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National prize winners' abstracts

NP-001 DEVELOPING AN IN-HOUSE COMPREHENSIVE MEDICATION REVIEW TRAINING PROGRAMME FOR CLINICAL PHARMACISTS IN A FINNISH HOSPITAL PHARMACY

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10.1136/ejhpharm-2025-eahp.1

Background and Importance Long-term continuing education programmes have been a key factor in shifting towards more patient-centred clinical pharmacy services.[1] Especially competences required for conducting medication reviews have been seen as core skills in conducting clinical pharmacy services. The increased demand for patient-centred clinical pharmacy services in secondary and tertiary care and the need to precisely obtain the special expertise for the Helsinki University Hospital (HUS) Pharmacy professional setting (university teaching hospital) led to the idea of developing a tailored in-house training programme for comprehensive medication reviews.

Aim and Objectives The aim of this project was to develop an in-house Comprehensive Medication Review Training Programme (CMRTP) for HUS Pharmacy. A commercial Finnish accreditation training programme for collaborative comprehensive medication reviews was benchmarked and modified to meet the needs of a university teaching hospital setting.

Materials and Methods The CMRTP was piloted in 2016 and further developed during the years 2017–2020. Feedback from training sessions and changes in the hospital environment were addressed in the development process.

Results The current programme focuses on developing the special skills and competencies needed in comprehensive medication reviews (CMRs), including interprofessional collaboration and pharmacotherapeutic knowledge.[2] The programme consists of two modules: (1) Pharmacist-Led Medication Reconciliation, and (2) CMR. The CMRTP includes teaching sessions, self-learning assignments, medication reconciliations, medication review cases, CMRs, a written final report, and a self-assessment of competence development. The 1 year program is coordinated by a clinical teacher. The programme is continuously developed based on the latest guidelines in evidence-based medicine and international benchmarking in cooperation with the University of Helsinki.

Conclusions and Relevance With the CMRTP, we have adopted a more patient-centred role for our clinical pharmacists and considerably expanded the services. This programme may be benchmarked in other countries where the local education system does not cover clinical pharmacy competence well enough and in hospitals where the clinical pharmacy services are not yet very patient-oriented.

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NP-002 IMPACT OF BLOOD SAMPLE HANDLING DURING 99MTC-CERETEC LEUKOCYTE LABELLING ON IMAGE QUALITY AND INTERPRETATION

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10.1136/ejhpharm-2025-eahp.2

Context and Objective In vitro labelling of leukocytes with 99mTc-HMPAO is a haematological test performed and optimised in specialised radiopharmacies in some university hospitals. It is used to differentiate between infection on implanted devices and inflammation in cases of pain. However, it requires high-quality biological samples. Several factors, including those related to the patient and healthcare professionals, affect the outcome. This study aims to establish a link between sample quality and image quality to improve our practices and patient care.

Materials and Methods We first established criteria to assess blood sample quality, such as the duration of collection, the type of equipment used, the puncture site, sedimentation time, hemolysis, and cell viability tests, alongside an associated score (≤2: excellent, 3≤ score ≤5: average, ≥6: poor). We then defined image quality criteria in the early phase, based on spleen/liver (S/L) activity ratios measured during imaging (a ratio <130% indicating good image quality, 130%–150% moderate quality, and >150% poor quality). Lastly, we statistically compared S/L ratios between two groups: good vs. average/poor samples.

Results Out of 23 samples, 18 were rated 'excellent,' two 'average,' and three 'poor.' Among the 'excellent' samples, 17 had S/L ratios <130%, corresponding to good image quality, while one had a ratio >150%. Among the five 'average/poor' samples, one had an S/L ratio <130%, one between 130%–150%, and three >150%. A significant difference ($P<0.05$) was found between the good and average/poor sample groups.

Conclusion/Discussion Our results suggest that sample quality affects image quality. However, certain biases, such as the small sample size and the low proportion of 'average/poor' samples (5/23), should be considered. The choice of quality criteria and scoring system may need refinement. Additionally, the patient's cell condition at the time of testing and the proximity of the suspected infection to organs like the liver and spleen may influence the results. A larger, long-term study could help develop optimal sampling recommendations.

NP-003 LEARNING PROGRESS OF ARTIFICIAL INTELLIGENCE IN ANSWERING CLINICAL-PHARMACEUTICAL QUESTIONS

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10.1136/ejhpharm-2025-eahp.3

Background An initial survey on the performance of ChatGPT 3.5 in drug information revealed its performance and risks. To investigate the dynamics in the development of large language models, the analysis was repeated with ChatGPT 4 in January 2024.

Research Question How has the performance of ChatGPT 4 changed in terms of response quality and safety in drug information?

The initial sample of questions was answered again by ChatGPT 4. The quality of the answers was assessed in a structured consensus by hospital pharmacists based on the categories of content, patient management and risk and compared with the answers from ChatGPT 3.5.

Results The content quality of ChatGPT 4 improved compared to its predecessor. Out of the 50 questions, ChatGPT 4 answered more questions correctly 38% (n=19) compared to 26% (n=13) and significantly fewer incorrectly (12%, n=6 compared to 38%, n=19), but these were less often feasible. Management was feasible for 52% (n=26) of the questions and impossible for 16% (n=8). For ChatGPT 3.5, the corresponding values were 72% (n=36) and 14% (n=7). We found 10% (n=5) of ChatGPT 4 responses resulted in a high patient risk and 52% (n=26) in no patient risk compared to 14% (n=7) and 46% (n=23) for ChatGPT 3.5. Overall, the number of responses that were correct, feasible and without risk improved from the initial 26% (n=13) to 36% (n=18) for ChatGPT 4. Compared to ChatGPT 3.5, ChatGPT 4 responses were longer on average (217.6 to 112.6 words) and the number of referenced responses increased (8% to 0%).

Discussion ChatGPT 4 showed improved performance compared to the previous version, particularly in terms of content and risk. The increased word count does not necessarily correlate with improved practicability. Nevertheless, an assessment by specialist personnel is essential for safe advice.

NP-004 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

Adina Fésüs, Phiona Baluku, Éva Sipos, Sándor Somodi, Enikő Berczi-Kun, István Lekli, Ildikó Bácskay, Ria Benkő, Attila Vaskó. *Medical and Health Science Centre of University of Debrecen, Faculty of Pharmacy, Debrecen, Hungary*

10.1136/ejhpharm-2025-eahp.4

Background Community-acquired pneumonia (CAP) is still one of the leading causes of death worldwide. Implementation of the Antibiotic Stewardship Programme (ASP) aimed to improve the correct and responsible antibiotic use by encouraging guideline adherence.

Objective 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.

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 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, 30-day mortality), antibiotic exposure and direct costs were compared between the two periods. Fisher's exact test and t-test were applied to compare categorical and continuous variables, respectively.

Results Significant p values were defined as below 0.05. Significant improvement in overall CAP guideline adherence (30.2%), sequential therapy (10.5%) and significant reduction in the total duration of antibiotic therapy (13.5%) were observed. Guideline non-adherent combination therapies with metronidazole decreased significantly by 28.1%. Antibiotic exposure decreased by 23.6% leading to a significant decrease of direct costs (33.2%). Moreover, ASP had benefits on clinical outcomes, length of stay decreased by 13.5% and 30-day survival increased by 5.9%.

Conclusion ASP may play an important role in optimising empirical antibiotic therapy in CAP having a sustained long-term effect.

NP-005 PENICILLIN ALLERGY AWARENESS AND DE-LABELLING

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10.1136/ejhpharm-2025-eahp.5

Background and Importance Approximately 10% of inpatients are labelled as penicillin allergic but the vast majority have not experienced a true allergic reaction. Having a label of penicillin allergy results in patients receiving sub-optimal alternative antibiotics and this may lead to poorer outcomes and increased costs. It is therefore beneficial to assess whether patients have experienced a true allergic reaction and consider removing the allergy label in those that have not.[1]

Aim and Objectives To introduce a penicillin allergy de-labelling service in Cavan and Monaghan Hospital.

To increase the documentation of drug and nature of reaction for patients with a self-reported penicillin allergy in the medication allergy assessment box by 10% over a 6-month period.

Materials and Methods The Antimicrobial Stewardship (AMS) Pharmacists adapted the Scottish Antimicrobial Prescribing Group (SAPG) penicillin allergy toolkit[2] complying with local governance requirements. This is designed to be used by non-allergy specialists and supports the identification and removal of penicillin allergy labels in patients who do not have a history of Type 1 or 4 hypersensitivity reactions.[1] We undertook education on the toolkit and on penicillin allergy assessment with staff and we support the process. It is also available on our AMS Application.

Results

Abstract NP-005 Table 1 Baseline audit; Oct 2022 and re-audit in July 2023

Audit	2022 (*n=67*)	2023 (*n=128*)
Allergy Box Completion	80%	100%
Documentation of Allergy Type	Antimicrobial: 78% Penicillin: 60%	Antimicrobial: 77% Penicillin: 75%
Type of reaction documented (penicillin)	14%	27%
% suitable for de-labelling	43%	53%

Record of patients assessed (18 October 2022 to 8 January 2024): 49 patients screened, 30 deemed eligible for de-labelling, of these 27 were successfully de-labelled.

Conclusion and Relevance There is an increased knowledge of how to assess penicillin allergy and we are de-labelling patients of penicillin allergy resulting in many being able to receive narrower spectrum/effective antimicrobials. We have incorporated this into our role and levels of staff engagement are improving with ongoing education and support. The study has been presented at national forums and is now being undertaken in other hospitals. We have also presented our results to the national Antimicrobial Resistance and Infection Control (AMRIC) Team who will hopefully implement this for use nationally.

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NP-006 PREVENTION MEASURES AGAINST *CANDIDA AURIS* DIFFUSION IN NOCOSOMIAL SETTINGS

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10.1136/ejhpharm-2025-eahp.6

Background and Importance *Candida auris (C. auris)* is a multiresistant yeast, which can colonise immunocompromised patients, causing invasive infections. Assuming its natural propension into developing biofilm, it can rapidly adapt to inert surfaces in hospital environments.

Aim and Objectives Our objective is to identify proper prevention measures to be applied in nosocomial settings in order to counteract its diffusion, finding the most efficient disinfectants and creating guidelines to contrast *C. auris* related infective emergencies.

Materials and Methods The sensitivity of the following disinfectants was evaluated in vitro on clinical and environmental strains of *C. auris*: 1) quaternary ammonium in ethyl alcohol; 2) polyesanide; 3) sodium hypochlorite, sodium hydroxide, sodium carbonate and sodium chloride; 4) phenols. Disinfectants have been used following manufacturer instructions. Molecules efficacy was tested by agar well diffusion method. In particular, 90 mm diameter dish containing agarose soil with Sabouraud were contaminated with *C. auris* strains isolated from a colonised patient, the environment and American Type Culture Collection (ATCC) standard strain. Then, on the seeded soils, 100 µl of each disinfectant was added to 10 mm diameter discs. After incubation at 37°C for 24/48 hours, the diameters of inhibition growth zones were measured. A growth zone of >14 mm diameter was interpreted as effective.

Results All the tested disinfectants were efficient, with a significant growth decrease of *C. auris* with the following results: 1) quaternary ammonium: sensitive - inhibition diameter of 26 mm; 2) polyhexanide: sensitive - inhibition diameter of 17 mm; 3) sodium hypochlorite, sodium hydroxide, sodium carbonate and sodium chloride: sensitive – inhibition diameter of 50 mm; 4) phenols: sensitive – inhibition diameter of 26 mm. No significant difference was found in the sensibility between the clinical strain and the environmental one.

Conclusions and Relevance The highest inhibition was achieved with the hypochlorite disinfectant, followed by quaternary ammonium salt. These results showed the availability of many effective molecules on *C. auris* strains, simplifying the periodic disinfectant replacement to prevent resistance from genetically predisposed strains.

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Conflict of Interest No conflict of interest.

NP-007 INFANT BOTULISM – EXPERIENCE OF THREE CASE REPORTS IN A PAEDIATRIC HOSPITAL

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10.1136/ejhpharm-2025-eahp.7

Background and Importance Infant botulism (IB) is a potentially life-threatening disorder that is caused by the ingestion of Clostridium botulinum spores, that consequently colonise and produce neurotoxins in the colon. IB occurs in children younger than 12 months, being more frequent in children younger than 6 months. The initial symptoms are constipation in 90%of cases, followed by neuromuscular paralysis, which begins with the cranial nerves and progresses to the peripheral and respiratory muscles. Clinical diagnosis is made through laboratory identification of the toxin or microorganisms in the faeces. Treatment is carried out after hospitalisation, with supportive measures, and should begin as soon as the diagnosis is suspected. Specific treatment is carried out with human botulism immune globulin (BIG-IV) and the earlier it is administered, the more effective it is and the lower the mortality rate.

Aim and Objectives Presentation of three cases of IB in a paediatric hospital and description of the procedures leading to their resolution.

Materials and Methods Admission of three infants with IB in three different years (2009, 2022 and 2023), aged less than or equal to 6 months. During the respective hospitalisations and after clinical suspicion of IB, the California Department of Health Services world reference centre was contacted to obtain guidelines for acquiring BIG-IV, since botulinum antitoxin from the national strategic reserve (RENAB) is only indicated from 12 months of age. After obtaining the appropriate authorisations from the Pharmacy and Therapeutics Committee, the hospital's Board of Directors and INFARMED, as well as finalising the administrative procedures, the process of sending the medication to Portugal was set in motion.

Results Clinical improvement in all three cases after the administration BIG-IV.

Conclusion and Relevance The administration of BIG-IV should be carried out as early as possible, as soon as there is clinical suspicion of infant botulism. Although RENAB has been set up to provide equine botulinum antitoxin (DGS Guideline 001/2020 of 16/01/2020), it is not indicated for children under 1 year of age, so it is essential to create a National Reserve that includes BIG-IV indicated for this age group.

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NP-008 COMPATIBILITY OF INTRAVENOUS MEDICATIONS ADMINISTERED VIA Y-SITE

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10.1136/ejhpharm-2025-eahp.8

Background and Importance Intravenous administration is the most common method of drug delivery in intensive care units.[1] Critically ill patients often have limited vascular access, necessitating the administration of multiple medications into the same lumen of the vascular catheter, which increases the risk of incompatibilities. The administration of incompatible medications can have serious consequences for the patient (treatment failure, microembolism, increased toxicity of the drug). For Y-site infusion, the drugs must be both physically and chemically compatible. There is often insufficient information on drug compatibility and where it exists, it is difficult to interpret.[2]

Aim and Objectives The aim of the work was to create a table of compatibilities for Y-site administration of intravenous drugs used in our hospital.

Materials and Methods In collaboration with nurses, we identified the most used medications administered by continuous infusion. The evaluation of compatibility was based on an extensive literature review, included SmPC, ASHP Injectable Drug Information, the Stabilis database and published articles. Due to limited published data, experimental *in vitro* compatibility testing was performed for several medications. The physical compatibility was assessed by mixing two drugs in 1:1 ratio at the concentrations used in clinical practice in our hospital in duplicates. Mixture was visually compared to the diluent solution using black and white backgrounds (Ph. Eur.2.9.20), immediately after mixing and 10 minutes later. Incompatibility was determined if any of the following occurred: precipitate formation, colour change, cloudiness of the solution.

Results A total of 30 drugs in 435 combinations were evaluated. Based on the literature review, we were able to identify 108 compatible, three incompatible mixtures of two drugs administered via a Y-site and 21 compatible mixtures only under certain conditions. Experimental *in vitro* testing was performed for 14 drugs in 67 combinations. We confirmed 59 compatible and eight incompatible mixtures, most often in combination with amiodarone and hydrocortisone.

Conclusion and Relevance As a result of this project an institutional guideline titled 'Compatibility of intravenously administered drugs via Y-site' was implemented in our institution. The purpose is to standardise practices across various departments of the hospital and ensure correct and safe Y-site administration.

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NP-009 DEVELOPMENT AND VALIDATION OF A POPULATION PHARMACOKINETIC MODEL OF TEICOPLANIN IN ADULT PATIENTS WITH HAEMATOLOGIC MALIGNANCIES

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10.1136/ejhpharm-2025-eahp.9

Background and Importance Teicoplanin is a widely used antibiotic in patients with haematologic malignancies (HM); however, a population pharmacokinetic (popPK) model for these patients is not available.

Aim and Objectives To develop a popPK model for teicoplanin in adult patients with HM and validate its predictive capacity for individualising dosages.

Materials and Methods Prospective and multidisciplinary study conducted from February 2021 to December 2023. Adult patients with HM undergoing teicoplanin treatment were included. Two-thirds of the patients were assigned to the development of the popPK model, and one-third to its validation.

All patients received an initial intravenous dose of 600 mg/12 h, and the dose was subsequently optimised through teicoplanin plasma concentrations (TPC) monitoring.

The PopPK model was developed using a pharmacostatistical approach based on nonlinear mixed-effects models with NONMEM v7.3 and the FOCEI method. Predictive accuracy was calculated using the mean prediction error (MPE), and precision using the mean absolute prediction error (MAPE). A visual predictive check (VPC) was performed to assess model performance. Results were processed using R software v4.3.2.

Results A total of 151 patients (65 females) were included, 100 assigned to the development group and 51 to the validation group. Median (range) age was 62 (17–87) years, and total body weight was 68 (41.5–130) kg. A total of 263 samples were analysed, with a mean (SD) TPC of 14.27 (6.81) µg/mL. The characteristics of both groups were well balanced.

The pharmacokinetics were characterised using a one-compartment model with first-order elimination. The volume of distribution (Vd) was estimated at 92L, and clearance (CL) was modelled by the following equation:

CL(L/h)= 1.28*[1–0.01*(AGE–62)]*[(eGFR/92)^0.4]*[(Adjusted ideal weight/61)^3,2]

Where Adjusted ideal weight (Kg)= ideal weight+ (total weight– ideal weight)*0.25; AGE in years; eGFR= estimated glomerular filtration rate using CKD-EPI.

External validation showed adequate accuracy and precision, with MPE and MAPE of 5.2% (95% CI: −15.2–39.3%) and 13.0% (95% CI: 0.8–39.3%), respectively. VPC graph confirmed the model's predictive ability.

Conclusion and Relevance A PopPK model was developed that characterises the kinetic behaviour of teicoplanin in HM patients, which included adjusted ideal weight, age and eGFR as factors influencing its clearance.

The model predicts TPC with adequate precision and accuracy, making it a useful tool for optimising teiclopanin dosage.

Introductory statements and governance

1ISG-001 USE OF A GOVERNMENT DIGITAL TOOL IN DRUG EVALUATION FOR HOSPITAL PHARMACIES

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10.1136/ejhpharm-2025-eahp.10

Background and Importance The National Pharmacy and Medicine Institute implemented in 2015 a Digital Assessment Decision Support Tool (SiNATS) to maximise health gains and sustainability, monitor drug use and its equitable access, based in a pharmacotherapeutic/economic evaluation leading to a Public Financing Report (RAFP) that grants Early Access to Medicines (PAP).

Aim and Objectives To characterise drug requests (DR) evaluated by SiNATS in hospital setting.

Material and Methods A 2-year retrospective study was conducted from 2022 to 2023 in an 800-bed hospital. Clinical, pharmaceutical and economic data were submitted in SiNATS digital platform for evaluation, after local drug and therapeutics committee approval, except those from the oncology department. Data were analysed in an Excel 5.0 database.

Results We enrolled 72 DR, three for stock and 69 per patient of which 75% were female and with an average age of 51 years, prescribed mainly by Internal Medicine (38%), Pneumology (21%) and Gastroenterology (11%) departments.

The main DR and those with a higher approval rate are mentioned in the following table:

Abstract 1ISG-001 Table 1

DR	n	%	Clinical Justification	% of approvals
Nintedanib	13	18	Inefficacy of corticotherapy	92%
Upadacitinib	11	16	Failure to first-line treatment	55%
Bulevirtide	6	9	Contraindication to interferon	100%
Mepolizumab	6	9	First-line treatment	40%
Belimumab	5	7	Failure to first-line treatment	40%
Tolvaptan	5	7	First-line treatment	100%

Overall, approval rate was 75%. Rejections were mainly due to lack of compliance to PAP requirements (61%) namely existing alternative first-line options (upadacitinib and mepolizumab) and RAFP already approved (33%) (belimumab and nintedanib).

Global economic budget was 969.652€ per year, of which, 667.238€ corresponding to approvals and 302.614€ to rejections.

Conclusion and Relevance Our data shows a high percentage of approvals. However, upadacitinib for Crohn's disease and mepolizumab for eosinophilic granulomatosis with polyangiitis showed higher rates of rejection, due to the existence of alternative first-line treatment options. Economic impact was high, showing the importance of the definition of utilisation criteria on a national level, by experts in the field, so that clinicians and pharmacists, as a team, can optimise treatment outcomes, in accordance with RAFP and international guidelines, while ensuring sustainability of public resources and enabling more patients to benefit from innovative therapies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

1ISG-002 ABSTRACT WITHDRAWN

1ISG-003 COST EVALUATION OF OFF-LABEL THERAPY OF METHICILLIN-RESISTANT S. AUREUS OSTEOMYELITIS (MRSA) WITH DALBAVANCIN VS STANDARD OF CARE IN A HEALTHCARE COMPANY

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Background and Importance Dalbavancin in off-label indication is used in osteomyelitis caused by MRSA (Methicillin-Resistant S. Aureus).[1] Osteoarticular infections are of considerable importance in clinical practice in terms of frequency, prognosis and complexity of treatment.

Aim and Objectives The aim of this work is to compare the costs of patients treated with standard of care (SoC) vs

dalbavancin therapy with MRSA-osteomyelitis including hospitalisation costs. Recommended dose of dalbavancin is 1500 mg administered as a single infusion or as 1000 mg followed, 1 week later, by 500 mg while SoC of antibiotic therapy in MRSA-osteomyelitis is composed of vancomycin 1g-IV every 12h and cefepime 2g-IV every 12h.

Material and Methods The cost of antibiotic therapies and processing the average days of hospitalisation in the two cases (SoC and dalbavancin) was calculated using the company management software. Cost of hospitalisation days in the osteomyelitis case was extrapolated from the available scientific literature. Dalbavancin is administered as reported in the literature and RCP.

Results In the period May 2023–May 2024 we treated 26 patients with MRSA-osteomyelitis. Dalbavancin was administered to patients after approval of the off-label procedure. Economic cost of dalbavancin therapy is € 1267,24 per patient. We calculated the cost of SoC therapy with cefepime 4g/day + vancomycin 2g/day equal to € 16,30/day for each patient. The average cost of a hospitalisation day is € 732.[2] The number of hospitalisation days for the treatment of osteomyelitis-MRSA with SoC therapy, in 2023, in our company was 22 days.

Conclusion and Relevance Cost analysis for patients in therapy with dalbavancin led to a value of € 3472,00 obtained from the economic value of the drug (€ 1276,24) and the cost of three days of hospitalisation (€ 2196,00) which are implemented according to company protocol; the second administration is carried out on an outpatient basis. SoC therapy with cefepime and vancomycin (22 days) have a cost of € 357,94 for the drug component. However, the cost of hospitalisation days (€ 16104,00) significantly affects the economic impact of SoC therapy, the total cost of which is € 16461,94. Dalbavancin therapy for 26 patients with MRSA-osteomyelitis allowed an overall saving of € 12989,7. The decrease in patient hospitalisation led to a reduction in healthcare associated infections with further savings in resources.

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Conflict of Interest No conflict of interest

1ISG-004 PHARMACOECONOMIC ANALYSIS OF LIPOSOMAL IRINOTECAN AS SECOND-LINE TREATMENT FOR ADVANCED PANCREATIC CANCER VERSUS STANDARD THERAPY FOLFIRINOX

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Background and Importance In a total of 21 studies (3,017 patients with locally advanced, unresectable or metastatic pancreatic cancer), the use of nal-IRI, together with 5-fluorouracil and leucovorin, led to a significant improvement in PFS and OS, with a pooled mean difference of 1.01 months (2.87 vs. 1.87 months) (95% CI = 0.97–1.05, $p<0.01$) and 0.29 months (95% CI = 0.18–0.39, $p<0.01$), respectively.

Aim and Objectives The aim of the study was to compare the costs of treatment with nanoliposomal-irinotecan in combination with fluorouracil and leucovorin (nal-IRI+5-FU/LV) versus modified FOLFIRINOX (mFFX) as second-line treatment after gemcitabine with nab-paclitaxel (GnP) for metastatic and recurrent pancreatic cancer.

Material and Methods We analysed the costs of nal-IRI+5-FU/LV or mFFX therapies in our hospital. Data were extracted from the AREAS management software and the purchase prices of drugs and DM necessary for the preparation of the therapies of each cycle were taken into account for an average patient of 80kg, 180cm tall and 2sqm. The nal-IRI+5-FU/LV has an average duration of 6 cycles (2.87 months) while mFFX of 4 cycles (1.87 months). The costs of the necessary personnel and indirect costs, not easily identifiable, were not taken into account. Furthermore, the incidence of side effects was evaluated for both alternatives.

Results nal-IRI+5-FU/LV has a cost of € 923.5/cycle (€ 5,541.27/6 cycles) while mFFX € 48.13/cycle (€ 192.52/4 cycles) with a difference of € 5,348.75 per patient, equivalent to the month gained in PFS. However, with nal-IRI+5-FU/LV an increased risk of neutropenia, anaemia, hypokalaemia, diarrhoea and vomiting of grade 3 or higher was also noted compared to mFFX, manageable adverse events.

Conclusion and Relevance Second-line treatments based on Nal-IRI have shown a significant improvement in PFS and OS compared to other available treatments in advanced pancreatic cancer, despite an increase in toxicity and healthcare costs required for the most modern treatment. Further research is also needed to define the role of nal-IRI both in the first and subsequent lines of therapy, also considering an increase in costs for the NHS, as in the NAPOLI-2 studies in biliary cancer (NCT04005339) and NAPOLI-3 in first-line pancreatic cancer.

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Conflict of Interest No conflict of interest

1ISG-005 ANALYSIS OF PHARMACEUTICAL INTERVENTIONS IN A MULTIDISCIPLINARY TELEPHARMACY PROGRAMME

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Background and Importance Telepharmacy improves access to treatments for frail patients with mobility limitations.

Aim and Objectives To assess pharmaceutical interventions (PI) in a multidisciplinary telepharmacy programme (MTP).

Material and Methods MTP included a healthcare team composed of hospital pharmacists, nurses, trained pharmacy technicians and nursing technicians. Patients included presented clinically stable chronic disease on treatment for >3 months, adequate tolerance to medication, adherence >90% and difficulty travelling to hospital. Pharmacists checked the pharmacotherapeutic context of this entire population. Patients were contacted by telephone (pharmacotherapeutic interview) 1-week before the drugs were sent to primary care centres every 2–3 months. PI between February and September 2024 were evaluated. Farmatools application and clinical history were used to obtain data for analysis: patients in MTP, distribution of PI in patients, therapies, prescribing medical departments and types of PI.

Results MTP included 516 patients. PI were 247, which were distributed among 157 patients. The most frequently involved therapies were: adalimumab 40 mg (N = 41; 16.6%), etanercept 50 mg (N = 29; 11.7%), tofacitinib 5 mg (N = 16; 6.5%), secukinumab 300 mg (N = 10; 4%) and dimethylfumarate 240 mg (N = 7; 2.8%). The medical departments with the most PI were Internal Medicine (N = 88; 35.6%), Dermatology (N = 46; 18.6%), Pneumology (N = 29; 11.7%), Neurology (N = 22; 8.9%) and Infectious Diseases (N = 15; 6.1%). Types of PI: close pharmacotherapeutic follow-up due to lack of medical follow-up (N = 94; 38.1%), monitoring or information on treatment adherence (N = 51; 20.6%), closer monitoring due to risk of inadequate therapy effectiveness (N = 29; 11.7%), reporting adverse event information (N = 24; 9.7%), review and information on drug interactions (N = 17; 6.9%), information on drug administration (N = 12; 4.9%) and others (N = 20; 8.1%).

Conclusion and Relevance Numerous PI were developed in MTP. Adalimumab 40 mg and etanercept 50 mg were the most frequently intervened therapies. The medical departments most frequently involved were Internal Medicine and Dermatology. The most common PI were close pharmacotherapeutic follow-up due to lack of medical follow-up and monitoring/provision of information on treatment adherence. Some PI addressed ineffectiveness, adverse events, interactions and drug administration.

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

1ISG-006 GENDER DIFFERENCES IN WORK ENVIRONMENT PERCEPTIONS AMONG HOSPITAL PHARMACISTS

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Background and Importance Gender may influence perceptions of working conditions and professional priorities in hospital pharmacy. There is scarce of research focused on identifying these differences that can provide data to improve the management of hospital pharmacy services.

Aim and Objectives This study aims to identify how gender influence among pharmacy specialists and residents on their perceptions of the current working environment in HPS and professional roles.

Material and Methods

- Survey design: Google Forms survey with 20 questions using a Likert scale (1–10) and multiple-choice options, covering demographics and professional aspects.
- The survey was validated through a focus group and distributed to members of the Spanish Society of Hospital Pharmacy (SEFH) via email and social media.
- Response period: January 16–29 2024.
- Statistical tests: ANOVA and Kruskal-Wallis.

Results Response rate: 16% (617 surveys), with a representative sample of age, gender and job position among SEFH members. Gender distribution: 26.4% men (163) and 73.6% women (454).

- Current roles (men vs women): Clinical (66.7% vs 54.9%), compounding (5.6% vs 13.8%), transversal activities such as safety and quality (1.8% vs 7.9%), logistics (10.2% vs 7.6%), management (12.9% vs 14.2%), and research (2.8% vs 1.6%). More men (32.4%) than women (19.4%) want to change their job responsibilities ($p<0.01$).
- Professional aspects: Pharmacists rated their hospital 7.8 (Men: 7.6; Women: 7.9; $p=0.098$) and their HPS 7.6 (Men: 7.2; Women:7.9; $p=0.004$). The most valued aspects of their work were a good work environment (65.0% men, 70.5% women; $p=0.2$) and work-life balance (46.0% men, 48.7% women; $p=0.5$). Significant gender differences were found in the importance of salary ($p=0.02$) and research opportunities ($p<0.01$), both more valued by men. Women valued working groups participation more ($p<0.01$).
- Both genders prioritised improving patient care as their primary motivation (74.8% men, 84.1% women; $p<0.01$), followed by improving system efficiency (52.1% men, 47.1% women; $p=0.3$).
- Men expressed greater interest in scientific societies (63.2% men, 50.2% women; $p<0.01$) and industry (18.4% men, 13.8% women; $p<0.05$).

Conclusion and Relevance The survey highlights key gender differences in Hospital Pharmacy Services (HPS). These differences should be considered in team strategies to improve work environment and to better address diverse professional priorities.

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

1ISG-007 COST ANALYSIS OF REMDESIVIR AND NIRMATRELVIR/RITONAVIR FOR THE EARLY TREATMENT OF COVID19 VULNERABLE PATIENTS

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Background and Importance Despite the end of the global health emergency, a vulnerable portion of the population remains at high-risk of developing severe forms of COVID-19. To address this, two antiviral drugs are used for early treatment: remdesivir (RDV), administered via intravenous infusion for 3-day outpatient, and nirmatrelvir/ritonavir (NRM/RTV), administered orally over 5 days.

Aim and Objectives This study aims to conduct a cost analysis between RDV and NRM/RTV in the early treatment of severe COVID-19.

Material and Methods A network meta-analysis was performed, based on the latest systematic review comparing RDV and NRM/RTV,[1] to estimate the relative risk (RR) of hospitalisation and severe adverse events. Assuming 100,000 eligible patients, two cost scenarios were estimated: all patients treated with RDV versus all treated with NRM/RTV. Costs include the ex-factory price of the drugs, hospitalisation, management of adverse events and outpatient settings for RDV, estimated

using a 'bottom-up' micro-costing approach. Event incidence data from the approval RCT for RDV were used.
Results The network meta-analysis reveals only indirect comparisons between RDV and NRM/RTV. The RR of hospitalisation for NRM/RTV compared to RDV is 2,80 (95% CI: 0,33–24,07), while for severe adverse events it is 0,92 (95% CI: 0,31–2,74). The SUCRA rank for hospitalisation is 0,91 for RDV and 0,58 for NRM/RTV; for adverse events it is 0,72 for RDV and 0,78 for NRM/RTV. The ex-factory cost is € 1.800,00 for RDV and € 1.336,29 for NRM/RTV. Hospitalisation costs € 8.081,29, adverse event management costs € 3.725,00, and the outpatient setting for RDV costs € 137,58. The total estimated cost in the RDV scenario is € 218.891.438,10 and in the NRM/RTV scenario € 180.267.256,68.
Conclusion and Relevance The analysis indicates no significant difference between therapies in preventing hospitalisations, but the SUCRA rank shows a higher efficacy and lower safety of RDV compared to NRM/RTV. In the RDV scenario, the total cost would be € 197.758.000,00 for treatment, € 14.465.688,10 for hospitalisations, and € 6.667.750,00 for adverse events. In the NRM/RTV scenario, the total cost would be € 133.629.000,00 for treatment, € 40.503.926,68 for hospitalisations, and € 6.134.330,00 for adverse events, resulting in savings of € 38.624.181,42.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

1ISG-008 ABSTRACT WITHDRAWN

1ISG-009 OPTIMISING NON-CLINICAL DRUG MANAGEMENT PROCESSES THROUGH ROOT CAUSE ANALYSIS

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Background and Importance Inefficient hospital drug management processes negatively affect professionals and patients, leading to excessive time spent on non-clinical tasks and reducing time for direct patient care, potentially affecting clinical outcomes. Conducting a thorough error analysis to identify root causes is essential for providing insights to effectively optimise these processes.
Aim and Objectives We aimed to identify causes of inefficiency in non-clinical management of hospital pharmacy drugs, analyse overall errors, and ascertain the most impactful causes. Future phases will develop solutions to streamline processes and reduce time lost on non-value-adding tasks.
Material and Methods Reiterative doubts regarding non-clinical drug management were detected among physicians, nurses, and pharmacy technicians through daily routine activities, with the pharmacy department keeping a record of the queries received. The responses provided by the pharmacists were heterogeneous.

A cause-effect diagram was constructed, based on the Ishikawa/6M methodology, which systematically identified and categorised primary factors contributing to inefficiencies, thereby facilitating evaluation and development of innovative solutions.
Results Five key process parameters were analysed, with subcategories for each. Weaknesses identified were:

1. Information sources: a) Outdated information b) Reliance on subjective professional knowledge.
2. Environment a) Fragmented information b) Restricted accessibility c) Lack of cross-functional integration.
3. Technology a) Outdated formats (e.g: paper, pdf) b) Unavailable on-line actualisation.
4. Training a) Insufficient training on available resources b) Lack of awareness regarding administrative processes.
5. Methodology a) Communication channels among professionals improperly established b) Centralisation of issue resolution within pharmacy staff, leading to work overload c) Delays in receiving required reports.

After subsequent validation with a multidisciplinary team, based on clinicians' perceived impact, inadequately established communication channels, unawareness of information sources and insufficient cross-functional integration of data systems were identified as critical. The 5-why methodology was applied to validated primary causes, leading to identification of the root cause.
Conclusion and Relevance This root cause analysis highlights the urgent need to transform our current information ecosystem and develop new, integrated data management tools. Improvement measures will be proposed and prioritised based on the ICE (impact, confidence, ease) scoring system.

More efficient information-gathering processes will facilitate the establishment of streamlined work methodologies, allowing healthcare professionals to focus more effectively on patient care and clinical tasks.

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

Selection, procurement and distribution

2SPD-001 ENVIRONMENTAL IMPACT MANAGEMENT OF INHALERS FROM THE HOSPITAL PHARMACY: THE GIMAFH PROJECT

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Background and Importance The healthcare system significantly contributes to global warming, with inhalers being a notable example due to their hydrofluoroalkane content, which has a greenhouse effect 1,000–3,500 times greater than CO_2. Proper use and disposal of these medications are crucial from both healthcare and environmental perspectives. Increasing patient

awareness and promoting sustainable management of inhalers is essential.

Aim and Objectives The GIMAFH project aims to minimise the environmental impact of inhalers through hospital pharmacy initiatives. The specific objectives are: (1) To assess the prevalence of proper disposal of inhalers at designated collection points (SIGRE); (2) To identify factors associated with improved management of inhaler waste; and (3) To evaluate whether patient education interventions enhance proper waste management practices.

Material and Methods This multicentre, observational, prospective study involves 42 hospitals across Spain and includes adult patients with uncontrolled severe asthma undergoing biological treatment. Clinical data are extracted from electronic health records, and a 16-item survey covering general health, environmental impact, and waste management is administered (phase 1). Additionally, an educational infographic on the environmental impact and proper disposal of inhalers has been developed for patient education and to be assessed consequently (phase 2). A minimum sample size of 394 patients was required. The study has been approved by the ethics committee.

Results We present interim results from the first 2 months of the ongoing study (phase 1), during which 244 patients were recruited, with an average age of 55.9 years (SD: 13.8); 34.2% were female. Of the participants, 59.4% used two or three different inhaler devices; 77.5% used pressurised inhalers. Notably, 68.0% of patients believe that inhalers have the same or less environmental impact as other medications. Although 91.4% were aware of the SIGRE collection point, only 69.2% used it, and just 46,3% disposed their inhalers there, highlighting the need for targeted interventions.

Conclusion and Relevance The GIMAFH project demonstrates the critical role of hospital pharmacists in empowering patients towards sustainable inhaler waste management. Although these are interim results, they reveal significant gaps in patient awareness and practices that this ongoing study aims to address. The project's framework can potentially be expanded to other hospital pharmacies to promote environmentally sustainable practices in healthcare.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-002 DEVELOPMENT AND IMPACT OF A DASHBOARD FOR DRUG SHORTAGE PREDICTION AND MANAGEMENT: A BEFORE AND AFTER STUDY

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Background and Importance Drug shortages pose major challenges, requiring innovative approaches for effective management and mitigation. To our knowledge, no system proactively monitors and anticipates shortages to support hospital pharmacists in daily routine.

Aim and Objectives This study aimed to develop and implement a dashboard to optimise drug shortage management and to evaluate its impact on logistical, financial, and time indicators.

Material and Methods A dashboard was developed in-house by integrating logistical data (stock levels from the central pharmacy and over 90 automated dispensing cabinets) with clinical data (prescriptions). Two types of shortages were assessed: internal stock-outs (defined as zero stock in the pharmacy) and supplier stock-outs (drugs unavailable at the time of order). A prospective interventional study evaluated the dashboard's impact by comparing data from a 3-month period without the tool (1 February to 30 April 2023) to a 3-month period with the tool in use (1 April to 30 June 2024).

Results The dashboard implementation led to a 57% reduction in internal stock-outs (from 600 to 260), achieved by identifying drugs with less than 2 weeks of stock and insufficient supply for 72-hours prescriptions. Supplier stock-outs also decreased by 42% (from 177 to 102), while the time spent managing stock-outs fell by 24% (from 430h to 326h), leading to a 26% reduction in additional HR costs (from EUR 19,308 to EUR 14,265). Weekly working hours decreased by 32% (from 33h to 25h). Overall, the cost of stock-outs dropped by 60%, from EUR 395,115 to EUR 156,098. Despite these improvements, the root causes of supplier stock-outs remained largely unidentified in 2024 (89%, n=91/102), similarly to 2023 (87%, n=154/177). Additionally, stock-out complexity increased, with longer durations (from 37 to 49 days), a higher proportion of critical drug shortages (from 38% to 52%), and a slight decrease in the availability of alternatives (from 85% to 81%).

Conclusion and Relevance Routinely implementing a dashboard significantly reduces internal stock-outs by 57% and associated costs by 60%, enhancing resilience in a complex supply chain environment. This highlights the potential of innovative technological solutions to anticipate and mitigate drug shortages in hospitals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-003 EVOLUTION OF TREATMENT CONSUMPTION IN SECONDARY-PROGRESSIVE MULTIPLE SCLEROSIS (2018–2023)

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10.1136/ejhpharm-2025-eahp.19

Background and Importance Secondary-progressive multiple sclerosis (SPMS) is a clinical phenotype that develops in about 50% of patients with relapsing-remitting multiple sclerosis (RRMS). There is a progressive worsening of symptoms without remission periods and progression may not present outbreaks.

Aim and Objectives The aim of our study is to compare the variation in consumption patterns of SPMS drugs dispensed in a Hospital Pharmacy Service during the 2018–2023 period.

Material and Methods This was a retrospective, single-centre and observational study, conducted from 2018–2023. The comparison of treatment consumption was carried out by calculating the defined daily doses (DDD)/1000 inhabitants/day through the DDD established by the WHO Collaborating Centre for Drug Statistics Methodology, the information provided by the Athos-Stock programme and the census of inhabitants of the hospital area.

