAGAA>C, c.2197insA, c.2242+1G>T, c.2324T>G and c.2087G>A). As a result of the programme, the cause for toxicity was found in 10% (9/91) of patients. The results of the test together with a dose adjustment recommendation were communicated to patients and included in their electronic medical record to make the information available for the oncologist and the rest of the clinical team.

Conclusion and Relevance This programme helped us to identify uncommon variants in the DPYD gene that were associated with toxicity to fluoropyrimidines in a clinical practice setting. These variants will be included in a new test that is currently under development. We believe that performing this extended test before initiating treatment can improve patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-001 INCIDENCE OF HEPATITIS B VIRUS REACTIVATION IN PSORIASIS PATIENTS TREATED WITH CYTOKINE INHIBITORS: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Background and Importance The safety of cytokine inhibitors in psoriasis patients with hepatitis B virus (HBV) remains uncertain due to their exclusion from clinical trials. Observational studies have recently raised clinical concerns about HBV reactivation (HBVr) risk in psoriasis patients using cytokine inhibitors, but a comprehensive systematic review is still lacking.

Aim and Objectives This study aimed to evaluate the risks of HBVr in psoriasis patients treated with cytokine inhibitors.

Material and Methods Following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses, we conducted a systematic literature search in PubMed, Embase, Web of Science, and Cochrane Central Register of Controlled Trials for relevant observational studies on 5 May 2023. We included studies with >5 cases and complete HBV status. Two independent reviewers performed the study selection and data extraction, and the discrepancies between reviewers would be solved by the full discussion. A random-effects meta-analysis assessed the pooled incidence of HBVr. We also conducted subgroup analyses to compare HBVr incidence across different cytokine inhibitors and HBsAb status.

Results Eight observational studies comprising 181 psoriasis patients were included. Among HBsAg+ individuals without antiviral prophylaxis, the pooled HBVr incidence was 25.3% (95% CI: 10.4 to 49.7%) with a median onset at 5 months (range: 3–7 months) from the cytokine inhibitor initiation. No HBVr events were observed in HBsAg+ individuals with antiviral prophylaxis. Among HBsAg−/HBcAb+ individuals, the pooled HBVr incidence was 5.0% (95% CI: 2.3 to 10.8%) with a median onset at 12 months from the cytokine inhibitor initiation. Subgroup analysis showed similar pooled HBVr incidence for IL-12/23 inhibitors (4.0%, 95% CI: 1.3 to 11.8%), IL-17 inhibitors (6.6%, 95% CI: 1.9 to 20.5%), and IL-23 inhibitors (5.0%, 95% CI: 0.3 to 47.5%). No significant risk difference was found between patients with and without HBsAb (risk difference: −0.01%; 95% CI −0.16 to 0.13%).

Conclusion and Relevance This systematic review and meta-analysis shed light on the incidence of HBVr associated with cytokine inhibitors in psoriasis patients. Prophylactic antiviral use is crucial for patients with HBV. Physicians and pharmacists must ensure proper HBV protection through prophylaxis and monitoring when administering cytokine inhibitors, in addition to adhering to recommended HBV vaccination.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-002 PRESCRIBING TREND OF FLUOROQUINOLONES FOLLOWING LATEST EMA RECOMMENDATIONS

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Background and Importance The European Medicines Agency (EMA), following a 2018 European-wide review to assess the risk of serious and disabling adverse reactions, has recommended that the use of fluoroquinolones should be restricted. In 2019, the use of these antibiotics was significantly limited. However, a subsequent study, showed that these drugs are still prescribed outside the recommended uses. For this reason the EMA, in May 2023, issued a reminder.

Aim and Objectives The aim is to analyse the prescribing trend of fluoroquinolones, following EMA's reminder.

Material and Methods Analysis of prescription (PR) dispensed through community pharmacies, relating to the active ingredients (p.a.) classified with the anatomic, therapeutic and chemical classification (ATC) J01MA. The period considered is from 2017 to 2022. The analysed data were in the pharmaceutical service database, grouped by p.a./ATC, patient's age and was processed via Microsoft Excel.

Results The number of PR of p.a. analysed decreases significantly starting from 2019. Pefloxacin and pipemidic acid are no longer prescribed from 2020. Approximately 50% of the PR, per single p.a., are intended for patients aged 65 or over (302314/601603 total PR in 6 years). The most prescribed p. a. are levofloxacin (273976 total PR) and ciprofloxacin (290553 total PR); the number of PR of these two p.a., in 2021, decreased by 66% (from 74705 to 25032) and 41% (from 65980 to 38916) respectively compared to 2017. However, in 2022 there was an increase of 14% (28741 PR) for levofloxacin and 7% (41785) for ciprofloxacin, compared to the previous year. In the remaining p.a., excluding moxifloxacin, no prescribing increase was observed between 2021 and 2022.

Conclusion and Relevance The restrictions introduced by EMA aim to reduce the risk of disabling and potentially irreversible side effects linked with fluoroquinolones use, especially in the elderly population. The results suggest that the restrictions introduced in 2019 have been adopted effectively, resulting in a decrease of prescriptions up to 2021. The increase of levofloxacin, ciprofloxacin and moxifloxacin observed in 2022 could be caused by reduced prescribing attention, shortage/

ineffectiveness of other antimicrobial classes, or local respiratory infections outbreak. The EMA recall released in May 2023 represents a tool to strengthen the attention about fluoroquinolones and avoid their prescription outside the recommended uses.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-003 IMPROVING MEDICINES MANAGEMENT OF INPATIENT PARKINSON'S DISEASE PATIENTS BY MAKING PHARMACY INTERVENTIONS

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Background and Importance Hospital admissions of Parkinson's disease (PD) patients can result in medication regimen disruptions causing adverse effects for PD patients. Evidence shows that interventions can reduce medication-errors and administration of contraindicated medicines in PD patients.
Aim and Objectives The study aim was to quantify the impact of a pharmacist's involvement in optimising medicines management of inpatient PD patients.
Material and Methods A 2-month 'baseline' audit was completed prior to intervention implementation and measured patient demographics, delay in first dose following admission, medication errors (missed/delayed doses), pharmacist medicines reviews and time until completion and patient outcome (prevalence of falls, delirium, rigidity). The outcome of patients who were 'nil by mouth' was also assessed. Three interventions were implemented over a 1-month period. These were priority pharmacist medicines reviews of PD patients, PD medication ward stock optimisation and doctor/nurse PD medicine management education sessions. A post-intervention audit identical to the 'baseline' audit was completed and both audits were compared.
Results The 'baseline' audit (mean age 81, 24 patients, 1,611 due doses) and the post-intervention audit (mean age 80, 30 patients, 1,840 due doses) were analysed. Medicine reviews increased from 79% to 97% ($p=0.042$) and these were completed 38.7 hours ($p<0.001$) sooner post-admission. A reduction in first dose delay was seen (13.5 vs 4.4 hours ($p<0.001$)), along with reductions in delayed (5% to 1% ($p=0.037$)) and missed doses (8% to 2% ($p<0.001$)). Omitted pre-admission PD medications reduced from 16% to 2% ($p=0.011$). Staff education contributed to recorded due times increasing from 44% to 97% ($p<0.001$). Contraindicated medicines were administered at reduced rates in the post-intervention audit. The length of admission was shorter due to the combination of interventions (19 vs 15 days ($p=0.475$)). These improvements resulted in a reduced prevalence of falls (25% to 17%), delirium episodes (29% to 7%) and rigidity (54% to 7%). Patients were more able to interact with allied health professionals in the post-intervention audit (46% vs 100%). Improvements in non-oral PD medicines prescribing occurred in 'nil by mouth' patients.
Conclusion and Relevance This study showed the introduction of the pharmacist-led interventions can improve PD inpatient outcomes, by reducing medication errors, decreasing the administration of contraindicated medicines and preventing delays in the administration of PD drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-004 COMPARISON BETWEEN BEERS 2019 CRITERIA AND THE EURO-FORTA 2018 LIST IN THE IDENTIFICATION OF POTENTIALLY INAPPROPRIATE MEDICATION IN ELDERLY PATIENTS IN THE PRIMARY HEALTHCARE CONTEXT

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Background and Importance Inappropriate prescription is a risk factor for adverse drug reactions and hospitalisations in the elderly. Concerns about its impact in this age group have led to the development of various strategies to address this issue, with a focus on tools for detecting potentially inappropriate medication (PIM), notably the Beers criteria and the EURO-FORTA list.
Aim and Objectives To compare the 2019 Beers criteria with the 2018 EURO-FORTA list and show their applicability on the primary healthcare context.
Material and Methods We conducted a cross-sectional observational study in a population of patients over 65 years old enrolled in a family health unit in Portugal. Classification of all drugs and active diagnoses in the family health unit according to the tools under analysis. Cross-referencing drugs identified as PIMs according to both instruments with the family health unit database, resulting in the identification of PIMs for each patient, considering their conditions.
Results Twenty-nine of the PIMs according to the Beers criteria are not PIMs according to the EURO-FORTA list; 54 of the PIMs according to the EURO-FORTA list are not PIMs according to the Beers criteria; 47 drugs recommended by the EURO-FORTA list are PIMs according to the Beers criteria. The study included 2,775 patients, 59.70% of whom were on polypharmacy. The prevalence of PIMs was 13.41% according to the Beers criteria and 35.78% according to the EURO-FORTA list, with a higher number of PIMs in women in both instruments. The most frequently prescribed PIMs were benzodiazepines for both tools, followed by antipsychotics and antidepressants.
Conclusion and Relevance The levels of polypharmacy and prescription of PIMs in the presence of certain diseases are considerable in the elderly, in the context of primary healthcare, with both tools being useful in the detection of PIMs. However, there are important differences in the drugs they include, which must be individually analysed from a pharmacotherapeutic point of view. Regarding the integration of these tools into a clinical decision support system, it is concluded that both instruments should be computerised together to take advantage of the benefits of each one and to address the shortcomings that both present.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-005 UTILITY OF THE THERAPEUTIC COMPLEXITY INDEX ADAPTED TO CRITICALLY ILL PATIENTS AS A METHOD OF STRATIFICATION FOR PHARMACEUTICAL CARE

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Background and Importance Intensive Care Unit workload pharmacist providing ICU clinical services has not been optimised.

Aim and Objectives To measure the complexity of medication regimens in adult ICU and analyse the utility of this indicator as a method for patient stratification in pharmaceutical care for critically ill patients.

Material and Methods Observational, descriptive, prospective study conducted at a third-level hospital. A cross-sectional approach was employed to review treatment regimens and measure the MRC-ICU (Medication Regimen Complexity Intensive Care Unit Index) for all ICU adult patients admitted.

Demographic variables and 23 items related to each patient's treatment and clinical conditions were collected, then these items were scored as defined in table 2 of Gwynn et al. The MRC-ICU was calculated by summing the total score of the 23 items.

Results Seventy-one patients were included in the study (70% bed occupancy; 65% male), with a mean age of 58 ± 16.6 years.

Among these, six patients (8%) were classified as neurocritical, 12 with respiratory failure, 11 with traumatic injuries, 11 with coronary conditions, four postoperative cardiac patients, 17 post-lung transplants, five with septic shock and five with digestive semi-critical conditions. The average number of prescribed medications per patient was 18 ± 7.

At the time of the study, the mean length of stay was 22 ± 24 days, and the mean MRC-ICU was 13 ± 8. Respiratory failure exhibited the highest MRC-ICU (median 19; IQR 10–23), followed by post-lung transplant patients (median 17; IQR 14–23), septic shock (median 12; IQR 10–16), post-operative cardiac cases (median 10.5; IQR 9–12), and neurocritical conditions (median 9; IQR 5–14). The drugs contributing most to complexity were antibiotics, continuous perfusion sedoanalgesia, and immunosuppressants.

Conclusion and Relevance In our study, patients admitted to the ICU due to Acute Respiratory Failure or following Lung Transplantation exhibited MRC-ICU.

These patients may be considered as candidates for prioritised pharmaceutical care.

To optimise resources It would be necessary to correlate the score with the interventions performed by the pharmacist upon admission to the unit and those accumulated until discharge.

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Conflict of Interest No conflict of interest.

5PSQ-006 FREQUENCY OF CREATININE TESTING AND ACUTE KIDNEY INJURY IDENTIFICATION AND STAGING

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Background and Importance Criteria to identify and stage acute kidney injury (AKI) establish time intervals when the serum creatinine (SCr) should increase to be considered AKI. These intervals range from 48 hours to 7 days (depending on AKIN or KDIGO criteria). Subsequently, a timely SCr test should be performed to inpatients, preferentially no longer than 48 hours.

Aim and Objectives To evaluate the impact of real-world SCr testing hospital practice for the identification and staging of AKI.

Material and Methods A historical cohort study with data from medical records of patients admitted to hospital between 1 June 2018 and 31 December 2020, was conducted. AKI stage was calculated using two criteria: AKIN and KDIGO. Identification and staging were first done considering the time intervals when the SCr increase should be identified as described in the two criteria. Then, a second staging process was conducted ignoring the time intervals and considering all the hospitalisation time. Length of stay (LoS) was calculated by adding 1 day to the difference between discharge and admission dates. Creatinine clearance was estimated using the Cockcroft-Gault equation. A list of drugs that require dose adjustment when CrCl achieves 50 mL/min was obtained from the Renal Drug Handbook 3rd edition.

Results During the study period, 17,269 hospitalisations and 62,255 SCr tests were recorded. Among the 17,032 hospitalisations with LoS >48h, 46.8% presented periods >48h with no SCr tests performed. In 3.5% of hospitalisations the patient's weight was not registered. Any stage of AKI was identified in 7.0% and in 9.1% of patients using AKI and KDIGO criteria, respectively. When ignoring time limits in both criteria, potential AKI could have occurred in 1,942 patients (11.2%). A total of 76 different drugs requiring dose adjustment in patients with eGFR ≤50 ml/min were prescribed in 78.5% admissions, and 30.3% of all admissions included patients prescribed with these drugs that reached eGFR <50 ml/min.

Conclusion and Relevance Our study suggests that real-world SCr testing hospital practice for the identification and staging of acute kidney injury may not be sufficient to identify all the AKI occurrences. Organisational or legal changes are necessary to contribute to timely use of analytic values to optimise therapy and thus increase patient safety.

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Conflict of Interest No conflict of interest.

5PSQ-007 A REVIEW OF MEDICATION RECONCILIATION IN THE PERIOPERATIVE PERIOD: VARIABLES THAT LEAD TO MEDICATION ERRORS

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Background and Importance Medication reconciliation (MR) builds the bridge between the patients' current medication, and their received treatment during hospitalisation. Pharmacists have an active role in preventing omissions, duplications, dosing errors, or drug interactions; this is all the more evident when it comes to the perioperative period, where a correct management on medication becomes imperative to the patients' safety.

Aim and Objectives To evaluate which pharmacological groups are prone to lead to medication errors during the perioperative period and to find a possible correlation between said errors and the patients' demographic factors and prescription-based factors.

Material and Methods Prospective observational study from July to September 2023 in a second-level hospital. We reviewed patients' prescriptions in traumatology, ophthalmology, urology and general surgery wards, and selected those with chronic medication with clinical evidence on their reconciliation during the perioperative period. We divided the perioperative period into pre-op and post-op, and analysed discrepancies in MR. Variables such as patients' age, gender, duration of admission and number of prescribed medications were taken into account. To obtain this information, we used Mambrino XXI® (electronic prescription software), and FarmaTools® for pharmaceutical validation processes.

Results Fifty-two patients' prescriptions were analysed and a total of 214 medications were reviewed. The median age for this group was 67 years, where 56% were male. The median number of medications per patient was four (1–13). The duration of admission had a median of 5 days (2–46 days). 50% of admitted patients' MR was successful on pre-op processes, in contrast to 42.3% in post-op processes. When reviewing the percentage of errors in variables included in the study, we found that: Statins (65% pre-op, 55% post-op) and diuretics (50% pre-op, 36% post-op) are the most affected groups. Duration of admission >5 vs. <5 days (64,7% vs. 65,7%). Number of prescriptions >4 vs. <4 (63% vs. 70%).

Conclusion and Relevance Although MR in the perioperative period can be a rigorous process; it is a must-have in any hospital to guarantee patients' safety. Pharmaceutical interventions are key to prevent risks due to medication errors; especially in those prone to error. A more precise statistical model is needed to figure out which variables lead to medication errors in the perioperative period.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-008 IMMUNE-MEDIATED HEPATITIS SECONDARY TO TREATMENT WITH PEMBROLIZUMAB. A CASE REPORT

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Background and Importance Immune-mediated reactions play a major role in immunotherapy, so it is important to monitor patients and follow-up to improve patient safety.

Aim and Objectives To describe a case of immune-mediated hepatitis secondary to the use of pembrolizumab and multidisciplinary intervention in its management.

Material and Methods An 81-year-old patient diagnosed with advanced amelanotic nodular melanoma, with lung and axillary metastasis. Data obtained from the digital medical record and from the chemotherapy electronic prescription program. Safety profile of pembrolizumab in its technical data sheet (TDS) and the literature reported cases of hepatobiliary disorders with pembrolizumab were reviewed.

Results The patient began treatment with pembrolizumab 200 mg/3weeks for metastatic disease. Prior to the third infusion, she reported regular general condition, asthenia and dysgeusia, with elevation of transaminases (aspartate-transaminase: 31U/L (1–32); alanine-transaminase: 130U/L (0–55)) and total bilirubin: 1.60 mg/dL (0.30–1.20), diagnosing grade 4 immune-mediated hepatitis.

Specialist contacted with the hospital pharmacist to confirm whether it was an adverse effect (AE) secondary to pembrolizumab. The pharmacist performed a review of the TDS and literature that confirmed the event (hepatitis is described as a frequent AE ($\geq$ 1/100 to < 1/10)).

Treatment with pembrolizumab suspended and the patient required immunosuppressive treatment (pulses of methylprednisolone and mycophenolate-mofetil). A control CT-scan showed a decrease in the size of the metastases.

After 2 weeks, the patient was asymptomatic and had grade 1 immune-mediated hepatitis, so restarted treatment with immunotherapy, switching to nivolumab 240 mg twice weekly. Close monitoring of transaminases levels and maintenance of immunosuppressive treatment continued.

The suspected AE notified to the Spanish Pharmacovigilance System and a causal relationship between the drug and the AE established according to the Naranjo Algorithm, obtaining a score of 5, which establishes a probable relationship.

Immune-mediated hepatitis is an AE also described with nivolumab, which was well tolerated by the patient, which did not occur with pembrolizumab despite having a similar safety profile.

Conclusion and Relevance Close monitoring and follow-up of AEs associated with drugs is important, as the participation of the pharmacist in multidisciplinary teams, validating treatments and carrying out their monitoring. All of this contributes to an improvement in the management of AEs and in patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-009 OFF-LABEL USE OF INTRAVENOUS CYCLOPHOSPHAMIDE IN SYSTEMIC LUPUS ERYTHEMATOSUS PRESENTING AS ACUTE LUPUS PNEUMONITIS: A CASE REPORT

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Background and Importance Systemic lupus erythematosus (SLE) is a multisystem autoimmune disease with wide-ranging pleuropulmonary manifestations. Acute lupus pneumonitis (ALP) is one of its uncommon complications. Systemic steroids associated with immunosuppressive therapy (cyclophosphamide, rituximab, hydroxychloroquine and intravenous immunoglobulin) are the mainstream treatment of ALP.

Aim and Objectives To describe the case of a patient with ALP treated with intravenous cyclophosphamide as well as to evaluate the effectiveness and safety of this treatment.

Material and Methods We report the case of a 67-year-old woman with a medical history of breast cancer and polymyalgia rheumatica treated with corticosteroids. She was referred to the emergency department due to intermittent fever, fatigue, generalised myalgia and arthralgia, mild dyspnoea and dry cough with sputum for the past 3 weeks. Multiple and bilateral lung opacities were present on chest X-ray so she was diagnosed with community-acquired pneumonia. The woman presented slight improvement despite empirical antibiotic and antifungal coverage. Subsequently, laboratory findings showed leukopenia and positive anti-double-stranded-DNA antibodies so the final diagnosis was ALP secondary to SLE. Systemic steroid treatment was initiated with a high-dose of methylprednisolone and hydroxychloroquine. Due to the severity of the pulmonary involvement, it was requested to start treatment with intravenous cyclophosphamide.

Results The patient received a total of three doses (600 mg/m2) of intravenous cyclophosphamide. MESNA, ondansetron and oral hydration were prescribed as supportive treatment. Despite the decrease in inflammatory analytical parameters, the woman presented modest reduction of lung injury and symptoms. She reported high-grade myalgia and vomiting after first infusion, which was successfully treated with paracetamol and metoclopramide. Sequential therapy with oral cyclophosphamide was considered, but because it is not funded for ALP and its adverse effect profile, treatment with methotrexate was started. Currently, the patient continues treatment with methotrexate, hydroxychloroquine and oral steroids. Computed tomography, performed 3 months after ending intravenous cyclophosphamide, showed stability of the disease.

Conclusion and Relevance Treatment with intravenous cyclophosphamide has not shown promising results in our patient although its safety profile is good. Because the therapeutic alternatives in patients with ALP are limited, it would have been interesting to verify that sequential therapy with oral cyclophosphamide improves the signs and symptoms of the disease, and long-term adverse effects could also be analysed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-010 NATIONAL STANDARDISATION OF PRETERM PARENTERAL NUTRITION IN NEONATAL UNITS

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Background and Importance Parenteral nutrition (PN) is a high alert medication, essential for the survival of infants born preterm. European expert guidelines recommend that standardised parenteral nutrition (SPN) rather the individualised (IPN) is used for the majority of infants, due to increased patient safety and resource efficiency.[1] There has been a failure to implement this practice, with large variations in the quality and models of PN provision and practices.[2,3]

Nationally, neonatal units (NUs) have introduced a precision SPN system, including two externally compounded SPN bags and accompanying clinical decision support tool. The SPN system, developed over 10 years of multidisciplinary translational research has demonstrated improved clinical and economic outcomes.[4,5] In 2018 the SPN system was endorsed as the national Model of Care for Preterm Standardised Parenteral Nutrition and an implementation group oversaw a national rollout, completed mid-2021.

Aim and Objectives To describe the pattern of preterm PN purchased by NUs from before implementation to the completion of national roll-out.

Material and Methods A retrospective analysis of preterm PN purchasing data from NUs (n=13) over 6 years, 2017 – 2022.[6]

Results The percentage of preterm SPN purchased by NUs increased nationally year on year from 56% (3,662/6,522) pre-implementation to 95% (4,823/5,074) in the first full year following a national rollout. This corresponded to a ~90% reduction in IPN purchased nationally.

Conclusion and Relevance This is the first time a country has reported this level of preterm SPN usage, delivering safe and equitable care. A national study is underway to evaluate the implementation and economic impact.

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Conflict of Interest No conflict of interest.

5PSQ-011 TOXICITY OF IMMUNOTHERAPY TREATMENT IN CLINICAL PRACTICE

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Background and Importance Immunotherapy has broken new ground in the treatment of oncological disease. However, it is not exempt from Adverse Events (AE).

Aim and Objectives To analyse and describe the toxicity profile of immunotherapy in clinical practice.

Material and Methods Multicentre descriptive observational retrospective study of patients who initiated immunotherapy treatment (June 2018 to June 2023). Clinical data were obtained from the computerised clinical histories (Doctoris®) and the eOncology® database. The following variables were collected: demographic data (sex and age), smoking status, comorbidities, history of autoimmune disease, oncological diagnosis and stage, treatment line, treatment regimen used, number of administered cycles, and toxicity assessed according to the CTCAE v5 (Common Terminology Criteria for Adverse Events) criteria of the NCI (National Cancer Institute).

Results During the study period, 40 patients (65% male) initiated immunotherapy treatment, median age 67 years [39–87]. 35% were active smokers and 47% were former smokers. The most frequent comorbidities were hypertension 47%, dyslipidaemia 42%, diabetes mellitus 27%, and psychiatric illness 17%. Two patients had an autoimmune disease.

57.5% lung cancer; 12.5% renal cancer; 12.5% melanoma; 10% bladder urothelial cancer; 2.5% gastric cancer; 2.5% hepatic cancer, and 2.5% pancreatic cancer. 63% in first-line immunotherapy treatment, 27% second-line, 10% third-line.

20 patients (50%) experienced at least one immune-mediated AE, mostly of grade 2 (moderate,48%), followed by grade 1 (mild,35%), and grade 3 or higher (severe and very severe,12.5%). Corticosteroids were used in 63%.

In 80% of patients treated with nivolumab, toxicity was observed (20% of which were severe), compared to 50% for durvalumab (non-severe), 50% avelumab (non-severe), 35% pembrolizumab (10% severe), and 16% atezolizumab (non-severe).

Digestive AEs were the most frequent (29.6%), followed by cutaneous AEs (22.2%), musculoskeletal (arthralgia, weakness) (18.5%), and pulmonary AEs (14.8%).

Conclusion and Relevance Immunotherapy is becoming a first-line treatment for several tumours.

Our real-world clinical experience shows that immunotherapy has been reasonably well tolerated, with most immune-mediated AEs being moderate or mild.

Corticosteroids were the most widely used drugs to treat this type of toxicity.

Severe immune-mediated reactions have required hospitalisation and discontinuation of treatment.

A larger sample size and an extended study period are needed to confirm the correlation between treatment response and toxicity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-012 ABSTRACT WITHDRAWN

5PSQ-013 NEW METHOD FOR ASSESSMENT OF ENVIRONMENTAL VIRAL CONTAMINATION OF LIQUIDS PREPARED IN CLOSED-SYSTEM DRUG TRANSFER DEVICES

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Background and Importance Closed system transfer devices (CSTDs) enable sterile preparation and administration of drugs.

Drugs contaminated by microbes harbour clinical risk to patients. Drugs suspected of contamination must be disposed of, adding economic burden to pharmacies. CSTDs can prevent contamination by bacteria and fungi.[1] However, a method for testing CSTDs' ability to prevent viral contamination is needed.

Aim and Objectives The aim was to develop a method for evaluating CSTDs' ability to prevent viral contamination,

including two case studies with CSTDs, only one of which has been published.[2]

Material and Methods Case studies were performed with Chemfort® and PhaSeal™ Optima CSTDs inside a glove box continuously aerosolised with human coronavirus HCoV-OC43. With Chemfort®, reconstitution was simulated by transferring sterile saline from IV bag to vial and back to IV bag. With Optima™, bolus preparation was simulated by transferring sterile saline from vial to syringe, and infusion preparation was simulated by transferring sterile saline into an IV bag. Three repetitions times three technical replicates were performed for each simulation. HCoV-OC43 RNA in syringes and IV bags was quantified by qPCR, including calibration samples. Air sampling verified the continued presence of viral aerosols in the glove box. For negative control, liquid transfers were performed in the presence of sterile medium aerosols.

Results Viral RNA could be quantified at concentrations ≥ 5 PFU/ml.

Chemfort®: No viral RNA traces were detected in any of the nine replicates Optima™: In bolus simulations, viral RNA traces were observed in all nine replicates and were within the quantifiable range for 56% of replicates. In infusion simulations, viral RNA traces were observed in 67% of replicates, but were below the quantifiable range.

Conclusion and Relevance A method was developed for testing CSTDs' ability to prevent viral contamination. The method was applied to two CSTDs for different simulated pharmacy tasks. The method can be applied for evaluation of additional CSTDs and for direct comparison between CSTD brands performing the same tasks. The knowledge gained could help protect vulnerable patients from viral infection.

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Maya Amichay declares no conflict of interest. relating to the material presented in the abstract. Elana Slutsky Smith is employed by Simplivia Healthcare Ltd, the manufacturer of Chemfort®.

5PSQ-014 ELECTRONIC COMMUNICATION OF THE DISCONTINUATION OF HOME TREATMENT PRESCRIBED TO PATIENTS IN A TERTIARY LEVEL HOSPITAL

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Background and Importance Despite its apparent benefits, electronic prescribing systems still face numerous challenges. Without effective electronic communication between prescribers and pharmacists, medication may be dispensed incorrectly, resulting in patient harm.

Aim and Objectives To determine potential errors in the prescription of home medication, preventively suspend this medication and alert the prescribing physician so that the error can be solved.

Material and Methods Prospective cross-sectional study from October 2022 to May 2023 in a tertiary level hospital. Potential errors in their electronic prescriptions were detected using an electronic program linked to the patients' home prescriptions. Errors and reasons for suspension of treatment were classified: incorrect dosage (1), treatment completed and not discontinued (2), incorrectly withdrawn treatment (3), incorrect presentation (5) and therapeutic duplicity (6).The interventions carried out in which the deadline for modification of the interventions by the prescribers expired (2 weeks) were also taken into account (4). Treatments and medical services involved were analysed. Average number of days between the detection and notification of the error and its resolution by the prescriber was also evaluated. The e-prescribing system was used as well as a micro-strategy data analysis system.

Results 340 potential home prescribing errors were detected of which 190 (55.9%) were real. 98 (51.58%) were women with a median age of 63 [20–73]. Of these patients 81 (42.63%) were polymedicated with 10 drugs and 34 (41.97%) had at least 15 or more drugs prescribed. The average number of drugs prescribed was 8 [4–13]. Most frequent errors were detected in: semaglutide (28.5%), triptorelin (15%), methotrexate (12.5%), denosumab (9%), aledronic (9%), leuprorelin (5%), dulaglutide (5%), ibandronic (4.7%), risedronic (3%), paliperidone (3%), aripiprazole (2.5%), lanreotide (1.5%) and estradiol (1.3%). The medical specialties with the highest number of prescription errors were rheumatology (31%), endocrinology (28.5%), cardiology (10%), oncology (7.3%) and urology (7.3%). An average of 7 [4–11] days was observed between precautionary annulment and correction of the error. The causes of preventive discontinuation of treatment were type 1 (74%), type 6 (11%), type 4 (6%), type 5 (9%). After the intervention, 98 treatments (51.57%) were discontinued for various reasons: 1 (30.6%), 6 (21.5%), 4 (16.3%), 2 (15.3%), 5 (15.3%) and 3 (1%).

Conclusion and Relevance Electronic communication of discontinuation of home treatment is an important functionality with potential to decrease adverse events due to medication errors and also to reduce costs for the healthcare system and for polymedicated patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-015 ANALYSIS OF THE OCCURRENCE OF ATRIAL FIBRILLATION WITH THE ADMINISTRATION OF IBRUTINIB: SHOULD WE BE CAREFUL WITH THIS DRUG?

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Background and Importance Ibrutinib is a Bruton's tyrosine kinase (BTK) inhibitor used for the treatment of chronic lymphocytic leukaemia (CLL). Ibrutinib has been associated with an increased incidence of atrial fibrillation (AF) in trials ranging from 5% to 16% (1).

Aim and Objectives To analyse the appearance of AF and the time of its debut, as well as the possible risk factors in patients being treated with ibrutinib in a tertiary hospital.
Material and Methods Observational, cross-sectional, retrospective, multicentre study. Patients with CLL treated with ibrutinib from July 2016 to September 23 for at least 2 months were included. Diraya®, FarmaTools® and Prisma® databases were consulted. Variables were collected: age, sex, cardiovascular risk factors: arterial hypertension (AHT), diabetes mellitus (DM) and obesity. Duration of treatment with ibrutinib, serum creatinine at the start of treatment, drugs prescribed after ibrutinib, appearance of AF, time to AF and whether hospitalisation was required.
Results Forty-six patients with CLL in the last 7 years were included (16 women, 35%); the median age was 63 years [45–88]. 22 patients (48%) had AHT, eight patients (17%) had DM and five patients (11%) were obese. The mean creatinine value was 0.97 [1.91–0]. Anticoagulation was prescribed to seven patients (15%) and renin angiotensin system blockers to five patients (11%). Thirty-one patients (67%) continue to be treated with ibrutinib. The mean duration of treatment in the 13 patients (28%) who discontinued treatment was 546 days. Of these, two patients (4%) developed AF on days 21 and 594. In the first case, hospitalisation was required and treatment was suspended. In the second, it was not related to ibrutinib because too much time had elapsed since onset, did not require hospitalisation and the drug was not discontinued. Two patients (4%) with previous chronic AF did not develop any new event. One patient (2%) with no risk factors developed ventricular extrasystoles.
Conclusion and Relevance According to our cohort, a considerable number of cases appeared after treatment with ibrutinib that can be extrapolated to the results obtained in previous studies[1] without appearing to be related to cardiovascular risk factors prior to treatment. Those responsible for these patients should be aware that this is a serious adverse effect that should be monitored.

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Conflict of Interest No conflict of interest.

5PSQ-016 ASSESSMENT OF THE ACCREDITATION AND CONTINUOUS EDUCATION TESTS FOR PHARMACY TECHNICIANS WITHIN A CYTOTOXIC RECONSTITUTION UNIT

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Background and Importance The new preparation good practices for 2023 require a staff assessment. We decided to implement an annual, specific and adapted test to our activity, with the aim of guaranteeing the authorisation of new pharmacy technicians (PT) and the continuous education (CE) of those already present.
Aim and Objectives Realisation of the 2023 annual examination for the accreditation of new pharmacy technicians and the continuous education of PTs already accredited.
Material and Methods The test lasts 30 minutes and consists of two parts. The first part is made up of 10 multiple choice questions (MCQ) covering the competencies of pharmacy technicians: pharmacology, environment, equipment, hygiene, asepsis, quality, risk management. The second part consists of three videos containing errors in the preparation methods (choice of the molecule, volume to be withdrawn, dilution) which have been exported from our digital double-check video system. A pass rate of over 75% is required to validate the examination. Below the required rate, a second session is mandatory. A debriefing session is organised with the provision of a document containing the questions that posed problems (with a pass rate below 80%) along with associated procedures.
Results In the context of the CE, 10 PTs were reassessed. The average pass rate for the test was 81.5% [75%-85%] with an average of 72.9% for MCQ and 100% for videos. For accreditation, two PTs were evaluated. The overall average of the test was 70.3% [55%-65%] with an average of 57.2% for MCQ and 83.4% for videos requiring a second session. The overall average of the second session was 90% with an average of 85.7% for MCQ and 100% for videos. Among the 10 MCQ, seven had a pass rate below 80% and required a reminder.
Conclusion and Relevance For the personnel having carried out their CE the results are satisfactory and all the staff have been rehabilitated in the first session. As for the new PT, the results were insufficient. They were required to rework all procedures. This annual assessment frequency contributes to the safeguarding of our process by keeping knowledge up-to-date and reinforcing good practices. A satisfaction survey among PT can be conducted to evolve our evaluation methods.

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Conflict of Interest No conflict of interest.

5PSQ-017 PHARMACEUTICAL INTERVENTIONS IN ORAL AND SUBCUTANEOUS MTX PRESCRIBING ERRORS

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Background and Importance Methotrexate (MTX) is a cytostatic drug used as an immunomodulator in non-oncological diseases, dosed at 7–25 mg per week orally/subcutaneously in adults. It is catalogued by the ISMP (Institute for Safe Medication Practices) as 'high-risk drugs', which incorrectly used have a higher likelihood of causing serious-fatal harm to patients. Folic acid (FA) is administered to prevent MTX toxicity.
Aim and Objectives To analyse pharmaceutical interventions (PIs) on oral/subcutaneous MTX and FA prescriptions and to assess the acceptance degree by the physicians.
Material and Methods Prospective observational study.

Oral/subcutaneous MTX prescriptions in adults between March to May 2023 of patients in a third-level hospital area were obtained. Filters applied to detect errors were: dosage of one tablet (2.5 mg) and administration frequency different from 7 days. Once patients were identified, MTX and FA

prescriptions were reviewed and the responsible physician was contacted. The acceptance degree of the PIs was measured.

The following variables were collected: number of patients on whom PIs were performed, sex, age, diagnosis, number and type of PIs identified.

Results Thirty-six patients with erroneous prescriptions were detected. 67% were female. The median age was 54 years (18–86).

The associated pathologies were included in the rheumatologic (n=23, 63.9%), dermatologic (n=8, 22.2%), and internal medicine (n=5, 13.9%) areas: rheumatologic arthritis (n=8, 22.2%), juvenile idiopathic arthritis (n=3,8.3%), psoriatic spondyloarthritis (n=4, 11.1%), polyarthritis (n=1, 2.8%), psoriasis (n=6, 16.7%) and others (n=14, 38.9%).

Of all the PIs performed (n=53), the pharmacist recommended adjustment of: MTX dosage (n=11), MTX administration frequency (n=30), FA administration frequency (n= 9) and lack of FA prescription (n=3).

The acceptance degree of the PIs were as follows: MTX dosage (45.5%), MTX administration frequency (80.0%), FA administration frequency (55.6%) and lack of FA prescription (66.7%).

Conclusion and Relevance Most of the PIs were about errors in prescribing the MTX administration frequency, daily instead of weekly, implying a high risk of intoxication. The acceptance degree of the PIs was very high, reinforcing the role of the pharmacist.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-018 ANALYSIS OF ERRORS IN THE MANUAL PREPARATION OF STERILE DRUGS FROM STOCK

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Background and Importance In recent years, pharmacy services have shifted towards centralised preparation of sterile drugs to ensure compatibility, stability, and sterility. Quality controls will identify preparation errors preventing them from reaching patients.

Aim and Objectives Analyse errors detected in the manual preparation of sterile drugs from stock during January 2022 to April 2023.

Material and Methods The preparation of sterile drugs requires a series of quality/safety controls to detect errors, preventing them from reaching patients. Following a manual work methodology, a pharmacy technician selects the medicines/materials, generates the labels and records quantities, batches and expiry dates on the processing sheet. Another technician performs a double safety check. Once prepared, the pharmacist records the conformity, after inspecting the preparation sheet together with one of the preparations of each batch.

The incidents noted in the elaboration sheets from January 2022 to April 2023 were reviewed. The errors were recorded in a Microsoft Excel file, being classified based on the type and severity, according to pharmacist criteria: minor (errors on the preparation sheet, labels or batches); and serious (errors in expiry date or dose on the label, wrong administration system; wrong drug/serum, excess/defect dose, presence of particles/air, unfinished packaging, and unprotection from light).

Results 88 errors were detected, affecting 4.4% of the batches produced. 44.3% were considered minor errors and 55.7% were considered serious. The most frequent error was the completion of the processing sheets (26%). Regarding labelling, the most detected errors were related to expiry date (15.9%), batch (11.36%), dose/name/colour (2.3% each) and label hiding the graduation of the syringe (1.13%). Other errors: 9.1% of non-complete final packaging; 5.68% excess doses, 6.81% defect doses; incorrect serum and infusion systems (3.4% each); unprotected from light (3.4%); presence of particles/air (2.3%) and duplicate batches (1.13%).

Conclusion and Relevance The error rate detected is lower than that reported in the literature. More than half of them were considered potentially serious if they had reached the patient.

According to our results and the literature, this methodology presents a low error detection, incorporating new technologies (comprehensive software, barcode verification, image capture, gravimetry) could enhance error detection and reduce preparation errors, ultimately leading to improved patient safety.

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Conflict of Interest No conflict of interest.

5PSQ-019 VALIDATION PRIOR TO THE DISPENSING OF MEDICINES AS A TOOL TO IMPROVE THE QUALITY OF THE PRESCRIPTION

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Background and Importance Prescription validation is the diligence, manual or electronic, by which it is authorised, for a specific patient, that certain medicines, medical devices (PS), enteral nutrition (NE) and dietotherapeutic products (PD) can be dispensed from public funds.

Aim and Objectives The objective of the study is to assess the usefulness of validation as a control tool in the prescription, through the analysis of the incidents/causes of denial of this validation, carried out by pharmacists of the validation unit (UV)of the pharmacy service (SF) in a tertiary hospital

Material and Methods The pharmacists received daily by telematic means in the electronic validation module, the validation reports (the prescription together with the clinical report), completed by the prescriber, which include the following data: administration schedule and duration of treatment, main diagnosis and indication. By means of validation, the conformity of the prescribed treatment is verified, with the indications authorised in the technical sheet and the financing conditions. As a support tool, the lists of drugs submitted to validation and the available protocols were used. Denial was made if incidents were detected

To classify the detected incidents, the following variables were recorded: medication, PS, NE and PD, medical specialty of the prescriber, date of the report and reason for pending data. According to the type of incident detected, they were classified into (1) unfunded indication; (2) completion errors; (3)absence of computerised validation report; (4) absence of clinical report; and (5) other causes.

Results A total of 16,039 reports were analysed for validation, between March and December 2022. The reports that registered some incidence were 1930 (12%), remaining pending observations and not validated. The reasons for refusal were the following: unfunded indication (58.8%), completion errors – insufficient or incorrect prescription data – (23.6%), absence of computerised validation report (13.5%), absence of clinical report (2.9%) and other causes -unauthorised indication in the technical sheet, hospital diagnostic medication without a specialist report and shortages (1.2%).
Conclusion and Relevance Validation is positioned as a useful tool for the proper use of medicines since it guarantees that they are used according to the indications authorised in the technical sheet. It represents an improvement in the quality of the prescription, because, although most prescriptions conform to their financed indication, some incidents have been detected that were resolved by pharmacists, thus avoiding errors that affect patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-020 EVALUATION OF THE EFFICACY AND SAFETY OF EPCORITAMAB-BYSP IN PATIENTS WITH FOLLICULAR B LYMPHOMA: A CASE REPORT

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Background and Importance Follicular B-lymphoma (FL) is an indolent lymphoid neoplasm derived from germinal centre mutated B-cells with a nodular or follicular histological pattern. Approximately 2–3% of patients will transform their neoplasm to diffuse large B-cell lymphoma (DLBCL). Epcoritamab-bysp (EPKINLY®) is a bispecific IgG1 antibody designed to simultaneously bind to CD3 on T-cells and CD20 on B-cells, and induces T-cell-mediated killing of CD20+ cells.
Aim and Objectives The aim of this study is to evaluate the efficacy and safety of epcoritamab-bysp in a patient with LF refractory to previous lines.
Material and Methods Retrospective study of a clinical case in which we follow-up a patient with Relapse/Refractory FL under treatment with epcoritamab-bysp. Administration was done in the lower abdomen or thigh and at a different site each time it was administered. Data were obtained using the digitised clinical history (Diraya) and the electronic chemotherapy or immunotherapy prescription programme (Oncofarm).
Results We present the case of a 57-year-old woman, 48.8 kg and 153 cm. Diagnosed in August 2020 with stage IV FL without B symptoms. FL was refractory to the first two lines of treatment (1L:R-CHOP, 2L:R-ESHAP), as well as to a clinical trial based on CAR-T therapy. In May 2023, expanded use of epcoritamab-bysp in monotherapy with weekly subcutaneous administration in C1 with dose step-up (0.16, 0.8, 48 mg); every 2 weeks C4–9 (48 mg), every 4 weeks from C10 to progression (48 mg) was decided. In all immunotherapy sessions the patient was admitted for 24h due to risk of severe adverse reactions (CRS or ICANS). In the second administration (0.8mg) of epcoritamab-bysp the patient had a CRS:G1, so in the administration of the first target dose (48 mg) 3ªweek of C1, the dose was reduced to 50% (24 mg). Even so, the patient had to be treated with IV tocilizumab (8mg/kg) by CRS: G2 and was admitted for observation for 48h. From C2 onwards, there were no further incidents. Regarding the clinical evolution of the LF PET-CT scan, a partial metabolic response (Deauville:4) was observed with respect to the previous study.
Conclusion and Relevance Despite the need for extended study time to evaluate the clinical benefit and safety in real clinical practice of epcoritamab-bysp in patients with FL or DLBCL, this immunotherapy offers an innovative mechanism of action and an interesting alternative for patients with non-Hodgkin's lymphoma refractory to conventional therapies.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-021 EVALUATION OF THE PREVALENCE OF MULTI-RESISTANT BACTERIA IN THE INTENSIVE CARE UNIT AFTER SELECTIVE DECONTAMINATION OF THE GASTROINTESTINAL TRACT

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Background and Importance One of the measures to reduce the rate of infections by multidrug-resistant bacteria in Intensive Care Unit (ICU) services promoted in the Pneumonia Zero (NZ) programme is oropharyngeal decontamination (DOF) and/or selective digestive decontamination (SDD). Of the different existing protocols, we implemented the administration of non-absorbable topical antimicrobials (colistin, gentamicin and nystatin) in the oropharynx (paste) and gastrointestinal tract (solution). Both were developed as magistral formulas. In the event of MRSA isolation or an increase in the MRSA rate in our hospital, vancomycin would be added.
Aim and Objectives The aim was to assess the effect of such a measure on studies of the prevalence of multidrug-resistant bacteria in critically ill patients, and to see if there is selection for resistance mechanisms.
Material and Methods Ambispective study comprising the pre-DDS (01/01/2022–30/04/2022) and DDS (01/01/2023–30/04/2023) periods conducted in the 22-bed ICU.

From July 2022, ICU patients with isolation of multidrug-resistant bacteria in both clinical or surveillance samples, as well as patients with estimated intubation >72 h or non-intubated patients with risk factors for developing pneumonia are administered DDS/DOF. In addition, nasal, pharyngo-tonsillar and perianal exudate samples are collected for microbiological surveillance cultures on admission and every Tuesday thereafter. Incubate at 37°C for 48h.
Results In the pre-DDS period in the ICU, 626 samples are received for colonisation studies from 132 patients. Excluding repeat isolates in each patient,2 3 multidrug-resistant bacteria were detected. In the DDS period, 537 samples are received from 124 patients, detecting nine multi-resistant bacteria. There is a significant difference (p=0.0138) between the proportion of multi-drug resistant bacteria detected in the surveillance studies after applying ICU decontamination measures.

In the first period, the following bacteria were detected: one MRSA, one Acinetobacter baumannii, eight extended-

spectrum beta-lactamase (ESBL)-producing enterobacteria and 13 carbapenemase-producing gram-negative bacilli.

Pathogens isolated in the post-decontamination period were: one MRSA, one A.baumannii and 8 BLEE-producing enterobacteria. None of the isolates are carbapenemase-producing.