Results The DDD/1000 inhabitants/day data obtained are: siponimod 2 mg (0;0;0;0.0083;0.0311; 0.038), interferon beta 1B 250 mcg (Betaferon/Extavia) (0.0229; 0.0224; 0.0139; 0.0115; 0.0088; 0.0082), interferon beta 1A 22/44 mcg (Rebif)(0.0119;0.0162;0.0088;0.011;0.0087;0.0104) and ofatumumab 20 mg (0;0;0;0.0021;0.0234).

These values show opposite patterns of evolution. On the one hand, siponimod and ofatumumab showed a growing trend in consumption. In 2022, subsidised use of ofatumumab was authorised, which explains why it reached a DDD of 0.0234 in just 2 years. It has a first-line indication for RRMS and a second-line indication for SPMS, and no distinctions have been made in consumption by indication. Siponimod was approved in 2021 as a first-line treatment, reaching a DDD of 0.038 in 2023, which makes it the most widely consumed drug in 2023.

Meanwhile, the consumption of the two types of interferon decreased during the same period. The Betaferon/Extavia reduction was more pronounced (65%) compared to the 2018 levels, while Rebif showed a more gradual reduction (12%). Both drugs are indicated for both RRMS and SPMS with relapses or active disease.

Conclusion and Relevance The consumption of IFN-based older treatments has shown a gradual decrease over the last 6 years, coinciding with an increase in the consumption of the new available therapeutic options. The appearance of siponimod has displaced the previous treatments indicated for SPMS, making it the most widely used drug in 2023. We expect that this increasing consumption will continue, favoured by the scarcity of alternatives for this clinical phenotype.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-004 IMPACT ON CONSUMPTION AND BUDGET DUE TO SUPPLY SHORTAGES

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Background and Importance Healthcare services are frequently hindered by supply shortages that force the acquisition of other generics and different drugs. These changes often generate a bewildering impact on the healthcare system.

Aim and Objectives To analyse the impact on the consumption of the therapeutic alternatives and the economic consequences.

Material and Methods Retrospective observational study using data collected by a university hospital from 2015–2024. The consumption of treatments was compared over intervals of equal duration during and before the shortage (7–54 months depending on drug pairs), by calculating the defined daily doses (DDD)/100 stays/day. An analysis of associated costs was conducted using the unit sale price. Data obtained from the *WHO Collaborating Centre for Drug Statistics Methodology* (established DDD), the annual hospital stay census, and the Athos-Stock management programme.

Results Expressing first the affected drug and then the alternative(s), the data obtained about DDD/100 stays/day (before/during the shortage) and increase (↑)/decrease (↓) in expenses derived from the exchange adjusted per month are shown in table 1:

Abstract 2SPD-004 Table 1

	DDD/100 STAYS/DAY		
DRUG PAIRS	**BEFORE SHORTAGE**	**DURING SHORTAGE**	**EXPENSES INCREASE(↑)-DECREASE(↓)**
Ranitidine (oral/IV)	0.0209 (oral)/ 0,040(IV)	0.0002 (oral)/ 0,0024(IV)	
Famotidine (oral/IV)	0 (oral)/0(IV)	0.0066 (oral)/ 0,0002(IV)	↓99.72€
Mitomycin (intravesical)	0.0048	0.0015	
Epirubicin (intravesical)	0	0.0048	
BCG (intravesical)	0.0001	0.0001	↓2,404.23€
Labetalol (oral)	0.0005	0.0004	
Methyldopa (oral)	0.0003	0.0003	↓3.80€
Alteplase (IV)	0.0006	0.0002	
Urokinase (IV)	0.0001	0.0005	↑4,094.90€
Cyclopentolate (eye drops)	0,0076	0,0025	
Atropine (eye drops)	0.0002	0.0002	↑50.53€
Clorazepate (IV)	0.0004	0.0003	
Diazepam (IV)	0.0821	0.0608	↓239.39€

The most notable changes in administration were: increases in famotidine (oral) by 7/100,000 stays and epirubicin (IV) by 5/100,000; decreases in diazepam (IV) by 21/100,000 and clorazepate (IV) by 5/100,000. Regarding the budgetary impact, the alteplase shortage generated the highest global/adjusted monthly expense (73,708.12€/18 months; 4,094.90€/month), while the mitomycin shortage generated the lowest global/adjusted monthly expense (125,019.72€/52 months; 2,404.23€/month).

Conclusion and Relevance No consumption increase was observed for BCG (decrease in mitomycin use was offset by the increase in epirubicin), methyldopa (possibly due to an increase in other antihypertensives), or diazepam (decrease observed, instead of the expected increase). Except for famotidine (oral/IV), epirubicin (intravesical), and urokinase (IV), the DDD/100 stays/day for all alternatives to drugs affected by shortages either remained unchanged or decreased, with little economic impact. While some shortages have resulted in significant associated costs (alteplase), most have led to reduced costs due to the proposed lower-cost therapeutic alternatives.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-005 CEMIPLIMAB PLUS CHEMOTHERAPY AS FIRST-LINE TREATMENT IN LOCALLY ADVANCED OR METASTATIC NON-SMALL-CELL LUNG CANCER IN PATIENTS WITH PDL-1 EXPRESSION ≥1%: COMPARISON VS. CURRENT ALTERNATIVES

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Background and Importance Cemiplimab, combined with chemotherapy, is a promising first-line treatment for locally advanced or metastatic non-small-cell lung cancer (NSCLC) with PDL-1 ≥1%.

Aim and Objectives The aim of this study is to conduct a network meta-analysis (NMA) of therapies for locally advanced or metastatic non-small-cell lung cancer (NSCLC) inpatients with PDL-1 expression ≥1%, focusing on the efficacy and safety of cemiplimab in combination with chemotherapy compared to alternative first-line treatments.

Material and Methods A systematic search was conducted on 6 June 2024, in PubMed to identify phase 3, randomised, double-blind, controlled clinical trials evaluating therapies for the treatment of patients with locally advanced or metastatic non-small-cell lung cancer (NSCLC) with PDL-1 expression ≥1%. The search strategy used the following terms: (Therapy/Narrow [filter]) AND (cemiplimab) AND (chemotherapy) AND (non-small-cell lung cancer). Studies were screened based on predefined inclusion criteria, which required reporting overall survival (OS) outcomes and relevance to the target population. Articles were excluded if they lacked sufficient survival data, focused on phase 1 or 2 trials, or did not meet quality standards for methodological rigour.

A network meta-analysis (NMA) was performed using the netmeta package in R statistical software, employing a Bayesian framework and a common-effects model. In the NMA, all platinum-based chemotherapy regimens classified as equivalent according to the NCCN guidelines were grouped and treated as a single category to ensure consistency in comparisons. Hazard ratios (HR) were calculated to compare alternative therapies against cemiplimab combined with chemotherapy (cemiplimab_QT).

Results The literature search yielded a total of seven studies that met the inclusion criteria. The overall survival analysis compared cemiplimab_QT with alternative therapies for patients with NSCLC. The results of the network meta-analysis were as follows:

- Atezolizumab_Bevacizumab_QT: HR = 1.38 (95% CI [0.96; 2.00]).
- Atezolizumab_QT: HR = 1.41 (95% CI [1.00; 1.99]).
- Durvalumab−Tremelimumab_QT: HR = 1.46 (95% CI [1.01; 2.11]).
- Nivolumab−Ipilimumab: HR = 1.48 (95% CI [1.06; 2.07]).
- Nivolumab−Ipilimumab_QT: HR = 1.35 (95% CI [0.93; 1.95]).
- Pembrolizumab_QT: HR = 1.22 (95% CI [0.87; 1.72]).
- Platinum-based chemotherapy: HR = 1.92 (95% CI [1.44; 2.58]).

Conclusion and Relevance The results highlight that, compared to durvalumab-tremelimumab and nivolumab-ipilimumab, Cemiplimab achieved a more favourable overall survival, especially when compared to platinum-based chemotherapy, which had the highest risk of death (HR =1.92).

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

2SPD-006 BUDGETARY IMPACT OF AZTREONAM SHORTAGE IN THE TREATMENT OF METALLO-BETA-LACTAMASE-PRODUCING GRAM-NEGATIVE BACTERIA

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Background and Importance Metallo-beta-lactamases are the most clinically significant acquired carbapenemases due to their ability to hydrolyse β-lactam antibiotics, except aztreonam and cefiderocol. Since April 2024, due to the aztreonam shortage, the national medicines and healthcare products agency (MHPA) established strict prioritisation criteria for its use. Aztreonam can only be employed in the context of metallo-beta-lactamases when cefiderocol cannot be used.

Aim and Objectives To estimate the budgetary impact of the aztreonam shortage in a medium-complexity hospital under different scenarios.

Material and Methods Economic evaluation conducted in September 2024 in a medium-complexity hospital. Using electronic health records, patients infected and/or colonised with metallo-beta-lactamases treated with ceftazidime-avibactam +aztreonam (CAZAVI-AZ) between January 2019 and December 2023 were identified. The annual incidence rate was calculated, based on the hospital's served population, along with the median treatment duration. Treatment costs were calculated using the laboratory reported selling prices (LRSP) and median treatment days. The budgetary impact (cefiderocol costs minus CAZAVI-AZ costs) was estimated for periods of 6 months, 1 year, and 2 years, comparing standard doses from the technical sheet. A sensitivity analysis was performed, considering the cost using the maximum doses of CAZAVI-AZ for this indication.

Results Over 4 years, the incidence was 8.8 cases per 100,000 inhabitants annually. The median treatment duration was 6.8 days [IQI 1.5–10.4]. LRSP per vial was € 161.82 for cefiderocol, € 14.83 for aztreonam, and € 125.42 for ceftazidime-avibactam. With standard doses, the total cost per patient was € 3,163.53 for CAZAVI-AZ and € 6,602.05 for cefiderocol. Assuming maximum CAZAVI-AZ doses, the total cost per patient was € 3,365.22. Considering annual incidence and the hospital's population (170,000), the budgetary impact was € 24,069.64 for 6 months, € 51,577.83 for 1 year, and € 103,155.66 for 2 years. Sensitivity analysis showed slightly lower impact with maximum CAZAVI-AZ doses: € 22,657.81 for 6 months, € 48,552.45 for 1 year, and € 97,104.9 for 2 years (5.87% difference).

Conclusion and Relevance The aztreonam shortage and high cefiderocol cost will significantly impact the treatment budget for metallo-beta-lactamase-producing gram-negative bacterial infections. The estimated annual impact was € 51,577.83, emphasising the importance of ensuring aztreonam supply and managing shortages effectively. Beyond the economic impact, it is crucial to assess the ecological consequences of the MHPA's strategy.

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

2SPD-007 CHARACTERISTICS OF PERIOPERATIVE IMMUNOTHERAPY CLINICAL TRIALS IN NON-SMALL-CELL LUNG CANCER: A SYSTEMATIC REVIEW

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Background and Importance Recently, several immunotherapy regimens were evaluated against chemotherapy (CT) as

perioperative treatment for resectable non-small-cell lung cancer (rNSCLC). Analysing randomised clinical trials (RCTs) characteristics is essential for future reliable indirect comparisons between schemes.

Aim and Objectives To perform a systematic search and evaluation of RCTs characteristics about the use of perioperative immunotherapies for rNSCLC.

Material and Methods Systematic search in Pubmed was conducted on September 17, 2024. The following search strategy was used with the filter 'Randomised Controlled Trial': *[Perioperative Resectable Non-Small-Cell Lung Cancer]*. Phase III RCTs with immunotherapies as perioperative treatment of rNSCLC and event-free survival (EFS) analysis were selected. The rest of studies were excluded. RCTs characteristics assessed: populations (baseline factors), intervention arm (exposure time and schemes used), comparator arm (differences in common drug regimen) and other study design aspects.

Results There were 55 results in the search. Review results excluded: nine without design of RCTs, 39 assessed different interventions, two with different clinical context and one evaluated different outcomes than EFS. Thus, four RCTs were included. Immunotherapies found: perioperative toripalimab (p-toripalimab), pembrolizumab (p-pembrolizumab), nivolumab (p-nivolumab) and durvalumab (p-durvalumab). Differences in baseline factors observed in RCT populations: patients with ≥65 years (31.2% in p-toripalimab vs 45–56% in the rest of therapeutic alternatives), squamous histology (77.7% in p-toripalimab vs 43–51% in other regimens), cancer stage IIIA-IIIB (99.2% in p-toripalimab vs 64–70% in the rest of schemes) and N2 stage (70% in p-toripalimab vs 39%–45% in other combinations). P-toripalimab presented an adjuvant CT cycle in intervention and control arms (three neoadjuvant toripalimab+CT cycles with one adjuvant toripalimab+CT cycle followed by adjuvant toripalimab). However, the remaining perioperative treatments contained four neoadjuvant immunotherapeutic agent+CT cycles with adjuvant immunotherapy. All perioperative schemes included carboplatin- or cisplatin-based regimens in CT, except p-pembrolizumab (only cisplatin therapies). Time of adjuvant exposure was 365 days for p-nivolumab vs 273–336 days for the rest of drug combinations. Patient follow-up was 11.7 months for p-durvalumab vs 18–25 months for other schemes.

Conclusion and Relevance RCT of p-toripalimab presented differences in populations, intervention and control arms compared to the rest of immunotherapies. Only p-pembrolizumab included exclusively cisplatinum-based regimens. P-nivolumab required a longer adjuvant exposure time. P-durvalumab developed the lowest patient follow-up.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-008 FIVE YEARS OF THE FALSIFIED MEDICINES DIRECTIVE: A COMPARATIVE ANALYSIS OF COMPLIANCE AND IMPACT IN HOSPITAL PHARMACY

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Background and Importance The Falsified Medicines Directive (2011/62/EU) (FMD), effective since 9 February 2019, establishes regulations to prevent falsified medicines from entering the legal supply chain. It ensures authenticity and traceability, providing greater patient safety. While the FMD provides valuable monitoring data, incomplete implementation impairs its full effectiveness.

Aim and Objectives To verify compliance with the FMD 5 years after its implementation and to compare the impacts in hospital pharmacy 6 months after the initial implementation.

Material and Methods Products received between 21 to 30 August 2024, were analysed using MS-Excel and compared with products received from 18 to 27 September 2019. Products not requiring a Unique Identifier Code (UIC) were excluded. The parameters analysed included the presence of a UIC, existence of an anti-tampering device (ATD), the timing of code scans, the quantity received, and any issues encountered with reading/scanning.

Results A comparative analysis of 163 products in 2024 (10611 packages) versus 201 products in 2019 (10935 packages) revealed that in 2024, 100% of products had a UIC, a significant improvement from 69% in 2019. Reading issues decreased to 1.9% in 2024 compared to 12.9% in 2019. The average UIC reading time reduced from 9.5 seconds in 2019 to 8.57 seconds in 2024 (including connecting software, verifying safety devices, positioning the package for scanning, and waiting for confirmation). In 2024, 99.5% of products had an ATD.

Conclusion and Relevance The analysis reveals a substantial improvement in compliance with the FMD, as evidenced by the increase in UIC implementation and the high rate of ATD presence, reflecting progress in enhancing patient safety. This includes outpatient products, where scanning at the point of dispensing could provide additional benefits, such as improved pharmacovigilance and pharmacoepidemiology. The reduction in scan issues and faster reading times are likely due to technological advancements and improved operational processes. However, challenges remain, including the time required for verifying safety features, which totals 25 hours over 8 working days (0.45 ETC), and ensuring the directive's full benefits for patient care, particularly in a limited number of countries, low level of connection of hospital pharmacies. Addressing these issues will be crucial in realising the FMD's potential for improved patient care.

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Conflict of Interest No conflict of interest

2SPD-009 IMPACT OF HOSPITAL TRANSPORT SYSTEMS, INCLUDING PNEUMATIC TUBES, ON PROTEIN STABILITY IN IV BAGS AND SYRINGES

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Background and Importance In hospitals with centralised compounding cleanrooms, high-quality standards are achieved, ensuring both a safe occupational environment and financial

benefits through vial sharing. However, reconstituted medications must be transported to the wards or patients via processes not described in the approved Summary of Product Characteristics. The use of pneumatic tubes is prohibited in many hospitals after studies demonstrating increased subvisible particles from protein aggregates[1] However, recent studies have reported no effect on product quality provided excipients are present in the IV bags.[2]

Aim and Objectives The aim of this study is to evaluate the impact of pneumatic tube systems and electric platform trucks on protein stability in IV bags and ready-to-use syringes.

Material and Methods Two examples of products were transported from a hospital compounding pharmacy using either a pneumatic tube system or an electric platform truck. Insulin was repackaged in disposable syringes to simulate vial sharing of expensive drugs and the monoclonal antibody trastuzumab was diluted in saline IV bags to represent compounding for oncological treatments. Smartlabels (CPI, UK) was used to investigate accelerometer data. Flow imaging microscopy, size-exclusion chromatography and visual inspection measurements were performed.

Results The results showed that syringes had increased levels of spherical particles, most likely silicone oil, after transport using pneumatic tubes. This was not seen for electric platform truck transport. For IV bags the transport using pneumatic tubes increased the total subvisible particle count when there was headspace in the IV bags. This was also the case for IV bags with no added drug product indicating that the particles were released from the material. Although polysorbate 20 prevented particles over 10µm, the total particle levels increased when the surfactant was added to the IV bags.

Conclusion and Relevance The high shock levels during transport using pneumatic tubes appear to release particles from the material in both syringes and IV bags. It is recommended to remove headspace during transport of IV bags especially during transport using pneumatic tube systems.

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2SPD-010 AN ADJUSTED INDIRECT COMPARISON OF THE EFFICACY OF EFGARTIGIMOD ALFA, RAVULIZUMAB, AND ECULIZUMAB FOR TREATING ACETYLCHOLINE RECEPTOR AUTO-ANTIBODY-POSITIVE (ACHR-AB+) GENERALISED MYASTHENIA GRAVIS

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Background and Importance Generalised myasthenia gravis (gMG) is a rare, chronic, neuromuscular autoimmune disease, mediated by pathogenic immunoglobulin auto-antibodies targeting the neuromuscular junction.

Approximately 10–15% of patients have refractory gMG, meaning they do not respond despite long-term treatment with corticosteroids and at least two different immunosuppressive therapies.

Biologic therapies approved in the European Union as a complementary treatment to standard therapy for AChR-Ab+ refractory gMG patients include eculizumab, ravulizumab and efgartigimod alfa.

Comparisons assessing the relative effectiveness of these drugs are lacking.

Aim and Objectives To assess the relative efficacy of three antibody-based biologic therapies (efgartigimod alfa, ravulizumab, and eculizumab) in this setting.

Material and Methods An adjusted indirect comparison (AIC) of randomised clinical trials was performed, using Bucher's method. Outcomes were Myasthenia Gravis-Activities of Daily Living (MG-ADL) reduction of $\geq$3 points (Δ = 19%), and Quantitative Myasthenia Gravis (QMG) score reduction of $\geq$5 points (Δ = 24,5%), both assessed at week 26. Equivalence was assessed using the equivalent therapeutic alternatives (ETA) guidelines.

The main limitation of the study was the exclusion of the other available biologic drugs for this condition, due to the heterogeneity of the outcomes used in the clinical trials.

Results Three trials met the inclusion criteria and shared similar baseline characteristics: CHAMPION (efgartigimod alfa vs. placebo), ADAPT (ravulizumab vs. placebo), and REGAIN (eculizumab vs. placebo).

AIC showed no statistically significant differences between the therapies regarding MG-ADL score reduction. For QMG score, ravulizumab showed lower efficacy than efgartigimod alfa (RAR −22.7% (IC95% −41.98 to −3.92), p=0.021). Despite no statistical differences for eculizumab, we observed a probably clinically relevant difference regarding QMG, compared to efgartigimod alfa.

Conclusion and Relevance In conclusion, our results show that eculizumab and efgartigimod alfa present a probable clinic equivalence (ETA category: C), but so are ravulizumab and efgartigimod alfa (ETA category: D) in terms of MG-ADL score reduction. However, there is some inconsistency in the case of ravulizumab as there could be statistically relevant differences versus efgartigimod alfa in terms of QMG.

According to ETA guidelines, in cases of inconclusive results such as ours, the absence of equivalence should be assumed. Therefore, more data are needed to position antibody-based biologic therapies.

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2SPD-011 COMPARATIVE ANALYSIS OF EXPIRY MANAGEMENT OF MEDICATIONS AFTER THE IMPLEMENTATION OF AUTOMATED DRUG DISPENSING SYSTEMS

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Background and Importance The pharmacy department (PD) has the responsibility to manage the distribution and control of medicine cabinets in clinical units. All this process is laborious to perform manually, resulting in oversized stocks and an economic loss due to expired medications.
Aim and Objectives To evaluate the new expiry management (EM) of medications after the implementation of automated drug dispensing systems (ADDS) compared to the previous one.
Material and Methods Descriptive retrospective study of the EM of medications stored at the Emergency Department (ED) at a secondary hospital. The ADDS were implemented in February 2023 and two periods were defined: February 2022–February 2023 EM was performed manually; February 2023–February 2024, it was performed in an assisted way.

Manual EM consisted in reviewing all ED stocks every 6 months, hiring an extra technician. Medication was stored following the FIFO (First In, First Out) system. All medications which expire ≤6 months were returned to the PD to ensure immediate consumption.

In the assisted circuit, the EM was performed daily during replenishment of the ADDS, and monthly lists were generated to physically check them. At the end of the month, the expired drugs were taken from the ADDS.

Data were obtained from internal records for manual EM and through the ADDS software for assisted EM. The results were analysed using Excel.
Results In the first period of the study, EM was performed in the three traditional medicine cabinets at the ED (500 references), and 173 (34.6%) different references expired, corresponding to 1855 units.

In the second period, EM was carried out in the seven ADDS (605 references), of which 818 units expired, of 84 (13.9%) different references.

Implementing the new EM avoided hiring a reinforcement. This resulted in a saving of € 535.85/year in personnel costs.
Conclusion and Relevance There was an increase in the number of references stored with the ADDS, improving quick access to medication.

The new EM managed to reduce wastage, becoming a system more sustainable and safe.

The technician responsible of the EM is also in charge of ADDS daily replenishment, achieving a greater specialisation of the personnel and better management of stocks.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-012 AUTOMATION OF NARCOTIC DRUG PROCESS: AN OPPORTUNITY FOR IMPROVEMENT

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Background and Importance An Automated Narcotic Drug Dispensing System (ANDS) has been implemented in the Pharmacy Service (PS) to facilitate daily distribution of Narcotic Drugs (ND) to Hospitalisation Units (HU).

Each dispensing process imputed the consumption to the HU and generates an electronic record in the Official Narcotics Accounting Book (ONAB), thereby eliminating the need for manual transcription and registration in the PS.

Incorporation of ND into Automated Dispensing Systems (ADS) in the HU has permitted programmed refills and have allowed the elimination of manual records in ONAB and handwritten Hospital Dispensing Orders (HDO) signed by physicians.
Aim and Objectives Analyse how the implementation of an ANDS in the PS and its integration with the ADS in the HU impacts on the reduction of HDO.
Material and Methods ONAB data were analysed from August 2023, when the ANDS was implemented in the PS, until September 2024.

All dispensing processes were done through the ANDS:

- In HU with ADS, an automatic programmed refill is generated to the ADS.
- In HU without ADS, HDO are maintained on demand.

Refill movements from PS-ANDS to HU-ADS were analysed, as well as the movements using HDO to HU without ADS.

The number of lines of ND dispensed to the ADS was quantified to determine the number of HDO avoided, assuming that each dispensed line required an HDO before the implementation of the ADS.
Results A total of 8,607 movements have been recorded in the ONAB during the period studied, of which 4,501 correspond to refill movements from PS-ANDS to HU-ADS. Therefore, 4,501 HDO signed by physicians have been avoided, representing 52.29% of the movements. Manual transcription to the ONAB has been reduced to 47.71%.

The total number of automatic refills to the ADS have been 1,159, which, in addition to allowing a better planning of activities in the PS, improves the efficiency of healthcare professionals by reducing administrative tasks of physicians and HDO transport by orderlies.
Conclusion and Relevance Implementation of ANDS improves efficiency in the use of ND, reducing HDO, as well as manual records in the ONAB.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-013 EFFECTIVENESS AND EFFICIENCY OF PCSK9 INHIBITORS: CLINICAL PRACTICE EXPERIENCE

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Background and Importance In recent years, the use of PCSK9 inhibitors (iPCSK9) has increased due to their results in lowering LDL cholesterol (LDL-C) and their corresponding impact on patients cardiovascular health.

Aim and Objectives The primary objective is to compare the effectiveness and efficiency in reducing LDL-C between the off-label use of alirocumab 150 mg/month and the other dosing regimens indicated in the drug's technical data sheet. The secondary objective is to compare the effectiveness between the iPCSK9 alirocumab and evolocumab.

Material and Methods A retrospective observational study was conducted with patients from our hospital receiving any iPCSK9 in various dosing regimens. The following data were collected: iPCSK9 drug, dosing regimen, indication, and lipid profile. Patients without a second blood test or with a treatment duration of less than 28 days were excluded. To compare the mean LDL reduction between different treatment regimens, the Student-Fisher t-test was used. For cost calculations, prices were obtained through the nomenclator.

Results 114 patients on iPCSK9 treatment were analysed, with 27 excluded. The overall reduction in LDL-C was −53.1 mg/dL (95% CI: −64.8 to −41.4). 20 patients on evolocumab achieved a mean LDL-C reduction of −61.36 mg/dL (95% CI: −89.1 to −33.6), while 67 patients on alirocumab demonstrated a mean LDL-C reduction of −50.6 mg/dL (95% CI: −63.7 to −37.5). No significant differences were observed between alirocumab and evolocumab: −10.8 mg/dL (95% CI: −38.6 to 17.1). Similarly, no significant differences were found between the 75 mg/2-week and 150 mg/4-week regimens of alirocumab, 14.5 mg/dL (95% CI: −24.5 to 53.5); nor between the 150 mg/2-week and 150 mg/4-week regimens, 6.4 mg/dL (95% CI: −50.8 to 30.8). The difference between alirocumab 300 mg/4-weeks and 150 mg/month was −13.7 mg/dL (95% CI: −58.3 to 30.8). All dosing regimens have the same monthly cost, except for the off-label regimen, which would result in a 50% cost reduction.

Conclusion and Relevance Given that the monthly cost is the same for all alirocumab dosing regimens, and no significant differences were found between the regimens, the administration of alirocumab 150 mg/month was identified as the most efficient regimen. We found no significant differences in LDL-C reduction between the various alirocumab dosing regimens. Additionally, no differences were observed between alirocumab and evolocumab.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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2SPD-014 REDUCTION OF CARBON FOOTPRINT BY IMPLEMENTING AUTOMATED MEDICINE DISPENSING SYSTEMS IN HOSPITALISATION UNITS

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Background and Importance The Pharmacy Service (PS) has modified the method of distributing medications for hospitalised patients. Previously, distribution was based on a unit dose dispensing system in medication trolleys and distributed to Hospitalisation Units (HU) once a day. Consequently, New Treatments (NT) not included had to be prepared in individualised plastic bags for each patient and then distributed from PS to HU. Implementation of Automated Medicine Dispensing System (AMDS) in HU facilitates access to NT, reducing the distribution of medication in plastic bags from the PS.

Furthermore, the inclusion of previously stock-requested medication in the AMDS has eliminated the need for bag preparation.

Aim and Objectives Compare the impact of carbon footprint in a PS before and after the implementation of AMDS in HU.

Material and Methods A 3month post-AMDS implementation period was studied, comparing it to the corresponding 3 months of the previous year in six HU. Reduction in the number of NT prepared by the PS was analysed, assuming all of a patient's daily NT were grouped into one bag, and one bag was used per request for the preparation of stock medications.

Impact on the carbon footprint is calculated by measuring the reduction in greenhouse gases (kgCO2). Average weight of a bag was calculated to convert it into kg CO2.

Results Prior to AMDS implementation, 15,434 NT were distributed using 5,939 bags. After implementation, 3,499 NT were distributed using 2,749 bags, representing a reduction of 11,935 NT and 3,190 bags (reduction into kg CO2=0.43).

- UH1:0.16 vs 0.09 kg CO2 (48.49% reduction).
- UH2:0.16 vs 0.08 kg CO2 (51.59%).
- UH3:0.13 vs 0.07 kg CO2 (49.61%).
- UH4:0.12 vs 0.02 kg CO2 (85.59%).
- UH5:0.10 vs 0.07 kg CO2 (29.47%).
- UH6:0.14 vs 0.07 kg CO2 (55.80%).

The median reduction in kg CO2 is 50.6%.

Before AMDS implementation, 918 stock medication were distributed in 918 bags. After implementation, 241 stock medication were prepared in 241 bags, resulting in a reduction of 677 bags (0.21 kg CO2).

In total, 3,867 bags have been reduced, equivalent to 0.63 kg CO2. Therefore, the expected annual reduction is 2.54 kg CO2 avoided in waste management.

Considering the impact of bag manufacturing, the total reduction expected is between 240.96 kg CO2 and 421.88 kg CO2.

Conclusion and Relevance Implementation of AMDS reduces the consumption of plastic bags for medication dispensing in all HU analysed, thereby reducing the carbon footprint of the PS.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

2SPD-015 MEDICO-ECONOMIC EVALUATION OF SINGLE-USE VERSUS REUSABLE HYSTEROSCOPES IN OUTPATIENT GYNAECOLOGICAL CONSULTATIONS

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Background and Importance Hysteroscopy is a commonly performed procedure for gynaecological diagnosis and surgeries, traditionally conducted in the operating room (OR). To free up OR slots and simplify patient's pathways, hysteroscopies were partially shifted to outpatient consultations. Due to the lack of reusable equipment, single-use hysteroscopes (SUH) were provided as a temporary solution. One year after implementation, a medico-economic analysis is essential to assess the long-term viability of these devices compared to rigid reusable hysteroscopes (RRH).

Aim and Objectives Comparing costs associated with SUH and RRH in outpatient consultations, while assessing the technical and organisational advantages and disadvantages of each solution.

Material and Methods A retrospective economic evaluation was carried out based on SUH usage between June 2023 and June 2024 in our institution. Medical supplies needs were identified, and a comparison was made between SUH and RRH from both technical (literature and user expertise) and economic perspectives (quotes from suppliers). Internal costs were estimated, including sterilisation process, waste management, and paramedical staff time.

Results A total of 66 hysteroscopies were performed between June 2023 and June 2024. Of these, 36 required a single-use crocodile forceps, leading to an average cost of € 300 per procedure, compared to € 165 with RRH. SUH eliminate cross-contamination risks and reduce paramedical staff time by avoiding pre-disinfection and transport to the sterilisation unit. However, their use exposes healthcare establisments to supply shortages and significant ecological impacts. Gynaecologists reported dissatisfaction with SUH due to the overly flexible tip, which complicates cervical passage and limits manoeuvrability. RRH significantly reduces average costs and offers superior image quality. However, reusable devices present disadvantages, such as cross-contamination risks, increased paramedical time for equipment management, and a risk of breakage, which can inflate costs.

Conclusion and Relevance Our study revealed that RRH remains, to this day, a more economical solution than SUH, especially since the costs related to supply chain management were not factored in. However, the growing use of single-use devices could lead to a reduction in their cost in the coming years. As a result, an investment request for RRH has been made. Nonetheless, it would be worthwhile to repeat this study in the future to observe the evolution of costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-016 SMART COUNTING: THE ROLE OF ARTIFICIAL INTELLIGENCE IN CONTROLLED MEDICATION MANAGEMENT

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Background and Importance The management of narcotics and other controlled medications is a critical responsibility of hospital pharmacists (HP), who must ensure their traceability. The traditional manual counting process for these medications is prone to human error and time-consuming. The application of artificial intelligence (AI) in the counting of narcotics can improve inventory control and reduce the need for human supervision, optimising the management of these high-risk products.

Aim and Objectives The objective of this study was to assess the ability of an AI model in counting narcotics and controlled medications, comparing its performance to the manual counting conducted by an HP.

Material and Methods The study included 39 narcotic medications and seven other controlled medications. The inclusion criteria required more than five packages per specialty, and the pharmaceutical forms considered included tablets, vials, ampoules, patches, and containers of active ingredients in powder form. Procedure:

1. A manual count of each medication was performed.
2. An AI application was trained using images of complete packages and loose units for recognition.
3. Images of both complete and loose packages were captured for each medication, and the AI performed the count.
4. The AI's results were compared with the manual count. If they did not match, the process was repeated up to three times before considering the AI count as incorrect.

Results Out of the 46 available medications, 36 were included in the study. Seven were excluded due to having fewer than five packages, and three were excluded due to their pharmaceutical form. The AI correctly counted 20 packages (55.6%) on the first attempt, six (16.7%) on the second attempt, and three (8.3%) on the third attempt. In seven cases (19.4%), the AI failed to count accurately.

Conclusion and Relevance AI has the potential to optimise the counting of controlled medications, saving time and human resources. However, its accuracy still depends on factors such as image quality, lighting, and packaging arrangement, indicating the need for further development of this technology to ensure more reliable and safer results before widespread implementation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-017 ABSTRACT WITHDRAWN

2SPD-018 ADJUSTED INDIRECT COMPARISON BETWEEN PLOZASIRAN AND ZODASIRAN IN MIXED HYPERLIPIDEMIA

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Background and Importance Plozasiran and zodasiran are RNA interference agents developed for the treatment of mixed hyperlipidemia. No direct comparisons between these drugs have been performed.

Aim and Objectives To conduct adjusted indirect comparisons (AICs) on efficacy between plozasiran and zodasiran in mixed hyperlipidemia.

Material and Methods A search was developed in Pubmed database to select pivotal randomised clinical trials (RCTs) including plozasiran and zodasiran in mixed hyperlipidemia. These RCTs had to presented comparable populations, follow-up periods, endpoints and comparator arms. AICs of regimens with best benefit-risk balance were developed using Bucher's method on the following endpoints: percentage change in plasma levels from baseline to week 24 of fasting triglyceride, non-HDL cholesterol, ApoB, LDL cholesterol, HDL cholesterol, remnant cholesterol and lipoprotein (a). The absolute risk reduction (ARR) was calculated for AICs.

Results Two phase II RCTs were selected, one of each drug. A total of 557 patients were included. Doses of plozasiran 25 mg quarterly (PLOZ-25q) and zodasiran 200 mg (ZOD-200) were selected based on their superior risk-benefit balance. Placebo was common comparator. AIC limitations: short patient follow-up and minor differences in population characteristics (percentage of high-intensity statins and fibrates received). The results of the trials and AICs are shown in table 1.

Conclusion and Relevance Significant favourable differences on differing surrogate endpoints were found for PLOZ-25q (HDL cholesterol) and ZOD-200 (non-HDL cholesterol, LDL cholesterol, remnant cholesterol) in mixed hyperlipidaemia. RCTs with harder endpoints and longer follow-up are needed to establish better therapeutic positioning.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

2SPD-019 HOSPITAL PHARMACISTS ADDRESSING MEDICATION SHORTAGES IN THE EUROPEAN UNION: A COMPARATIVE ANALYSIS OF CAUSES AND SOLUTIONS IN BULGARIA AND THE EU

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Background and Importance Medication shortages have emerged as a critical public health issue throughout the European Union (EU), impacting patient care, treatment continuity, and the efficacy of healthcare systems. The shortages, intensified by the COVID-19 pandemic and regulatory complexity, have increased the necessity for integrated efforts to manage pharmaceutical supply chains.

Aim and Objectives The objective of this study is to examine the factors contributing to medicine shortages inside the EU, particularly in Bulgaria, and their association with the hospital pharmacist's role. The study aims to identify critical areas for enhancement by analysing national and EU-level data on supply chain disruptions, regulatory frameworks, and treatment deficiencies. The objectives encompass identifying the therapeutic areas most adversely affected, evaluating the implications for public health, and recommending evidence-based methods to alleviate future shortages.

Material and Methods A mixed-methods approach was utilised to examine drug shortages, incorporating both quantitative and qualitative data. Information regarding medicine shortages was obtained from official reports and registers issued by the European Medicines Agency (EMA), the Bulgarian Drug Agency, and several national health authorities within the EU. The quantitative research encompassed the frequency, duration, and severity of shortages, while the qualitative methods employed theme analysis of regulation documents and expert perspectives. A comparison analysis was performed between Bulgaria and other EU nations, concentrating on drug classifications, therapeutic domains, and supply chain weaknesses.

Results The study revealed 61 drugs in short supply in Bulgaria, many of which are critical for managing chronic conditions such as hypertension, diabetes, and cancer. Cancer and immunotherapy are the areas of therapy most affected by the

Abstract 2SPD-018 Table 1

ENDPOINTS	ARR (IC95%)	ARR (IC95%)	AICs: ARR (IC95%)
(percentage change in plasma levels from baseline to week-24)	PLOZ-25q vs. placebo	ZOD-200 vs. placebo	PLOZ-25q vs. ZOD-200
Triglyceride	−56.0% (−65.1%, −46.8%)	−63.1% (−73.6%, −52.7%)	7% (−7.16%, 21.16%)
Non-HDL cholesterol	−17.5% (−25.1%, −9.8%)	−36.4% (−45.5%, −27.2%)	19% (6.96%, 31.04%)
ApoB	−13.0% (−20.6%, −5.4%)	−21.9% (−29.7%, −14.1%)	8% (−2.61%, 18.61%)
LDL cholesterol	−2.7% (−12.4%, 7.0%)	−19.9% (−31.0%, −8.8%)	17% (2.08%, 31.92%)
HDL cholesterol	42.0% (32.1%, 52.0%)	−24.5% (−32.6%, −16.5%)	66% (53.19%, 78.81%)
Remnant cholesterol	−48.9% (−62.7%, −35.2%)	−82.0% (−103.4%, −60.6%)	34% (8.61%, 59.39%)
Lipoprotein(a)	−23.8% (−134.1%, 86.4%)	−17.1% (−31.9%, −2.3%)	−6% (−116.95%, 104.95%)

PLOZ-25q showed significant benefit on HDL cholesterol. ZOD-200 presented significant favourable differences in non-HDL cholesterol, LDL cholesterol and remnant cholesterol.

lack of important drugs, such as chemotherapeutic and immunomodulatory therapies. Contributing variables encompass restricted production capacities, heightened demand, and regulatory challenges in medicine pricing and approval procedures.
Conclusion and Relevance Medication shortages in Bulgaria and throughout the EU represent a substantial risk to public health and a challenge for hospital pharmacists. Mitigating these shortages necessitates synchronised regulatory actions, bolstered supply chain robustness, and greater communication among pharmaceutical companies, healthcare practitioners, and regulatory agencies. EMA and national agencies have enacted emergency solutions, including digital tracking systems and regulation modifications, shortages continue to challenge hospital pharmacies.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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2. Bulgarian Drug Agency reports

Conflict of Interest No conflict of interest

Production and compounding

3PC-001 STORAGE OF FARICIMAB AND HIGH-DOSE AFLIBERCEPT IN POLYPROPYLENE SYRINGES DOES NOT IMPAIR ANTIBODY INTEGRITY AFTER 28 DAYS

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Background and Importance For more than a decade, intravitreal injections of anti-vascular endothelial growth factor (anti-VEGF) drugs have been the mainstay treatment of neovascular age-related macular degeneration (nAMD). The IgG1 derived antibody faricimab and the recently approved high-dose formulation of the fusion protein aflibercept (114,3mg/mL) represent promising therapeutic approaches. However, in both cases, reliable stability data to enable compounding and storage in syringes are scarce.
Aim and Objectives The aim of this study was to evaluate the long-term integrity of faricimab and aflibercept in polypropylene syringes. We analysed the compounded drug formulations for their chemical and physical stability, sterility, and binding affinity to their antigens after compounding for up to 28 days. The stability test was conducted based on the regulations of the GMP-guidelines, ICH Q5C and Ph.Eur.
Material and Methods Both formulations were compounded under controlled clean room A conditions in a GMP-certified hospital pharmacy and stored under light protection and refrigeration (2°C to 8°C) for at least 28 days. Product characteristics were analysed using size-exclusion chromatography, nano differential scanning fluorimetry (thermal stability), UV-Vis (3D structure and aggregation index), dynamic light scattering (particle size distribution), pH measurement, sterility tests and endotoxin quantification. For quantification of binding affinity, we established a new method based on grating-coupled interferometry. In the case of faricimab, this method enabled the evaluation of the simultaneous binding mechanism of both VEGF and Ang-2 in solution, closely mimicking the mode of action after intravitreal injection.
Results Both chemical and physical stability analyses revealed no impaired functionality of faricimab and aflibercept in polypropylene syringes after at least 28 days. Additionally, no significant alteration of the binding affinity to their antigens (VEGF and Ang-2 for faricimab; VEGF for aflibercept) was detected. The safety of the compounding process and the reliability of the primary packaging system were confirmed by product sterility and absence of bacterial endotoxins.
Conclusion and Relevance The results of our stability study confirm that both faricimab and high-dose aflibercept are stable in ready-to-use polypropylene syringes for up to 28 days under refrigeration. This facilitates batch compounding and increases cost-effectiveness while maintaining patient safety.

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

3PC-002 EVALUATION STUDY OF A PAEDIATRIC NON-HAZARDOUS ROBOTIC COMPOUNDING SYSTEM: IS IT SAFE AND DOSE ACCURATE?

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Background and Importance Robotic-compounding-systems (RCS) ensure parental medications through fully automated system controlled by a software. To reduce the working area's contaminations and medication errors during paediatric manipulations, a new RCS was located into our Hospital Pharmacy's centralised intravenous additive service (CIVAS) in 2021. APOTECAped can compound standard-dose/personalised paediatric medications into appropriate final containers; all equipment used is carried out into the clean room through a barcode-system. It guarantees an aseptic process thanks to HEPA filters and a controlled environment.
Aim and Objectives With this work we evaluated APOTECAped's productivity (total compounding time, dose accuracy) and drugs' sterility.
Material and Methods APOTECAped's productivity was evaluated in a production batch of 10 Pantoprazole 4 mg/ml 10 ml and 10 Cefotaxime 50 mg/ml 20 ml syringes (data collected from APOTECAped's final reports); dose accuracy was analysed through gravimetric and volumetric controls. Bacteria and fungi's contamination was tested by the Hospital's Hygiene Department at time 0 and after 7 days from preparation (one syringe of each drug each time) after inoculation into TSB broth solutions and incubation for 7 days. Endotoxins' quantification was done by the hospital pharmacist using a chromogenic kinetik LAL-test method. The Endotoxines-Limit (EL) was 4,17 EU/mg for Pantoprazole (data based on the maximum dose administered to a paediatric patient) and 0,05 UE/mg for Cefotaxime (data from European Pharmacopoeia). We calculated the maximum dilution volume (MDV) to avoid interferences during test; for

our analysis we used MDV/2 (1:800 for pantoprazole, 1:125 for cefotaxime).
Results Pantoprazole syringes were prepared using 40 mg lyophilised powder and 10 ml of NaCl 0,9% solution; mean of dose error was – 3,87%, total time to make the production batch was 57 minutes (approximately 5 minutes/syringe). Cefotaxime syringes were prepared using 1000 mg lyophilised powder, 4 ml of sterile-injectable-water (reconstitution) and 16 ml of NaCl 0,9% (dilution); mean of dose error was −2,12%, total time to make the production batch was 88 minutes (approximately 8 minutes/syringe). Microbiological tests demonstrated the absence of bacteria and fungi's growth, LAL-test that the endotoxins' quantification was under the EL.
Conclusion and Relevance APOTECAped guaranteed dose accuracy and drug sterility during the compounding. Even if the total robotic preparation time was longer than manual, RCS could reduce human errors and increase drug safety.

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

3PC-003 FORMULATION OF AN ORAL PAEDIATRIC SUSPENSION OF AMLODIPINE 1 MG/ML: ADAPTATION TO THE NATIONAL FORMULARY AND STABILITY TESTING

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Background and Importance Amlodipine is a calcium channel blocker used to treat high blood pressure. In paediatric patients it is administered in liquid formulations with a recommended dose of 2.5 mg to 5 mg daily single dose.

At the hospital, the available formulation was an oral suspension that, when settling, formed a compact cake that was difficult to redisperse. Therefore, the paediatric department requested a new formulation that was more easily redispersible but with the same concentration.
Aim and Objectives Formulate a readily redispersible oral suspension of amlodipine 1 mg/mL and assess its quality and stability.
Material and Methods The original formulation was adapted according to the National Formulary (NF), replacing the methylcellulose with propylene glycol-free preservative water and reducing the simple syrup. The concentration was adjusted to 1 mg/mL (the formulation described in the NF is 0.5 mg/mL) using 10 mg amlodipine tablets, as the pure product was not available.

The period of validity was determined according to the Guide to Good Practice in the Preparation of Medicines in Hospital Pharmacy Services.

During validation, parameters such as redispersion time, colour, odour and pH were evaluated weekly.
Results A shelf life of 30 days in a refrigerator (2–8°C) was assigned as it was considered an oral, non-sterile magistral formula, with physicochemical stability studies, with preservatives (nipagin, nipasol) but without microbiological stability studies.

During the study period the formulation was maintained with an immediate redispersion time, easy redispersion was observed after gentle agitation, the colour of the formulation as well as the odour remained unchanged, and the pH was maintained at values between 5.5–6.5 as indicated by the NF.
Conclusion and Relevance The formulation was successfully adapted to that indicated in the NF, maintaining the concentration of the original. It is evident that the formulation developed maintains its stability for 30 days, being effective and safe, improving redispersion and facilitating the work of the nursing staff.

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

3PC-004 IMPLEMENTATION OF AN ASEPTIC TECHNIQUE VALIDATION PROTOCOL IN A PHARMACY DEPARTMENT

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Background and Importance Aseptic technique validation is crucial in ensuring the safety and quality of sterile products, reducing contamination risks in hospital pharmacy preparations.
Aim and Objectives To establish a protocol for the validation of aseptic technique (VTA) in the Pharmacy Department (PD) through simulation, assessing the performance of personnel working in aseptic conditions in compliance with good practice standards.
Material and Methods Following a literature review, the recommendations outlined in Chapter 797 of the United States Pharmacopeia (USP) and the guide on good preparation practices in hospital pharmacy services were adopted. According to USP guidelines, the process simulation test should closely mimic standard aseptic manufacturing, using a liquid culture medium instead of the usual products. The USP categorises sterile preparations into three risk levels: low, medium, and high, detailing quality control standards for each. We implemented a high-risk protocol, involving the preparation of sterile products where either a non-sterile product or device is used, utilising thioglycolate as the liquid culture medium. This scenario represents the highest risk conditions that could occur in a laminar flow hood.
Results The following protocol was developed:

1. Approximately 50 mL of non-bacteriostatic water is measured into a beaker.
2. A 0.2-micron filter is attached to a 5 mL syringe, and 3 mL of water is drawn.
3. A new 0.2-micron filter is applied, and 2.4 mL of water is injected into a vial containing thioglycolate. This procedure is repeated with another vial.
4. Three different 1 mL syringes are used to draw 0.5 mL of water each and injected into the thioglycolate vials.
5. Finally, the content of both vials is transferred to a 100 mL vacuum flask using a 50 mL syringe, labelled, and sealed.
6. A positive control (CP) is prepared by swabbing the forearm skin and placing the swab in a new thioglycolate vial. The preparations, along with the CP and a negative control (NC), are stored at room temperature for 14 days. After the incubation period, a visual inspection is performed. If the vials remain clear, like the NC, they are considered free from

contamination. Any turbidity indicates non-compliance, necessitating corrective measures, including revalidation.

Conclusion and Relevance VTA is a simple, cost-effective, and easy-to-implement process that ensures the safety and quality of sterile products.

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

3PC-005 COMPOUNDING IMIQUIMOD SUPPOSITORIES FOR CONDILOMA ACUMINATA

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Background and Importance Condylomata acuminata (CA), or anogenital warts, are typically found on the penis, vulva, perianal skin and rectal mucosa. CA may also involve the cervix and urethral canal. Topical imiquimod 5% cream containing 12.5 mg per sachet is a first-line treatment option for external CA. However, its efficacy and safety can be compromised by the difficulty of administration in the anal canal. Some authors have published the efficacy and tolerability of imiquimod suppositories, but a standardised method to compound them remains unpublished.
Aim and Objectives To review the scientific literature of imiquimod suppository compounding formulations and to compound suppositories of imiquimod 12.5 mg.
Material and Methods A literature review was carried out in PubMed and Embase using 'Imiquimod,' 'suppository,' and 'anal' as keywords. Only clinical studies were analysed. Ingredients, equipment, method of preparation, quality control, packaging, and labelling were described.
Results Imiquimod suppositories were used in four of the seven identified clinical studies. Three of them were observational studies, and one was a clinical trial. However, none explained how to compound imiquimod suppositories.

Ingredients for 240 imiquimod 12.5 mg suppositories included: imiquimod 3g, massa esteranium 637g as suppository base (no calculations for dose replacement were needed). Equipment: analytical balance, beaker, porcelain mortar and pestle, suppository mould. Personal protective equipment: gloves, gown, eye protection, FFP2 mask. Environment: cleanroom, class one laminar flow hood. Method: 1) bring mould to room temperature. 2) Weigh imiquimod powder. 3) Melt suppository base using microwaves. 4) Disperse imiquimod in melted base using mortar and pestle. 5) Pour mixture into mould cavities (no lubricant needed). 6) Cool mould in refrigerator for 1 hour. 7) Remove excess material from mould top using a spatula. Quality control: weight variation +/- 5% and visual observation. Package in a tight, light-resistant container and label. Beyond use date: 6 months.
Conclusion and Relevance Variability in imiquimod formulations likely caused contradictory results in the efficacy and tolerability of imiquimod suppositories for CA. Administering imiquimod suppositories following this preparation method may improve efficacy and safety in patients with CA who have difficulties or aversion to administering imiquimod cream in the anal canal.

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

3PC-006 SWITCHING TO SILICONE OIL-FREE SYRINGES FOR INTRAVITREAL APPLICATION: DESIGN OF A REGULATORY COMPLIANT CONTAINER CLOSURE INTEGRITY TEST REALISABLE IN A HOSPITAL PHARMACY

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Background and Importance Our hospital pharmacy compounds medicinal products for intravitreal application into ready-to-use syringes. The commonly used lubricant silicone oil has been shown in studies, since over 15 years, to elicit adverse reactions like floaters, inflammatory reactions and rapid intraocular pressure spikes. Silicone oil-free alternatives, with minimal dead space, have only recently been available and are currently a hot topic for hospital use. Before using them in production, all primary packaging containers in aseptic processes must be checked for closure integrity.
Aim and Objectives This study describes the design of a container closure integrity test (CCIT) according to regulatory guidelines EU GMP Annex 1 using resources available to our hospital pharmacy. All silicone oil-free syringes that were locally available and suitable for intravitreal application were investigated. Three products met these conditions and were tested as stopper capped systems (i.e. no needle attached).
Material and Methods Applicable guidelines do not provide precise experimental detail on how the CCIT should be executed, rather the manufacturer needs to design and validate an experiment. EU GMP Annex 1 8.23 and 8.25 demand validated methods, that include environmental parameters which can negatively impact packaging integrity (i.e. decompression during transport). A dye ingress test under complete submersion and reduced pressure with UV-Vis quantification and visual readout was designed.
Results All syringe systems tested passed the integrity test and all artificially created positive controls showed a strong signal. The limit of detection using methylene blue dye was 1.7 ng/mL. The two different syringe tip closure types, luer lock (threaded sleeve fitting) and luer slip (tapered friction fitting, without threads) showed no difference.
Conclusion and Relevance All syringes used oleamide as the lubrication agent mixed into the polypropylene barrel material and passed testing. The devices needed for CCIT were kept economical and broadly available to enable hospital pharmacies with limited budget to design a GMP compliant CCIT. The designed test is not applicable for on-line testing but rather meant for validation off-line on representative syringe samples. Summarising, the CCIT described in this work requires roughly two hours start to finish but can be executed with minimal prerequisites at low cost compared to other methods used in industrial settings.

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

3PC-007 ACCURACY AND STERILITY PERFORMANCE OF A NEW PHARMACY ROBOT-CLOSED SYSTEM TRANSFER DEVICE COMBINATION

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Background and Importance Oncology pharmacists must provide sterile and accurate preparations, while limiting exposure to hazardous drugs. Robotic compounding may provide a partial solution for short-staffed pharmacies. One new automation solution is designed to work together with a closed system transfer device (CSTD) to maintain drug sterility and prevent hazardous drug release, while streamlining CSTD implementation for administration according to USP <800>. Accuracy and sterility must be verified when integrating the robot into production. Incidence of incorrect drug concentration with manual production can reach 88%,[1] while reported robot failure rates range from 0.9–18.7%.[2]

Aim and Objectives The aim was to determine cytotoxic drug dilution accuracy and verify sterility using an automated compounder combined with a CSTD.

Material and Methods Tests were performed at Remedix Care, a preparation centre with ISO/IEC 17025:2017 accreditation.

Dose accuracy was determined for 522 preparations of carboplatin, endoxan, 5-fluorouracil, gemcitabine, oxaliplatin, and paclitaxel. Injected volumes ranged from 7 to 83 ml. The robot self-checks accuracy by mass increase of IV bags. Deviation of actual vs. expected concentrations was determined.

Media fill tests were performed on 210 infusion bags over 4 days. A range of typical manipulations to the bags were performed using the robot with CSTD. The bags were incubated at 25–30 °C for 14 days. Growth promotion tests (GPT) were performed by injecting 10 microorganism species into a sample of bags and repeating incubation.

Results Ninety-seven percent of preparations met the strict criterion of <5% deviation. Mean deviation for all preparations was ±1.6%.

None of the 210 infusion bags showed any growth in the media fill test, while all GPT controls exhibited growth.

Conclusion and Relevance The new robot + CSTD combination system was found to maintain sterility in prepared infusion bags and to reliably produce doses of the correct concentration. Comparison to other studies is difficult, due to variation in drugs prepared, acceptance criteria, and variable inclusion of a CSTD. The new combination device represents a new paradigm for safe and accurate cytotoxic preparation. Future studies will evaluate whether it can reduce cytotoxic contamination of the environment.

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Conflict of Interest Corporate sponsored research or other substantive relationships:

KM, OS, and NH declare no conflict of interest. IT and EASS are employed by Simplivia Healthcare, Ltd., a CSTD manufacturer.

3PC-008 PHYSICOCHEMICAL STABILITY OF FIVE BETA-LACTAM ANTIBIOTICS UNDER SIMULATED REAL-LIFE CONDITIONS IN OUTPATIENT PARENTERAL ANTIMICROBIAL THERAPY (OPAT)

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Background and Importance The use of OPAT is growing exponentially due to its advantages for both patients and healthcare systems. However, one of its major challenges is ensuring drug stability under the variable conditions encountered in outpatient settings.

Aim and Objectives To evaluate the physicochemical stability of five beta-lactam antibiotics in two different containers at three different external temperature conditions.

Material and Methods The antibiotics studied were: meropenem 12mg/mL, ceftazidime 24mg/mL, ceftazidime/avibactam 24/6mg/mL, cefiderocol 10mg/mL, and ceftaroline fosamil 6mg/mL, all in 0.9% saline polyolefin bags. Pyridine concentration, a degradation product of ceftazidime, was also analysed.

Physical characteristics and pH were evaluated. Antibiotic concentrations were measured by UHPLC. All samples were analysed in triplicate at four storage temperatures: below 10°C, 15°C, 23°C and 30°C.

Temperature evolution inside portable thermal bags and porexpan boxes was monitored for 24h at three different external temperatures: 23°C, 30°C and 40°C.

Finally, antibiotic stability was correlated with the temperature inside the portable coolbox to define the maximum stability time for each antibiotic under specific external temperature conditions.

Results Chromatographic methods for the six molecules were developed and validated.

No changes in physical characteristics or pH were observed.

Time above 90% of the initial concentration for each antibiotic is shown in table 1.

Pyridine concentration did not exceed European Pharmacopoeia limits (<500ppm) at any point during the study.

Temperature inside the porexpan box remained below 23°C for 24h and below 10°C for 16h, regardless of the external temperature tested.

In the portable coolbox, the internal temperature stayed below 23°C for 24h when external temperature was 23°C; for 12h at 30°C, and for only 8h at 40°C.

Abstract 3PC-008 Table 1

Temperature	Meropenem	Ceftazidime	Avibactam	Cefiderocol	Ceftaroline fosamil
3–10°C	72h	72h	72h	72h	72h
15±2°C	24h	48h	48h	48h	48h
23±2°C	24h	48h	48h	48h	24h
30±2°C	10h	30h	30h	30h	8h

Conclusion and Relevance All antibiotics studied remained stable for at least 24h, even at the highest temperature tested, when stored in a porexpan box. When stored in a portable coolbox, all antibiotics were stable for at least 24h at 23°C. However, at 30°C, only ceftazidime, ceftazidime/avibactam, and cefiderocol remained stable for 24h. At higher temperatures, a more hermetic container would be recommended to ensure 24-hour stability.

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

3PC-009 ECONOMIC IMPACT ASSOCIATED WITH A FARICIMAB VIAL SHARING PROTOCOL IN PATIENTS WITH AGE-RELATED MACULAR DEGENERATION IN THE HOSPITAL OF SAGUNTO

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Background and Importance Faricimab has proved to be an important therapeutic tool for age-related macular degeneration and diabetic macular oedema.
Aim and Objectives This study sought to determine the cost savings that can be achieved by implementing a faricimab vial sharing protocol in patients with age-related macular degeneration.
Material and Methods A 5-month technical, observational, and retrospective study performed from 1 May to 30 October 2024 at the Hospital of Sagunto.

Faricimab fractioning method consisted of aliquoting the product in a laminar flow hood following US Pharmacopeia standard. For preparing each batch, 10 vials of Vabysmo 120 mg/ml 1 VIAL 0,24 ml were needed. We used Zero Residual silicone oil-free filter needles and the auxiliary Zero Residual Bubble Adapter.

Faricimab was passed into the sterile glass vial and finally, repackaged in Zero residual syringe 0.2 ml with sterile protective cap. Each syringe was filled with 0.08 ml of faricimab solution. Ten vials of Vabysmo were used for each batch prepared, 25 syringes of faricimab were obtained, resulting in 2.5 IVI doses of faricimab (0.08ml) from one vial of Vabysmo. The prepared syringes were placed in a sterile photoprotector bag and stored 2–8°C. Intavitreal injections (IVI) were administered in the theatre, following the Royal College of Ophthalmologists' Guidelines for IVI Procedure, within the next 8 days after the fractioning process.
Results A total of 433 IVI (6mg/0,05 ml) of faricimab were administered to 156 patients with AMD-DME from 1 May to 30 October 2024 in the ophthalmology department of the Hospital of Sagunto. Cost savings were calculated for the total number of IVI administered. The cost of 433 IVI would have been 404.876,65€ considering that a faricimab vial is acquired for 935,05€ . With the fractioning method, 174 vials were used for all the injections (three 2.5 doses prepared from a vial), costing 161.950,70€ and thus saving 242.925,95€ (59.8%), reducing the single IVI's cost from 935,05€ to 374,02€ . The estimated total cost savings between these 5 months, when the compounding was commissioned, was 242.925,95€ .
Conclusion and Relevance Faricimab vial sharing from a single vial showed that this mab is also fractioned with a significant reduction in public health care costs associated with antiangiogenic treatment.

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

3PC-010 ABSTRACT WITHDRAWN

3PC-011 ABSTRACT WITHDRAWN

3PC-012 SODIUM PENTOBARBITAL RECTAL PREPARATIONS: OPTIMISATION OF A MANUFACTURING PROCESS, AND DEVELOPMENT OF FORMULATION

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Background and Importance Pentobarbital (PTB) is a barbiturate used for paediatric sedation, without existing marketed specialties. This requires the use of hospital preparations. In our pharmaceutical department, PTB suppositories are produced. Between 2018 and 2023, batches revealed significant non-compliance issues, particularly with uniformity of content. To improve patient safety and efficacy, optimising paediatric sedation was necessary by improving the suppository manufacturing process and the development of a more stable alternative - a rectal solution of PTB.
Aim and Objectives The aim of this study is to optimise paediatrics sedation by developing a new formulation (pentobarbital rectal solution) and determining its stability.
Material and Methods An intra-rectal PTB solution in a sterile water-based formulation was prepared. The protocol included developing and validating a stability-indicating High-Performance Liquid Chromatography (HPLC) method to quantify pentobarbital, detect degradation products, and conduct a stability study. The HPLC method, developed using an XSelect column and a mobile phase composed of water (pH 3) and acetonitrile (65:35 v/v) in isocratic elution (flow rate 0.4 mL/min). Quantification was performed using UV detection analysed at 210 nm. Forced degradation tests under acidic, alkaline, oxidative, and thermal stress conditions were conducted. To assess physical-chemical stability, three batches were prepared, packaged in amber glass vials and syringes (two pieces) at 2–8°C and 25°C/60% relative humidity. Visual appearance, PTB concentration, pH and osmolality were evaluated throughout the study period (183 days).
Results Degradation products were observed. Validation of the analytical method was carried out in accordance with ICH Q2 guidelines over 3 days, by two different operators. The validated method showed good repeatability, resolution, specificity, precision, accuracy, and linearity.

The last day (Day 183) PTB concentration remained above 95% of the initial concentration for all batches. pH and osmolality and remained stable. An impurity appeared in D59

coeluted at room temperature (no appearance at 2–8°C) representing 0,8% (relative-area).
Conclusion and Relevance Pentobarbital rectal solution can be produced and stored for 183 days at 2–8°C in vials and syringes, two pieces. The formation of coeluted impurities suggests that storage at room temperature is not recommended. Syringe packaging enables standard doses to be produced, limiting the risk of error and simplifying the administration process.

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

3PC-013 IN THIS ABSTRACT WE EXPLAIN THE COMPOUNDING OF BEVACIZUMAB EYE DROPS FOR NEOVASCULARISATION, SOME STUDIES HAVE DEMONSTRATED THEIR EFFICACY, IT HAS 1 MONTH STABILITY

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Background and Importance Vascular endothelial growth factor (VEGF) is a mediator in the process of neovascularisation in the cornea. VEGF inhibitors, such as, bevacizumab are currently one of the treatments of neovascular age-related macular degeneration (AMD). Bevacizumab is a full-length humanised antibody against VEGF and has been approved for use in oncology but is also widely used as an off-label treatment for choroidal neovascularisation, central retina occlusion, proliferative diabetic retinopathy and iris neovascularisation, with good results. Recently, the off-label use of topical as well as subconjunctival bevacizumab has been considered as a new treatment modality for corneal neovascularisation.
Aim and Objectives The compounding of bevacizumab eye drops in two different concentrations.
Material and Methods Bevacizumab eye drops in a sterile compounding can be prepared in two different concentrations in vertical laminar flow hood in a sterile environment and applying the Good Manufacturing Practices:

Bevacizumab 1% eye drops: in a sterile dropper 10 mL container add 4 mL of bevacizumab (avastin 400 mg/16 mL) and 6 mL of physiological saline solution.

Bevacizumab 0.5% eye drops: in a sterile dropper 10 mL container add 2 mL of bevacizumab (avastin 400 mg/16 mL) and 8 mL of physiological saline solution.

The recommended stability is 1 month at 2–8°C not open and 7 days at 2–8°C once open.
Results Bevacizumab eye drops can easily prepared as a sterile compounding and used when the intravitreal syringes of bevacizumab are not appropriate for use.
Conclusion and Relevance The off-label use of topical bevacizumab for corneal neovascularisation is an option for patients with choroidal neovascularisation, central retina occlusion, proliferative diabetic retinopathy, iris neovascularisation and age-related macular degeneration.

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Conflict of Interest No conflict of interest

3PC-014 APPLICATION OF 3D PRINTING TO THE FORMULATION OF A NOVEL ANTICANCER AGENT FOR PAEDIATRIC DIFFUSE INTRINSIC PONTINE GLIOMA

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Background and Importance The administration of medications in paediatric care can be challenging and cumbersome, impacting both acceptability and clinical outcomes. Three-dimensional (3D) printing is an additive manufacturing technology that enables the customisation of medications in terms of size, dose, and release profile. Semi-solid extrusion allows the production of dosage forms, such as 'gummies' from a gel, offering an alternative to oral solutions and capsules. ONC201 is an anticancer molecule used in the treatment of diffuse intrinsic pontine glioma. However, it is currently only available in fixed-dose capsules.
Aim and Objectives This study aims to develop a 3D-printable ONC201 hydrogel and evaluate the physicochemical characteristics of the resulting dosage forms.
Material and Methods A M3DIMAKER pharmaceutical 3D printing machine with a pressure-driven motorised SSE print head was used. Physicochemical characteristics were assessed using X-ray diffraction (XRPD), Fourier-transform infrared spectroscopy (FTIR), and thermal analysis. A MCR302 rheometer was employed to study the rheological properties essential for transforming a design into a 3D object. The dissolution profile was established using a USP Type II dissolution apparatus after treatment with artificial saliva. Finally, content uniformity and mass uniformity measurements were performed using high-performance liquid chromatography, according to European Pharmacopoeia (Ph.Eur.) requirements for solid oral dosage forms.
Results A hydrogel formulation was developed, in which the water component (60% w/w) contains solubilised ONC201, with gelatine serving as the gelling agent. The hydrogels were extruded through a 20G nozzle at room temperature under constant pressure, producing oval, self-supporting chewable prints, each containing 100 mg of the active ingredient. A 24-hour drying period resulted in a 15% mass loss before primary packaging. ONC remains in a solubilised form within the gummy according to XRPD data and is distributed homogeneously according to FTIR. The dissolution profile reached 80% within 45 minutes in an acidic medium with pretreatment, meeting Ph.Eur. recommendations with good physicochemical stability over time. The mass and content uniformity complied with Ph.Eur. standards.
Conclusion and Relevance As demonstrated by the development of ONC201 gummies, 3D printing of medications offers an innovative solution for the personalisation of paediatric

treatments. The results indicate a stable and effective formulation, with rapid dissolution and content uniformity.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-015 DEVELOPMENT AND PREPARATION OF A GEL FOR URETHRAL ADMINISTRATION OF 5-FLUOROURACIL AND LIDOCAINE FOR THE TREATMENT OF CONDYLOMA ACUMINATUM

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Background and Importance Condyloma acuminatum are warts in the genital and perianal regions caused by human papillomavirus (HPV), with 9–17% of men with external warts also having intraurethral warts. Though benign, these warts have a potential for malignancy.

Treatment options include topical therapies, ablative treatments like surgical excision, and systemic immunotherapy.

The lack of suitable therapies in the Portuguese market, prompted the Urology Department to request our collaboration to develop a local alternative with 5-fluorouracil (5-FU) and lidocaine.

Aim and Objectives Pharmaceutical development and preparation of a compounded medication (CM) containing 5-FU and lidocaine to treat condyloma acuminatum intraurethral warts.

Quality control of the prepared pharmaceutical form.

Material and Methods Pharmaceutical development began with a literature review of the pharmacological and physicochemical properties of the active pharmaceutical ingredient (API). Based on this information, a procedure was defined, and an operating procedure was elaborated. A test formula was prepared, and its stability concerning appearance and pH was studied over 10 days.

Results 5-FU is an antimetabolite, used either alone or in combination for the local treatment of condyloma acuminatum, being generally well tolerated.

There is emerging evidence that lidocaine, an anaesthetic, may also have antitumor properties, potentially impacting disease progression and enhancing the effects of 5-FU.

Literature regarding the combination of these API in extemporaneously prepared non-sterile ointments exists.

A gel containing 11 ml with 2.5% 5-FU and 1% lidocaine was prepared in a sterile environment, suitable for cytotoxic drug preparation, using a closed system. It was stored between 2 and 8°C, and its appearance and pH were evaluated over 10 days. As no changes were observed, a beyond use date of 10 days was assigned according to the United States Pharmacopeia guidelines.

After approval, the CM was available to use in the institution. The administration was well tolerated by the patient, with no significant complications.

Conclusion and Relevance This pharmaceutical intervention provided a personalised therapeutic solution in the absence of commercially available treatments. The method used allows for the safe preparation of the CM, ensuring its quality, particularly in terms of sterility.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-016 STABILITY EVALUATION OF FOUR METHADONE INTRAVENOUS MIXTURES USED IN PALLIATIVE SEDATION

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Background and Importance In palliative care, drug infusions containing opioids are commonly used, but stability data regarding methadone mixtures are limited.

Aim and Objectives To evaluate the physicochemical stability of four quaternary mixtures containing methadone in different diluents and storage conditions, as well as to validate a high-performance liquid chromatography (HPLC) method for this purpose.

Material and Methods Composition of four intravenous mixtures to be studied was agreed upon by a multidisciplinary team including pharmacists and palliative care physicians: methadone 5 mg, midazolam 30 mg, buthylscopolamine 60 mg and haloperidol 5 mg in 250 mL saline (M1) and 500 mL 1/3 glucosaline (M2); methadone 250 mg, midazolam 250 mg, buthylscopolamine 240 mg and haloperidol 30 mg in 250 mL saline (M3) and 500 mL 1/3 glucosaline (M4).

Two samples of each mixture were respectively stored at light exposed/protected conditions during 48 hours at room temperature. From each sample 1 mL was filtered and analysed by triplicate. Visual inspection, pH measurement and drug content were considered at 0, 24 and 48 hours. Stability was defined as the absence of visual changes, not significant pH variation and a remaining drug concentration of 90–110% of the initial concentration.

Drug quantification was performed by RP-HPLC-DAD. Chromatographic conditions were: flow rate 0.6 mL/min, mobile phase monopotassium phosphate 10 mM buffer (pH=2.5): methanol (gradient: 0–10 min 75:25, 10–18 min 60:40, 19–23 min 75:25), column C18, 100x4.6 mm, 2.6µm, temperature 25°C, injection volume 1µL, detector wavelength 220 nm and analysis time 23 min.

Results A linear regression equation was obtained for each drug studied to validate method. Coefficient of determination showed the method was linear in the range of concentrations considered. Time of retention for each drug was, in minutes: butylscopolamine 8.54; midazolam 11.23; haloperidol 12.37 and methadone 13.76. Precision and accuracy were also evaluated. Selectivity and specificity were confirmed by 2D-ultraviolet spectral analysis.

After 24 and 48 hours, none of the mixtures experienced visual changes. pH values among days did not change significantly either. The remaining concentration of all drugs was considered acceptable according to the established considerations.

Conclusion and Relevance The HPLC method was successfully validated. All four methadone mixtures remained stable for 48 hours under both light exposed and protected conditions. This confirms their stability and suitability for use over this period.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-017 ASSESSING THE CARBON IMPACT RELATED TO THE PRODUCTION OF ANTICANCER DRUGS IN ISOLATOR AND AUTOMATED CHEMOTHERAPY PREPARATION ROBOT

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Background and Importance Healthcare activities are significant emitters of greenhouse gases, notably CO2, a major contributor to global warming. Recently, automation systems for chemotherapy compounding have emerged in hospital pharmacies, offering benefits: increased productivity, smoother workflow, and reduced risk of musculoskeletal dysfunctions.
Aim and Objectives This study aims to evaluate the CO2 equivalents emitted related to the preparation of an anticancer drug using an isolator (manual preparation) and a robot (automated preparation).
Material and Methods This study focuses on the standardised production of 500 mg rituximab in 250 mL infusion bags. To reflect usual practices, calculations were based on campaigns of seven preparations, then extrapolated to estimate annual production. The analysis includes resources used (energy consumption, staff mobilisation, waste management, etc.,) and products consumed (medications, medical devices, consumables). Data collection relied on product weighting, information from manufacturers and service providers, and literature. These data were converted into CO2 equivalents using the public databases CareBone (Paris Hospital) and Empreinte (French Agency for Ecological Transition).

Total uncertainty was calculated by factoring in uncertainties related to emission factors and activity data, weighted by carbon emissions of each category.
Results The carbon footprint of producing 315 rituximab 500 mg infusion bags annually was 25778 kg CO2 eq in an isolator, or 25669 kg CO2 eq with the robot. The relative difference is 0.43%. The largest contributor is the medication supply chain, accounting for 98.4% and 98.8% of total emissions, respectively.

In the isolator, medical devices and consumables contribute 193.5 kg CO2 eq, and staff mobilisation 184.5 kg CO2 eq. With the robot, these values are 139.5 kg and 2.8 kg CO2 eq, respectively. The uncertainty rate is 64%.
Conclusion and Relevance Both production methods result in nearly identical carbon emissions. The robot requires significantly less staff, reducing its carbon footprint. However, its greater weight and energy consumption lead to slightly higher emissions overall compared to the isolator. One limitation of this study is the use of a monetary factor to convert rituximab into CO2 equivalents. Nevertheless, it appears that the most effective strategy for reducing the carbon footprint, beyond the choice between manual or automated production, lies in conducting production through campaigns, minimising consumable use.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-018 POORLY WATER-SOLUBLE DRUGS: IS THE COMPOUNDING OF ADAPTED DOSES BETTER THAN PHARMACEUTICAL MARKETED SPECIALTIES? EXAMPLE OF DIAZOXIDE

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Background and Importance Diazoxide is a first-line treatment for hyperinsulinemic hypoglycaemia in children.[1] While a 50 mg/mL oral suspension (Proglycem) is available through compassionate use, its high concentration and numerous excipients make it unsuitable for premature infants. In the neonatology department, diazoxide 25 mg capsules (Proglicem) are opened and dissolved in 5 mL of water. A specific volume, calculated based on the child's weight, is then drawn with a syringe and administered. However, diazoxide is almost insoluble in water,[2] which raises concerns about its effectiveness in this preparation.
Aim and Objectives The main objective was to measure the quantity administered to the patient by applying the service protocol. Possible alternatives to optimise the therapeutic management and secure the dose administered were also studied.
Material and Methods The analysis and quantification of diazoxide in solution were conducted using UV spectrophotometry (λ = 280 nm). As this assay method was already routinely used in the control laboratory, the analytical validation criteria – linearity, accuracy, precision, and specificity – had been previously verified. The assays were performed using 25 mg capsules (Proglicem). The results were compared with a similar protocol using 5 mg capsules, prepared in-house as part of hospital formulations. Additionally, multiple rinses of the container were carried out to ensure the full recovery of the dissolved dose, aiming to optimise the administration process.
Results After an adapted dilution in sodium hydroxide 0.1 M, the expected theoretical concentration of diazoxide was 10 µg/mL. The average concentrations ($\overline{C}$) obtained from the dissolution tests (n=5) were as follows:

- 25 mg capsule (in 5 mL of water): $\overline{C}$ = 5.64 µg/mL (± 0.93 µg/mL).
- 5 mg capsule (in 5 mL of water): $\overline{C}$ = 6.87 µg/mL (± 0.29 µg/mL).
- 5 mg capsule (with successive rinses using 2+2+1 mL of water): $\overline{C}$ = 7.06 µg/mL (± 0.098 µg/mL).

The Student's t-test comparing the average concentrations obtained through the different processes showed no significant difference at a 5% significance level.
Conclusion and Relevance These trials highlight variability in current administration methods, with significant risks of under-dosing. The use of appropriately dosed capsules avoids dilution, improving the security of the administered dose. However, developing ready-to-use oral suspension could improve dosing accuracy and security.

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Conflict of Interest No conflict of interest

3PC-019 DEVELOPMENT OF A SODIUM THIOSULPHATE 15% + ZINC OXIDE 15% TOPICAL FORMULATION FOR THE TREATMENT OF CALCINOSIS CUTIS

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Background and Importance Calcinosis cutis is a rare, severe and chronic condition characterised by the deposition of insoluble calcium salts in the skin and subcutaneous tissue. These calcium salts cause reduced mobility, pain and chronic infections related to the development of ulcers. The preferred initial treatment is topical or intralesional sodium thiosulphate (STS). Intralesional administration is related to important adverse effects such infections and local pain, which make topical administration a preferred route.
Aim and Objectives The aim was to develop and use a topical formulation based on STS to treat skin calcifications, promoting wound re-epithelialisation and facilitating the removal of calcium deposits.
Material and Methods Based on existing literature a range of concentration of 10–25% STS formulations can be used. Zinc oxide was added due to its strong capacity to absorb exudates and skin secretions, as well as its wound healing and antiseptic properties. After testing various concentrations, the chosen formula was a 15% STS + 15% zinc oxide formulated in a water-in-oil (W/O) emulsion. According to the '*Guía de buenas prácticas de preparación de medicamentos en servicios de farmacia hospitalaria*' *(Guide to good practices for preparing medications in hospital pharmacy services)* of the Spanish government, a beyond use date of 30 days at room temperature was established.
Results The described formula was successfully used in six patients. The 15% of STS was enough to dissolve calcium deposits and consequently, to facilitate the manual deposits withdrawal by nursing. Additionally, the use of zinc oxide accelerated ulcer healing, allowing the treatment of the peri-wound skin, where non-visible small calcium deposits may be present. Moreover, this formula allows to space topical therapy every 48 hours, reducing potential local irritation caused by STS.
Conclusion and Relevance Sodium thiosulphate 15% + zinc oxide 15% W/O emulsion is an useful treatment in calcinosis cutis, improving wound healing and reducing potential complications associated to this process.

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

3PC-020 COMPARISON OF ROBOTIC AND MANUAL RECONSTITUTION: STABILITY ASSESSMENT OF PROTEIN DRUGS IN HOSPITAL COMPOUNDING

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Background and Importance Reconstitution of protein drugs (PDs) in hospitals is typically done manually by trained staff. Despite strict protocols, human error and post-reconstitution stressors can affect PD stability, leading to immunogenicity, reduced efficacy, or adverse reactions.[1 2] Robotic reconstitution systems offer benefits, such as standardising procedures and improving occupational health through ergonomic advantages. These systems reduce reliance on manual preparation, which may lead to more consistent product quality.
Aim and Objectives The study aims to compare the stability of four model PDs reconstituted using different robotic programmes. Traditional and advanced analytical techniques were used to evaluate whether robotic reconstitution programmes preserve PD quality and stability.
Material and Methods Four protein drugs, including nanobodies and bispecific antibodies, were reconstituted using a Kiro Grifols chemotherapy robot. Five different methods were compared: four robotic programmes (Slow 3, Slow 10, Fast, Wave) and one manual process. Analytical tools included Dynamic Light Scattering (DLS), Flow Imaging Microscopy (FIM), Size-Exclusion Chromatography (SEC), and visual inspection. Additionally, smart labels (CPI, UK) monitored environmental factors (e.g., vibration, shock), and Principal Component Analysis (PCA) was applied to identify correlations between protein stability and reconstitution conditions.
Results Protein A showed significant air bubbles and particles (>25 μm), especially with the robotic Wave programme, while Protein B exhibited minimal foaming. Proteins C and D demonstrated varying particle counts across all reconstitution methods, with protein morphology influenced by factors like vial dimensions. The PCA revealed that mechanical factors such as vibration did not significantly impact stability, suggesting that robotic methods are on par with manual processes.
Conclusion and Relevance Robotic reconstitution systems provide equivalent stability compared to manual methods for the studied drugs, offering advantages in reducing human error and standardising preparation processes. While particle formation was observed, it was not directly tied to the robotic method used. Further optimisation of robotic reconstitution programmes may enhance PD stability and hospital compounding practices.

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Conflict of Interest No conflict of interest

3PC-021 ANAKINRA EYE DROPS FOR THE TREATMENT OF DRY EYE ASSOCIATED WITH GRAFT-VERSUS-HOST DISEASE (GVHD): CASE REPORT

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Background and Importance Severe dry eye syndrome affects the ocular surface, causing discomfort and visual disturbances.
Aim and Objectives To describe a clinical case of a patient with severe dry eye syndrome treated with 2.5% Anakinra eye drops as an off-label use for topical ophthalmic administration to manage ocular dryness associated with graft-versus-host disease (GVHD). Anakinra, an interleukin-1 (IL-1) receptor antagonist, is commonly used for juvenile idiopathic arthritis and rheumatoid arthritis, but it is not approved for ophthalmic use.
Material and Methods A 62-year-old male patient with keratopathy due to severe dry eye syndrome secondary to graft-versus-host disease. The patient, who also has leukaemia, received therapy with antibodies and immune system-produced substances (TASPE) in August 2021 and reported a decrease in visual acuity.
Results The patient, who did not respond to standard treatments (0.05% cyclosporine eye drops, insulin, and 20% autologous serum), received 2.5% Anakinra eye drops as off-label treatment. The ophthalmology service requested the formulation of the eye drops from the pharmacy compounding service. After reviewing the available literature, the eye drops were prepared under sterile conditions using a horizontal laminar flow hood. The total volume of an Anakinra syringe (0.67 ml) was diluted in a carboxymethylcellulose gel (Viscofresh) to achieve the required concentration. The final volume of the preparation was 4 ml, with a shelf life of 7 days when refrigerated.
Conclusion and Relevance The patient began treatment on 29 March 2023, with a regimen of 1 drop every 8 hours. As of 25 September 2023, the frequency was adjusted to 1 drop every 12 hours. During regular follow-up visits with the ophthalmology service, the patient reported symptomatic improvement.

Although the existing literature on the use of 2.5% Anakinra eye drops is very limited, the clinical improvement reported by the patient since the beginning of treatment suggests that this formulation could be a promising alternative for managing severe dry eye syndrome.