Conclusion and Relevance The DDS/DOF protocols applied in the ICU of our hospital have shown a significant decrease in colonisation by multidrug-resistant bacteria in critically ill patients. As for MRSA, no differences could be seen in this period, so it would be advisable to extend the study period. However, the role of this measure in the disappearance of carbapenemase-producing bacteria should be highlighted.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-022 DRUG-INDUCED APLASTIC ANAEMIA: AN ANALYSIS OF THE FDA ADVERSE EVENT REPORTING SYSTEM (FAERS)

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Background and Importance Aplastic anaemia (AA) is a rare condition resulting from a deficit in hematopoietic stem and progenitor cells, characterised by a huge social and economic burden. AA is included in the Designated Medical Event (DME) list developed by the European Medicines Agency (EMA), which contains medical conditions that are inherently serious and often medicine-related.

Aim and Objectives In this analysis, we aimed to shed light on the most frequent aplastic anaemia associated drugs in real-life by mining the FDA Adverse Event Reporting System (FAERS). FAERS is one of the largest spontaneous reporting databases in the world, used to perform signal detection in pharmacovigilance.

Material and Methods A disproportionality analysis of the FAERS was conducted by analysing the Individual Case Safety Reports (ICSRs) from the first quarter of 2004 (2004 Q1) to the third quarter of 2021 (2021 Q3). The reporting odds ratio (ROR) with a relevant 95% confidence interval (95% CI) as a disproportional measure was calculated. The ROR was considered statistically significant when the lower limit of the 95% CI of the ROR exceeded 1, with at least three cases reported ($N \geq 3$).

Results Overall, during the examined period (2004 Q1–2021 Q3), on a total of N=11.631.635 reports, N=3.413 ICSRs containing the preferred term 'aplastic anaemia' were retrieved. AA affected people with a median age of 49.62 (±25.08) years, mostly female (N=1.645, 54.9%). According to the ROR value, ferrous phosphate 594.82 (95% CI 184.68–1.915,80), sucrose 98.86 (95% CI 36.89–264.90), aminopyrine 82.04 (95% CI 26.32–255.76), levosimendan 81.41 (95% CI 54.90–120.73) and methenolone 81.41 (95% CI 54.90–120.73) were associated with disproportionate reporting, resulting in a potential signal. Regarding the number of ICSRs, the most frequent AA-associated drugs on FAERS were eculizumab N=431, lymphocyte immune globulin, anti-thymocyte globulin N=228, eltrombopag N=204, pentamidine N=77 and ethosuximide N=28.

Conclusion and Relevance Knowing the drugs associated with aplastic anaemia is essential for promoting appropriate use of them and improving patient safety during therapy. Furthermore, healthcare professionals should be aware of the necessity of strictly monitoring patients treated with these drugs and promptly recognising signs and symptoms of drug-associated AA. Further investigations are required to confirm if these drugs play a role in the development of AA.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-023 SAFETY AND TOLERABILITY OF VORICONAZOLE TREATMENT: A RETROSPECTIVE OBSERVATIONAL STUDY

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Background and Importance Voriconazole is an antifungal agent with concentration-dependent activity and high individual variability. It is generally well tolerated. However, adverse effects (AEs) may occur, requiring dose reduction (DR) or discontinuation of treatment.

Aim and Objectives To describe the safety and tolerability of voriconazole treatment in a cohort of patients admitted to a tertiary hospital.

Material and Methods Retrospective observational cohort study that included patients treated with voriconazole during 2022.

Variables collected were age, sex, diagnosis, route of administration, treatment start date, date and type of AEs, post-AE measures, and therapeutic drug monitoring (TDM).

Voriconazole AEs were classified as concentration-dependent or non-concentration-dependent.

Results A total of 135 patients were treated with voriconazole. The median age was 64 years (4–91). Men represented 61%. Most patients were immunocompromised (42%).

Treatment was empiric in 21%, prophylaxis in 10% and targeted therapy in 69%. The main diagnosis was Aspergillus (81%), 11% Candida and 8% other infections. It was administered intravenously in 45%, orally in 30%, and 25% were switched from intravenous to oral. The median duration of treatment was nine days.

Voriconazole-related AEs occurred in 38 patients (28%). The median time to AE onset was five days.

Concentration-related AEs were hepatotoxicity in seven patients (18%), visual disturbances in 11 patients (29%), psychiatric disorders in 12 patients (31%) such as hallucinations (10) or confusional syndrome (2) and neurologic disturbances in 12 patients (31%) who experienced somnolence (4), vivid dreams (4), tremor (3) or disorientation (3). Four patients required DR and 10 discontinued treatment.

Non-concentration-related AEs were dermatologic reactions in eight patients (21%), including photosensitivity (3), alopecia (2), erythema (4), or warm sensation (4), and digestive disorders (diarrhoea) in one patient. Two patients discontinued treatment.

Of 38 patients with AEs, 22 (58%) had voriconazole TDM: 17 had therapeutic concentrations, two infratherapeutic and three supratherapeutic, of whom two tolerated treatment with DR and one discontinued voriconazole for other reasons.

Conclusion and Relevance Approximately 1 in 3 patients experienced AEs. The most common AEs were visual disturbances and hallucinations. We cannot confirm that these AEs were due to supratherapeutic concentrations as 45% had concentrations in the therapeutic range but TDM may be an interesting strategy to improve tolerability to voriconazole.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-024 ENHANCING SAFETY AND EFFICIENCY IN CHEMOTHERAPY PREPARATION AND ADMINISTRATION IN A SMALL ONCOLOGY HOSPITAL

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Background and Importance Optimising and standardising the preparation and administration of parenteral drugs in healthcare facilities may minimise medication errors, ultimately leading to safer, more efficient, and potentially cost-effective therapy.
Aim and Objectives Our objective was to create an informative manual containing data on the reconstitution and administration of all cytostatic drugs prepared in our hospital pharmacy. This manual was designed to surpass traditional chemotherapy orders for preparation and administration, as errors or unnecessary orders were often caught and corrected by pharmacists. Our study aimed to quantify the impact of this manual on preventing medication errors, cost savings, reduction in nursing time, and the mitigation of plastic waste.
Material and Methods We performed a retrospective analysis of all chemotherapy orders from March to August 2023, focusing on errors in preparation and administration orders. Our analysis included calculations of the cost savings from avoiding unnecessary infusion bottles and closed system devices, as well as reductions in plastic waste by weight. Additionally, we calculated the saved nursing hours during chemotherapy administration, converting this saved time into the average hourly cost of nurses' work in our county.
Results Over a six-month period, we prepared 6,163 doses of chemotherapy. Our analysis revealed prescription errors in 17.86% of cases, primarily related to excessive drug dilution, potentially compromising drug stability, safety, and efficacy. In 6.25% of cases, drugs were needlessly ordered to be diluted in multiple bottles. These errors resulted in cost savings of € 2,712.27 and prevented the generation of 34,824.5 grams of plastic waste. Furthermore, in 7.56% of cases, drugs were ordered to be administered over longer durations than necessary, leading to the prevention of 445.5 unnecessary nursing hours. When recalculated to the average hourly cost of nurses' work, this equated to € 10585,08 in savings.
Conclusion and Relevance Our study underscores the critical role of standardising the preparation and administration of parenteral drugs in healthcare establishments, not only enhancing safety and efficacy but also reducing the overall cost of treatment, minimising nursing time, and mitigating plastic waste. This investigation additionally highlights the indispensable contribution of pharmacists as integral members of the oncology team.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-025 AUDIT ON THE CORRECT USE OF MEDICAL DEVICES FOR URINARY CATHETERISATION

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Background and Importance Urinary catheterisation is a common practice, but complex because of a large number of medical devices, each with its own particularities (materials, insertion time, indications).
Aim and Objectives The aim of the audit was to assess nurses's theoretical knowledge of our hospital about this procedure and medical devices referenced. Depending on the results, assistance and information tools on the correct use will be proposed.
Material and Methods An audit was carried out among nurses between June and July 2023. The audit included 15 questions concerning general items of urinary catheterisation, such as traceability and legislation. Aspects relating to urinary catheter's choice and installation methods (closed system fitting's criteria, hourly diuresis system's criteria catheter's material according to the installation duration) were also discussed.
Results The audit included 81 nurses from 19 different units.

Obligatory trackability information in the patient's file was known by 35% of nurses questioned.

Catheter insertion times depending on the material (PVC, latex, silicone) were unknown by nurses.

For closed systems (with latex hydrogel), 8% of nurses gave the right indication for these systems and 16% the correct use duration.

For closed Foley catheters with hourly diuresis, the majority (65%) of nurses knew the use indication but not the duration of installation.

In accidental disconnection of a closed system bag, 49% put a new collection bag on the catheter already in place rather than changing the entire system. Finally, 52% of nurses thought they were not sufficiently informed about urinary catheterisation devices.
Conclusion and Relevance This audit highlights a good level on urinary catheterisation generalities. However, the use of closed systems and the correlation between catheter material and insertion time are often unknown.

Nurses's knowledge of our hospital policies is therefore heterogeneous, as noted in literature. (1)

Action to raise awareness of the correct use of urinary devices have been proposed and a review of available medical devices was carried out.

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Conflict of Interest No conflict of interest.

5PSQ-026 THE POTENTIAL OF PHARMACOVIGILANCE DATABASES TO ASSESS TOXICOLOGICAL RISK OF DIETARY SUPPLEMENTS AND OTHER UNSUPERVISED HEALTH PRODUCTS USED BY PATIENTS

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Background and Importance When executing the medication use review or medication reconciliation, and if there is a sudden new symptom or sign of toxicity, the potential role of health products taken by patients without the supervision of the health care professionals should not be forgotten. However, there is no standardised approach to assess toxicity of these products in everyday practice.
Aim and Objectives Our aim was to search for and evaluate methods that can be added or standardised to assess illegal or unsupervised health products from toxicological perspective. We wanted to know whether there any databases that can be used and if they are eligible for this role based on information content or applicability.
Material and Methods In addition to the literature search, we identified and reviewed four Open Access databases: EudraVigilance; US FDA Adverse Events Reporting System (FAERS); US FDA CFSAN Adverse Event Reporting System (CAERS); Health Fraud Product Database. For the initial screening we chose as a model substance cannabidiol (CBD) (excluding authorised medicines) due to its popularity and potential adverse effects.
Results We identified 371 cases in the EudraVigilance database from 2021 to 2023 (2021: 126, 2022: 196, 2023: 49). Fatal cases were 7.55% of all cases (n=28). From the concomitant medications used with CBD, clobazam was the most frequent (n=16). In the FAERS database there 276 cases were registered from 2015 to 2023, with 67.4% (n=186) being severe and 2.5% (n=7) fatal. The three most common reactions identified were: General disorders and administration site conditions (n=117), Nervous system disorders (n=103) and Psychiatric disorders (n=85). In the CAERS database 163 cases were found (2016–2023) with one fatal. The most common reactions with MedDRA preferred terms were related to gastrointestinal disorders (e.g.: diarrhoea, vomiting, nausea). In the Health Fraud Product Database CBD related cases were 33 in the period of 2019–2021.
Conclusion and Relevance The application of open access databases containing pharmacovigilance and toxicovigilance data are suitable for assessing the real-world toxicity of dietary supplements and identifying high risk products. The incorporation of our results into the clinical practice can be a competency of a clinical pharmacist.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-027 VARIABILITY IN VANCOMYCIN PLASMA CONCENTRATION IN NEUTROPENIC PATIENTS

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Background and Importance There are currently conflicting results in numerous studies on the effect of neutropenia on vancomycin plasma concentrations.
Aim and Objectives To evaluate the effect of neutropenia on pharmacokinetic parameters in patients treated with vancomycin.
Material and Methods Observational and retrospective study in patients treated with vancomycin in a tertiary level hospital, between July and June 2023. The clinical history was consulted and the following variables were collected: sex, age, creatinine, neutrophil count and vancomycin trough levels in blood. Neutropenic patients were considered if their levels were less than 1.5x10^9 neutrophils/L and vancomycin clearance (CLv) was calculated by the Matzke and Moellering methods. The data were processed in the SPSS v.25 statistical program: the Shapiro Wilks test was performed as a normality test and a statistical test was carried out according to the results (Student's t-test or Mann-Whitney U-test).
Results We analysed 68 samples in 37 patients; of which 17 were male and a median age of 65 [18–90] years. Patients were classified into two groups according to the number of neutrophils, eight (11%) neutropenic patients and the 60 (89%) non-neutropenic. The Shapiro Wilks normality test showed normality in all variables, however the sample size of one group made it necessary to use a non-parametric test (Mann-Whitney U test). Mean trough levels in neutropenic patients were 9.6 (SD2.96) vs. 11 (SD7.04) in non-neutropenic patients (p=0.991). The mean CLv by Matzke and Moellering methods was 107,83 (SD39) and 88 (SD2.34) respectively in the group of neutropenic patients and in non-neutropenic patients it was 105.13 (SD39.3) and 85 (SD2.21); p=0.228 in both groups.
Conclusion and Relevance Although no statistically significant differences were found, probably due to the sample size, it can be observed that the group of neutropenic patients had lower vancomycin trough levels and a higher clearance than the non-neutropenic group. Furthermore, we can conclude that both methods of calculating Clv are similar in both groups of patients. Further studies are needed to demonstrate the effect of neutropenia on vancomycin levels and its consequences on treatment efficacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-028 CASE REPORT: ANTITUMOR ACTIVITY AND TOXICITIES OF ENTRECTINIB IN A PATIENT WITH A PRIMARY CENTRAL NEUROCYTOMA

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Background and Importance Entrectinib is an oral, CNS active, potent inhibitor of tyrosine approved for use in patients with NTRK gene fusion-positive solid tumours. Here, we report the antitumour activity and safety of entrectinib in a patient with central neurocytoma, an uncommon neoplasm with few drug treatment alternatives.
Aim and Objectives To summarise the overall safety and report the antitumour activity of entrectinib in a 50 year-old female with a primary central neurocytoma initially treated with

surgery and radiotherapy. The patient began entrectinib after tumour NTRK fusion tested positive.

Material and Methods Diagnostic and follow-up tests and therapy were obtained by the review of medical records.

Foundation One NTRK fusion-positive tumour

Cardiac stress magnetic resonance imaging (MRI) with adenosine: Subclinical cardiotoxicity.

Results A 50 year-old female patient with a primary central neurocytoma. She received surgery as primary treatment in July 2020. After radiographic response and progression shortly, she was treated with adjuvant radiotherapy.

The tumour was tested for genetic mutations establishing a NTRK fusion-positive. Entrectinib treatment was authorised under compassionate use. The patient started treatment- in March 2021 at the full 600 mg daily dose.

After 1 month of treatment, the patient developed electrocardiogram and cardiac MRI alterations. She was diagnosed of subclinical cardiotoxicity grade 2 associated with entrectinib, given the temporal match. Dose was reduced to 400 mg daily and the patient was started on bisoprolol. In January 2022, MRI confirmed complete response. However, the patient was assessed by the neurologist and psychiatrist due to greater cognitive impairment and delusions. Duloxetine was started. In addition, entrectinib dose was reduced to 200 mg daily. In July 2022, entrectinib treatment was stopped and close follow-up was started. She experienced progressive neurologic improvement and less anxiety and depressive symptoms. In September 2022, MRI showed stable disease and after cardiologist and psychiatric evaluation, duloxetine and bisoprolol where withdrawn from treatment. In December 2022, clinical and radiologic stability were observed. Therefore, entrectinib was restarted at 200 mg daily with good tolerance until at least, today (October 2023).

Conclusion and Relevance Entrectinib has been shown to be active against those gene fusions in a primary CNS disease. However, it is still associated with moderate adverse events that require mandatory pharmacovigilance in our pharmacist daily practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-029 THE OVERRIDING OF DRUG SAFETY ALERTS FIRED BY THE CLINICAL DECISION SUPPORT TOOL: EVALUATION OF APPROPRIATE RESPONSES AND ALERT FATIGUE SOLUTIONS

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Background and Importance Most CPOE software come with clinical decision support (CDS) that assist prescribers and notify them about adverse drug reactions that play an important role in reducing medication errors and enhancing patient safety. An excessive number of alerts in a repeated and non-relevant manner leads to alert fatigue and enforces physicians and pharmacists to alert overrides.

Aim and Objectives Our primary objective was to determine which alerts are overridden and their association with an appropriate action. To assess the appropriate responses for red alerts (pDDI, overdose, and allergy). Our second objective was to decrease the number of unnecessary red alerts.

Material and Methods The study was a retrospective chart review carried out in the inpatient setting that included all red alerts that required comments and were overridden by a physician and pharmacist.

Results In this retrospective study, we determined which alerts are clinically irrelevant and need modifications. We found that more than half of the alerts were pDDI, and the drug allergy alerts had the most appropriate responses by both prescribers and pharmacists when compared to other alert classes (OR = 1.65, OR = 1.54, respectively; $p < 0.05$). For diminishing the unnecessary alerts, we provided 14 alert refinement strategies and advised turning off four alerts. Applying this will terminate 32% of irrelevant alerts.

Conclusion and Relevance In this retrospective study, we described which alerts are clinically irrelevant and need modifications. We found that more than half of the alerts were pDDI, and the drug allergy alerts had the most appropriate responses by both prescribers and pharmacists when compared to other alert classes (OR = 1.65, OR = 1.54, respectively; $p < 0.05$). We anticipate that our recommendations can lead to consistent and clinically relevant content for interruptive DDIs, and thus decline alert fatigue and enhance patient safety.

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Conflict of Interest No conflict of interest.

5PSQ-030 CONCORDANCE OF MEDICATION PRESCRIPTION RECORDS IN THE HOSPITALISED SURGICAL PATIENT

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Background and Importance Electronic prescriptions allow pharmacists to communicate with the rest of the multidisciplinary team, facilitate pharmacotherapeutic monitoring.

Aim and Objectives Assess the reliability of electronic prescription by analysing concordance, the presence or absence of discrepancy, by studying the active medication in these prescriptions and the pharmacist's interview with the patient and/or caregiver.

Material and Methods Retrospective observational study carried out in a third-level general hospital. During a period of 12 months, all patients belonging to the Traumatology, Urology and Neurosurgery Service in whom the responsible physician indicated medication reconciliation by the Pharmacy Service were included. Demographic variables (sex, age), pharmacotherapeutic variables (treatment lines reviewed, total number of drugs (F) prescribed and not prescribed, cause of discordance (F prescribed but the patient is not on current treatment, changes in dosage), occasional consumption, F not prescribed), presence or not of polypharmacy (5 or > medications), majority ATC classification of discordant drugs).

Results 378 patients were analysed,169 men (44.7%) and 209 women (55.3%), with a mean age of 69 years [11.8] and 71 years [11.6], respectively. It was observed that 60.6% of patients presented at least one discrepancy in the treatment reflected in the electronic prescription. The pharmacist reviewed 2426 prescribed lines of treatment and 401 discordant drugs were detected: 98 (24.5%) drugs not prescribed, 187 (47%) drugs prescribed but that the patient does not take, 75 (18.5%) drugs with changes in the dosage regimen not reflected in the prescription, 41(10%) drugs with occasional consumption. The presence or absence of polypharmacy was evaluated stratified by sex: 110 men (65%) and 130 women(62%). In turn, age ranges were established, observing the presence of polypharmacy in the population of 61–80 years with an average of six drugs and 81–100 years with an average of eight drugs. Finally, it was studied that the majority ATC group of drugs that the patient did not take despite being prescribed, was group N, highlighting benzodiazepines, antidepressants and antiepileptics. The majority of ATC group of drugs not prescribed but that the patient did take were group A, highlighting proton pump inhibitors, vitamin D, calcium and magnesium; and group C, mostly statins, angiotensin II receptor antagonists, ACE inhibitors and beta blockers.

Conclusion and Relevance In view of the results obtained and the high percentage of patients (60.6%) in whom a discrepancy is found in the electronic prescription, it would be advisable to extrapolate the pharmaceutical action carried out in the Traumatology, Urology and Neurosurgery services to all the hospital's clinical services in order to avoid possible medication errors and adverse effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-031 ABSTRACT WITHDRAWN

5PSQ-032 USE OF THE 'PRECAUTIONARY ANNULMENTS' TOOL BY A HOSPITAL PHARMACY SERVICE

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Background and Importance The main objective of precautionary annulments (PA) is to contribute to patient safety, preventing dispensing of erroneous medications at the outpatient pharmacy level. This is a new tool carried out by both hospital and primary care pharmacists.

Aim and Objectives To analyse the different PA conducted by hospital pharmacists, and to evaluate their degree of acceptance by doctors.

Material and Methods This is a prospective study, carried out from May to September 2023. All patients in whom a PA was carried out, either during a hospital admission or by proactively obtaining the information through the 'Microstrategy' database, were included.

Variables collected age, sex, therapeutic group of the drug and prescribing service.

The PA were distinguished according to whether they were therapeutic duplications, dosing errors, or inappropriate medication prescription. Finally, the degree of acceptance by the physicians was measured.

Data obtained through the e-prescription module, digital medical record and through the 'Microstrategy' database.

Results A total of 38 patients were included (with one PA each). 60.5% were women (n=23), with a median age of 56 years (IQR=69–41).

In terms of therapeutic group, the highest percentage of PA was in the group of anti-rheumatics (28.9%), followed by anti-ulcers (18.5%), anti-osteoporosis (15.9%) and anti-diabetics (10.5%). Other drugs cancelled were: vitamins (5.3%), anti-anginal drugs (5.3%), anti-anaemics (2.6%), anti-asthmatics (2.6%), antipsychotics (2.6%), antihypertensives (2.6%),

pancreatic deficiency substitutes (2.6%), and medical devices (2.6%).

The prescribers were primary care physicians (39.5%), rheumatologists (13.2%), gastroenterologists (10.5%), gynaecologists (10.5%), internists (8%), paediatricians (5.3%), rehabilitators (2.6%), cardiologists (2.6%), psychiatrists (2.6%), oncologists (2.6%) and vascular physicians (2.6%).

In the anti-rheumatics group (n=11), the drug discontinued in all of them was methotrexate. Of all the PA in this group, six had not yet been renewed by the prescribing physician, so the patient is currently unable to take the treatment.

Regarding the type of error that led to the PA, 65.8% were due to dosage errors; 26.3% to therapeutic duplications and 7.9% to inappropriate prescribing.

Of all the PA made, only 39.5% were accepted by the prescribing physician; the rest were discontinued because the cancellation period had expired without response.

Conclusion and Relevance Although PA are intended to improve patient safety, it is important that they are well reviewed and accepted by the prescribing physician.

Of particular note are the PA carried out for methotrexate, a drug considered high-risk according to ISMP (Institute for Safe Medication Practices) Spain.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-033 ABSTRACT WITHDRAWN

5PSQ-034 COMPARISON OF TOXICITY IN CLINICAL PRACTICE OF ANTI-PD-1/PD-L1 ANTIBODIES IN MONOTHERAPY IN NON-SMALL-CELL LUNG CANCER

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Background and Importance The leading cause of cancer-related death remains lung cancer. Anti PD-1/PD-L1 antibodies exhibit unique immune-related adverse events (IrAEs). The assessment and comparison of different safety profiles in real clinical practice at our centres are necessary.

Aim and Objectives Evaluation and comparison of the safety in routine clinical practice of anti-PD-1/PD-L1 monoclonal antibodies (nivolumab, pembrolizumab and atezolizumab) used as monotherapy in the treatment of non-small cell-lung cancer (NSCLC).

Material and Methods Retrospective observational study that included patients with NSCLC treated with anti-PD-1/PD-L1 for 7 years in a third-level hospital. Demographic, clinical, treatment, and safety variables were collected. Data were obtained from the electronic medical record. Adverse effect (AE) incidences were calculated and compared between subgroups.

Results 44 patients were included, 18 with pembrolizumab, 17 with atezolizumab and 9 with nivolumab. 84.1% were men with stage IV in 88.6% of the cases. 70.5% had an ECOG Performance status between 0–1. All had negative mutations for targeted therapies and 75% had records of determination of PD-L1 expression, with 61.9% being high expressors (≥50%). The median duration of treatment was 108 (49.5–223.7) days. Regarding the toxicity analysis, 68.2% had a record of some AE, 70.7% grade 1–2 and 38.6% immune related. Regarding the different drugs, pembrolizumab

presented more cases of AE in general and a higher incidence of IrAE (44.4%) compared with atezolizumab (29.4%). Due to toxicity, the administration of immunotherapy was delayed in 46.6% of the patients, 26.6% suspended treatment, and 16.7% required hospital admission to manage the toxicity. No statistically significant differences were observed between the different subgroups.

Conclusion and Relevance The incidence of AE in treatment with anti-PD-1/PD-L1 was similar to that available in the literature (68.2%). Approximately 30% were grade 3–4 and we observed a frequency of pneumonitis greater than 15%. The different antibodies present a similar incidence of AE, but atezolizumab seems to have a less immune related safety profile statistically non-significant than the other alternatives. It is essential to increase the sample size and follow-up time to confirm these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-035 SACITUZUMAB-GOVITECAN IN METASTATIC TRIPLE-NEGATIVE BREAST CANCER: A MULTICENTRE EFFECTIVENESS AND SAFETY STUDY

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Background and Importance Sacituzumab-govitecan (SG) is a new antibody-drug conjugate approved for unresectable/metastatic triple negative breast cancer (TNBC), available from the end of 2022 in the Spanish public health system, so there is still little published real-life data.

Aim and Objectives To analyse the effectiveness and safety of SG in TNBC of patients from the three main hospitals of a city.

Material and Methods Retrospective, observational, and multicentre study was conducted, including all patients treated with SG until July 2023. Data were obtained from the electronic medical record and prescription software. SPSS-Statistics v.21® was used for processing. Variables collected: sex, age, body mass index (BMI), hormone receptor (HR) and human epidermal growth receptor-2 (HER2) status, primary granulocyte-colony-stimulating factor (G-CSF) prophylaxis, location of metastases, breast-cancer-gene (BRCA) mutational status, Eastern-Cooperative-Oncology-Group (ECOG) score, duration of treatment, objective response rate (ORR) according to RECIST-v1.1 criteria, progression-free survival (PFS), overall survival (OS), cause of treatment discontinuation, previous chemotherapy (CT) lines, and adverse effects (AEs) according to Common Terminology Criteria for Adverse Events-v5 (CTCAE).

Results Thirty-six patients were included (100% female); median age 52.5 [Interquartile range (IQR) =64.3–46.8]. Mean BMI 25.8 [standard deviation (SD)=4.9]. 97% HR-negative and 100% HER2-negative. 30.6% received primary prophylaxis with G-CSF. Lung metastases were the most frequent (63.9%), followed by bone (36%), hepatic (30.5%) and ganglionic (25%). 61.1% BRCA-negative, 5.6% BRCA2 and 33.3% not available. Most of the patients had a baseline ECOG 0–1 (75%). To date, 14 patients were still on treatment. ORR is 25% (22.2% partial response and 2.8% complete response), stable disease in 22.2% and progression in the rest. Median PFS was 4 months (IC 95%: 2.9–5.3); Median OS not reached. 47.2% of patients discontinued treatment due to disease progression and 13.9% exits. Median total of SG cycles received was 4 (IQR=8.1–2.4) and a median of 2 (IQR=3–1) previous CT-lines in metastatic-stage.

97.2% of the patients had some AE during treatment. Most frequent were: asthenia (80.5% (G3–4:2.8%)), anaemia (61% (G3–4:8.3%)), neutropenia (50%(G3–4:16.7%)), diarrhoea (44.4% (G3–4:11.1%)), alopecia (44.4% (G3–4:5.5%)). 69.4% had some reduction or delay of dose because of toxicity and no patient discontinued treatment due to an AE.

Conclusion and Relevance Median PFS was lower than in the pivotal ASCENT trial. Although the majority presented some AE, in no case did these force treatment discontinuation. Further studies with a larger sample size and longer follow-up period are needed to confirm these real-life results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-036 ANALYSIS OF PHARMACEUTICAL INTERVENTIONS ON ANTIMICROBIAL PRESCRIPTIONS IN THE POST-OPERATIVE RESUSCITATION UNIT

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Background and Importance Multidrug-resistant microorganisms represent one of the greatest challenges in medicine today. The Antibiotic Stewardship Programme (ASP) reviews antimicrobial prescribing and makes recommendations to prescribers to achieve rational use of antibiotics and reduce the risk of resistance development.

Aim and Objectives To analyse the interventions carried out on antimicrobial treatment by the ASP in patients admitted to a postoperative resuscitation unit (PRU) and to evaluate the degree of acceptance of them.

Material and Methods Retrospective and observational study of the interventions performed by the ASP through daily multidisciplinary meetings from January 2022 to July 2023 in a third-level hospital. Antifungals and broad-spectrum antibiotics considered as 'restricted' in our hospital were reviewed. These included carbapenems, linezolid, daptomycin, caspofungin, voriconazole, etc.

Data collected patient demographics, diagnosis (type of infection), treatment (empirical, prophylactic or targeted), restricted antibiotics prescribed and their appropriateness, recommendations made and rate of acceptance.

Results 62 patients (53.2% men) were included. 130 restricted antibiotics were reviewed. The most reviewed antimicrobials were, in first place, meropenem (46.9%), followed by caspofungin (24.6%) and linezolid (15.4%).

75.6% of the antibiotic prescriptions were empirical, 22.1% targeted and 2.3% prophylactic. The most common types of infections were intra-abdominal (56.9%), respiratory (20.9%), urinary (10.5%), bacteremia (3.5%), skin and soft tissue infections (2.3%); and less frequently osteoarticular infections (1,2%), febrile neutropenia (1.2%) and candidemia (1.2%).

51.2% prescriptions were considered appropriate and 48.8% inappropriate.

51 interventions were made. The type of recommendations made were de-escalate (45.1%), discontinuation (25.5%), adjust dose (11.8%), request supplementary test (11.8%) and change the antibiotic (5.8%).

86.7% of the interventions were accepted by the prescribers.

Conclusion and Relevance Our study highlights the critical need to take measures to promote the proper use of antibiotics to prevent the spread of antibiotic resistance. The high percentage of accepted interventions indicates a significant level of confidence in the ASP in our hospital. Nevertheless, there is still room for improvement in this regard.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-037 PERIPHERAL BLOOD BIOMARKERS DYNAMICS PREDICT CLINICAL RESPONSE TO PEMBROLIZUMAB PLUS CHEMOTHERAPY IN PATIENTS WITH NON-SQUAMOUS METASTATIC NON-SMALL-CELL LUNG CANCER

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Background and Importance Heterogeneity in response to immunotherapy in patients with advanced non-small-cell lung cancer (NSCLC) highlights the need to identify predictive biomarkers. Peripheral blood biomarkers have been associated with the prognosis in advanced NSCLC treated with immunotherapy.

Aim and Objectives To analyse the correlation between the response to pembrolizumab plus chemotherapy and peripheral blood biomarker dynamics in patients with non-squamous metastatic NSCLC.

Material and Methods Retrospective and observational study including all patients treated with pembrolizumab plus pemetrexed plus platinum-based chemotherapy from January 2020 to December 2021. Variables collected: sex, age, baseline Eastern Cooperative Oncology Group (ECOG) scale, and lymphocyte, neutrophil and eosinophil absolute counts (ALC, ANC and AEC, respectively) at three timepoints: baseline (before treatment), week 4 of treatment and first computerised tomography (CT) scan. Neutrophil-to-lymphocyte ratio (NLR) was calculated for each timepoint. Patients were classified as responders (partial response or stable disease) or non-responders (progression at first CT scan). Statistical analysis was performed with software SPSS 24.0.

Results

Sixty patients were included 76.7% were male with a median age of 62 years. 88.3% presented baseline ECOG <2 and 76.7% of patients were categorised as responders (23.3% non-responders). Baseline NLR was similar between responders and non-responders. Median NLR at week 4 was significantly higher in non-responders (3.3 vs 1.99; p=0.04). Median NLR at first CT scan was also significantly higher in non-responders (3.5 vs 1.9; p=0.01). Among responders, there was a significant decrease (p<0.01) between baseline NRL and at time of first CT, while non-significant changes were found in the non-responder group. ANC was similar at baseline and first CT among responders and non-responders. However, there were significant differences at week 4 (p=0.036). Regarding ALC, significant differences were only found between both groups at first CT (p=0.015). Finally, for AEC, we did not find significant differences at any of the measured timepoints.

Conclusion and Relevance Our results suggest that NLR behaves as a predictive biomarker of response to immunotherapy. ANC showed significant differences among responders and non-responders at week 4, and ALC at the first evaluation. AEC did not show correlation with response.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-038 REAL-WORLD SAFETY OF IBRUTINIB IN CLINICAL PRACTICE IN PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKAEMIA

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Background and Importance Ibrutinib was well-tolerated in clinical trials. However, there is limited data on the safety of Ibrutinib-treated patients with chronic lymphocytic leukaemia (CLL) in routine clinical practice.

Aim and Objectives To describe the safety of ibrutinib in CLL patients in a real-world setting.

Material and Methods Retrospective study in a third-level hospital. All CLL patients treated with ibrutinib (July 2016 to June 2022) were included. Collected variables: age, sex, mutations, Binet stage at baseline, B symptoms at baseline, baseline ECOG, comorbidities, line of therapy, starting dose, discontinuation of treatment and reason. Presence of high-risk cytogenetics was determined: 17p deletion, TP53 mutation, 11q deletion, immunoglobulin heavy chain mutational status (IGHV). Safety variables: adverse events observed and their severity according to Common Terminology Criteria for Adverse Events v.5.0. Information was taken from medical records and the Outpatient Dispensing software. SPSS® was used for data analysis.

Results 47 patients were included, 68% male, mean(±SD) age of 69.2±11 years. 91.5% were >50 years old. 19.2% patients had TP53 alteration, 59.5% unmutated IGHV, 8.5% 11q deletion, and 8.5% 17p deletion. Binet staging classification was: A (42.6%), B (19.1%), C (21.3%) and undetermined in 17%. 42.6% of patients had B symptoms at baseline. 51% of patients presented ECOG 1 at initiation and 40.4% presented ECOG 0. 61.7% of patients had two or more comorbidities: hypertension (63.8% patients), diabetes mellitus (19.15%), dyslipidaemia (19.2%) and atrial fibrillation (12.8%). 66% of patients started as a first-line treatment. All received doses of 420 mg and four had dose reductions due to toxicity and one due to intolerance. In terms of safety, 14.9% patients had to discontinue due to the occurrence of adverse reactions. 80.8% patients experienced G1-type adverse reactions, the most frequent being asthenia (39.5%), arthralgias (26.6%) and haematomas (21.5%). 34% of patients had G2 reactions, most frequently haemorrhages and anaemia (18.7%), neutropenia (15.5%) and atrial fibrillation (12.5%).10.6% patients had G3 reactions, these being pneumonitis, neutropenia, uveitis, rectorrhagia and a cardiovascular event. Median follow-up until progression was 55.8±3.8 months. Median PFS was not reached.

Conclusion and Relevance Overall, results are consistent with those reported in clinical trials and other real-world studies.

In addition, no increased risk of serious adverse events was observed. Further follow-up is needed to confirm long-term safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-039 IMPACT OF TAILORED SCREENING INTERVALS ON THE BURDEN OF DRUG-DRUG INTERACTION ALERTS: AN INTERRUPTED TIME SERIES ANALYSIS

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Background and Importance Using fixed as well as broad screening intervals for drug-drug interaction (DDI) alerts leads to an excess of false positive alerts, contributing to alert fatigue among prescribers.
Aim and Objectives We aimed to investigate the effect of tailored screening intervals on the occurrence of DDI alerts.
Material and Methods An interrupted time series analysis was performed to evaluate the effect of a pragmatic intervention on the daily percentage of DDI alerts. The study period consisted of 100 randomly selected days between April 2021 and December 2022. A fixed screening interval of 7 days before and after prescribing a drug had been used to screen for DDIs, until implementation of the intervention. The intervention comprised embedding tailored screening intervals for 27 selected DDIs into the hospital information system. The daily percentage of DDI alerts was defined as the ratio of the number of DDI alerts to the number of new prescriptions per day.
Results During the study period, a mean of 5731 (±2909) daily new prescriptions was created. Daily DDI alerts decreased from an average of 8.6% (±2.2) in the pre-intervention period to 6.6% (±1.4) in the post-intervention period. A significant immediate absolute reduction of 4.5% (95% CI: -6.2; -2.8%, $p<0.0001$) in the number of prescriptions with a DDI alert was observed, which translated to approximately 258 (0.045*5731) false positive DDI alerts avoided per day.
Conclusion and relevance Defining and implementing tailored screening intervals was feasible and effective in reducing the burden of DDI alerts.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-040 VOLUNTARY MEDICATION ERRORS REPORTING SYSTEM IN AN ORTHOPAEDIC SURGERY AND TRAUMATOLOGY UNIT

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Background and Importance Medication errors (ME) are incidents that can occur at any stage of medication use in patient's care process. Voluntary incident reporting has proven to be a useful tool to identify contributing factors and establish improvement actions. Surgical patients have one of the highest rates of MEs because of their vulnerable profile and their multiple care transitions.
Aim and Objectives To analyse the voluntary ME notifications made in the Orthopedic surgery and Traumatology unit of a tertiary level hospital with electronic prescription, validation and administration system, to identify the most important contributing factors and to describe improvement actions.
Material and Methods ME reported in the Orthopedic surgery and Traumatology unit were analysed monthly by Hospital Safe Medication Use Committee from February 2022 to June 2023. Notifications were classified according to three factors: causality (prescription, administration, reconciliation, monitoring, transfers, labeling, dispensing, similarity of packaging and/or name), severity (potential circumstance to produce ME, incident that does not reach the patient, incident without harm and adverse events) and notifying personnel (physicians, nurses or pharmacists). Contributing factors were also identified and improvement actions were proposed.
Results A total of 83 ME voluntary reports were analysed. 74.6% of them were prescription errors, 6% were related to administration and 4.8% were related to reconciliation and monitoring. In terms of severity, 47.8% were harmless incidents, 26.5% were potential ME-causing circumstances, 19.3% were incidents that did not reach the patient and 7.2% were adverse events that did cause harm. The reporting personnel were mostly nurses (58%) and pharmacists (25%). The main contributing factors identified were daily review electronic prescriptions failure, lack of reconciliation of the patient's regular medication and variability in paediatric patient prescriptions. Improvement actions implemented were a specific protocol for the management of paediatric trauma patients, a multidisciplinary study of prescription errors and an informative session in the Orthopaedic surgery and traumatology unit where we explain the reported ME and specific recommendations were given to avoid them.
Conclusion and Relevance The analysis of the reported ME has allowed us to identify the contributing factors and to establish recommendations to modify them. Further studies of prescription errors will allow us to monitor the impact of the implemented actions.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-041 IMPACT OF INTRODUCING PREFILLED ATROPINE SYRINGES IN OCULAR SURGERY: PROACTIVE ASSESSMENT OF DRUG COSTS AND MEDICATION SAFETY

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Background and Importance Intravenous atropine injection is used to treat acute bradycardia during ocular surgery. It has been observed that a significant amount of ampoule-drawn atropine injections were unused and wasted yearly in a large ocular surgery unit. Some potential medication safety risks have also been recognised. Although ready-to-use prefilled atropine syringes are recommended to improve medication

safety of intravenous drugs, they are still rarely used in our country.

Aim and Objectives The aim of our project was to compare the drug costs and medication safety risks associated with the use of atropine ampoules and atropine prefilled syringes to treat acute bradycardia in ocular surgery.

Material and Methods First, the effects of prefilled syringes on drug costs were investigated by a literature search and by gathering data from other surgical units that already used prefilled syringes. Atropin-related drug costs of other surgical units were calculated before and after transition to prefilled syringes. After that, a Failure Mode and Effects Analysis 'FMEA' conducted by an interprofessional expert group was used to evaluate risks associated with the medication management and use process of both atropine products.

Results The introduction of prefilled syringes had decreased the costs of atropine injections in other surgical units more than 50% in average when compared to atropine ampoules. The savings we observed resulted mainly from wastage minimisation, because the shelf life of ampoule-drawn atropine injection is limited. Our literature search supported this observation. The FMEA analysis identified more medication safety risks related to the use of atropine ampoules (n=14, risk profile number 'RPN' 297) when compared to the prefilled syringes (n=7, RPN 74). The most significant difference came from the risks related to preparation of atropine injection (i.e. limited shelf life) and look-alike, sound-alike 'LASA'-risks associated with the use of atropine ampoules.

Conclusion and Relevance Based on cost analysis and proactive risk assessment by FMEA the transition to prefilled syringes appears to decrease costs and increase medication safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-042 FOCUS ON MEDICATION ERRORS ON HIGH-RISK MEDICATIONS IN A HOSPITAL'S ELECTRONIC INCIDENT REPORTING SYSTEM

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Background and Importance High-risk medications, i.e. anticoagulants, digoxin, gentamicin, insulin, potassium, opioids and low-dose methotrexate, have an increased risk of causing patient harm when used incorrectly.

Barcode medication administration (BCMA) systems can reduce the risk of medication errors by focusing on the five R's in medication management, i.e., the right patient, the right drug, the right dose, the right route, and the right time.

Aim and Objectives The aims were 1) to analyse and quantify medication errors in an electronic reporting system handling adverse events in a hospital with BMCA, and 2) to quantify the extent of high-risk medications that lacked a barcode at medicine unit level.

Material and Methods We analysed medication errors reported by hospital employees in the hospital's electronic incident reporting system that handles adverse events. We have read and categorised the errors carefully in terms of type, frequency and where in drug handling the errors had occurred.

Results Hospital staff reported 1,777 medication errors and nearly 30% (n=467) were associated with high-risk medications. Most errors occurred during prescribing (n=133, 28%) and drug administration (n=189, 40%). Anticoagulants and opioids were most frequently reported. This also corresponds with that 14% (n=41) of the 293 different high-risk medication packages lacked barcodes at medicine unit level, most of which were anticoagulants and opioids.

Conclusion and Relevance Assigning a barcode to all high-risk medication packages, so high-risk medications can be scanned, can prevent future medication errors. Labelling barcodes at medicines unit level on anticoagulants and opioids should be prioritised.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-043 DESCRIPTIVE STUDY OF MARKETED MEDICINES CONTAINING ASPARTAME

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Background and Importance Recently, the International Agency for Research on Cancer (IARC) has classified aspartame as possibly carcinogenic to humans. Furthermore, the Joint Expert Committee on Food Additives (JECFA) administered by the Food and Agriculture Organization of the United Nations in partnership with the World Health Organization has accepted a daily intake of 40 mg/kg body weight as safety threshold.

Aim and Objectives The primary objective was to compare the maximum daily intake of aspartame (MDIa) for every oral medicine marketed in our country with the safety threshold established by the JECFA. MDIa was defined as the daily amount of aspartame taken if using the maximum dose of the corresponding drug according to its label dosage recommendations.

Secondary objectives included describing the main features of these medicines and analysing their association with MDIa.

Material and Methods Bibliographic unicentric study carried out in a tertiary hospital.

Collected variables included medicine name, dosage form, authorised indication and milligrams of aspartame per unit in solid forms or per millilitre in liquid forms. Data were expressed as amount (percentage) for qualitative variables and median (interquartile range) for quantitative variables. Difference of medians was assessed through Mann-Whitney U test.

Results 370 medicines declared containing aspartame. According to their respective authorised indications, 222 (60.0%) were considered medication for chronic use and 148 (40.0%) acute care drugs. Regarding dosage form, 283 (76.5%) were fast disintegrating tablets, 68 (18.4%) oral solutions/suspensions or powders for oral solution/suspension and 19 (5.1%) other.

Median dose of aspartame was 3.0 mg/unit (1.3–8.0) for solid forms, and 12.5 mg/mL (5.0–30.0) for liquid forms. For the total population of study, MDIa was 9.0 mg per unit or mL (3.0–20.8) and the absolute largest observation was 420.0 mg/mL. Specifically, median MDIa for solid forms was 8.0 mg/unit (2.1–11.2) and for liquid forms was 75.0 mg/mL

(30.0–90.0); the difference between these medians was statistically significant ($p<0.001$).

Conclusion and Relevance All medicines marketed in our country containing aspartame remain under the threshold established by the JECFA for most adult population. However, since liquid forms contain considerable amounts, their suitability as chronic treatments should be reconsidered for children or other very-low weight patients during medication review, especially if polymedicated.

These results should be comparable to the rest of European countries.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-044 SAFETY OF PEMBROLIZUMAB +/- CHEMOTHERAPY IN FIRST-LINE METASTATIC NON-SMALL-CELL LUNG CARCINOMA IN REAL-WORLD PRACTICE

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Background and Importance Cancer patients with comorbidities are usually excluded from clinical trials. Real-life observational studies are of particular interest to elucidate the safety of these new therapies.

Safety of pembrolizumab +/- chemotherapy in metastatic non-small-cell lung carcinoma (NSCLC) was assessed in KEYNOTE-024, 189 and 407 pivotal trials.

Aim and Objectives To assess the safety of pembrolizumab +/- platinum-based chemotherapy in first-line treatment of metastatic NSCLC in real-world practice.

Material and Methods Observational, retrospective, single-centre study including 130 adult patients with stage IV NSCLC treated in first-line from 1 December 2017 to 31 December 2022, without EGFR or ALK mutations, autoimmune diseases or brain metastases, and performance status 0–1.

Patients with PD-L1 $\geq$ 50% received pembrolizumab 200 mg or 2 mg/kg IV every 3 weeks. Those with non-squamous histology and PD-L1 < 50% received pembrolizumab + cisplatin IV 75 mg/m2 or carboplatin IV 6 AUC plus pemetrexed IV 500 mg/m2 every 3 weeks for 4 cycles plus maintenance with pembrolizumab + pemetrexed. Squamous cells and PD-L1 < 50% received pembrolizumab + IV carboplatin 6 AUC and IV paclitaxel 200 mg/m2 every 3 weeks for 4 cycles plus maintenance with pembrolizumab. Treatments were prolonged until progression or toxicity for a maximum of 2 years.

A database was created to record adverse events (AEs) obtained from electronic medical records and according to Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0.

Results In total, 491 AE of any grade and 78 of grade 3–4 were recorded. 10 patients discontinued treatment due to toxicity. AEs with incidence > 15% were (any grade – grade 3–4): anaemia (36–11), anorexia (51–2), asthenia (96–10), nausea (43–3), diarrhoea (25 -2), constipation (20–0), mucositis (21–2), neurotoxicity (22–1). Immune-mediated AEs were (any grade – grade 3–4): hepatotoxicity (7–3), nephritis (3–1), myocarditis (1–1), duodenojejunitis (1–1), pneumonitis (1–0).