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

3PC-022 OPTIMISATION OF QUALITY CONTROLFOR 68GA-EDOTREOTIDE (SOMAKIT): TIME IS OF THE ESSENCE..

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Background and Importance Edotreotide (SomaKit), radiolabelled with 68Ga, is used in PET imaging to study somatostatin receptor overexpression. Quality control (QC), as outlined in the product summary (SmPC), includes determining radiochemical purity (RCP) via a two-system radiochromatographic method. The eluent migration step is the most time-consuming in this process.
Aim and Objectives This study aimed to optimise the radiochromatographic method by reducing the migration distance (Dm) while maintaining acceptable analytical performance.
Material and Methods Ten trials were conducted, each with two radiochromatographic systems:

System 1: ITLC-SG stationary phase and 77g/L ammonium acetate in a 50:50 water/methanol mobile phase.

System 2: ITLC-SG stationary phase and 0.1 mol/L sodium citrate in water mobile phase.

Each trial used four chromatography strips: two following the SmPC (12 cm strips with 9 cm Dm) and two with an alternative method (4 cm strips with 3 cm Dm). Migration times (Tm) were recorded, and radiochromatograms were analysed with Gina software for RCP and resolution (Rs). Results were expressed as mean ± standard deviation, and a significance level of $\alpha = 0.05$ was used to compare RCP means. All chromatograms required Rs > 1.5 (EANM standard).
Results For **System 1**, the average migration times were 22.67 ± 1.53 minutes for a 9 cm Dm and 2.67 ± 0.29 minutes for a 4 cm Dm.

For **System 2**, the average migration times were 7.08 ± 0.80 minutes for a 9 cm Dm and 1.50 ± 0.50 minutes for a 4 cm Dm. The average RCP was 98.39 ± 1.16% for a 9 cm Dm and 97.98 ± 1.65% for a 4 cm Dm. There was no significant difference in RCP between the two Dm values ($p = 0.7$).

All radiochromatograms showed an acceptable resolution (Rs > 1.5). On average, the optimised method with a reduced Dm of 4 cm resulted in a time saving of approximately 20 minutes.
Conclusion and Relevance Reducing the migration distance significantly reduced QC time while maintaining satisfactory analytical characteristics (Rs > 1.5) and comparable RCP to the reference method ($p \geq 0.05$). This time saving, taking into account the radioactive half-life of 68Ga (67.8 minutes), allowed us to increase the average number of doses dispensed per preparation.

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

3PC-023 FORMULATION AND CHARACTERISATION OF FLUORESCEIN SODIUM SOLUTION FOR INJECTION FOR DIAGNOSTIC ANGIOGRAPHY

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Background and Importance Fluorescein sodium as diagnostic contrast agent belongs to the World Health Organization's List of Essential Medicines. In our hospital fluorescein sodium injection is used in diagnostic fluorescein angiography to diagnose and monitor various eye diseases. After intravenous injection, dye quickly circulates through the blood vessels of the eye and illuminates them, thus enabling photographs to be taken with a special camera. However, due to shortage of fluorescein sodium injection on our market during the past year, a formulation had to be developed.
Aim and Objectives The aim of this work was to formulate and characterise fluorescein sodium solution for injection and determine the stability at room temperature (25 ± 2°C) during its shelf life period.
Material and Methods Fluorescein sodium solution for injection is prepared in laminar flow cabinet. Fluorescein sodium is completely dissolved in water for injection, then filtered through membrane filter with 0.22 μm pore size and packed into glass container. Obtained product was autoclaved at 120°C for 20 minutes, in its final container. Characterisation in terms of determination of drug content, sterility testing and test for pyrogens was carried out after sterilisation and during a 6 month period. Drug content analysis was performed using spectrophotometric method according to USP by our control laboratory. Sterility (Ph. Eur., general chapter 2.6.1) and pyrogen testing (Ph. Eur., general chapter 2.6.8) were conducted by an external lab.
Results A brownish and homogenous solution of fluorescein sodium was obtained. No visual changes were observed during 6 month period. Obtained fluorescein sodium concentration after sterilisation was 98.58% of the defined concentration and it increased slightly from 99.20% (after 3 months) to 100.22% (after 6 months). Final product maintained to be sterile and pyrogen-free after 6 months. Therefore, shelf life period was proven to be 6 months at room temperature (25 ± 2°C).
Conclusion and Relevance Fluorescein sodium injection is an indispensable diagnostic medicine in ophthalmology. The formulation of fluorescein sodium solution for injection (500 mg/2.5 mL) was successfully developed in our hospital pharmacy service. The solution has been prepared since August 2023 and remained stable and active for at least 6 months.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-024 EFFECTIVENESS OF PLERIXAFOR IN HAEMATOPOIETIC STEM CELL MOBILISATION AND REPACKAGING STRATEGY TO REDUCE COST

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Background and Importance Plerixafor is indicated in combination with granulocyte-colony stimulating factor (G-CSF) to enhance mobilisation of haematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in adult patients with lymphoma or multiple myeloma whose cells mobilise poorly.
Aim and Objectives Assessing the use of plerixafor in routine clinical practice and to evaluate its effectiveness, and perform an economic analysis of the cost avoided by repackaging vials.
Material and Methods Observational, retrospective, descriptive study that included all patients who received plerixafor between January 2018-July 2024. Data were collected using the electronic medical record. Variables analysed: age, sex, diagnosis, type of previous mobilisation therapies, CD34+ cell concentration in peripheral blood (PB) and plerixafor dose administered. Apheresis requires a minimum CD34+ cells count in PB >10 cells/μL. Standard successful mobilisation was considered to be the collection of $\geq 2x10^6$ CD34+cells/kg and optimal in the case of $\geq 5x10^6$ CD34+cells/kg. An analysis of the avoided cost associated with the repackaging of vials is also performed.
Results Forty-two patients were included. The median age was 58.65±10.71 years old and 52.38% (n=22) were men. The diagnoses were 21 (50%) multiple myeloma, eight (18.04%) non-Hodgkin's lymphoma, seven (16.66%) donors, four (9.52%) Hodgkin's lymphoma, one (2.38%) lymphomatoid-granulomatosis; therefore, in 81.96% (34/42) of the cases, its use has been adjusted to the Summary of Product Characteristics. Previous therapies: 18 patients failed to mobilise with G-CSF, 12 with etoposide-G-CSF, seven cyclophosphamide-G-CSF, four etoposide-G-CSF and cyclophosphamide-G-CSF, one etoposide-G-CSF and gemcitabine. 36 patients (85.71%) reached an adequate level of CD34+ cells in PB to perform apheresis. The dose of plerixafor used was 0.24 mg/kg/day with an average dose of 18.6-mg. Plerixafor has been prepared in a horizontal laminar flow hood, keeping the unused drug fraction in a refrigerator, stability of 84 days. The average wholesale price of a 24-mg vial of plerixafor is € 4,846.36. If it had not been repackaged, the total cost would have been € 203,547.12, but it was € 150,242.37, representing a saving cost of € 53,304.75.
Conclusion and Relevance Plerixafor has been shown to be effective for the mobilisation of haematopoietic progenitors in patients refractory to standard regimens. The development of a repackaging strategy has been shown to be efficient since more patients can be treated with the same budget.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-025 IMPLEMENTATION OF FULLY AUTOMATISED IN-HOUSE SYNTHESIS OF THERAPEUTIC RADIOPHARMACEUTICAL [^{177}LU]LU-DOTA-TOC

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Background and Importance [^{177}Lu]Lu-DOTA-TOC is a beta particle-emitting radiopharmaceutical indicated for the peptide receptor radiotherapy of advanced neuroendocrine tumours

(NET). The substance is characterised by affinity to somatostatin receptors, which are overexpressed in NET patients. The synthesis of this radiopharmaceutical can be performed inside specially designed isolators, manually or automatically using synthesiser and represents a challenge for every department of nuclear medicine.

Aim and Objectives The aim was to implement automatised in-house synthesis of [^{177}Lu]Lu-DOTA-TOC to improve NET patient management in the department of nuclear medicine.

Material and Methods Using a fully automated cassette-based synthesiser, a radiolabelling process was developed. The complexation reaction was performed in ascorbate buffer and with thermal heating of 115 µg DOTA-TOC and 8.0–8.4 GBq of $^{177}LuCl_3$ solution. At the end, drug substance was eluted through sterile filter into the product vial. Then, saline was added to dilute the solution. Radiochemical purity (RCP) of [^{177}Lu]Lu-DOTA-TOC was determined by radio-HPLC and TLC. For TLC two mobile phases (0.1 M citrate buffer pH 5.5 and 1 M ammonium acetate/methanol 1:1) were used both based on ITLC-SG strips as solid phase. Confirmation of [^{177}Lu]Lu-DOTA-TOC identity was done by UV HPLC using a non-radioactive standard. In accordance with European Pharmacopoeia, sterility and endotoxine tests were performed. An automated filter integrity test was performed on the final sterile filter.

Results The three validation batches of [^{177}Lu]Lu -DOTA-TOC were synthesised with an activity of 7.55 ± 0.15 GBq. The application volume was from 19 mL to 20 mL. The RCP determined by HPLC was 99.6 ± 0.5% and with TLC was 99,2 ± 0,5%. The [^{177}Lu]Lu-chloride and [^{177}Lu]Lu -colloid determined by TLC were quantified and the results obtained were 0.7, 0.14, and 0.31% for [^{177}Lu]Lu-chloride and 0.4, 0.2, and 0.4% for [^{177}Lu]Lu-colloid respectively. The retention time comparison between the standard and [^{177}Lu]Lu-DOTA-TOC was inferior to 12s. The bubble point test passed for each batch. The drug products were sterile and endotoxin-free.

Conclusion and Relevance The automatised synthesis of [^{177}Lu] Lu-DOTA-TOC was successfully implemented. The reproducibility and the cost of this in-house synthesis give an opportunity to increase the access of the patients with NET to this innovative therapeutic radiopharmaceutical.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-026 LEACHABLES IN SYRINGES CONTAINING ETHANOL, PROPOFOL OR MRNA VACCINE

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Background and Importance Leachables are chemical compounds that migrate from packaging materials into pharmaceutical formulations during regular use and can cause potential health risks alone or in interaction with other compounds of the pharmaceutical formulation. We expect a higher risk in solvents such as complex emulsions. Especially in new formulations such as mRNA vaccines, leachables may cause unknown interactions and are present in higher amounts. Identifying and quantifying these compounds is crucial to ensure product safety. As the stability of the vaccine in syringes is 12 hours after filling into the syringes, knowledge about the leachable situation in syringes is of interest.

Aim and Objectives Our aim is to quantify the concentration of leachables during the official shelf life of Comirnaty Vaccine (12 hours, room temperature 15–25).

Material and Methods Emulsions of Comirnaty, Propofol and ethanol were stored at room temperature in plastic syringes for 2 weeks. Leachables were quantified at 3, 5, 12 hours and 14 days after filling. The samples were analysed by HPLC (Ultimate 3000, ThermoScientific) coupled with massspectrometry (4000 qTrap, Sciex), GC-MS (8890GC System, Agilent) and UV-Spectrometry (DrugLog, Pharmacolog).

Results Using GC-MS, Vulkanox BKF could be identified, which was also confirmed and quantified by HPLC-MS on a Raptor Biphenyl column. UV-Vis (Druglog) provided more general confirmation of leachables but lacked the specificity required for precise quantification. The concentration of leachables increased over time in all three solvents. The concentration of Vulkanox BKF in the Comirnaty vaccine and Propofol was similar increased. In Ethanol was the concentration ca. 10 times higher compared with the emulsions.

Conclusion and Relevance Vulkanox was detected in measurable quantities, but it is not possible to evaluate whether this substance is harmful at these levels due to the lack of available toxicological data. Regulatory guidelines should ensure that the migration of such leachables remains below hazardous levels and possible influence on the stability of the mRNA vaccine is excluded. However, prolonged exposure or higher concentrations of these compounds could increase health risks.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-027 OPTIMISATION OF THE LIQUID ORAL FORMS PROCESS: EXAMPLE OF A SEMI-AUTOMATED DEVICE AND ITS QUALIFICATION

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Background and Importance The manual production of oral suspensions leads to the development of musculoskeletal disorders in operators and limits the size of batches. Faced with ever-increasing needs, the batch sizes of some oral formulations have been uprated. The pharmacy already has a mixer, which is used for mixing powders, and theoretically has the capacity to mix liquid forms.

Aim and Objectives The study aimed to evaluate the ability of the equipment to produce oral suspensions by the optimisation and qualification of the semi-automated process.

Material and Methods The frequent formulation that presented some non-conformities (uniformity of content issues) was chosen. A Topitec Touch mixer was used to perform the study. Melatonin powder (Inresa, France) and Syrspend (Fagron, the Netherlands) were selected. Firstly, for powder trituration, three speeds and three crushing times were tested in triplicates. Secondly, with optimum crushing parameters, the powder was mixed with the vehicle: two speeds and three times were evaluated in triplicates. Uniformity of content was performed by High-Performance Liquid Chromatography assay

to study the homogeneity of the suspensions for all tested parameters. Statistical analyses of the variables were carried out using Excel software (alpha risk=5%).
Results For the three trituration speeds and three trituration times, three samples were realised (top, middle, bottom). Statistical analysis of the results using a two-factor ANOVA test without repeating the experiment showed no difference between all samples (p-value=0.22) and between experiments (p-value=0.18). To limit container's wear, trituration speed was set at 300 rpm, 1 minute.
Second step Three mixing speeds and three trituration times, three samples were also performed. Statistical analysis showed no difference between all samples (p-value=0.87) and between experiments (p-value=0.36). To limit container's wear, the mixing speed was set at 300 rpm for 4 minutes.

To produce larger batches, parameters were progressively increased (mixing, speeds).Three batches were carried out by two technicians, were compliant and validated the qualification. Difficulties encountered included static electricity, which interfered with the proper mixing of the powder due to friction.
Conclusion and Relevance The process for melatonin oral suspensions was optimised, qualified, and validated, enabling semi-automated production using the Topitec Touch. Applicability to other drugs and vehicles will be investigated.

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

3PC-028 EVALUATION AND ANALYSIS OF HUMAN HEALTH HAZARDS OF RAW MATERIALS USED FOR COMPOUNDING IN THE HOSPITAL PHARMACY DEPARTMENT

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Background and Importance The 1272/2008 CLP-Regulation aims to ensure a high level of protection of human health and environment, harmonising the classification, labelling and packaging for dangerous substances and mixtures. This information is presented in the raw material (RM) safety data sheet (SDS).

In our pharmacy department (PD), RM are mainly acquired from two suppliers and the hazards to human health (HHH) are evaluated to ensure professionals' safety.
Aim and Objectives Evaluate the SDS from the two suppliers of all RM used for compounding, describe HHH, analyse any discrepancies that may exist and make a decision.
Material and Methods A descriptive observational study was carried out, including all RM.

The SDS from both suppliers were evaluated.
The variables collected were CAS number, SDS revision date, CLP-Classification and HHH.

The following HHH categories were defined:

- Category 1: reproductive-toxicity/lactation (H360, H631, H362).
- Category 2: mutagenicity/carcinogenicity (H340, H341, H350, H351).
- Category 3: organ-toxicity (H370, H371, H372, H373).
- Category 4: Eye-damage/irritation (H318, H319, H314).
- Category 5: Skin/dermal toxicity (H310, H311, H312, H315, H317).
- Category 6: inhaled-toxicity/sensitisation/respiratory irritation (H330, H304, H331, H332, H334, H335).

Oral toxicity or narcosis hazard was excluded from the analysis.
Results 113 SDS were evaluated of a total of 59 RM.

58 RM were classified under CLP-Regulation by at least one supplier. 37/58(63,8%) presented any HHH.

34/37(91,9%) had SDS from both suppliers, founding discrepancies in 13 RM(38,2%):

- 2/13(15,4%) were hazardous by only one supplier (erythromycin and yellowish-eosin).
- 2/13(15,4%) had completely different HHH(enalapril and pyrazinamide).
- 9/13(69,2%) had more HHH assigned by one supplier.

Of these 34 RM, the discrepancies between suppliers within the HHH-category were:

- Category 1: 4/34 (11,7%): triamcinolone acetonide, spironolactone, captopril and erythromycin (only had HHH by one supplier).
- Category 2: 3/34 (8,8%):anise-essence, spironolactone and metronidazole. Only metronidazole had HHH by both suppliers.
- Category 3: 3/34 (8,8%): enalapril, metronidazole and spironolactone. Only spironolactone had HHH by both suppliers.
- Category 4: 6/34 (17,6%): borax, yellowish-eosin, omeprazole, captopril, isoniazid and enalapril (only enalapril had HHH by both suppliers).
- Category 5: 6/34 (17,6%): captopril, anise-essence, isoniazid, omeprazole, pyrazinamide and spironolactone (only spironolactone had HHH by one supplier).
- Category 6: 5/34 (14%): omeprazole, pyrazinamide, erythromycin, spironolactone and isoniazid. Omeprazole and pyrazinamide had HHH by both suppliers.

2 RM have SDS not updated in the last 5 years (yellowish-eosin and pyrazinamide).
Conclusion and Relevance More than half of RM used in compounding in our PD have any HHH (highlighting the percentage of discrepancies found depending on the supplier reviewed). Thus, it is worth requesting SDS from all suppliers, carrying out an evaluation and analysis by the hospital pharmacist. In case of discrepancies, we have decided to choose the most restrictive to ensure the compounding professionals' safety.

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

3PC-029 COMPATIBILITY OF AGE-APPROPRIATE COMPOUNDED ORAL SUSPENSIONS

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Background and Importance Oral administration is the primary route for drug delivery; however, standard licensed

medications often fail to meet the specific needs of neonates, infants, young children, and older adults. Challenges such as dose adjustments and swallowing difficulties can compromise treatment efficacy and adherence, as common practices like splitting or crushing pills may lead to inaccurate dosing and reduced drug stability. Compounded medications offer a valuable alternative by allowing (hospital)pharmacists to create tailored formulations that address individual patient requirements. In addition, compounded medications may help overcome shortages of oral-liquid medications.

Aim and Objectives This study evaluated the compatibility of various oral suspensions compounded with the ready-to-use suspending agent SyrSpend SF and assessed their suitability for age-appropriate formulations across ten different pharmacological classes.

Material and Methods Nineteen APIs were compounded with SyrSpend SF PH4 liquid and stored at refrigerated (2–8°C) and room temperatures (20–25°C). Physical-chemical compatibility was assessed over 90 days by measuring percent recovery using a stability-indicating high-performance liquid chromatography (HPLC-UV) method. At the end of the shelf life, the antimicrobial effectiveness (AET) was performed according to the current EP guideline.

Results Most compounded suspensions remained compatible for 90 days under both refrigerated and room temperature conditions, with the following exceptions: Cefadroxil was stable for 60 days when refrigerated and for 7 days at room temperature; Cimetidine was stable for 30 days at room temperature. Losartan Potassium, Nystatin, and Theophylline were not stable at room temperature, while Pyridostigmine Bromide was not stable when refrigerated. All other APIs and conditions were stable for at least 90 days. Additionally, all compounds met AET specifications. Notably, the pH of cimetidine was adjusted to approximately four during compounding.

Conclusion and Relevance Compounded oral suspensions demonstrated potential as personalised, age-appropriate formulations, ensuring dose consistency and stability across a diverse group of APIs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest Corporate sponsored research or other substantive relationships:

ECF Dijkers, M Kousteliou, and HC Polonini are employees of Fagron BV.

The National and Kapodistrian University of Athens has received financial compensation for the performance of the stability studies.

3PC-030 DESIGN AND DEVELOPMENT OF A MAGISTRAL FORMULATION OF MOUTHWASH FOR THE TREATMENT OF MUCOSITIS: A CASE REPORT

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Background and Importance Oral mucositis is an inflammatory condition from cancer therapies, which causes pain, infection and ulceration. Standard treatment with mouthwashes and systemic analgesics is not always effective, leading to the use of more personalised therapeutic options, such as the design of a magistral formulation (MF).

Aim and Objectives To formulate a mouthwash by galenic validation and describe its use in the treatment of mucositis.

Material and Methods A 17-year-old patient with severe spinal cord aplasia developed grade four of mucositis, with severe pain and oral aphthous ulcers. After the failure of conventional treatments, such as oral viscous lidocaine and chlorhexidine, a MF was formulated and designed through a literature review (pharmacopoeia, Pubmed). Galenic validation included organoleptic (smell, colour), chemical (ph measurement) and microbiological controls.

Results The components of the MF aimed to reduce pain (lidocaine), irritation (dexchlorpheniramine), inflammation (triamcinolone), prevent superinfections (nystatin) and regulate mucosal pH (sodium bicarbonate). The excipients used were Tween 80, glycerine, and 1% carboxymethylcellulose.

Preparation of 250 mL:

- Mix triamcinolone acetonide (0.125 g) and nystatin (460 mg); add Tween 80 (3 drops), glycerine (25 mL), and 1% carboxymethylcellulose (40 mL), homogenising after each addition.
- In a separate container, mix lidocaine (5 g) and sodium bicarbonate (2.5 g); add glycerine (25 mL), dexchlorpheniramine solution 0,4 mg/ml (40 mL) and 1% carboxymethylcellulose (40 mL), homogenising after each addition.
- Combine in a beaker, and adjust the volume to 250 mL with 1% carboxymethylcellulose, then homogenise.

Galenic validation of the MF was carried out for one month. In the second week, the pH remained stable at 8, with no crystals or colour variations. In the third week, the pH increased to 9 and small crystals appeared. Despite this, the microbiological control was negative. With these data, a shelf life of 14 days was established for the MF, stored in a topaz glass container and kept in a refrigerator at 2–8°C.

After 1 month of treatment with a dosage regimen of 10 ml three times a day, the patient experienced a significant improvement in oral aphthous ulcers and pain, avoiding the use of morphics and improving oral tolerance.

Conclusion and Relevance The MF was validated and proved effective for the treatment of mucositis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-031 STUDY ON THE ADSORPTION OF RADIOPHARMACEUTICALS ON SYRINGE WALLS AND STERILISATION FILTERS

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Background and Importance Radiopharmaceuticals (RPs) are prepared in plastic syringes, but adsorption can compromise dose accuracy and treatment effectiveness. Additionally, sterilisation filters used in homemade RPs may retain activity, affecting yield synthesis. This study aims to address the lack of knowledge on RP retention in plastic syringes and sterilisation filters.

Aim and Objectives This study aimed to screen RPs used in scintigraphy and positron emission tomography (PET) for their tendency to adsorb onto plastic syringes, and to evaluate the activity retention of two experimental RPs on selected sterilisation filters.
Material and Methods Seven technetium-based RPs (99mTc-hydroxy-diphosphonate, 99mTc-sestamibi, 99mTc-albumin, 99mTc-dimercaptosuccinic acid, 99mTc-mercaptoacetyltriglycine, 99mTc-macroaggregates of albumin, and 99mTc-nanocolloid) and seven PET RPs (18F-choline, 18F-dopa, 18F-fluorodeoxyglucose, 18F-fluorothymidine, 18F-fluoroestradiol, 68Ga-DOTA-TOC, and 68Ga-PSMA) were tested. Two types of syringes were compared: 2-part (5 ml, Bbraun) and 3-part (3 ml, BD Plastipak). Residual activity was measured ($n \geq 3$) after filling, emptying, and rinsing the syringes with saline.

Retention tests were performed on 0.22 µm final sterilisation filters for 68Ga-NODAGA-Exendin-4 and 68Ga-EMP100. Six Filters with varying membrane compositions were tested: polyvinylidene fluoride, polytetrafluoroethylene, polyether sulfone, and cellulose esters. Filters were rinsed with saline, and their activity and collection vials were measured to determine retention.
Results Most RPs showed minimal adsorption (<5%) on syringe. Only 99mTc-sestamibi exhibited significant adsorption in 3-part syringes, retaining 20% of the RP compared to 5% for 2-part syringes. The use of 2-part syringes for 99mTc-sestamibi has reduced acquisition time by up to 17% compared to the 3-part syringes used before.

For sterilisation filters, a polyvinylidene fluoride filter showed the lowest retention for both 68Ga-NODAGA-Exendin-4 and 68Ga-EMP100 (10.4% and 7.5% retention, respectively). In contrast, the cellulose esters filter retained 97.7% and 93.1% of the RPs.
Conclusion and Relevance For clinical RPs, this study demonstrates significant adsorption of 99mTc-sestamibi in 3-part syringes, indicating that the type of syringe can affect the accuracy of the dose administered.

For sterilisation filters, a polyvinylidene fluoride filter had the lowest activity retention for 68Ga-NODAGA-Exendin-4 and 68Ga-EMP100, guiding the selection of the filter for their synthesis.

These results highlight the importance of selecting appropriate syringes and filters for radiopharmaceutical preparation. This work should be generalised to all clinical and experimental RPs.

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

3PC-032 METRONIDAZOLE 2%+ LIDOCAINE 2% GEL IN CUTANEOUS SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK – CASE REPORT

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Background and Importance Cutaneous squamous cell carcinoma (SCC) is characterised by the abnormal and accelerated growth of cells in the superficial layers of the skin. SCC can appear as thick, scaly lesions that can crust, bleed and itch and are difficult to heal.
Aim and Objectives To describe the preparation of a magistral formula (FM) of metronidazole 2% and lidocaine 2% gel for the treatment of localised head lesions with a strong painful and malodorous component in a patient with SCC of the head and neck. To evaluate the efficacy of FM.
Material and Methods Observational and descriptive study of the development of a topical gel containing metronidazole 2% and lidocaine 2% for the treatment of lesions in a patient with SCC of the head and necks.

A literature search was conducted to review the FMs described in the literature.

Galenic development and validation of the formula was obtained in the second edition of the 'palliative care and master formulation' manual.

Efficacy was analysed by weekly monitoring of wound healing together with palliative care.
Results From the palliative care service we were asked to develop a metronidazole 2% and lidocaine 2% gel to control pain and odour during the treatment of scalp lesions in an 82 year-old patient diagnosed with cutaneous squamous cell carcinoma of the head and neck.

Modus operandi for the preparation of 500 g of gel was:

1. Dissolve 0.8 g methylparaben sodium and 0.1 g propylparaben sodium in 500 ml water. Sprinkle 5 g of carbomer 940 over the mixture and leave to stand for 24 hours until a gel forms.
2. Neutralise to ph 7 with triethanolamine (0,8–1%) to increase the viscosity of the gel.
3. Weigh 10 g metronidazole and 10 g lidocaine. Pulverise in a mortar and pestle and form a paste with glycerine.
4. Add the gel formed in step 1 to the paste and homogenise.

During the 6-month follow-up period, the patient's pain on dressing has decreased significantly, although purulent exudate continued to appear.
Conclusion and Relevance The magistral formula has been very effective for pain control but has not been effective for control of purulent exudate or odour.

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

3PC-033 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. Recently, 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 a month, admitting up to 6 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 wasn't 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 doesn't seem to maintain chemical stability at 45 days, so it is assumed that at 2 months it has no stability.

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

3PC-034 DEVELOPMENT OF A DENSITY MEASUREMENT PROTOCOL FOR INJECTABLE STERILE DRUGS: APPLICATION TO AMSACRINE IN A HOSPITAL PHARMACY

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Background and Importance Gravimetric Control (GC) is an in-and post-process control technique used for monitoring the preparation of sterile injectable drugs. However, it requires precise data on the density of molecules, which are not always available in the summary of product characteristics or from pharmaceutical laboratories.
Aim and Objectives Hospital pharmacies may need to perform these density measurements themselves. This study aims to develop an accurate, and reproducible density measurement protocol, suitable for use in hospital pharmacies, using amsacrine as an example.
Material and Methods The measurement method using a pycnometer (PYC) (monograph 2.2.5 'density measurement', Ph. Eur., 11th ed.) was chosen. A PYC (Megal) and a precision balance (QUINTIX) were used. The density (ρ = m/V) was determined by weighing a 25 mL sample. The relative density (da) of the samples was obtained using the formula $d_a = \rho_a / \rho_{WFI}$, after measuring the density of water for injectable preparations (WFI). Measurements performed on amsacrine solutions (Amsalyo 75 mg, 1.5 mg/mL) were compared to five standard solutions (0.9% NaCl, 5% and 30% Dextrose (Dex), Methanol (MeOH), Dichloromethane (DCM)) and repeated 3 times at fixed temperature.
Results The protocol implemented produced results consistent with expected values (calculated mean density vs theoretical density) for the standard solutions (0.9% NaCl : 1.006 vs 1.005; 5% Dex: 1.019 vs 1.020; 30% Dex: 1.113 vs 1.112; MeOH: 0.796 vs 0.790; DCM : 1.332 vs 1.330), thus validating our method. Measurements performed on amsacrine solutions determined a density of 1.001. This result is consistent with the excipient composition of Amsalyo (lactic acid and WFI).

Density measurement using a PYC is a simple technique, but it requires a significant volume of solution, considerable execution time (5 min/sample), and adequate protection against the risk of chemical contamination (CC). In comparison, the hydrometer method presents similar drawbacks, requiring a larger volume and offering lower precision. Using an electronic densimeter would allow for faster, serial measurements, with less risk of CC, but it comes with a high cost (€ 3,000 vs € 35 for a PYC).
Conclusion and Relevance Our study, conducted in the context of GC within a sterile drug production unit, allowed the establishment of a simple and reliable protocol suitable for occasional measurements.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest Corporate sponsored research or other substantive relationships:
Lucane Pharma

3PC-035 THE STABILITY OF CYCLOPHOSPHAMIDE (CPA) AND MESNA MIXTURE IS SHORTENED BY CYCLOPHOSPHAMIDE INSTABILITY CAUSING QUICK PH DECREASE IN SOLUTION

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Background and Importance Cyclophosphamide (CPA) and mesna are commonly co-administered in oncological therapies to prevent bladder toxicity caused by metabolisation of CPA. Stability studies could allow the anticipated preparation of the mixture in centralised unit in hospital pharmacy.
Aim and Objectives This study aims to evaluate the stability CPA/mesna mixture in polyolefin bags at 5°C and 25°C.
Material and Methods CPA/mesna were prepared in polyolefin bags diluted in 0.9% sodium chloride at concentrations of 10/3.33 mg/mL (high concentration HC) and 1/0.33 mg/mL (low concentration LC). Samples were stored at 5°C and 25°C for 30 days. HPLC analysis for CPA and mesna were conducted at regular intervals alongside pH measurements, as well as visual inspections and osmolarity testing. pH was also assessed on solutions of CPA and mesna alone conserved at 25°C to evaluate their influence in the mixture.
Results Osmolarity and visual examination showed great stability of the mixture over the 30 days period. The HPLC analysis showed active substance concentration fall under 90% of initial concentration from 8 days of conservation at 25°C or 14 days of conservation at 5°C. Notably, pH levels showed a steady decline in samples stored at 25°C, with a drop of

more than 1 pH unit after 2 days. This decline was slightly slowed with 5°C conservation, with a drop superior to 1 unit which occurred between day 2 and day 8 of conservation for LC preparations. This decrease in pH occurred before any significant quantitative decrease of CPA or mesna in HPLC analysis, emphasising the critical role of pH monitoring in stability studies. Considering CPA and mesna solutions, a fast pH drop was only observed in CPA solutions over a 4 days period at 25°C.

Conclusion and Relevance Because of pH drop, the shelf life of CPA/mesna mixtures should not be longer than 48 hours at 5°C conservation. The study underlines the importance of pH measurement for parenteral preparations, while pH instability could cause a preparation to be improper for intravenous administration. Interestingly, CPA stability studies which concluded 7 days conservation didn't assed pH. New studies with exploration of pH could conclude to a shorter shelf life for CPA preparations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-036 NEW THERAPEUTIC APPROACH FOR DIFFUSE MIDLINE GLIOMA: 3-YEAR EVALUATION OF ACCESS TO ONC201 IN FRANCE AND EUROPE

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Background and Importance H3K27M-altered diffuse midline gliomas have a poor prognosis in adults and children (less than 1 year after the diagnosis), with current treatment strategies relying on radiation therapy that merely slows disease progression. Recently, ONC201 (dordaviprone), a drug developed by Chimerix, demonstrated promising results in a clinical trial conducted in the US only. To address the lack of availability in France, the French Medicines Agency (ANSM), following recommendations from paediatric oncology and neuro-oncology experts, initiated a compassionate use programme led by Gustave Roussy. This programme allows French and European patients access to ONC201 through a compounding mechanism and the S2 reimbursement process.

Aim and Objectives The primary aim was to ensure and centralise ONC201 safe access to patients in France and abroad. This paper reports a 3-year compassionate use programme, addressing medical and pharmaceutical aspects.

Material and Methods A national access was established, where the medical indication for ONC201 was determined through national multidisciplinary meetings. Only patients with validated indications could access the treatment, and real-world data were collected to support the SACHA study. Due to the absence of pharmaceutical grade ONC201, raw materials were requalified, and identification and purity tests were carried out in collaboration with the ANSM quality control laboratory. The pharmacy department developed hard capsules and an oral solution (for patients unable to swallow) in accordance to French hospital compounding regulations. Stability of these formulations was evaluated using methods following ICH guidelines.

Results More than 100 batches of capsules and 20 batches of oral solution were produced with a stability of 12 months. Over 3 years, 234 patients from 52 centres and 13 countries were treated, with a median of five treatment cycles. 10% of patients received more than 10 cycles, and seven patients (3%) exhibited a prolonged response beyond 18 months, achieving partial or complete remission. No severe adverse effects were reported.

Conclusion and Relevance This study highlights the clinical potential of ONC201, with encouraging outcomes compared to gold standard radiation therapy. This collaboration between patients associations, ANSM, clinicians and pharmacists highlights the importance of hospital pharmacy for formulation development and manufacturing of safe medicines to bridge the gap of unmet clinical needs for rare disease in cancer treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-037 STABILITY STUDY OF HYDROCORTISONE 1MG/ML ORAL SUSPENSION FOR NEONATAL USE

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Background and Importance The neonatal department uses therapies that require adjustments in dosage and formulations, including hydrocortisone (HCT) which prevent bronchopulmonary dysplasia in premature newborns. At present, HCT capsules are opened and diluted extemporaneously, highlighting the need for a ready-to-use oral suspension.

Aim and Objectives The aim of the study was to produce an oral suspension of hydrocortisone free from excipients with known effects (EKE) framed by microbiological and physicochemical stability studies.

Material and Methods Following the literature and the usual dosage regimens, the concentration of HCT oral suspension was set at 1mg/mL, using the EKE-free Syrspend SF PH4 Dry vehicle. Thirteen batches were produced. Six batches of 10 amber 20mL vials were designated to study stability before opening up to 84 days : batches 1 to 3 at room temperature (RT) and batches 4 to 6 at refrigerated temperature (4°C). Two batches of 200mL amber vials were designated to study post-opening stability up to 28 days : batch 7 at RT and batch 8 at 4°C. Batches 9 to 13 simulated temperature excursions after 7 and 14 days for 12h or 24h. An HPLC/UV assay was carried out at each control point, with measurement of pH, osmolality and visual inspection. Microbiological quality was checked, with specific testing for E.coli, in accordance with European Pharmacopoeia 11th edition.

Results Results showed physicochemical stability at 4°C before and after opening, with HCT content between 98–101% of initial content (1.00±0.01mg/mL) pre-opening and 101–103% of initial content (0.99±0.03mg/mL) post-opening. pH was stable (4.24±0.08), as was osmolality (43 ±4mOsm/kg). At RT before opening, a 20.93% deviation in osmolality was observed at D56, while after opening a 10.64% deviation from the initial content was observed at D14. With the exception of two measurements at 4°C on

D14, for which external contamination is suspected, microbiological quality was compliant. E.coli testing was negative. Physicochemical stability was not affected after 12 or 24-hour temperature excursions.

Conclusion and Relevance This study enables us to store HCT oral suspension without EKE at 4°C for 3 months. Once opened, it should be stored at 4°C and used within 14 days. Drinkable suspension makes HCT administration safer and can now be deployed in neonatal department.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-038 COMPOUNDING AND PHYSICOCHEMICAL STABILITY STUDY OF DEXAMETHASONE MOUTHWASH 0.1 MG/ML TO PREVENT STOMATITIS ASSOCIATED WITH EVEROLIMUS

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Background and Importance Stomatitis is the inflammation of the oral mucosa, which usually manifests itself with swelling and ulcerous and painful lesions. It is a common adverse effect secondary to antineoplastic treatments, including everolimus. Due to its anti-inflammatory properties, Dexamethasone mouthwash is often used to alleviate these symptoms. However, there is no commercially available dexamethasone mouthwash in Spain.

Aim and Objectives To determine the physicochemical stability of a compounded dexamethasone 0.1mg/ml mouthwash formula.

Material and Methods A bibliographic search of different formulations was conducted to identify suitable formulations, and pharmacotechnical forms were consulted. Technical data sheets of raw materials were reviewed to ensure compatibility. The composition of the developed formulation is shown in table 1.

Seven batches of two amber glass containers were prepared and stored refrigerated at 5°C. Appearance, organoleptic properties and precipitation were evaluated by visual inspection. Mass uniformity test was assessed in accordance with Ph. Eur. 2.9.27 test for multidose liquid preparations. Chemical stability of the formulations stored at 5 **± 0.1** °C was determined by UHPLC (Ultra-High Performance Liquid Chromatography) in an Acquity UPLC H-Class System chromatograph (Waters, Corporation Milford, MA). Dexamethasone content was assessed in duplicate at times 0, 7, 14, 28, and 60 days for closed containers and under normal use conditions. Results were expressed as a percentage of the remaining declared value (%DV). In addition, the pH of the formulations was determined throughout the stability study using a Crison GLP 21 pH Metre.

Results No significant changes in organoleptic characteristics (colourless, odourless, sweet taste, light viscous consistency, and particles in suspension) were observed. The developed formulation met with the mass uniformity test (Ph. Eur. 2.9.27).

Abstract 3PC-038 Table 1

Dexamethasone 21 sodium phosphate	0.013g
Sorbitol powder	15g
Water preserved without propylene glycol qs	100mL

The stability period established at 5°C for formulations under normal conditions was 28 days (103.09 ± 1.2 %DV) and 60 days for closed containers (96,4 ± 0,7% DV).

Conclusion and Relevance This study demonstrates the physicochemical stability of the compounded dexamethasone 0.1 mg/ml mouthwash for 28 days under normal use conditions and 60 days in closed containers at 5°C. Further studies, including microbiological stability testing, are underway to ensure long-term safety and efficacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-039 PREPARATION AND STABILITY OF READY-TO-ADMINISTER DEXAMETHASONE DIHYDROGEN PHOSPHATE 8 MG/ML/0.02% HYALURONIC ACID INTRATYMPANAL INJECTION SOLUTION

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Background and Importance Intratympanal injection of glucocorticoids is utilised to treat morbus menière which is characterised by vertigo, acute hearing loss, and tinnitus. As respective licensed products are not available, pharmaceutical preparations for intratympanal injection are aseptically prepared in hospital pharmacies by using licensed medicinal products as starting material. Recently we developed an updated formulation of dexamethasone dihydrogen phosphate (H_2PO_4) 8 mg/mL/ 0.02% hyaluronic acid injection solution. Hyaluronic acid increases viscosity and enhances diffusion of dexamethasone into the inner ear. As preparation is done in batches for stock, release and stability tests and assessment of shelf life are required.

Aim and Objectives Preparation process validation and stability testing of ready-to-administer (RTA) dexamethasone $H_2PO_4$8 mg/mL/ 0.02% hyaluronic acid intratympanal injection solution aseptically prepared by using licensed medicinal products as starting material.

Material and Methods For a batch of 180 preparations, 100 mL Dexa-ratiopharm 40 mg injection solution (40 mg/5 mL dexamethasone H_2PO_4, water for injection, Na-edetate, NaCl, NaOH) and 2 mL Hyalart (20 mg/2 mL sodium hyaluronate in water for injection, phosphate buffered) were transferred aseptically into an empty infusion bag, mixed, and 0.5 mL each filled into 1 mL Luer plastic syringes, capped, and labelled. 10 mL mixture were transferred into blood culture bottles for rapid sterility testing. Preparations were stored at 2–8 °C and samples withdrawn at day 0, 7, 14, 28, 60, 90. Dexamethasone content and physicochemical stability were determined by quantitative UV-Vis spectroscopy at 238 nm. pH and osmolality were measured in parallel.

Results Dexamethasone H_2PO_4/hyaluronic acid preparations fulfilled the specifications set. At day 28, the dexamethasone

H_2PO_4 concentration amounted to 100.4% ± 0.7% of the initially measured concentration. pH and osmolality of the preparation amounted to stability-improving pH 7.8 and 285 mOsmol/kg, respectively. Both parameters remained unchanged over the observation period. Refrigeration is recommended because of microbiological reasons.
Conclusion and Relevance The chosen batch-wise preparation process of RTA dexamethasone $H_2PO_4$8 mg/mL/ 0.02% hyaluronic acid intratympanal injection solution was successfully validated. Stability testing is ongoing and shelf life proven for at least 1 month.

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

3PC-040 ORAL SUSPENSION OF DAPSONE 2 MG/ML. EFFICACY, SAFETY AND FORMULATION IN PAEDIATRIC PATIENT WITH LINEAR IG A DERMATOSIS: A CASE REPORT

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Background and Importance Linear Ig A dermatosis of childhood is a rare autoimmune disorder, which manifests with outbreaks of vesicular and bullous lesions. The first-line treatment is dapsone.
Aim and Objectives To evaluate the efficacy and safety of treatment with mastered formula (FM) of dapsone 2 mg/ml oral suspension in a child with linear Ig A dermatosis. Describe the preparation of the FM.
Material and Methods Retrospective observational study of a child with linear Ig A dermatosis treated with dapsone. The variables collected: sex, age, analytical data (blood count, reticulocytes, glucose 6-phosphate dehydrogenase (G6PD) deficiency test, kidney and liver function), previous treatments and data related to treatment with dapsone. (concentration, dose, frequency of administration, duration of treatment, efficacy and safety). The clinical history and FM preparation protocols were reviewed.
Results 23-month-old patient with blistering lesions in different locations. Skin biopsy compatible with linear Ig A dermatosis confirmed with direct immunofluorescence test. Previously treated with oral prednisone. He has normal G6PD activity and a normal blood count, and oral dapsone 1.5 mg/kg/day is started. A bibliographic search was carried out, finding an oral suspension preparation from dapsone tablets and SyrSpend SF PH4, with physicochemical stability of 90 days at room temperature and in the refrigerator. A microbiological risk matrix was applied, assigning a validity period of 90 days in the refrigerator and 30 days at room temperature. From the beginning, a favourable evolution was observed, with rapid resolution of injuries. Five months after starting treatment, he had an outbreak with perioral lesions, increasing the dose of dapsone to 2 mg/kg/day. Two months later, in a control analysis, haemoglobin values of 9.5 g/dl and MCV of 87.9 fL were observed, diagnosing megaloblastic anaemia secondary to the medication. Treatment is temporarily suspended, with analytical values normalising after 40 days. It was decided to treat again with dapsone 0.5 g/kg/day. Currently the patient has no active lesions and no significant analytical abnormalities.
Conclusion and Relevance FM dapsone 2 mg/ml oral suspension was found to be effective for the treatment of linear Ig A dermatosis with excellent short-term response and prolonged remissions. Regarding safety, periodic analytical controls are recommended to avoid the appearance of megaloblastic anaemia.

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

3PC-041 EPICUTANEOUS PATCH TEST PREPARATION IN IDENTIFYING ALLERGENIC COMPONENTS IN A COSMETIC CREAM: A CASE REPORT

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Background and Importance Cosmetic products often contain multiple ingredients, some of which may cause undesirable effects such as hypersensitivity. For this reason, cosmetovigilance is crucial and healthcare professionals are required to report serious adverse reactions linked to the use of cosmetic products. Once reported, the manufacturer may provide the ingredients in a form that is not suitable for direct skin application. The pharmacy department plays a key role in preparing patch tests to allow diagnosis.
Aim and Objectives To describe the work procedure for patch tests preparation in the pharmacy department to meet the demand for epicutaneous patches.
Material and Methods The dermatology department reached out to the pharmacy department concerning an unusual case of allergic contact dermatitis in a 71-year-old woman following the use of a cosmetic cream. The manufacturer was notified of the adverse reaction and provided 28 purified ingredients. A literature review (manufacturers datasheets, PubChem, European Pharmacopoeia) was conducted to select the appropriate vehicle (petrolatum or glycerin) for each ingredient based on their solubility (octanol-water partition coefficient) and desired concentration.
Results The 28 patch tests were prepared in a non-sterile compounding area, with one ingredient (perfume) prepared in a Class IIB biosafety cabinet due to its irritant nature. The required concentrations (0.1% to 30%) were formulated in 5 mL polypropylene syringes. Of the 28 ingredients, 23 were dissolved in liquid petrolatum, and five in water. Due to the lack of stability studies, a 72-hour shelf life at 2–8°C was assigned to the preparations. Organoleptic properties and spreadability were assessed for galenic validation. The 28 preparations were applied to the patient's back, and patch test results were evaluated at 48 and 72 hours. At both time points, allergic reactions (erythema, oedema) were observed with 1% p-hydroxyacetophenone (SymSave H), a preservative commonly used in cosmetic products, and 0.1% Bakuchiol, used for its anti-ageing properties. These findings were promptly communicated to the manufacturer's cosmetovigilance department.

Conclusion and Relevance This case has led to the establishment of a work procedure for patch test preparation in a tertiary care hospital and shows the importance of cosmetovigilance and documentation of allergic reactions, offering valuable insights for future allergic reactions caused by this or other cosmetic products.

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

3PC-042 CYBER-RESILIENCE: DEVELOPMENT OF A DIGITAL CLINICAL CONTINUITY SOLUTION TO MAINTAIN SAFE PRESCRIPTION AND COMPOUNDING ASSISTANCE IN ONCOLOGY

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Background and Importance In France, the growing threat of cyberattacks on healthcare has led health authorities to mandate the deployment of clinical continuity plan in each hospital department. In Oncology, care units and hospital pharmacy often share the same Electronic Medical Record (EMR) CHIMIO (Computer Engineering) which combines a Computerised Physician Order Entry (CPOE) with an intra-venous compounding workflow management system (IVWMS). This digital workflow is dramatically sensitive to cyberattacks and its unplanned interruption can disrupt care and force patients to be rerouted to other hospitals
Aim and Objectives The aim was to develop a digital contingency plan in oncology, in order to maintain the oncology workflow safe and secure, avoiding going back to pen and papers in case of cyberattacks.
Material and Methods Design of the software was carried out in three steps: 1) Project specifications based on our nationwide survey of hospital pharmacists collecting information on the perceptions and expectations of cyberattack 2) Extraction and transformation of specific tables used by CHIMIO 3) Multi-centre demonstration of prototypes with benchmark test and improvements based on feedback.
Results Eighty-eight surveys responses lead project specification to include: fast and easy recovery solution, secure, automated and equivalent calculation of regimens and compounding formulas and backward compatibility with the two versions of CHIMIO.

The software is based on the extraction of dozens of tables from the database used by CHIMIO. Although unique in each hospital, these tables are digested by a PowerQuery code (Microsoft Excel) which is able to assist prescribers and pharmacists in prescription and dispensation the same way as usual. It works off-line and is easily communicable between computers from care units to the hospital pharmacy.

The prototype has been tested in five different hospitals, approaching a comprehensive coverage of oncology protocols (paediatric, haematologic, home health care).
Conclusion and Relevance The success of these multiples demonstrations claims transposable results in each hospital using CHIMIO. Although usable by oncologist and pharmacist, the next step is to embed the code in an Excel-free solution. In the future, this consolidate version could handle stock management and be qualified as a stand-alone solution of cyber-resilience in the chemotherapy workflow.

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

3PC-043 HOW RELIABLE IS PATCH TESTING? APPLICABILITY IN REAL-LIFE PRACTICE FOR THE DIAGNOSIS OF ALLERGIC REACTIONS

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Background and Importance Patients are often labelled as allergic to antimicrobials without an accurate diagnosis. Such over-labelling can lead to both individual health and global public health consequences. To achieve an accurate diagnosis, various in vitro and in vivo tests are conducted. In this context, hospital pharmacy services frequently contribute to the development of diagnostic tests, including prick tests, intradermal tests (IDT), patch tests (PT) and drug provocation tests (DPT).
Aim and Objectives Compare the PT results with the final diagnosis established by the allergist through clinical assessment and additional tests.
Material and Methods Observational and retrospective study at a tertiary level hospital including patients who were dispensed at least one antimicrobial patch test kit from the pharmacy service between October 2020 and September 2024. Each kit contains a single antimicrobial agent, delivered in multiple doses or vehicles. The data were collected from the electronic health record (EHR) and pharmacy dispensing programme.
Results A total of 49 antimicrobial patch tests kits were conducted on 32 patients referred to the allergology department for suspected adverse drug reactions. The primary reason for consultation was exanthematous reactions (62.5%) with more severe reactions such as DRESS syndrome and toxic epidermal necrolysis also noted. Of the antimicrobials tested, 91.8% were antibiotics, notably the beta-lactam group (22.2%), clindamycin (17.8%) and sulfamethoxazole/trimethoprim (13.3%). Of the 49 drugs tested, eight (16.3%) were positive in the DPT, which is the gold standard method in a drug allergy assessment. Additionally, two drugs demonstrated a positive outcome in skin tests, increasing the positivity rate to 20.41%. Nevertheless, there are 14 additional drugs that represent unconfirmed allergies through either skin tests or DPT. A positive patch test reaction occurred once, representing 12.5% of confirmed reactions via DPT and 4.5% when considering those patients exhibiting unconfirmed allergies. The positive predictive value (PPV) of the PTs is 100% and the negative predictive value (NPV) is 40%.
Conclusion and Relevance PT are an appropriate diagnostic tool for type IV hypersensitivity-related reactions, given their 100% PPV. However, the limited value of negative results must be considered. Investigating methods to enhance the reliability of negative results would be beneficial, minimising reliance on DPT and optimising patient safety.

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

3PC-044 NOVEL METHOD OF COMPOUNDING AN ORAL TEMOZOLOMIDE SUSPENSION FOR PAEDIATRIC CANCER PATIENTS

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Background and Importance Temozolmide (TMZ) is a chemotherapeutic drug used to treat paediatric patients with neuroblastoma or solid brain tumours. Although TMZ is frequently prescribed for very young children, worldwide only hard capsules are available for oral treatment. Swallowing capsules is often not possible for young children and opening of the capsules is not recommended by the marketing authorisation holder. However, based on literature, capsules might be opened and mixed with applesauce/acidic juice or processed into an oral suspension. This approach poses a risk to health care workers and/or relatives preparing the drug when not working in an isolator.
Aim and Objectives An oral TMZ suspension was developed, based on published literature and prepared using a novel compounding method. Commonly available capsules were processed with a wet mill to create a liquid preparation suitable for children.
Material and Methods After a comprehensive literature search, a modified TMZ suspension 20 mg/ml was prepared using a wet mill (WetMill Compact, FagronLab^{TM}). This device can process whole tablets and hard capsules in a closed system without having to grind or open them first. TMZ hard capsules were placed in the WetMill bottle together with preserved water (0,14% potassium sorbate), povidone K 25, sucralose and a strawberry flavour and wet-milled for 46 minutes. Syrspend SF pH4 powder was added after the milling process, as wet-milling is more effective in low-viscosity media. Finally, the suspension was shaken vigorously.
Results The visual inspection revealed a homogeneous suspension that could be applied directly from the WetMill bottle. Considering the modified TMZ formulation and lack of additional stability data, shelf life of the final product was limited to 2 weeks at 2–8 °C. The suspension can be administered via nasogastric tube or orally. No handling problems or palatability issues were reported.
Conclusion and Relevance This new compounding method enables the safe production of liquid dosage forms of anti-cancer drugs or other carcinogenic, mutagenic or toxic drugs and represents a further step towards individualised treatment approaches. Suspension formulations for other antiviral and cytostatic drugs are in development.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

3PC-045 ABSTRACT WITHDRAWN

Clinical pharmacy services

4CPS-001 MONITORIZATION OF OFF-LABEL USE OF MONOCLONAL ANTIBODIES

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Background and Importance The off-label use of monoclonal antibody (mAbs) therapy is sometimes the only alternative when there are no official indication approved drugs regarding the disease or when the approved ones are ineffective or patients experience drug adverse events to the approved ones.
Aim and Objectives To identify efficacy and safety of mAbs off-label use
Material and Methods Retrospective observational study was conducted in adult patients with mAbs off-label prescription, at hospital setting, except Oncology Department, approved by Local Commission of Pharmacy and Therapeutics (CPT) between January 2021 and December 2022. Information on efficacy and safety was extracted from CPT files and Soarian Clinics files, and analysed using Microsoft Excel 5.0. Treatment was considered effective when it was referred in the patient files and/or when the administration of mAbs was maintained for at least 6 months. The study was authorised by Local Ethical Committee.
Results We included 69 patients, with an average age of 51 years, mostly women (62%) and followed in Immune-Mediated Diseases Consultation (52%). The mAbs mostly used were Rituximab (RTX) (65%) in Glomerulopathy, Purpura idiopathic thrombocytopenia (PTI) and Systemic Lupus Erythematosus; Infliximab (IFX) (15%) in Sarcoidosis and Tocilizumab (TCZ) (10%) in severe chronic urticaria. In 90% of patients, off-label treatment was effective, in three cases it was partially effective and in two cases ineffective. In those 100% effective, patients were treated with Omalizumab (OMA) and TCZ, in partial response with Natalizumab in fulminant multiple sclerosis and two RTX for PTI and optical neuromyelitis. In patients unresponsive to treatment, RTX and IFX were the main drugs involved. Regarding safety, of the 49% of patients that had adverse events, 12% patients had infections, 7% worsening tiredness, 6% aphthous and 2% non-severe allergic reaction at the injection site of administration. Of the uneventful patients, mostly were treated with RTX and OMA. Two died during treatment due to severe pneumonia.
Conclusion and Relevance The results showed high rates of efficacy to off-label treatment with mAbs, in line with other studies, as well as the minor and major complications found, namely infections. Additionally, autoimmune disease itself may be a risk factor for infection and further studies are needed to ascertain causal relationships.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-002 MICRO-ELIMINATION OF HEPATITIS C IN A MIGRANT AREA: DECENTRALISATION OF THE OUTPATIENT CLINIC

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Background and Importance There is a significant number of untreated viraemic patients and improvable diagnosis rates, due to what we call 'diagnostic exhaustion' of the hepatitis C virus (HCV) and which is due to the fact that there is a certain number of patients who do not attend the health system because they belong to social groups at risk of exclusion.
Aim and Objectives To assess the effectiveness of a comprehensive HCV micro-elimination strategy in the main migrant settlements in our province.
Material and Methods Local intervention in the main migrant settlement sites, accompanied by specialised Cruz Roja. A serological test was carried out on saliva samples as a screening technique. In those patients who tested positive, we proceeded to perform an in situ viral load test using capillary finger prick using the POC GeneXpert technique. Those in whom active HCV viral load was detected were referred to the Hepatology and Hospital Pharmacy team for on-site assessment and treatment. Diagnosis, information and dispensing, and decentralised pharmaceutical care in the settlement itself was carried out in a single act. Since a sustained viral response is associated with a 97–100% chance of cure, we assumed a probable cure for those patients adherent to treatment due to the impossibility of extensive follow-up.
Results A total of 234 patients were screened from: Ghana (85), Morocco (70), Romania (56), Mali (14), Senegal (4), Spain (1), and other countries (4). With a mean age of 37 years (RIQ: 29–45). 51 (21.8%) women and 183 (78.2%) men. Two patients were HCV seropositive and both had detectable viral load (0.85%). Only one of them was treated, as the other migrant was diagnosed with hepatocarcinoma. The treated patient was prescribed sofosbuvir/velpatasvir 400/100 mg, and the medication was dispensed for 12 weeks in a single act by the pharmacy service.

The patient was followed-up at subsequent visits to the settlement, corroborating good adherence to treatment.
Conclusion and Relevance The decentralisation and single act of both diagnosis and treatment of HCV in the migrant population, achieved total screening of this population and cure/treatment of 100% of the patients detected, proving to be an effective strategy for the micro-elimination of the virus.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-003 ABSTRACT WITHDRAWN

4CPS-004 REAL-WORLD OUTCOMES OF ALPELISIB: IMPLICATIONS OF PIK3CA VARIANTS

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Background and Importance Among the multiple PIK3CA gene variants, only 11 of them have been represented in randomised controlled trials (RCT) of alpelisib, mainly in pivotal trials BYLieve and SOLAR-1.
Aim and Objectives To evaluate alpelisib results in real-world setting and assess whether there are different findings in population with PIK3CA mutations other than the ones included in above-mentioned RCT.
Material and Methods Ambispective observational study of patients with locally advanced or metastatic PIK3CA-mutated breast cancer treated with alpelisib plus fulvestrant between November 2019 and March 2024, previously treated with CDK4/6 inhibitors and an aromatase inhibitor, with ECOG performance status of 0 or 1.

Patients were classified in two groups: group 1 did NOT have variants included in RCT; group 2 did.

Effectiveness was evaluated through progression-free survival (PFS) and overall survival (OS) medians using the Kaplan-Meier method. Then, log-rank tests were performed to verify statistically significant differences between groups. R Commander software was used for statistical analysis.
Results 31 patients, all women (median age 61.76 [range 34.17–76.83]), received alpelisib therapy, although 3 were excluded from analysis due to off-label use. Median treatment duration: 6.71 months (range: 1.61–39.93).

Group 1: 5 patients; Group 2: 21 patients; 2 patients were excluded from subgroup analysis (as PIK3CA variant has not been reported).
Total population PFS was 6.89 months (95% confidence interval [CI], 4.49–12.33). OS was 20, 59 months (95% CI: 16.92-Not reached (NR)).

As compared to phase III RCT SOLAR-1 results, our study showed lower PFS (6.89 vs 11.0 months), but similar to other real-world cohorts.
Subgroup analysis Group 1. PFS: 13.90 months (95% CI = 6.89, NR). OS 20, 59 months (CI 95% = 15.61, NR).

Group 2. PFS: 5.61 months (95% CI = 3.41, 12, 33). OS: NR (CI 95% = 11.21, NR).

There were no statistically significant differences in PFS or OS between groups (p = 0.09 and p = 0.3, respectively). Nonetheless, results suggest a trend in favour of group 1 outcomes.
Conclusion and Relevance Our results show a modest benefit observed with alpelisib in real-world clinical practice when used as second-line therapy.

Finally, the clinical utility of PIK3CA mutations requires further research that to detect potential benefits from mutation guided treatment algorithms to optimise and ease clinical decisions, improving outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-005 REAL-LIFE USE OF CEFTAZIDIME-AVIBACTAM

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Background and Importance Ceftazidime-avibactam is a novel synthetic beta-lactam/beta-lactamase inhibitor combination active against Ambler class A, including extended-spectrum β-lactamases (ESBLs) and KPC, some class D enzymes (OXA-48 carbapenemases) and AmpC enzymes producing bacteria.

Pharmacy and therapeutics (PyT) committee protocol includes its use in targeted treatment in severe infections with KPC-or-OXA 48-producing bacteria and combined with aztreonam in metallo-beta-lactamase-producing bacteria (VIM). Empiric treatment in severe infections and risk of colonisation by carbapenemase-producing bacteria without bacterial culture results.

Aim and Objectives Analyse the degree of protocol compliance established by the PyT committee on the use of ceftazidime-avibactam.

Material and Methods A retrospective observational study was carried out in all patients treated with ceftazidime-avibactam from January 2020 to June 2024.

Collected data: demographics (age, sex), prescription service, indication, dosage, duration of treatment, isolated microorganism, adverse drug reactions.

Data sources: electronic prescription programme and electronic medical records.

Results 31 patients were included, 64.5% male; median age 63 years (IQR=77–55).

Prescribing services were ICU and infectious diseases. In five patients the prescribed dose was adjusted according to renal function. The median duration of treatment was 7 days (IQR: 3–11).

71% patients received targeted treatment and 29% empiric treatment.

Indications for targeted treatment were sepsis (27.3%), complicated urinary tract infections (22.7%), complicated intra-abdominal infections (13.6%), vascular lesions/amputations (9.1%), pneumonia (9.1%), colonisation (9.1%) (one patient colonised at intra-abdominal level and another at skin and soft tissue level), infections due to fractures (4.5%) and infections due to surgery (4.5%).

Isolated microorganisms in targeted treatment were: VIM-producing *Klebsiella pneumoniae* (22.7%), OXA 48-producing *Escherichia coli* (22.7%), VIM-producing *Enterobacter cloacae* (13.6%), KPC-producing *Klebsiella pneumoniae* (13.6%), OXA 48-producing *Klebsiella pneumoniae* (9.1%), KPC-producing *Klebsiella aerogenes* (9.1%), multidrug-resistant *Pseudomonas aeruginosa* (4.5%), and VIM-producing *Enterobacter aerogenes* (4.5%).

Regarding indications for empiric treatment group were: pneumonia (33.3%), gastrointestinal tract involvement (22.2%), sepsis (33.3%) and complicated urinary tract infections (11.1%).

Isolated microorganisms in empiric treatment were: 77.7% were multidrug-resistant *Pseudomonas aeruginosa*, one patient with COVID and another with *Klebsiella pneumoniae* ESBL. Treatment antibiotic was de-escalated when laboratory testing became available.

Adverse drug reactions observed: betalactamic encephalopathy (one patient).

Conclusion and Relevance The degree of compliance with the protocol established by the PyT committee was high. In our case, ceftazidime-avibactam was used for targeted treatment of complicated urinary tract infections and sepsis in most cases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-006 CLINICAL PHARMACIST INTERVENTIONS WITHIN A GERIATRIC MOBILE TEAM

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Background and Importance Frail and complex older inpatients might receive an intervention from the Geriatric Mobile Team (GMT) of our hospital after request. The GMT provides specialised medico-social advice and optimises the patients' care. Since 2020, a clinical pharmacist works with the GMT on the patients' drug management by carrying out medication reconciliation and pharmaceutical analysis of their prescription within a national care pathway for the elderly.

Aim and Objectives The aim of this study is to assess the pharmacist activity within the GMT and its potential impact on drug management and hospital readmission at 3 months after discharge.

Material and Methods All inpatients assessed by the GMT and hospitalised in acute medicine unit, arrived via the emergency department, between 1 January 2020 and 31 December 2023 were included in this retrospective cohort study. The variables collected were: age, sex, length of stay, readmission in the hospital in the 3 months after discharge, drug class managed by the PI, drug related problems (DRP) identified, nature of the advice given, and acceptance rate by doctors. A PI is notified in the prescription software and can be discussed orally with the medical team. They are considered as accepted if they lead to a change in the prescription.

Results Overall, 203 patients were included (mean age 87.4 ± 5.7 years, 51.7% female). Among them, 138 had a PI in their prescription: 246 PIs in total with an acceptance rate of 76.4%. Patients with a PI had longest length of stay (18.7 ± 12.5 vs 14.6 ± 6.2 days, p=0.01) and more prescribed drugs (9.2 ± 3.6 vs 7.8 ± 3.3, p = 0.01). No significant difference was observed in readmission rate (28.1% vs 33.9%, p=0.49). The drugs with most PIs were 'supplements' (14.6%), 'proton pump inhibitors' (10.6%) and 'anticoagulants' (8.5%). The most frequent DRPs highlighted were 'Non conformity to guidelines or contraindication' (28.1%), 'Supratherapeutic dosage' (24.4%) and 'Drug without indication' (23.2%). The advice proposed by the pharmacist were 'Dose adjustment' (32.5%), 'Drug switch' (26.4%) and 'Drug discontinuation' (22.4%).

Conclusion and Relevance This multidisciplinary team encourages optimal prescriptions in these complex inpatients. Further research is necessary to explore and improve our impact on the patients' readmission rate.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-007 EFFICACY AND SAFETY OF AVELUMAB IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA

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Background and Importance The majority of patients with metastatic urothelial carcinoma experience disease progression within 9 months of initiating chemotherapy. This has led to the exploration of maintenance therapy aimed at prolonging the chemotherapy response for as long as possible.

Avelumab, a monoclonal antibody targeting the programmed death-ligand 1 (PD-L1), is approved for first-line maintenance treatment in adult patients with locally advanced or metastatic urothelial carcinoma (UC) who have not progressed after platinum-based chemotherapy.

Aim and Objectives To determine the efficacy and safety of avelumab in patients with metastatic bladder cancer.

Material and Methods This was a retrospective, observational, single-centre study conducted at a tertiary care hospital over 39.2 months, from January 2021 to March 2024. Efficacy endpoints included progression-free survival (PFS) and overall survival (OS), while safety endpoints included adverse events and their severity.

The statistical analysis was performed using R Commander 2.9–1.

Results A total of 30 patients were included with the following characteristics: 73% were male, with a median age of 73 years (range 40–87) and baseline ECOG performance status was 0 (47%) or $\geq$1 (53%). In terms of first-line induction chemotherapy, 30% of patients received Gemcitabine-Cisplatin, 67% received Gemcitabine-Carboplatin, and 3% received both. 90% of patients achieved a complete response (CR) or partial response (PR) to prior platinum-based therapy and 10% had stable disease (SD). Additionally, 43% of patients had visceral metastases, and 23% of tumours expressed PD-L1.

The median OS was 21.3 months (95% confidence interval (CI): 10.4-not reached (NR)), and the median PFS was 4.8 months (95% CI: 3.3–13.8).

23% of patients experienced adverse events of any-grade related to the medication, including fatigue, dysuria, and urinary tract infection. Grade 3–4 adverse reactions were observed in 6.7% of patients, and treatment administration was delayed in 10% of cases.

Conclusion and Relevance Clinical practice outcomes demonstrate efficacy results comparable to those obtained in the pivotal JAVELIN Bladder 100 trial, which reported a median OS of 22.1 months and a PFS of 3.7 months. Regarding safety, the toxicity profile in our study was better than that observed in the pivotal trial (98% adverse events). These findings support the use of Avelumab in clinical practice, highlighting the importance of its funding for these patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-008 IS LINEZOLID PENETRATION IN THE MEDIASTINUM ADEQUATE? A CASE REPORT

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Background and Importance Mediastinitis is a relatively uncommon infection that affects structures within the mediastinum and can result from various underlying etiologies, including oesophageal perforation. Antibiotic penetration into mediastinal space is typically low due to its separation from the bloodstream. It's been demonstrated that linezolid's diffusion into tissues is superior to vancomycin. Given that linezolid has good tissue penetration (mediastinum/plasma ratio=1.32), it may be an effective treatment for mediastinitis. However, there is limited evidence regarding its penetration into the mediastinum.

Aim and Objectives Determine linezolid levels in plasma and mediastinum and confirm their correlation with existing literature.

Material and Methods 71-year-old woman presented to emergency department with sensation of foreign body in oesophagus, accompanied by pain and feeling of dyspnoea. A rigid esophagoscopy revealed oesophageal perforation caused by a foreign body in Killian's mouth, leading to her hospitalisation. On day+2, a computed tomography (CT) scan showed pneumomediastinum. The patient began to experience dysphagia and chest pain. After a febrile peak, piperacillin-tazobactam (P/T) was initiated. On day+4, patient's respiratory condition worsened, requiring CPAP support. CT scan revealed extensive mediastinitis with a retroesophageal collection and left pleural effusion. An urgent surgical intervention with drainage placement were performed. S.anginosus and S.merionis, multisensitive, were isolated, leading to de-escalation to amoxicillin/clavulanic. The patient showed good progress but several febrile peaks. On day+23, CT scan revealed significant worsening of collections. Antibiotic treatment was changed to meropenem+vancomycin+caspofungin, and a drainage of the collections were performed. In new cultures grew N.favescens and S.epidermidis, initiating targeted treatment with P/T+linezolid 600mg/12h, resulting in radiological and analytical improvement.

On day+7 of linezolid, plasma levels were determined by High-Performance Liquid Chromatography(HPLC-UV).

Results After obtaining subtherapeutic levels of linezolid (0.88mcg/mL, therapeutic range=2–7mcg/mL), it was decided to adjust the dosage to 600mg/8h. Additionally, new levels were requested two days after, both in plasma and mediastinum, to assess whether the concentrations in the mediastinum were adequate: 5.06 and 7.64mcg/mL in plasma and mediastinum, respectively (mediastinum/plasma ratio=1.51). Given patient's favourable progress and levels within therapeutic range, it was recommended to maintain current regimen.

Conclusion and Relevance These values align with ranges published in literature, confirmed by a series of cases, and demonstrate good tissue penetration of linezolid in mediastinum and pleural tissue.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-009 RESOLUTION OF ELECTRONIC PRESCRIBING ERRORS AFTER INTERVENTION FROM A SPECIALISED HOSPITAL PHARMACIST OR NON-SPECIALISED HOSPITAL PHARMACIST: A RETROSPECTIVE CROSS-SECTIONAL STUDY

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Background and Importance Pharmacists, integrated in the medical team on the ward, improve medication safety. However, when this specialised hospital pharmacist is not available, the pharmaceutical care will be conducted by another, non-specialised hospital pharmacist with less clinical experience for that specific patient group. It is unknown if advice from a specialised hospital pharmacist results in the resolution of prescribing errors more often than advice given by non-specialised hospital pharmacists. Furthermore, it is unknown whether other characteristics of the hospital pharmacists as well as characteristics of the prescriber, patient, drug or the intervention itself are associated with the resolution of prescribing errors.

Aim and Objectives The aim was to compare the resolution rate of prescribing errors between specialised hospital pharmacists and non-specialised hospital pharmacists. Furthermore, we investigated whether other characteristics of the pharmacists, the prescriber, patient, drug or intervention itself were associated with the resolution rate.

Material and Methods A retrospective cross-sectional study was conducted to assess the resolution of prescribing errors, based on the analysis of electronic prescriptions. Prescriptions for all inpatients were collected in June 2021. To identify prescribing errors, a medical doctor and hospital pharmacist analysed all alerts that were retained to be checked by a pharmacist. A prescribing error was defined as an alert that required intervention of the pharmacist to prevent harm or to optimise therapy. Resolution of a prescribing error was defined as resolution of the error within 24 hours after detection.

Results In total, 145,574 medication prescriptions were analysed and 448 prescribing errors were detected. 94.0% of the prescribing errors were resolved within 24 hours. No differences were found between the resolution rates of specialised and non-specialised hospital pharmacists (94.4% versus 91.9%, p=0,145 (Chi-squared test)). No other characteristics of the pharmacist, prescriber, patient, the drug involved, or the intervention itself were associated with the resolution of the prescribing error.

Conclusion and Relevance After implementation of specialised pharmacists on the ward the vast majority of the prescribing errors are resolved. In the absence of the specialised pharmacists, the resolution rate remains high in this setting. The high resolution rate gives ground for the integration of a hospital pharmacist in the medical team on the ward.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-010 RECONCILIATION OF EYE DROPS FOR GLAUCOMA IN THE EMERGENCY DEPARTMENT

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Background and Importance The recognition of glaucoma as a relevant medical problem on admission to the emergency department (ED) is variable. Most ophthalmic treatments are absorbed into the systemic circulation and their discontinuation may worsen this condition. For eye drops adjustment, the patient´s clinical situation and concomitant medications must be taken into account.

Aim and Objectives To analyse the reconciliation of treatment for glaucoma at admission and to optimise the process.

Material and Methods Interventional study that included patients diagnosed with glaucoma under treatment with eye drops who were admitted to the emergency observation ward during the pharmaceutical presence period (December 2023 to February 2024, Monday to Friday from 8 a.m. to 3 p.m.).

Collected data included demographic variables, drug, glaucoma diagnostic record in patient‘s admission history and ophthalmic treatment reconciliation.

A priori unjustified discrepancies between hospital and home prescriptions were classified as justified discrepancies (at the discretion of a physician) or as reconciliation errors (RE) if they resulted in a prescription modification after pharmacist’s intervention. The extent of pharmaceutical medication revision within 24 hours of admission to the ED was measured.

Results A total of 49 eye drops prescriptions corresponding to 34 patients (50% men) with a median age of 79 (53–95) years were revised.

There were 27 hospital prescriptions (55%) that did not require clarification, five (10%) justified discrepancies and 17 (35%) RE: 16 (94%) omissions and one (6%) inappropriate prescription (dorzolamide in a patient with severe renal failure).

The most frequently prescribed drugs were: brinzolamide (27%), bimatoprost (16%), latanoprost (16%), dorzolamide-timolol (8%), brinzolamide-timolol (4%), carteolol (4%), timolol (4%), travoprost (4%).

There was no glaucoma diagnostic record in the admission history of 12 (35%) patients. In seven of them, eye drops omissions were detected, which resulted in RE in all cases.

A total of 28 (82%) patients were revised by pharmacists within 24h after hospitalisation. The others were admitted on Saturday or remained previously more than 24h in other ED subunits without a pharmacist.

Conclusion and Relevance In the ED there is room for improvement in the reconciliation of eye drops for glaucoma and in its consideration as a relevant medical problem that requires correct anamnesis and pharmacotherapeutic follow-up. Pharmaceutical presence improves ophthalmic treatment reconciliation and provided healthcare.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-011 ANTIMICROBIAL STEWARDSHIP RECOMMENDATIONS IN PATIENTS WITH RESPIRATORY TRACT INFECTIONS IN AN INTERMEDIATE CARE HOSPITAL

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Background and Importance Antimicrobial Stewardship Programmes (ASP) aim to optimise antimicrobial use to minimise unnecessary exposure and adverse outcomes. Respiratory tract infections are highly prevalent and are associated with high morbidity and mortality rates.

Aim and Objectives - Define patient profile with respiratory tract infections (RTIs) admitted to an Intermediate Care Hospital (ICH).

-Examine common etiological agents and prescribed antimicrobial treatments.

-Assess the ASP team recommendations and their acceptance by prescribers.

Material and Methods We conducted an observational, retrospective study of patients admitted to a 116-bed ICH from September 2022 to February 2024, with RTI reviewed by the ASP team.

Variables included age, gender, infection type (pneumonia (P) or lower respiratory tract infection (LRTI)), microbiological tests performed, prescribed antibiotics, empirical or targeted treatment, adherence to clinical guidelines, ASP recommendation and acceptance.

Quantitative variables were expressed with median and interquartile range, and qualitative variables with number and percentage.

Results 273 treatments were reviewed. 74% were LRTI and 26% were P. The median age was 87 years [80–90], with 52% females. Microbiological tests were performed in 48% (n=130): antigenuria (n=80), sputum (n=52), and blood cultures (n=43). Antigenuria was positive in 11 patients (14%), all due to *Streptococcus pneumoniae*. Sputum cultures were positive in 35 patients (67%). Identifying *Pseudomonas aeruginosa* (n=14) most frequently, followed by *Staphylococcus aureus* (n=6, 3 methicillin-resistant) and *Escherichia coli* (n=4, 2 extended-spectrum beta-lactamase(ESBL) producers). 1 blood culture (2%) was positive for an ESBL producer *Klebsiella pneumoniae*. 89% of treatments were empirical, 81% following guidelines. The most prescribed antibiotics were amoxicillin/clavulanate (31%), levofloxacin (27%), and piperacillin-tazobactam (18%).

ASP team recommendations were 56% (n=153) stop antibiotic, 21% (n=56) switch to oral route, 18% (n=48) maintain treatment, 4% (n=12) reduce spectrum, 1% (n=2) increase spectrum and 1% (n=2) change in dosage. Recommendations were accepted in 82% of cases (n=118).

Conclusion and Relevance Patients with RTIs were predominantly elderly with LRTIs. Sputum cultures were the most informative, with *Pseudomonas aeruginosa* being the most common isolate. Most treatments were empirical, with high adherence to guidelines. The ASP team effectively optimised treatment duration, with high acceptance of its recommendations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-012 CLASSIFICATION AND ASSESSMENT OF THE COMPLEXITY OF ONCO-HAEMATOLOGY CLINICAL TRIALS FROM A PHARMACY SERVICE PERSPECTIVE

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Background and Importance Clinical trials in onco-haematology are a breakthrough in cancer treatment, but require meticulous management by the pharmacy service (PS) due to their complexity.

Aim and Objectives To classify onco-haematology clinical trials (CTs) and to assess their complexity from the point of view of the PS.

Material and Methods Retrospective observational descriptive study of onco-haematological CTs initiated in 2023 in a tertiary hospital. Following characteristics were analysed/collected for each CT: research phase and pathology treated. Complexity was assessed using the Calvin et al. complexity scale, considering aspects like blinding, number of drugs, PS professionals involved, dispensing method, IT system usage, dosing, storage conditions, and need for special packaging. CT complexity was categorised as low (6–10 points), moderate (11–19 points), and high (20–33 points). Overall complexity was calculated by pathology and phase. Fundanet was used for data extraction and Excel for data analysis.

Results In 2023, 84 CTs were initiated, 58 (69%) in oncology and 26 (31%) in haematology. Of the total CTs, 25 (30%) were in phase I, 30 (36%) in phase II, 27 (32%) in phase III, and 2 (2%) in phase IV. In oncology, lung and breast cancer were the pathologies with the most CTs (16 CTs, 28% and 12 CTs, 22% respectively), while in haematology, lymphomas had 7 CTs (28%) followed by leukaemia with 6 CTs (23%).

Of the evaluated CTs, 62 (74%) had moderate complexity (mean score 16; SD: 4), 15 (18%) low (10; SD: 1), and 7 (8%) high (21; SD: 4). The aspects that most increased complexity were: number of drugs involved, dispensing method, and storage conditions.

Of the 7 highly complex CTs, acute myeloid leukaemia (AML) and lung cancer were the most frequent pathologies, 29% in both cases. Most highly complex trials were phase I (57%).

Conclusion and Relevance 36% of analysed CTs included phase II drugs. The most studied pathologies were lung cancer, breast cancer, lymphomas, and leukaemias.

74% of CTs had a moderate overall complexity. AML and lung cancer were the most complex pathologies, and phase I trials scored the highest on the Calvin et al. Scale.

Performing such evaluations allows to understand the complexity of CTs and allocate resources more efficiently.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-013 OPTIMISATION OF EMPIRICAL USE OF CEFTAZIDIME/AVIBACTAM IN A MEDIUM-COMPLEXITY HOSPITAL: IMPACT OF ANTIMICROBIAL STEWARDSHIP PROGRAMME MULTIDISCIPLINARY TEAM INTERVENTIONS

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Background and Importance Ceftazidime/avibactam is critical for managing multidrug-resistant infections. With rising antibiotic resistance, optimising its empirical use via Antimicrobial Stewardship Programme (ASP) interventions is crucial for improving treatment appropriateness and patient safety.
Aim and Objectives To assess the appropriateness of empirical ceftazidime/avibactam prescriptions and recommendations from the Antimicrobial Stewardship Programme (ASP) team.
Material and Methods A retrospective observational study was conducted, including empirical prescriptions of ceftazidime/avibactam between January and December 2023 at a medium-complexity hospital. Data were collected from the Hospital Pharmacy programme's inpatient module and electronic health records, including variables: sex, age, origin from long-term care facilities or intermediate care hospitals (LTCF/ICH), history of infection or colonisation by carbapenemase-producing microorganisms (CPMs), treatment duration, infection focus, empirical treatment (ET) appropriateness, ASP intervention and acceptance, and treatment duration. The appropriateness of ET was evaluated based on guidelines from the Infectious Disease Commission.

Statistical analysis was conducted using IBM SPSS-Statistics 29.0, with the McNemar test applied to analyse differences in time-dependent ordinal variables.
Results 45 ETs with ceftazidime/avibactam were reviewed in 32 patients (19 men) with a median age of 82.1 years (IQR 75.5–88.1). Of these, 46.9% (n=15) came from LTCF/ICH. A total of 43.8% (n=14) of patients had a positive colonisation study for CPM, 31.2% (n=10) had no history of CPM infection, and 25.0% (n=8) had a history of CPM infection but a negative colonisation study.

The most frequent infection focus was urinary (48.9%), followed by respiratory (28.9%), skin and soft tissue (13.4%), abdominal (4.4%), surgical prophylaxis (2.2%), and unknown focus (2.2%). Additionally, 22.2% of patients had bacteraemia.

ASP team reviewed 80% (n=36) of the ETs; all treatments exceeding 3 days were reviewed. Recommendations included: escalation to ceftazidime/avibactam (14/36), continuation of empirical therapy with ceftazidime/avibactam(8/36), de-escalation (7/36), dosage adjustment for renal function (3/36), initiation of antibiotic therapy (2/36), and discontinuation (2/36). All recommendations were accepted (100%).

Initially, 31.1%(14/45) of ETs were deemed appropriate. Post-ASP intervention, appropriateness rose to 88.9% (40/45), with a statistically significant difference ($p<0.05$).
Conclusion and Relevance The study highlighted that elderly patients from LTCF/ICH, often with CPM-related histories, were the primary recipients of ceftazidime/avibactam ET in our hospital, with urinary infections most common.

ASP interventions significantly improved treatment appropriateness, underscoring the critical role of the ASP in enhancing clinical practice and patient safety. The ASP team's recommendations had an excellent acceptance rate.