Conclusion and Relevance Most patients suffered more than one AE. Even so, no deaths were related to toxicity (there were no grade 5 AEs). The six grade 3–4 immune-mediated AEs should be highlighted.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-045 ANALYSIS OF A PHARMACEUTICAL INTERVENTION IN POLYMEDICATED PATIENTS WITH DEMENTIA AND IN TREATMENT WITH HIGH ANTICHOLINERGIC ACTIVITY DRUGS

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Background and Importance Medicines with anticholinergic properties are frequently prescribed in older populations for different medical conditions increasing the risk of cognitive and functional disorders. Patients with dementia in treatment with acetylcholinesterase inhibitors (donepezil, rivastigmine, galantamine) are also more vulnerable to these drug-related problems, not only because of the adverse impact of the cumulative anticholinergic effect but also because the effects of anticholinergics and acetylcholinesterase inhibitors (AChEi) oppose each other and may result in a diminished therapeutic effect.

Aim and Objectives To analyse the pharmaceutical intervention carried out in polymedicated patients with dementia and taking high anticholinergic activity drugs.

Material and Methods Observational, descriptive and prospective study in which the pharmaceutical interventions performed between June to August 2023 in five primary healthcare centres. Polymedicated patients ($\geq$ 5 drugs) with dementia and AChEi drugs and concomitant treatment with high anticholinergic burden were selected. The clinician received a review of the potential drug interaction with clinical evidence and a list of patients eligible for deprescription. After one month we reviewed if the pharmaceutical intervention was accepted or not with any patient prescription change: reduced dose of anticholinergic drug, suspension or substitution of any drug.

Results During the study period, 49 polymedicated outpatients were included, 29% men, 79 (75–96) years median age. Median prescribed drugs 12 (10–22). According to the ATC classification, the high anticholinergic activity drug prescribed were: 21% (10) Antimuscarinic overactive bladder, 4% (2) Antimuscarinic spasmolytic, 8% (4) Antihistamines, 8% (4) Antipsychotropic, 41% (20) Tricyclic antidepressants, 18% (9) Selective serotonin reuptake inhibitor. Acceptance of pharmaceutical intervention with any change in prescription: 43% (21). 14 (66%) anticholinergic drugs were suspended, 2 (10%) reduce dose of anticholinergic drug, 2 (10%) increase dose of AChEi drugs or added memantine, 3 (14%) change the high anticholinergic activity drug.

Conclusion and Relevance This study highlights the need and importance to review the chronic medication and to measure the anticholinergic burden in old patients above all in dementia diagnosis. Most guides recommend the avoidance of the combination of anticholinergic drug and acetylcholinesterase inhibitors drugs if it is possible and this study gives us an

idea of the benefit of having a pharmacist as part of the multidisciplinary team reviewing polymedicated patients to prioritise interventions in patients at highest risk of suffering adverse drug events.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-046 SYNDROME OF INAPPROPRIATE SECRETION OF ANTIDIURETIC HORMONE INDUCED BY ALPRAZOLAM: A CASE REPORT

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Background and Importance The correlation between psychotropic drugs and iatrogenic syndrome of inappropriate antidiuretic hormone secretion (SIADH) has been well documented. In regards to anxiolytics and hypnotic drugs, however, a recent expert consensus finds only low-level evidence supporting the relationship between benzodiazepines and SIADH. In this report we present a case of patient with diagnosed alprazolam-induced SIADH.

Aim and Objectives A 67 year-old woman was diagnosed with SIADH possibly induced by alprazolam benzodiazepine. The patient, with a long history of anxiety syndrome, was treated with alprazolam 0.25 mg 3 times daily for more than 10 years. The patient also suffered from Hashimoto's thyroiditis, pulmonary arterial hypertension, paroxysmal atrial fibrillation, mitral valvuloplasty, Gilbert's syndrome and underwent polypharmacy treatment with furosemide 25 mg, rivaroxaban 20 mg, bisoprolol 5 mg, ramipril 5 mg, amlodipine 20 mg, atorvastatin 10 mg and cholecalciferol 10.000 UI/ml.

Material and Methods In 2020, the patient attended the emergency department after syncope and diarrhoea. Blood tests revealed sodium levels of 126 mmol/L. Furosemide was immediately suspended and sodium with inulin supplementation was initiated. The subsequent follow-up tests excluded hypocorticism or thyroid dysfunction; copeptin and sodium and potassium excretion levels were all in range; all other possible causes were excluded. Due to the anxiety syndrome, benzodiazepine therapy was not discontinued but alprazolam was replaced with bromazepam 1.25 mg twice daily.

Results Since last check-ups, the patient has been presenting stable mild hyponatremia (around 130 mmol/L) and is continuing daily oral sodium and inulin supplementation. Periodic electrolyte tests and monitoring for symptoms such as confusion, psychomotor retardation, nausea or vomiting are recommended at every visit.

Conclusion and Relevance The patient presented in this case report was diagnosed with an alprazolam-induced SIADH after differential diagnosis. Risk factors known to potentially cause SIADH, such as age >=60 years, female gender, polypharmacy and medical comorbidities, all present in the described patient, had to be taken into consideration for diagnosis. Benzodiazepine-induced SIADH could be considered in case of hyponatraemic patients presenting underlying risk factors and in the absence of other clinical causes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

5PSQ-047 THE PERCEIVED IMPACT ON PATIENT SAFETY AND QUALITY OF CARE OF PHARMACEUTICAL TECHNICAL ASSISTANTS ON NURSING WARDS: A QUALITATIVE STUDY

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Background and Importance Staff shortages challenges hospital nurses to maintain high-quality medicine management. To support nurses, pharmaceutical technical assistants (PTAs) have been introduced on hospital wards to dispense medication. However, evidence is lacking regarding the impact of PTAs on the quality of care and patient safety.

Aim and Objectives This study explored nurses', PTAs' and pharmacists' experiences and perceptions regarding the implementation of PTAs to support medication dispensation on hospital wards. The process of implementation, role development, and impact on safety and quality of care were investigated to determine critical success factors and opportunities.

Material and Methods Semi-structured interviews with involved healthcare professionals were conducted (December 2022 to March 2023), audio recorded, and transcribed verbatim. Thematic analysis was performed.

Results Twenty-eight interviews were conducted with nine nurses, seven head nurses, 10 PTAs and two pharmacists on internal, surgical and geriatric hospital wards. Three main themes emerged: patient safety and quality of care, organisation of care, and role development and collaboration. Implementation of PTAs on hospital wards was perceived to a lower risk of medication errors without compromising care quality. Successful implementation requires a clear role description of PTAs and uniform communication procedure to improve medication safety and care quality, hospital wards must be structurally allocated to the same PTAs, for them to become part of the team. Being part of the team is considered an important aspect to ensure an optimal cooperation between nurses and PTAs. Nurses indicated that collaboration with PTAs challenged them in their role of supervising care and co-working in the team, but it resulted also in reduced workload for pharmaceutical care tasks. PTAs perceived their implementation on hospital wards as a welcome expansion of their role.

Conclusion and Relevance All participants were convinced that implementation of PTAs on hospital wards had a positive effect on nurses' workload, patient safety and quality of care. Organisational barriers mentioned were limited, yet, will help

to further optimise processes and outcomes. In other European countries, PTAs are allowed to perform more tasks on hospital wards.

Critical success factors for the implementation include dedicated assignment of PTAs to hospital wards, clear role description and mutual expectations in the collaboration and communication between PTAs and nurses.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-048 COST-SAVING IMPACT OF USING NUSINERSEN BY CLINICAL TRIALS FOR SPINAL MUSCULAR ATROPHY

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Background and Importance Nusinersen is an antisense oligonucleotide that increases the production of full-length, functional survival of motor neuron (SMN) protein. It was the first disease modifying therapy approved for Spinal Muscular Atrophy 5q (SMA). SMA is a progressive neuromuscular rare disease, however the cost of available treatments implies a high economic burden for the sanitary system.
Aim and Objectives To analyse the economic advantage of treating SMA in clinical trials (CT) with nusinersen provided by the sponsor.
Material and Methods Retrospective, observational, single-centre, multidisciplinary economic study calculating the cost-saving impact of the use of intrathecal nusinersen in CT between February 2021 and September 2023.

Clinical data was extracted from Farmis-Oncofarm® and pkEnsayos®, whereas economic data [Laboratory Purchase Price (LPP) without Value-Added Tax (VAT)] was obtained from Orion-Logis®.
The variables analysed were age, anthropometric data (basal weight), diagnosis, pharmacotherapeutic data (cycles received and administrations) and consumption data (preparations and avoided costs). The results were expressed as: percentage, and median with interquartile range (IQR).
Results Two active CT for SMA using nusinersen were selected to be included: a phase II/III trial, and the phase III extension. Seven patients were treated with nusinersen in both CT: 5 paediatric patients (71.4%) and 2 adults (28.6%). The median paediatric age and weight were 2.8 years [IQR 2.5–7.4] and 10.0 kg [IQR 6.5–23.0], respectively. The adults' median age and weight were respectively 34.8 years (31.4 y 38.1) and 78.5 kg (48.0 y 109.0).

A total of 53 drug preparations were made, with a median of nine per patient [IQR 5–9], that resulted in a total consumption of 1,394 mg (178 mg per patient [IQR 162–240]). The global cost-saving was 5,148,443.7 €, that represents annually an economic impact of 2,067,648.1 €.

The median treatment cost avoided per CT and patient were 2,574,221.9 € (2,415,410.5 y 2,733,033.3) and 598,312.7 € [IQR 3,871.3- 88,639.2], respectively.
Conclusion and Relevance SMA is considered one of the world's most expensive treatment disease, and nusinersen is the standard of care. The promotion to participate in SMA CT allows access to innovative treatments for patients and hospitals with the aim of reducing the large underlying budgetary burden.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-049 MEDICATION PRESCRIBING ERRORS PROSPECTIVE OBSERVATIONAL STUDY IN AN INTENSIVE CARE UNIT

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Background and Importance Prescribing errors (PE) are an important cause of medication-related adverse events in Intensive Care Units (ICU) but limited data are available in ICU with electronic prescribing and administration (ePA) systems.
Aim and Objectives To determine the rate of PE in an ICU with ePA system, to classify incident types and to identify critical points where measures should be implemented to improve patient safety.
Material and Methods Prospective, observational and cross-sectional study in an ICU with ePA system during five working days (november 2021). The inclusion criteria were ICU inpatients with an electronic prescription. Prescriptions were recollected and analysed by a multidisciplinary team comprised of a pharmacist, an ICU physician, a nurse and the person in charge of the hospital's Medication Errors Committee. PE were reported to the hospital's patient safety-related incident notification system.
Results 30 patient prescriptions, with 441 medications prescribed, were revised during the study period. The patients' average age was 60.7 ± (SD=13.2) years and each prescription had an average of 14.7 medications. PE were reported in 31 cases and two situations with the capacity to cause errors were detected. The rate of PE was 1.03 errors per patient, 0.07 per prescribed medication and 53% of patient prescriptions were PE free. The most common types of PE were wrong dose (33.3%), excessive duration (29.0%), drug not indicated by clinical situation (12.9%) and no administration prescribed medication (12.9%). Results were communicated to staff physicians and residents with recommendations to minimise them: enteral nutrition adjustment if a propofol treatment initiated or modified, use available protocols in ePA system, review and eliminate non-active treatments and be especially careful with care transitions.
Conclusion and Relevance This study has made it possible to identify the weak points of medication prescription in our ICU. The realisation of periodic PE studies allows us to establish the impact of the implemented actions and to define new objectives to improve patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-050 IS IT POSSIBLE TO IMPROVE THE HIPOPOTASEMIC MANAGEMENT IN THE HOSPITAL?

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Background and Importance Potassium metabolism disorders are the most frequent electrolyte alteration in clinical practice. Early detection of hypokalaemia could prevent future complications.

Aim and Objectives To know the prevalence of hypokalaemia disorders in adults admitted in a third-level hospital. Evaluate the aetiology and the corrective treatment during the following 24 hours. To identify improvement actions.

Material and Methods Descriptive observational study of three cross-sections carried out during December 2022. In each section, all the analytical determinations that included potassium determination were selected, and the medical records of patients with hypokalaemia (K <3.5 mEq/L) were reviewed.

The severity of the alteration and the corrective treatment were determined within 24 hours after the analytical determination.

Hypokalaemia was classified according to severity as: mild (3–3.49 mEq/L), moderate (2.51–2.99 mEq/L) or severe (≤2.5 mEq/L). Possible causes were considered: hypomagnesemia, pharmacological, idiopathic or insufficient intake (nothing by mouth without potassium supplement).

Results In each section, were identified 116, 116 and 112 (344 in total) patients with potassium determination. The patients admitted each day were 327, 323 and 321, respectively. 45/344 (13%; 95% CI [9.5–16.6]) had hypokalaemia (40 mild, 4 moderate and 1 severe).

21/45 patients had a pharmacological cause (46.7%; 95% CI [32.1–61.2]), furosemide being prescribed in 15 of them. 11/45 patients presented hypomagnesemia as a probable aetiology (24.4%; 95% CI [11.9–37]). It was identified as a possible idiopathic cause in 9/45 patients (20%; 95%CI [8.3–31]) and in 4/45 (8.9%; 95%CI [6–17.2]) insufficient supply of potassium was observed (patients on an absolute diet without supplementation).

18/45 patients did not receive corrective treatment (40%; 95% CI [25.7–54.3]).

Conclusion and Relevance Hypokalaemia occurs in 13% of daily laboratory analysis in the hospital, the main cause being pharmacological. In the first 24 hours, 40% of patients do not receive corrective treatment.

The establishment of a systematised computerised extraction of patients with alterations in potassium levels would detect unidentified alterations. It could be possible to establish corrective treatment earlier, and this fact could be able to benefit more than 5,000 patients annually in our setting.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-051 EFFECTIVENESS AND SAFETY OF NIRMATRELVIR/RITONAVIR IN OLDER PATIENTS AT A NURSING HOME WITH COVID-19

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Background and Importance The use of the antiviral drug nirmatrelvir/ritonavir in nursing home patients with COVID-19 has reduced its main complications, although due to comorbidity and polypharmacy there are often problems with interactions.

Aim and Objectives To evaluate the effectiveness and safety of nirmatrelvir/ritonavir in nursing home patients with COVID-19 infection.

Material and Methods Retrospective observational study including all nursing home patients attended by a Geriatrics Liaison Unit from a hospital in Madrid between May 2022 and July 2023 and treated with nirmatrelvir/ritonavir. We collected the number of referrals to the emergency department, hospitalisations and mortality due to COVID-19 a month after treatment with nirmatrelvir/ritonavir and interactions and adverse events detected associated with the drug.

Sociodemographic, clinical and pharmacological variables were collected from the electronic medical record.

Results A total of 111 patients (76.6% women) with a median age of 89.5 years (68–102) and a Charlson index of 2 (0–5) points were included, from 18 different nursing homes. Overall, 58.6% (65) had dementia, 40.5% (45) Barthel ≤40 and 33.3% (37) impaired renal function receiving reduced doses of nirmatrelvir/ritonavir.

Clinically, 96.4% (107) had mild symptoms (cough, fever, myalgia, diarrhoea) and 0.9% (1) were asymptomatic and 53.2% of them (59) previously received four doses of vaccine. No symptoms were recorded in 2.7% (3) of the patients.

A total of 283 interactions of nirmatrelvir/ritonavir with 62 different chronic drugs were detected: trazodone (8.8%), metamizole (8.1%), quetiapine (7.4%), amlodipine (7.4%), mirtazapine (6%), atorvastatin (4.6%) were the most frequent. We observed at least one interaction in 93.8% of the patients, with a mean number of 2.6 interactions per patient. Eighty-two interactions were severe requiring discontinuation, 180 were moderate of which 81 required monitoring and 99 required drug adjustment including change of dose, frequency, regimen or substitution with another drug.

One month after treatment with nirmatrelvir/ritonavir, 2.7% (3) of patients were referred to the emergency department for Covid-19 of whom 66.7% (2) required hospital admission, while just one patient presented potential adverse reaction to treatment (dysgeusia) and no patient died during this month due to COVID-19.

Conclusion and Relevance Nirmartrelvir/ritonavir is effective and safe for the treatment of Covid-19 in nursing home patients but requires a review of clinical history and drug interactions to adjust chronic treatments during administration.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-052 ANALYSIS OF POTENTIAL PROGNOSTIC FACTORS OF EFFICACY IN TISAGENLECLEUCEL TREATMENT IN A COHORT OF PATIENTS WITH DIFFUSE LARGE B-CELL LYMPHOMA

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Background and Importance In the context of B-cell non-Hodgkin lymphomas, the use of CAR T-cell therapy offered new treatment possibilities. The evolution of these therapies can improve the treatment arsenal and patients' life expectancy. However, some patients experience treatment failure: the identification of predictors can be crucial for a cost-effective use of this therapy.

Aim and Objectives The purpose of this analysis was to evaluate the correlation between some possible predictive factors and outcome after tisagenlecleucel infusion in patients with diffuse B-cell lymphoma. A retrospective observational study was conducted on a cohort of 35 patients treated with tisagenlecleucel from clinical practice in an Italian Oncologic Institute from December 2019 to August 2023. Patients were evaluated based on their response to the therapy in terms of overall response rate over an 18-month period following infusion. The analysed factors included age, gender, development of cytokine release syndrome and its grade, tocilizumab administration, steroid administration, lymphocyte count at the time of leukapheresis, lymphocyte count at day 14 and day 30 post-infusion, c-reactive protein at day 0, peak of c-reactive protein within 14 days post-infusion, ferritin at day 0, peak ferritin within 14 days, previous therapy lines, previous autologous marrow transplantation, disease stage, bridge therapy received.

Material and Methods Factors that could influence response were analysed by stratified analysis dividing patients into responders (complete remission, partial remission) and non-responders (death and progression) at 18 months; Mann-Whitney U test for continuous variables and Fisher's exact test for categorical variables were used. Univariate logistic regression was used to assess the independent contribution of each factor on the probability of response to therapy. Statistical significance was considered for a value of $p<0.05$.

Results Elevated baseline levels of c-reactive protein and ferritin increase the risk of therapy failure. Higher ferritin peaks within 14 days also increase the risk of failure. Higher lymphocyte expansion at day 30 is associated with a better response; previous autologous marrow transplantation correlates with a better response.

Conclusion and Relevance The patient's inflammatory status before therapy should be carefully evaluated: elevated levels of inflammatory markers are associated with therapy failure. Previous autologous marrow transplantation correlates with a better response; the analysis of factors that can predict the possibility of treatment failure is important.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-053 EFFECTIVENESS AND SAFETY OF GALCANEZUMAB. REAL-LIFE RESULTS

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Background and Importance Galcanezumab is a monoclonal antibody that binds the calcitonin gene-related peptide, indicated for migraine prophylaxis.

Aim and Objectives To assess the effectiveness and safety of galcanezumab six months after initiation of treatment.

Material and Methods A retrospective observational study including patients treated with galcanezumab, from September 2020 to August 2023 was conducted. Collected variables comprised age, sex, type of migraine, median number of migraine days per month (MDM), HIT-6 score, galcanezumab treatment duration, and adverse effects. Treatment with galcanezumab was considered effective if a reduction of at least 50% in MDM or a reduction of more than 5 points on the HIT-6 scale was achieved at 6 months of treatment. For the assessment of drug safety, adverse effects reported by the patient were considered.

Results A total of 32 cases were reviewed (median age 49 years; 25 women [71.4%]), 75% (n=24) of patients had chronic migraine without aura, 9.4% (n=3) had chronic migraine with aura, and 15.6% (n=5) had high-frequency episodic migraine. The change in MDM before and after six months of treatment was 15 versus 5, and the HIT-6 index was 69 versus 57. Median duration of galcanezumab treatment was 19 months. At the end of the study period, 84.6% of patients continued with the treatment, while 15.4% discontinued it due to side effects or ineffectiveness. Regarding the type of adverse effects, two patients reported dizziness (7.7%), and one reported intense itching (3.8%). The observed frequencies are higher than those reported in pivotal clinical trials, with an incidence of 1.2% for dizziness and itching. The adverse effects reported were in all cases, mild or moderate, and the discontinuation rate awed to this reason was less than 4%.

Conclusion and Relevance Treatment with galcanezumab has proved to be effective and safe in most patients. Despite adequate monitoring at six months from the initiation of monoclonal antibody treatment, further and longer-term studies would be necessary to establish the utility of this drug, its impact on quality of life, and its long-term safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-054 EVALUATION OF AN APPLICATION TO HELP FOR THE ADEQUACY OF THE DOSAGE OF ANTIBIOTICS IN RENAL FAILURE

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Background and Importance Due to the aging of the population, there are more and more patients with chronic renal failure who require prolonged hospitalisation. There are also many patients who, during a hospital admission, see their renal function worsen and are therefore candidates for a dosage adjustment of certain drugs.

For this reason we designed within our drug prescription system, a module to guarantee safety in the prescription of drugs that require adjustment according to glomerular filtration rate (GFR).

Aim and Objectives To improve the safety of prescribing antibiotics requiring renal adjustment during hospital admission.

Material and Methods In the drug prescription system we can indicate the recommended dosage according to the GFR interval of each drug.

If from a certain GFR, its prescription is not recommended, the program warns you and advises against its use.

Different GFR intervals can be added and if necessary a different dose of the same drug can be associated. Thus, when the program alerts that the drug requires a change of dose, the program proposes it automatically, which entails agility at the time of making the prescription.

Within the prescription program, the value of the patient's last GFR can be displayed with the date of the analysis. It is with this value that the program makes the proposal to change the dosage.

If dosage adjustment is not necessary according to clinical criteria, the conventional regimen can also be prescribed.

Results During the 4 years after implantation, 28,701 dosage adjustments have been made according to renal function. Of these, 6,081 (21%) correspond to antibiotics.

Of the total dosages changed, 1,410 (23%) correspond to piperacillin-tazobactam, 1,138 (18.7%) to ciprofloxacin, 822 (13.5%) to amoxicillin-clavulanic acid, 380 (6.2%) to meropenem, 330 (5.4%) to levofloxacin, 183 (3%) to fosfomycin, 176 (3%) to cefepime, 163 (2.6%) to imipenem, 160 (2.6%) to cefazolin, 141 (2.3%) to vancomycin and 139 (2.2%) to ceftriaxone.

The remaining 1,039 (17%) antibiotics carry the remaining 1,039 (17%) prescriptions.

Conclusion and Relevance This application has helped us to improve the adequacy of the dosage of antibiotics in case of renal failure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-055 EFFICACY AND SAFETY OF DALBAVANCIN IN GRAM-POSITIVE INFECTIONS TREATMENT

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Background and Importance Dalbavancin is a semi-synthetic lipoglycopeptide with activity against gram-positives, including methicillin-resistant Staphylococcus aureus, indicated for skin and soft tissue infections. Unlike other glycopeptides, it has an extremely long half-life, allowing for weekly or biweekly dosing.

Aim and Objectives The aim of the study was to evaluate the effectiveness and safety of dalbavancin in gram-positive infection treatment in patients at a tertiary-level hospital.

Material and Methods Retrospective, single-centre study. Patients receiving dalbavancin from September 2021 to August 2023 were included. Clinical and analytical data were obtained from medical records. Variables collected: gender, age, antibiotic allergies, type of infection, causative microorganism, previous antibiotic therapy. Regarding treatment: dosage, duration, diagnosis, concomitant antibiotics, clinical and microbiological resolution, adverse reactions (ARs) and discontinuation due to them. Clinical resolution was defined as absence of infection signs, and microbiological resolution as obtaining a negative culture.

Results 35 patients were included, with mean age (±SD) of 70 (±11.54) years, 60.7%male. Only one had antibiotic allergy (amoxicillin-clavulanate). All patients had received prior antibiotic treatment before dalbavancin, except one, average duration (±SD) of 20 (±8.5) days.

Dalbavancin was prescribed as targeted treatment except for two empiric cases. The indications were: endocarditis 60.0%; prosthetic infection 20.0%; pacemaker infection 8.6%; and the remaining 11.4% included osteomyelitis, septic pseudoarthritis, mycotic aneurysm, and mediastinitis (1 each).

Causative microorganisms Staphylococcus epidermidis 28.6%, Viridans-group Streptococcus 20.0%, Methicillin-sensitive S. aureus 14.3%, Enterococcus spp.11.4% (3 E.faecium and 1 E. faecalis), Clostridium spp.11.4%, Methicillin-resistant S.aureus 5.7%, Abiotrophia spp.2.9%.

Dosage regimen 48.6% (17) weekly regimen (initial dose 1000 mg, maintenance 500 mg); 34.3% (12) biweekly treatment (initial dose 1500 mg, maintenance 1000 mg); and 17.1% (6) single dose of 1500 mg. Mean duration (±SD) was 4.32 (±3.38) weeks. One patient received concomitant antibiotic treatment due to a polymicrobial infection.

Reasons for using dalbavancin was to facilitate discharge and avoid prolonged hospital stays in 27/35 patients, three failed to previous antibiotics, and five had ARs to previous antibiotics.

Clinical and microbiological remission was achieved in 85.7%. No patient experienced ARs to the drug.

Conclusion and Relevance In our experience, dalbavancin is effective and safe in gram-positive infections requiring prolonged treatments, such as endocarditis. Its pharmacokinetic characteristics enable outpatient-type administration that reduces patient's hospital stay, resulting in increased patient safety and quality of life, as well as significant cost savings in hospital expenses.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-056 VACCINATION COVERAGE AGAINST PENUMOCOCCUS FOR PEOPLE LIVING WITH HIV BEFORE AND AFTER THE COVID-19 PANDEMIC

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Background and Importance Immunisation is the best prevention against pneumococcal diseases in people living with HIV (PLHIV). From 2010 to 2022, the recommended vaccination schedule was sequential: 13v conjugate vaccine followed by the 23v polysaccharide vaccine.
Aim and Objectives The aim of the study was to describe and compare vaccine coverage against pneumococcus before and after the COVID-19 pandemic in (PLHIV).
Material and Methods The sample was obtained from patients who attended the Pharmacy Department of a tertiary hospital in the years 2019 and 2022 to receive their antiretroviral drugs. Vaccination data were obtained from the SISPAL database of the Community of Madrid. Vaccination coverage between 2019 and 2022 was estimated and compared using bivariate logistic regression.
Results In total, PLHIV were 2,978 and 3,169 in 2019 and 2022 respectively. The median age was 47 (37–53) and 46 (35–53) respectively. Men were more prevalent, with 81.5% in 2019 and 81.9% in 2022. 62.7% and 68.5% received the sequential anti-pneumococcal regimen in 2019 and 2022, respectively (OR 1.29 95%; CI: 1.13–1.48; $p<0.05$). 29.6% (2019) and 22.6% (2022) of the patients did not complete the sequential vaccine regimen, and 7.7% (2019) and 8.9% (2022) did not receive any vaccine in both years.
Conclusion and Relevance Vaccine coverage in people living with HIV against pneumococcus increased in 2022 compared to 2019, prior to the COVID-19 pandemic.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-057 ANTICHOLINERGIC BURDEN ASSESSMENT IN INSTITUTIONALISED PATIENTS

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Background and Importance Pluripathology, polymedication, dependence and frailty are common situations in institutionalised populations. Due to these circumstances is very important to monitor drug safety in these patients, especially the risk of anticholinergic effects that can significantly affect quality of life.
Aim and Objectives To identify the drugs that add anticholinergic burden (AB) prescribed in nursing home residents, as well as to quantify the overall AB.
Material and Methods Cross-sectional study carried out in nursing home residents attached to a hospital pharmacy service. All patients institutionalised in September 2023 were included. Variables collected: Age, sex and number of drugs prescribed.

The Anticholinergic Burden Calculator was used to identify drugs with AB according to the 10 scales included in the calculator. The anticholinergic risk (AR) obtained was quantified with the Anticholinergic Cognitive Burden Scale (ACB), which classifies the patient with a high (>3), medium (2) and low (1) risk of presenting anticholinergic adverse effects.

Subsequently, patients were categorised into four groups according to the number of drugs prescribed (1–5, 6–10, 11–15 and >15) and the AB was quantified according to ACB of each group.
Data sources electronic medical sources and electronic prescribing software. Microsoft Excel 2020® was used to process the data.
Results Eighty-two patients were included, male 69.5% (n=57), mean age 74.5±8.5 years, with a mean of 9.0±4.3 prescribed medications per resident.

According to ACB 32.9% (n=27) had low, 4.9% (n=4) medium and 24.4% (n=20) high risk of manifesting anticholinergic adverse effects; 37.8% (n=31) of patients had no AR.

The most prescribed drugs with AB were: furosemide 7.1% (n=15), tamsulosin 6.2% (n=13), tramadol 6.2% (n=13) and metformin 5.2% (n=11); the drugs with the highest AB were: oxybutynin 0.5% (n=1), paroxetine 0.9% (n=2) and olanzapine 1.4% (n=3).

The mean AB found according to the number of drugs prescribed was: 0.2±0.4 for the 1–5 group (n=16,19.5%),1.5 ±1.7 in 6–10 (n=39,47.6%), 1.4±1.2 in 11–15 (n=20,24.4%) and 3.3±1.6 in patients with >15 (n=7,8.5%) drugs prescribed.
Conclusion and Relevance In our study a high percentage of patients showed AR, however the most prescribed drugs had low AB. On the other hand, AB was higher as the number of drugs prescribed increased.

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Conflict of Interest No conflict of interest.

5PSQ-058 EFFICACY EVALUATION OF ANTI-PCSK9 DRUGS FOR THE TREATMENT OF PRIMARY HYPERCHOLESTEROLAEMIA OR MIXED DYSLIPIDAEMIA

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Background and Importance The anti-PCSK9 monoclonal antibodies alirocumab and evolocumab were authorised in 2015 for the treatment of primary hypercholesterolaemia (heterozygous HeFH or non-family noFH) or mixed dyslipidaemia

(MD). They have been studied in statin-intolerant patients, in combination with a statin or as monotherapy and have been shown to reduce LDL cholesterol by 50–70% overall.[1]

Aim and Objectives The analysis aimed to evaluate, by checking AIFA monitoring registers, the efficacy of alirocumab and evolocumab and the therapeutic adherence in patients who completed the treatment for primary hypercholesterolaemia or mixed dyslipidaemia.

Material and Methods The C-LDL and C-HDL values at the beginning and at the end of treatment were compared as therapy efficacy indicators. In addition, comorbidities and concomitant therapies were analysed. The data reported refer to the overall average duration of treatment for each patient.

Results Of the 37 patients (mean age 63 years, 36–81), 28 received alirocumab and nine received evolocumab. The average duration of treatment was 34.7 months (4.6–73,9) and 76% had at least two comorbidities. Also, 83,8% of patients were taking ezetimibe, 19% rosuvastatin and 13,5% atorvastatin. 57% of the sample was eligible for noFH, 32% for MD and 11% for HeFH. The mean C-LDL reduction from baseline after therapy with alirocumab was 39,9% while with evolocumab it was 42,8%. An average C-HDL increase of 13% occurred in both therapies.

Conclusion and Relevance Anti-PCSK9 are effective in reducing C-LDL levels: a 40% reduction was reported for alirocumab 75 mg over an average of 35,5 months of treatment (2–62,3), 41% for alirocumab 150 mg over 35,2 months (10,8–64,9) and 42,5% for evolocumab over 34,7 months (8–73,9). These values are lower than those of the registrative clinical studies although they refer to shorter treatment periods (2–3 months). These data suggest that in addition to efficacy, it is important to monitor patients' adherence and tolerability: in the former case, 76% of patients changed therapy after an average of 355 months and in the latter case, 13.5% discontinued therapy due to the occurrence of adverse reactions after an average of 17,7 months.

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Conflict of Interest No conflict of interest.

5PSQ-059 STUDY OF THE USE OF CEFTAZIDIME/AVIBACTAM IN A FIRST-LEVEL HOSPITAL

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Background and Importance Ceftazidime/avibactam is a combination antibiotic treatment considered to be of restricted use due to its novelty and low resistance. Its use is justified as a targeted therapy in the presence of multi-resistant gram-negative aerobic bacteria according to the antibiotic optimisation programme protocol.

Aim and Objectives To analyse the use and prescribing services of ceftazidime/avibactam in inpatients during 365 days.

Material and Methods A retrospective and descriptive observational study of the use of ceftazidime/avibactam during a 24-month period in the Hospital Universitario Torrecárdenas was carried out, analysing 46 patients. Data were extracted from the clinical database of the Andalusian Health System (Diraya), the database of the laboratories of Almeria (Modulab) and the location of the treatment was consulted in the Dominion – Unidosis database.

Results The group analysed consisted of 46 patients of whom 16 died, and of the total of 30 survivors, four were still in hospital at the time of the study.

The group consisted of 26% women and 74% men. Mortality in females was 33% compared to 35% in males. Total mortality was 37%.

Of the total, 48% received a targeted treatment for a multi-resistant bacterium, with 10% prescribed by the infectious disease service and 38% by other services. Only 28% were targeted treatments for multi-resistant gram- resistant bacteria.

In contrast, 52% of the total received ceftazidime/avibactam as empirical treatment. In 37% of the empirical cases the bacteria were found to be non-resistant.

Of the 48% of targeted treatments:

20% of gram-positive
1 Staphylococcus petrasii
5 Staphylococcus epidermidis MRSA
2 Staphylococcus haemoliticum MRSA
1 Staphylococcus aureus MRSA

28% of gram-negative
7 Pseudomona aeruginosa mR
1 Escherichia coli OXA-48
1 Klebsiella pneumoniae BLEA
1 Enterococcus faecium VanR
3 Stenotrophomonas maltophila

Conclusion and Relevance The data revealed by the study do not conform to the centre protocol highlighting its use as empirical and targeted treatment for gram-positives. Ceftazidime/avibactam is considered to be of extremely restricted use limited by antibiograms or sepsis codes in the presence of multidrug-resistant gram-positive bacteria.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-060 REAL-LIFE DATA ON THE EFFECTIVENESS AND SAFETY OF CABOTEGRAVIR/RILPIVIRINE IN A THIRD-LEVEL HOSPITAL

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Background and Importance The combination of cabotegravir and rilpivirine (C/R) is the first commercialised long-acting injectable for treating HIV-1. Real-life data in Spain is still scarce.

Aim and Objectives To analyse the effectiveness and safety of patients treated with C/R in a tertiary hospital.

Material and Methods A descriptive observational study of patients treated with C/R from 1 February 2023 (date of inclusion in the Hospital Drug Guide) until 31 August 2023 in a tertiary hospital. All patients on an oral regimen and with an undetectable viral load (VL) were included. Those

that came from the pivotal trials were excluded. Effectiveness was measured as the percentage of patients who remained with undetectable VL on 24 September 2023. To measure safety, the adverse reactions (AR) recorded in the electronic medical records were reviewed.

Results One hundred and seventy-five patients were included: 156 cis-men (89%), 18 cis-women (10%) and one trans-woman (1%), with a median age of 45 years (IQR=36–57). The most common prior treatments were bictegravir/emtricitabine/tenofovir alafenamide (48%) and dolutegravir/lamivudine (23%). One hundred and thirty-seven patients had at least one analysis since the first administration, 15 had two, and the rest had no analysis since the first administration of C/R. Only two patients (1.1%) had detectable VL in their first analysis (log 1.64 and 1.74), but in both, a new analysis was done at 29 and 7 days, respectively, and again had undetectable VL.

The most prevalent AR was pain at the administration site (53.0%), followed by diarrhoea (2.2%), fatigue (1.7%), pyrexia (1.7%), headache (1.7%), and induration (0.6%). The rest of the patients (39.1%) did not present any AR. Two patients (1.1%) discontinued treatment due to AR, one due to pain at the site of administration and another due to fatigue and weight loss [DS1] . The duration of AR had a median of 2 days, and all of them resolved within 7 days of administration.

Conclusion and Relevance The intramuscular association of cabotegravir and rilpivirine effectively maintains VL supressed and it is safe. The most reported adverse reaction is pain at the injection site.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-061 CURRENT PRACTICE OF PAEDIATRIC OFF-LABEL PRESCRIPTIONS IN A PAEDIATRIC HOSPITAL

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Background and Importance Data concerning drugs' dose, efficacy and safety in paediatric are very limited and this gap of knowledge induces the off-label (OL) drug use. A study showed that 60% of paediatric prescriptions were OL and the main OL-drug classes were antibacterials/antiasthmatics/analgesics. Over the last 30 years the Drug-Agency has approved laws to ensure an appropriate use of OL-medications (Law 648/96, Law 94/98, Law 326/03, Law 7/9/2017).

Aim and Objectives The aim of this work was to evaluate the paediatric OL-drug use and safety in our hospital in the last 2 years according to the Law 94/98 and the Law 326/03.

Material and Methods We analysed OL-prescriptions evaluated by the Hospital-OL-Committee (HOLC) (composed by a Hospital-Pharmacist/Pharmacologist/Clinician) from January-2021/December-2022. We calculated how many paediatric patients were involved, which OL-drug was the most prescribed and for what type of disease (if rare disease according to the national-rare-disease-database), how many patients presented an Adverse-Drug-Reaction (ADR). We considered OL all the Intravenous-Immunoglobulins (IgIv) that were not prescribed according to our regional 'Operative-Procedure-for-the-appropriate-use-of-IgIv'.

Results The HOLC evaluated 258 OL prescriptions according to the Law 94/98 and 69 (27%) administered to 49 paediatric patients (two patients received two OL-drugs). 25 different OL-drugs were used to treat 33 conditions (20 rare diseases); seven drugs(28%) did not have the paediatric license. The most prescribed OL drug (second-level ATC) was J06-Immune-Serum-and-Immunoglobulins (20%) represented by IgIv to treat Idiopathic-Dermatomyositis/Giant-cell-Hepatitis with Autoimmune-Haemolytic-Anemia/Chronic-Polyradiculoneuritis (with or without anti-MOG antibodies)/Autoimmune-Encephalitis/Rasmussen-Syndrome/Opsoclone-Myoclone-Syndrome followed by L01-Cytostatic (17,5%) represented by bevacizumab to treat glioma and L04-immunosuppressant (17,5%) represented by adalimumab to treat Bechet-Syndrome/Systemic-Vasculitis. In the same period six patients received OL drugs according to the Law 326/03 and 4(67%) were paediatric. Three OL-drugs were used to treat two rare conditions: two patients received ivacaftor/tezacaftor/elexacaftor+ivacaftor to treat cystic-fibrosis and two fenfluramine to treat Dravet-Syndrome. Four ADRs referred to four OL therapies were reported in four paediatric patients induced by Ponatinib, IgIv, Arsenic-Trioxide, Rituximab.

Conclusion and Relevance The paediatric OL drug use in a common practice and over the last 30 years several strategies were adopted to guarantee an early and safe access to paediatric OL-medications. For example in our hospital, since 2007, all drugs included in the Hospital-Therapeutic-Formulary can be prescribed (without the HOLC's evaluation) if they are on-label for indication but off-label for age/dosage/frequency.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-062 SAFETY EVALUATION OF PEMBROLIZUMAB IN MONOTHERAPY

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Background and Importance Checkpoint inhibition immunotherapy (ICIs) have substantially improved the prognosis for patients with many advanced malignancies. Despite important clinical benefits, ICIs are associated with a unique spectrum of side effects known as immune-related adverse events (irAEs). IrAEs include dermatologic, gastrointestinal, hepatic, endocrine, and other less common inflammatory events. Therefore, prompt recognition and management of irAEs is important.

Aim and Objectives To describe the occurrence of adverse events (AEs) during treatment with pembrolizumab monotherapy, regardless of indication, in routine clinical practice.

Material and Methods We conducted a retrospective, observational study that included all patients treated with pembrolizumab from September 2022 to September 2023 at our centre.

The variables collected were age, sex, previous immunological disease, number of cycles received, AE and degree of toxicity, as well as delays due to toxicity. The computerised clinical history was used for this purpose. Adverse events were classified according to the National Cancer Institute (NCI)

Common Terminology Criteria for Adverse Events (CTCAE) classification.

Results Data were collected from 44 patients (54.54% male) with a mean age of 71 years ± 10.9 SD.

29.54% diagnosed with lung adenocarcinoma, 27.27% with melanoma, 11.36% with renal cell carcinoma, 13.63% with non-small-cell epidermoid lung cancer, epidermoid carcinoma, 2.27% with Hodgkin's Lymphoma, 2.27% with gastric cancer and 2.27% with malignant mesothelioma. Mean treatment duration 42.65 weeks ± 13.1SD.

22 patients (50%) presented some AE, being grade 1: 59.45%, grade 2: 18.91% and grade 3–4: 21.6%. Grade 3–4 AEs were: three cases of skin toxicity (37.5%), two cases of neurotoxicity (25%), one case of arthralgias (12.5%), one case of limiting diarrhoea (12.5%) and one case of hepatitis (12.5%).

Toxicity led to temporary discontinuation of treatment in six patients and definitive discontinuation in three patients.

Conclusion and Relevance Treatment with pembrolizumab monotherapy proved safe. It was generally well tolerated and AEs were as expected according to technical sheet, with no new toxicity profiles noted. Cutaneous immune-related adverse events (irAEs) was the most common grade ≥3 adverse events. Only 8/44 patients had grade 3–4 AE, being limiting in 3/44 patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-063 ADJUVANTE ANALGESICS INTERACTIONS: HOW TO MANAGE PAIN IN PATIENTS RECEIVING ORAL THERAPY FOR BREAST CANCER TREATMENT

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Background and Importance Pain is an unpleasant sensory and emotional experience associated, or similar to that associated, with actual or potential tissue damage. This is a dominant symptom in cancer patients and affects their day-to-day life. The World Health Organization published an analgesia implementation model consisting of three levels. This model includes adjuvant analgesics, which are drugs marketed for indications other than pain, very useful when associated with opioid therapy.

Aim and Objectives The aim of the study was to collect and analyse the drug interactions that exist in the concomitant use of adjuvant analgesics used to control pain in patients with breast cancer undergoing oral therapy, in a hospital institution.

Material and Methods A list of adjuvant analgesics and oral medications used in the treatment of breast cancer was drawn up.

The adjuvant analgesics studied were carbamazepine, gabapentin, oxcarbazepine, pregabalin, amitriptyline, duloxetine, venlafaxine, dexamethasone, methylprednisolone and prednisolone. The oral breast cancer drugs were abemaciclib, capecitabine, everolimus, lapatinib, olaparib, palbociclib, ribociclib, tucatinib and vinorelbine.

Cancer Drugs Interaction, Drugs.com and Lexicomp® were consulted and the interactions were collected, evaluated and divided into four groups: 1) severe interaction, 2) moderate interaction, 3) weak interactions and 4) no known interactions.

Tables were created and analgesic adjuvants interaction rates were calculated.

Results

The following results were obtained 1) Severe interaction: carbamazepine (77,8%), oxcarbazepine (55.6%), dexamethasone (33.3%), amitriptyline (11.1%) and venlafaxine (11.1%).

2) Moderate interaction: dexamethasone (55.6%), methylprednisolone (33.33%), oxcarbazepine (33.33%), prednisolone (33.33%) and venlafaxine (33.33%), amitriptyline (11.1%), carbamazepine (11.1%) and duloxetine (11.1%).

3) Weak interactions: amitriptyline (22.2%) and venlafaxine (22.2%) and methylprednisolone (11.1%) and prednisolone (11.1%).

4) No known interactions: gabapentin (100%), pregabalin (100%), duloxetine (88.9%) amitriptyline

(55.6%), methylprednisolone (55.6%), prednisolone (55.6%) venlafaxine (33.3%), carbamazepine (11.1%), dexamethasone (11.1%) and oxcarbazepine (11.1%).

Conclusion and Relevance The study concludes that there are many serious, moderate and weak interactions to be taken into account when treating pain in patients undergoing oral therapy for breast cancer. Depending on the degree of interaction, the pharmacist may suggest replacing or closely monitoring these patients.

These data reinforce the importance of the pharmacist as an element of the healthcare team, providing information in decision-making process and improving patient therapeutic outcomes.

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Conflict of Interest No conflict of interest.

5PSQ-064 ANALYSIS OF PHARMACEUTICAL INTERVENTIONS ON DIRECT ACTING ORAL ANTICOAGULANTS IN A TERTIARY CARE HOSPITAL

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Background and Importance Direct acting oral anticoagulants (DOACs) are a group of drugs used for the prevention of stroke and systemic embolism in patients with atrial fibrillation. As they are considered high-risk drugs, it is important that the dosage is correctly adjusted.

Aim and Objectives To analyse pharmaceutical interventions (PI) on DOAC in electronic prescribing to hospitalised patients in a tertiary hospital and their degree of acceptance by prescribers. To detect erroneous dosage adjustments and, by means of a pharmacotherapeutic recommendation, to adapt the prescription to the patient's profile in order to reduce the risk of adverse effects associated with DOAC.

Material and Methods Observational, retrospective study. All patients who were prescribed a DOAC (apixaban, rivaroxaban, edoxaban and dabigatran) during their admission between 1

January 2022 and 31 December 2022 were included. The variables collected, from the 'Unidosis Management' module of the FarmaTools software application (v.3.0), were: date of prescription, age, sex, creatinine clearance, drug, regimen, PI performed and acceptance by the prescriber.

Results A total of 892 DOACs prescriptions were evaluated. Intervention was necessary in 53 patients (5.94%). The DOACs involved were: 29 apixaban (55%), 14 rivaroxaban (26%), nine edoxaban (17%) and one dabigatran (2%). The median age of patients undergoing PI was 85 years (75–95), with 34 men (64%). The PI performed were:

- adjustment for poor renal function in 31 patients (59%)
- adjustment for patient weight in 11 patients (20%).
- unjustified duplication of anticoagulation therapy with DOAC and low-molecular-weight heparin (LMWH) in nine patients (17%).
- modification of the dose of the DOAC prescribed on admission due to poor treatment reconciliation in one patient (2%).
- dose increase due to under-dosing in one patient (2%).

Twenty-six interventions were accepted (49%).

Conclusion and Relevance Most DOAC prescriptions are appropriate to the patient's situation.

In cases of error, the most frequent intervention is dose adjustment due to poor renal function, followed by weight and simultaneous prescription of DOAC and LMWH.

The overall level of acceptance of the PI is high.

Periodic weight and renal function controls are identified as points for improvement in order to assess possible dose adjustments and improve the effectiveness of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-065 INTESTINAL PERFORATION AFTER CRS AND ICANS IN A CAR-T TREATED PATIENT: A CLINICAL CASE REPORT

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Background and Importance Brexucabtagene autoleucel, an autologous anti-CD19 CAR T-cell therapy with a chimeric antigen receptor (CAR), represents the first FDA-EMA approved CAR-T for relapsed/refractory mantle cell lymphoma (MCL). While CAR T-cell therapy is an innovation, it also comes with unique toxicities.

Aim and Objectives Here, we describe the case of a patient with relapsed-refractory mantle cell lymphoma treated with brexucabtagene autoleucel who experienced Cytokine Release Syndrome (CRS), Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), evaluated with a Naranjo scale score of 5–8, and intestinal perforation in the days following therapy. This abstract has been written in order to share the clinical difficulties of CAR-T patient management and to highlight the potential role of anti-IL6 medicines in this singular adverse drug reaction.

Material and Methods The patient received tocilizumab and dexamethasone for CRS, effectively managing it but faced substantial ICANS symptoms. Anakinra and high-dose dexamethasone led to notable improvement. On day +34, acute abdominal symptoms emerged, leading to a CT scan revealing diverticulitis complications, necessitating exploratory laparotomy and colonic resection. Remarkably, histological analysis showed no lymphoma or extensive CAR T-cell infiltration but revealed neutrophilic inflammation and Cytomegalovirus (CMV) presence, treated with antivirals.

Results With the increasing adoption of CAR-T therapy in haematology, the accurate management of side effects becomes crucial. A search in our country's pharmacovigilance database did not reveal other reports of intestinal perforation possibly related to tocilizumab in patients treated with brexucabtagene autoleucel apart from this case, evaluated with a score of 1–4 on the Naranjo scale. Clinical-data and post-marketing surveillance have reported an increased risk of gastrointestinal perforation in patients treated with axicabtagene ciloleucel, but there have been no reports of intestinal perforation associated with brexucabtagene autoleucel. However, the setting remains similar: patients undergo lymphodepleting chemotherapy and receive a high dose of IL-6 receptor inhibitor and corticosteroids.

Conclusion and Relevance Intestinal perforation in CAR-T treated patients is mentioned in the ESMO-guidelines for the management of Immune Effector Cell-Associated Hypersensitivity (ICAH) and a correlation between tocilizumab and intestinal perforations has been suggested (5–8 Naranjo scale score), as observed in clinical trials and post-marketing analysis among patients with rheumatoid arthritis. This case underscores the importance of meticulous monitoring and understanding CAR-T therapy intricacies and toxicity management.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-066 ABSTRACT WITHDRAWN

5PSQ-067 DRUG UTILISATION PROFILES OF ADVANCED THERAPY MEDICINAL PRODUCTS: A REAL-WORLD EVIDENCE STUDY

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Background and Importance Advanced therapy medicinal products (ATMPs) represent the forefront of healthcare innovation. Despite the approval of the first ATMP in Italy in 2016, there is currently a lack of scientific evidence concerning the utilisation patterns of ATMPs.

Aim and Objectives Study aim was to evaluate the drug utilisation patterns among patients receiving ATMP treatments in Italy.

Material and Methods Retrospective study using data sourced from the Monitoring Registries of the Italian Medicine Agency, specifically the Drug Product Registry (DPR) containing information on dispensed treatments and clinical data for patients utilising ATMPs in Campania Region (~6 million, 10% of the national population) and residents treated in a different Italian Region. Final cohort included individuals who received at least one prescription for ATMP drugs in the Italian market between 2016 and 2023. We analysed prescription patterns focusing on the index treatment, diagnoses, treatment interruptions, mortality rates and adverse events.

Results In total, 92 patients initiated ATMP treatments between 1 January 2016 and 1 September 2023. 21.6% received voretigene neparvovec, 25% onasemnogene abeparvovec, 22.8% tisagenlecleucel and 21.7% axicabtagene ciloleucel. The overall occurrence of adverse events was low (1.1%), primarily associated with autologous human corneal epithelial cells treatments. The overall mortality rate was 12%, affecting only two drugs: 28.6% tisagenlecleucel and 25.0% axicabtagene ciloleucel. Notably, nearly 90% of subjects completed their treatment without experiencing adverse events or mortality.

Conclusion and Relevance This study highlights the low occurrence of adverse events and mortality associated with ATMPs, emphasising their potential as a promising frontier for treating severe diseases lacking therapeutic alternatives in real-world scenarios.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-068 THE HOSPITAL PHARMACIST'S INTERVENTIONS IN THE POST-MARKETING PHARMACOVIGILANCE OF ANTI-ASTHMATIC BIOLOGICS: A REAL-LIFE ANALYSIS

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Background and Importance Pharmacovigilance is an important tool for monitoring drug post-marketing safety. Hospital Pharmacist (HP) plays a primary role in the identification of suspected Adverse Drug Reaction (ADRs) due to his direct contact with the patient. In fact, through the application of indirect pharmacovigilance tools in a real-life context, can lead to the identification of hidden or underestimated ADRs.

Aim and Objectives The aim of the study was to evaluate the increase of suspected ADRs reports to biological drugs for the treatment of severe refractory hypereosinophilic asthma (omalizumab, dupilumab, mepolizumab and benralizumab) obtained following the interventions of HP.

Material and Methods A 7-months (October 2022 to May 2023) post-marketing safety study was conducted. The data were collected via a questionnaire consisting of two sections: general data (sex, age, comorbidities, drugs taken and start of therapy) and list reporting the most common side effects where the patient can indicate one or more suspected ADRs among those reported and/or enter any side effect that is potentially linked to the drug. The questionnaire was illustrated and given to the patients at the time of dispensing. The data were also compared with the clinical trials and all adverse reactions reported by patients were entered into the pharmacovigilance network.

Results Initially there were no reports of ADRs for any of the drugs considered. Following the HP's interventions, 55% (55/100) of patients reported one or more adverse reactions (Mepolizumab 65%, 26/40; dupilumab 54.5%, 12/22; omalizumab 53.3%, 8/15; benralizumab 39.1%, 9/23) bringing the number of reports to 122 (76 mepolizumab; 14 dupilumab; 16 omalizumab; 16 benralizumab). The study also highlighted ADRs not reported in the trials; for mepolizumab were found diffuse petechiae, haemorrhagic period and frequent urination problems with recurrent cystitis (3.5%; 1/26) while for dupilumab was found a higher incidence of herpetic development and alopecia (4.5%; 1/22). A higher percentage of pyrexia was found for benralizumab compared to trials (3%; 12/320 vs 13%; 3/26).

Conclusion and Relevance The data analysis confirmed the importance of the HP role in pharmacovigilance. The investigation in a real-world context characterised by a high heterogenicity of patient characteristics (age, comorbidity, adherence)

led to an improvement in the incidence of ADRs reports and to the highlighting of side effects not detected during the clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-069 COMPARISON OF RENAL GLOMERULAR FILTRATION ESTIMATION FORMULAS IN VANCOMYCIN PHARMACOKINETIC MONITORING

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Background and Importance This retrospective study aimed to assess the utility of renal glomerular filtration rate (GFR) estimation formulas, including Cockcroft-Gault (CG), Modification of Diet in Renal Disease (MDRD-4), and Chronic Kidney Disease Epidemiology (CKD-EPI), in the pharmacokinetic monitoring of vancomycin.
Aim and Objectives The study aimed to evaluate the correlation between estimated GFR using different formulas and the actual clearance of vancomycin in patients, providing valuable insights for pharmacokinetic monitoring and dosing adjustments.
Material and Methods Retrospective study (October 2022 to March 2023) on patients monitored by the Clinical Pharmacokinetics Unit during vancomycin treatment. Inclusion criteria: age $\geq$ 18, $\geq$ two vancomycin trough plasma concentrations (Cmin), and stable serum creatinine (+/- 0.5 mg/dL) during monitoring. Recorded variables: gender, age, weight (kg), height (cm), serum creatinine mg/dL), estimated glomerular filtration rate (eGFR) (mL/min) using various formulas, observed vancomycin Cmin (mcg/mL), and predicted Cmin (mcg/mL) based on Bayesian adjustment (software: Mw-Pharm++®). Linear regression analysed the relationship between initial estimated vancomycin plasma clearance (Clp) using eGFR data and patient's actual Clp obtained through Bayesian estimation (considering monitored vancomycin concentrations).
Results A total of 34 patients were recruited (65.70% males, mean age ± standard deviation: 68.06 ± 16.89 years). The mean estimated glomerular filtration rate (GFR) values were: 84.44 ± 49.87mL/min, 116.23 ± 52.95mL/min, 91.53 ± 28.22mL/min for the CG, MDRD-4, and CKD-EPI formulas, respectively. The mean observed vancomycin Cmin in the second analytical determination was 16.13 ± 6.56 mcg/mL. The mean predicted Cmin values were 17.15 ± 8.08 mcg/mL, 14.03 ± 8.26 mcg/mL, and 14.57 ± 7.56 mcg/mL for the CG, MDRD-4, and CKD-EPI formulas, respectively. Based on the coefficients of determination calculated from the regression lines, 83%, 76%, and 86% of the variations found in the actual vancomycin clearance can be explained by variations in the estimated clearance using GFR data obtained with the CG, MDRD-4, and CKD-EPI formulas, respectively.
Conclusion and Relevance In this study, the Cockcroft-Gault and CKD-EPI formulas exhibited better correlation with actual vancomycin clearance compared to MDRD-4. The findings suggest a potential risk of overdosing when using MDRD-4. Although initial vancomycin dosing based on estimated GFR formulas provides a reasonable approach, pharmacokinetic monitoring of plasma concentrations remains a safer approach for antibiotic dosing.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-070 DUPILUMAB IS A MONOCLONAL ANTIBODY USED FOR THE TREATMENT OF ATOPIC DERMATITIS. THIS STUDY EVALUATES THE EFFECTIVENESS AND PERSISTENCE. DUPILUMAB PRESENTS GOOD EFFECTIVENESS AND PERSISTENCE

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Background and Importance Atopic dermatitis (AD) is a relapsing inflammatory skin disease characterised by severe itching, skin lesions and dysregulation of the immune system. Dupilumab is an anti-IL-4/13 monoclonal antibody approved for the treatment of moderate to severe AD.
Aim and Objectives To evaluate the effectiveness and persistence of dupilumab in moderate-severe AD.
Material and Methods Observational and retrospective study of patients on treatment with dupilumab for moderate-severe AD from March 2020 to September 2023 in a tertiary hospital. Variables collected: age, sex, previous use of topical (Ct) and systemic (Ci) corticosteroids, topical tacrolimus, antihistamine and cyclosporine, dosage, and duration of treatment. The effectiveness variables are the EASI (Eczema Area and Severity Index) and IGA (Investigator Global Assessment) scales in weeks 16, 24 and 52. Treatment was considered effective when the EASI had been reduced by 50% (EASI50) and when the IGA had been reduced by <2 points. Data were obtained from the electronic medical record (Abucasis®). Quantitative variables were described as mean (minimum and maximum) and qualitative variables as percentages.
Results A total of 39 patients were included, mean age 30.7 years (4–64), 58.9% of the patients were male. 100% of the patients have worn Ct and 30% continue to wear them. 69% have taken Ci, 31% tacrolimus, 79% antihistamines, 66% cyclosporine. 56% of patients are on the 300 mg every 2 weeks regimen. The median treatment time with dupilumab in the included patients was 21.7 months (0.9–68.4). At week 16, 89.6% (n=33) of the included patients reached EASI 50, at week 24 EASI 50 was reached by 93% (n=32) and at week 52 it was reached by 100% (n=25). 63% (n=33) of the patients achieved an IGA of 0–1 at week 16, 81% at week 24 and at week 52 the percentage was 100% (n=27) achieving an IGA of 0–1. 10% of patients had treatment failure with Dupilumab, 7% switched to tralokinumab and 3% to upadacitinib.
Conclusion and Relevance Dupilumab treatment shows good persistence and effectiveness in AD, although further studies of longer duration are needed to establish the usefulness of dupilumab in long-term clinical practice conditions.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-071 MULTIDISCIPLINARY MANAGEMENT OF DRESS SYNDROME: A CASE REPORT

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Background and Importance Dress Syndrome (DS) is a very rare but potentially life-threatening drug-induced hypersensitivity syndrome. It is characterised by an extensive skin rash associated with visceral organ involvement, lymphadenopathy, eosinophilia and atypical lymphocytosis.

Drugs most frequently associated with DS are allopurinol and dapsone. Other less frequently associated are beta-lactam antibiotics.

Aim and Objectives Describe the case of a patient with surgically removed squamous cell carcinoma (SCC) who develops surgical wound infection and the multidisciplinary intervention for its management.

Material and Methods We conducted a retrospective descriptive study in a patient in treatment with antibiotics who developed DS. Data were obtained from Diraya (digital clinical history). Literature review was performed in UptoDate.

Results The case of a 70 year-old female patient diagnosed with SCC is presented. No episodes of allergy to beta-lactam antibiotics was previously described. Patient underwent surgical treatment on 1 February 2023. Bacterial growth was isolated and ceftazidime was started according to the antibiogram. On 16 February 2023 purulent material was collected after opening the dura mater. A **literature review of the available evidence for suspected infection meningeal with recent surgery was performed. Treatment with ceftazidime or carbapenemics was recommended.** *Pseudomona aeruginosa* resistance to ceftazidime was isolated on 23 February 2023 and antibiotherapy was modified to meropenem.

After several days of treatment, a torpid clinical course was observed with elevation of C-reactive protein, deterioration of renal function, transaminases increased, leucocytosis, eosinophilia and appearance of erythematous macules. An atypical DS was diagnosed (3/7 diagnostic criteria score). **We performed a review of the possible causes that could be associated with DS, as well as a medication review. Technical sheets of ceftazidime and meropenem were reviewed. In both DS is described with an unknown frequency.** Naranjo algorithms establish the causality relationship between the two (score of 2). The Spanish Pharmacovigilance Centre was notified. Multiorgan failure compatible with sepsis was observed and the patient died three days later.

Conclusion and Relevance DS should be considered in patients with eosinophilia, skin rashes and internal organ involvement when associated with recent beta-lactam antibiotics treatment in the absence of other causes. Early detection of DS is essential to avoid a fatal outcome.

The pharmacist's collaboration in multidisciplinary teams and the monitoring of possible adverse events associated with drugs is essential.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-072 TREATMENT WITH GALCANEZUMAB IN REAL-WORLD DATA: SAFETY

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Background and Importance Galcanezumab is a recombinant humanised monoclonal antibody that binds to calcitonin gene-related peptide (CGRP). It is used for the prophylaxis of chronic migraine in adults due to It has demonstrated its safety and effectiveness in reducing the frequency of episodes and improving patient functionality in the EVOLVE-1, EVOLVE-2 and REGAIN studies. However, there is no evidence on its effectiveness, tolerance and causes of treatment limitation in a real-world data.

Aim and Objectives To describe the frequency of discontinuations of treatment with galcanezumab and evaluate the causes responsible for these suspensions in our patient cohort.

Material and Methods Observational, retrospective and descriptive study developed with patients diagnosed with migraine who have received treatment with galcanezumab and it has already been suspended at the time of the study (September 2023) under follow-up by the pharmacy service of a tertiary hospital (years 2020–2023). Variables collected: demographic (sex and age) and clinical (duration of treatment with galcanezumab, diagnosis, monthly migraine episodes, previous treatments, rate reasons for discontinuation: low effectiveness, defined by a reduction below 50% in migraine attacks, intolerance and personal decision).

Results 110 patients were studied, all of them with a diagnosis of chronic migraine. 76.5% women. Mean age: 44.7 years (22–75).

Mean number of previous migraine episodes over 8 months. All of our patients had received previous treatment with three or more treatments (beta blockers, antiepileptics, antidepressants and botulinum toxin) without satisfactory experience.

17 patients discontinued treatment with galcanezumab in our hospital during the study period (15.5%). Suspension rates: 64.7% low effectiveness; 29.4% intolerance (local reaction: two patients; weight gain: one; constipation and generalised itching: one); 5.9% personal decision (upcoming pregnancy).

Conclusion and Relevance Galcanezumab has had a low dropout rate in our patients, making us consider it a safe drug in our cohort.

The percentage of suspensions due to drug intolerance has been very low, compared to the pivotal trials in which it represented the most frequent cause (mainly local reactions to the injection).

In routine clinical practice, we continue to monitor side effects of our patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-073 RISK SCORE FOR DRUG DISCREPANCY AND ADHERENCE IN CLINICAL TRIAL PATIENTS

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Background and Importance The main challenge in clinical trials (CT) is to detect poor adherence to oral treatments which may influence on treatment effectiveness. Therefore, a tool is needed to help us stratify patients according to the risk of non-compliance.

Aim and Objectives To assess adherence in patients with oral experimental treatment and validate a predefined score to detect patients with poor or non-adherence.

Material and Methods An experimental, prospective, single-centre study was conducted, with mainly onco-haematologic patients, in a clinical trials unit of a tertiary hospital. A scoring was designed to detect non-adherence. Patients were stratified based on demographic information (age, native), clinical data (pathology, status) and trial characteristics (phase, protocol, complexity). All risk variables were at the same level and each received a 1-point score. Risk level of non-adherence was considered high (4–7), medium (3) and low (1–2). Patients were contacted by telephone to detect compliance discrepancies, patient concerns/questions in reference to the real adherence. The software used were SAP (clinical history), Fundanet (clinical trial platform), Excel (data collection form). The project was approved by Hospital's Ethics Committee.

Results Thirty-five patients were recruited from 1 July to 20 September 2023. The mean age of the patients was 63.4 years. The mean non-adherence score was 2.2 (±0.92). Nine out of 35 (25.7%) of the patients were on treatment with more than one drug at the same CT and 80% were on treatment with other drugs outside the clinical trial. 75% of the patients were accompanied by another person (family or partner) when starting treatment at the pharmacy´s clinical trial unit. The CT phases with the highest recruitment were: II (29.3%) and III (27.4%). In 95% of patients no concerns on drug administration were detected, with a 'real' adherence rate of 92%.

Conclusion and Relevance Clinical trial patients included in this study showed good adherence to the experimental treatment. However, a larger sample size might be needed to verify these results.

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Conflict of Interest No conflict of interest.

5PSQ-074 PHARMACEUTICAL INTERVENTIONS IN PAIN MANAGEMENT

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Background and Importance Hospital pain protocol is a crucial element in improving patient's quality of life, as effective pain management not only alleviates suffering but also promotes recovery.

The involvement of the pharmacist through pharmaceutical interventions (PIs) facilitates the implementation of the pain protocol.

Aim and Objectives To describe and analyse PIs associated with analgesic medications in accordance with the institutional pain protocol for patients admitted to a secondary level hospital.

Material and Methods An observational, descriptive and retrospective study that analyse PIs conducted with the Computerized Physician Order Entry (CPOE) Silicon® during the validation of prescriptions containing analgesics in hospitalised patients from January to December 2022.

Results 455 PIs were recorded with 64% of them involving surgical patients. The most common type of PIs were dose modification (272/455; 59,8%); drug suspension (138/455; 30,3%); drug changes (14/455; 3,1%); frequency adjustments (13/455; 2,9%); reconciliation upon admission (11/455; 2,4%); route of administration or pharmaceutical form modification (4/455; 0,9%) and incomplete medical order (3/455; 0,6%).

Medications most frequently involved in PIs were dexketoprofen (116/455; 25,5%), metamizole (113/455; 24,8%), tramadol (94/455; 20,7%) and acetaminophen (87/455; 19,1%).

Among dexketoprofen PIs, 39,7% (46/116) were attributed to contraindications. PIs related to excessive dosage were accounted for 57,5% (65/113) of all metamizole interventions, 72,3% (68/94) of tramadol interventions and 70,1% (61/87) of acetaminophen interventions. Furthermore, there were 34 IP detecting interactions of which metamizole was implicated in 79,4% (27/34) of the cases.

The level of acceptance among doctors was as follows: 61,8% overall with individual acceptance rates of 79,3% (69/87) for acetaminophen, 68,1% (77/113) for metamizole, 55,3% (52/94) for tramadol and 53,4% (62/116) for dexketoprofen.

Conclusion and Relevance Dose modification was the most frequent PIs, mainly due to excessive dosage.

The drugs that received the most PIs were dexketoprofen and metamizole.

The degree of acceptance of PIs was high, which supports the integration of the pharmacist in the multidisciplinary team and improves the safety of the patient's analgesic treatment.

This study provides useful information to detect areas for improvement in the implementation of pain protocols and the importance of interdisciplinary collaboration.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-075 ADHERENCE TO LOCAL ANTIBIOTIC PRESCRIBING GUIDELINES WITHIN 48 HOURS OF INPATIENT ADMISSION

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Background and Importance Optimisation of antibiotic (ATB) administration is vital for improving infection treatment effectiveness. An ATB stewardship programme can help clinicians rationalise ATB prescribing. There is no simple and effective tool. Last year we conducted an adherence audit with the local guidelines (LG).
Aim and Objectives This study aimed to review the adherence of clinicians to LG in terms of ATB prescribing and administration.
Material and Methods Single-centre prospective audit for prescribed ATB treatment in at least 50 inpatients admitted to the university hospital with ATB initiation within the first 48 hours of admission. Adherence to LG for ATB was assessed using the adopted audit tool.[1] The patient selection was generated from the hospital's electronic prescribing system based on emergency department admission and subsequent hospitalisation and ATC code for ATB prescribed within 48 hours. Adherence was assessed as full compliance with LG. Partial adherence was attributed when minor deviation from LG occurred. Nonadherence was defined as an incorrect choice of ATB.
Results During the audited period, there were 1,842 new admissions and ATB were initiated within 48 hours in 478 inpatients (26%). A total of 74 patients with 117 ATB agents were audited and 77 indications for newly prescribed ATB therapy were found. For 46 indications (59.7%) ATB was given in an indication that is included in available LG. The overall adherence to ATB LG was observed in 33 indications (i.e. 71.7% of 46). Partial adherence was found in 11 indications (23.9%). Non-adherence was shown in two indications (4.3%). These involved ATB for surgical prophylaxis. Out of 117 ATB, there was 72% adherence with LG. Incorrect administration of ATB were the most common reasons for partial adherence (21%).
Conclusion and Relevance We found that adherence in 72% of prescribed ATB agents with recommended practices is considered a satisfactory outcome. The audit results were presented to management and shall be repeated in future.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

5PSQ-076 EFFICACY AND SAFETY OF NIVOLUMAB MONOTHERAPY VS NIVOLUMAB PLUS IPILIMUMAB IN RENAL CELL CARCINOMA IN CLINICAL PRACTICE

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Background and Importance Nivolumab is indicated for advanced renal cell carcinoma (RCC) both as monotherapy (second-line) and in combination with ipilimumab (first-line). It is not known the benefit to add ipilimumab to nivolumab, also it must been taken the possible worse security profile.
Aim and Objectives The aim of this study is to determine the efficacy and security of nivolumab plus ipilimumab vs nivolumab monotherapy in the clinical practice.
Material and Methods This is a descriptive, observational and retrospective study (January 2016 to September 2023) of 30 patients treated with nivolumab or nivolumab plus ipilimumab in a third-level hospital. The data were obtained from the electronic medical records of the patients and the FarmaTools Management programme. Data were processed by Microsoft Excel and SPSS software.
Results In this study 30 patients were included in total, 11 treated with dual therapy and 19 with monotherapy. Patient demographics and disease characteristics are described in table 1. Median progression-free survival was 4.9 months (95% CI: 0–10.8) for nivolumab and 10.7 months (95% CI: 0–26.5) for the combination therapy. However, when we compared the two treatments using the log-rank test, the p-value was 0.799. The median overall survival was 43.4 months (95% CI: 0–97.4) for nivolumab, but it was not reached for the combination treatment. The most prevalent adverse reactions in the monotherapy vs dual therapy group, respectively, were hepatic (5.3% vs 45.5%), endocrine (36.8 vs 63.6) and skin (57.9 vs 36.4). It should be noted that one patient with the combination therapy had myositis, myocarditis, and hepatitis. This patient ultimately died.

Abstract 5PSQ-076 Table 1

Characteristic	Nivolumab plus Ipilimumab (n=11)	Nivolumab (n=19)
Age, median (range), years	62 (44–74)	57 (37–83)
Male	6 (54.5)	16 (84.2)
Histology		
Clear cell RCR	10 (90.9)	13 (68.4)
Papillary RCR	0 (0)	3 (15.8)
Not specified	1 (9.1)	3 (15.8)
ECOG (*Eastern Cooperative Oncology Group*) performance status		
0	5 (45.5)	11 (57.9)
1	5 (45.5)	3 (15.8)
Not specified	1 (9.1)	5 (26.3)
Lung metastases	8 (72.7)	16 (84.2)
Liver metastases	2 (18.2)	6 (31.6)

NOTE: Data are No. (%).

Conclusion and Relevance No differences were observed in efficacy, but there were differences in safety. However, our study is limited since it involves few patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-077 ADEQUATE NUTRITIONAL THERAPY IN CRITICAL PATIENTS WITH CORONAVIRUS DISEASE (COVID-19)

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Background and Importance The critical patient is by definition a patient at nutritional risk for presenting a hypermetabolic state which leads to a rapid process of malnutrition. Nutrometabolic treatment in this type of patient is a fundamental part of a better clinical evolution.
Aim and Objectives To describe how the parenteral nutrition prescription was adapted to the nutrition guidelines in patients with COVID-19 disease in critical care units (ICU).
Material and Methods Retrospective observational study of patients with total parenteral nutrition (TPN) in critical care units between March and May 2020.

Data from the Electronic Medical Record and the TPN prescription were recorded: age, sex, weight, days of admission to the ICU, TPN indication, duration of TPN therapy, co-administration of Enteral Nutrition (EN) (if applicable), total energy intake and daily prescribed protein and complications from TPN.

Energy and protein requirements were calculated based on the ASPEN 'Guidelines for the Provision and Assessment of Nutrition Support Therapy in the Adult Critically Ill Patient' and the hospital's COVID-19 Nutrition Protocol: 11–14 Kcal/Kg/day for obese patients and 25 Kcal/Kg/day for non-obese patients. 1.5g/Kg/day of protein was calculated for all patients.

The agreement with the guidelines was accepted if the percentage of total energy and protein requirements was within 80–120%.
Results Thirteen patients with TPN were identified (table 1).

Abstract 5PSQ-077 Table 1

Sex	10 men, 3 women
Median age	60 years (50-79)
Median weight	85.5 Kg (109-72)
Reason for starting TPN	7 NE intolerance, 4 paralytic ileus, 1 pancreatitis, 1 ischemic colitis
Reason for ending TPN	13 good tolerance to NE
Complementary EN	8 patients
Complications due to TPN	5 patients suffered catheter bacteremia

Median number of days in the critical unit was 38 days (12–73). Median number of days with TPN was 13 (2–53). Median percentage of days with TPN (compared to the total days spent in the critical care unit) was 36.8% (7.1–72.6). Median calculated energy requirements were 1,800 Kcal/day (1150–2137), and median protein requirements per day were 130.5 grams of protein (105–163.5). A total of 28 prescriptions were recorded. Median total Kcal prescribed per day was 1,827 Kcal (1035–2475), and median protein intake was 100 grams (57–147.5). 18 (64.3%) total daily Kcal prescriptions and 9 (32%) of the protein prescriptions were adapted to the guidelines.
Conclusion and Relevance We found low adaptation of the prescriptions to the guidelines in relation to grams of protein (kidney involvement could be responsible), although the total energy requirements were adapted. The high rate of catheter bacteraemia was striking.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-078 HYPOPHOSPHATEMIA AFTER FERRIC CARBOXYMALTOSE ADMINISTRATION IN A COHORT OF ELDERLY PATIENTS WITH HIP FRACTURE

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Background and Importance Hypophosphatemia after intravenous ferric carboxymaltose (FCM) is a well-documented adverse reaction. However, there is scant evidence about its prevalence among elderly patients with hip fracture, a complex polymedicated pluripathologic population exposed to these formulations in perioperative care.
Aim and Objectives The aim of this study was to identify the incidence of hypophosphatemia in patients over 65 years old treated with FCM in the context of hip surgery.
Material and Methods Observational retrospective study including all patients admitted to the Orthogeriatric Unit of a tertiary hospital from June 2023 to August 2023 for hip fracture and treated with FCM. Analytical treatment-related data were collected from electronic medical records. For descriptive analysis, categorical variables are presented as counts and percentages. Continuous variables as medians and interquartile range.
Results 65 patients were included (51/65[78.5%] women, 88 ±7 years old), with a median hospital stay of 13 days. The total doses used were 500 mg (69.2% of patients), 1 g (24.6%) or higher. On the gathered data are shown elevated parathormone and low cholecalciferol levels, and an altered glomerular filtration rate. Of the patients included, 28 had both pre- and post-iron administration phosphate levels measured. Among them, 21 (75%) experienced a phosphate level reduction with a mean change of -36.4[19.1–51.4]% from their initial levels to the second measurement, mirroring the overall trend shown in the table 1. Within this group, 5 out of 28 patients (17.9%) had initial phosphate levels below 2.5 mg/dL. After iron administration, this increased up to 12 (42.9%). None of them showed any relevant clinical signs associated.

Abstract 5PSQ-078 Table 1

Variable	N	Median[P25-P75]
Before iron administration:		
Phosphate (mg/dL)	45	3.5[2.8–4.1]
Hemoglobin (g/dL)	46	10.3[9.1–11.4]
Parathormone (pg/mL)	35	86.4[59.2–103.5]
Cholecalciferol (ng/mL)	37	23.2[13.6–33.9]
Glomerular filtration rate (ml/min/1.73 m2)	46	56[32–77.8]
After iron administration:		
Days between iron administration and phosphate determination	42	6.5[3.0–9.8]
Phosphate (mg/dL)	42	2.6[1.9–2.9]

Conclusion and Relevance Blood phosphate levels tend to decrease notably after FCM administration, suggesting a potential correlation. However, hyperparathyroidism and vitamin D deficiency are common in this population and may

also influence this outcome. Phosphatemia monitoring and phosphate supplementation are measures that need to be considered to reduce possible clinical consequences, especially in elderly patients with additional risk factors.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-079 PHARMACEUTICAL INTERVENTIONS IN A HEALTH MANAGEMENT AREA

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

Aim and Objectives To analyse and intervene on active prescriptions of medicines subject to Rational Use of Medicines (RUM) strategies established by the Andalusian Public Health System based on the available scientific evidence.

Material and Methods A descriptive study of the interventions carried out on two lists of patients with active prescriptions provided by our Health System from January to June 2023 was conducted. Group A: patients with two or more proton pump inhibitors (PPIs) and Group B: patients with bisphosphonates prescribed for more than 5 years, given that the optimal duration of treatment in osteoporosis has not been established in the technical data sheet, indicating the need for periodic reevaluation, especially after more than 5 years.

The interventions carried out by the pharmacist were to inform the prescribing physicians by corporate email to reevaluate the treatment and carry out Precautionary Overrides (PO). The main objective of PO is to contribute to patient safety by avoiding the dispensing of prescribed medications when there is a manifest error in the prescription, inappropriateness, safety alert or any other reason that means a risk to the patient.

Results 155 patients were reviewed from January to June 2023: 17 in Group A and 138 in Group B. 100% of prescriptions were communicated to prescribing physicians. We proceeded to carry out 35 PO (22.5%). In Group A: 13 PO (76.5%) due to therapeutic duplication, four (23.5%) patients were not evaluable due to medical cancellation prior to the review. Group B: 22 PO (15.9%) due to lack of adherence to treatment. In this group, it was found that 31 patients (22.4%) did not have an indication for the use of bisphosphonates recorded in their clinical history. 27 PO (77.1%) were accepted by the prescribing physicians, six in Group A and 27 in Group B.

Conclusion and Relevance The analysis aimed at active prescriptions susceptible to intervention is essential to meet RUM objectives, to guarantee a sustainable and quality Public Health System, with the pharmacist having a key role in achieving them.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-080 CLINICAL INTERVENTIONS IN PATIENTS UNDERGOING ANTI-PARKINSONIAN TREATMENT: THE IMPORTANCE OF CORRECT RECONCILIATION

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Background and Importance The purpose of the anti-Parkinsonian pharmacological treatment is to optimise dopamine levels and control of disease symptoms. Therefore, it is essential to implement a correct reconciliation procedure at hospitalisation to avoid adverse effects associated with the medication.[1 2]

Aim and Objectives To describe the interventions performed in hospitalised patients undergoing anti-Parkinsonian treatment, by hospital pharmacists in the area of pharmaceutical validation, and to evaluate their acceptance degree by clinicians.

Material and Methods This was a prospective, single-centre and interventional study, conducted from September 2022 to September 2023. The study included all the hospitalised patients showing a discordance between their domiciliary anti-Parkinsonian treatment and at hospitalisation. Demographic (sex, age), clinical [clinical judgements(CJ) and inpatient clinical service] and pharmacotherapeutic [number of chronic medicines and polymedication ($\geq$6 drugs)] variables were collected. Interventions were reported to clinician via e-prescribing software. They were classified into: adequacy (detection of prescribing error/therapy reconciliation error), initiation (usual treatment not prescribed), posology modification (dosage increase/decrease, frequency/schedule modification), suspension (duplicity/unnecessary medication). Patient lists and data were collected through medical records and e-prescribing software, and processed using LibreOffice spreadsheet-7.5.1.2®.

Results The study included 34 patients (64.7% male; 35.3% female; median age 76 years; IQR=84–71). Most frequent CJ: urinary infection (11.8%), surgical intervention (11.8%) and deterioration of general condition (8.8%). Inpatient clinical services: Internal Medicine (47.1%), Gastroenterology (17.6%), Urology (5.9%), Cardiology (5.9%), Pneumology (5.9%) and Traumatology (5.9%). The median number of active medications was 11 (IQR=11–8). Polymedicated patients raised up to 85.3%. The number of interventions performed was 60 (n=12 'not accepted' because of discharge/non-acceptance by the clinician). With regard to those accepted (n=48), 8.3% related to adequacy (4.2% detection of prescribing error, 4.2% therapy reconciliation error), 4.2% related to initiation (usual treatment not prescribed), 58.3% related to posology modification (27.1% dosage increase/decrease, 31.2% frequency/schedule modification) and 29.2% to suspension (2.1% duplicity and 27.1% prescription of unnecessary medication). Most interventions affected levodopa/carbidopa treatment but other medications represented a reduced percentage (10%) (safinamide, levodopa/benserazide or rasagiline).

Conclusion and Relevance The supervision of Parkinsonian patients at hospitalisation is a pharmaceutical daily work. This study showed that the reconciliation procedure has a high degree of acceptance, improving the quality and safety of the therapy.

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Conflict of Interest No conflict of interest.

5PSQ-081 SATISFACTION OF PHYSICIANS AND HOSPITAL PHARMACISTS OF A HYPERSENSITIVITY DOCUMENTATION TOOL WITH DE-LABELING FEATURE IN CLINICAL PRACTICE

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Background and Importance Poor documentation of drug hypersensitivities in patient records can lead to allergic reactions. Developing tools for accurate hypersensitivity documentation can prevent prescription errors. However, there is no consensus on how hypersensitivities should be routinely documented electronically. We developed a new structured and coded hypersensitivity documentation tool with a semi-automatic de-labelling feature in collaboration with end-users[1] and implemented it in our university hospital in May 2022.

Aim and Objectives To evaluate the satisfaction of physicians and hospital pharmacists with the new hypersensitivity documentation tool after implementation in clinical practice.

Material and Methods An electronic survey was sent to physicians and hospital pharmacists to evaluate the tool's satisfaction in clinical practice. Data collected between April and September 2023 included demographics, user satisfaction, experience with the tool, and suggestions for improvement. The System Usability Scale (SUS) was used to evaluate satisfaction. Closed-ended responses were analysed using descriptive statistics and inferential analysis (Mann-Whitney U test).

Results Survey was completed by 286 physicians (47%) and nine hospital pharmacists (90%), of which 167 (57%) reported using the tool. Reasons for non-use included tool unawareness (52%), preference for free text documentation (28%), no time (14%) and no patients with drug allergies (14%). The median SUS score of users was 60 (IQR=20), translating in an adjective rating of 'OK'. Hospital pharmacists had a significantly higher median SUS score (75, IQR=25) than physicians (55, IQR=18), corresponding to adjective ratings 'Good' and 'OK', respectively ($Z=2.838$, $p=0.005$). Only 81 participants (28%) indicated being familiar with inactivating hypersensitivities. About 35% of physicians reported prescribing medications to which patients have an allergy. Physicians expressed concern about documentation burden and wanted allergy alerts when prescribing.

Conclusion and Relevance Training physicians could increase awareness about drug hypersensitivities and use of the documentation tool. Although users considered the new tool relatively good in clinical practice, its efficiency can still be improved. Bridging the gap between minimal documentation requirements for an alert system and physicians' time constraints to document is crucial. Involving hospital pharmacists could reduce the time burden for physicians and improve accurate documentation of hypersensitivities.

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5PSQ-082 THIRD-GENERATION HOSPITAL-EXCLUSIVE CEPHALOSPORINS: DIFFERENT SAFETY PROFILES?

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Background and Importance Third-generation cephalosporins are clinically relevant due to their broad spectrum of activity against gram-negative, gram-positive, and Pseudomonas aeruginosa bacteria. Monitoring the safety profile of these medicinal products in a real-world setting is of paramount importance, aiming to protect both individual and collective health. To our knowledge, no study with the aim of comparing the safety profiles of these medicinal products has been conducted in the Portuguese context.

Aim and Objectives Assess the reports of suspected adverse drug reactions (ADRs) received by the Portuguese National Pharmacovigilance System concerning third-generation hospital-exclusive cephalosporins, with the aim of comparing the safety profile of these medicinal products.

Material and Methods A retrospective study was conducted using data from the Portal RAM between 1 January 2013, and 31 March 2023. Individual Case Safety Reports (ICSRs) were selected if they identified only one third-generation hospital-exclusive cephalosporin as the suspect drug, namely cefotaxime (CEFO), ceftriaxone (CEF), ceftazidime (CEFT), or ceftazidime + avibactam (CEFT/AV). Demographic data of the patient, ADR category (MedDRA Preferred Terms (PT)), Important/Designated Medical Event (IME and DME) terms, and case outcomes were analysed.

Results The search returned 269 ICSRs of interest., with the majority related to CEF (84.8%). For all the cephalosporins under study, there was a predominance of male patients, with a median age over 50 years, except for CEFO (15.0 ±10.0). Most ICSRs were classified as severe (CEFO: 80.0%; CEF: 88.2%; CEFT: 82.4%; CEFT/AV: 64.3%). Regarding the number of ICSRs containing IME terms, CEFT/AV had the highest percentage at 64.3%, while 25.4% of CEF ICSRs contained a DME term. The highest percentage of ICSRs with PT terms related to off-label use and lack of efficacy belonged to CEFT, with 11.8% and 23.5%, respectively. In all cephalosporins, the majority of ICSRs evolved towards recovery.

Conclusion and Relevance Our results appear to indicate that there are no significant differences in the safety profile of these medicinal products. However, further studies are needed. The implementation of active pharmacovigilance protocols at the hospital level may contribute to a safer and more rational use of these drugs, minimising the impact of ADRs on Public Health, both in terms of economic burden on healthcare systems and morbidity and mortality for citizens.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-083 MARIBAVIR-INDUCED TOXIC EPIDERMAL NECROLYSIS IN A LIVER TRANSPLANT PATIENT: A CASE REPORT

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Background and Importance Cytomegalovirus (CMV) infection poses a significant threat to transplant recipients,[1] often necessitating antiviral treatment. Ganciclovir and valganciclovir have been mainstays, but CMV resistance in over 20% of cases requires alternatives like foscarnet or cidofovir.[2] Maribavir, a novel CMV UL97 protein kinase inhibitor, has emerged as an effective option.[3] Here, we unveil a previously unreported adverse effect (AE) associated with maribavir.

Aim and Objectives Our aim is to report a case of toxic epidermal necrolysis (TEN) linked to maribavir intake.

Material and Methods In March 2021, a male liver-transplanted patient with CMV-related retinal necrosis developed severe pancytopenia during valganciclovir treatment, subsequently receiving foscarnet in multiple hospitalisations. In May 2023, maribavir was initiated, marking the first such case in our hospital. Within a month, the patient was readmitted with painful skin lesions and mucositis in oral and genital mucosa. TEN diagnose was assumed, evidenced by tense bullae, extensive epidermal detachment (60% of Body Surface Area), and a clearly positive Nikolsky sign. He was transferred to the ICU 3 days later and treated with a 5-day-course of 125 mg intravenous methylprednisolone and 2g/kg immunoglobulin.

Results The patient's overall status improved, with reduced lesions and epidermal detachment. After 10 days, only scarring remained. This AE was classified as probable causality due to maribavir, with a score of 6 on the Naranjo Scale.[4] The Spanish System for Pharmacovigilance of Human Drugs was informed of this event by the Pharmacy Service.

Conclusion and Relevance TEN, a life-threatening drug-associated AE, must be considered when prescribing. While antibiotics cause 25% of TEN cases, antivirals rarely induce it.[5] This AE is especially noteworthy since maribavir, marketed in November 2022, has limited exposure to patients in Spain. Early-phase pharmacovigilance is crucial for detecting unreported AEs. Establishing multidisciplinary teams comprising physicians and pharmacists is essential to ensure drug safety, mitigating severe AEs.

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Conflict of Interest No conflict of interest.

5PSQ-084 EROSIVE BALANITIS AS A POSSIBLE ADVERSE EFFECT TO TREATMENT WITH TOFACITINIB. A CASE REPORT

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Background and Importance Tofacitinib is a selective inhibitor of the Janus kinase family indicated for the treatment of various rheumatological pathologies such as rheumatoid arthritis (RA) and psoriatic arthritis. According to the technical data sheet (TDS), most frequently reported adverse effects (AE) during the first 3 months of clinical studies were headache, upper respiratory tract infections and viral respiratory tract infections upper. Pharmacovigilance collects information and analyses and notifies cases of suspected adverse drug reactions to prevent them occurring in the future.

Aim and Objectives Describe the causal relationship in a patient who suffers from erosive balanitis after the administration of tofacitinib, besides the multidisciplinary intervention in its management.

Material and Methods Retrospective and multidisciplinary study, which describes the case of a 66-year-old patient diagnosed with RA since 2007 and who, in 2019, after numerous failures with disease-modifying drugs (DMARDs), began treatment with tofacitinib 5 mg every 12 hours. Data were obtained from Diraya® digital medical record. Safety profile of tofacitinib was reviewed in its TDS and the Naranjo Algorithm was applied to establish the drug-adverse reaction causal relationship.

Results In January 2022, the patient was referred from primary care to the dermatology clinic due to erythema in glans area that had been developing for a month, reporting that he had an outbreak with the same characteristic's previous year. Following this event, the precautionary suspension of tofacitinib was agreed with rheumatology team. Specialists contact the Hospital Pharmacy Service to confirm whether it is an AE secondary to tofacitinib. After this, the pharmacist performed a review of the TDS and literature confirming that there was no evidence of erosive balanitis as an AE of tofacinib. The suspected AE was reported to the Spanish Pharmacovigilance System and a causal relationship was established between the drug and the AE according to the Naranjo Algorithm, obtaining a score of 1 that established a possible relationship between the drug of interest and the AE. After topical cures for 2- months, treatment with tofacitinib was restarted in May 2022 without reporting new incidents.

Conclusion and Relevance Multidisciplinary participation in the detection, notification and actions, to establish the causal relationship of AE associated with drugs, contributes to improving patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-085 SAFETY ASSESSMENT OF JANUS KINASE INHIBITORS IN CLINICAL PRACTICE

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Background and Importance Janus kinase inhibitors (JAKi) tofacitinib, baricitinib, upadacitinib and filgotinib are immunosuppressants indicated for the treatment of chronic inflammatory disorders. Concern regarding their safety has recently arisen since publication of new data in recent years.

Abstract 5PSQ-085 Table 1

	BARICITINIB	TOFACITINIB	UPADACITINIB	FILGOTINIB
Total patients n	142	105	20	4
Toxicity n patients (%)	66 (46,5)	49 (46,6)	5 (25)	2 (50)
Total AR	101	65	5	4
Gastrointestinal disorders (GD)	**9**	**13**	**0**	**2**
Diarrhea	1	1	0	0
Abdominal pain	1	4	0	0
Nausea	1	0	0	1
No specified GD	6	8	0	1
Infections	**18**	**7**	**0**	**0**
Herpes zoster	4	2		
Septic shock	2	0		
Others	12	5		
Blood test parameters	**44**	**22**	**3**	**1**
Hypertriglyceridaemia	5	4	1	0
Hypercholesterolaemia	21	15	1	1
Anaemia	5	0	1	0
Lymphopenia	8	0	0	0
Thrombocytosis	2	0	0	0
Hepatic transaminase elevations	3	3	0	0
Cardiovascular disorders (%)	**9**	**2**	**1**	**0**
Heart murmur	2	0	0	0
Tachycardia	0	0	1	0
Chest pain	4	1	0	0
Hypertension	3	1	0	0
Headache	**5**	**6**	**0**	**0**
Dyspnea	**4**	**3**	**0**	**0**
Skin disorders	**1**	**1**	**1**	**0**
Others	11	11	0	1

Aim and Objectives To assess the safety of tofacitinib, baricitinib, upadacitinib and filgotinib for the treatment of chronic inflammatory disorders in real clinical practice. To compare it with the clinical trials (CT) results.

Material and Methods Observational restrospective study including all patients treated with JAKi from January 2019 to August 2023 in a tertiary hospital. Data were obtained by review of electronic medical records and laboratory database. Variables studied were: patient demographics, prescribing units, adverse reactions(AR), treatment duration and motive of interruption.