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

4CPS-014 SAFETY PROFILE OF ENZALUTAMIDE IN PATIENTS WITH CASTRATION-RESISTANT PROSTATE CANCER: REAL-LIFE DATA

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Background and Importance Enzalutamide's real-world safety in mCRPC requires validation to identify and manage adverse reactions effectively.
Aim and Objectives To describe the safety profile of enzalutamide in metastatic castration-resistant prostate cancer (mCRPC) patients.
Material and Methods This retrospective study included mCRPC patients treated with enzalutamide from January 2015 to December 2023. Data were collected from the Hospital Pharmacy programme's outpatient module and electronic medical record, including: age, ECOG status, PSA at the start of treatment, Gleason score, metastasis location, treatment line, and reason for discontinuation.

Adverse reactions (ARs) and toxicity grades were classified by CTCAE v5 and grouped by system according to MedDRA. Descriptive statistics were used for analysis.
Results Twenty-nine men received enzalutamide (240 mg/day), median age 76.9 years (IQR 67.5–84.9); 82.8% had ECOG 0–1, 13.8% ECOG $\geq$2. Median PSA was 32.7 ng/mL (IQR 7.1–90.6). Gleason scores were $\leq$6 in 10.3%, 7 in 17.2%, $\geq$8 in 65.6%. Metastasis locations were lymph nodes in 55.2%, bones in 37.9%, and bones+visceral in 6.9%. Enzalutamide was first-line in 20.7%, second-line in 55.2%, and third/fourth-line in 24.1%.

Treatment was discontinued in 23 (79.3%) patients, with 16 (69.6%) due to progression, 5 (21.7%) due to toxicity, and 2 (8.7%) due to general health deterioration unrelated to enzalutamide. Toxicity-related discontinuations included persistent Grade II nausea, Grade III seizures, Grade III hypersensitivity reactions, Grade IV asthenia, and Grade III focal seizures. Patients experiencing neurological ARs had no prior neurological history. No patients reduced their dose due to toxicity.

Twenty-five (86.2%) patients experienced ARs, with 36 ARs recorded: 83.3% were Grade I-II and 16.7% Grade III-IV. Grade I-II ARs included: 3 haematologic and lymphatic system disorders (anaemia), 2 nervous system disorders(headache, behavioural changes), 4 vascular disorders (hot flashes), 2 ocular disorders (visual acuity loss), 6 gastrointestinal disorders (nausea, constipation, anorexia, diarrhoea), 2 renal and urinary disorders (fluid retention), 2 respiratory disorders (dyspnoea), 4 skin disorders (cutaneous reactions), 2 musculoskeletal disorders (tremor, muscle pain), and 9 general disorders (asthenia)

Grade III-IV ARs included: 2 cases of asthenia,1 fluid retention,1 hypersensitivity reaction,1 anorexia,1 tremor,1 seizure,1 hypertension, and 1 focal seizures.

Conclusion and Relevance Enzalutamide was generally well tolerated, with most ARs being Grade I-II. Toxicity-related discontinuation was higher than in clinical trials but lower than in some real-world studies.

Visual acuity loss and tremor, not listed in the official drug label. Both events have been reported to FEDRA and Eudra Vigilance pharmacovigilance systems.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-015 THERAPEUTIC OPTIMISATION IN OLDER INPATIENTS: IS MELATONIN A REAL DEAL?

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Background and Importance Melatonin is used for treating insomnia or circadian rhythm sleep-wake disorders. For frail older inpatients with sleep deprivation its use might be interesting to reduce polypharmacy and consumption of benzodiazepines (BZD) or hypnotic drugs with potential serious adverse effects. In our country, drugs containing melatonin aren't reimbursed due to a lack of evidence of efficiency. Our hospital has referenced it, despite sub-costs, for the treatment of insomnia in patients with Lewy-Body Dementia (LBD).

Aim and Objectives This study's aim is to assess the compliance of Melatonin prescriptions with our Drug Committee referencing criteria, the co-prescription rate of Melatonin with BZD/hypnotics and the rate of continuation of Melatonin by the patient within 6 months of hospitalisation.

Material and Methods All prescriptions of Melatonin in patients aged over 75, hospitalised in acute medicine unit, between 1 June and 30 November 2023 were included in this retrospective cohort study. The variables collected were: age, sex, diagnostic of LBD, insomnia symptoms, history of falls, prescription of BZD/hypnotics, treatment follow-up after 6 months (city pharmacies or residential care facilities were contacted).

Results The study included 96 patients (55.2% female, mean age 86.2 ± 5.9 years). Among them, 4 (4.2%) had a LBD diagnosed. Melatonin was prescribed with BZD/hypnotics for 62.5% of patients during hospitalisation – most of them (68.3%) having a history of falls. Fewer patients reported sleep improvement on melatonin only (7.5%) than with an addition of another drug (43.4%). The continuation rate 6 months after discharge is 38.9%: the reasons given for discontinuing Melatonin were inefficiency and cost. However, 85.7% of those patients are still treated with BZD/hypnotics.

Conclusion and Relevance Few prescriptions meet our referencing criteria. Although it has been used with wider indications, Melatonin has difficulties to demonstrate its efficacy in improving the drug management of elderly inpatients as the co-prescription rate with BZD/hypnotics is important. Pharmacist-led interviews with an aim of deprescribing those drugs might be a support for the medical team to find a more secure way to treat insomnia than using profusely a 'trendy' – but expensive- drug. Large-scale clinical trials are needed to determine its impact on older inpatients (relevant dosage, indication) and consider possible reimbursement.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-016 EVALUATION OF A PHARMACIST-LED DEPRESCRIBING INTERVENTION IN A POLYMEDICATED ELDERLY POPULATION USING THE CLEO TOOL: OPTIMISING PHARMACOTHERAPY IN CHRONIC PATIENTS

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Background and Importance Polypharmacy is a common healthcare problem in elderly patients. Pharmaceutical care aims to optimise medicine use and improve patients' health outcomes by performing pharmaceutical interventions (PIs) that, ultimately, result in patients' treatment changes.

Aim and Objectives To evaluate the impact of PIs in institutionalised elderly patients (>65 years), identifying potentially inappropriate drugs (contraindication, incorrect dosage, lack of indication or potential pharmacological interaction) and proposing their deprescription/adjustment of dosage.

Material and Methods All patients who were admitted to the Sociosanitary Pharmacy Service of La Florida nursing home (Alicante, Spain) were included. Terminally ill patients were excluded.

START/STOPP criteria, LESS-CHRON, Garfinkel's geriatric/palliative good clinical practice algorithm, dysphagia register, Barthel scale, anticholinergic load calculators and electronic tools (MedStopper) were used. After analysing the patients' clinical situation, two hospital pharmacists agreed on the changes proposed to the prescriber and performed the analysis with CLEO tool. Disagreements were discussed until consensus was reached.

Results The clinical records of 70 institutionalised patients with a 2:1 gender distribution (female: male) and a median age of 86.5 years were analysed. The median Barthel Scale score was 45 points. Dysphagia was detected in 9 patients (≈13%). Moderate anticholinergic risk was identified in 22 (31.4%) and low risk in 3 (≈4%) patients.

A total of 50 treatment modifications (28 discontinuations and 22 dose reductions) were proposed, with an acceptance rate of 68% by the prescribing physician (20 discontinuations and 14 dose reductions). Of the discontinued drugs, 5 (20%) were analgesics, 3 (15%) antispasmodics and 2 (10%) vitamin D. Among the drugs with dose reductions 4 (29%) antidiabetics, 3 (21%) antidepressants and 2 (15%) antivertigo agents.

When analysed using the CLEO tool, agreement was reached in 32 of the 34 initial ratings (agreement: 95%) for the clinical impact and 100% for the economic and organisational impact. Of the 34 changes, 30 (88%) were considered to have a moderate clinical impact and 4 (12%) were considered to have a major clinical impact on patients. At the economic level, all 34 (100%) interventions were found to reduce costs. At the organisational level, none of the interventions resulted in a significant logistical change.

Conclusion and Relevance Pharmaceutical interventions aimed at pharmacotherapy optimisation promote clinical safety improving quality of care and efficiency of resources.

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

4CPS-017 EVALUATION OF EFFECTIVENESS AND SAFETY OF ALIROCUMAB AND EVOLOCUMAB IN REAL-WORLD SETTINGS

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Background and Importance Proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors are monoclonal antibodies that bind to PCSK9, regulating low-density lipoprotein (LDL) metabolism and LDL receptor degradation.
Aim and Objectives The aim of this study was to evaluate effectiveness and safety of PCSK9 inhibitors in management of primary hypercholesterolaemia and mixed dyslipidemia.
Material and Methods Observational, descriptive, and retrospective study including patients treated with PCSK9 inhibitors from 2021 to 2023. Analysed sociodemographic variables were sex and age. Clinical variables included diagnosis, treatment, concomitant high-dose statin therapy (yes/no), and baseline and final LDL levels. Effectiveness was assessed by LDL reduction, treatment persistence, cardiovascular-related hospitalisations, and overall survival. Safety was evaluated by the occurrence of adverse reactions (ARs).

High-dose statin therapy was defined as atorvastatin 80 mg/day or rosuvastatin 20 mg/day or higher.
Results 33 patients were included with a median age of 57 (21–80) years and 50% were male. Primary hypercholesterolaemia was diagnosed in 53.12%, while 46.88% had mixed dyslipidemia. Alirocumab was given to 59.38% of patients, and 40.63% received Evolocumab. Half of the patients received high-dose statin therapy.

The median baseline LDL level was 132 mg/dl (range 62–320), and the median final LDL level was 67 mg/dl (range 25–158). LDL levels were reduced by at least 50% in 39.39% of patients. Median persistence, hospitalisation, and overall survival were not reached.

ARs occurred in 15.15% of patients, with upper respiratory tract infections (40%), arthralgia (20%), hypersensitivity (20%), and pruritus (20%).
Conclusion and Relevance PCSK9 inhibitors proved effective and safe for managing primary hypercholesterolaemia and mixed dyslipidemia. However, due to the small sample size, the results are mostly limited to surrogate markers like LDL reduction. This reduction was less than in clinical trials, where a 50% decrease was noted at 24 months; in our study, only 40% of patients achieved this. The difference may stem from lower adherence to lifestyle and medication outside clinical trials.

Safety data showed good tolerability, with fewer reported adverse reactions, possibly due to underreporting in real-world settings.

Larger studies with longer follow-up are needed to fully understand these drugs' impact.

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

4CPS-018 AVOIDED COST IN COAGULATION FACTORS IN CONGENITAL COAGULOPATHIES CLINICAL TRIALS

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Background and Importance It is necessary know the profitability of clinical trials (CT) due to sponsors provided drugs free of charge, particularly in pathologies which have a high economic impact on hospital budget.
Aim and Objectives To quantify the avoided cost (AC) of coagulation factors derived from participation on congenital coagulopathies (CC) CT.
Material and Methods Retrospective, observational study of CT conducted in CC at a tertiary hospital during 2022–2023. Inclusion criteria: active CT during the study period in CC. Exclusion criteria: CT without included patients. Data sources: CT management software, pharmacy service management database, and electronic medical records. Recorded data: protocol code, sponsor, pathology, patients included/CT, prior treatment (medicinal product and posology) before enrollement in the CT, cost of that treatment (laboratory purchase price [LPP] + value added tax - applied discounts on LPP), and time elapsed from inclusion in the CT to the prescription of a new treatment. Variables: total AC during 2022–2023, average AC/CT, and average AC/patient. For the calculation of AC, considered medicinal product and posology that patients received before enrolment in CT and doses they would have received if not enrolled.
Results 5 CT in CC were carried out between 2022–2023. 1/5 CT excluded for not recruiting patients. The 4 included CT were open and sponsored by the pharmaceutical industry. 2 CT studied haemophilia A and 2 CT haemophilia A or B. 5 patients were enrolled (range 1–2), all diagnosed with severe haemophilia A. Prior treatment to CT was standard half-life (SHL) factor VIII (FVIII) in 3 patients and extended half-life (EHL) FVIII in 2 patients. Total AC: 829,545€. AC in SHL FVIII: 491,650€, and in EHL FVIII: 337,896€. The total expenditure on FVIII in our hospital between 2022–2023 was 2,065,202€ for SHL FVIII and 4,771,999€ for EHL FVIII, so the 4 included CT represented 23.8% and 7.1% economic savings for hospital, respectively, on the total expense. Average AC/CT: 207,386€ (range: 77,064€ -453,980€). Average AC/patient: 165,909€ (range: 77,064€ –260,832€).
Conclusion and Relevance Avoided cost of medications associated with participation in CT contributes to the sustainability of the healthcare system. Also, CT increase scientific knowledge and allow early access for patients to innovative treatments.

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

4CPS-019 ANALYSIS OF CLINICAL TRIAL SITE SELECTION VISITS

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Background and Importance The Selection Visit (SV) of a clinical trial (CT) determines whether the site meets the Sponsor's requirements. The decision to include a site in a specific clinical trial depends on numerous factors, with the characteristics and service portfolio of the Pharmacy Service (PS) being particularly significant.

Aim and Objectives To analyse the results and evolution of selection visits for clinical trials conducted in the Pharmacy Service at a tertiary hospital during the period from 2014 to 2023.

Material and Methods Retrospective, observational study. All selection visits conducted in the PS during the period from 2014 to 2023 were included. Data were extracted from PS's SV registry and the CT management programme. Collected data included the date of the SV, protocol code, sponsor, clinical service of the principal investigator, studied pathology, acceptance/rejection of the centre, and whether the reason for rejection was related to the PS.

Results During the study period, 247 SVs were conducted, broken down by year of SV: 16 (6%) in 2014; 23 (9%) in 2015; 33 (13%) in 2016; 22 (9%) in 2017; 24 (10%) in 2018; 18 (7%) in 2019; 26 (11%) in 2020; 20 (8%) in 2021; 26 (11%) in 2022; 39 (16%) in 2023. Average SV/year: 25 (range 16–39). In 95% of the SVs conducted, the trial sponsor was the pharmaceutical industry, compared to 5% (12 SVs) where the sponsor was an independent research group. The clinical service with the highest number of SVs was Rheumatology with 82 SVs (33%), followed by Endocrinology 40 (16%); Cardiology 27 (11%); Internal Medicine 25 (10%); Urology 18 (7%); Neurology 16 (7%); and other services 39 (16%). The centre was selected in 148/247 (60%) visits. In none of the cases was the reason for the centre's rejection related to the PS.

Conclusion and Relevance This study shows an upward trend in the number of selection visits conducted and the number of times the centre is chosen. In no case was the reason for rejection due to the Pharmacy Service.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-020 ABSTRACT WITHDRAWN

4CPS-021 ANALYSIS OF GLYCAEMIC CONTROL IN ELDERLY TYPE 2 DIABETIC PATIENTS INSTITUTIONALISED IN SOCIO-HEALTHCARE CENTRES

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Background and Importance Diabetes affects between 25–33% of the elderly, with higher prevalence in those >65 who have greater risk for complications significantly impacting their quality of life.

Aim and Objectives Evaluate the control of type 2 diabetes mellitus(DM2) in patients institutionalised in socio-healthcare centres (SHC) through haemoglobin A1c (HbA1c) values adjusted for frailty criteria.

Material and Methods Retrospective multicentre observational study conducted from January-March-2024. Elderly patients (>65 years) with a diagnosis of DM2 institutionalised in 3 SHCs were included. The following variables were collected from the electronic medical records:

Demographic Age, gender

Clinical

1. The latest HbA1c value(2023–2024 period).
2. Frailty: Patients were stratified according to the criteria established by the American Diabetes Association(ADA) and the geriatric assessment, differentiating:
   - Healthy patient >65 years:0–1 chronic diseases, intact functional/cognitive status, life expectancy>10 years. HbA1c:7–7.5%.
   - Pre-frail patient:2–3 chronic diseases, mild functional/cognitive impairment(Barthel ≥60 or Katz C-D). HbA1c:7.5–8%.
   - Frail patient:≥3 comorbidities, severe functional/cognitive impairment(Barthel 40–35, Katz E-F).HbA1c:8–8.5%.
   - Dependent/end of life patient: Katz G,Barthel ≤35, immobile, and dependent. Do not measure HbA1c.

Based on these criteria, it was assessed whether the latest HbA1c value was adjusted according to frailty.

Results Out of a total of 512 patients institutionalised in 3different SHCs, 124 DM2 patients (24%) were selected, with a mean age of 84±7 years, 64% women.

HbA1c data were not determined in 15% of the patients (19), the value was between 0–7% in 43% (53), between 7–7.5% in 16% (20), between 7.5–8% in 5% (6), between 8–8.5% in 7% (9), and above 8.5% in 14% (17) of the total patients.

Regarding the frailty assessment, 20% (25) were considered healthy elderly, 36% (45) pre-frail, 25% (31) frail, 17% (21) dependent, and frailty data were not available for 2% (2).

Concerning the previously established objectives regarding the adjustment of HbA1c based on frailty, it was determined that HbA1c was adjusted in 11% (14) of the cases, not adjusted in 56% (69), it was deemed unnecessary to measure HbA1c in 15% (18) due to the patient's dependency or terminal status, and no recent HbA1c data were available in 19% (23) of the cases.

Conclusion and Relevance In most cases in the study, glycaemic control by HbA1c was not adjusted according to frailty, and in 43%of cases, it was below the appropriate range for healthy elderly patients. The presence of a pharmacist in SHCs would be advisable to optimise the use of antidiabetic medications.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-022 CONTROVERSIES IN THE PREOPERATIVE MANAGEMENT OF SGLT2 INHIBITORS

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Background and Importance Sodium-glucose co-transporter type 2 inhibitors (iSGLT2) are increasingly used for glycaemic control. However, diabetic ketoacidosis (DKA) is a serious side effect. To minimise the risk of perioperative DKA, the FDA recommends discontinuing iSGLT2 at least three days before surgery.

Aim and Objectives The primary objective is to describe glycaemic variations and incidence of DKA in patients treated with ISGLT2 undergoing surgery according to the actual time of drug discontinuation by the patient.

Secondary objectives include to analyse adequacy of anaesthesia recommendations and to describe pharmacist interventions in the preoperative management.

Material and Methods A 4-months prospective intervention study (March-June 2024) was conducted on hospitalised patients undergoing surgery while on iSGLT2 therapy. Patients undergoing outpatient surgery were excluded. The following variables were recorded and a descriptive analysis was carried out.

- Demographic: age, gender, body mass Index (BMI), and type of iSGLT2.
- Anaesthesia recommendation: no recommendation, <72-hour, =72-hour (considered adequate recommendation).
- Pharmaceutical interventions in the preoperative consultation.
- Real-time of iSGLT2 withdrawal before surgery (detected by the pharmacist at patient admission).
- Diabetic ketoacidosis and pH.
- Perioperative glycaemia.

Results The study included 53 patients, 42 male and 11 female, with a mean age of 75 years and a mean BMI of 27.6. Dapagliflozin was prescribed in 73.6% of cases.

In total, 30.2% of patients did not receive the adequate recommendation and 20% did not recall anaesthesia recommendations. The pharmacist ensured patients understanding of the anaesthesia recommendations on chronic drug management before surgery and insisted on the necessity of stopping iSGLT2 72 hours before surgery, achieving an 88.7% compliance rate.

30% of patients exhibited preoperative hyperglycaemia. Six patients did not discontinue the medication, two of whom experienced hypoglycaemia. No significance differences were detected in the levels of glucose in the perioperative period. No cases of DKA were recorded, and all patients maintained normal pH levels.

Conclusion and Relevance No patients developed DKA, supporting the recommendation of a 72-hour discontinuation period for iSGLT2 before surgery.

Pharmacists are integral in ensuring adherence to preoperative medication protocols, enhancing patient understanding and compliance.

To address controversies, a pharmacist-led clinical session was conducted to improve hospital protocol adherence for iSGLT2 preoperative management to Anaesthesia and Pharmacy departments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-023 OCCURRENCE OF POTENTIAL PRESCRIBING CASCADES AFTER HOSPITAL DISCHARGE: A COHORT STUDY

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Background and Importance A prescribing cascade occurs when a first (index) medication causes an adverse drug reaction, which is subsequently addressed by prescribing an additional (marker) medication. Medication started in the hospital can cause post-discharge adverse drug reactions and prescribing cascades, especially because multiple healthcare providers (HCPs) are involved in the post-discharge period. It is unknown how often prescribing cascades occur post-discharge.

Aim and Objectives To assess the cumulative incidence of 20 potential prescribing cascades post-discharge and to identify the HCPs involved in prescribing the marker.

Material and Methods A cohort study was conducted in a teaching hospital with adult patients admitted between 2019 and 2023, who started an index medication related to a potential prescribing cascade during their hospital stay. Data from the hospital and the Nationwide Medication Record System were used to identify patients with a potential prescribing cascade within a year post-discharge (if patients provided consent for information exchange). The primary outcome was the cumulative incidence of the prescribing cascade (calculated when $\geq$10 patients initiated the index medication). The secondary outcome was the number of prescribing cascades for which $\geq$50% of marker medication was prescribed by HCPs from outside the hospital (calculated when $\geq$10 patients initiated the marker medication). Data analysis was performed using descriptive statistics.

Results Of 24,282 patients prescribed a new index medication, 502 experienced a potential prescribing cascade. Cumulative incidence was calculated for 17 prescribing cascades, ranging from 0% to 12.3% (mean age: 68.9 years, standard deviation 11.8). For nine out of 12 prescribing cascades the marker medication was started by HCPs from outside the hospital in $\geq$50% of patients.

Examples included ACE-inhibitors causing cough followed by antitussives (cumulative incidence 5.4%, 92.8% started by HCPs outside the hospital), dihydropyridines causing peripheral oedema followed by high-ceiling diuretics (cum. incidence 6.3%), and amiodarone causing hypothyroidism followed by thyroid hormones (cum. incidence 4.0%).

Conclusion and Relevance The cumulative incidence of potential prescribing cascades post-discharge can be substantial, frequently involved older adults and most marker medication were prescribed by another HCP. Our study underscores the need for improved monitoring and increased recognition of

adverse drug reactions to prevent prescribing cascades post-discharge. Hospital pharmacists can play a key role in this.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-024 IMPLEMENTATION OF A PATIENT STRATIFICATION METHOD TO PRIORITISE MEDICATION RECONCILIATION AT ADMISSION IN THE EMERGENCY DEPARTMENT

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Background and Importance Medication reconciliation (MR) in the Emergency Service (ES) involves creating a complete list of a patient's prior medications, comparing it to the current prescription, and resolving any discrepancies. *REDFASTER* group found that 79% of patients show medication discrepancies. Implementing a patient stratification system is essential to prioritise MR.

Aim and Objectives To implement a patient stratification method to prioritise MR performed by the pharmacist at admission for patients in ES.

To prioritise MR conducted by the pharmacist for target patients receiving high-risk medications (HRM).

Material and Methods A stratification tool was created to prioritise MR for high-risk patients in the ES, using Microsoft Forms, scoring variables.

Phases

1. Form design (12/2023–01/2024).
2. Inclusion of variables in the form:
   - Age: ≥75 years (2 points), 65–74 years (1 point), <65 years (0 points).
   - Chronic treatment (CT), categorised by drug groups:
- Oral cytostatics, immunosuppressants, antiretrovirals, hospital-dispensed medications (5 points).
- Alpha-adrenergic agonists, oral anticoagulants, antiplatelets, antidepressants, anti-Parkinsonians, antiepileptics, antipsychotics, benzodiazepines, beta blockers, amiodarone/dronedarone or digoxin, corticosteroids >3 months, opioids or non-steroidal anti-inflammatory drugs, diuretics, ocular and respiratory therapy (1 point).

3. stratification levels:
   - N1: Patients with 2 points for age and ≥5 points for CT.
   - N2: Patients with ≥5 points for CT.
   - N3: Patients with <5 points for CT.

The pharmacotherapy history of N1 patients is collected, and discrepancies are identified. Discrepancies are communicated and resolved with the responsible physician.

Implementation After the form was developed, emergency pharmacists began performing patient stratification. To evaluate the activity over 10 days, RE were recorded across the three stratification levels.

Results Se estratificaron 612 pacientes en total, con un promedio de 18,54 pacientes por día. La media de pacientes diarios por nivel de estratificación fue: N1 (2,84), N2 (1,48) y N3 (14,21). La distribución fue:

- N1: 15,36% (n=94).
- N2: 8,01% (n=49).
- N3: 76,63% (n=469).

En total se produjeron 39 errores de ER en 83 pacientes. El número medio de errores por paciente en cada grupo fue:

- N1: 1,23 errores/paciente.
- N2: 0,50 errores/paciente.
- N3: 0,31 errores/paciente.

La principal causa de error en todos los grupos fue la omisión.

Conclusion and Relevance This method effectively streamlines medication reconciliation (MR) and is easily implementable for Pharmacy Services with electronic chronic medication records and an emergency department pharmacist.

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Conflict of Interest No conflict of interest

4CPS-025 MEDICATION EXTRAVASATION MANAGEMENT AND OUTCOMES IN PATIENTS WHO EXPERIENCED AN EXTRAVASATION OF MEDICATION DURING HOSPITAL ADMISSION: A MIXED-METHOD STUDY

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Background and Importance Intravenous (IV) medication administration, a routine procedure in hospitalised patients, carries risks of complications such as extravasations. Extravasations, the unintentional leakage of a vesicant drug into surrounding tissue, can result in tissue damage and necessitates prompt intervention. Current literature lacks comprehensive data on the prevalence, management and patient outcomes associated with extravasations.

Aim and Objectives To determine the prevalence, nature and deployed management strategies of extravasations in hospitalised patients and to assess patient-reported outcomes post-discharge.

Material and Methods A single-centre, retrospective, mixed-method study. All admitted patients who experienced extravasations between 1 January 2022 and 1 January 2024 were included. Eligible patients were invited to complete a questionnaire. Primary outcome: prevalence and nature of extravasations, including deployed management strategies. Secondary outcomes: patients' outcomes after extravasation post-discharge, including their experiences regarding the extravasation during and after admission. Data were extracted from the Electronical Health Record (EHR) system and questionnaires were analysed using descriptive statistics.

Results We included 200 patients with 205 extravasations, yielding a prevalence of 0.014% (of IV administrations). Among the 74 drugs involved, anti-infectives were most common (32.7%). Peripheral parenteral nutrition was most frequently extravasated, both in absolute numbers (n=19), as in relation to its number of administrations (4.2%), followed by acyclovir (n=11 and 0.5% resp.). Extravasations

predominantly occurred in the arm (61.5%) and were of moderate severity. Symptoms were most prevalent on day 1 and often disappeared in 2–3 days. Top 3: swelling (70.8%), redness (40.9%) and pain (38.5%). Standard management strategies were applied in 96.6% of cases. Drug-specific management strategies particularly encompassed cold compresses alone n=69 (33.7%) and hot compresses with hyaluronidase n=65 (31.7%). The patient questionnaire (n=41) revealed that 70.7% of patients mainly recalled experiencing swelling, pain and redness. A burning feeling was recollected far more often than was documented in the EHR: n=19 (46.3%) versus n=1 (0.6%). Less than half of patients indicated that treatment led to a reduction in symptoms. Post-discharge, 34.1% continued to suffer from symptoms.

Conclusion and Relevance This study is the first to comprehensively assess prevalence, nature, deployed management strategies and patient outcomes after extravasation. The results indicate room for improvement in management strategies and patient follow-up after extravasation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-026 CLINICAL EVOLUTION COMPARED BETWEEN SINGLE-TABLET REGIMENS AND LONG-ACTING ANTIRETROVIRALS AFTER 12 MONTHS OF TREATMENT

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Background and Importance Long-acting antiretrovirals (LAAR) are a recently introduced type of intramuscular antiretroviral treatment (ART) that have made it possible to avoid the daily administration of tablets in those patients without prior resistance or virological failure and an undetectable viral load.

Aim and Objectives Describe whether the clinical and analytical evolution with LAAR (cabotegravir and rilpivirine) is non-inferior to that achieved with STR [Dolutegravir/Lamivudine: (DTG/3TC) or Bictegravir/Emtricitabine/Tenofovir alafenamide: (BIC/FTC/TAF)].

Material and Methods To evaluate the effectiveness of CAB +RPV, the clinical and analytical response was analysed through viral loads, CD4/CD8 ratio, and hepatic, lipid, and renal profiles. We followed-up on those patients with a minimum duration of 12 months with LAAR.

Results We followed-up 67 patients (46 men) undergoing treatment with LAAR, with a mean age of 44.5 years (28–63), all of them with DTG/3TC (32) or BIC/FTC/TAF (35) and at least 1 year of treatment with LAAR. All were classified in stages A2 (14–28% CD4)) and A3 (<14% CD4), except two of them classified as B3. As a condition for switch, everyone had to have an undetectable viral load (<50 cop/ml). Only in six of them was a blip detected and never with VL>200 cop/ml. After at least 1 year of treatment with LAAR, the mean CD4/CD8 ratio was 0.91 (0.5–1.36). The mean renal function was 0.94 mg/dL (0.56–1.76) except for some discordant values, probably due to long-standing old therapies with TDF. The average lipid profile was preserved in its different biomarkers Tc: 168 mg/dL and HDLc: 69 mg/dL, with the exception of LDL-C: 123 mg/dL (<100 mg/dL) and TG: 220 mg/dL (<150 mg/dL). The mean values of GGT, ALT and AST were 128 IU, 45 IU and 69 IU. Only one patient showed a body mass index greater than 30 kg/m2 (17.5–32). 21 patients reported adverse effects in the administration procedure, with intramuscular administration being a painful route.

Conclusion and Relevance Given our experience after a minimum of 12 months of treatment with LAAR and whose previous treatments have been DTG/3TC and BIC/FTC/TAF, cabotegravir and rilpivirine constitute a suitable alternative for patients with positive HIV infection, maintaining virological suppression and an adequate immunological profile.

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Conflict of Interest No conflict of interest

4CPS-027 NEOADJUVANT DOUBLE ANTI-HER2 BLOCKADE COMBINED WITH ANTHRACYCLINE-FREE CHEMOTHERAPY, RESULTS IN LOCALLY ADVANCED BREAST CANCER

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Background and Importance Double anti-Her2 blockade plus chemotherapy is a standard regimen in Her2+ locally advanced breast cancer (LABC). Docetaxel-carboplatin-trastuzumab-pertuzumab (TCHP) provides more anti-Her2 treatment, better pathological complete response (pCR) rates and less cardiotoxicity. It is not a very widespread option due to the risk of toxicity.

Aim and Objectives Evaluate the efficacy and safety of TCHP by adding pegfilgrastim as primary prophylaxis.

Material and Methods Describe our experience with neoadjuvant TCHP and pegfilgrastim combination between years 2017–2023 and compared with other schemes.

Results 62 patients, median age 48 years; 61.3% were premenopausal; 54.8% were stage II and 45.2% were stage III; 67.7% had N+; 62.9% had RH-. A total of six cycles were completed in 85.5%; eight patients discontinued treatment due to toxicity. The most frequent adverse events were haematological (grade 3–4 in 8.1%) and digestive (grade 3–4 in 19.4%). No cardiac event was reported. 6.5% were hospitalised due to toxicity (3.2% febrile neutropenia). Dose reduction was needed in 43.5%. Clinical response occurred in 98.4% and radiological response in 87.1% (complete in 38.7%). pCR was obtained in 67.7% (66.7% in N+; 77.4% in RH-). Up to now, four patients have relapsed (three of them had pRC) and three have died. After median 24.5 months of follow-up, the median relapse-free and overall survival by Kaplan-Meier have not been reached. Cox regression shows that getting pCR does not impact survival. The odds ratio shows a higher proportion of obtaining pCR in the RH- and N+ subgroups, but without statistically significant differences.

Conclusion and Relevance Our data of TCHP and pegfilgrastim shows considerable efficacy with an acceptable toxicity

profile. The main advantage is the intensification of double lock dose, without anti Her2 window period, avoiding the addition of anthracyclines and, therefore, cardiac toxicity. pRC and toxicity profile results were better than other regimen proposed in other studies. Our data shows that pRC has no impact on survival. We assume a favourable association between pRC and N+ and HR-, although not statistically significant, probably due to the small amount of patients. Based on these favourable results, we believe that the priority use of TCHP-GCSF should be considered in the neoadjuvant treatment of Her2+ LABC.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-028 REAL-LIFE STUDY OF THE USE OF CYCLIN-DEPENDENT KINASE INHIBITORS IN HORMONE RECEPTOR-POSITIVE BREAST CANCER

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Background and Importance There are no head-to-head comparisons between these three molecules in certain aspects that are important to know in the day-to-day patient medication management.

Aim and Objectives The main objectives are to analyse whether there are differences between each of the treatment groups (ribociclib, palbociclib, abemaciclib) in terms of treatment discontinuations, interruptions and dose reductions. In addition, to determine whether there are differences in the number of visits to the oncology department, emergency room or number of admissions.

Secondary objectives are to find out whether patients with lower BMI (under 25) or older (over 60) require greater dose reductions and/or greater number of treatment interruptions.

Material and Methods Descriptive, retrospective, multidisciplinary study (oncologist) using a pseudonymised database of 120 patients (40 in each group). Data were collected from the medical records.

All statistical tests were applied with a confidence level of 95% and IBM SPSS version 26.0 was used.

Results The mean time to first treatment discontinuation was 29.2 (± 16.4) days in the total group, with no statistically significant differences between the three groups (P= 0.389).

There were statistically significant differences at 3 months in the number of emergency department visits and admissions in the abemaciclib group compared to the other two groups, with the abemaciclib group having the most hospital visits for either of these two reasons (P= 0.042 and P=0.013 respectively).

Ribociclib was the drug with the highest number of treatment discontinuations due to adverse effects (20%) with no differences between groups (p=0.271).

Furthermore, at 3 months of treatment only 20% of patients had required a dose reduction. At 6 months of treatment this percentage was 33.3%,similar to the percentages in clinical trials. There was no difference in the number of patients with reduced dose at 6 months (p=0.671).

Patients with BMI less than 25 had more treatment interruptions during the first 3 months (p=0.014), not reflected in greater dose reductions.

There were no statistically significant differences at 3 months (p=0.144) or 6 months (p=0.065) in dose reductions according to age.

Conclusion and Relevance These are fairly safe drugs, responsible for few discontinuations or dose reductions due to adverse effects.

Neither age nor BMI are parameters that are clearly associated with greater dose reductions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-029 COST-EFFECTIVENESS OF ECULIZUMAB FOR ACTIVE ANTIBODY-MEDIATED REJECTION IN EARLY POST-KIDNEY TRANSPLANTATION PATIENTS

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Background and Importance The presence of donor-specific antibodies (DSA) is the main cause of the development of acute humoral rejection (AHR), which is associated with a four-fold higher risk of graft loss. Eculizumab is a humanised anti-C5a antibody that inhibits the complement system.

Aim and Objectives The objective is to evaluate the cost-effectiveness of eculizumab in a cohort of patients with AHR and DSA.

Material and Methods Patients treated with eculizumab for AHR and DSA since 2016 at a tertiary care hospital. Effectiveness is measured in time free from renal replacement therapy (RRT) after AHR and treatment with eculizumab. The cost is measured as the cost of the medication, and the differential direct healthcare cost between haemodialysis and non-dialysis patients. The price of eculizumab used is the national health system price with VAT, and the direct cost is 144.5€ / day (Data from the Renal Anaemia Institute).

Descriptive analysis is presented as mean and standard deviation (SD). Inferential analysis was performed using the Kaplan-Meier statistical test.

Results Nine patients, mean age 49 years (range 22–63 years), 56% women, and with DSA, were treated with eculizumab for AHR. The mean follow-up time was 784 days (112–2364), and the mean cumulative dose of eculizumab was 8633 mg (range 900–33600 mg). The pre-treatment estimated glomerular filtration rate (eGFR), creatinine, and proteinuria were, respectively, 28.3 mL/min/1.73m2 (7–90 mL/min/1.73m2), 4.7 mg/dL (1.4–7.2 mg/dL), and 14763 mg/g creatinine (329.7–111689.1 mg/g creatinine). Post-treatment values (28 days) were 45.3 mL/min/1.73m2 (16–90 mL/min/1.73m2), 1.95 mg/dL (0.8–4.5 mg/dL), and 819.5 mg/g creatinine (59.8–2635.2 mg/g creatinine); and at the end of follow-up, 45.4 mL/min/1.73m2 (16–90 mL/min/1.73m2), 1.99 mg/dL (1.0–6.3 mg/dL), and 576.5 mg/g creatinine (102.3–2621.3 mg/g creatinine).

The mean cost of treatment was 94690.7€ (SD, 5484.5–377884.4 €); the mean cost avoided per RRT was 113352.2€ (16184.0–341598.0€), for the actual follow-up time.

During the follow-up period, 1/9 patients transitioned to RRT. The estimated mean time free from RRT is 1851.0 days (95% CI, 1140.0–2562.0 days). In inferential estimation, the mean cost avoided per RRT is 267469.5€ (95% CI, 164730–370209.0€).

Conclusion and Relevance Eculizumab is effective in treating patients with AHR and the presence of DSA. Additionally, it is dominant in the cost-effectiveness analysis (−172778.8€ , for 1851.0 days).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-030 PATIENT-REPORTED OUTCOMES IN INTERSTITIAL LUNG DISEASE AND ADHERENCE TO ANTIFIBROTIC THERAPY

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Background and Importance Interstitial lung disease (ILD) is a debilitating disease and there are limited therapies which focus on slowing disease progression.

Aim and Objectives To describe Patient-Reported Outcomes (PROs) on ILD and analyse the relationship with disease perception, satisfaction with antifibrotic therapy and adherence.

Material and Methods Retrospective, observational, descriptive study conducted by telephone surveys during February-March 2024 among patients with antifibrotic therapy. Surveys included: perception of disease, satisfaction with treatment (SATMED-Q survey) and Morisky-Green test (MG).

Other variables collected were sex, age, education, type of ILD, duration of treatment and adherence (dispensing records in Farmatools (optimal >80%)).

Results 46 patients were included. 85% were male, median age 72 years.

13% had no education, 33% primary, 30% secondary and 24% university education.

41% were diagnosed with ILD with usual interstitial pneumonia pattern, 30% with idiopathic pulmonary fibrosis, 11% with ILD associated with autoimmune diseases and the rest with other ILDs.

85% were treated with nintedanib, 15% with pirfenidone. Median treatment duration: 13 months.

Regarding perception of the disease 52% felt that ILD affected their daily life, 54% felt physically limited, 35% felt emotionally limited, 32% felt their social life was affected, 41% felt their sleep quality was affected and 48% of patients had stopped performing daily activities.

67% had an adverse event, mainly gastrointestinal. 20% of patients had their dose reduced. According to the SATMED-Q, the mean satisfaction with treatment was 74%.

The MG test showed 30% non-adherence (NA), of which 85% was due to forgetting to take the medicine.

According to dispensing records, 92% patients were adherent (A). Correlation with the MG test was low in NAs (only 14% detected) but high in As (91%).

Of the 31 patients who had adverse events, 71% were adherent according to the MG test compared to 67% of the 15 patients who had no adverse effects.

Conclusion and Relevance ILD is a disabling disease which make patients committed to their treatment despite the side effects.

No relationship was found between education, adverse events or SATMED-Q score and adherence

The most important factor associated with NA is forgetting to take medication; it would be important to use reminders in this population.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-031 EVALUATION OF PHARMACIST'S CONTRIBUTION TO THE PREVENTION OF SURGICAL SITE INFECTIONS (SSI)

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Background and Importance Antibiotic prophylaxis in surgical environment is an essential step in the fight against surgical site infections (SSI). Our hospital pharmacists are involved in the proper use of antibiotics.

Aim and Objectives The objective of this study is to determine whether pharmacists' actions have improved antibiotic prophylaxis in surgical environment and resulted in a reduction in the number SSI.

Material and Methods Patients who underwent surgery in the operating room were included in this retrospective study. Pharmacist and hygienist doctor analysed 11 items in patient's files operated on in 2022 and then a comparison was made from new files of patients operated on in 2023 after the implementation of corrective actions. A comparison test of means ($n \geq 30$; $\alpha = 0.05$) comparing each item before and after the implementation of improvement actions was carried out. SSI rate 2022 was compared to SSI rate 2023.

Results A pharmacist specialising in antibiotic therapy joined hospital's antibiotic committee. A specific antibiotic prophylaxis protocol for surgical procedures performed in our institution was defined. These guidelines were presented to anaesthesiologists and nurses during awareness sessions. This retrospective study was conducted on 60 patients who received antibiotic prophylaxis, 43% had undergone orthopaedic surgery, 34% digestive surgery, 13% urological surgery and 10% gynaecological surgery. Results show a statistically significant improvement on certain criteria: antibiotic prophylaxis scheduled during anaesthesia consultation 3% VS 63%; surgical incision time recorded 47% VS 100%; antibiotic compliant with protocol 67% vs 100%; dose compliant with protocol 57% vs 100%. However, there was no statistically significant improvement for other criteria: patient background reported 100% vs 100%; time of antibiotic prophylaxis injection recorded 100% vs 100%; dose of antibiotic prophylaxis recorded 93% vs 100%; duration of antibiotic prophylaxis < 48 hours 93% vs 100%. The proportion of deep SSIs is higher in 2023 ($p = 0.0008$), increasing from 0.02% in 2022 to 0.39% in 2023. The majority of SSIs (62.5%) are caused by Staphylococcus aureus.