Results 271 (74,5% women) patients were included in this study, with a median age of 55 (18–92) years. 243 had rheumatology disorders, 21 digestive disorders, 3 dermatology disorders and 4 both rheumatology and digestive disorders. 122 (45%) patients suffered some kind of toxicity during treatment with JAKi. The most frequently registered AR by drug are shown in the table 1:

In 43 (15.9%) patients treatment was stopped due to toxicity (16 baricitinib, 19 tofacitinib, two upadacitinib, one filgotinib). The most frequent AR that led to interruption were gastrointestinal disorders with tofacitinib and infections with baricitinib.

Treatment had to be stopped in five patients because of neoplasm diagnosis (three baricitinib, two tofacitinib). Two patients died during period of study (one tofacitinib, one baricitinib).

Dose reduction because of toxicity was required in one patient treated with tofacitinib and in 12 treated with baricitinib.

Conclusion and Relevance In general terms, for tofacitinib and baricitinib, our study carried out in real-world clinical practice shows a toxicity profile similar to the one described in CT. All AR are described in the literature.

Infections and hypercholesterolaemia are among the most frequent AR in our study and in CT.

Although most of the AR were tolerable, there were several cases of severe AR led to treatment interruption.

In contrast to recent CT results, no major adverse cardiovascular events were registered in our study.

A bigger sample is needed to make conclusions about upadacitinib and filgotinib safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-086 ADMINISTRATION OF TYROSINE KINASE INHIBITOR DRUGS IN PATIENTS WITH ENTERAL FEEDING TUBES

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Background and Importance Swallowing problems are common in paediatric patients, elderly patients and some pathologies. A common nursing practice is the administration of enteral nutrition (EN) formulas together with drugs through feeding tubes. In recent years, the number of tyrosine kinase inhibitor (TKI) drugs for the treatment of oncohaematological pathologies has grown enormously.

Aim and Objectives To identify alternatives to oral administration of TKIs in patients with swallowing problems.

Material and Methods A literature review was performed in August 2023 on the conditions for handling and administration of the TKIs used in our hospital in patients with swallowing problems. The respective technical data sheets and

clinical practice guidelines were reviewed, as well as specific articles.
Variables possibility of administration by feeding tubes, manipulative technique of the dosage form, dissolution medium, need to prepare a magistral formula in the Pharmacy Service, special administration conditions and compatibility with EN.
Results 31 TKI drugs were identified in our hospital. Of these, information was available for 24.

Of the drugs with information (possibility of administration by feeding tubes: 22; alternative dosage form exists: 1; no alternative exists: 1). By manipulative technique (crush and dissolve: 15; disperse without crushing: 7), dissolution medium (10–20ml of water: 6; >20ml of water: 5; acid and >20ml: 2; >40°C and 10–20ml of water: 3; >40°C and >20ml: 1; others: 5). 4 drugs require the preparation of a magistral formula in the Pharmacy Service. Special administration conditions (photoprotection: 3; 1: >8Fr feeding tubes: 1). 14 ITKs are compatible with EN; in the remaining cases, separate administration is recommended (1 hour before or 2 hours later).
Conclusion and Relevance Despite numerous sources of information, there is a 20% of TKI without evidence. Furthermore, compatibility with EN administration is based on analogy with oral forms of administration.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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Conflict of Interest No conflict of interest.

5PSQ-087 ANALYSIS OF EFFECTIVENESS AND SAFETY OF TRALOKINUMAB IN MODERATE-SEVERE ATOPIC DERMATITIS

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Background and Importance Atopic dermatitis (AD) is a chronic inflammatory skin disease characterised by severe pruritus, eczema and xerosis. A systemic treatment option for moderate-severe AD is tralokinumab, a human monoclonal antibody targeting IL-13.
Aim and Objectives The aim of the study is to evaluate the effectiveness and safety of tralokinumab in patients with moderate-severe AD in three tertiary hospitals.
Material and Methods Observational, retrospective, multicentred study of patients treated with tralokinumab from April 2022 to September 2023. Variables collected: age, sex, previous treatments, initiation and duration of treatment, adverse effects (AE) and the severity of AD was analysed using the scales: *Eczema Area and Severity Index* (EASI) and *Body Surface Area* (BSA).

Effectiveness was evaluated assessing the number of patients with a reduction of at least 50% or 75% in the values of EASI (EASI50 and EASI75, respectively) and number of patients with a reduction in BSA, during week 16 approximately. Sources of information: application of electronic prescription Prisma® and computerised clinical history Diraya®.
Results We included 39 patients, of whom 32 (18 women, 14 men) had reached week 16 of treatment or higher, with an average age of 37.63 years (range 16–66 years) and with a median follow-up of 26.6 weeks. All received previous treatment with topical corticosteroids and cyclosporine, 11 had received treatment with dupilumab and 6 with JAK inhibitors.

The basal medium of EASI was 27.05 and after the assessment carried out, 33% (13/39) achieved EASI50 and 23% (9/39) EASI75. With a median dermatologist assessment of 20 weeks, the number of patients remaining on EASI50 was 11 and on EASI75 9. The basal median of BSA was 21, where 3 (8%) patients suffered an increase and 17 (44%) reduced it, reaching 7 of them to values of 0–1. 15 patients (38%) discontinued treatment, 14 due to lack of efficacy and 1 due to AE.

Four patients with AD were reported: syncope, respiratory infection, headache and conjunctivitis together with generalised xerosis, whose patient had to discontinue treatment.
Conclusion and Relevance Tralokinumab is an innovative alternative in patients with moderate-severe AD refractory to other therapies. More data on long-term efficacy and safety are needed.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-088 ADHERENCE TO ANTIRETROVIRAL THERAPY IN HIV PATIENTS

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Background and Importance The goal of antiretroviral therapy (ART) is virological suppression since subtherapeutic levels of antiretrovirals can lead to development of resistance. A correct adherence treatment is crucial to achieve that issue.
Aim and Objectives To identify the degree of adherence to ART in HIV-positive patients and analyse whether it is related to virological results and the type of ART used.
Material and Methods Retrospective observational study of HIV patients attended at our Pharmacy Outpatient Unit during the year 2022. The following variables were collected: sex, age, viral load (VL), type of ART (drugs, number of tablets), excluding those in treatment less of 6 months.

Adherence was estimated with the indirect method of the medication possession ratio (MPR), defined as the percentage of days covered with the dispensed medication compared to total days with the prescribed medication x 100. Good adherence was defined as an MPR 95–100%, intermediate adherence: MPR 80–95% and poor adherence: MPR<80%.
Results 53 patients were eligible for the study (69.8% men with a mean age of 49.2±10.3 years and 50.9±9.4 years in women), of which 84.9% received triple therapy, 11.3% double therapy and 3.8% monotherapy.

The overall mean adherence was 95.1±7.2% (95.7% in women and 94.9% in men), of which 67.9% had good adherence (52±10.2 years), 22.6% intermediate adherence (47±7.9 years) and 9.4% poor adherence(42±5.9 years).

VL was undetectable in 84.9% of cases (mean adherence 95.9%) and unknown in 9.4% during the study year. Only three patients (5.7%) were detectable, two with good adherence and one with intermediate adherence.

Regarding the number of daily tablets, adherence was good in patients who took 1, 2 and 3 tablets daily (95.3±7.3%)

and intermediate in those who took 4 tablets daily (90.7 ±8.7%).

Conclusion and Relevance Most patients in our study have good adherence and it is higher in older patients and the less tablets daily they take. No relationship was found between patient gender and adherence. The cases of detectable VL were not associated with poor adherence to ART, which could be due to patient resistance or limitations of the adherence measurement method.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-089 OUTCOME OF MOLNUPIRAVIR TREATMENT IN RENAL TRANSPLANT PATIENTS WITH COVID-19

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Background and Importance According to the global recommendations for COVID-19 therapy, adult patients at risk of severe disease (including patients after organ transplantation) should be treated with antivirals: preferably nirmatrelvir/ritonavir (Paxlovid) or remdesivir (Veklury). Alternative choice is unlicensed use of molnupiravir (Lagevrio).

Aim and Objectives Our study focused on evaluating the effectiveness and safety of molnupiravir in patients with COVID-19 after successful kidney transplantation (KTx).

Material and Methods A cohort of 93 patients (62 males) was retrospectively evaluated, with 89.0% of patients having had a first KTx (the remainder having had a second KTx) and 39.0% with diabetes mellitus. The mean age of the patients at the time of molnupiravir therapy was 56 years (SD 12.9) and they received molnupiravir with mean of 2.24 days (SD 1.67) since confirmation of SARS-2-positivity. Immunosuppressive therapy was adjusted uniformly according to the site protocol and prednisone was increased for a maximum of two to three weeks. The safety of the proposed procedure concerning graft function and risk of rejection was evaluated based on the trend in creatininemia and urinary protein/creatinine index. Nonparametric Wilcoxon test was used.

Results The median serum creatinine value in the study population was 127 µmol/l (IQR 52) before COVID-19. Outpatient follow-up was within 1 month after quarantine with median 124 µmol/l post-disease creatinine (IQR 53,2). The difference in median creatinine values before and after molnupiravir therapy was not statistically significant ($p = 0.8175$). COVID-19 related hospitalisation occurred in 5.4% patients, one patient in the cohort died due to COVID-19 disease. Short-term discontinuation or modification of immunosuppression did not induce any rejection episode.

Conclusion and Relevance Our experience demonstrates that early initiation of molnupiravir may be an effective and safe therapy for COVID-19 disease in patients after kidney transplantation (where it is authorised in the Czech Republic until the end of 2023). Moreover, compared to Paxlovid, its use is not limited by drug-drug interactions and thus can be administered with calcineurin inhibitors.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

5PSQ-090 CAPSAICIN 8% PATCH IN TREATMENT OF PERIPHERAL NEUROPATHIC PAIN

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Background and Importance The International Association for the Study of Pain defines neuropathic pain as pain caused by a lesion or disease of the somatosensory nervous system, central or peripheral.

Capsaicin 8% cutaneous patch is indicated for the treatment of peripheral neuropathic pain (PNP) in adults either alone or in combination with other medicinal products for the treatment of pain.

Aim and Objectives This study aimed to evaluate the clinical efficacy and tolerability of capsaicin patch in PNP in a usual clinical practice at a third-level hospital.

Material and Methods Retrospective observational study conducted between January 2019 and December 2022 of patients with PNP who underwent treatment in the hospital. All of them signed informed consent. Data were collected from clinical history and pharmacy program.

Therapeutic efficacy was evaluated through pain intensity, using the Visual Analogue Scale (VAS), at baseline and a week after treatment. Patients were considered as responders to therapy if VAS decreases ≥ 3.

Patients were included in one of the following groups according to the localisation pain: Back, Hip, Knee, Feet, Upper limbs (hands, arms).

Endpoints included demographic and clinical characteristics (age, sex), therapeutic outcomes (change in basal pain intensity), adverse events (AEs), site reactions.

Results 686 patients were included in the study (65% women, median age 60.5 years). Localisation area application were: Knee (21.6%), Back (8.5%), Hip (6.6%) Upper limbs/feet (19.7%).

The median VAS baseline score (6,9) decreased a week after treatment (5.7).

A median percentage of patients (42.4%, n=291) improved VAS scale and 42% (n=122) of them were considered responders to treatment (decrease baseline VAS ≥ 3).

Adverse events (mild to moderate in intensity) were: erythema (13,1%), burning sensation (29,8%) and pruritus (21.4%). No severe adverse events were observed.

Conclusion and Relevance Capsaicin patch use in peripheral neuropathic pain seems to be effective, decreasing pain intensity in treated conditions.

Treatment was generally well tolerated adverse events were transient and self-limiting.

More studies are needed to evaluate the long-term effectiveness and safety of capsaicin 8% cutaneous patch.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-091 SUITABILITY OF TERIPARATIDE AND LEVEL OF ACCEPTANCE OF PHARMACOTHERAPEUTIC RECOMMENDATIONS IN AN AREA OF HEALTH MANAGEMENT

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Background and Importance The use of teriparatide treatment has resulted in an increase of great economic impact at the hospital level in recent years.
Aim and Objectives To analyse the appropriateness of the prescription of teriparatide in the treatment of osteoporosis in the Orthopedic Surgery and Traumatology Service and to evaluate the degree of acceptance by the physician of the interventions performed.
Material and Methods A prospective, single-centre intervention study has been carried out between March-April 2023. Adult patients with an active prescription of teraparatide from the Orthopedic Surgery and Traumatology Service whose last dispensation was in January 2023 were included. The variables collected were: age, sex, treatment duration, dosing regimen, previous fracture and type of fracture, previous treatment, contraindications, osteoporosis.
Information sources electronic prescription application Prisma®, computerised medical records Diraya® and dispensing data using MicroStrategy software.

In case of inadequacy of treatment, individualised letters were prepared for each patient and sent to the responsible medical specialists along with recommendations for teriparatide treatment. The degree of acceptance of the interventions was measured by the percentage of patients with suspension or modification of treatment after pharmaceutical intervention.
Results A total of 43 patients (76.74% women) with a median age of 76.5 years (range 30–92 years) were included. 18.60% (n=8) of patients had treatment errors, of which 62.5% (n=5) due to dosing regimen >2 years, 12.5% (n=1) due to an error in the regimen and 25% (n=2) due to contraindications. In addition, 13 were prescriptions with a previous non-vertebral fracture, where 84.61% (n=11) were first-line teriparatide treatments, when it is not recommended. The degree of acceptance by the specialists after the intervention was 62.5%. The prescriber's modifications were suspension of teriparatide treatment for > 2 years and initiation of bisphosphonates, modification of the regimen error, and replacement of drugs that had contraindications with first-line drugs.
Conclusion and Relevance Although there are not many errors in the treatment in active prescriptions of teriparatide, the interventions carried out were partly accepted by physicians, but they continue being prescribed as first-line treatments when it is not recommended. In addition, prescription errors were reduced and medication safety increased, reflecting the importance of the role of the pharmacist at the hospital level.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-092 ALTERED PHARMACOKINETICS PARAMETERS OF VANCOMYCIN IN PATIENTS WITH HAEMATOLOGIC MALIGNANCY WITH FEBRILE NEUTROPENIA, A BAYESIAN SOFTWARE ESTIMATION

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Background and Importance The pharmacokinetics of vancomycin vary significantly between specific groups of patients, such as patients with haematological malignancy with febrile neutropenia. Recent evidence suggests that the use of the usual standard dose of antibiotics in patients with febrile neutropenia may not offer adequate exposure due to pharmacokinetic variability.
Aim and Objectives To assess the effect of febrile neutropenia on the AUC0–24 hours as a key parameter for vancomycin monitoring, as well as to determine which vancomycin pharmacokinetics parameters are affected by the presence of febrile neutropenia using Bayesian software PrecisePK in haematological malignancy with febrile neutropenia.

To evaluate the difference in estimated AUC0–24 between febrile neutropenia and non-febrile neutropenia among patients with haematological malignancies.
Material and Methods The study included adult patients admitted between January 2017 and December 2020, who received vancomycin with measured steady-state trough concentrations before the fourth dose. Of the 297 patients treated, 217 met the inclusion criteria. Pharmacokinetic parameters for both neutropenic and non-neutropenic patients were estimated using the precise PK Bayesian platform.
Results The result showed that AUC0–24 was lower in febrile neutropenic patients $p < 0.05$ (403 vs. 461 mg·h/L) compared to non-febrile neutropenia patients. Also, there was a significant difference ($p < 0.05$) in vancomycin clearance, the volume of distribution at a steady state, the volume of distribution for the peripheral compartment, the half-life for the elimination phase, and the first-order rate constant for the elimination process in febrile neutropenia group compared to non-febrile neutropenic patients.
Conclusion and Relevance Febrile neutropenia has a significant effect on the pharmacokinetics parameters of vancomycin and AUC0–24, which may require specific consideration during the treatment initiation.

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5PSQ-093 DOES EXPOSURE TO ANTIBIOTICS PRIOR TO TREATMENT WITH IMMUNE CHECKPOINT INHIBITORS AFFECT THEIR EFFECTIVENESS?

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Background and Importance Taking antibiotics weeks before immunotherapy alters the gut microbiota. It is therefore questionable whether the use of antibiotics prior to immunotherapy is associated with decreased effectiveness in cancer patients.
Aim and Objectives To evaluate the influence of the use of antibiotic therapy on the effectiveness of immunotherapy treatment in cancer patients.
Material and Methods Observational, retrospective, 68-month, retrospective study (January 2018 to August 2023) in patients diagnosed with renal cell, non-small-cell lung and head and neck cancers.

The difference in effectiveness was measured by comparing the median progression-free survival (mPFS) and median overall survival (mOS) of patients who received antibiotic therapy 2 months prior to the start of immunotherapy and those who did not receive antibiotic therapy.
Variables age, sex, *Eastern Cooperative Oncology Group* (ECOG) scale, immunotherapy received, number of previous lines, antibiotic prescription 2 months prior to the start of immunotherapy and duration of treatment.
Data source computerised medical records and electronic prescribing programme.
Results A total of 138 patients (71.0% male; median age 67 years) were analysed. Of the patients, 42.0% received antibiotic therapy 2 months prior to the start of immunotherapy.

The group receiving antibiotherapy (56.8% male; median age 68 years): ECOG < 1 (89%), by immunotherapy (pembrolizumab: 58%; atezolizumab: 23%; nivolumab: 19%), number of previous lines (2[1–3] median). mPFS was 5.1 (3.2–7.1) months and mOS was 16.4 (12.7–22.5) months.

The antibiotic-naive group (81% male; median age 65 years): ECOG < 1 (91%), by immunotherapy (pembrolizumab: 54%; atezolizumab: 28%; nivolumab: 18%), number of prior lines (2[1–3] median). mPFS was 5.6 (4.6–9.5) months and mOS was 17.8 (12.6–21.8) months.

The differences in both groups on mPFS and mOS were not statistically significant (p=0.57) and (p=0.78), respectively.
Conclusion and Relevance Despite limitations in sample size, our study reveals that the use of antibiotic therapy 2-months prior to the start of immunotherapy does not make a difference to the effectiveness of immunotherapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

5PSQ-094 INCIDENCE OF HYPERSENSITIVITY REACTIONS IN PACLITAXEL INFUSIONS FOLLOWING THE DISCONTINUATION OF RANITIDINE

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Background and Importance Current literature supports that the use of H2 antihistamines in paclitaxel-containing regimens is not essential, although publications are scarce.[1]
Aim and Objectives To determine the incidence of hypersensitivity reactions (HRs) during paclitaxel infusion after the withdrawal of ranitidine from the market.
Material and Methods Observational, retrospective and descriptive study in which patients undergoing chemotherapy with paclitaxel-containing schemes for adjuvant (ABC) and neoadjuvant (NBC) breast cancer, cervical cancer (CC), ovarian (OC) and endometrial (EC) were included. The study period was from 2 February 2022 (cessation of marketing of ranitidine) to 31 August 2023.

HRs were analysed after modification of the premedication protocol, which included the same treatment guidelines, excluding ranitidine.
Variables age, sex, type of neoplasm, line of treatment, treatment schedule, administration time, premedication, HRs and measure adopted.
Data source computerised medical records and electronic prescribing programme.
Results A total of 493 administrations of paclitaxel were infused to 68 patients (100% female) with a median age of 64 years [31–89]. 20% corresponded with ABC, 29% OC, 14% CC, 11% EC and 26% NBC. Sixty-seven percent of patients were first-line.

Six HRs were observed during the first or second cycle. Three (50%) were related to paclitaxel administration, one in ABC (paclitaxel 80 mg/m^2 weekly over 1 hour), one in OC (paclitaxel 175 mg/m^2 over 3 hours) and one in EC (paclitaxel 175 mg/m2 over 3 hours). The remaining three were related to the administration of carboplatin in patients on OC.

HRs appeared in patients aged 43–67 years. One required discontinuation of treatment, the rest were given premedication the day before the cycle and increased infusion time.
Conclusion and Relevance The use of premedication protocols without H2 antihistamines appears to be a safe practice. Our study has limitations in terms of sample size. However, it is important to know the role of these drugs and it is necessary to involve the pharmacist in the development of hospital protocols to identify patients to benefit from these drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

5PSQ-095 HOSPITAL PHARMACISTS ENGAGEMENT IN PHARMACOVIGILANCE PRACTICES DURING COVID-19 IN THE NORTH MACEDONIA

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Background and Importance Pharmacists are acknowledged as safety leaders worldwide, since they have high impact of patients' safety, and it was confirmed during COVID-19 pandemic. In the Republic of North Macedonia hospital pharmacists (HPs) were nationally recognised as a key factor for implementation of good pharmacovigilance (PV) practices and since 2017 they are engaged in PV working group in

Macedonian Regulatory Agency (MALMED), actively working on rising the awareness and improvement of Adverse Events (AEs) reporting.

Aim and Objectives The questionnaire-based research aimed to evaluate the curtail role of HPs in implementation of good PV practices during COVID-19 pandemic in overloaded hospitals.

Material and Methods Non-Interventional, questionnaire-based study evaluating the knowledge, attitudes and engagement HPs for pharmacovigilance during COVID-19 pandemic was performed among HPs in the Republic of North Macedonia in July 2022. Obtained data were computed and assessed using statistical software STATGRAPHICS Centurion XVI evaluation (StatPoint technologies Inc., USA).

Results The survey was completed by 35 (representing almost 50%) of HPs in our country. The average age of respondents was 45.4±12.9 years, more than 40% have over 20 years working experience as HPs and almost 70% are working in public hospitals. Although 83% of HPs confirmed that have reported an adverse event (AE) during their working practice and are experienced in implementation of good PV practices, only 13% of HPs strongly agreed and 39.1% agreed, that received the information for AEs associated to COVID-19 treatment and almost the same percentage of HPs reported the AEs to the Agency. Low level of reporting by HPs (17.4%) was observed also for off-label use of drugs during the pandemic. Additionally, only 17.4% of HPs were consulted for the procedure of adverse event reporting to the Agency by other healthcare professionals suggesting that they are still not recognised as safety leaders in hospitals.

Conclusion and Relevance Although HPs are nationally recognised as stakeholders in the improvement of good PV practices, they were not fully engaged in AEs identification and reporting during COVID-19 and appreciation of their PV expertise in hospitals have to be improved. Appropriate PV education alongside with utilisation of contemporary software opportunities is suitable approach for improvement of AEs reporting, medicines safety and public health.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-096 DESCRIPTION OF INMMUNOGLOBULIN REPLACEMENT THERAPY IN MULTIPLE MYELOMA PATIENTS WITH ANTI-BCMA CART

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Background and Importance Multiple Myeloma (MM) is a plasma cell neoplasm. The reduction and dysfunctionality of normal plasma cells together with treatment with anti-BCMA CAR-T leads to a deficit in humoral immunity that manifests as hypogammaglobulinemia and an increase in infections risk, which lead to the need to administer replacement therapy with intravenous polyclonal immunoglobulins (IgRT).

Aim and Objectives The primary objective of this study is to describe the use of immunoglobulins in patients who have received anti-BCMA CAR-T therapy (ide-cel, cilta-cel, ARI0002) for the treatment of MM in a clinical trial or as compassionate use.

Material and Methods This is a single-centre, observational, descriptive and retrospective study to describe the use of immunoglobulins in patients who had hypogammaglobulinemia, defined as IgG levels < 400 mg/dL, or any IgG level along with infectious events that require treatment with immunoglobulins. An institutional review board (IRB) approved the study.

Results 47 patients received an anti-BCMA CAR-T, with Ide-Cel being the CART in 70.21% (n=33) of them. Plasma IgG levels decreased progressively over time (median nadir month 7= 208 mg/dL (range 100–465) presenting a recovery around the eighth month post-infusion. Of these 47 patients, 22 (58.64%) received, at least once, IgRT. In these 22 patients, the median time until the start of treatment with IgRT was 123 days (range: 69 to 799). The rate of infectious events and febrile neutropenia grade 3–4 was 68.18% (15/22) in patients who received IgRT and 56% (14/25) in patients who did not receive IgRT (p=0.391).

Conclusion and Relevance These results reveal a period of hypogammaglobulinemia after anti-BCMA CAR T-cell therapy. The role and when to begin IgRT needs further exploration, as in this study has not improved the rate of grade 3–4 infectious events in patients who received it.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-097 AN APPROACH TO THE USE OF MACHINE LEARNING TOOLS FOR THE PREDICTION OF ADVERSE EVENTS IN CANCER PATIENTS ON IMMUNOTHERAPY

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Background and Importance The FDA Adverse Reporting System (FAERS) is a tool to voluntary report adverse events (AE), These data can be downloaded and used to apply 'Machine learning'(ML) techniques. The bibliography is limited, although it has already been the subject of a systematic review (Kim et al, 2022). FAERS data set could be useful to elaborate potential predictive modelling.

Aim and Objectives To test a tool of ML to develop a potential predictive model of AE caused by immune checkpoint inhibitors (ICI), using FAERS data set.

To contrast and explain the ML results with a reference model (RM), obtained through conventional processing data (spreadsheet).

Material and Methods All FAERS records from 2022 were downloaded, selecting those of the group ICIs group notified as 'main suspected drug' (inclusion criteria). Collected variables from FAERS data set were:AE, age, drug and sex. The ML decision tree classification algorithm J48 implemented in the Weka application (version 3.8.6) was used to elaborate the ML model. The RM was built using a spreadsheet to tabulate and analyse the data (pivot tables and descriptive statistics).

Results 1,702,222 notifications were downloaded and 86,053 records were selected according to inclusion criteria. The J48 algorithm applied to a subset including 'adverse effect', 'sex'

and 'drug', allowed us to estimate, for each AE the most likely responsible ICI drug. The metrics of the ML model obtained were satisfactory and compatible with the RM analysis. The J48 algorithm produced a complex tree (to be expected given the large number of AE). The application of J48 on another subset that includes 'adverse effect', 'age' and 'drug', had a lower predictive capacity, due to the lower consistency of the data (age is only recorded as younger or older than 65 years) and that there is a higher proportion of missing values. The RM allows the results obtained with ML to be easily explained and understood.

Conclusion and Relevance The results of the J48 algorithm were useful for the association between AE, sex and drug. Despite the inherent limitations of voluntary AE reporting, this study will serve as a starting point for applying ML techniques in any other group, using FAERS data.

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Conflict of Interest No conflict of interest.

5PSQ-098 ABSTRACT WITHDRAWN

5PSQ-099 DRUG-RELATED PROBLEMS ASSOCIATED WITH THE TREATMENT OF POLYCYSTIC OVARY SYNDROME

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Background and Importance Polycystic ovary syndrome (PCOS) is a severe public health problem and a major determinant of various reproductive, metabolic, and psychological outcomes. The pharmacological management of PCOS is complex and should be individualised based on the multifactorial manifestation of the disease in the individual patient and her reproductive desires.

Aim and Objectives To identify the most common drug-related problems (DRPs) by reviewing and analysing data from the scientific literature and PCOS treatment guidelines.

Material and Methods A review of international scientific databases, projects, initiatives to improve the therapeutic management of PCOS and normative regulations in the field of pharmaceutical practice was carried out. Both comparative and critical content analysis of therapeutic guidelines and good practice initiatives for the treatment of PCOS, as well as general research methods (historical, internet reference and content review, theoretical deductive analysis method) were used.

Results DRPs related to the lack of sufficient efficacy data to support drug use, as well as inadequate therapy selection to address the complex phenotype of PCOS, and DRPs related to safety and tolerability concerns (mainly associated with metformin and letrozole treatment) are among the main issues identified. The safety profile of oral contraceptives as the primary therapeutic approach for PCOS treatment is also a source of DRPs. The possibility that the choice of therapeutic approach may not be tailored to specific patient characteristics, usually through the selection of subeffective doses and dosage forms, remains a critical concern in the context of PCOS pharmacotherapy. Drug misuse, off-label prescribing or prescribing of repurposed drugs, and DRP due to the long duration of therapy required are other major group of concerns related to the management of PCOS.

Conclusion and Relevance The implementation of complex pharmaceutical care interventions by hospital pharmacists tailored to the specific needs of patients with PCOS and the addressing of the identified DRPs will lead to better control

of disease-related symptoms, better overall health outcomes, higher quality of life, and greater patient satisfaction compared to standard disease control approaches.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-100 SURVEY OF PATIENT INVOLVEMENT IN ADVERSE DRUG REACTION MONITORING: THEIR INFORMATION SOURCES AND NEEDS

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Background and Importance Adverse drug reactions (ADRs) have resulted in a significant proportion of morbidity and mortality. Patients have access to several sources of information about adverse drug reactions (ADRs), which contribute to improving medication safety. There have been few published studies on sources of ADR information used and the information needed by patients.

Aim and Objectives To explore patients' use of information sources and their information needs in the monitoring process of adverse drug reactions (ADRs) and to evaluate factors related to both information sources and information needs.

Material and Methods A cross-sectional survey, using a self-administered questionnaire, was distributed to patients through purposive sampling, who were visiting outpatient departments of two university hospitals from January to July 2020. Patients aged 18 and over were asked about their information sources and needs about the experienced ADRs.

Results Of the total 617 questionnaires distributed, 479 were completed (77.6%). Respondents were asked about sources of information used to confirm ADR symptoms. Of the total 476 respondents, 316 (66.4%) claimed that they consulted their physicians to confirm ADRs, 194 (40.8%) relied on their own experiences, and 66 (13.9%) consulted pharmacists. The top two information that patients needed in ADR identification were healthcare professional advice (75.0%) and ADR information documents (48.1%). The major needed information regarding ADR management included the treatment of ADR symptoms (33.9%) and switching to other drugs (32.9%). Major information needs related to ADR prevention were recording a history of drug allergies (40.6%) and ADR surveillance and detection methods (29.0%). Patients with bachelor's degree or higher educational levels were more likely to use medicine labels as a source of ADR information ($p = 0.047$). Patients aged less than 60 years ($p=0.018$) and patients having three underlying diseases or less ($p=0.043$) were more likely to require the ADR information.

Conclusion and Relevance Healthcare professionals (HCPs) are the primary sources of information for patients. Younger patients and less underlying diseases were found to be associated with a greater need for information. Therefore, HCPs should ensure that patients receive sufficient ADR information particularly older patients to enhance medication safety.

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Conflict of Interest No conflict of interest.

5PSQ-101 MEDICAL DEVICES INCIDENT REPORTS: AN ITALIAN EXPERIENCE

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Background and Importance Dispovigilance is the Italian Ministry of Health's database that supports the National Vigilance Device Network since October 2022. It is an essential tool in the reporting system for serious, non-serious incidents and safety actions related to medical and in vitro diagnostic devices (MDs and IVDs).

The National Classification of Medical Devices (CND) groups MDs into homogeneous categories of products for similar diagnostic and/or therapeutic intervention.

The European Medical Device Nomenclature (EMDN), Regulations 2017/745 and 2017/746, is based on the Italian CND. The Regulations also classify MDs into different classes according to risk management.

Aim and Objectives The purpose was to investigate MDs involved in incidents occurred at an Italian hospital, to provide real world evidence.

Material and Methods This study was performed on incident reports collected through Dispovigilance between January 2022 and September 2023. CND, risk class (I, IIA, IIB, III) and reporter were analysed.

Results A total of 42 reports were collected; of these, 17 (40%) during 2022 and 25 (60%) in the first nine months of 2023. According to CND, the most frequently reported DMs belonged to 'C, Cardiocirculatory System Devices' (20 cases, 23%); 'P, Implantable Prosthetic and Osteosynthesis Devices' (8 cases, 19%) and 'A, Devices for Administration, Withdrawal and Collection' (7 cases, 16%). Based on the class of risk, 1 MD referred to class I, 15 to class IIA, 13 to class IIB, 13 to class III. Most accidents were reported by clinicians (25 cases), followed by pharmacists (7 cases) and nurses (7 cases).

Conclusion and Relevance The analysis shows an increasing reporting trend in 2023 compared to 2022, probably due to the advent of Dispovigilance, although underreporting is still present especially for low-risk devices. Most reports refer to medium and high-risk devices.

Based on CND, C and P are frequently notified; the reason could be the greater attention on these high-risk devices. According to our results, clinicians are the predominant reporters, together with pharmacists and other healthcare professionals since they are directly involved in the management and use of DMs.

This study highlights the essential role of vigilance of medical devices.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-102 ANALYSIS OF REPEATED EMERGENCY DEPARTMENT VISITS AND THEIR RELATIONSHIP TO MEDICATION

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Background and Importance Analysing the reasons of repeated Emergency Department (ED) visits could help establish a pharmacotherapeutic follow-up consultation, in order to reduce the number of re-consultations

Aim and Objectives Analyse the percentage of repeated visits to ED in relation to pharmaceutically-approved patients' medication or patients' medication that have received a thorough pharmacotherapy revision (approved/thoroughly checked patients).

Material and Methods An observational, retrospective study developed in a second-level hospital from September to December 2022. All patients approved and thoroughly checked by Pharmacy team from ED were included, meaning all those who appeared in at least one of Emergency Pharmacy Activity (EPA) forms. The main variable considered was the percentage of patients that came back to ED, counting $\geq$2 EPA registrations, compared to the total amount of approved/thoroughly checked patients in that period. Other variables considered were the percentage of patients coming back with the same issue, the main issues the repeat a visit, the percentage of repeated visits related to pharmacotherapy and the main pharmacotherapeutic related groups (ATC code). Data were acquired from the electronic clinical history. Data were statistically evaluated through a software descriptive frequency analysis.

Results During the study period, 673 patients were included. From them, 50.52% were women (median age: 72 years old). The number of patients that visited ED again was 11.44% (77/673). The total amount of repeated visits was 83. Several patients [46.75% (36/77)] came back due to same issue. The main issues to revisit were respiratory infection [11.68% (9/77)], unbalanced heart failure and urinary tract infection [both 10.38%(8/77)], and COPD flare-ups [7.8% (6/77)]. The repeated visits related to medication were 57.83% (48/83) of cases. The main pharmacotherapeutic groups related to the ED were: cardiovascular-system [35.41% (17/48)], anti-infective group [20.83% (10/48)] and respiratory-system [12.5%(6/48)].

Conclusion and Relevance From the approved/thoroughly checked patients that came to ED, 1/10 came back at least once and. In over half of the cases, repeated visits were related to medication, and specifically to issues where cardiovascular or anti-infectious medication were involved. To learn about the repeated visits to ED and how they are related to pharmacotherapy could help select patients who could benefit from an outpatient pharmacotherapeutic appointment after being discharged, aiming to reduce the amount of repeated ED visits related to medication.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-103 VANCOMYCIN-INDUCED RENAL TOXICITY THROUGH THERAPEUTIC DRUG MONITORING IN DAILY PRACTICE

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Background and Importance Vancomycin is used in the treatment of resistant gram-positive microorganism infections. Due to a narrow therapeutic range, its use is limited by its nephrotoxicity, which ranges from 5–43% according to the literature. Therefore, it's important to identify patients who may benefit from pharmacokinetic monitoring. The duration of treatment and a high minimum concentration of vancomycin are factors associated with nephrotoxicity.

Aim and Objectives To determine the incidence of nephrotoxicity associated with the use of vancomycin in monitored patients and identify factors related to its occurrence.

Material and Methods Retrospective, observational study in patients who underwent pharmacokinetic monitoring between 2022 and January 2023, in a third-level hospital. Demographic data and information related to antibiotic treatment were collected, including duration and indication, initial dose and frequency of administration, minimum steady-state concentration of vancomycin, and renal function data: baseline creatinine, creatinine at the start of antibiotic treatment, and at two days to assess the development of Acute Kidney Injury (AKI), defined by the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines as an increase in creatinine by 0.3mg/dL compared to the initial value after two consecutive days of treatment.

These data were analysed with Jamovi software.

Results 93 patients, 71% men, mean age 62 (18–92).

8.6% of the patients met the criteria for AKI secondary to vancomycin.

Factors associated with nephrotoxicity age equal to or greater than 65 years (p=0,04), being female (p=<0,001) and having a BMI equal to or greater than 30kg/m2 (p=0,03).

There was no observed higher incidence of nephrotoxicity based on the use of high doses or the location of the infection.

Conclusion and Relevance In our study, we observed an advanced age, being female, a BMI over 30kg/m2 and a high minimum concentration of vancomycin as factors associated with nephrotoxicity. Given the incidence of AKI secondary to vancomycin treatment, it's important to recognise the factors associated with its occurrence in order to identify patients who may benefit from pharmacokinetic monitoring, thus optimising treatment and limiting nephrotoxicity.

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Conflict of Interest No conflict of interest.

5PSQ-104 REAL-WORLD EVIDENCE: IS IBRUTINIB AS SAFE AS EVIDENCE TELLS?

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Background and Importance Ibrutinib is a Bruton tyrosine-kinase inhibitor used in first and subsequent lines of treatment of chronic lymphocythic leukaemia (CLL). Ibrutinib has demonstrated its efficacy and safety in many studies published to date. There is also experience available about this topic in real- world practice. However, the safety's evidence is different between both scenarios. Because the use of ibrutinib may vary among different countries and hospitals in the same country, we question whether safety's information in our patients is according to real-world evidence.
Aim and Objectives To analyse the safety profile of ibrutinib in CLL all-lines of treatment, and the management of its toxicity.
Secondary endpoints to determine ibrutinib's type responses.
Material and Methods Observational, descriptive, single-centre, retrospective and longitudinal study. Inclusion criteria: patients CLL diagnosed who started single-agent ibrutinib treatment from January 2016 to December 2022, aged $\geq$18 years-old. Patients treated in clinical trials and compassionate use contexts, were excluded. Quantitative variables will be described with means or medians (ranges); qualitative variables with absolute and relative frequencies.
Results Sixty patients were included, 35% received ibrutinib in first-line setting. 642 adverse events (AEs) were described, average: 10,7 (2–32) AEs/patient. Most common AEs of any grade were haematological toxicity (18,1%) mainly anaemia and neutropenia, and infections (15.9%). As special interest EAs, it was found arterial hypertension (3.7%), atrial fibrillation (1.2%) and heart failure (0.8%). Most frequent grade $\geq$3 AEs were: infections (27%) especially respiratory infections, haematological toxicity (16%) and arterial hypertension (13%). Five patients died during ibrutinib treatment. Temporary interruptions occurred in 68% patients, mostly because AEs (69%) and surgical procedures/diagnostics tests. 27% of patients needed dose reductions for toxicity management. Any patient required a second reduction for its management. Main reasons for treatment end were AEs (32%), disease progression (19%) and death (19%). Treatment response was evaluated in 51 patients: complete response (56%), partial response (20%) and stable disease progression (7%).
Conclusion and Relevance Despite the elevated number of AEs detected, none of special of interest. not previously described have been found. Safety profile shown by ibrutinib in our treated population is comparable to that described in previous published studies. Surprisingly, complete response frequency detected is higher than reported in other studies.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-105 PATTERNS OF USE AND APPROPRIATENESS OF ANTICOAGULATION IN ATRIAL FIBRILLATION: AN OBSERVATIONAL STUDY AMONG GERIATRIC INPATIENTS

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Background and Importance Atrial fibrillation (AF) is a common arrhythmia, affecting nearly half of all geriatric patients. AF poses a significant ischemic stroke risk, making effective anticoagulation essential. Direct oral anticoagulants (DOACs) have emerged as effective stroke-prevention agents, yet underutilisation remains a concern, especially in geriatric patients. To improve pharmacotherapy, including anticoagulation, a clinical pharmacy program was implemented on the geriatric units.
Aim and Objectives On that background, we sought to characterise anticoagulant utilisation patterns and inappropriateness among geriatric AF inpatients.
Material and Methods An observational study was performed at the acute geriatric units of an academic hospital. The first 90 AF patients for 2020, 2021 and 2022, who received at least one oral anticoagulant, were included. Anticoagulant use at discharge and therapy appropriateness were assessed. Determinants for underdosing were evaluated using multivariable logistic regression. Temporal associations for appropriateness (yes or no) and anticoagulant class (Vitamin K antagonist (VKA) vs. DOAC) were assessed using Fisher's exact analysis.
Results Mean age was 86.5 ($\pm$5.3) years with median CHA_2DS_2-VASc score 5 [4–6]. At discharge, 256 (94.8%) patients used a DOAC, 9 (3.3%) used a VKA, 1 (0.4%) a DOAC-antiplatelet combination, and in 4 (1.5%) anticoagulant use was discontinued. Apixaban was most commonly prescribed (40.7%) and a majority of patients (64.4%) received a reduced DOAC dose. Thirty-nine (14.4%) patients received inappropriate therapy and for 23/39 (59.0%) no deviation rationale was documented. The year '2022' (odds ratio 0.104; 95% confidence interval, 0.012–0.878) was the only determinant for underdosing. There was no temporal association regarding appropriateness (P=0.533) or anticoagulant class (P=0.479).
Conclusion and Relevance A majority received anticoagulation at discharge, mostly reduced DOAC doses. Only a minority was managed inappropriately. The reassuring findings over the 3-year period might be explained by the success of the clinical pharmacy programme. In conclusion, on a background of said pharmacy services, most AF patients were treated according to current guidelines. However, deviation from clinical guidelines still occurred consistently, frequently without a documented rationale and largely explained by underdosing in the context of a high bleeding risk. Accordingly, more trial data on the most appropriate anticoagulation strategy are urgently needed in geriatric AF patients with (very) high bleeding risks.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-106 FALL-INCREASING RISK DRUGS (FRIDS) AND FALL-RELATED FRACTURES

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Background and Importance Falls are a major public health issue, often resulting from interacting risks, being fall-risk-increasing drugs (FRIDs) use one of the prominent risk factors. Falls carry a high risk of functional dependence, hospitalisation, institutionalisation and mortality. STOPP falls was built through a Delphi process of experts and resulted in a list of FRIDs.[1] Consensus was reached for anticholinergics, diuretics, alpha-blockers used as antihypertensives, opioids, antidepressants, antipsychotics, antiepileptics, benzodiazepines and benzodiazepine-related drugs, centrally-acting antihypertensives, alpha-blockers for prostate hyperplasia, antihistamines and vasodilators used in cardiac diseases and overactive bladder and urge incontinence.

Aim and Objectives Characterise FRIDs prescription profile in fall-caused admissions in an Orthopaedics service.

Material and Methods All patients aged 65 years or over, admitted to Orthopaedics service, with a diagnosis of fracture due to a fall between 1 January 2023 and 30 June 2023 were included. Sociodemographic data and medication history were obtained using electronic medical record.

Results The study included 154 patients, mostly women (78%). The average age was 83 years. The majority of the patients (49%) used to take 5–9 medications, 41% 0–4 medications and 10% more than 10 medications. Were found 222 FRIDs prescriptions, which corresponds to 1.44 FRIDs prescribed/patient. The most common FRIDs prescribed were antidepressants (25%), diuretics (21%) and benzodiazepines (21%).

Conclusion and Relevance Besides the number of FRIDs/patient is lower than in other studies (1.44*vs*2.6),[2,3] the most common prescribed drug classes are much the same. Regarding age and gender, results are similar to the Spanish study. A limitation is that only data about FRIDs' number was assessed, regardless of the defined daily dosage of each drug. This later hypothesis could have delivered better understanding of whether drug dosage affects fall risk. It is important to promote FRIDs desprescription. Therefore, the upfront use and dissemination of desprescribing tools as STOPFalls among healthcare professionals should be encouraged alongside with a multifactorial strategy to reduce falls.

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Conflict of Interest No conflict of interest.

5PSQ-107 COMPLIANCE OF FLUOROQUINOLONES PRESCRIPTIONS: A HOSPITAL ACQUIRED RESISTANCE?

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Background and Importance In Europe, the annual death toll from antibiotic-resistant bacteria has risen from 25,000 to 35,000[1]. In 2020, France reported a 16% resistance rate to fluoroquinolone (FQ) in hospital[2]. FQ are no longer recommended as first-line treatment and are restricted to some urinary, pulmonary, intra-abdominal, soft tissue infections, and bacteraemia cases.

Aim and Objectives This study aims to assess the compliance of FQ prescriptions with guidelines provided by the local healthcare product safety commission, Summaries of Product Characteristics, and the French Society of Infectious Pathology (SPLIF).

Material and Methods The study (1 December 2022 -to 1 May 2023) was conducted across the following specialties: hepatogastroenterology, vascular medicine, home hospitalisation, neurology, ophthalmology, dermatology, haematology, and intensive care departments.

Using the DxCare® prescription software, ciprofloxacin, ofloxacin, levofloxacin, and moxifloxacin were analysed, focusing on the conformity of: indication, dosage, duration, documentation, the interval between two FQ, and pharmaceutical validation.

Results 197 prescriptions were extracted. 100% were validated. 41% (81) were compliant. Compliance rates were 85% (168) for indications and 94% (185) for dosage. 59% of prescriptions (117) were first line, 33% (65) second line, 5% (9) third line, and 2% (3) fourth line. 70% (137) adhered to the recommended treatment duration and 83% (164) respected the minimum 6-month interval between two FQ. 47% (92) of prescriptions were documented, 34% (67) were probabilistic, and 19% (39) were prophylaxis, of which 13 (30%) were compliant.

85% of strains were sensitive to FQ, with 16% sensitive at higher doses, and 3% exhibiting resistance.

Among the 59% non-compliant prescriptions (116), indications were principally: 5% male urinary tract (10), 6% skin and soft tissue (12), 9% (17) for both pulmonary and female urinary tract.

Conclusion and Relevance Considering the high rate of non-compliant prescriptions (59%), there is a need to review internal guidelines of the principal non-compliant infections, to be more intuitive. We could produce an informational note to physicians and pharmacists to emphasise the need to adhere to strict indications and to document infections, since less than half were documented. This was a 6-month study in select hospital departments, it could have been extended to the university hospital centre in 2022.

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Conflict of Interest No conflict of interest.

5PSQ-108 EFFICACY AND SAFETY OF INFLIXIMAB IN NF-KB ESSENTIAL MODULATOR DELETED EXON 5 AUTO-INFLAMMATORY SYNDROME: A CASE REPORT

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Background and Importance The NF-KB essential modulator deleted exon 5 auto-inflammatory syndrome (NEMO-NDAS) is an X-linked auto-inflammatory disease belonging to the systemic auto-inflammatory diseases (SAIDs). NEMO-NDAS affects the skin (ectodermal dysplasia) and the immune system. A few cases have been reported in France.
Aim and Objectives The objective of this case report was to describe the use of infliximab and its safety in NEMO-NDAS.
Material and Methods We report a 9-month-old baby who initially presented a long-lasting fever and a panniculitis. No infectious nor autoimmune causes were found, and the interferon signature was low. A corticosteroid treatment was started. Further genetic analyses showed an anomaly of the NEMO gene compatible with a NEMO-NDAS. Several pathways are modified, including the interferon pathway, which was increased. No recommendations nor relevant literature for specific treatment was found.
Results Anti-TNF-alpha such as adalimumab or infliximab could be used to down regulate this interferon pathway. Infliximab was introduced at a dose of 5mg/kg every 15 days for a month and a half, then every month. After the first injection, no fever, infection nor cutaneous manifestation were reported by the parents. The patient seemed to suffer less. Following the second injection, the corticosteroid treatment was decreased and stopped over a 15-day period.

One month after the introduction of infliximab, the patient presented a total apyrexia and no clinical signs of infection. On clinical examination, a hypertrophy of the lymphatic system was found (bilateral painless mobile axillary adenopathies, anterior cervical and supra-clavicular adenopathies). In spite of this, the patient was considered to be in clinical and biological remission (C-reactive protein = 1 mg/L, sedimentation rate < 2 mm in the first hour, amyloid A serum < 6,4 mg/L, transcriptomic signature of negative interferon gamma). Infliximab is currently being continued.
Conclusion and Relevance Infliximab was used successfully in our case and led to remission in 1 month with good tolerance and no adverse effect. Infliximab seems to be a well-tolerated treatment option for NEMO-NDAS in infants.

Introduction of infliximab allowed a total remission in 1 month without any adverse effect on the patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-109 HAEMOASSIST: A DIGITAL BRIDGE BETWEEN HAEMOPHILIA PATIENTS AND PHARMACISTS

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Background and Importance Patients with severe haemophilia will need regular parenteral treatment throughout their lives to restore their haemostasis.

These patients reach a high degree of autonomy and their follow-up can be a challenge for healthcare professionals.

In 2020 our Pharmacy Service (PS) offered a mobile application (Haemoassist®) to 315 patients so that they could record their pharmacological administrations, specifying whether for prophylactic purposes or to treat active bleeding.
Aim and Objectives Compare app usage data obtained in 2022, with the data published in 2020, to know if we are achieving:

- Increase the number of patients using the app.
- Improve the quality of the data entered in the app.

Material and Methods

- Count the number of patients who used the app in 2022.
- We studied the degree of concordance between the adherence offered by the app (reported administered doses/prescribed doses) and that calculated from the PS (dispensed doses/prescribed doses).
- Check whether all patients who, according to the data collected in the hospital's medical record, had bled and were using the app, had reported these bleeds in the app.

We compared these 2022 data with those published in 2020.
Results 190 patients used the app on some occasion during 2022 compared to 169 patients in 2020.

In 2022, the median adherence achieved by the 190 patients, according to the app, was 8% and the Interquartile Range (IR):0–57% and according to the SF dispensations was 92% (IR: 77 -99%). The degree of concordance between the two calculation methods was 18%. In 2020, concordance was 9%.

Of the 190 patients using the app in 2022, according to the hospital's medical records, 153 of them had a bleeding episode, but only 74 reported their bleeds in the app. The 48% of patients reported their bleeds in the app in 2022 versus 54% in 2020.
Conclusion and Relevance The number of patients using the app has been increasing. The quality of patient-reported data is slowly improving.

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Conflict of Interest No conflict of interest.

5PSQ-110 DESENSITISATION TO MONOCLONAL ANTIBODIES IN ONCOHAEMATOLOGICAL PATIENTS

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Background and Importance The increased use of monoclonal antibodies (mAb) for cancer treatment has been associated with a higher incidence of hypersensitivity reactions (HR). Drug desensitisation is a procedure that, by inducing temporary tolerance, allows patients who have developed a drug HR to safely receive it. This technique is performed according to previously published studies and plays a significant role for patients with HR, enabling treatment continuation.
Aim and Objectives To conduct a descriptive analysis of the use of mAb as a desensitisation protocol and to evaluate their effectiveness in a series of cases.
Material and Methods All oncological-haematological patients, who underwent desensitisation using a 3-concentration protocol due to HR to mAb in a University Hospital between 2019 and 2022, were included. Clinical information was retrospectively collected from medical records (SAP®, Genomi®), including oncohaematologic cancer type, mAb desensitised, time and severity of the reaction, allergology study results (skin test and/or Basophil Activation Test (BAT)), suspected underlying mechanism (Inmunoglobulin E (IgE) mediated or non-IgE mediated), breakthrough reactions during any of the desensitisation and final outcome.
Results Thirty-six patients received mAb desensitisation regimens, with a total of 357 desensitisations of eight different drugs [rituximab (123), cetuximab (87), daratumumab (68), trastuzumab (45), brentuximab (13), Obinutuzumab (9), isatuximab (9), trastuzumab entamsine (3)]. Each patient received an average of 10 administrations (1–52) in desensitisation regimen. Twenty-eight patients had haematological pathologies (77%), most of them treated with rituximab. Seventeen out of 36 (47%) patients desensitised experienced a reaction at first contact with the drug. Half of all patients (18) suffered moderate to severe HR; and only five patients had a confirmed IgE-mediated HR, confirmed by skin tests or BAT. 86% of the patients did not experience any reaction (breakthrough reactions) during the desensitisation. The remaining experienced some mild reaction during at least one of the desensitisations, but after adjusting the infusion regimen they tolerated treatment adequately. All (100%) of the desensitisations were successful; patients were able to receive the medication they were being treated without experiencing any adverse reactions that require discontinuation.
Conclusion and Relevance The high success of desensitisations to mAb in our hospital highlights the importance of this technique preventing switching to other treatments that might be more expensive and less effective.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-111 SODIUM-GLUCOSE COTRANSPORTER 2 INHIBITORS AFTER HEART TRANSPLANTATION

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Background and Importance Sodium-glucose cotransporter 2 inhibitors (SGTL2i) are widely used to manage diabetes mellitus (DM) and heart failure (HF). Recently, safety studies have been published on their use in renal recipients, however, no evidence exists in heart transplant recipients (HTR).
Aim and Objectives To evaluate safety, tolerability and effectiveness of SGTL2i in HTR.
Material and Methods Retrospective descriptive cohort study conducted in a tertiary hospital. All adults undergoing heart transplantation (HT) from January 2016 to July 2023 treated with SGLT2i were included. Demographic, clinical and pharmacological data were recorded. Outcome measures: Body Mass Index (BMI) and HbA1c evolution, number of hospitalisations in patients with HF and adverse events (AE).
Results Among 154 HTR, 28 patients were on SGLT2i, 21.4% women, 62.1 [50.9 – 63.4] years old), 9 (32.1%) with dapagliflozin and 19 (67.9%) with empagliflozin.

SGLT2i indication were: 75% DM, 21% HF and 4% DM +HF. A total of 22 (78.6%) patients were DM, 81,8% of whom were on a combined antihyperglycemic therapy. Seven (25%) patients developed DM after HT. Median time from HT to SGTL2i initiation was 20 [4–40] months.

Three patients (10.7%) reported AE while on SGLT2i: two suffered urinary tract infections and one cephalic instability. Moreover, two patients discontinued SGTL2i, one after 4 months due to intolerance and the other after 11 months because of HbA1c normalisation. At 6 months after initiation of ISGLT2, a reduction in HbA1c of 0.2 [-1,9 – 0.3] points was observed. It was also noted a reduction in BMI of 1.4 [-2,4 – 0,8] points. In patients with HF, no HF hospitalisations occurred after initiation.
Conclusion and Relevance Our results show that SGTL2i are well-tolerated in HTR. Although these data are consistent with findings in renal recipients[1], further investigation is needed.

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Conflict of Interest No conflict of interest.

5PSQ-112 A SURVEY OF HOME STORAGE TEMPERATURE OF IN-USE INSULINS AND ANALYSIS OF THEIR STABILITIES UNDER THE SIMULATED HIGHEST HOME TEMPERATURE

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Background and Importance Insulins remain essential for people living with diabetes worldwide. As a biological product, it is susceptible to heat, light and sheer conditions. Little is known about actual household storage temperature of insulins, especially in the setting where room temperature is far beyond 25°C, under which insulin stability might be compromised.
Aim and Objectives To determine home storage temperature of in-use human insulins among ambulatory type 2 diabetes (T2D) people and to subsequently test insulin stability under the simulated maximum storage temperature identified.

Material and Methods People with T2D who collected prescribed insulins from a hospital dispensary and received a self-assembly pen with either regular insulin (RI), isophane (NPH) or premixed RI/NPH insulins, were given a temperature logger to track their home storage temperature of insulins for 5–7 days (N=47). The maximum out of the recommended range temperature identified was simulated in laboratory where the insulins were kept for 4 weeks. The percentages label amount of the insulins imitated daily use were then analysed at a weekly interval, following the 42nd ed. United State Pharmacopoeia. The acceptable range was 95 -105% with reference to standard. Descriptive statistics were used to present the recorded temperature.
Results Majority (81%) of the patients keeping insulin in a refrigerator had temperature outside the 2 to 8°C range. Room temperature storage was totally above 30°C (maximum 43.6 °C). At the simulated isothermal 42±2°C, RI, NPH and premixed RI/NPH insulins had percentage label amounts in the acceptable range at 2, 3 and 4 weeks, respectively.
Conclusion and Relevance Actual home storage temperatures of the insulins were out of the appropriate ranges. These were similar to Braune at al.[1] Under the simulated 42±2°C, in-use human insulins retained acceptable content, with regular insulin being stable up to week 2; NPH and the premixed insulin up to week 3 and week 4, respectively. The results were in line with the Kenya study[2] but they set the maximum temperature at 37°C. Pharmacists should be aware of true household storage temperature of insulin products and take into account the number of days it takes for one insulin cartridge to be finished against with the probable stability duration.

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5PSQ-113 ROOT CAUSE ANALYSIS: STATEGY FOR A SUSTAINABLE ANTIBLASTIC THERAPY MANAGEMENT SYSTEM

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Background and Importance The cost of unused antiblastic therapies (UAT) has a considerable impact on a General Hospital (GH) budget. In order to optimise resources allocation/limit waste, it is possible to analyse the process that goes from the physician request for patient care to validation carried out by the Hospital Pharmacist, to preparation/distribution/therapy administration for detecting weak points and turn towards a more sustainable company modus operandi.
Aim and Objectives Objective of the study was to analyse antiblastic drug management process in a GH, by means of Root Cause Analysis, detecting weak links economic consequences and promoting corporate awareness work on the issue.
Material and Methods The analysis covered the period December 2022 to May 2023. According to data collected, an Excel file was drawn up (showing protocol name/dosage/department/non-administration reason); it was also specified whether therapy was reused for another patient or disposed of and, if so, how much this choice has impacted on GH's expenditure, making an estimate of the monetary value costs incurred for drug/preparation. An audit composed of physicians/pharmacists/nurses met to investigate non-administration causes for finding a sustainable company policy.
Results Of 12,150 therapies set up, 97 were UAT; of these, 26/97 were re-used and 71/97 disposed of, for an economic loss of approximately 33,961.82 Euros, considering an estimate of 150 Euros for set-up costs (personnel-resources employed). Root Cause Analysis showed that the main reasons for non-administration were: prescribing errors 7.22% (7/97), inability to reach GH 20.6% (20/97), Adverse Drug Reactions (ADRs) 44.33% (43/97), illness not ADRs related 14.43% (14/97), other factors [anti-Covid test positivity, therapy refusal, falls, etc] 13.40% (13/97).
Conclusion and Relevance For each non-administration reason corrective actions were identified. It would be desirable for Physician to confirm therapy to Compounding Antiblastic Unit (CAU) only when knows really that patient can receive it, following the visit/assessment of clinical analyses, to direct therapies setting up only towards patients who are truly eligible for conditions/availability/therapeutic reconciliation. Ideal would be the timely communication to CAU of any UAT so that it can be assessed, according to drug's technical data sheet, whether drug can be reused on the same day or within the stability time. Finally, it would be useful having software alert/constraint system for cycles exceeding numbers permitted, established at the time of protocol coding.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-114 HEAD AND NECK ERYTHEMA ASSOCIATED WITH THE USE OF DUPILUMAB IN PATIENTS WITH ATOPIC DERMATITIS

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Background and Importance Adverse reaction (erythema on head and neck) not described in the technical datasheet.
Aim and Objectives Describing the resolution of erythema associated with dupilumab by extending the dosing interval.
Material and Methods Descriptive, retrospective study of a series of cases presenting erythema as an adverse reaction associated with the use of dupilumab. Patients with atopic dermatitis on treatment with dupilumab in January 2023 were selected. By telephone interview, electronic medical records and outpatient dispensing module, the following information was collected: sex, age, date of treatment initiation, date of erythema onset, other adverse reactions, dosage, extension of dupilumab dosing interval, date of change of dosage, resolution or not of erythema and other adverse effects after dosing adjustment, influence of alcohol consumption on erythema.
Results At the time of the study, 44 patients were receiving dupilumab, three patients developed erythema (6.81%), mainly on their head and neck. All three were women, receiving 300 mg/2 weeks at the time of erythema onset. Two of the patients reported the resolution of erythema one month after

spacing dupilumab to 300 mg/3 weeks. One of them debuted with facial erythema a year after starting with dupilumab, the dose spacing was made the same month as the appearance of erythema. The other one presented erythema one month after the start of dupilumab, starting the dosing schedule 5 months after the onset of erythema. The third patient reported erythema one month after the start of dupilumab. Three months after the onset of erythema, she discontinued treatment due to primary inefficacy. One month after discontinuation of dupilumab, the erythema completely subsided. All three patients also experienced ocular adverse effects (dryness, irritation and/or conjunctivitis episodes), which resolved completely with dosage adjustment or discontinuation of dupilumab. A possible trigger for dupilumab-associated erythema is alcohol consumption. Two of the three patients confirmed worsening of erythema after alcohol consumption.

Conclusion and Relevance Head and neck erythema appears to be associated with the use of dupilumab, as an adverse effect not described in the data sheet. Extension of the experimental dosing interval to 300 mg/3 weeks or discontinuation of dupilumab partially or completely resolves the erythema in the patients in this case series.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-115 EVALUATION OF HYPOTHYROIDISM ASSOCIATED WITH APALUTAMIDE AND ENZALUTAMIDE TREATMENT IN METASTATIC PROSTATE CANCER USING THE EUROPEAN ADVERSE EFFECT DATABASE (EUDRAVIGILANCE)

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Background and Importance Hypothyroidism is a limiting and underestimated adverse effect of metastatic prostate cancer treatments, the impact of which in elderly patients is more significant. Apalutamide and enzalutamide are drugs with similar chemical structure, but differ in terms of adverse effect profile. Hypothyroidism is described as a common adverse reaction for apalutamide, but has not been evaluated in pivotal trials of enzalutamide.

Aim and Objectives To compare the incidence of hypothyroidism with apalutamide and enzalutamide by analysing spontaneous real-life reports obtained from EudraVigilance database.

Material and Methods Spontaneous notifications concerning the evaluated drugs were obtained from EudraVigilance, the European Medicines Agency's database for suspected adverse drug reactions. For each drug-event combination, the following were calculated as measures of disproportionality: the proportional reporting ratio (PRR), the 95% confidence interval (CI95%), the Chi-square (χ^2) and the number of reported cases. Among all reported adverse reactions, only those classified as hypothyroidism (event) were considered. The analysis periods were 2019–2023 for apalutamide and 2013–2023 for enzalutamide (from the date of authorisation). For the generation of an alert signal, the following 3 criteria must be met: PRR$\geq$2, $\chi^2\geq$4 and the number of new cases reported $\geq$3 (1).

Results In the period studied, for both drugs, a total of 26.077 adverse reaction reports were collected. Of these, 4.274 (16%) were for apalutamide and 21.803 (84%) for enzalutamide, of which 74 (1.7%) and 14 (0.06%) corresponded to hypothyroidism, respectively. The values of the disproportionality measures of apalutamide with respect to enzalutamide calculated were: PRR= 26.96 (15.24–47.69), χ^2=295.32 and number of hypothyroidism cases for apalutamide=74. According to these values, when all three criteria are met, a hypothyroidism alert for apalutamide would be generated.

Abstract 5PSQ-115 Figure 1

Conclusion and Relevance Our analysis performed on the EudraVigilance real-life database confirms the high incidence of hypothyroidism in patients treated with apalutamide, according to the SPARTAN and TITAN pivotal trials, compared to enzalutamide. On the other hand, a much lower incidence of hypothyroidism is evident for enzalutamide. The importance of monitoring for signs of hypothyroidism in patients treated with apalutamide is highlighted.

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Conflict of Interest No conflict of interest.

5PSQ-116 REAL-WORLD PERSISTENCE WITH GUSELKUMAB AMONG ADULTS WITH PSORIATIC ARTHRITIS

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Background and Importance Guselkumab is a monoclonal antibody that selectively binds to interleukin 23 protein with a label indication in plaque psoriasis and psoriatic arthritis (PsA). Little information about real-world persistence with guselkumab therapy for PsA is known.

Aim and Objectives The aim was to evaluate persistence with guselkumab therapy in PsA.

Material and Methods Retrospective observational study was conducted in a tertiary level hospital. Patients who started treatment with guselkumab between 01/05/2020–01/09/2023 were included. Those with less than 9 months' treatment duration were excluded. The variables collected were sex, age, underlying pathology and comorbidities, previous treatments, and start-end date of treatment. Data analysis was performed using SPSS® version 24 statistical software. A descriptive analysis of the data was performed, comparative statistical tests, as well as a Kaplan-Meier survival analysis.

Results Among the 69 patients in the database who initiated guselkumab during the study period, 50 met the study inclusion criteria. The mean (SD) age was 53.3 (12.7) years and 58% were female. 44% (22/50) had been treated with four or

more PsA drugs before guselkumab and 74% used an anti-TNF drug.

The median drug survival (SD) was 20.6 (2.7) months. 52% of patients experienced the event (discontinuation of treatment) within 30 months of treatment. Persistence was 69.3% (ES:0.07) at 1 year of treatment and it decreased to 43.7% (ES:0.08) at 2 years of treatment.

There were no statistical differences between patients who had been treated with more or less than four previous treatments nor patients with and without comorbidities. However, we found some differences between patients with previous anti-TNF treatments and the ones who didn't use them. 30.8% of patients without Anti-TNF discontinued treatment vs 59.5% who used Anti-TNF before (p=0,075), mean drug survival in the first group (no anti-TNF) (SD) was 26.0(2.0) vs 16.4 (1.8) in the second group (p=0.02). The reason for these results may be because guselkumab is used in initial stages of the disease due to contraindications to anti-TNF.

Conclusion and Relevance As in clinical trials and another real-world study, high persistence rates were observed with guselkumab during the first year. Further real-world research should be conducted to correlate the differences found between patients with previous anti-TNF treatment, as no such differences were found in clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-117 TRACEABILITY OF IMPLANTABLE MEDICAL DEVICES/ PATIENT INFORMATION: WHERE DO WE STAND?

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Background and Importance Health traceability of implantable medical devices (IMD) is a major public health issue. In the event of materiovigilance, this information can be used to trace patients who have received an IMD. Legal information relating to IMD is included in the patient file and must be transmitted to the patient on an implant card (Article R5212–42, French Public Health Code).

Aim and Objectives To assess the compliance of this traceability in our facility to comply with the new version of the Contract for the Improvement of Quality and Efficiency of Care (CAQES).

Material and Methods Ten IMD representative of the facility's activity, with different management and financing modes were selected and 50 interventions were analysed. Twenty-seven items were evaluated divided into four areas: traceability by pharmacy (9), by user service (6), traceability of patient information in the electronic patient record (EPR – 9) and transmission to the patients (3). This retrospective analysis was compared to a similar audit conducted in 2020.

Results Compliance rates are 86% for pharmacy traceability, 84% for service traceability, 52% for patient information traceability in the EPR and 96% for information transmission to the patient. There is a loss of information observed between traceability in business software and information recorded as transmitted to the patient, especially for IMD denomination, manufacturer name, lot and serial numbers. Practices vary depending on surgical specialties. The main non-compliances concern the provision of the implant card, the Unique Device Identifier (UDI), and the Individual Healthcare Identifiers (IHI) number, which are not tracked. Since 2020, practices have improved, especially in terms of patient information traceability, which has increased by 43%.

Conclusion and Relevance Despite the positive results for pharmacy and service traceability, the target set by CAQES for 2022–2024 (>75%) is not met for all criteria. Improvement areas include UDI traceability upon receipt and use, integration of the IHI number into the business software, and harmonising processes across different operating rooms. Improvement avenues for patient information traceability involve standardising liaison letters between surgical specialties, interoperability of business software, and traceability of the delivery of the operative report and implant card to the patient, all to maintain a high level of care quality.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-118 NON-ACTIVE PRESCRIPTIONS IN AMBULATORY PATIENTS: ANALYSIS AND EFFECT IN CONSULTATION WAITING TIME

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Background and Importance The optimisation of time within the Hospital Outpatient Pharmacy has become an urgent challenge in light of the remarkable surge in activity over recent years. A substantial number of patients arrive without an active prescription, rendering it impossible to dispense their medications promptly, consequently resulting in consultation delays and patient inconvenience.

Aim and Objectives The primary aim of this study is to delineate the chief causes of non-active prescriptions at the point of dispensation and to assess their impact on patient waiting times when attending the Hospital Outpatient Pharmacy.

Material and Methods Between January 2022 and September 2023, we conducted a prospective registration of patients lacking active prescriptions and subsequently selected a random sample for analysis. This investigation encompassed an assessment of the clinical service to which patients were affiliated, the reasons underpinning prescription unavailability, and the temporal discrepancy between the scheduled appointment time and the actual consultation conclusion time. It is essential to emphasise that we considered the appointment time as the moment of consultation entry, assuming zero delays. Data were meticulously gathered from the electronic prescribing software.

Results Our study encompassed a cohort of 81 patients. Among the patients who presented with non-active prescriptions, the implicated Clinical Services comprised Nephrology (21.0%), Rheumatology (21.0%), Neurology (16.0%), Pulmonology (11.1%), Internal Medicine (9.9%), Urology (7.4%), Dermatology (3.7%), Gastroenterology (3.7%), Endocrinology and Nutrition (2.5%), Allergy (1.2%), Haematology (1.2%), and Paediatrics (1.2%).

The rationales behind non-active prescriptions were multifarious: failure to renew prescriptions during the previous

consultation (63.0%), prescriptions with inadequate validity until the subsequent consultation (21.0%), prescription errors (8.6%), patient non-attendance at the preceding consultation (4.9%), absence of a patient consultation within the last year (1.2%), and rescheduling of the previous consultation (1.2%).

Within our sampled cohort, the median consultation waiting time amounted to 36 minutes, with an extreme delay reaching up to 3 hours.

Conclusion and Relevance As evidenced by this investigation, the absence of an active prescription at the dispensation juncture exerts an adverse influence on the day-to-day operations of the Hospital Outpatient Pharmacy. It is our assertion that enhanced training and more robust communication with the implicated clinical services could prove invaluable in proactively addressing this predicament.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-119 REVIEW OF REAL-WORLD MANAGEMENT OF NATALIZUMAB TREATMENT IN MULTIPLE SCLEROSIS: A DOUBLE-EDGED WEAPON

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Background and Importance We know that natalizumab is an effective treatment in patients with relapsing-remitting multiple sclerosis with high activity. More doubts arise regarding its safety which will lead to having to closely monitor the patient.

Aim and Objectives To evaluate the safety of treatment with natalizumab for relapsing-remitting multiple sclerosis (RRMS), specifically John Cunningham virus (JCV) infection that can cause Progressive Multifocal Leukoencephalopathy (PML). Also evaluate effectiveness by counting outbreaks during treatment and time in treatment.

Material and Methods Retrospective observational study since the approval of the drug. All patients with RRMS under treatment with natalizumab were included and the variables sex, age, previous and subsequent treatments, positive JCV serology at any time, duration of treatment, relapses and number of them, and reason for discontinuing treatment were collected. Data was extracted from FarmaTools® software database and the electronic medical.

Results A total of 75 patients were analysed, 47 (63%) of them women. Mean age at the time of initiation of treatment of 41 years (28–69), median number of previous lines of 1 (0–5), being used as first line in 15 patients (20%), second line in 42 patients (56%). The patients analysed were on treatment for an average of 2.6 years, the reasons for suspension being: Positive JCV serology 39 (52%), adverse effects 11 (15%), outbreaks six (8%), progressive worsening five (7%), unknown cause three (4%) and 2 (3%) discontinued due to pregnancy. Nine (12%) are still receiving treatment. Sixteen patients (21%) had an outbreak during the time on treatment.

Conclusion and Relevance A large proportion of the patients analysed manage to reach the 2-year treatment period, after which the risk of JCV infection increases. At that point, the majority of patients discontinue treatment. The drug is well tolerated, with little suspension of treatment due to adverse effects, and is usually chronic fatigue (also associated with the disease). Effective drug, with only 16 patients having an outbreak during treatment. With these data, we can conclude that in our patients it has been an effective treatment, used once the patient has high activity to stop it. Regarding safety, JCV would be the main drawback, requiring close monitoring for possible infection.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

5PSQ-120 PEMBROLIZUMAB IMMUNE-MEDIATED TOXICITY

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Background and Importance Checkpoint inhibitors (ICI) are increasingly used in various cancers. While they offer clinical benefits, they also introduce drug management challenges due to their adverse effects (AE). A notable concern is the potential for severe immune-mediated toxicities, which can pose significant risks to patients. The presented case is unique as it underscores the severe repercussions of immune-mediated toxicity from pembrolizumab.

Aim and Objectives This reports a case of a 70s male with clear cell renal cell carcinoma (ccRCC) who developed severe immune-mediated toxicity following treatment with pembrolizumab. The patient had a history of some comorbidities. The initial presentation was incidental detection of ccRCC post-trauma. His subsequent treatment, adverse reactions, and outcomes form the crux of this case.

Material and Methods The patient was in his 70s, caucasian male, 1.64 m, 58 kg, non-smoker, and non-alcoholic. His medical history included type 2 diabetes, hypertension, nephrolithiasis, benign prostatic hyperplasia, pacemaker implant due to bradycardia. Daily medication: metformin, amlodipine, perindopril/indapamide, acetylsalicylic acid, dutasteride, afluzosin, lactulose, sodium picosulfate. First line treatment with intravenous pembrolizumab 400 mg (6/6 weeks) and axitinib 5 mg twice daily.

Results Days after the first cycle of treatment, the patient presented to the emergency service (ES) with swallowing difficulties, imbalance, and muscle pain. A probable diagnosis of G3 polymyositis with suspected pembrolizumab-induced myopathy was made. Despite suspending the oncology treatment and initiating high-dose corticosteroid therapy, the patient's condition deteriorated. He developed myocarditis leading to severe global dysfunction of left ventricular systolic function. Subsequent treatments including human immunoglobulin and abatacept were unsuccessful, and the patient unfortunately succumbed to cardiorespiratory arrest two weeks later.

Conclusion and Relevance This case report brings attention to the severe immune-mediated toxicity, emphasising the challenges in its management. While acute AE can often be managed with symptom-based approaches and high-dose corticosteroids,[1] this case demonstrates that these measures may sometimes be insufficient. Creating structured protocols and conducting in-depth research is imperative. Medical professionals should remain vigilant to such adverse effects. This case underlines the importance of risk assessment and continuous monitoring of patients on immunotherapies.

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This case has never been reported/published before.

Conflict of Interest No conflict of interest.

5PSQ-121 A REVIEW OF THE EXPOSURE TO POTENTIALLY HARMFUL EXCIPIENTS THROUGH ORAL LIQUID FORMS IN PAEDIATRIC INPATIENTS IN FRANCE

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Background and Importance Despite growing interests for the use of excipients with described toxicities (excipients of interest., EOI) in children and neonates, even today the lack of paediatric data makes it difficult to establish precise recommendations about quantitative levels of EOI in commercialised paediatric formulations.

Aim and Objectives The primary objective of this work is to identify the EOI present in oral liquid forms used in paediatric departments. The secondary endpoint is to quantify the EOI exposure for often-prescribed molecules (originator formulations and generic brands) used in recommended posology ranges, for different age categories.

Material and Methods A review of medications used in French hospitals has allowed establishing a list of oral liquid forms used for paediatrics and neonatology inpatients. The formulation of each medication has been examined using the summaries of product characteristics (SmPC). Ten of the most prescribed molecules have been selected concerning princeps and generics formulations for a total of 31 formulations. EOI exposure has been calculated and STEP Database and European Médicine Agency (EMA) recommendations were used to evaluate the exposure levels.

Results The analysis involved 219 formulations including 123 active molecules and 140 excipients. Sixteen excipients were present in above 10% of the formulations and nine of them are recognised as EOI (ethanol, propylene glycol, glycerol, sodium benzoate, methyl and propyl paraben, aspartame, sorbitol, saccharose). A total of 95% of all studied formulations involve at least one EOI. The amounts of EOI found in the 10 studied molecules outcome the recommended levels for 45% of the 31 formulations. A rate of 73% of the drugs with neonatalogy marketing authorisation include at least one excipient not recommended in this age category.

Conclusion and Relevance Pediatric and neonates inpatients are receiving a wide range of harmful excipients, among others through the administration of oral liquid forms. Although specific studies tend to enlarge the knowledge about specific use and toxicity of the excipients in paediatrics, too little remains, especially in preterm. When EOI cannot be avoided, quantitative information about their amount in drug formulations should be easily known to help physicians and pharmacist to select the most appropriate drugs and anticipate possible adverse effects or adapt drugs posology.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-122 SEQUENTIAL CHANGE OF DOSING INTERVAL OF PALIPERIDONE PALMITATE BASED ON PLASMA CONCENTRATION MONITORING

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Background and Importance Paliperidone is an antipsychotic used for the treatment of schizophrenia. To increase adherence to treatment and thus reduce the risk of relapse, it was formulated as an extended-release injectable. There are 3 types of formulations: monthly, quarterly and semi-annually. Monitoring of paliperidone plasma concentrations can help to optimise treatment, as patients who do not require dose adjustments may benefit from the longer therapeutic interval formulations (quarterly and semi-annual)

Aim and Objectives To analyse the relationship between the change of presentation of paliperidone palmitate and its pharmacokinetic monitoring

Material and Methods Retrospective observational study in which all patients whose plasma concentrations of paliperidone were determined from January to July 2023 were included. Patients on treatment with oral paliperidone were excluded.

The variables collected were sex, age, current plasma concentrations of paliperidone palmitate, type of paliperidone palmitate formulation used in current treatment, initiation of paliperidone palmitate, presence of previous controls of another type of paliperidone palmitate formulation, previous plasma concentrations of paliperidone palmitate.

Results Sixty-nine patients were included, 69.6% male with a median age of 50 years (20–72).

Of the patients, 42.0% had plasma paliperidone palmitate concentrations within the therapeutic range. Of the patients, 36.3% were on paliperidone palmitate monthly, 42.0% were on paliperidone palmitate quarterly, and 21.7% were on paliperidone palmitate semi-annually.

A change of paliperidone palmitate presentation had occurred in 87.0% of the patients. Of these, only 43.3% had pharmacokinetic monitoring prior to the change of presentation. Of these patients, 46.2% had plasma concentrations in range in the control with the previous presentation of paliperidone palmitate.

Conclusion and Relevance Although the pharmacokinetic determination of plasma concentrations of paliperidone palmitate allows individualising the treatment to each patient, the decision to switch from one formulation of injectable paliperidone palmitate to another with a different dosing interval was not based on the plasma concentrations of the drug in our population.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-123 SIMULATION OF A DISCHARGE CONTROL: AN EFFECTIVE TOOL FOR QUALIFYING STAFF

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Background and Importance The preparation of chemotherapy (CT) at our centre represents a major activity (42,000 preparations per year). One of the riskiest stages is discharge control (DC). To ensure the safety of this stage, in line with national guidelines on staff training, we decided to set up a DC simulation.

Aim and Objectives This work aimed to create a simulation to ensure that theoretical training in DC was understood and implemented; it was designed to enable initial qualification and periodic reassessment of pharmaceutical staff.

Material and Methods A theoretical evaluation (TE) and a practical evaluation (PE) were created. The DC most frequent and riskiest errors were defined during a Failure Modes, Effects and Criticality Analysis (FMECA). The criticality defined was used to establish whether the error was eliminatory.

For the TE a 28-item questionnaire was created (13 eliminatory questions).

For the PE, a simulation of DC including 20 dummy CT preparations (4 compliant and 16 non-compliant) reflecting our centre's activity was designed. Ten responses were eliminatory.

The evaluations were carried out under real-life conditions. The validation threshold was 100% of correct answers to eliminatory questions.

Results Since the tool was created, 12 pharmaceutical staff have been assessed.

The average score for the TE was 17/20 (minimum 15.2/20 and maximum 19.8/20). Of the five most frequent errors, two corresponded to rare cases (specific paediatric protocols), two to production specificities (CT for weekends and the operating room), and one to a lack of knowledge of the circuit. All TEs were validated.

The average score for the PE was 17.6/20 (minimum 14.5/20 and maximum 19.5/20). One error, corresponding to a specificity linked to the device used, recurred regularly. Two person who made eliminatory errors (solvent error, expired and leaky pouch) had to be reformed and reassessed.

Conclusion and Relevance Implementing this simulation allowed for an exhaustive and entertaining evaluation of the individuals authorised for DC. Reviewing the errors made during the assessment enabled us to revise the initial training and emphasise the critical points. As a result, we decided to carry out a unitary release, integrated into our management software (CHIMIO®), a pop-up listing all the critical points to be monitored.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-124 THE TREATMENT OF PRESSURE ULCERS WITH BACTERIA BINDING MEDICATION AS A VALID THERAPEUTIC OPPORTUNITY

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Background and Importance The pressure ulcer (PU), tissue lesion consequence of high or prolonged constant pressure over time, represents the third most costly disease for the health care system, causing over 60,000 deaths each year[1].

The use, during the Sars-Cov-2 pandemic, of the bacteria binding medication (BBM) to reduce PU, was the starting point that allowed the spread of BBM in many hospital departments, as a possible therapeutic alternative to iodoform gauze (IG). BBM, consisting of fabric saturated with dialkylcarbamoylchloride (DACC), is able to capture bacteria and fungi thanks to a physical mechanism (hydrophobic interaction) instead of IG that control the wound microenvironment in the short term with an high risk of possible toxicity due to the systemic absorption of iodine.

Aim and Objectives Considering the increased incidence of PU related to care services, the Hospital Pharmacy, assisted by wound care specialists (WCS), has monitored in the period from 2020 to 2023 the prescriptive appropriateness and the consumption of BBM in different departments in order to demonstrate the greater safety and effectiveness than the IG.

Material and Methods Since September 2020 the Hospital Pharmacy has selected some pilot wards in which a WCS operate, and subsequently equipped them with BBM. A cost-effectiveness analysis was conducted by comparing IG and BBM.

After reviewing the excellent performance of the device in the first selected departments, the Pharmacy, the clinicians and WCS have collaborated to identify in which clinical situations it was possible to replace IG with BBM and when to prefer other therapeutic choices.

Results The performed analysis showed that, in the single service, the cost of BBM is 3% higher than IG, but in prolonged treatment the use of BBM is advantageous. BBM, compared to IG, can be left in place for up to 7 days reducing care costs (MD and WCS service) and the frequency of wound manipulation, limiting clinical complications and eliminating the risk of systemic iodine absorption caused by the IG.

Conclusion and Relevance

PUs require long-term treatment BBM represent a cost-effective alternative and the Pharmacy has decided to introduce definitively the BBM into the hospital formulary and to dismiss IG.

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Conflict of Interest No conflict of interest.

5PSQ-125 ANALYSIS OF INTRODUCING PROBIOTICS FOR THE PREVENTION OF NECROTISING ENTEROCOLITIS IN PREMATURE NEONATES IN A NEONATAL UNIT

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Background and Importance Necrotising Enterocolitis (NEC) is a life-threatening intestinal inflammatory disease that primarily affects preterm infants. Risk factors include prematurity, low birth weight, and altered intestinal microbiota. Gastrointestinal colonisation by probiotic strains can avoid the overgrowth of potential pathogens.

Aim and Objectives Evaluate the use of a probiotic combination aiming to reduce the incidence of NEC in a level IV neonatal unit.

Material and Methods In April 2022, oral administration of a combination of probiotic bacteria (*Bifidobacterium infantis, Bifidobacterium lactis* and *Streptococcus termophilus,* Proprems®*)* was started aiming at decreasing NEC incidence in our unit. This probiotic combination is recommended by the most recent European Guidelines.

Neonates of gestational age (GA) ≤ 32 weeks, and GA ≤ 34,8 weeks with birth weight ≤ 1500 g were selected to receive probiotic (1 oral sachet/day, started in the first 72h of life), because of their high risk. They received it until post-menstrual age (PMA) of 34 weeks and 35,8 weeks respectively.

We conducted a retrospective observational review of medical records from April 2022–March 2023, collecting: GA, weight, days of life at start, treatment duration and breaks, PMA at removal and NEC episodes.

Results 50 out of 55 patients met criteria to receive probiotic (27 boys/23 girls). Median GA was 29,4 weeks (range: 23–34,7), median birth weight was 1kg (0,5–1,85) and 2 days of life at start, with 37 patients starting probiotic with less than 72h of life. Median of treatment duration was 24 days (2–71). As for removal, it was correct in 35 patients (11 patients later than indicated).

Treatment was safe and well-tolerated in all patients. No episodes of sepsis by the probiotic strains were recorded during this period.

NEC incidence on target population was 11,6%, with seven cases in 2022, decreased compared to 16% in 2020. Between April-December of 2022 there were four episodes of NEC, two of which have received probiotic.

Conclusion and Relevance The main deviations in the use of the probiotic according to established criteria were both late initiation and removal.

The selected formulation was safe and well-tolerated.

In the study period, a reduction of NEC incidence was observed associated to different measures and among them, the use of probiotic.

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Conflict of Interest No conflict of interest.

5PSQ-126 THE ANALYSIS OF INTERACTIONS AND POTENTIALLY INAPPROPRIATE MEDICATIONS IN HOSPITALISED SENIORS

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Background and Importance In our country should be placed greater emphasis to the health care of the elderly patients. It is necessary to monitor the drug-use, suggested to use the PIM wisely or prevent their use, monitor the possible interactions between drugs.

Aim and Objectives To follow the pharmacotherapy of the patients over the age 65 years hospitalised in the inpatient department of geriatric department for a half year (September-December 2018). Further, to analyse interactions between drugs, to monitor and quantify the PIMs, follow the number of hospitalisations and find correlations between these values.

Material and Methods Retrospective analysis of the medical records of 127 patients in age over 65 years hospitalised in the inpatient department of geriatric department, who were admitted at least on the day. Possible drug interactions were evaluated by program Lexicomp®. PIMs were evaluated according to the EU(7)-PIM list. Results were statistically analysed.

Results In the study group the average age was 83 [69–95;80] years. Each patient used 6 [0–15; 5] drugs/day. We identified 425 possible interactions, 3[0–13;0] interactions/patient. Only 26 patients did not have any drug interactions. The greatest value of used drugs in one patient was 16. Number of PIM/patient/day was 1[0–5;1]. The three most frequently used PIM were pantoprazole, alprazolam, digoxin. The difference in the number of PIM was statistically significant ($p<0.05$) in patients with/without interaction in therapy. There was confirmed a moderate relationship between the number of used drugs and the number of PIM ($\rho=0.611$, $R2=0.915$, $p<0.01$). In the study group patients were hospitalised 2[1–13;1] times in the period. There was found that the number of hospitalisations did not correlate with the number of used drugs ($\rho=0.054$, $R2=0.0178$, NS), or the number of PIMs ($\rho=-0.002$,$R2=0.1249$,NS), but had a weak relationship with the number of potential interactions ($\rho=0.19$,$R2=0.5086$;$p<0.05$).

Conclusion and Relevance In the observed group of hospitalised elderly patients one person took on average 6 drugs/day. There was found that if in the patient's treatment more potential interactions are present, there is a greater likelihood of hospitalisation ($p<0.05$). Further, if a patient takes more drugs, there is a greater possibility to take a PIM ($p<0.01$).

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Conflict of Interest No conflict of interest.

5PSQ-127 MEDICATION-RELATED FALLS IN A NURSING HOME: IDENTIFICATION AND HOSPITAL PHARMACY INTERVENTIONS

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Background and Importance Medication use is a modifiable risk factor and has a high prevalence in older people, where polypharmacy is common. For this reason, medication review is one of the key components of multifactorial fall prevention interventions.

Aim and Objectives The objective of this study is to determine if falls in a nursing home are related to pharmacological treatment as well as to evaluate if a pharmacist can improve treatment through pharmacological recommendations.

Material and Methods Study design: non-comparative intervention study. Inclusion criteria: patients in whom falls were recorded in a nursing home with 201 residents between 22/05/2023–03/09/2023. A record of incidents, falls and injuries was prepared and coordinated from the Nursing Unit in which the following data were collected: demographic data of the resident, type of fall, description of the fall, condition of the resident after the fall, comorbidities and usual medication. The treatment of all patients in whom falls were recorded was reviewed by the pharmacist, assessing whether they were caused by drugs with a high risk of causing falls. Pharmacological recommendations were made by the hospital pharmacist aimed at preventing falls.

Results During the study period 40 falls were recorded, corresponding to 25 patients, 48% were men with a median age of 84 years (72.5–95.5). A total of 67.5% were identified as related to drug treatment. The hospital pharmacist carried out 27 pharmacological interventions that included: gradually reducing the dose of sedative hypnotics until discontinuation (33.3%), optimisation of antihypertensive treatment (25.9%), prescribing capillary glycaemia controls, assessing the adjustment of basal insulin units (7.4%) and reducing the anticholinergic burden of treatment (7.4%).

Conclusion and Relevance Falls related to drug treatment are common in institutionalised patients and can be identified by the hospital pharmacist. Hospital pharmacists can also contribute to optimising patient treatment through pharmacological interventions, which were well accepted in our case.

The improvement measures that we intend to develop are the implementation of a fall notification protocol to the Pharmacy Service to identify those caused by pharmacological treatment and recommend changes in the medical team of the geriatric centres assigned to our Pharmacy Service (1,000 residents).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-128 COST-EFFECTIVENESS OF PHARMACEUTICAL PREOPERATIVE CONSULTATIONS: A FIVE-YEAR ANALYSIS

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Background and Importance 2.5% of operations are cancelled because of preoperative medication errors. Pharmaceutical preoperative consultations are an effective tool in detection and prevention of these errors, but cost-effectiveness of their implementation has not been evaluated.

Aim and Objectives To determine the cost-effectiveness of the implementation of a pharmaceutical preoperative consultation to review the correct medication management of patients undergoing surgery.

Material and Methods A retrospective, single-center study was conducted to analyze all medication errors prevented by a pharmacist during a preoperative care consultation since their implementation in 2016 until 12/2020. The pharmacist reconciled medication and reviewed their appropriate preoperative management. Recommendations were made based on an institutional protocol.

To assess the economic impact of prevented medication errors, a team of pharmacists and anesthesiologists assigned each error a probability of resulting in a patient-impacting adverse event (p). Following Nebit et al methodology, values of 0, 0.01, 0.1, 0.4, or 0.6 were assigned to each error, with 0.6 being the maximum probability as a conservative measure.

A cost of € 6,924 per adverse event was established based on data from the Spanish Ministry of Health in 2005 and adjusted for the consumer price index in 2020. The cost of each prevented error was calculated as € 6,924 x p. The annual cost of a hospital pharmacy specialist in Spain was € 45,494 in 2020.

A sensitivity analysis was conducted, recalculating the results if the average cost of an adverse event was 20% higher (€ 8,309) or lower (€ 5,539).

Results The consultation was attended by 3,105 patients (mean age 67.0 years) and 1,179 medication errors were prevented. Six were classified as p=0, 224 as p=0.01, 346 as p=0.1, 497 as p=0.4, and 106 as p=0.6, corresponding to 299.2 prevented adverse events.

In monetary terms, the savings associated with these prevented adverse events were € 2,076,785 over 5 years, while the cost of employing a pharmacist was € 227,470. The net savings were € 1,849,315, and the euro saved/invested ratio was 9.1/1. Applying the sensitivity analysis, this ratio would range from 7.3/1 to 10.9/1.