Conclusion and Relevance In our hospital overall compliance increasing from 63% to 93%. Awareness-raising actions have

also improved the reporting of ISOs. Pharmacists play a vital role in raising awareness and alerting prescribers in the event of a discrepancy with the recommendations.

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

4CPS-032 PALBOCICLIB AND RIBOCICLIB: DOSE ADJUSTMENT BY TOXICITY AND ITS IMPACT IN HEALTH OUTCOMES

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Background and Importance Most patients treated CDK4/6 inhibitors require dose adjustments due to toxicity.
Aim and Objectives To analyse the toxicity associated with palbociclib and ribociclib leading to dose reduction and its weighting in health outcomes, measured in overall survival (OS).
Material and Methods Descriptive, retrospective, single-centre study that included patients with hormone receptor-positive and HER2-negative advanced or metastatic luminal breast cancer treated with palbociclib or ribociclib between 1 January 2018, and 1 April 2022. Data analysis was completed on 31 January 2023.

Demographic and clinical variables were obtained from the electronic medical record programme and treatment-related from the outpatient dispensing programme. Position measures (median and interquartile range) were used for quantitative variables and frequencies for qualitative, segmented by drug. Differences between drugs were assessed with statistical tests such as Kolmogorov-Smirnov, Shapiro-Wilk, Student's t-test and Chi-squared. For OS, the Kaplan-Meier method and the Log-Rank test were applied, considering p values <0.05 as significant (SPSSv28).
Results Forty-five patients were included, all women. 51% were treated with palbociclib, the median age at treatment initiation was 61 years (IQR 51–67) for palbociclib and 53 years (IQR 46–62) for ribociclib. It was first-line treatment for 52% in palbociclib and 68% in ribociclib. 91% of the palbociclib group started full dose and 86% for ribociclib.

96% of the palbociclib group and 100% of the ribociclib group presented some toxicity, requiring dose adjustment in 43% and 50% of patients with palbociclib and ribociclib respectively. Among the toxicities that led to dose adjustment, neutropenia stands out (90% palbociclib and 55% ribociclib). Other toxicities that required adjustment for palbociclib group were asthenia and anaemia. And for ribociclib, dermal toxicity (27%), hypertransaminasemia and diarrhoea (9% in both). Without significant differences dose adjustment in both groups.

The OS was 39.5 months (95% CI 31 to 48) for palbociclib and 29.1 months (95% CI 24 to 34) for ribociclib. No significant differences between both curves. $p=0.47$.
Conclusion and Relevance Although no significant differences in toxicity management are observed between palbociclib and ribociclib in clinical practice, there are statistically proven differences in toxicities that motivate dose adjustment.

The OS data obtained in both groups are comparable, which is expected since there are no differences in the management of dose adjustment.

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

4CPS-033 ABIRATERONE OFF-LABEL USE IN COMBINATION WITH DOCETAXEL AND ANDROGEN DEPRIVATION THERAPY IN PATIENTS WITH METASTASIC HORMONE SENSITIVE PROSTATE CANCER: A REAL-WORLD EXPERIENCE

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Background and Importance Initial therapy for males with metastatic hormonosensitive prostate cancer (mHSPC) consist of combination of oral antiandrogens (abiraterone, apalutamide or enzalutamide) or docetaxel with androgen deprivation therapy (ADT). Recently, combinations of ADT with docetaxel plus a second systemic agent (abiraterone or darolutamide) have been shown to improve survival over ADT plus docetaxel alone.
Aim and Objectives To compare the efficacy profile, safety and clinical follow-up of patients with synchronous mHSPC treated with triplet therapy (TT) (docetaxel+TDA+abiraterone) versus patients treated only with abiraterone plus TDA (doublet therapy) (DT) due to ineligibility to docetaxel or diagnosis mHSPC before approval of triplet therapy protocol with abiraterone off-label at hospital.
Material and Methods A retrospective observational study was conducted on patients with mHSPC who initiated TT and DT in a third-level hospital. The variables collected were stage, burden and risk disease, PSA evolution, toxicity and progression-free survival. The clinical data cut-off date established was 3 August 2024. All patients had a minimal follow-up of 6 months.
Results A total of 31 patients (67±6 years) were included. 16 patients were treated with TT and 15 patients with DT. All patients had synchronous mHSPC with high disease burden and high-risk disease. At diagnosis, bone metastasis were predominant in both groups. Visceral metastases were present in 31,2% of patients in triple therapy group (TTG) versus none in double therapy group (DTT).The median pre-treatment PSA level in TTG was 378,4 (9,3–1000) ng/ml versus 149,2 (4.8–756,4) ng/ml in the DTG. At 3 months,100% of patients achieved >90% reduction in baseline PSA in the TTG versus 93,3% in the DTG. At data cut-off, median time treatment in TTG was 13,4±4 months versus 11,1±5 months in DTG.93,7% of patients had no disease progression in the TTG versus 53,3% in the DTG. There were no deaths in the TTG compared to 20% of patients in DTG due to progression disease. Only one patient in each group had treatment interruption and doses reduction due to toxicity to abiraterone.
Conclusion and Relevance Abiraterone plus docetaxel and TDA in real-world setting demonstrates a better efficacy profile compared to abiraterone plus TDA despite patients in TTG had higher baseline PSA levels and a high percentage of patients with visceral metastases. Abiraterone plus docetaxel and TDA proves a favourable safety profile in agreement with previous data published.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-034 REAL-WORLD STUDY OF TRIFLURIDINE/TIPIRACIL-BEVACIZUMAB IN METASTATIC COLORECTAL CANCER

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Background and Importance Due to the high incidence of this type of cancer in our area we consider it interesting to do this investigation.

Aim and Objectives Evaluate the efficacy and safety of: tifluridine/tipiracil (TAS)-bevacizumab in patients with metastatic colorectal cancer (mCRC).

Material and Methods Observational, retrospective study including patients with mCRCC treated with TAS-bevacizumab from 1 January 2022 to 30 July 2024. Variables collected: age, sex, ECOG and mutations, previous treatments, adverse events (AEs) and type of response using the electronic medical record DRAGO-AE.

Efficacy has been evaluated in terms of progression-free survival (PFS) and overall survival (OS), defined as the time elapsed from the start of treatment to progression (PFS) or death (OS), calculated using the Kaplan-Meier method. Safety was assessed through the recorded treatment-related AEs, measuring their severity according to the Common Terminology Criteria for Adverse Events (CTCAEv4.0) toxicity scale. Descriptive statistical analysis was performed using SPSS-Statistics 22 software.

Results 42 patients (29 men,13 women) whose median age was 62.5 (39–85) were included. The initial ECOG was 0–1 in 66.67% and 2 in 33.33%. KRAS mutation was present in 50% and BRAF in 4.77%.

Treatment was prescribed as 2nd line in 2.38%, as 3rd line in 80.95% and as 4th line in 16.67%. The end of treatment was because of disease progression in 88.6%, toxicity in 5.7% and discontinuing in 5.7%. 83.33% of the patients presented AEs of any-grade and up to 53,38% of grade 3–4.

The median PFS was 4.05 months (95% CI 3.38–4.71) and the median OS was 11.51 months (95% CI 7.57–15.45). The best response obtained during treatment was partial response in 2.38%, stable disease in 23.81%, disease progression in 54.76% and no response in 19.05% (50% exitus and 50% less than 3 cycles of treatment).

Conclusion and Relevance The PFS obtained in our study was lower than that described in the SUNLIGHT study (5.6 months), this could be due to a greater number of patients starting treatment with an ECOG=2 in our study. The OS obtained in our study was longer compared to the literature (10.8 months). EAs of any-grade were similar to those described in the literature, but a lower percentage of grade 3–4 events were detected in our study.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-035 PERSISTENCE OF UPADACITINIB TREATMENT IN ITS DIFFERENT INDICATIONS

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Background and Importance Upadacitinib, a Janus kinase (JAK) inhibitor, is widely used to treat chronic inflammatory conditions such as rheumatoid arthritis (RA), psoriatic arthritis (PsA), atopic dermatitis (AD), Crohn's disease (CD), and ankylosing spondylitis (AS). Understanding treatment persistence – how long patients stay on therapy without discontinuation – is key to evaluating the drug's real-world effectiveness and long-term benefits. Persistent treatment often indicates better disease control, while early discontinuation may suggest therapeutic failure or intolerance.

Aim and Objectives The study aimed to determine the persistence of upadacitinib treatment across its various indications, including PsA, RA, AD, CD, and AS.

Material and Methods This descriptive, observational, retrospective study involved adult patients treated with upadacitinib between January 2021 and January 2024. Data collected included patient demographics (sex, age), diagnosis, treatment line, start and end dates, and reasons for discontinuation (e.g., primary failure, secondary failure, intolerance, or loss of follow-up). Persistence was assessed at 12 and 24 months and analysed by condition and treatment line.

Data were sourced from hospital pharmacy records (Savac) and clinical histories (Selene), and statistical analysis was performed using SPSS-Statistics version 23.

Results A total of 72 patients were included, with an average age of 54 ± 15 years, and 69.4% (n=50) were women. Upadacitinib indications were: 8.3% PsA, 68.1% RA, 15.2% AD, 1.4% CD, and 6.9% AS. Most patients were in the sixth or later lines of treatment (37.5%).

During the study, 41.7% (n=30) discontinued treatment, with an average duration of 7.4 ± 5.4 months. The discontinuation rate at 12 months was 34.7%, mainly due to secondary failure (43.3%), primary failure (20%), and intolerance (20%).

Overall, 41.7% of patients maintained treatment for 12 months or more, and 18.1% for 24 months or longer. Persistence was highest in RA patients (15.7 ± 9.8 months) and those in earlier treatment lines (13.6 ± 9.5 months for second and third lines).

Conclusion and Relevance Upadacitinib persistence is influenced by the specific condition and timing of treatment initiation. Higher persistence was observed in RA patients and those treated in earlier lines of therapy, which may reduce therapeutic failure. Further studies with larger sample sizes are needed to confirm the true persistence of upadacitinib across different conditions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-036 ANALYSIS OF PHARMACOTHERAPEUTIC INTERVENTIONS AT EMERGENCY DEPARTMENT

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Background and Importance The severity and instability of patients, together with the high degree of medication complexity, make the Emergency Room (ER) a critical area of medication related problems.
Aim and Objectives The aim of our study was to analyse and evaluate the clinical activity performed by the resident clinical pharmacist in the ER team.
Material and Methods A descriptive, prospective, 8-week study. The pharmacist joined the ER multidisciplinary team. Pharmacotherapeutic interventions (PIs) performed and the degree of acceptance were recorded.
Results We recorded 338 PIs on 187 patients with a 75% acceptance rate. Most of the PIs were omission of baseline treatment (53%), other interventions (14%), change in posology (13%), suspension of treatment (13%) and initiation of new treatment (7%). An 18% of patients were interviewed. Of the PIs accepted, a 65% influenced the efficacy and 35% the safety of the treatment. The drugs that have been susceptible to generate more actions have been N-Nervous (35%), C-Cardiovascular (24%), A-Digestive apparatus and metabolism (12%), J-Anti-infectious (10%), B-Blood (9%), H-Systemic hormonal preparations (6%), R-Respiratory system (3%), and L-Antineoplastic agents and immunomodulators (2%). The medical specialties that were most susceptible to intervention were Surgery, Internal Medicine, Cardiology and Digestive.
Conclusion and Relevance Most PIs are related to drugs of the nervous and cardiovascular systems and the most frequent type of PI is medication reconciliation due to unjustified omissions of the patient's baseline treatment. The clinical pharmacist integrated in the multidisciplinary ER team can add value to the pharmacotherapeutic process of the emergency patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-037 ABSTRACT WITHDRAWN

4CPS-038 REAL-LIFE STUDY OF THE USE OF TUMOUR NECROSIS FACTOR INHIBITORS IN PAEDIATRIC PATIENTS WITH INFLAMMATORY BOWEL DISEASE

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Background and Importance Paediatric inflammatory bowel disease (PIBD) is a chronic immune-mediated pathology with increasingly early diagnosis. The only approved biologics drugs for PIBD are infliximab (IFX) and adalimumab (ADA), both tumour necrosis factor inhibitors (anti-TNF).
Aim and Objectives The aim of this study is to describe the use of IFX and ADA as first-line therapies for PIBD and to assess their effectiveness and safety.
Material and Methods Retrospective observational study at a paediatric hospital, including patients who began anti-TNF treatment from January 2021 to March 2024.
Collected variables demographics (age, sex, weight, diagnosis), pharmacological (prescribed drugs, dose and frequency of administration), analytical (drug and faecal calprotectin (FC) levels), and adverse reactions.
Cut-off points

- Drug intensification: higher doses/frequencies than IFX and ADA data sheet.
- Analytical response: last 5 FC averages ≤ 120 µg/g.
- Optimal maintenance plasma levels seeking mucosal healing: IFX ≥ 7–10 µg/mL, ADA ≥ 5–8 µg/mL.

Data sources: Electronic Health Record (HCIS), Modulab, Farmatools. Statistical analysis: median and frequency distribution (%).
Results 54 patients were included, 35 boys (64,8%), with a median age of 14 years (2–18 years). Ulcerative colitis (UC) was present in 13 (24.1%) patients, and Crohn's disease (CD) in 41 (75.9%).

- 31 (57.4%) started with infliximab (IFX); 20 had CD and 11 had UC. 16 (51.6%) continued it, 9 (29%) switched to second-line, and 6 (19.4%) to third-line treatment.
- 23 (42.6%) started with adalimumab (ADA); 21 CD and 2 UC. 11 (47.8%) continued, 6 (26.1%) moved to second-line, 5 (21.7%) to third, and 1 (4.4%) to a fourth drug.
- 24 (44.4%) began on standard doses; 18 with ADA, 6 with IFX.
- 30 (55.6%) required intensified frequency of administration; 8 with ADA, 22 with IFX.
- 29 (53.7%) patients presented decrease in CF ≤ 120 µg/g.
- 36 (66.7%) reached optimal drug levels, with 17 (31.5%) achieving this on standard dosing.

Target changes were due to anti-TNF antibodies or clinical worsening in 25 of 27 patients; two reported adverse reactions (psoriasis).
Conclusion and Relevance Our study shows that IFX and ADA are highly effective and safe for PIBD, although many patients need higher doses or intensified regimens. Close monitoring of drug levels and analytical parameters are crucial for personalised treatment and effective management of paediatric patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-039 SIX-MONTH EVALUATION OF THE CLINICAL AND ECONOMIC IMPACT OF PHARMACEUTICAL COUNSELLING IN MULTIDISCIPLINARY DAY HOSPITALS FOR GERIATRICS

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Background and Importance For over 6 months, a geriatric Day Hospital (DH) (Onco-geriatric, memory, and fall assessment) has been established at our 428-bed hospital centre. These DH aim to optimise patient care by reducing medication related iatrogenesis among other things.

Aim and Objectives The objective is to evaluate the clinical and economic impact of the pharmacist's role in geriatric DH.

Material and Methods This monocentric retrospective study took place from 1 September 2023 to 29 February 2024 in the outpatient medicine department of our establishment. The evaluation of pharmaceutical interventions (PI) was conducted using the French CLEO version 3 scale from the French Society of Clinical Pharmacy (SFPC). Only the clinical impact of a multidisciplinary team was assessed by using the CLEO scale. The economic evaluation of our hospital centre and internal pharmacy was carried out according to the French fee-for-service pricing of the Medicalisation Programme for Information Systems.

Results In total, over 6 months, a pharmacist or pharmacy intern intervened in 88 DH sessions for 88 patients. A total of 183 pharmaceutical interventions (PIs) were made for an average of 2.1 PIs per patient. The CLEO clinical scale's evaluation revealed that none of the PIs were harmful; 1% of the PIs (n=2) had a zero score, 26% (n=48) had a minor impact, 36% (n=67) had a moderate impact, 31% (n=57) had a major impact, and 2% (n=4) had a major impact that could prevent harm or lead to hospitalisation. An addition of 3% PIs (n=5) had an indeterminate score.

From an economic perspective according to the French fee-for-service pricing, the average revenue is € 744.26 for each DH session, resulting in a gain for the centre estimated at € 65,494.88 over 6 months. With the intervention of 5 participants per DH session, the gain for the pharmacy would be € 13,098.

Conclusion and Relevance In total, at least 60 pharmaceutical interventions (PIs) contributed to a reduction in medication related iatrogenesis, preventing serious side effects for patients or hospitalisation.

Pharmaceutical presence in DH has a positive clinical and economic impact, strengthening the safety and optimisation of care of elderly patients. It seems relevant to continue developing DH in other patient care pathways.

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

4CPS-040 EVALUATION OF CHEMOTHERAPY-INDUCED NAUSEA AND VOMITING IN LOW, MODERATE, AND HIGH EMETIC CHEMOTHERAPY BETWEEN SEXES

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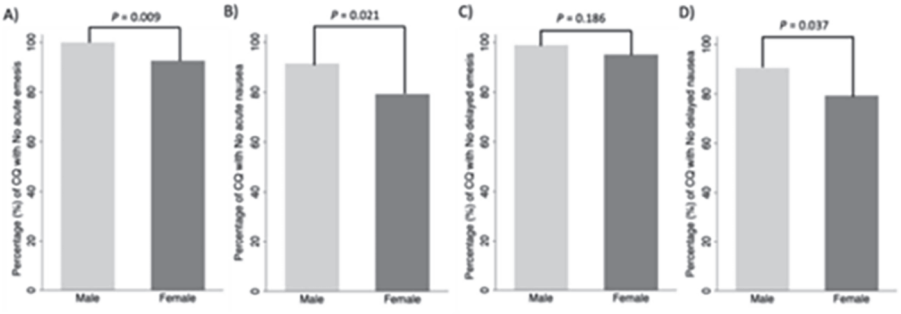
Background and Importance Chemotherapy-induced nausea and vomiting (CINV) is one of the adverse events that most interfere with the quality of life of oncologic patients. The most important factor influencing CINV has been reported to be the emetic potential of chemotherapy. However, other factors like young age, female sex, poor functional status, cancer type, pregnancy-related nausea and vomiting, susceptibility to motion sickness and non-habitual alcohol and tobacco consumption, may influence CINV. Nevertheless, in clinical practice, males and females still receive the same antiemetic prophylaxis.

Aim and Objectives We compared CINV between sexes in patients with different emetic risk schemes (high, moderate and low) and evaluated the predisposing factors and main adverse effects caused by antiemetics.

Material and Methods A prospective observational study was conducted in a tertiary care hospital from February 2023 to May 2024 in naïve chemotherapy patients. CINV was evaluated using MASCC antiemetic tool, in acute (<24h) and delayed phase (24–120h). Results were analysed using χ^2 test or Fisher's exact test. The primary endpoint was complete response (CR) rate, defined as no CINV and no use of rescue drugs. Univariate and multivariate logistic regressions were used to identify patient-related risk factors associated with non-CR.

Results A total of 176 completed questionnaires (CQ): 94 for males and 82 for females, from 54 patients were collected. The proportion of males who remained emesis-free was superior to females in the acute phase (100% versus 92.7%, p=0.009). Likewise, a higher proportion of males remained



Abstract 4CPS-040 Figure 1

nausea-free in the acute (91.5% versus 79.3%, p=0.021) and delayed phase (90.4% versus 79.3%, p=0.037). In males, no predisposing factors were identified, while in females, young age (<60 years) and previous nausea and vomiting during pregnancy may contribute to non-CR. A high proportion of patients reported adverse events like constipation and insomnia. Females suffered more constipation than males (52.4% versus 37.2%,p=0.043).

Conclusion and Relevance Males and females do not experience CINV similarly. Females experienced more CINV than males, with the consequences that entails, especially in quality of life. We provide valuable information for managing CINV according to gender, allowing early identification of patients at higher risk. Antiemetic prophylaxis should be personalised, considering sex and age and not only the chemotherapy emetic potential.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-041 ANALYSIS OF ADHERENCE TO JANUS KINASE INHIBITORS IN PATIENTS WITH AUTOIMMUNE DISEASES: INFLUENCING FACTORS AND OUTCOMES

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Background and Importance Janus kinase inhibitors (JAKi) have been used for years in autoimmune diseases (AD). Adherence to these treatments is important to understand the clinical response. This study aimed to evaluate the adherence of different JAKi used in different pathologies in a real-world setting.

Aim and Objectives Evaluate the adherence to treatment with JAKi in patients with AD, to determine those variables that most influence it and analyse in-depth those patients with poor adherence.

Material and Methods Observational, retrospective, single-centre study was conducted between August 2017 and August 2024 in patients with JAKi. We included patients ≥14 years old, with different diagnosis: dermatological disease (alopecia areata, atopic dermatitis); rheumatological (psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, axial spondylitis); digestive (ulcerative colitis, Crohn's disease). We excluded patients with ≤ 3 months of treatment. Sociodemographic data, adherence and treatment were evaluated. Percentages were used for categorical variables; means and standard deviations for continuous variables.

Results 161 patients were included, 63.35% female, the median age was 56 years (IQR=47–63). 13% were naïve to biologics. 54.66% received upadacitinib, 34.78% baricitinib, 7.45% tofacitinib, 2.48% filgotinib and 0.62% ritlectinib. 75% were rheumatological patients, 13% digestive and 12% dermatological. The mean exposure was 13months. 70% were treated previously with anti TNFα.

During the treatment with JAKi, 44 patients (31%) receive at the same time DMARD (Disease-modifying antirheumatic drugs) treatment such as methotrexate, sulfasalazine, hydroxychloroquine or leflunomide. Therefore, just 14.59% of the patients receive oral corticoids during the study.

The mean adherence was 95.92% (SD±6.82). 20 patients have adherence <90% (just 6 ≤80%). Analysing these patients, 16 are rheumatological (13 rheumatoid arthritis, 2 ankylosing spondylitis and 1 axial spondylitis), 3 digestive (ulcerative colitis) and 1 dermatological (atopic dermatitis). That is, 13% of rheumatologists are poor adherents, 14% digestive and 6% dermatological. Only 3 patients take the treatment twice a day (tofacitinib-ulcerative colitis).

Conclusion and Relevance The majority of patients exhibited a good adherence to treatment. The use of corticosteroids can predict poor control of the disease. The least adherent were the rheumatological patients, although they were also the most prevalent with an JAKi as treatment. This study helps us to identify the patients with adherence problems and produce some pharmaceutical interventions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-042 EXPERIENCE WITH INTRANASAL ESKETAMINE IN TREATMENT-RESISTANT DEPRESSION

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Background and Importance Major depressive disorder (MDD) is the most common mental illness and is one of the global causes of disability. Intranasal esketamine is a new approved alternative for treatment-resistant MDD (TRD), in combination with selective serotonin (SSRI) or serotonin and norepinephrine (SNRI) reuptake inhibitors.

Hospital-administered medication that requires 90' of observation to control temporary side effects.

MADRS scale calculates the change in the intensity of depressive symptoms as a result of the treatment.

Aim and Objectives Evaluate the effectiveness and safety of intranasal esketamine for treatment-resistant depression.

Material and Methods This retrospective observational study included patients with TRD treated with esketamine (January 2023 to February 2024) according to the technical data sheet. Demographic, clinical and treatment data were collected. Per protocol, follow-up data are collected at 4, 8 and 28 weeks after baseline.

Effectiveness was defined as follows; remission was considered if MADRS≤12, response to treatment if reduction ≥50% and partial response if reduction ≥35% and ≤49 on the baseline MADRS, taking into account patients with at least one value of MADRS follow-up.

Results 43 patients (63% women, 55 years ±9.27) with TRD in treatment with esketamine were included. Predominant symptoms were anhedonia, apathy, anxiety and insomnia. 25 (58.1%) had psychiatric comorbidities such as personality disorders. Concomitant antidepressant were SSRI (37.21%), SNRI (51.16%), antipsychotics (51.16%) and others (48.84%).

Considering the 34 patients with at least one follow-up MADRS value, the treatment was effective in 18 (52.94%) patients: 6 (17.67%) remission, 10 (29.4%) response and 7 (20.59%) partial response. The mean MADRS reduction was 15.66 (SD 11.56).

Regarding treatment discontinuation, 12 (27.90%) patients uncomplete the treatment: 4(9.30%) due to patient decision, 4 (9.30%) due to unacceptable toxicity, 2 (4.65%) due to loss of response and 2 (4.65%) by referral.

The treatment was generally well tolerated. Most adverse effects were temporary and occurred during the administration. For patients who experienced unacceptable toxicity, the notable issues included vasovagal symptoms, nightmares, and nasal bleeding.

Conclusion and Relevance Approximately 60% of patients had psychiatric comorbidities.

Moderate/high effectiveness where more than 50% of patients have presented remission and/or response.

Regarding safety, esketamine is generally well tolerated, though it does require hospital observation and some patients may experience adverse effects during administration.

A longer follow-up is necessary to provide more effectiveness and safety data.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-043 ASSOCIATIONS BETWEEN ROUTINE BLOOD TESTS AND MEDICATION USE WITH ADVERSE CLINICAL OUTCOMES IN ACUTELY ADMITTED MEDICAL PATIENTS

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Background and Importance Medication review aims to address inappropriate prescribing, and patient stratification is crucial for effective resource utilisation in the emergency department (ED). The inconsistent impact of medication review on adverse clinical outcomes suggests that stratification based solely on age and number of medications, without considering disease burden, is inadequate.

Aim and Objectives The objective was to investigate the associations between FI-OutRef (a frailty index based on number of abnormal routine blood tests) and medication use with readmission and mortality.

Material and Methods This was a single-centre observational register-based cohort study of patients presenting to the ED between November 2013 and March 2017. Patients were followed for readmission or mortality after hospital discharge. The study included acutely admitted medical patients who had routine blood tests analysed. Patients were excluded if they were <18 years old, were missing ≥8 standard biomarkers, or died during index admission. Routine blood tests included a panel of 17 standard biomarkers, and FI-OutRef was defined as the number of biomarkers outside reference ranges. Medications were included if redeemed within 4 months prior to index admission. The outcome was time to readmission or mortality within 90 days of hospital discharge.

Results Among 27,873 acutely admitted medical patients (52.5% female, median age 59.3 years (IQR: 41.7–74.5)), increasing FI-OutRef and medication use were individually associated with increasing risks of readmission and mortality. Increasing medication use within each FI-OutRef group was also generally associated with increasing risks of readmission and mortality, but the impact of medication use was most pronounced in patients with FI-OutRef ≤4.

Conclusion and Relevance Both FI-OutRef and medication use yield relevant information about adverse clinical outcomes and can easily be incorporated within the electronic medical record system to identify patients who would benefit most from medication review.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest Corporate sponsored research or other substantive relationships:

Ove Andersen is named inventor on patents covering suPAR, owned by the Copenhagen University Hospital Amager and Hvidovre, Hvidovre, Denmark. The remaining authors declare no conflicts of interest.

4CPS-044 PROACTIVE MONITORING OF INFLIXIMAB IN PAEDIATRIC INFLAMMATORY BOWEL DISEASE OVER A 4-YEAR PERIOD

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Background and Importance Preliminary data suggest that proactive therapeutic drug monitoring (TDM) guides dose adjustment to achieve appropriate trough concentrations (Cmin), reducing the risk of treatment failure (TF) and improving safety.

Aim and Objectives To analyse the experience of a multidisciplinary proactive TDM programme for infliximab (IFX) dose adjustment in paediatric patients with inflammatory bowel disease (IBD) (Crohn's disease (CD) and Ulcerative Colitis (UC)).

Material and Methods Prospective, single-centre study including children with IBD treated with IFX from September 2019 to September 2023. Demographic, clinical, analytical and pharmacotherapeutic monitoring variables were collected. IFX Cmin and anti-infliximab antibodies (ATI) were determined by ELISA or chemiluminescence. Dose individualisation was performed using the population pharmacokinetic model of Fasanmade et al., (2011), implemented in NONMEM v7.4.3. IFX Cmin was monitored at induction and every 6 months thereafter. Efficacy endpoints were: TF, IBD-related surgery and hospitalisation. Finally, adverse reactions (ARs) were recorded.

Results Thirty-three patients were included, 21 male. Eighteen with CD and 15 with UC. The median (interquartile range (IQR)) age at diagnosis was 11.58 (6.87–14.04) years. There were 794 administrations with a mean (SD) dose of 8.66 (2.22) mg/kg. The mean (SD) IFX Cmin was 25.71 (19.50) µg/ml at weeks 1–3, 13.63 (7.73) µg/ml at weeks 6–7, 14.60 (8.01) µg/ml at week 14 and 10.47 (8.47) µg/ml at maintenance. A total of 106 dose adjustments were made out of 290 (36.55%) IFX Cmin. Regarding efficacy, 6 (18.18%) patients had TF during the 4 years of follow-up; 2 primary

and 4 secondary TF. TF was due to: 1) pharmacodynamic failure (66.67%); 2) severe infusion reaction related to ATI (16.67%); and 3) other ARs (16.67%). Six (18.18%) patients were hospitalised, 62.50% of the admissions were for IBD complications and 37.50% AR. Four (12.12%) patients had emergency visits, 100% due to ARs. Thirty-nine ARs were recorded: 23.08% infusion reactions, 61.54% infections and 15.38% paradoxical psoriasis; 48.72% of the ARs were classified as severe. Two patients had ATIs, one reversed by intensifying treatment. One (3.03%) patient underwent colectomy.

Conclusion and Relevance Multidisciplinary proactive TDM programme has allowed to successfully adjust IFX doses in paediatric patients, obtaining promising clinical results similar to those reported in adults (Papamichael et al. 2017 and Sánchez-Hernández et al. 2020).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-045 LONG-TERM EFFECTIVENESS AND SAFETY OF PROACTIVE THERAPEUTIC DRUG MONITORING OF INFLIXIMAB IN PAEDIATRIC INFLAMMATORY BOWEL DISEASE: A REAL-WORLD STUDY

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Background and Importance Therapeutic drug monitoring (TDM) strategies can be categorised as reactive or proactive. Reactive TDM is used to assess partial response and secondary loss of response, while proactive TDM guides dose individualisation to target appropriate trough serum concentrations (Cmin), potentially reducing the risk of disease relapse, treatment failure, and drug immunogenicity.

Aim and Objectives To evaluate long-term effectiveness and safety of a multidisciplinary early proactive TDM programme combined with Bayesian forecasting for infliximab (IFX) dose adjustment in a real-world dataset of paediatric patients with inflammatory bowel disease (IBD).

Material and Methods A descriptive, ambispective, single-centre study of paediatric patients with IBD who underwent IFX Cmin measurement between September 2015 and September 2023 was performed. Patients received reactive TDM before September 2019 (n=17) and proactive TDM thereafter (n=21). We analysed clinical, biological, and endoscopic remission, treatment failure, hospitalisations, emergency visits and adverse drug reactions. IFX doses were adjusted to maintain Cmin $\geq$ 5 µg/ml, with specific targets for proactive TDM based on ECCO-ESPGHAN guidelines. Statistical analyses included t-test, Wilcoxon test, $\chi 2$ test, likelihood ratio, Kaplan-Meier survival analysis, and Cox proportional hazards models.

Results Of the 38 patients, 21 (55.26%) had Crohn's disease (CD), 16 (42.11%) ulcerative colitis (UC), and 1 (2.63%) undetermined IBD. The mean (standard deviation) IFX Cmin was 6.83 (5.66) µg/ml (reactive) and 12.38 (9.24) µg/ml (proactive) (p=0.08). No statistically significant differences between groups were found in remission rates or treatment failure. The proactive group had fewer hospitalisations (14.29% vs. 23.53%) and shorter median hospitalisation days (6 vs.19), although not statistically significant. Adverse reactions were higher in the proactive group, mainly infections, but not significantly different.

Conclusion and Relevance Proactive TDM showed no significant differences in treatment outcomes compared to reactive TDM. However, the results in our reactive TDM group were similar to proactive TDM results reported in other studies, which prevented us from observing significant differences. Further studies with larger samples are needed to optimise treatment strategies for paediatric IBD patients.

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Conflict of Interest No conflict of interest

4CPS-046 THERAPEUTIC DRUG MONITORING OF INFLIXIMAB IN PAEDIATRIC SEVERE VERY EARLY-ONSET INFLAMMATORY BOWEL DISEASE

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Background and Importance Very early-onset inflammatory bowel disease (VEOIBD), patients whose age of onset is younger than 6 years, is a heterogeneous condition that tends to be refractory to conventional treatment. Infliximab (IFX) therapeutic drug monitoring (TDM) can guide high-dose therapy and improve response rates.

Aim and Objectives To assess the effectiveness and safety of IFX through a multidisciplinary TDM programme combined with Bayesian forecasting in severe VEOIBD (S-VEOIBD) patients compared to other children with inflammatory bowel disease (O-IBD).

Material and Methods Retrospective study including patients treated with IFX between September 2015 and September 2023 in a tertiary hospital. We analysed biological and clinical remission, treatment failure (TF), hospitalisations, emergency visits and adverse reactions (ARs). S-VEOIBD patients were considered those requiring intensified doses and frequencies during maintenance treatment to achieve IFX trough concentrations (Cmin) >10 µg/ml.

Results Four (10.5%) patients were classified as S-VEOIBD and compared with 34 O-IBD patients. Median age at diagnosis was 1.96 (interquartile range (IQR) 1.01–2.99) and 12.06 (9.78–14.53) years, and median (IQR) duration of follow-up was 1.03 (0.84–1.45) and 1.84 (1.08–2.54) years for S-VEOIBD and O-IBD groups, respectively. Mean [standard

deviation, (SD)] dose was 10.27 (2.37) and 7.80 (1.87) mg/kg, the frequency in maintenance [mean (SD)] was 3.29 (1.38) and 6.50 (1.62) weeks and mean (SD) IFX Cmin in maintenance, 18.26 (12.77) and 8.55 (5.01) µg/mL for S-VEOIBD and O-IBD, respectively. Although there was no TF IFX in S-VEOIBD during induction (0.0% vs. 5.9%; p=0.50), any patient achieved remission at week 14 (0.0% vs. 73.5%; p <0.01). At week 54, S-VEOIBD had more TF (25.0% vs 6.5%; p=0.25) and less children in remission (50.00% vs. 64.51%; p=0.58). Kaplan-Meier analysis did not demonstrate higher cumulative probability of TF in S-VEOIBD compared with O-IBD (log-rank P=0.62). Hospitalisations (50.0% vs. 14.7%) and emergency visits (25.0% vs. 8.8%) were higher in S-VEOIBD. ARs were more common in S-VEOIBD (75.0% vs. 26.5%); 88.9% were infections and 11.1% infusion-related reactions.

Conclusion and Relevance Compared with O-IBD, S-VEOIBD patients did not have higher cumulative probability of TF. Accelerated induction and maintenance drug monitoring with high Cmin can prevent TF in S-VEOIBD. High-dose regimens may be associated with a higher rate of ARs, mainly infectious.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-047 TREATMENT OF WARM ANTIBODIES HAEMOLYTIC ANAEMIA WITH ABATACEPT – CASE REPORT

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Background and Importance Autoimmune haemolytic anaemia (AIHA) due to warm antibodies is the most common type of autoimmune haemolytic anaemia, usually IgG.

As first-line treatment, after splenectomy in necessary cases, glucocorticoids with or without rituximab and intravenous immunoglobulins are used. In refractory or persistent cases, immunosuppressive agents and cytostatics such as mycophenolate mofetil, sirolimus or cyclophosphamide are used.

Aim and Objectives To evaluate the off-label treatment of abatacept for a patient with refractory warm antibody AIHA. The patient was diagnosed with autoimmune bicytopenia with anaemia, plateletopenia, and splenomegaly. The direct Coombs' test was IgG positive, giving the diagnosis of warm antibody AIHA probably in the context of splenic lymphoproliferative syndrome.

He received treatment with corticosteroids and rituximab and underwent splenectomy in 2019.

Material and Methods We describe treatment with abatacept, CTLA-4 agonist, in a 54-year-old patient with AIHA due to warm antibodies refractory to splenectomy and corticosteroids plus rituximab at 375 mg/m2 weekly from February 2021, being retreated from February to April 2022. During all this time, he required numerous blood transfusions. The patient is a heterozygous carrier of the p.(Arg51+) variant in the CTLA4 gene, considered pathogenic and associated with the development of autoimmune lymphoproliferative syndrome, an increase in autoreactive B lymphocytes and the appearance of autoimmune cytopenia.

Results Haemoglobin values and transfusion requirements were analysed. Treatments with glucocorticoids plus rituximab had a mean haemoglobin of 11.3 g/dL (1.97;14.6–9.3) during the period February 2021 to March 2021 and 10.8 g/dL (1.4;12.9–9.7) during February to April 2022. Prior to these treatments, the patient required 7 blood transfusions and 3 transfusions during the treatment period. During abatacept treatment from August 2022 to June 2024 the mean haemoglobin was 12.5 g/dL (1.2;14.6–10.6) and no blood transfusions were required.

Conclusion and Relevance Treatment with abatacept for patients with refractory warm antibody AIHA is poorly documented. The results obtained show a clear improvement in analytical parameters and a disappearance of haemolytic phenomena and transfusion needs. It is a valuable option for this type of patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-048 BROLUCIZUMAB: EFFECTIVENESS AND SAFETY IN ROUTINE CLINICAL PRACTICE

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Background and Importance Management of neovascular age-related macular degeneration (AMD) and diabetic macular oedema (DMO) includes lifelong anti-VEGF injections. Brolucizumab, a newer longer-acting anti-VEGF agent, has demonstrated efficacy and allowed extended treatment intervals in clinical trials. However, intraocular inflammation-related adverse events (AEs) have been associated to brolucizumab. Therefore, there is limited data from real-world clinical practice.

Aim and Objectives To evaluate the effectiveness and safety of intravitreal brolucizumab in patients with AMD or DMO in clinical practice.

Material and Methods This observational, retrospective study included patients diagnosed with AMD or DMO treated with brolucizumab from October 2022 to March 2024. Data were collected from prescription system and medical records, including demographics, ocular pathology, previous AMD or DMO intravitreal treatments, reasons for switching to brolucizumab, dosage, duration, AEs and reasons for discontinuation. Effectiveness was evaluated in terms of visual acuity (VA). Patients who had received prior treatment with other anti-VEGF did not receive a loading dose of brolucizumab.

Results A total of 60 patients (68 eyes) were included, with a mean age of 78.3 years. 82% had AMD and 18% had DMO. Prior to brolucizumab, 59% of eyes had been treated with one anti-VEGF, 37% with two or more, and only one (1.5%) patient was treatment-naïve. Reasons for switching included lack of response (67.6%), loss of efficacy (1.5%), and AEs (2.9%).

Baseline VA was 0.35. After brolucizumab VA improved significantly from 0.30 to 0.38 (p=0.005). The mean treatment interval was 8.5 weeks, with 25% of patients receiving a single dose. In 6.7% of patients, a dosing interval of 12 weeks or more was achieved within 1 year.

AEs, including uveitis (n=1), photophobia (n=1), increased intraocular pressure (n=1) and choroidopathy (n=1), led to discontinuation in four patients. Other reasons for discontinuation included lack of efficacy (n=3) and loss of response (n=3).

Conclusion and Relevance This study suggests that brolucizumab may be an effective alternative for patients unresponsive to other anti-VEGF treatments, potentially allowing longer dosing intervals. However, due to the study's limitations, further research with larger sample sizes is required to confirm its safety profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-049 EFFECTIVENESS AND SAFETY OF RISANKIZUMAB AS INDUCTION THERAPY FOR CROHN'S DISEASE

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Background and Importance Risankizumab is indicated for the treatment of adult patients with moderately to severely active Crohn's disease and an inadequate response or intolerance to the conventional treatment and a biological anti-TNF-α drug or in contraindication of these. Different studies have demonstrated promising efficacy and safety with risankizumab. Real-life studies are commonly performed to confirm these results.

Aim and Objectives To analyse the effectiveness and safety of risankizumab as induction therapy in clinical practice for the treatment of Crohn's disease in a tertiary hospital.

Material and Methods Observational, retrospective, single-centre study that included all patients with moderately to severely active Crohn's disease treated with risankizumab between September/2023-April/2024. Those patients who had not completed the induction period were excluded from the study. Variables collected: age, sex, previous biological therapies, adverse events (AEs), interruptions and their causes. To evaluate effectiveness, the symptomatic improvement reported by patients was analysed(improvement being considered the absence of abdominal pain, fever and vomiting). In addition, the average daily stool frequency and faecal calprotectin (CPF) value were measured before and after completed induction. Data were obtained from the electronic medical record and prescription software.