Conclusion and Relevance The implementation of a Pharmaceutical Preoperative Care consultation was cost-effective for the healthcare system, with a cost savings ranging from 7.3 and 10.9 euros per euro invested.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-001 HEALTHCARE RESOURCE UTILISATION AND COSTS OF INTRAVITREAL RANIBIZUMAB OR AFLIBERCEPT VS. DEXAMETHASONE FOR DIABETIC MACULAR EDEMA IN TAIWAN

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Background and Importance Treatment options for diabetic macular edema (DME) include intravitreal anti-vascular endothelial growth factor (anti-VEGF) drugs and dexamethasone implant (DEX-implant), both with their own treatment pros and cons. To date, few studies have examined the healthcare resource utilisation and medical costs associated with these two drug classes for DME treatment.
Aim and Objectives To compare DME-related healthcare utilisation and medical costs of patients with DME receiving intravitreal anti-VEGF drugs or DEX-implant in clinical practice.
Material and Methods We conducted a retrospective cohort study by analysing the largest multi-institutional electronic medical records database in Taiwan. We included adult patients with DME newly receiving intravitreal anti-VEGF drugs (ranibizumab and aflibercept), and DEX-implant during 2017–2021. To ensure the homogeneous comparisons, we apply the 1:1 propensity score matching approach to control the potential confounders. The primary outcome was the 1-year DME-related healthcare utilisation and direct medical cost per patient with DME that was reimbursed by Taiwan's National Health Insurance. We used the mean ± standard deviation to present descriptive statistics and applied t-tests to determine statistical differences between the two treatment groups for continuous outcomes.
Results We included a total of 214 patients with DME newly receiving intravitreal anti-VEGF drugs (n=107) and DEX-implant (n=107). The mean age (67.0±9.0 vs. 67.0±12.8 years) and HbA1c (7.6±1.1 vs. 7.7±1.3%) and eGFR levels (70.5±26.7 vs. 70.1±22.0 mL/min/1.73m2) were similar for the two treatment groups. The average outpatient medical cost per person for eye care was lower for the DEX-implant group (NTD 81,838± 54,752 vs. 105,109±62,481; p=0.004), compared to the anti-VEGF drug group during the 1-year follow-up period. The average intravitreal injections per person for eye care were lower for the DEX-implant group (1.8±1.4 vs. 3.9±2.6; p<0.001), compared to the anti-VEGF group, during the 1-year follow-up period. However, patients with DEX-implant received more pneumotonometry (3.3±3.7 vs. 2.0 ±2.6; p=0.004), compared to the anti-VEGF drug group, during the 1-year follow-up period.
Conclusion and Relevance Compared to the anti-VEGF drug group, DME patients with intravitreal DEX-implant were associated with lower average direct outpatient medical costs for eye care and lower number of intravitreal injections during the first year of treatment in Taiwan.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-002 POSITIVE PREDICTIVE VALUES OF ANAPHYLAXIS DIAGNOSIS IN CLAIMS DATA: A MULTI-INSTITUTIONAL STUDY IN TAIWAN

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Background and Importance Real-world data sources can facilitate essential understanding of the epidemiological features of anaphylaxis. However, the accuracy of case-identifying definitions based on diagnosis codes for anaphylaxis in healthcare databases remains understudied.
Aim and Objectives To evaluate the accuracy of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes to identify anaphylaxis in claims data from the largest healthcare system in Taiwan.
Material and Methods We conducted a cross-sectional study analysing claims data from the largest multi-institutional healthcare system in Taiwan from 2017 to 2021. We included patients with incident anaphylaxis identified by either ICD-10-CM codes for anaphylaxis (Group 1) or ICD-10-CM codes for severe allergic or drug adverse events and additional modifier codes for acute allergy events (e.g., epinephrine, intramuscular or intravascular injection) (Group 2). We randomly selected 20% of the cases to determine the positive predictive value (PPV) of anaphylaxis case-identifying definitions in Groups 1 and 2 after independent review of electronic medical records by two physicians. The clinical criteria for anaphylaxis, proposed at the Second National Institute of Allergy and Infectious Disease/Food Allergy and Anaphylaxis Network, served as the gold standard to confirm anaphylaxis diagnosis (Groups 1 and 2).
Results From the original cohort (n=2,176), we randomly selected 433 patients (20%) with either a diagnosis of anaphylaxis (Group 1), or a diagnosis of severe allergic and drug adverse events with additional modifier codes for acute allergy events (Group 2). In Group 1, we judged 135/170 patients as true anaphylaxis cases (median age: 47 years; female: 46.5%), giving a PPV of 79.4% (95% CI: 73.3–85.5). In Group 2, we judged 47/263 patients as true anaphylaxis cases (median age: 48 years; female: 54.0%), giving a PPV of 17.9% (95% CI: 13.3–22.5). The underlying causes for false-positive anaphylaxis identification in Group 2 were urticaria (76.7%) and angioedema (23.4%).
Conclusion and Relevance Acceptable PPVs were observed when anaphylaxis cases were identified by ICD-10-CM codes for anaphylaxis, but not by ICD-10-CM codes for severe allergic or drug adverse event with additional modifier codes for acute allergy events. Our multi-institutional findings could serve as a fundamental reference for further studies of anaphylaxis based on real-world healthcare databases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-003 ASSESSMENT OF OVERALL SURVIVAL AND SAFETY IN NEWLY APPROVED ONCOHAEMATOLOGIC DRUGS

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Background and Importance To be included on the World Health Organization (WHO) Model List of Essential Medicines, cancer drugs should increase overall survival (OS) by at least 4–6 months.

Aim and Objectives To evaluate OS benefit and safety of oncohaematological drugs approved by the European Medicines Agency (EMA) from 2017 to 2020.

Material and Methods This retrospective observational study identified the first indication of new oncohaematological drugs approved by the EMA between 2017 and 2020. The following variables were collected using the European Public Assessment Reports: drug, primary endpoint, Hazard Ratio (HR) of OS with confidence intervals, OS benefit in months (if medians were reached) and total grade 3 or 4 adverse events (AE) for both drug and comparator. A Student's t-test was conducted to compare AE.

Results A total of 49 indications were identified. The primary endpoint used was surrogate in 41 indications (83.7%): Response rate in 20 (40.8%); progression-free survival in 15 (30.6%); disease-free survival in two (4.1%); metastasis-free survival in two (4.1%); and invasive disease-free survival in one indication (2.0%). One drug (2.0%) was approved with a pharmacokinetic equivalence outcome.

In the remaining eight indications (16.3%), the primary endpoint was OS with a median HR of 0.71 [IQI 0.59–0.77] and a median interval width (upper minus lower interval) of 0.36 [IQI 0.29–0.42]. In four additional indications (8.2%), there was benefit for OS as a secondary endpoint.

Globally, OS benefits were reported in 12 indications (24.5%) (8 as primary and four as secondary endpoint), but median OS had not been reached in two. Median benefit was 4.1 months [IQI 3.6–16.7], with six indications (6/10) demonstrating benefits equal to or exceeding 4 months.

Regarding safety, the mean of serious AE ($\geq$ grade 3) in the 49 indications was 63.6% in the experimental groups and 52.2% in the control groups, with a difference of 11.4% (95% CI: 0.74–22.1).

Conclusion and Relevance OS was the primary endpoint in 1 in 6 approved indications. While HR values were acceptable, considerable interval widths were noted.

Approximately one-quarter of indications demonstrated OS benefit and six approved indications met the lower limit for inclusion in the WHO Model List of Essential Medicines.

Despite modest OS outcomes, statistically significant increases in AE were observed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-004 VISION RELATED QUALITY OF LIFE IN PATIENTS WITH DIABETIC MACULAR OEDEMA AND AGE-RELATED MACULAR DEGENERATION TREATED WITH ANTI-VASCULAR GROWTH FACTOR THERAPY OR DEXAMETHASONE

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Background and Importance Age-related macular degeneration (AMD) and diabetic macular oedema (DME) stand as the foremost causes of visual impairment among the elderly in developed nations, often resulting in severe loss of visual function or blindness. Visual impairment significantly hinders individuals' ability to carry out daily activities and compromises their mobility.

Aim and Objectives The primary goal of this study was to assess the impact of intravitreal anti-vascular endothelial growth factor therapies (anti-VEGF) such as aflibercept, ranibizumab, or bevacizumab, as well as dexamethasone, on the improvement of vision-related quality of life (VQoL) in patients with AMD or DME.

Material and Methods This study encompassed patients with AMD or DME who received treatment with intravitreal anti-VEGF agents or dexamethasone. The recruitment period extended from November 2022 to August 2023, with a follow-up period of 6 months after the initiation or change of treatment. Follow-up and evaluation were facilitated through a remote tool that gathered patient-reported outcome questionnaires.

Two questionnaires were employed

- Spanish Low Vision Quality of Life Questionnaire (SLVQOL): Comprising 25 items, this questionnaire explored four distinct dimensions—distance vision, mobility and illumination, adaptation, reading and precision work, and daily life activities.
- National Eye Institute Visual Functioning Questionnaire 25 (NEI VFQ-25): This questionnaire featured 25 questions, assessing 12 aspects including general health, general vision, ocular pain, near vision activities, distance vision activities, social functioning, vision-specific role difficulties, vision-specific mental health, dependency due to vision, driving, peripheral vision, and colour vision.Statistical analysis included paired t-tests using STATA software to compare means.

Results A total of 54 patients were enrolled, 47% being female and a mean age of 66.9 years. Among them, 72.3% had age-related macular degeneration, 27.7% had diabetic macular oedema, and 92.6% received treatment with anti-VEGF drugs (including 74% aflibercept, 3.8% bevacizumab, and 14.8% ranibizumab), while 7.4% were treated with dexamethasone.

From the baseline visit to the 6-month follow-up, an improvement in VQoL score was observed, although it did not achieve statistical significance:

SLVQOL from 97,31 points +28,43 to 101,57 + 31,6 **(p=0.6)**

NEI VFQ-25 from 66,47 points +18,32 to 68,57+23,91 **(p=0.74)**

Conclusion and Relevance In our study, the utilisation of anti-VEGF therapies or dexamethasone led to an enhancement in VQoL score at the 6-month mark, albeit not reaching statistical significance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-005 DRUG WASTAGE: A HIDDEN COST OF CANCER CARE

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Background and Importance Our country's legislation bans the return of dispensed drugs to Pharmacy Services, potentially leading to increased costs for the National Health System.

Aim and Objectives To estimate the cost of pill wastage due to dose modifications and discontinuation for oral anticancer drugs.

Material and Methods Retrospective economic evaluation carried out in an intermediate complexity hospital. Using the electronic medical record, dispensations of oral anticancer drugs between July 2022 and July 2023 were identified.

The following variables were collected drug, date of dispensing, tablets dispensed, date the patient needs to return to the pharmacy, treatment interruption and cause, date of interruption and leftover tablets.

The laboratories' sales prices were used to calculate the costs. We calculated the potential number of dispensations that the wastage could have covered by dividing the total wastage by the median price per dispensation.

Dose modifications were not taken into account in drugs which had pill strengths divisible at each dose-reduction level.

Unmarketed drugs in our country were excluded.

Results 1239 dispensations were identified. The most dispensed drugs were enzalutamide 40 mg with 308 dispensations (25%) ribociclib 200 mg with 219 (18%), niraparib 100 mg with 143 (12%) and lenvatinib 10 mg with 66 (5%). The median number of days for which medication was dispensed was 30 [IQI 28–35]. The median price per dispensing was € 3,173 [IQI 1,866–4,445] and the total annual expenditure was € 3,759,172.

63 (5%) dispensations were interrupted. The most frequent causes were disease progression for 33 drugs (52%) and toxicity for 19 (30%). The median price per dispensing was € 3,173 [IQI 1,155–4,445] and the total price was € 186,327.

In 34 of the interruptions (54%) patients had tablets remaining. The median wastage per patient was € 1,393 [IQI 645–2,503] and the total wastage was € 56,459 (1.5% of the annual expenditure and 30.3% of the discontinued treatments).

Seventeen dispensations (1.4%) could have been covered with the total cost of pill wastage.

Conclusion and Relevance Although few treatments were discontinued, significant economic wastage occurred due to drug prices. To minimise it, it has been suggested that companies refund money for unused tablets and manufacture appropriate pill strengths[1]. Additionally, hospital pharmacists could be empowered to decide on the return of medications.

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Conflict of Interest No conflict of interest.

6ER-006 LABOUR PRODUCTIVITY GROWTH IN PATIENTS WITH IMMUNE-MEDIATED INFLAMMATORY DISEASES UNDERGOING BIOLOGICAL OR JANUS KINASE INHIBITOR TREATMENT

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Background and Importance Work disability is a major health problem with considerable social and economic implications, especially evident in patients with immune-mediated inflammatory diseases (IMIDs). Among the pharmacological treatments for IMIDs, biological therapies and Janus kinase inhibitors (JAKi) stand out. Considering the impact of both the treatment and the disease on the patient's work life is crucial to making informed treatment decisions. Evidence-based analyses comparing the safety, efficacy and costs of biologic therapies and JAKi for IMIDs are essential to assist healthcare professionals and policy makers

Aim and Objectives This study aims to evaluate the labour productivity impact of biologic therapies and JAKi in patients with rheumatic (rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis), dermatological (psoriasis, urticarial, atopic dermatitis), and gastrointestinal autoimmune conditions (Crohn's disease and ulcerative colitis). The assessment will employ the Work Role Functioning Questionnaire (WRFQ), designed to measure work disability and the perceived influence of health conditions on job performance.

Material and Methods A cohort of 138 patients diagnosed with Immune-Mediated Inflammatory Diseases (IMIDs) was selected from five Spanish public hospitals. The study spanned from April 2021 to August 2022, with a one-year follow-up after initiating or switching to biologic therapy or JAK inhibitors (JAKi). Remote data collection utilised the Work-related Fatigue Questionnaire (WRFQ), comprising 27 items in five subscales. Comparative analysis employed a paired t-test with STATA 17.0

Results Of the participants, 53.4% were female, and the mean age was 50.5 years (range: 18–90). Over the 12-month follow-up, notable improvements in work performance were observed, indicated by score increases:

Work scheduling demands from 65 points+34,63 to 84,49 +26,16 **(p=0.013)**

Output demands from 67,08 points+35,48 to 86,25+22,95 **(p=0.001)**

Physical demands from 51,8 points+38,06 to 78,33+31,06 **(p=0.0093)**

Mental demands from 73,26 points+32,46 to 85,6+22,51 (p=0.0694)

Social demands from 77,77 points+31,57 to 91,66 + 19,24 (p=0.054)

Global score from from 68,34 + 32,68 to 84,66+ 4,46 **(p=0.026)**

Conclusion and Relevance This study underscores a significant improvement in work performance among patients utilising biologic drugs or JAKi therapies. This positive outcome serves to reinforce the value and cost-effectiveness of these treatments, thereby mitigating their substantial impact on healthcare budgets. The findings hold relevance for healthcare professionals and policymakers alike, guiding them toward more informed decisions regarding IMIDs management.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-007 REDUCING OUR MEDICINES' CARBON FOOTPRINT BY TACKLING NITROUS OXIDE WASTE

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Background and Importance There is a focus on the NHS becoming greener underpinned by the NHS Green Plan and closing the gap to net zero. One of the biggest contributors to the NHS carbon footprint is medicines, accounting for 25%. Nitrous oxide confers the largest carbon footprint of the anaesthetic gases within the acute sector accounting for at least 75% of the total footprint.

It is crucial we work to reduce our carbon footprint – the climate crisis is a health crisis, and it is our duty as health care professionals to act to protect our patients and planet.

Aim and Objectives Our project aimed to tackle the largest cause of anaesthetic emissions, nitrous oxide. Nitrous oxide is a bigger problem than most gases due to frequency of use and reliance in dental and paediatric procedures. Our goal was to reduce our carbon footprint of these gases by tackling waste.

Material and Methods We carried out a clinical audit across all clinical areas that are served by piped nitrous oxide, 1605 litres were used weekly on average (83,460 litres per year). We were able to compare our clinical audit data with the total gas bought into the trust (915,000 litres per year). Figure 2 shows clinical use of 5%, and therefore 95% waste.

Results In establishing a solution to the problem we knew the main source of waste of nitrous oxide was from the piped supply. Therefore, our plan was to completely decommission areas that had zero clinical usage and convert anaesthetic gas machines to take portable cylinders in all other areas. Converting to smaller, portable cylinders we could provide a leaner supply with no change in patient care or experience.

Conclusion and Relevance From switching to a leaner supply of medical gases, we have saved over 250 tonnes of CO_2e since beginning our project, as well as over £20,000. The project continues with aims to reduce to less than 100 tonnes of CO_2 emissions per year from our nitrous oxide footprint.

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Conflict of Interest No conflict of interest.

6ER-008 QUALITY, GAPS AND OPPORTUNITIES IN SMARTPHONE APPLICATIONS FOR PULMONARY HYPERTENSION: AN EVALUATION FROM HOSPITAL PHARMACISTS' AND PATIENTS' PERSPECTIVES

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Background and Importance Hospital pharmacists and patients face challenges in identifying high-quality, functional smartphone applications (apps) for aiding pulmonary hypertension (PH) management. A thorough, user-centred evaluation is required due to these app's role in medication management and patient education.

Aim and Objectives To evaluate the quality and utility of PH-focused apps from the perspectives of hospital pharmacists and patients.

Material and Methods An observational study was conducted on freely available apps intended for PH patients and healthcare providers on Android and iOS platforms. Variables such as platform (Android/iOS), last update date, intended purpose and stakeholder involvement were collected. The Mobile Application Rating Scale (MARS) framework was used for quality assessment, and Mann-Whitney U tests were applied to compare mean MARS scores based on specific variables (healthcare professional participation, pharmaceutical industry involvement, or target population).

Results Our evaluation encompassed 20 PH-specific applications across two platforms: Android (9), iOS (7), and both (4). Of these, 11 targeted healthcare professionals and 9 were designed for patients or general population use. Eleven apps were updated within the past year.

Only 10 apps were developed with healthcare professional input, and none involved PH patients. Five applications were pharmaceutical-industry-developed, and 8 benefited from pharmaceutical funding.

Despite a universal emphasis on the few apps identified on disseminating PH general information, none offered features for patient self-management like adverse effect monitoring or medication tracking. Likewise, they lacked functionalities crucial for hospital pharmacists, such as drug interaction checks or allowing direct communication with patients.

Quality assessment via the MARS scale yielded a median score of 3.4 (1.8–3.9), indicating acceptable quality. Analyses found no significant impact of healthcare professional participation, pharmaceutical industry involvement, or target population on the app´s quality.

Conclusion and Relevance While the few existing PH apps offer educational features for patients and healthcare providers of acceptable quality, they neglect the specialised needs of hospital pharmacists and PH patients. Our findings accentuate the imperative for focused, collaborative development

of apps to better serve these specific stakeholders in PH management.

While this development has the potential to improve patient care, this proposition warrants empirical validation. Therefore, it is advisable to conduct studies in controlled settings to generate robust evidence regarding the efficacy of these tools.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

6ER-009 PRESCRIBING PATTERNS AND EFFECTIVENESS OF RANIBIZUMAB AND AFLIBERCEPT IN PATIENTS WITH CENTRAL RETINAL VEIN OCCLUSION: A RETROSPECTIVE COHORT STUDY IN TAIWAN

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Background and Importance Intravitreal injections of ranibizumab and aflibercept are established initial therapies for managing macular oedema arising from central retinal vein occlusion (CRVO). However, there is a lack of extensive studies evaluating the prescribing patterns and therapeutic effectiveness of these two drugs.
Aim and Objectives To scrutinise the patients' characteristics, particularly focusing on the initial severity of the CRVO, and to evaluate the effectiveness of ranibizumab and aflibercept in patients with CRVO eyes.
Material and Methods We performed a retrospective examination of electronic health records data from three hospitals in Northern Taiwan. We included adult patients with CRVO who initiated either intravitreal ranibizumab or aflibercept from 2017 to 2021. Central retinal thickness (CRT) and visual acuity (VA) were evaluated before the treatment and through a follow-up period lasting up to 2 years. For statistical analyses, VA was transcribed into LogMAR (logarithm of the minimum angle of resolution) VA values. Independent t-test and paired t-test analyses were employed to assess the difference of baseline CRT and LogMAR VA between ranibizumab and aflibercept and changes of CRT and LogMAR VA after treatments, respectively.
Results The study cohort consisted of 220 patients (average age: 65.6±13.8 years; 55.9% male) and included 127 eyes intravitreally treated with ranibizumab and 93 eyes treated with aflibercept. Aflibercept-treated eyes displayed a markedly higher initial CRT (577.7 μm vs. 510.8 μm, p=0.006), but no significant differences in initial LogMAR VA were seen (0.92 vs. 0.87, p=0.29), compared to those with ranibizumab. Both medications led to considerable reductions in CRT after 1-year (ranibizumab: 510.8 vs. 343.5 μm, p<0.001; aflibercept: 577.7 vs. 346.5 μm, p<0.001) and 2-year treatments (ranibizumab: 510.8 vs. 310.6 μm, p<0.001; aflibercept: 577.7 vs. 298.5 μm, p<0.001). Nevertheless, neither drug contributed to noteworthy improvements in LogMAR VA after 1-year (ranibizumab: 0.87 vs. 0.92, p=0.51; aflibercept: 0.92 vs. 0.92, p=0.90) or 2-year treatments (ranibizumab: 0.87 vs. 0.92, p=0.49; aflibercept: 0.92 vs. 0.93, p=0.91).
Conclusion and Relevance Both intravitreal ranibizumab and aflibercept for CRVO produced significant reductions in CRT and remained the VA in the routine care from Taiwan. Our data suggest that upcoming comparative studies between these treatments should consider the observed baseline differences in CRT.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

6ER-010 INVESTIGATING NEED AND APPROPRIATENESS FOR PHARMACIST-LED VACCINATION SERVICES WITHIN A HEALTHCARE SYSTEM

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Background and Importance Pharmacist-led vaccination services are an opportunity to improve patient access to vaccination and improve uptake.
Aim and Objectives To assess drivers for pharmacist-led vaccination services and to understand patient expectations and pharmacist-preparedness for pharmacist-led vaccination services.
Material and Methods Two self-administered questionnaires were developed and validated; one for pharmacists and the other for general public. The pharmacist questionnaire evaluated knowledge and skills on the preparation and administration of vaccines and service provision. The patient questionnaire evaluated vaccine education and administration by pharmacists. The questionnaires were distributed electronically (n=40 pharmacists; n=140 patients) and physically from 2 community pharmacies and snowball sampling (n=22 pharmacists; n=23 patients).
Results Pharmacist questionnaire (N=62): 45 female, 17 male, 23–69 years, where 19 pharmacists prefer to administer vaccines to the adult group over the paediatric group (n=3). Pharmacists are aware of errors during preparation and administration of vaccines (n=31), as well as contraindications (n=45), the current national guidelines (n=42) and the procedure of vaccine storage (n=58). Community pharmacists agreed that it is feasible to carry out vaccination services at the pharmacy (n=47), some of whom stated that the premises require further modifications (n=28). Pharmacists commented on the importance of proper training for the service to be carried out efficiently.

Patient questionnaire (N=163): 97 female, 66 male, 18–70 + years, where 102 patients approach pharmacists with concerns on varying aspects including side effects, general information, concerns, uses and other information regarding vaccines, 71 reported that they were satisfied with the pharmacist's responses, and 146 trust the pharmacist to administer the influenza vaccine. Seventy-five patients are willing to pay € 5 for the service provided by pharmacists, and 37 patients are not willing to pay.
Conclusion and Relevance The drivers that contribute to the implementation of pharmacist-led vaccination services include

patient expectations and the level of preparedness among pharmacists.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-011 AN ASSESSMENT OF PHARMACISTS' CONFIDENCE AND BEHAVIOURS IN DISPENSING OPIOID MEDICATIONS

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Background and Importance Opioid prescribing has been associated with what is described as an 'opioid crisis' in the United States. Pharmacists are in unique positions to offer beneficial services to promote the safe use of opioid medicines. Low confidence, knowledge, and training have been associated with barriers in providing opioid dispensing services.[1]

Aim and Objectives The primary aim was to investigate the association between community pharmacists' confidence and practice behaviours in the dispensing of opioid medications.

Material and Methods A modified version of the Opioid Therapy Provider Survey was sent 178 community pharmacists between April and September 2023 to assess their confidence and behaviours in dispensing opioid medicines. Participants confidence was assessed with ten statements around counselling and advice, dispensing, abuse perception, communication with providers, and practice protocols that were measured using Spearman's statistical correlation.

Results The study response was 28%. Staff pharmacists accounted for 35% and pharmacy managers 32% of the respondents. Thirty-five percent of the pharmacists had been in practice for more than 7 years. Forty-seven percent (47%) of the pharmacists dispensed over 30 opioid medicines per week. Ninety-one (91%) percent of the respondents felt confident in dispensing opioids in their practice. There was a strong, positive correlation between pharmacists' comfort when: (1) following a recommended opioid dispensing protocol (r_s = .593, p <.001), (2) counselling patients on side effects (r_s = .480, p = .0o5, (3) information provided by pain specialists (r_s = .515, p = .002). and (4) having a consistent practice approach in dispensing opioids (r_s = .604, p <.001).

Conclusion and Relevance Most community pharmacists appear to feel confident in dispensing opioid medicines. There is a strong level of confidence among community pharmacists in counselling patients on opioid side effects, overdose, and antidotes. Pharmacists are most comfortable in dispensing opioids when there are management approved dispensing protocols and medical information is provided by the prescribing pain specialist.

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Conflict of Interest No conflict of interest.

6ER-012 EVALUATION OF THE EFFECT OF CLOSED SYSTEM TRANSFER DEVICE SYRINGE ADAPTOR CONNECTION IN THE ISOLATOR ON CYTOTOXIC RESIDUE CONTAMINATION DURING INTRAVENOUS ADMINISTRATION

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Background and Importance The European Biosafety Network recommends that cytotoxic drug surface contamination in pharmacy and patient wards not exceed 0.1 ng/cm^2. Among other mitigations, closed system transfer devices (CSTDs) are recommended in several guidances in the US, Europe, and UK for reduction of surface contamination. In the UK, CSTDs are not part of standard cytotoxic preparation procedures in isolators, but the NHS recommends the use of CSTD syringe adaptors (SAs) with syringes used for intravenous administration. At University Hospitals Birmingham, standard practice is to connect Luer caps in the isolator and remove them for administration.

Aim and Objectives The aim was to determine if the addition of a CSTD SA in the isolator reduces cytotoxic residue contamination during intravenous bolus administration.

Material and Methods Surface contamination of syringes, gauze pads placed at the administration site, and nurses' gloves were compared between two procedures: connecting AMD hub caps in the isolator and removal in the ward vs. connecting Tevadaptor SA Locks (SALs) in the isolator during preparation.

In a negative pressure isolator, 25 cyclophosphamide syringes were prepared with hub caps and 25 with SALs. Syringes were wiped with 50% methanol prior to removal from the isolator. In the ward, syringes were swabbed. Gauze pads placed under connection sites for bolus administration were collected. Following administration, nurses' gloves were swabbed. Cyclophosphamide on swabs and gauze pads was quantified by LC/MS.

Results

When SALs replaced hub caps median cyclophosphamide contamination decreased from 8.29 ng to 0.62 ng on syringes, from 384.82 ng to 0.01 ng on gauze pads, and from 1.11 ng to 0.00 ng on gloves. When hub caps were used, 12/25 syringes, 19/25 gauze pads, and 2/25 gloves exceeded the recommended limit of 0.1 ng/cm^2, while with SAL, no samples exceeded this limit.

Conclusion and Relevance Addition of Tevadaptor SALs to syringes in the isolator reduced cytotoxic residue on syringe surfaces, nurses' gloves, and on connect/disconnect, compared to the addition of standard hub caps. Thus, Tevadaptor SALs are beneficial in reducing cytotoxic drug exposure to nurses administering IV syringes and may reduce the risk of mutagenic adverse events.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

6ER-013 ENHANCING PATIENT-CENTREED CARE THROUGH PREDICTIVE MODELLING OF PATIENT-REPORTED OUTCOMES IN HOSPITAL PHARMACY SETTING

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Background and Importance Patient-reported Outcomes (PROs) have established themselves as key tools for measuring the real impact of medical interventions from the patient's perspective. However, to maximise their usefulness, it is crucial to anticipate and understand these outcomes. Machine learning is emerging as a powerful solution to predict PROs and optimise healthcare.
Aim and Objectives This study presents a novel predictive model based on the Random Forest algorithm for the prediction of PRO scores from sociodemographic variables and medication registries obtained in hospital pharmacy practice.
Material and Methods Data from 400 Spanish chronic patients (including psoriasis, asthma, HIV and migraine among others) from the NAVETA telemedicine program were analysed. Sociodemographic variables were included as well as the drugs dispensed by hospital pharmacies. Using these variables, a Random Forest model predicted the PRO values. Predictions were evaluated using an ad hoc metric based on the mean squared error (MSE). The maximum allowable error was taken as 25% of the total response range of each PRO (e.g. 0–100). Predictions were then rated as 'excellent' if the MSE was within 25% of this reference value, 'good' within 50%, 'moderate' within 75% and 'out of range' in case of exceeding 76% of the reference value. This method provides a weighted assessment of the quality of the predictions made by our model.
Results The Random Forest model demonstrated outstanding predictive ability with an R2 of 0.93, effectively capturing the variability of the PRO measurements. The MSE was 0.07, indicating good accuracy. Based on the prediction quality rating, our system ranked 40% of the questionnaires as 'excellent' or 'good', including the WRFQ (Work Role Functioning Questionnaire), HIV SI (HIV Symptom Index), MOS30 HIV (Medical Outcomes Study-short form 30 items) and DLQI (Dermatology Life Quality Index), suggesting a good performance of the model in predicting PROs scores.
Conclusion and Relevance The results indicate that Hospital Pharmacy records obtained from the NAVETA cohort significantly predict patient health outcomes. The use of this predictive model in telemedicine systems such as NAVETA would improve patient care by helping to quickly identify needs and tailor treatments, leading to accurate, patient-centred care in the context of hospital pharmacy.

6ER-014 ASSESSING ADHERENCE TO ESC/ERS GUIDELINES FOR VASOREACTIVITY TESTING AND PRESCRIPTION OF CALCIUM CHANNEL BLOCKERS IN PULMONARY HYPERTENSION PATIENTS

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Background and Importance The ESC/ERS Guidelines for treating pulmonary hypertension (PH) recommend vasoreactivity testing (VT) during right heart catheterisation for patients with idiopathic/hereditable/drug-associated PH (IPH/HPH/DAPH) and subsequent treatment with calcium channel blockers in those with a positive result.
Aim and Objectives To evaluate the consistency in conducting VT in patients with IPH/HPH/DAPH and to ascertain whether positive test outcomes lead to the initiation of calcium channel blocker therapy.
Material and Methods We carried a multicentre cross-sectional observational study in three hospitals including adults treated between 2006 and 2023. We reviewed clinical charts for all patients with a PH type-I diagnosis to identify IPH/HPH/DAPH patients. For these patients we reviewed catheterisation data to find VT; If a positive result was found, prescription ambulatory data was reviewed in search for prescriptions of calcium channel blockers.

We estimated the number of patients who could potentially benefit from calcium channel blockers, based on the assumption that 10% of patients will exhibit a positive VT test.
Results The study encompassed 176 Type-I PH patients across three tertiary hospitals, including 125 women (71.0%) with a median age of 58 (IQR: 24). Underlying aetiologies were congenital heart disease 38.6% (68), Connective Tissue Disease 27.8% (49), Portopulmonary Hypertension 6.8% (12), HIV 3.4% (6), IPH 15.3% (27), and 1.1% DAPH (2).

VT was reviewed for a subset of 29 patients (27 IPH and two DAPH). Of these, 12 underwent VT with five returning positive results and consequently receiving prescriptions for calcium channel blockers. For the remaining 17 patients, four had missing catheterisation data, and 13 underwent catheterisation but were not tested for vasoreactivity. If the aforementioned rate remains consistent, an estimated 1–2 patients could benefit from calcium channel blockers.
Conclusion and Relevance VT was not consistently carried out in IPH/HPH/ADPH patients; a subset of patients could benefit from high dose calcium channel blockers. For those patients with a positive result, calcium channel blockers were adequately prescribed.

Hospital pharmacists could play a role in reviewing new prescriptions of PH-specific therapy in order to identify patients not tested for vasoreactivity.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

6ER-015 RETRACTED PHARMACOLOGY ARTICLES: A CROSS-SECTIONAL STUDY USING THE RETRACTION WATCH DATABASE

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Background and Importance Retractions in scientific literature can profoundly impact healthcare professionals, potentially misleading hospital pharmacists and affecting patient safety.

Aim and Objectives This study aimed to provide a focused examination of article retractions in pharmacological research.

Material and Methods A cross-sectional observational study was carried out using data from the recently released (10/09/2023) 'Retraction Watch Database'* which compiles data from retracted scientific articles since the early 70s. We included data from retracted articles categorised as 'Medicine-Pharmacology' involving European researchers. We excluded data from article reinstatements.

We studied variables such as: type of study, date of article publication, date of article retraction, and reasons for retraction.

Time to retraction was calculated as date of article retraction – date of article publication. As most articles had several reasons for retraction, they were presented in a heat mat of pairwise combinations.

Results A total of 516 articles were retracted within the study period. Retracted articles were original studies 61.2% (316), reviews 27.1% (140), Review and meta-analysis 3.9% (20) and others 7.8% (40).

Abstract 6ER-015 Table 1

Year period	Article publication N (%)	Article retraction N (%)
1975–1999	63 (12.2)	6 (1.2)
2000–2004	94 (18.2)	12 (2.3)
2005–2009	116 (22.5)	22 (4.3)
2010–2014	138 (26.7)	174 (33.7)
2015–2019	66 (12.8)	138 (26.74)
2020–2023	39 (7.6)	164 (31.8)

The median time to retraction was 2135 (IQR: 3680) days.

Conclusion and Relevance This study revealed a significant number of retracted pharmacology articles, often with substantial time lags from publication to retraction for several significant reasons. Hospital pharmacists must be aware of this issue, as it influences clinical decision-making. Discernment in citing articles is imperative to minimise associated risks.

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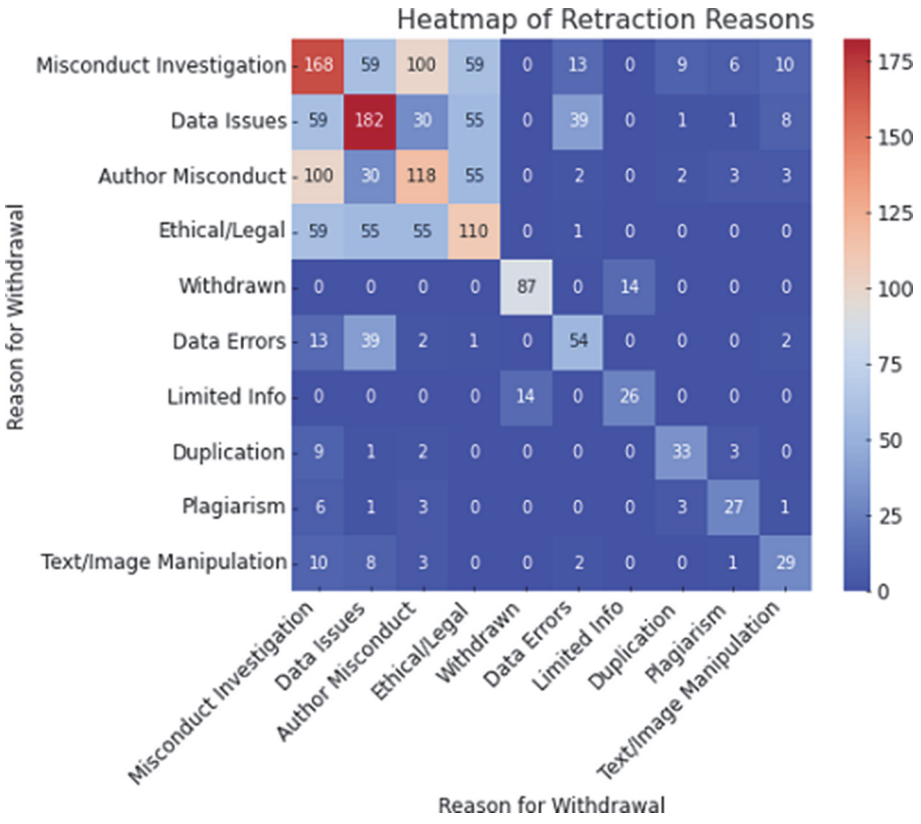
Conflict of Interest No conflict of interest.



Abstract 6ER-015 Figure 1

6ER-016 ABSTRACT WITHDRAWN

6ER-017 FACTORS PREDICTIVE OF CLINICAL OUTCOME IN ADVANCED NON-SMALL-CELL LUNG CANCER PATIENTS RECEIVING OSIMERTINIB TREATMENT: A REAL-WORLD EXPERIENCE

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Background and Importance Osimertinib, a third-generation irreversible tyrosine kinase inhibitor of both activating EGFR mutations and resistance-associated T790M point mutation, was approved for treating advanced non-small cell lung cancer (NSCLC).

Aim and Objectives The aim of this study was to investigate the factors predictive of clinical outcome in advanced NSCLC patients receiving osimertinib treatment.

Material and Methods We conducted a retrospective study using a multi-institutional electronic medical records database in Taiwan. We included advanced NSCLC patients newly receiving osimertinib as second-line or beyond systemic therapy between January 2020 and December 2020. The clinical outcomes were median progression-free survival (PFS) based on the Response Evaluation Criteria in Solid Tumors (RECIST), overall survival (OS). We applied Kaplan-Meier methods to estimate median PFS and OS. Uni-variable and multi-variable Cox regression models were applied to identify the prognostic factors.

Results We included 286 osimertinib naive users with a median age of 66.8 (IQR: 58.8–73.1) years, of whom 61.5% were female and 99.7% were stage 4. The median PFS and OS were 12.0 months and non-reach, respectively. Moreover, ECOG performance (HR: 1.82, 95% CI: 1.06–3.13), exon 19 deletion (HR: 0.57, 95% CI: 0.41–0.80), and liver metastasis (HR: 1.88, 1.24 – 2.85) were significantly related to PFS in the multi-variable analysis. In addition, we analysed the patients with ΔCT value of EGFR mutation. We found that the patients with higher value of ΔCT between T790M and L858R mutation had significantly worse OS (HR: 1.46, 95% CI: 1.08–1.96) and PFS (HR: 1.47, 95% CI: 1.15–1.81).

Conclusion and Relevance Osimertinib was an effective treatment option for advanced NSCLC patients in real-world experience. Tumour burden liver metastasis, ECOG performance and a mutation in exon 19 deletion were independent predictive factors for progression-free survival. Moreover, ΔCT between T790M and L858R mutation was also a predictive factor while using osimertinib. Future real-world studies with large sample size are suggested to confirm our findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-018 THE EFFECTIVENESS OF ADRENERGIC ALPHA ANTAGONISTS ON REDUCING RE-CATHETERISATION RATES IN ADULTS WITH URINARY CATHETERS: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Background and Importance Hospitalised patients often require indwelling urinary catheters due to urinary retention, surgery, or other reasons, and catheterisation may increase the risk of catheter-associated urinary tract infection (CAUTI) and death. Alpha-blockers can reduce muscle tension and relieve dysuria in patients with benign prostatic hyperplasia (BPH). However, there is considerable uncertainty about whether alpha-blockers aid in catheter removal.

Aim and Objectives To assess the effectiveness of alpha-blockers on successful resumption of micturition after removal of a short-term urinary catheter in adults.

Material and Methods We searched PubMed, Embase and Cochrane databases from 1983 to July 2023 for all randomised controlled trials (RCTs). No language or other restrictions were imposed on the searches. Two review authors independently screened the titles and abstracts of each trial

before obtaining the full text for all potentially eligible trials and assessed the included trials for risk of bias. A random-effects meta-analysis was applied to pool event rates with 95% confidence intervals (CIs). We made appropriate clinical treatment recommendations by GRADE Evidence to Decision (EtD) frameworks.
Results A total of 33 RCTs were included with 14 studies in the non-surgical group and all patients with BPH. There was high quality evidence to suggest that the rate of successful trial without catheter (TWOC) favoured alpha-blockers over placebo (odds ratio [OR], 2.2; 95% CI:1.6–3.0). There was moderate quality evidence to reduce the risk of requiring re-catheterisation (OR: 0.5; 95% CI: 0.3–0.7). There was low quality evidence to reduce the incidence of recurrent urinary retention (OR: 0.2; 95% CI: 0.1–0.7). In 19 studies with BPH and non-BPH patients undergoing surgery, there was moderate quality evidence to reduce the risk of postoperative urinary retention (POUR) regardless of gynaecological surgery.
Conclusion and Relevance We strongly recommend patients with a history of BPH or suspected with BPH to accept prophylactic alpha-blockers before catheter removal. Surgical patients are moderately recommended using alpha-blockers to prevent POUR. As for other patients, we must evaluate many factors such as age, gender, medical history, risk of adverse effects, previous urinary catheter experience and indications of indwelling urinary catheters before alpha-blockers application.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

6ER-019 TREATMENT BEYOND PROGRESSION WITH PEMBROLIZUMAB IN ADVANCED NON-SMALL-CELL LUNG CANCER

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Background and Importance While pembrolizumab became a new standard of care in advanced non-small-cell lung cancer (aNSCLC), limited studies proved the effectiveness of continuing use of pembrolizumab after disease progression.
Aim and Objectives We aimed to evaluate the effectiveness of treatment beyond progression (TBP) of pembrolizumab in aNSCLC patients.
Material and Methods This multicentre study retrospectively analysed electronic medical records from databases of two medical centres and two local hospitals. Patients confirmed aNSCLC who received pembrolizumab (monotherapy or combination therapy) and experienced progression disease between 2016 and December 2021 were enrolled. The first date of disease progression after pembrolizumab used was defined as the index date. We defined patients with at least one pembrolizumab within 60 days as TBP group, other patients were defined as switched group. We followed each patient until death, loss of follow-up and end of June 2023. The primary outcome was overall survival (OS), and the baseline characteristic would be adjusted by inverse probability treatment weighting method. We also evaluated prognostic factors, including progression pattern, metastatic sites and baseline characteristics by using a Cox regression model.
Results A total of 307 aNSCLC were included. Among all, 141 (45.9%) continued receiving pembrolizumab beyond progression, while 166 patients (54.1%) switched to other treatments. Overall, median age was 63.3 y/o, 73.3% were male, 90.6% were with ECOG performance 0–1 and 61.3% had high programmed death ligand-1(PD-L1) expression (≥50%). With median 6.2 (2.0–13.1) months follow-up time, the TBP group had a longer OS than the switched group (median OS: 11.1 vs. 4.5 months, $P < 0.01$).
Conclusion and Relevance While the TBP group was associated with better OS, additional studies are needed to further validate our findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

6ER-020 WOULD CHATGPT PASS THE RESIDENT INTERNAL PHARMACIST EXAM?

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10.1136/ejhpharm-2024-eahp.482

Background and Importance Assessing ChatGPT's performance in the Health Training exam for Pharmacy specialisation (FIR) holds significance in gauging AI's role in healthcare education.
Aim and Objectives To assess ChatGPT's ability to respond to and potentially pass the Health Training exam for Pharmacy specialisation (FIR).
Material and Methods A multidisciplinary team consisting of hospital pharmacists, physicians and biomedical engineers selected an exam version for the 2022 session. One question was excluded due to the presence of an image. A brief introduction, providing context about the FIR exam and its contents, was added at the beginning of the conversation.

ChatGPT's performance, defined as the percentage of correct answers, was evaluated through three different approaches:

1. Two sets of 50 randomly selected questions were manually input into the OpenAI web interface during the same conversation.
2. A total of 209 questions, including both questions and their four possible answers were solved by the Application Programming Interface (API) for Python from a spreadsheet.
3. Open-ended questions lacking predefined possible answers were extracted by API for Python, followed by the application of Natural Language Processing (NLP). NLP assessed the similarity between API-generated responses and actual responses, providing a more accurate evaluation of ChatGPT's human-like performance in a multiple-choice exam. The similarity metric compared feature vectors of sentences and generated a value representing the degree of similarity, with a maximum value of 1 signifying a perfect match and thus a correct answer.

Correct answers received a value of 3 points, while incorrect ones subtract incurred a deduction of 1 point. In the 2022 call, a minimum score of 97 points was necessary to be eligible for allocation of FIR positions.
Results Using the manual inclusion method, we achieved 60% and 66% accuracy in 50 randomly selected questions (score equivalent to 280 and 328 points, respectively). The second method yielded a success a success rate of 45.5 to 49.0%,

equating to 164–192 points. In the third method, values of 50.2–52.6% (200–220 points) were obtained.

Conclusion and Relevance The findings demonstrate ChatGPT's variable ability to provide correct responses to FIR questions depending on the methodology employed. Regardless of the approach, ChatGPT consistently achieved the minimum score required for participation in the allocation of FIR positions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-021 OPIOID-SPARING STRATEGIES FOR DISCHARGE ANALGESIA PRESCRIBING IN NON-COMPLEX SURGERIES – A MISSED OPPORTUNITY

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Background and Importance Opioids are an integral element of post-operative management for moderate to strong pain. Despite their effectiveness they are associated with a range of adverse effects and excessive opioid prescribing has contributed to a widespread international crisis of addiction and overdose, including across Europe and in Australia. Even minor surgeries can serve as an initial event for opioid-naive patients to become persistent opioid users. In Australia, opioid-related harm and associated deaths have risen along with opioid prescribing.

Guidelines recommend paracetamol and nonsteroidal anti-inflammatory drugs (NSAIDs) to reduce the opioid analgesics use. NSAIDs in particular work synergistically with opioids, providing opioid-sparing effects. Usage in the final 24 hours of hospital admission guides decision-making around prescribing of discharge analgesia.

Aim and Objectives We retrospectively assessed analgesia use patterns in opioid-naive patients undergoing non-complex surgery (length-of-stay 1–4 days post-operatively). We had a particular focus on intermediary analgesia use (NSAIDs and tramadol) and possible NSAIDs contra-indications to short-term use.

Material and Methods Patients undergoing surgery under general surgical teams with a post-operative length-of-stay of 1–4 days were retrospectively identified using case mix codes. Use of opiods, non-steroidal anti-inflammatories, tramadol and paracetamol in the final 24 hours of admission were quantified along with possible contra-indications for use and discharge prescribing.

Results Of 1015 patients assessed there were 555 (55.7%) who were eligible for NSAIDs and/or tramadol and not prescribed this as an inpatient option, although 310 (55.9%) of these patients still received opioids.

In the final 24h of admission 759 patients with no contra-indication to NSAIDs or tramadol did not receive these medications but 314 (41.4%) still received discharge opioids.

79 (7.8%) patients required no opioid analgesia in the final 24 hours but were still prescribed opioid at discharge.

A further 122 (12.0%) were not prescribed inpatient paracetamol 31 (25%) but received discharge opioids.

Conclusion and Relevance There is an abundance of missed opportunity for opioid-sparing strategies to be employed in this cohort. These poor prescribing patterns were largely driven by engrained culture and/or junior prescriber unawareness of options. Further work is underway to define post-discharge analgesia use patterns in order to inform development of clinical decision support to address this issue.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-022 KNOWLEDGE, ATTITUDE AND PRACTICE ABOUT PHARMACEUTICALS IN THE ENVIRONMENT AMONG HOSPITAL PHARMACISTS IN SPAIN

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Background and Importance Healthcare professionals need to be more aware of the negative environmental impact of pharmaceuticals. Hospital pharmacists, in particular, play an essential role in the life cycle of drugs. Their contribution to tackle the problem is going to be pivotal. So far, scant information is available about the level of knowledge, attitude and practice about the issue among hospital pharmacists.

Aim and Objectives To evaluate the knowledge, attitude and practice about the issue of pharmaceuticals in the environment (PiE) among hospital pharmacists in Spain.

Material and Methods A self-administered on-line questionnaire (Microsoft Forms) consisting of 18 questions about knowledge, 10 about attitude, 2 about practice and 3 others was sent via e-mail to all members of the Spanish Society of Hospital Pharmacists (n=4451). The scale used for knowledge questions was variable. The attitude scale, previously validated, is an agreement scale (being 0 'totally disagree' and 10 'totally agree'). Descriptive statistics were performed.

Results 149 hospital pharmacists (3.4%) answered the survey. (75.2% women, mean age 43.7 years). 92 professionals (61.7%) did not know the concept 'emerging pollutants', and 85 participants (57.0%), had not heard of 'One Health'. Only 19 (12.7%) knew about the Environmental Risk Assessment reports of the European Medicines Agency, and the majority (n = 98; 66.2%) responded 'do not to know/no answer' to the question about the most famous ecotoxicological disaster in Asian vultures caused by veterinary diclofenac. 111 (74.5%) knew nothing about the destiny of their hospital wastewaters and 58 (38.9%) admitted to having doubts about pharmaceutical waste management in their setting. On the contrary, 130 (87.2%) correctly identified metered dose inhalers (MDIs) having a higher carbon footprint. Acquiring knowledge about drug pollution was considered very positive (mean score 8.61). Only 17 responders (11.4%) admitted to considering environmental aspects to develop hospital formularies.

Conclusion and Relevance This study shows that there is room for improvement in the knowledge about PiE among hospital

pharmacists in Spain. There is a high level of knowledge about MDIs carbon footprint, and the attitude towards the issue is positive, but environmental criteria are not considered to develop hospital formularies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-023 A MULTI-SECTOR SIMULATED EXPERIENTIAL PRACTICE EVENT FOR YEAR 1 PHARMACY STUDENTS

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Background and Importance Simulation-based education complements traditional teaching, improving students' knowledge, understanding, as well as supporting the development of students' teamwork, decision-making, and consultation skills[1,2], as well as supporting professional identity formation[3]. Year 1 students across the country participated in a pre-placement workshop and a simulated multi-sector experiential event.

Aim and Objectives To evaluate Year 1 pharmacy students' and participating staff' experiences of a simulated multi-sector Experiential Event designed to develop clinical and consultation skills.

Material and Methods The year 1 Experiential Event was delivered in both Universities in the country in March 2022. Staff (n=16) and students (n=222) were invited to complete a post-Event evaluation on Microsoft Forms to inform ongoing improvement of the Event.

Ethical approval was not required as this formed part of the review of the module

Results Seventy-five percent of staff responded (n=12) with 42% (n=5) respondents believing that students were competent conducting medication history, counselling and simple prescribing decisions. Seventy-seven percent of students (171/222) responded; 85% (n=145) and 81% (n=139) respectively believed that the medication history and consultation checklists developed in the pre-placement workshop prepared them for 'real' patient consultations. Students were confident in conducting BP and peak flow examinations (73%, n=125) and in prescribing medication (83%, n=142). Eighty-six percent (n=147) of respondents believed that the event had made them feel more like a pharmacist.

Conclusion and Relevance Year 1 respondents showed an appreciation for the experiential event, believing that it improved their clinical and consultation skills. The majority of student respondents believed that the event supported their professional identity formation. Staff respondents agreed that students developed core clinical skills but to a lesser extent than student participants, believing curriculum redesign will facilitate enhanced student engagement with the event.

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Conflict of Interest No conflict of interest.

6ER-024 LYELL'S SYNDROME IN CAR-T TREATED PATIENTS: A CASE STUDY

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Background and Importance Lyell's syndrome - a toxic epidermal necrolysis - is a rare and potentially life-threatening disease that affects the skin and mucous membranes. The drugs commonly implicated in toxic epidermal necrolysis (TEN) include non-steroidal anti-inflammatory drugs, chemotherapy, antibiotics and anticonvulsants.

Aim and Objectives This case report explores potential triggers of Lyell's syndrome in 39-year-old woman diagnosed with relapse and diffuse refractory large cell B lymphoma (DLBCL) who underwent Third Line Therapy with Axicabtageneciloleucel. After the infusion, CRS (cytokine release syndrome) was reported, which progressed from grade 1 to G2 within 3 days. This was complicated by the onset of ICANS (immune-effector cell-associated neurotoxicity syndrome) progressed to G3 within 3 days. Subsequently, the HLH/MAS framework (Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome) was reported. To control her persistent high fever and to reduce the risk of convulsions, was somministrated levetiracetam. Despite anti-cytokine therapies and steroids were continued, after 6 days Toxic epidermolysis affected 90% of the body surface area, confirmed by histological examination of the skin rhomboid, consistent with TEN/Lyell syndrome. Levetiracetam was discontinued.

Material and Methods Medical records and National Pharmacovigilance Network were used to collect data.

Results The patient was admitted to the intensive care unit for 32 days, receiving treatments comparable to those given to patients with severe burns. Drugs administered: ruxolitinib, methylprednisolone, daptomycin, amine, piperacillin/tazobactam, tocilizumab, entanercept, anakinra, and high-dose fluids. The pharmacist provided critical support to CAR-T team, playing a key role in the management of drug selection and occasionally resort to off-label use of medicines. A sterile paraffin tulle gras dressing led to re-epithelialisation and disappearance of the blisters. DLBCL progression led to death 9 months later.

Conclusion and Relevance The co-administration of several drugs, the lack of available data on adverse drug reactions (ADRs) in response to CAR-T, and the temporal relationship between levetiracetam and onset of ADR lead to the conclusion that a metabolite of anticonvulsants, identified in the literature as a potential trigger, was responsible for the ADR. The decision to use anti-TNF-alpha was critical in the management of the syndrome. A comparable ADR was subsequently reported in Eudravigilance, raising uncertainty about the potential involvement of levetiracetam as a trigger of the ADR.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

6ER-025 ANTIMICROBIAL ACTIVITY OF SUBCRITICAL CO2 EXTRACT OBTAINED FROM UNDERGROUND FERULA ASAFOETIDA L

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Background and Importance Literature review showed that various extracts of *Ferula asafoetida* L. have wound healing, anti-inflammatory, antinociceptive, antimicrobial, antitumour, anti-diabetic effects. However, there is a lack of studies regarding CO_2 extracts of *Ferula asafoetida* L. This raises the need for phytochemical and antimicrobial study of this extract.
Aim and Objectives The possibility of creating to consider an antimicrobial preparation based on CO_2 extract of *Ferula asafoetida* L. used in pharmacy practice.
Material and Methods Determination of the constituents of the CO_2 extract of *Ferula asafoetida* L. was done by GC-MS and identified by comparing the obtained spectra with the existing NIST library.
Results GC-MS analysis of the CO_2 extract of *Ferula asafoetida* L. showed that some components of sulfur compounds (34.69%) were in rather high concentrations. In the course of the studies, the minimum inhibitory concentrations (MIC) of the CO_2 extract of *Ferula asafoetida* L. were determined by the method of serial dilutions in liquid nutrient medium: *Staphylococcus aureus* 7.81 μg/*ml*, *Bacillus subtilis* 31.25 μg/*ml*, *Escherichia coli, Klebsiella pneumoniae, Salmonella enterica* 15.63 μg/*ml*, *Candida albicans, Aspergillus niger* 62.5 μg/*ml*. In the second method, the CO_2 extract of *Ferula asafoetida* L. is more active than the comparison drug amoxicillin against *Staphylococcus aureus* and spore bacterium *Bacillus subtilis* by 1.2-fold, *Escherichia coli* by 1.5-fold and *Salmonella enterica* by 1.4-fold. And also this extract showed fungicidal activity against *Candida albicans* 1.5 times more than fluconazole.
Conclusion and Relevance The wide range of antimicrobial properties of the CO_2 extract of *Ferula asafoetida* L. is associated with the presence of sulfur compounds in its chemical composition. As a result of comparing the antimicrobial activity of this extract with literature data, we found that the antimicrobial activity of CO_2-extract of *Ferula asafoetida* L. is higher than that of polar extracts of this plant, and that of essential oils it is higher against *Escherichia coli* and *Bacillus subtilis*. In view of the above, the CO_2-extract of *Ferula asafoetida* L. can be used in pharmaceutical practice as a medicinal herbal remedy with antimicrobial action.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

6ER-026 THE IMPORTANCE OF PHARMACY DEPARTMENT CLINICAL TRIALS UNIT INTERVENTION IN A REFERENCE CENTRE FOR THE TREATMENT OF PARAMYLOIDOSIS

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Background and Importance As a reference centre for the treatment of familial paramyloidosis, our hospital receives patients from all over the country.[1] The emergence of new therapeutic options is essential to ensure treatment and reduce the impact that the disease has on individuals and families.

Clinical Trials (CT) using new molecules such as tafamidis, inotersen and patisiran represent significant advances in the treatment of patients with Hereditary Transthyretin Amyloidosis (hATTR), instead of liver transplant.[2]
Aim and Objectives Describing the activity of the Pharmacy Department Clinical Trials Unit (PDCTU) in a reference centre for the investigation and treatment of hATTR, between 2006 and 2023.
Material and Methods Retrospective analysis of the participation of the PDCTU of our hospital in the clinical investigation of hATTR. For this analysis, the number of CT started each year, the number of ongoing CT and the number of patients included in CT associated with hATTR were evaluated.
Results Since 2006, our PDCTU has participated in 21 CT. It has made a significant contribution to the approval of emerging therapies, some of which have already been granted Marketing Authorisation, as is the case of transthyretin (TTR) stabilisers and TTR level reducing agents.

In total, since 2006, 327 patients have taken part in hATTR-related CT, 64 of whom are still taking part in a set of 6 CT, all of them of phase 3.

Each trial associated with hATTR had an average participation of eight patients, an average well above the average of patients/trial (two patients/trial) at our centre.
Conclusion and Relevance Since 2015 there has been a growing trend in the inclusion of hospital in new CT. The centre is evaluating various investigational therapies for the treatment of hATTR, including agents that stabilise TTR, antibodies, antisense oligonucleotides and RNAi therapies.

The pharmacists at the PDCTU, contribute to the development and approval of new therapeutics, guidelines and protocols. Since they are responsible for the entire investigational product circuit, they ensure that trials are well conducted.

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Conflict of Interest No conflict of interest.

6ER-027 ECONOMIC BENEFIT AND CLINICAL ADVANTAGES WITH THE INCLUSION OF PATIENTS IN CLINICAL TRIALS RELATED TO PARAMYLOIDOSIS

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Background and Importance Access to innovative medicines requires extensive and careful pharmaco-economic evaluation.

The inclusion of patients in Clinical Trials (CT) allows early access to new experimental medicines and considerable economic saving for the healthcare system.

Aim and Objectives Evaluate the economic benefit of including patients with hereditary transthyretin amyloidosis (hATTR) in clinical trials between 2018 and 2023.

Material and Methods Retrospective analysis of paramyloidosis-related clinical trials taking place at the centre since 2018. The data collected were the number of paramyloidosis-related CT, the number of patients included the time of participation in the CT and the average price of conventional treatment.

Results At our Clinical Trials Unit there are currently 6 Paramyloidosis-related CT underway, involving a total of 65 patients.

In economic terms, patient participation on ongoing CT related to Paramyloidosis has led to a cumulative saving of 15,667,487.98€ , compared to the costs of conventional therapy (tafamidis[1],inotersen[2] and patisiran[3]).

The distribution of annual savings was:

- 2019: 644.396,70€
- 2020: 2.447.335,64€
- 2021: 4.465.670,09€
- 2022: 4.206.997,00€
- August of 2023: 3.903.088,55 €

Conclusion and Relevance Participation in CT allows early access to new experimental therapies and contributes to the development of new drugs and/or new therapeutic indications. In Paramyloidosis, new agents like TTR stabilisers, subcutaneous antisense oligonucleotides and iRNA therapies are potential new alternatives.[4]

By participating in CT, centres obtain an extra source of funding. The participation of patients in CT also allows for a reduction in costs, through the preservation of financial resources and medication.

The savings generated by the participation in CT help to provide better care and an efficiency healthcare system.

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Conflict of Interest No conflict of interest.

6ER-028 REAL-WORLD TREATMENT PATTERN AND EFFECTIVENESS OF PIRFENIDONE AND NINTEDANIB IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS: A MULTI-INSTITUTIONAL STUDY IN TAIWAN

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Background and Importance Pirfenidone and nintedanib have been proven survival benefits and been currently approved for idiopathic pulmonary fibrosis (IPF). However, real-world comparison of effectiveness between two antifibrotics remains limited in Asia.

Aim and Objectives Our study was aimed to assess: (1) factors associated with the choice of pirfenidone versus nintedanib; (2) dose modification during treatment; (3) overall survival (OS).

Material and Methods We conducted a retrospective cohort study by using the largest multi-institutional electronic medical records in Taiwan. We included IPF patients newly receiving pirfenidone or nintedanib during 2018–2020. We followed up included patients to death, loss of follow-up or December 2022. The clinical factors included age, sex, lung function, biochemical data, comorbidities and co-medications. Multiple logistic regression analysis was used to assess factors associated with drug choice. Dose modification was assessed every 3 months by using dose intensity in follow-up period based on as-treated analysis. In OS analysis, we applied probability of treatment weighting (IPTW) and Cox regression model to enhance the comparability of study subjects and estimate hazard ratio (HR) between two treatment groups, respectively.

Results A total of 86 patients receiving pirfenidone and 142 patients receiving nintedanib. Mean age and Forced vital capacity (FVC) were 70.7 11.3 years and 68.8 17.4%, respectively. The use of nintedanib was positively associated with the patients with chronic kidney disease (CKD) (odds ratio: 2.1, 95% CI: 1.06 – 4.18). Dose reduction rate was similar between two groups (59.3% vs. 65.4%, P = 0.34). After a median of 25.5 months follow-up, nintedanib users were associated with worsen OS than pirfenidone users (adjusted HR: 2.07, 95% CI: 1.24 – 3.45).

Conclusion and Relevance Our study showed CKD patients were likely prescribed nintedanib. Pirfenidone users had association of better all-cause mortality than nintedanib users. Further studies are suggested to confirm our findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-029 A SYSTEMATIC REVIEW OF COMBINED POLY (ADP-RIBOSE) POLYMERASE INHIBITOR AND ANDROGEN RECEPTOR ANTAGONISTS IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

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Background and Importance According to latest practice guideline, concurrent administration of poly (ADP-ribose) polymerase inhibitors (PARPi) and androgen deprivation therapy (ADT) may have synergistic efficacy for metastatic castration-resistant prostate cancer (mCRPC) patients. However, the effectiveness of PARPi and ADT was highly depended on mCRPC patients' heterogeneous gene status. To move toward precision medicine in mCRPC treatment, high level of evidence summarising newest clinical trials was unmet need.
Aim and Objectives To conduct a systematic review and meta-analysis to estimate effectiveness of PARP inhibitors combined with ADT versus standard ADT in the mCRPC patients with homologous recombination repair (HRR) positive and negative.
Material and Methods We searched PubMed, Embase and Cochrane databases from 2009 to September 2023 for all randomised clinical trials. No language or other restrictions were imposed on the searches. Two review authors independently screened the titles and abstracts of each trial before obtaining the full text for all potentially eligible trials and assessed the included trials for risk of bias. The outcomes included progression free survival and overall survival among all patients, HRR+ and HRR-. A fixed-effects meta-analysis was applied to pool hazard ratio (HR) with 95% confidence intervals (CIs).
Results A total of five studies with a total of 1207 PARPi and 1206 placebo patients were included. Compared to standard ADT, the PARPi plus ADT was associated with a 38% PFS improvement (HR: 0.62; 95% CI: 0.54–0.72) and OS prolong (HR: 0.85, 0.73–0.99) in the overall patients. Among HRR+ patients, the pooled PFS and OS were 0.65 (0.52–0.81) and 0.66 (0.45–0.95), respectively. Among HRR- patients, the pooled PFS and OS were 0.74 (0.59–0.92) and 0.89 (0.70–1.14), respectively.
Conclusion and relevance Based on current evidence, we suggest that the combination of PARPi and ADT in patients with mCRPC to significantly improved both progression-free survival and overall survival rates, especially for HRR+ patients. As hospital pharmacists, we play an auxiliary role in shared decision-making system. We can use skill of evidence-based medicine to integrate and explain evidence and provide patients with more precisely and effectively therapeutic strategies.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

6ER-030 EVALUATION OF A GROUP-BASED ONLINE INFORMED CONSENT CONVERSATION (ECONSENT) IN PARTICIPANTS FROM A VACCINATION CLINICAL TRIAL: A MIXED METHOD STUDY

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Background and Importance Use of digital consent (eConsent) has expanded in the last few years in Europe especially during the pandemic. Slow recruitment rate and limitation in reaching out to participants from different backgrounds are the challenges often faced in clinical research. Given the benefits of eConsent and group counselling reported in the literature, group eConsent was implemented in study recruitment for the SWITCH-ON trial.
Aim and Objectives We aim to explore the experience of participants who attended group eConsent for the SWITCH-ON study and evaluate its potential for future use.
Material and Methods SWITCH-ON study aims to analyse the immunogenicity of healthy population following bivalent COVID-19 booster vaccination. 434 healthcare workers aged between 18 and 65 were successfully recruited and were sent a questionnaire about their experience with group eConsent after their informed consent session. Out of 399 completed questionnaires received (response rate 92%), 39 participants did not join group eConsent. The remaining 360 responses were included in the final analysis. Quantitative and qualitative data were reported using descriptive statistical analysis and thematic analysis respectively.
Results Participants found group eConsent efficient, useful to hear questions from others and being in a group created a sense of togetherness. However, limited privacy, barriers to ask questions in a group and peer pressure can limit the use of group eConsent. 165 (46%) participants thought that group eConsent was also suitable to recruit participants with disease or conditions while 87 (24%) reported limitations with this method. The remaining participants suggested that applicability of group eConsent depended on the diseases or conditions of the study population and one-to-one conversation should always be available. Participants who had experience both one-to-one and group eConsent shared different preferred consent formats for future studies.
Conclusion and Relevance Group eConsent can be an effective tool for research recruitment with further optimisations to overcome the limitations raised by participants. Using webinars to providegeneral information about the study, followed by an individual session for each participant will retain the benefits of group eConsent and minimise the limitations it posed. This proposed setting will address the privacy questions and makes group eConsent easier to be implemented in many study populations.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

6ER-031 EXCLUSION OF PEOPLE LIVING WITH HIV FROM ONCOHAEMATOLOGICAL CLINICAL TRIALS WITH IMMUNE CHECKPOINT INHIBITORS

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Background and Importance Previous research highlighted that people living with HIV(PLWHIV) are frequently excluded from clinical trials (CT) aimed at cancer treatment with immune checkpoint inhibitors (ICI), even if HIV is well controlled. Scientific societies and regulators have issued recommendations to correct this, and real-life evidence supports that the use of ICI in PLWHIV appears to be safe. There is no recent data on whether this trend has changed.
Aim and Objectives To determine whether HIV infection is an exclusion criterion in oncohaematological CT involving ICI available at our centre.

Material and Methods Observational, single-centre, retrospective study, which included all oncohaematological CT whose experimental intervention involved the use of ICI initiated in a tertiary hospital from January 2018 to December 2022. Expansion studies were excluded. The following variables were collected: neoplasm, locations (unicentre/multicentre; national/international), ICI, intervention (monotherapy/combination), control (yes/no), phase, clinical context (adjuvant/neoadjuvant/locally advanced/metastatic/haematological malignancy with curative intent/haematological malignancy with palliative intent), intention (curative/palliative), inclusion criteria for PLWHIV (explicitly excluded/conditional inclusion/not mentioned) and, among conditional inclusion, conditions established (viral load/antiretroviral treatment/lymphocyte count). Data were extracted from clinicaltrials.gov, the EU Clinical Trials Register and the Spanish CT Register.

Results One hundred and twenty-six CTs were identified, of which 123 (97.6%) involved solid tumours. The most studied neoplasms were lung cancer (n=17; 13.5%), basket trials (n=16; 12.7%) and melanoma (n=14; 11.1%).CTs were mainly international (n=114; 90.5%) and multicentre (n=125; 99.2%). The intervention consisted of ICI combined with other agents (n=89; 70.6%), ICI monotherapy (n=25; 19.8%), and ICI dual therapy (n=22; 17.5%). Pembrolizumab was the most frequently studied ICI (n=34; 27.0%), followed by atezolizumab (n=22; 17.5%) and nivolumab (n=20; 15.9%). Seventy (55.6%) CT were controlled. Sixty-three were phase II (n=63; 50.0%), III (51; 40.5%), and I (n=12; 9.5%). Most were conducted in the metastatic setting (n=98; 77.8%) and with palliative intent (n=103; 81.7%).PLWHIV were explicitly excluded from 91 (72.2%), 24 (19.0%) did not mention HIV infection among their inclusion/exclusion criteria, and 11 (8.7%) allowed the inclusion of PLWHIV if certain conditions were met regarding viral load (n=6; 54.5%), antiretroviral treatment (n=8; 72.7%), lymphocyte count (n=6; 54.5%), and 3 (27.3%) stated adequate HIV control, without further detail.

Conclusion and Relevance PLWHIV are frequently excluded from oncohaematological CTs testing ICI.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-032 ADJUSTED INDIRECT COMPARISON OF CEMIPLIMAB IN COMBINATION WITH CHEMOTHERAPY VS IMMUNOTHERAPY ALONE IN THE FIRST-LINE TREATMENT OF METASTATIC NON-SMALL-CELL LUNG CANCER IN PATIENTS WITH PD-L1≥50%

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Background and Importance Cemiplimab with chemotherapy is licensed for the treatment of first line adult patients with locally advanced NSCLC who are not candidates for chemoradiation, or metastatic, expressing PD-L1≥1%. Cemiplimab alone has the same indication in patients expressing PD-L1≥50%. Pembrolizumab and atezolizumab are also indicated in metastatic stage in patients with PD-L1≥50%.

Aim and Objectives To know whether cemiplimab in combination with chemotherapy (ct) and mono-immunotherapy can be declared equivalent therapeutic alternatives (ETA).

Material and Methods A literature search was performed in MEDLINE-PubMed for phase III randomised clinical trials (CT)with similar population and duration. An adjusted indirect comparison (IC)was performed using Bucher's method (ITC calculator). The primary endpoint was overall survival in patients with PD-L1≥50%. Therapeutic alternatives were compared with cemiplimab monotherapy. The delta value (Δ), maximum clinically irrelevant difference, was taken as the value from the ESMO-MCBS Guidelines to consider substantial benefit, HR 0.70 and its inverse 1.43 . To declare them as ETA, the GENESIS-GHEMA guidelines were applied.

Results Data from CT against a common comparator, platinum-based chemotherapy, were included. The studies were similar, although the CT of cemiplimab-chemotherapy and cemiplimab included patients with stage IIIB, IIIC and IV, while the other CT only included stage IV; furthermore, the CT of cemiplimab excluded never-smokers (less than 100 cigarettes through life), and the small amount of never-smokers included on other monotherapy trials showed uncertain benefits. The following results were obtained: HR (cemiplimab vs cemiplimab+ct) 0.93 [95%CI 0.52–1.68] p 0.81; HR (cemiplimab vs pembrolizumab) 0.95 [95%CI 0.58–1.55] p 0.84; HR (cemiplimab vs atezolizumab) 0.97 [95%CI 0.59–1.60] p 0.89.

According to the ETA guidelines, cemiplimab+ct, atezolizumab, pembrolizumab and cemiplimab showed 'probable clinical equivalence'. Clinically relevant differences between them cannot be discarded, since the confidence intervals exceed the equivalence margins, but this occurs at both extremes, and they can be considered as alternatives with similar effectiveness. Cemiplimab+ct presents a comparative handicap on safety because of the toxicity of chemotherapy.

Conclusion and Relevance In this setting, atezolizumab, cemiplimab and pembrolizumab monotherapies can be positioned as ETA; their selection should be based on economic comparisons. Among the never-smoker subpopulation, the comparative effectiveness between immune-chemotherapy and mono-immunotherapy should be assessed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-033 ADJUSTED INDIRECT COMPARISON OF CEMIPLIMAB IN COMBINATION WITH CHEMOTHERAPY VS IMMUNOTHERAPY ALONE IN THE FIRST-LINE TREATMENT OF METASTATIC NON-SMALL-CELL LUNG CANCER IN PATIENTS WITH PD-L1≥1%

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Background and Importance Cemiplimab, pembrolizumab, atezolizumab ± bevacizumab, nivolumab + ipilimumab and durvalumab + tremelimumab in combination with chemotherapy, and nivolumab + ipilimumab, are licensed for the treatment of 1L adult patients with metastatic NSCLC expressing PD-L1≥1%.

Aim and Objectives To know if the combinations of immunotherapy and chemotherapy (ct) can be declared equivalent therapeutic alternatives (ETA).

Material and Methods Phase III randomised clinical trials (CT) with similar characteristics were searched in MEDLINE-Pubmed. An adjusted indirect comparison (IC) was performed using Bucher's method (ITC calculator). Overall survival outcomes in patients with PD-L1≥1% were taken as the primary endpoint. All the combinations were compared with cemiplimab-ct. Delta value (Δ), maximum clinically irrelevant difference, was taken as the value from the ESMO-MCBS Guidelines to consider substantial benefit, HR=0.70 and its inverse 1.43. To declare them as ETA, the GENESIS-GHEMA guidelines were applied.

Results Data from CT against a common comparator were included. The studies were similar, although the cemiplimab-chemotherapy CT included patients with stage IIIB, IIIC and IV, while the other CT included only stage IV; furthermore, some trials included only patients with squamous or non-squamous histology and others both. The following results were obtained: HR (cemiplimab-ct vs pembrolizumab-ct non-squamous histology) 0.82 [95% CI 0.55 – 1.22] p 0.34; HR (cemiplimab-ct vs pembrolizumab-ct squamous) 0.81 [95% CI 0.56 – 1.18] p 0.27; HR (cemiplimab-ct vs atezolizumab ±bevacizumab-ct non-squamous) 0.72 [95% CI 0.50 – 1.04] p 0.08; HR (cemiplimab-ct vs nivolumab-ipilimumab) 0.67 [95% CI 0.48 – 0.94] p 0.02; HR (cemiplimab-ct vs nivolumab-ipilimumab-ct) 0.74 [95% CI 0.51 – 0.94] p 0.12; HR (cemiplimab-ct vs durvalumab-tremelimumab-ct) 0.68 [95% CI 0.47 – 0.98] p 0.04.

Conclusion and Relevance According to the ETA guidelines, combinations of atezolizumab±bevacizumab, nivolumab-ipilimumab and pembrolizumab in combination with chemotherapy showed type C positioning 'probable clinical equivalence'. Nivolumab-ipilimumab and durvalumab-tremelimumab-chemotherapy showed type F positioning 'probably relevant difference'.

There are no statistically significant differences between cemiplimab-chemotherapy and the other approved combinations with the exception of durvalumab-tremelimumab-chemotherapy and nivolumab-ipilimumab in favour of cemiplimab-chemotherapy. Combinations of immunotherapy and chemotherapy do not meet strict criteria for (ETA) as there is uncertainty as to whether there may be clinically relevant differences.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

6ER-034 EFFICACY OF NEOADJUVANT TREATMENT WITH IMMUNE CHECKPOINT INHIBITORS IN NON-SMALL-CELL LUNG CANCER IN EARLY STAGES: A SYSTEMATIC REVIEW

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Background and Importance Immune checkpoint inhibitors (ICIs) are currently part of the standard treatment of non-small-cell lung cancer (NSCLC) in the context of adjuvant therapy. However, its use in neoadjuvant therapy (NAT), although relatively more recent, has encouraging potential.

Aim and Objectives To evaluate the efficacy of ICIs-based NAT in the early stages of lung cancer.

Material and Methods A systematic review was carried out through Medline, for articles published until August 2023.

The methods used were based the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). We searched for phase-2/3 randomised clinical trials (RCTs) that evaluated the efficacy of NAT with ICIs both in monotherapy and in combination with chemotherapy NSCLC in stages I-III.

Two reviewers independently assessed the eligibility of each study. To evaluate their quality, the Grades scale was used.

Results 10 studies met the inclusion criteria: two were phase 3, six used PD-1 inhibitors and four used PD-L1 inhibitors. Moreover, three studies continued adjuvant treatment with ICIs.

NADIM trial studied nivolumab+chemotherapy before surgery and obtained a progression-free survival (PFS) of 77.1% and a pCR rate of 63.4%. Subsequently, in **NADIM II**, patients were randomised to receive nivolumab+chemotherapy or chemotherapy alone, showing a better pCR rate (36.2% vs 6.8%) and better PFS with nivolumab.

In **CheckMate 816**, nivolumab+chemotherapy resulted in a higher median event-free supervenience (EFS) than chemotherapy alone (31.6 vs. 20.8 months) as well as a higher pCR rate.

The NEOSTARstudy showed a higher pCR rate of the nivolumab+ipilimumab combination compared to nivolumab monotherapy Other studies, such as **Shue et al**. using atezolizumab +chemotherapy, or **LCMC3**, also supported the efficacy of neoadjuvant immunotherapy (NAIT), with improvements in response rates.

KEYNOTE 671 evaluated pembrolizumab+chemotherapy showing better EFS and RCp in the pembrolizumab group compared to placebo use.

Finally, **PRINCESS** and **IONESCO** studied the use of atezolizumab and durvalumab, respectively, and did not provide favourable results.

Conclusion and Relevance These studies support the use of NAIT in patients with resectable NSCLC, with promising results in terms of survival and pCR. Currently, nivolumab is used in resectable lung cancer according to CheckMate 816.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

6ER-035 ABSTRACT WITHDRAWN

Results Seven studies met the inclusion criteria: four included patients with triple-negative histology, one included both triple-negative and hormone receptor (HR) positive/human epidermal growth factor 2 (HER-2) negative receptors. One included HER-2 positive patients and another included patients with Luminal B-like (LumB-like) molecular histology.

3 studies used PD-1 inhibitors and 4 used PD-L1 inhibitors. Additionally, 3 studies continued adjuvant treatment with ICIs. In the GeparNuevo trial, durvalumab improved survival despite a modest increase in pCR.

In Keynote-522, chemotherapy+pembrolizumab resulted in increased pCR and event-free survival in patients with triple-negative breast cancer (TNBC).

The I-SPY2 study explored multiple treatments in high-risk BC, showing benefits of pembrolizumab in patients with different molecular subtypes (HER-2 negative, HR positive/HER-2 negative and TNBC)

In IMpassion031, chemotherapy+atezolizumab increased the pCR rate in TNBC patients. These results were consistent with NeoTRIP.

For HER-2 positive BC, NeoPATH suggested that immunotherapy-chemotherapy combination could be beneficial, especially in HR negative and PD-L1 positive patients.

In the GIADA-trial evaluating nivolumab in LumB-like BC, the hypothesis for pCR rate was not met.

Conclusion and Relevance Although immunotherapy shows promising advances in NAT, especially in TNBC, since it is the most immunogenic subtype, more research is needed to better understand its mechanisms and find predictive biomarkers of response. Currently, pembrolizumab is used in TNBC according to Keynote-522.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

6ER-036 EVALUATION OF THE EFFICACY OF NEOADJUVANT TREATMENT WITH IMMUNOTHERAPY IN EARLY-STAGE BREAST CANCER: A SYSTEMATIC REVIEW

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Background and Importance Immunotherapy is used in advanced cancers, but its use in early stages is a new area of study. Neoadjuvant therapy (NAT) with immune checkpoint inhibitors (ICIs) could be advantageous, stimulating the immune response before surgery.

Aim and Objectives To evaluate the efficacy of ICIs-based NAT in the early stages of breast cancer (BC).

Material and Methods This study followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) methodology. Pubmed was consulted to identify all clinical trials published between January 2018-August 2023 that included patients with resectable early-stage BC, who were treated with ICIs in monotherapy or combined with chemotherapy prior to surgery.

Only those reporting efficacy data, such as pathological complete response (pCR) and disease-free survival were included, alongside phase-2 and phase-3 trials. Article selection and data extraction was carried out by peer review and the evaluation of discrepancies was done by a third party.

6ER-037 PHARMACO-UTILISATION OF IBRUTINIB IN CLL: A SINGLE CENTRE STUDY

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Background and Importance Chronic lymphocytic leukaemia (CLL) is a B-cell neoplasm characterised by the clonal expansion of mature B lymphocytes. Ibrutinib, an irreversible inhibitor of Bruton tyrosine kinase, is prescribed for CLL treatment at all stages. Being an oral treatment, strict adherence is closely linked to clinical outcomes.

Aim and Objectives The study aims to measure ibrutinib adherence and persistence in real-world CLL patients, and analyse their correlation with patient demographics, clinical factors, and genetics in a Northern Italian University Hospital.

Material and Methods This retrospective study included CLL patients aged 18 or older who received ibrutinib monotherapy for at least 6 months (observed between 2016 and 30/06/2023). Prescription data came from electronic prescribing software, and clinical information was sourced from AIFA Registries. Adherence was assessed using the ratio of received to prescribed daily doses (RDD/PDD), and persistence was determined by the average duration of therapy before discontinuation (in days). Patients with a RDD/PDD ratio $\geq$ 0.9 were considered adherent.

Results Among the 42 subjects in this study, the average ibrutinib adherence rate was 0.75 (ranging from 0.45 to 1).There were no notable differences in adherence rates based on demographic or clinical characteristics. Interestingly, a majority of patients (57%) with unfavourable cytogenetics had an RDD/PDD ratio below 0.9. Among patients who experienced adverse reactions, 86% belonged to the low adherence group, while seven subjects with disease progression were evenly split between the two adherence groups. Out of the20 patients who discontinued treatment, only one had a favourable cytogenetic profile (IGHV-mutated; noTP53 mutation or del(17p)). The average time to discontinuation was shorter for subjects who experienced toxicity (976 days) compared to those who had disease progression (1312 days).
Conclusion and Relevance In patients with CLL treated with ibrutinib, mean adherence was lower than rates seen in clinical trials. Apparently, demographic and clinical characteristics did not influence treatment adherence. However, a lower adherence rate was observed in higher-risk groups, and nearly all patients who discontinued treatment exhibited an unfavourable cytogenetic profile. It's worth noting that the connection between high-risk cytogenetics and poor adherence has not been explored in literature, highlighting the need to investigate this relationship in a larger patient sample.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

6ER-038 ELABORATION OF A COMPETENCY FRAMEWORK FOR PATIENTS UNDERGOING PERCUTANEOUS CLOSURE OF PATENT FORAMEN OVALE OR ATRIAL SEPTAL DEFECT

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Background and Importance Patent foramen ovale (PFO) and atrial septal defect (ASD) are heart diseases characterised by persistent communication between the two atria. Percutaneous closure of PFO or ASD is required depending on the patient and is performed by interventional cardiologists. It requires the use of an occluder which is an implantable medical device (IMD). It ensures a complete closure of the interatrial shunt. After the intervention, there is still a risk associated with the procedure and drug treatments. These patients have a short hospital stay. Caregivers do not necessarily have the time to teach their patients the skills they need to live safely with their prosthesis in their daily lives when they return home.
Aim and Objectives The aim of this project is to elaborate a competency framework for patients undergoing percutaneous closure of PFO and ASD. This will serve as a support for the development of educational tools.
Material and Methods Multicentre meetings with healthcare professionals (pharmacists, interventional cardiologists, qualified nurses) from two university hospital centres and one patient were held to develop a competency framework. An information sheet and an interview guide were then produced to help patients acquire the skills considered a priority in the management of their disease. Interviews were conducted with 19 patients over a 3-month period to evaluate the interview guide and the first version of an information sheet.
Results The competency framework includes 89 skills for patients with FOP and 92 for patients with CIA. All patients surveyed were satisfied with the interviews and the first version of the information sheet. Most patients preferred to have the interview before the intervention, as it reassured them and gave them confidence for the rest of their treatment.
Conclusion and Relevance This competency framework could serve as a support for the development of therapeutic patient education programmes for these patients. Hospital pharmacists, who are responsible for the proper use of healthcare products including drugs and medical devices, could play a beneficial role in these programmes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest.

6ER-039 PAIN MANAGEMENT: OPIOID USE IN HOSPITALS

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Background and Importance Adequate pain control is a basic and unquestionable human right. Opioids are the most potent pharmacological treatment for a variety of pains. Opiod use is always of interest. due to their potential overuse and abuse and the contrary limited access to them. Hospital care data on opioid utilisation is scarce in the literature and no data is available for our country.
Aim and Objectives Therefore we aimed to analyse opioid utilisation in hospitals nationwide between 2015 and 2021.
Material and Methods Population based drug utilisation sales data were obtained on analgesics (ATC code: N02A). Utilisation scale and trends were calculated based on the WHO defined Anatomical Therapeutic Chemical Classification/Defined Daily Dose (ATC/DDD) methodology. Aggregated utilisation data were standardised for 100 patient-days (i.e. DDD per 100 patient-days). National and regional level analyses were performed.
Results Total opioid values ranged between 8.12 to 8.86 DDDs per 100 patient-days in various study years. Oral administration of opioid analgesics was dominant with relative share of 53.9% in 2015 and 60.1% in 2021. Tramadol, fentanyl, morphine, and nalbufine were the most used opioid analgesics in 2015 with 62.9%, 22%, 6.8% and 2.5% relative share while in 2021 the top agents were tramadol (42.3% share), fentanyl (25.9%) and then two tramadol combinations on the 3rd and 4th place in the ranking. Large interregional differences were detected (5.7 vs 17.2 DDD per 100 patient-days) with maximum/minimum ratio of 3.03 in the final year of analysis.
Conclusion and Relevance Trends of opioid utilisation in national hospitals has not changed over time, with the dominant use of weak oral opioids. Regional disparities are substantial.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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6ER-040 A TOOL PROPOSAL FOR IDENTIFYING THE RISK OF POLYPHARMACY IN NURSING HOMES FOR ELDERLY PEOPLE

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Background and Importance The new model of pharmaceutical care in nursing homes consists of creating drug deposits linked to hospital pharmacy services where hospital pharmacists have the responsibility to provide pharmaceutical care. Besides, polypharmacy is commonly defined as the number of medications taken concurrently using standard cut-offs, but several studies have highlighted the need for multidimensional assessment.
Aim and Objectives The aim of this study is to identify polymedicated residents at risk. For this goal, it is proposed to design a score based on medication indicators.
Material and Methods A score is designed based on demographic data and hazardous drugs for elderly people: age, sex, number of total and chronic prescriptions (Np, Npc), number of prescriptions for: proton pump inhibitors (PPI), cardiovascular drugs (CRZ), vitamin K antagonists (VKA), oral anticoagulants (ACOD), platelet antiaggregant [IGG1] (PAA), neuroleptics (NLP), benzodiazepines (BZD), antidementia drugs (DEM), antidepressants (DEP), opioids (OPI), drugs with high and low anticholinergic effect (Aca, Acb) and concomitant use of NLP, BZD, DEP and DEM (POKER). The weight of each indicator is adjusted according to bibliography and expert opinion.
Results The tool is applied for a population of 3,010 people from 25 centres. More than 90% of the population obtains a result less than 0.6 (2,731 people), 9.5% of the population obtains a result more than 0.6 (288 people) and 1.3% more than 0.9 (39 people).

A practical example: two people with the same number of total prescriptions (15) and chronic prescriptions (12) but with differences in the number of prescriptions per group, have a different score: >0.9 the first one and <0.5 the other one.
Conclusion and Relevance This tool could give us a score that allows to distinguish the risk associated with polypharmacy based on the amount of prescriptions and prescripted hazardous drugs. In the future, it will be necessary to design a study that collects events prospectively, so each indicator could be assigned a weight corresponding to its risk.

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6ER-041 ROLE OF CHECKPOINT INHIBITORS POST-ALLOGENEIC HAEMATOPOIETIC STEM CELL TRANSPLANTATION IN ACUTE MYELOID LEUKAEMIA

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Background and Importance Immune checkpoint inhibitors (ICI) post-allogeneic haematopoietic stem cell transplantation has emerged as a promising strategy in the treatment of acute myeloid leukaemia (AML). AML is a type of blood cancer characterised by an uncontrolled proliferation of immature myeloid cells in the bone marrow. Allogeneic haematopoietic transplantation is a treatment for AML in high-risk cases or in cases of recurrence after intensive chemotherapy, but it can lead to complications such as graft-versus-host disease (GVHD) and disease relapse.
Aim and Objectives The aim was to know the current situation of ICI post allogeneic haematopoietic stem cell transplantation.
Material and Methods A qualitative systematic review has been developed.

We systematically searched in PubMed, Google Scholar and Scopus. Articles was applied to the following review, 'Immune *checkpoint inhibitors*' AND/OR 'LMA', '*Immune checkpoint inhibitors*' AND/OR '*post hematopoietic allogeneic transplantation*', '*LMA*' AND/OR '*post hematopoietic allogeneic transplantation*'.
Inclusion criteria articles published in the last 5 years and articles that provided conclusive results on the use of ICI.
Exclusion criteria articles that, meeting the inclusion criteria, were inconclusive due to lack of data, reproducibility or no significant differences between treatments.
Results Ninety-four articles that could be analysed to fulfill the purposes of this work have been found, of which nine met the inclusion and exclusion criteria.

Various studies have highlighted the importance of immune checkpoint inhibitors in the post-allogeneic haematopoietic transplant, which offer a new therapeutic alternative in the treatment of AML, their ability to improve the immune response against leukaemic cells and regulate the GVHD response offers hope for better survival and quality of life of AML patients undergoing post-allogeneic haematopoietic transplantation.
Conclusion and Relevance Immunotherapy based on ICI in combination with intensive chemotherapy, hypomethylating agents, or other targeted therapies is gaining interest in the treatment of haematologic malignancies such as AML. However, the results obtained from clinical trials are modest and limited by both the type of design and the phase of the trial. The prospective study of responses to this type of treatments according to different biological profiles could provide strategies to identify those patients who may benefit from ICI.

More studies are needed to determine its long-term efficacy and to establish clear guidelines for its clinical use.

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6ER-042 THE DISASTER PREPAREDNESS AND MANAGEMENT OF HEALTHCARE PRACTITIONERS: A SYSTEMATIC REVIEW OF THE ASSESSMENT INSTRUMENTS

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Background and Importance Disasters have been traditionally considered as one of the main threats to healthcare delivery worldwide, with no country being immune to them. The delivery of healthcare services during disasters is the responsibility of healthcare practitioners (HCPs), who should ideally be prepared to manage disasters. Therefore, it is important to accurately assess the disaster preparedness and management of HCPs.

Aim and Objectives The aim of this systematic review is to identify and evaluate the psychometric properties of disaster preparedness and management instruments that were developed for assessing the disaster preparedness and management of HCPs.

Material and Methods A systematic review search strategy was utilised to identify the relevant original research articles, utilising PubMed, ProQuest Public Health, and CINAHL databases. The key concepts used were: disasters, health personnel, preparedness, management, and questionnaire. The identified instruments in the included articles were summarised according to their measurement scope/context, psychometric properties, and strengths and limitations. Data about the validity and reliability of the included instruments were summarised according to content validity, response process, internal structure, relation to other variables, and consequence validity.

Results The reviewed articles possessed minimal quality for validity and reliability evidence. Most retrieved instruments have undergone minor psychometric evaluations, predominantly emphasising the 'content' and 'internal structure' validities. The most used instrument was the Emergency Preparedness Information Questionnaire (EPIQ), while the most valid and reliable instruments were the Provider Response to Emergency Pandemic (PREP) and the Korean version of the Disaster Preparedness Evaluation Tool (DPET). The key domains measured in the included instruments were knowledge, training, and willingness to report to work during disasters.

Conclusion and Relevance The findings of this review highlighted the sacristy of adequately validated assessment instruments that can be employed to assess disaster management and preparedness of HCPs. This calls for future collaborative research initiatives to design and adequately validate disaster management and preparedness instruments in order to evaluate and ultimately improve disaster management and preparedness of HCPs.

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6ER-043 DEVELOPING AND VALIDATING A DISASTER MANAGEMENT ASSESSMENT TOOL FOR HEALTHCARE PRACTITIONERS

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Background and Importance Over the past five decades, disasters have become more frequent, making it crucial for healthcare practitioners, including pharmacists, to be well-prepared for disaster management. However, there is a sacristy of adequately developed and tested assessment tools that can be employed to examine disaster preparedness amongst HCPs from different healthcare disciplines and in different disaster situations.

Aim and Objectives To develop and evaluate the Disaster Management Assessment Tool for Health Care Practitioners (DMAT_HCP).

Material and Methods DMAT_HCP was developed based on the four stages of the 'disaster management framework' and a literature review of similar previously validated tools. Content validity was assessed through two rounds of review by nine and five experts, whereas face validity was assessed by 11 HCPs. DMAT_HCP was tested on 107 HCPs from different health disciplines and settings to evaluate the structural (factor analysis) and construct (convergent and divergent) validities as well as internal consistency reliability. Statistical analysis was performed using Stata 17 software.

Results DMAT_HCP comprised five Likert scales that assess the perceptions of HCPs for knowledge, attitude, practice, willingness to continue practicing duties, and organisation-based management during disaster situations. The content validity indices indicated that all scales demonstrated satisfactory relevance and clarity, yet further improvements were made following the review of HCPs. Factor analyses revealed models that all items in each scale loaded significantly on their respective factors and demonstrated a good fit to data. Evaluation of construct validity and reliability of DMAT_HCP revealed that each scale item can adequately measure the constructs they are designed to measure, and had excellent internal consistency, respectively.

Conclusion and Relevance This study established that DMAT_HCP is a conceptually and methodologically valid and reliable tool that is relevant to various health disciplines in responding to the challenges of disasters. This use of this tool will allow stakeholders to highlight key areas for improvement and innovation, optimise training programmes, resource allocation, and strategic planning to better prepare healthcare professionals for disasters.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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