Results 35 patients (42.9% men) were included; median age 45 (interquartile range (IQR) =19–75) years. 82.9% patients had received anti-TNF-α therapy, with a median 2 (IQR=0–4) previous biological treatments. At the date of data collection, all patients had received a dose of 360mg at week-12, with a median treatment duration of 28 weeks. 15 patients (42.9%) reported symptomatic improvement at the end of the study, although 60% (n=21) continued with abdominal pain and the daily frequency of bowel movements remained high (>5 per day) in 54.3% (n=19). The median level of CPF was reduced by 56.6% [973.4 (IQR10.7–5051.4) *vs* 422.4 (IQR0–5217.3) mcg/g] after induction with risankizumab and no patient had disease outbreak during induction treatment. One patient reported oedema in the lower limbs. No patient discontinued treatment due to AEs.

Conclusion and Relevance Risankizumab was effective and well tolerated as induction therapy in our patients, although it appears to improve analytical parameters to a greater extent without this translating into symptomatic improvement. 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

4CPS-050 MULTICENTRE EVALUATION OF MIGRAINE PREVENTIVE TREATMENT WITH CALCITONIN GENE-RELATED PEPTIDE RECEPTOR ANTIBODIES EFFICACY AFTER A THERAPEUTIC HOLIDAY

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Background and Importance Efficacy and tolerability of Calcitonin Gene-Related Peptide (CGRP) receptor monoclonal antibodies (mAbs) have been demonstrated and corroborated by numerous real-world studies. However, several questions remain regarding the management. One significant issue is determining the optimal treatment duration and whether treatment should be discontinued after a period of successful therapy.

Aim and Objectives To evaluate the course of migraine after therapeutic holiday.

Material and Methods Multicentre, observational retrospective cohort study that included patients diagnosed with episodic or chronic migraine according to International Classification of Headache Disorders (ICHD)-3 criteria. Patients received preventive treatment with anti-CGRP mAbs and attempted discontinuation after at least 8 months of therapy. Quantitative variables: age, year of diagnosis, monthly days of migraine and headaches, duration of treatment and therapeutic rest periods. Qualitative variables: sex, type of migraine, aura presence, first anti-CGRP received, treatment change and effectiveness post-therapeutic rest. Data were sourced from electronic prescription and electronic medical records and analysed using R Commander.

Results A total of 47 patients were analysed, with 83% female and a median age of 47 years. Most patients (64.8%) had chronic migraine, and 52.8% experienced auras. Prior to treatment, patients had a median of 14(IQR 15–12) migraine days and 11(IQR 15–10)headache days per month. Erenumab was the most commonly used initial anti-CGRP medication (60.3%), followed by galcanezumab (22.6%) and fremanezumab (17.1%). The median treatment duration was 15.4(IQR 35.7–10,5) months, with 22.7% switching medications after a median of 9.3(IQR 20,6–3.9) months. Dose adjustments were necessary for 30.2% of patients, typically after 6.5(IQR 12–13,5) months. All patients took a therapeutic holiday lasting a median of 6.2(IQR 11,4–3,2) months, during which they had a median of 9.5(IQR 16–6) migraine days. After the break, 50.9% maintained treatment effectiveness, while 26.4% required a medication change, and 5.8% switched to a different anti-CGRP, primarily fremanezumab (53,3%), followed by erenumab (26.6%), eptinezumab (13.3%), and rimegepant (6.8%).

Conclusion and Relevance A consistent response upon restarting would support temporarily stopping and then resuming treatment if needed. However, according to our results, it

seems that a second treatment cycle might be less effective due to potential habituation. Thus, evaluating headache parameters during a second cycle is crucial for better migraine patient care.

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

4CPS-051 EVALUATION OF THE RESPONSE OF MONOCLONAL ANTIBODIES AGAINST MIGRAINE AFTER THE APPLICATION OF A TREATMENT INTERRUPTION PROTOCOL

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Background and Importance Monoclonal antibodies targeting the calcitonin gene-related peptide (CGRP) ligand or its receptor are available for migraine prevention. European guidelines suggest discontinuing monoclonal antibody therapy after 12–18 months, although treatment can also be continued if deemed necessary.
Aim and Objectives To establish the effectiveness of antibodies CGRP in the treatment of migraine and to analyse the response to retreatment in patients who discontinued therapy after 1 year of treatment.
Material and Methods Observational and retrospective study. All patients who initiated treatment between August 2020 to June 2024 were included. Demographic data were collected (age, sex), clinical variables (type of migraine) and pharmacotherapeutic variables (type of monoclonal antibody, switch). Treatment effectiveness was calculated as the mean number of monthly migraine days (MMD) and the reduction ≥50% of MMD. According to our centre's protocol, these treatments should be withdrawn after 1 year. Response was assessed after 1 year of treatment and evolution after withdrawal (resumption of treatment versus maintenance of response) and 3 months after restarting treatment. Response was analysed in patient subgroups: type of migraine, type of antagonist and time to reintroduction. The statistical software SPSS v. 25 was used for the analysis.
Results Fifty-five patients were included, of whom 90.9% (n=50) were women. Median age: 47 years (38–55). 72.7% of patients (n=40) had chronic migraine. The effectiveness results are detailed in table 1. 27.3% (n=15) required a change of treatment due to ineffectiveness. 70.9% (n=39) achieved a ≥50% reduction in MMD (p=0.005). 34.5% (n=19) did not need to restart treatment with a median maintenance of response of 9.5 months (3–15), while 58.2% (n=32) of patients were reintroduced due to clinical deterioration. After restart, 53.1% (n=17) achieved a ≥50% reduction in MDD (p=0.102). Regarding the response of the different subgroups of patients requiring reintroduction, no significant differences were found.
Conclusion and Relevance Half of the patients requiring reintroduction of treatment achieve the goal within 3 months. One third of patients maintain response after 1 year of treatment.

Abstract 4CPS-051 Table 1 Effectiveness results

	Galcanezumab	Erenumab	Fremanezumab
Total	58,2% (n=32)	34,5% (n=19)	7,3% (n=4)
MMD at baseline	14,5 (8–30)	11(8–24)	4,5 (9–29)
MMD after withdrawal	10 (3–26) (p=0,01)	7 (3–14) (p=0,01)	3,5 (10–15) (p=0,01)
MMD at restart	11 (6–20)	10(2–20)	15 (12–20
MMD after 3 months of restart	7,5 (1–13) (p=0,04)	5 (1–10) (p=0,04)	5(2–7) (p=0,04)

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

4CPS-052 IDENTIFYING HIV PRE-EXPOSURE PROPHYLAXIS CANDIDATES AMONG PATIENTS WHO RECEIVED POST-EXPOSURE PROPHYLAXIS. PHARMACEUTICAL INTERVENTION IN THE OUTPATIENT PHARMACY AREA

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Background and Importance In 2023, 1.3 million people became newly infected with HIV. Prevention strategies such as the use of pre-exposure prophylaxis (PrEP) with antiretroviral therapy (ART) has shown efficacy reducing new HIV infections. Consequently, it is highly important, to promote PrEP between patients who are at ongoing high-risk for HIV infection. A good method to identify these patients is to select those who come to the outpatient area for post-exposure prophylaxis (PEP), as this indicates that they have had some form of risk exposure.
Aim and Objectives Identify candidates for initiating PrEP among patients who visit the outpatient pharmacy area to receive post-exposure prophylaxis, and examine awareness of this treatment to determine the reasons they are not currently receiving this treatment.
Material and Methods We retrospectively analysed the data of patients who received PEP from January 2023 to August 2024. Patients who were considered in high-risk of acquiring HIV (such as those who have engaged in condomless anal sex or had a documented bacterial sexually transmitted infection) were selected to conduct a phone interview. An informational brochure was written in collaboration with the Preventive Medicine Department for patients who requested more information.
Results In this period, 203 PEP were given to our patients (137 men and 66 women). 71 of them were in high-risk for HIV infection, among them, 21 had already started PrEP when we contacted them and 7 declined to participate in the interview. Therefore, we conducted 43 interviews (median age 34 years [IQR 20–54]); 41 of our patients were men and have heard of PrEP before. However, 42% (18/43) were unfamiliar with the specifics of the treatment and 53% (23/43) did not know how to access it. Additionally, 58% (25/41) requested our informational brochure for further details.
Conclusion and Relevance Currently, there are still many patients who could benefit from PrEP but have not accessed it due to a lack of awareness. From the outpatient pharmacy area, efforts can be made to raise awareness and identify patients at risk of HIV to connect them with PrEP and reduce the incidence of HIV in the population.

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

4CPS-053 PHARMACISTS' AND PHYSICIANS' VIEWS ON THE ROLE OF PHARMACISTS IN PALLIATIVE CARE AND DEPRESCRIBING: A CROSS-SECTIONAL SURVEY

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Background and Importance The global demand for palliative care is growing but only 14% receive adequate care.[1] Complex medication regimens lead to polypharmacy, potentially jeopardising patient safety. Pharmacists may enhance safety through interventions such as deprescribing. Data on pharmacists' involvement in deprescribing in palliative care remains limited.
Aim and Objectives To explore the attitudes and views of physicians, hospital pharmacists and community pharmacists towards the role of pharmacists in palliative care, focusing on deprescribing at the end of life.
Material and Methods A literature informed questionnaire, was piloted, tested for face and content validity, including sections on demographics, educational background, attitudes towards and suggestions for multidisciplinary collaboration and knowledge of deprescribing practices all in the context of palliative care. Answer options included 5-point Likert scale responses, open- and closed-ended questions. Following necessary ethical approval, distribution was through national palliative care and pharmacy networks.
Results A total of 3527 healthcare professionals were targeted through these associations. No official data exists on how many of these engage in palliative care routinely, so response rate is unknown. Of 110 responses, 53 indicated routine contact with palliative patients and were included [physicians (Ph) n=19; pharmacists (P) n=34, 51% hospital (HP), 49% community pharmacy (CP)]. Further education in palliative care varied by occupation [(Ph) n=16, 84%; (P) n=6, 18%], only 34% indicating a pharmacist was on the palliative care team. Strong agreement existed on the importance of pharmacists' roles in addressing 'polypharmacy' (Ph: 74%, HP: 94%, CP: 88%) and minimising 'Risk of potential drug-drug interactions' (Ph: 84%; HP: 89%; CP: 88%). Ph (OR 2.573; 95% CI) and HPs (OR 1.571; 95% CI) regularly used deprescribing resources. 71% of CPs did not engage in deprescribing activities. Ph relied more on clinical experience (n=10;77%) and literature (n=11;85%), whereas HP favoured explicit deprescribing tools.
Conclusion and Relevance The study reveals an underrepresentation of pharmacists in palliative care. Addressing gaps in education and encouraging engagement in deprescribing activities, particularly in community pharmacy, are likely to enhance patient safety.

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Conflict of Interest No conflict of interest

4CPS-054 PERSISTENCE OF INHIBITORS OF INTERLEUKIN-17 (ANTI-IL-17) FOR THE TREATMENT OF MODERATE TO SEVERE PSORIASIS (MSPS) IN THE ROUTINE CLINICAL PRACTICE CONDITIONS

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Background and Importance Anti-IL-17 have emerged as safe and effective options for the treatment of msPs
Aim and Objectives Evaluate the persistence of anti-IL-17 (secukinumab, ixekizumab, bimekizumab and brodalumab) in patients with msPs. Secondarily, these patients' clinical outcomes and health-related quality of life (HRQL) and the safety profile were also assessed.
Material and Methods Retrospective observational study from January 2020 to June 2024. Patients with msPs receiving anti-IL-17 were included. Demographic (sex, age) and clinical data (previous treatments, optimised therapy and baseline Psoriasis Area Severity Index (PASI)) were collected from the digital medical record. Non-persistence was defined as treatment discontinuation or a treatment gap > 90 days. The cumulative probability of treatment persistence was analysed by Kaplan-Meier method. Secondary endpoint: clinical outcomes (PASI90 response at 1 year), change in HRQL through dermatology life quality index (DLQI) at 1 year, and safety profile.
Results 68 patients were included (40.2% women), 29 received secukinumab, 33 ixekizumab, 4 bimekizumab and 2 brodalumab. Mean age was 70.4 years. 81.9% received biologic therapies before and 94.4% conventional systemic treatment. Dose interval was extended only for 7 secukinumab patients (>4weeks). The cumulative probability of secukinumab, ixekizumab, bimekizumab and brodalumab treatment persistence was 73.5% (95%IC 57.3–89.6), 41.6% (95%IC 31.7–51.5), 8.3% (95%IC 3.5–13.4) and 22.9% (95%IC 0–46.4) at 1 year. Secondary endpoint: the median baseline PASI was 8.0, 6.25, 5.50 and 4.0 respectively. 62.1%, 48.5%, 25% and 0% of patients respectively achieved PASI90 at 1 year. 48.3%, 27.3%, 50% and 100% of patients respectively achieved a minimal clinically significant difference (>4-point reduction) in DLQI at 1 year. 3 patient with secukinumab experienced adverse reactions (fatigue, gastrointestinal and infections), 8 with ixekizumab (3-gastrointestinal, 1-infections, 2-fatigue and 2-injection site reactions) and 1 patient with bimekizumab (allergy).
Conclusion and Relevance Our cohort shows a moderate persistence rate and PASI improvement at 1 year with secukinumab; the other anti-IL-17 show low clinical profits. High benefit in improving HRQL was reached with bimekizumab and brodalumab while secukinumab and ixekizumab showed modest results. No important adverse reactions were found, without treatment withdrawals.

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

4CPS-055 IMPACT OF EXTRACORPOREAL MEMBRANE OXYGENATION CIRCUIT ON FENTANYL PHARMACOKINETICS IN CRITICALLY ILL PATIENTS

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Background and Importance Fentanyl's lipophilicity and protein binding may contribute to a sequestration of the drug in the extracorporeal membrane oxygenation (ECMO) circuit, which could impact to pharmacokinetic and response in critically ill patients.

Aim and Objectives To assess the impact of ECMO circuit on the plasma concentration (Pk) of fentanyl in critically ill patients.

Material and Methods Observational, prospective, multidisciplinary, cohort study. Adult critically ill patients in treatment with standard fentanyl perfusion for more than 48h between 2020–2021 were included. Demographical and clinical variables, concomitant treatments(sedative/CYP3A4 inducer-inhibitor metabolism), mechanical ventilation (VM) and continuous renal replacement techniques (CRRT) were collected. Pk was determined at 24h (pk1) and 48h (pk2) after the start of perfusion by ultra-high performance liquid chromatography-mass spectrometry. Pain was evaluated with Escala de conductas indicadoras de dolor (ESCID score). Two cohorts were differentiated: ECMO and non-ECMO. Variables were expressed as mean (standard deviation) or median(range)/absolute (relative) frequency. The Student´s t-test/Mann-Whitney test was used to compare quantitative variables, Pearson´s Chi-squared/Fisher´s exact test for qualitative (STATAv.14.2). Statistically significant was considered if $p \leq 0.05$

Results Seventy-six patients were included of 55.49 (13.52) years; 54 (71.05) male; 13 (17.11) with ECMO support. No significant differences for clinical variables (SAPS3, predisposing conditions, body mass index, liver or renal function) were found, however patients in the ECMO group were younger (48.68vs56.90, $p=0.045$), all male ($p=0.015$). Median fentanyl infusion rate was 0.64 (0.14) in ECMO vs 0.53(0.03) mcg/kg/h in non-ECMO $p=0.212$) during first 24h, 0.41(0.05) vs 0.49 (0.04) mcg/kg/h ($p=0.444$) during next 24h. Plasma levels at 24h were higher in non-ECMO group: pk1: 3.88 (11.01) vs2.07(0.99) ng/mL, but no significative differences were found ($p=0.557$), nevertheless higher levels was reached at 48h in ECMO: pk2: 1.92 (1.24) vs2.41(1.29) ng/mL, $p=0.261$. No differences were found with regarding to the use of CRRT, MV or concomitant treatment. No differences on the ESCID scale were found (at 24h): non-ECMO 0(0–5)vs ECMO 0 (0–3), $p=0.463$; (at 48h): non-ECMO 0 (0–4) vs ECMO 0 (0–3),$p=0.774$ because most of the patients had correct pain control (ESCID<3): 24h: 96%;48h: 95.52%

Conclusion and Relevance In our series, the use of ECMO had no significant impact on fentanyl Pk during the first 48h. Using a standard perfusion in patients on extracorporeal support to dose according to the response guided by the ESCID scale is safe to achieve adequate pain control.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-056 EFFICACY OF ANTI-CALCITONIN GENE-RELATED PEPTIDE THERAPIES IN CHRONIC MIGRAINE: AN INDIRECT TREATMENT COMPARISON

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Background and Importance Several treatments targeting the calcitonin gene-related peptide (CGRP) pathway are used for the prevention of chronic migraine (CM). There are no head-to-head comparisons of these drugs to help guide therapeutic positioning.

Aim and Objectives To analyse whether fremanezumab, galcanezumab, erenumab, eptinezumab and atogepant could be considered as equivalent therapeutic alternatives (ETA) in CM using an adjusted indirect treatment comparison (ITC).

Material and Methods A systematic bibliographic search of Pubmed for clinical trials (CTs) was performed. Inclusion criteria: phase II/III, randomised with similar populations, comparator, follow-up period and CM definition (15 headache days/month, of which 8 were migraine days). The comparative efficacy endpoint was a 50% reduction in migraine days/month (measured after 12 weeks of treatment). ITC was performed using the Bucher method. The delta value (Δ, maximum acceptable difference used as a clinical criterion of equivalence) was calculated according to the ETA guidelines(1): half of the absolute risk reduction (ARR) obtained in the meta-analysis of RCTs used for the ITC (pooled ARR: 17%, Δ: 7.5%).

Results Five randomised CTs were finally selected, one per treatment. The rest were not included in the ITC because they did not meet the inclusion criteria. The results of the ITC are shown in the table 1:

Abstract 4CPS-056 Table 1

Treatment	Proportion of patients with ≥50% reduction in migraine days/month. ARR indirect (95% CI).
Fremanezumab monthly	Reference
Fremanezumab quarterly	-3.0% (−11.9% to 5.9%)
Erenumab 70 mg	-6.0% (−16.6% to 4.6%)
Erenumab 140 mg	-5.0% (−15.7% to 5.7%)
Eptinezumab 300 mg	-0.9% (−10,4% to 8.6%)
Eptinezumab 100 mg	-4.8% (−14.3% to 4.8%)
Atogepant 30 mg	-6.1% (−18.1% to 6%)
Atogepant 60 mg	-8.0% (−18.3% to 2.3%)
Galcanezumab 120 mg	-10.8% (−19.6% to −2.0%)
Galcanezumab 240 mg	-10.9% (−19.7% to −2.1%)

Conclusion and Relevance ITC showed no statistically or clinically significant differences among fremanezumab, erenumab, eptinezumab and atogepant. Nevertheless, significant statistical and clinical differences were identified between galcanezumab and the other options.

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4CPS-057 IS THE SWITCH FROM INTRAVITREAL AFLIBERCEPT AND RANIBIZUMAB TO FARICIMAB AN EFFICIENT AND SAFE STRATEGY?

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Background and Importance Faricimab is a novel intravitreal drug licensed for neovascular age-related macular degeneration (nAMD) or diabetic macular oedema (DME). Faricimab's wider administration-interval compared to its alternatives aflibercept and ranibizumab makes it a more convenient option and, therefore, most patients are switching to faricimab. However, faricimab is only an efficient option if unitary-dose syringes are prepared from multi-dose commercial vials in the Pharmacy Service's clean rooms to maximise the fractioning of the vials.

Aim and Objectives Given that health resources are limited and faricimab is a drug with elevated economic impact, the economic savings of unitary-dose syringes preparation was studied, as well as the efficacy and safety of switching from aflibercept/ranibizumab to faricimab.

Material and Methods Retrospective, observational study in patients with nAMD or DME receiving at least 3 intravitreal injections in a regional, 105-beds hospital (November 2023 to August 2024).

Efficacy variables: improvement in best-corrected visual acuity (VA) and reduction in macular oedema(ME).

Safety: adverse reactions described in faricimab information sheet.

Statistics: paired T-test.

Unitary faricimab 6 mg/0.05 mL syringes were prepared. To assess the economic impact, direct costs were included: vials, material and elaborator personnel.

Results 56 patients were included in the efficacy and safety analysis, 30 (53.6%) females, with median (range) age of 79 years (47–94), 42 (75%) diagnosed with nAMD and 14 (25%) with DME.

After switching to faricimab, 28(50%) improved VA, 12 (21%) remained stable and 16(29%) worsened. Regarding ME, 27(48%) improved, 12(21%) were stable and 17(31%) worsened. Only 4(7%) patients worsened in both variables, with a reduced administration-interval at present and pending reevaluation.

There was a statistically significant difference in the mean administration-interval (standard deviation) between previous drug and faricimab [6.1 weeks (±2.2 weeks) vs 9.6 weeks (±2.4 weeks), $p<0.001$].

One patient(3.6%) reported an abrupt acute decrease in vision lasting one hour after the seventh dose, with adequate resolution.

341 unitary syringes were prepared from 149 vials, with a final cost of 70.013€, which has supposed a saving of 88.671€ comparing to having used 341 vials of faricimab without fractioning (158.684€).

Conclusion and Relevance Faricimab treatment leads to fewer intravitreal administrations, improving patients' quality of life, in addition to being an effective and safe strategy. The single-dose-syringe production of faricimab in the Pharmacy Service represents a saving of 56% of the expenses.

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

4CPS-058 REAL-LIFE STUDY OF EFFECTIVENESS AND QUALITY OF LIFE IN PATIENTS WITH MODERATE/SEVERE HIDRADENITIS SUPPURATIVA TREATED WITH MONOCLONAL ANTIBODIES

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Background and Importance Hidradenitis suppurativa (HS) is a chronic inflammatory skin disease that causes painful lesions in apocrine gland-bearing areas, significantly impacting patients' quality of life(QoL). Treatment combines surgical and medical therapies, with monoclonal antibodies(MoAbs) playing a key role.

Aim and Objectives To evaluate the profile of patients with moderate/severe HS treated with MoAbs and assess treatment effectiveness and QoL outcomes.

Material and Methods A retrospective observational study was conducted between 07/2016–03/2024 in a 3rd-level university hospital. Patients with moderate/severe HS treated with MoAbs were included. Data from clinical histories, including demographics, family history, Hurley index (HI), concomitant treatments and comorbidities, were collected. Effectiveness and QoL were assessed for all treatments lasting at least 12–16 weeks. Data on MoAbs received, treatment duration, and DLQI at baseline, weeks 12–16 and 48 were recorded. Continuous variables were expressed as means ± standard deviation and qualitative variables as percentages.

Results Sixty-one patients were analysed: 55.74% male, mean age 39.26 years(±6.94), mean BMI 30.19(±6.94) and 62.30% smokers. 79.31% had HI-III, 29.50% had a family history of HS, and 63.38% had comorbidities, predominantly psychiatric (26.76%), immune-mediated (18.32%) and metabolic (14.09%). Among 87 MoAb treatments, the distribution was: Adalimumab 60.87%, Secukinumab 21.74%, Guselkumab 11.59%, Ustekinumab 2.90%, Bimekizumab 1.45%, and Risankizumab 1.45%. At the cut-off, 100% of patients remained on Guselkumab, Risankizumab, or Bimekizumab, while 47.37% were on Adalimumab and 47.06% on Secukinumab. Median duration on treatment ranged from 37 days (Bimekizumab) to 669 days (Ustekinumab). QoL improved with Risankizumab achieving a 91.67% reduction in DLQI at week 12–16, followed by Guselkumab (45.14%), Adalimumab (30.98%), Ustekinumab (28.01%), and Secukinumab (19.16%). By week-48, Guselkumab showed a 64.32% reduction, Ustekinumab 37.50% and Adalimumab 32.54%.

Conclusion and Relevance This study underscores the complexity of managing patients with moderate/severe HS, often necessitating a multidisciplinary approach due to the high prevalence of comorbidities. While Adalimumab and Secukinumab are most commonly used, as they are the only biologics currently approved for HS, newer MoAbs used off-label under approved protocols show promising early results in terms of QoL improvements. Despite the limited sample size, these

findings suggest that emerging biologics could offer valuable alternatives. Continued research is essential to validate their long-term effectiveness and safety profiles.

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

4CPS-059 PREDICTIVE MARKERS OF RESPONSE TO ADJUVANT TREATMENT IN LOCALLY ADVANCED OVARIAN CANCER

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Background and Importance Along with mutations in the BRCA genes and homologous recombination deficiency, the rate of CA-125 biomarker clearance during the first cycles of chemotherapy is emerging as an indicator of chemosensitivity in ovarian cancer. The validated indicator for this clearance rate, KELIM (CA-125 ELIMination Rate Constant K), has demonstrated its prognostic value for the benefit obtained after treatment in several clinical trials.
Aim and Objectives Our objective was to validate the KELIM score in clinical practice in patients with ovarian cancer treated with adjuvant chemotherapy and to determine whether the KELIM score is predictive of progression-free (PFS) and overall survival (OS).
Material and Methods Patients with stage III ovarian cancer who had received adjuvant chemotherapy following cytoreductive primary surgery at our centre from January 2014 to January 2024 were included.

Patients treated in the recurrent setting were excluded.

Demographic and clinical parameters were collected and a multiple logistic regression analysis was conducted to identify the most significant predictor variables.

KELIM was calculated, using a validated formula (https://www.biomarker-kinetics.org/CA-125), based on CA-125 values during each treatment cycle within the first 100 days of chemotherapy. At least three values were required, and the obtained score was considered favourable (KELIM $\geq$1) or unfavourable (KELIM <1), indicating high or low chemosensitivity, respectively.

Kaplan-Meier survival analyses was performed for PFS and OS.
Results 43 patients were included in the analysis. Mean age was 60 years. 56.1% had a favourable KELIM score.

In those patients where BRCA status was available, there was a mutation in 20.7%.

88.5% of patients had an optimal surgical cytoreduction.

Bevacizumab was added to chemotherapy in 25% of patients.

Median follow-up was 4.98 years.

Age, BRCA mutation status and antiangiogenic treatment did not show a statistically significant effect on survival.

An unfavourable KELIM score was associated with a non-statistically significant lower estimated median PFS (6.00 vs 7.66 years, p=0.167) and OS (6.37 vs 8.06 years, p=0.126) as compared to a favourable KELIM.
Conclusion and Relevance Patients with ovarian cancer treated with adjuvant chemotherapy with a calculated KELIM score <1 were more likely to have a lower PFS and lower OS when compared to patients with a KELIM score $\geq$1.

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

4CPS-060 COMPARISON OF THREE-YEAR PERSISTENCE IN PSORIASIS PATIENTS TREATED WITH GUSELKUMAB OR SECUKINUMAB IN REAL-WORLD SETTING

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Background and Importance Real-world data on long-term treatment patterns associated with guselkumab and secukinumab in plaque psoriasis are lacking.
Aim and Objectives The aim was to compare the real-world persistence, effectiveness, and safety of guselkumab and secukinumab in adult patients with moderate to severe psoriasis in two different hospitals.
Material and Methods Retrospective cohort study that used registries and medical records from 2 different hospitals (February 2015 to June 2024). Adults with moderate to severe psoriasis who initiated guselkumab or secukinumab were identified and followed-up until June 2024, or disenrollment. Baseline demographic: sex, age at diagnosis, weight, prior failed treatments, duration of treatment and psoriasis area severity index score (PASI). Exclusion criteria: patients with psoriatic arthritis. Adherence was measured using medication possession ratio (MPR); patients with MPR $\geq$ 80% were considered adherent. Persistence, effectiveness, safety, and dosage regimen of guselkumab and secukinumab were collected. Persistence on guselkumab and secukinumab was calculated based on the dates of initiation and end of treatment. Biologic treatment persistence was estimated using the Kaplan-Meier method with 1-year intervals, and comparisons were made using the *log-rank* test.
Results A total of 62 guselkumab and 88 secukinumab patients with moderate to severe psoriasis were included, of whom 18 (29%) guselkumab and 45 secukinumab (51.1%) had not received prior biological treatment. Guselkumab baseline PASI score was 15.4 $\pm$ 1,7 and patients received 1.9 $\pm$ 0.9 prior biological treatments. Secukinumab baseline PASI score was 15.0 $\pm$ 2.9 and patients received 1.4 $\pm$ 0.8 prior biological treatments. 5 (8.1%) patients discontinued guselkumab treatment due to the following reasons: lack of effectiveness (4.8%), transaminase elevation (1.6%) and pregnancy (1.6%). 34 (38.6%) patients discontinued secukinumab treatment due to the following reasons: 19 (21.5%) due to a lack of effectiveness, 7 (7.9%) due to adverse effects. Guselkumab persistence was 21.6 $\pm$ [2.0] months for all patients. Secukinumab persistence was 61.5 $\pm$ [21.7] months for all patients. Guselkumab persistence at 1 year, 2 years and 3 years was 98.4%, 95.6% and 91.8%, respectively. Secukinumab persistence at 1 year, 2 years and 3 years was 72.7%, 51.1% and 39.8%, respectively.
Conclusion and Relevance Over 36 months, guselkumab patients exhibited better persistence and a lower discontinuation rate than secukinumab patients in real-world settings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-061 ASSESMENT OF THE EFFECTIVENESS AND SAFETY OF MEPOLIZUMAB IN A REAL-WORLD LONG-TERM STUDY

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Background and Importance Mepolizumab is an anti-IL-5 monoclonal antibody used for the treatment of uncontrolled severe asthma (USA). The treatment of USA with biological therapy is considered a challenge due to the lack of long-term real-world information.

Aim and Objectives The objective is to asses real-world Mepolizumab treatment carried out in patients with USA to determine its long-term effectiveness and safety.

Material and Methods Retrospective real-world observational study in patients treated with Mepolizumab between 01/2015 and 12/2022. Variables analysed before the start of mepolizumab, 1 year after treatment, and at the last medical consultation recorded in the Electronic Health Record: demographic data (sex, age, Body Mass Index (BMI)), eosinophil level (cells/microliter), percentage of Forced Expiratory Volume in one second (FEV1 (%)), Asthma Control Test (ACT) score, number of glucocorticoid cycles, number of hospital admissions/emergency visits in the last year, cases and causes of discontinuation. Results expressed as median and interquartile range (IQR).

Results Sample of 96 patients (70.83% women), starting age 59 years (50 - 69), and BMI 29.03 (24.01 – 31.21). Variables before the start of treatment: eosinophil level (cells/microliter) 800 (500 – 1300), FEV1 (%) 76 (60.5 – 87.5), ACT 15 (10 – 18), glucocorticoid cycles 2 (1 – 3), hospital admissions/emergency visits 1 (0 – 1).

Results after 1 year of treatment: eosinophils (cells/microliter) 100 (0 – 100), FEV1 (%) 86 (73 - 97), ACT 21 (IQR 19 – 24), glucocorticoid cycles 0 (0 – 1), hospital admissions/emergency visits 0 (0 – 0).

Outcomes of the last medical consultation: eosinophils (cells/microliter) 100 (0 – 100), FEV1 (%) 85 (73 - 90), ACT 21 (19 – 25), glucocorticoid cycles 0 (0 – 1), hospital admissions/emergency visits 0 (0 – 1).

There were 19 discontinuations (19.79%) due to inefficacy (84.21%) and intolerance (15.79%).

Conclusion and Relevance The use of mepolizumab improves lung capacity (increase in FEV1), clinical control of the disease (increase of up to 6 points in ACT), and reduces the number of exacerbations and hospital admissions/emergency visits. Therefore, treatment with mepolizumab can be considered effective (functional and clinical improvement) and safe in the long-term. Further studies are needed to allow for better treatment selection to reduce discontinuations due to inefficacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-062 CLINICAL AND ECONOMIC IMPACT OF INAPPROPRIATE USE OF TOTAL PARENTERAL NUTRITION IN ADULTS

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Background and Importance According to the latest clinical nutrition guidelines, total parenteral nutrition(TPN) is recommended for hospitalised patients at high-risk of malnutrition when nutrient intake via the digestive tract is expected to be impossible or insufficient for more than 5–7days.

Aim and Objectives To evaluate the appropriateness of TPN use in a tertiary care hospital and the economic impact resulting from its improper indication.

Material and Methods We conducted a retrospective review of medical records from adult patients who received TPN at a tertiary hospital in 2023. Using two software applications for electronic health record access,SAP and Pharmasuite, we extracted data on TPN duration, the number of TPN bags prepared, and the reasons for initiating and discontinuing TPN. For patients on TPN≤5 days, we also recorded type of TPN prescribed and calculated preparation costs. Data were collected in Excel database.

To obtain the results, data were analysed by using SPSS-Statistics software.Qualitative variables were reported as percentages,and quantitatives as means±standard deviation.

Results A total of 401 patients were included. Of these,16.9% received TPN for 5 days or fewer:36.8% for 5 days, 27.9% for 4 days, 17.6% for 3 days, 7.4% for 2 days, 4.4% for 1 day and 5.9% didn't start TPN. A total of 5653 TPN bags were prepared,5.2% of which were for patients with TPN≤5 days.

The main reasons for starting TPN were:23.5% digestive surgery, 23.5% paralytic ileus, 10.3% intolerance to enteral nutrition(EN), 10.3% persistent vomiting/diarrhoea, 7.4% peritonitis, 5.9% inadequate oral tolerance, 5.9% diverticulitis, 5.9% intestinal obstruction,4.4% pancreatitis and 2.9% mucositis. Reasons for discontinuation were:61.8% oral diet tolerance, 17.6% patient death, 7.4% EN tolerance, 4.4% patient decision,4.4% lack of central venous catheter,2.8% discharge and 1.5% TPN associated complications.The direct cost associated with TPN for ≤ 5 days was 12,102.14€ , with an average cost of 177.97±61.18€ per patient.

Conclusion and Relevance

- One-sixth of TPN prescriptions did not align with clinical guidelines, causing a significant economic impact.
- Early initiation of oral diet was a key factor in TPN≤5 days.
- Proper planning of fasting duration and transition to oral intake is crucial to reduce costs, complications, and logistical burdens.

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Conflict of Interest No conflict of interest

4CPS-063 PATIENT SATISFACTION SURVEY ABOUT INTRAMUSCULAR INJECTIONS OF LONG-ACTING ANTIRETROVIRAL TREATMENT FOR HIV

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Background and Importance The intramuscular (IM) injections of long-acting cabotegravir and rilpivirine is a new alternative antiretroviral treatment for HIV that may increase patient satisfaction, reducing stigma, and facilitate adherence. Real-world data could provide information on patient satisfaction about their HIV therapy.

Aim and Objectives To assess motive and patient satisfaction of switching from oral antiretroviral treatment to IM injections of long-acting cabotegravir and rilpivirine.

Material and Methods Prospective observational study of patients that change from oral antiretroviral treatments to long-acting HIV treatment. All the patients who received IM treatment at the hospital between march and september 2024 were included. Informed consent was obtained. The information was obtained through an anonymous Likert type survey with 10 questions, randomly assigned. This survey was developed from two validated questionnaires (satisfaction scale ESTAR and questionnaire CESTA). Time receiving long-acting HIV treatment and causes of changing were registered. Different issues about long-acting HIV treatment were scored. Responses were reported on a 6-point Likert scale, ranging from very dissatisfied (0) to very satisfied (6), assuming that: satisfaction (6–5), partial satisfaction (4,3,2) and unsatisfied (1,0).

Results During data collection period a total of 84 patients received IM treatment and 38 (45%) answered the survey. Population (n=38) mean time receiving long-acting treatment were 4 months (1–15). Motives for switching were: to avoid forgetting doses (n=21); convenience (n=18); reduce social/familiar impact (n=6), reduce diary reminders of HIV (n=4); others (n=2); no answered (n=2). Responses to the different issues of the survey were:

Conclusion and Relevance The main motivation for switching were improving adherence and convenience. Long-acting HIV treatment showed good results in terms of satisfaction, clearly improving the adaptation of the therapy to the HIV patients lifestyle.

Abstract 4CPS-063 Table 1

Question	Satisfaction	Partial satisfaction	Unsatisfaction
1. Switching satisfaction	100% (n=38)	0	0
2. IM adverse events	94,7% (n=36)	5,3% (n=2)	0
3. IM requirements	94,7% (n=36)	5,3% (n=2)	0
4. IM convenience	100% (n=38)	0	0
5. Oral flexibility	50% (n=19)	36,8% (n=14)	13,2% (n=5)
6. IM flexibility	86,8% (n=33)	13,2% (n=5)	0
7. Oral lifestyle adjustment	39,5% (n=15)	44,7% (n=17)	15,8% (n=6)
8. IM lifestyle adjustment	100% (n=38)	0	0
9. Switching recommendation	100% (n=38)	0	0
10. Willingness to continue	100% (n=38)	0	0

REFERENCES AND/OR ACKNOWLEDGEMENTS

None

Conflict of Interest No conflict of interest

4CPS-064 PHARMACOKINETIC MONITORING OF SUBCUTANEOUS INFLIXIMAB IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE

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Background and Importance Subcutaneous infliximab(SC-IFX) shows stable drug concentrations over time in patients with inflammatory bowel disease(IBD). Establishing an optimal cut-off would help ensure treatment effectiveness and safety.

Aim and Objectives To analyse the variability of trough concentration(Cmin) of SC-IFX and establishing a cut-off to achieve clinical response(CR), biochemical remission(RemBq) and clinical remission(RemC) during the maintenance phase in IBD patients.

Material and Methods Ambispective, observational study involving IBD patients with IFX Cmin starting SC-IFLX treatment between January 2020-June 2024.

Clinical data were extracted from the Abucasis/MDIS programme. Variables analysed were sex, age, weight, diagnosis (Crohn disease(CD)/Ulcerative colitis(UC), pharmacotherapeutic data(Cmin, previous biological therapy), biochemical parameters(albumin, faecal calprotectin(FCP), C-reactive protein(CRP)) and clinical score(UC:Partial-Mayo Score(MS)/CD:Harvey-Bradshaw index(HB)) at each time point.

Study objectives were defined as: Clinical Response(CR: maintaining a clinical score equal to/lower than the baseline); Biochemical Remission(RemBq: FCP<250µg/g and CRP<5mg/L); and Clinical Remission(RemC: HB<5 and MS<2). As a limitation due to the ambispective design, the available patient's drug levels were variable at 3rd, 6th and 12th months(n=52,n=41,n=40). SC-IFLX Cmin was determined using a chemiluminescence assay(Theradiag).

The results were expressed as percentage, and median[interquartile range(IQR)]. The Friedman test assessed differences between Cmin, and ROC curve analysis determined the optimal cut-off to maximise sensitivity(S) and specificity(E), using R v.4.3.3 for data analysis.

Results Samples from 52 patients(n=42;CD) were analysed: 27 were male(51.9%). The median age and weight were 45.0 years[34.0–56.0] and 70.0 kg[62.0–83.0], respectively. A total of 8 patients had prior treatment with a biological therapy other than infliximab.

Cmin at 3, 6, and 12 months were 15.1µg/mL[IQR:10.4–19.4], 13.7µg/mL[IQR:10.0–16.7], and 14.3µg/mL[IQR:10.2–17.4],p=0.226, respectively. Analytic parameters in the three visits were: albumin (4.4[IQR:4.2–4.6]; 4.4[IQR:4.2–4.5]; 4.4 [IQR:4.3–4.7]g/dL), CRP(1.3[IQR:1.0–3.3]; 1.5[IQR:1.0–3.1]; 1.4[IQR:1.0–3.0]mg/L) and FCP(58.0[IQR:30.5–199.4]; 105.2 [IQR:37.4 −265.1]; 75.6[IQR:32.3–316.2]µg/g, respectively.

SC-IFX cut-off for CR at the 3rd and 12th months was 13.5µg/mL (AUC=0.90 [95% CI:0.82–0.98],p=0.024,S=0.83, E=0.87) and 13.7µg/mL (AUC=0.77 [95% CI:0.61–0.93], p=0.02,S=0.68,E=0.88), respectively. For RemBq, the cut-off

at the 3rd month was 16.8µg/mL(AUC=0.76 [95% CI:0.63–0.90],p=0.07,S=0.53,E=0.92). No statistically significant differences were found for other study objectives.
Conclusion and Relevance Based on the results, SC-IFLX Cmin remained stable over the follow-up period. A cut-off for CR was identified at 13.5µg/mL and 13.7µg/mL, and a cut-off of 16.8µg/mL for RemBq. However, further studies are required to confirm these findings and establish an optimal cut-off that ensures favourable clinical outcomes.

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

4CPS-065 ABSTRACT WITHDRAWN

4CPS-066 INFLUENCE OF JAK1 GENE POLYMORPHISMS ON TREATMENT RESPONSE TO JAK INHIBITORS IN RHEUMATOID ARTHRITIS PATIENTS

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Background and Importance JAK inhibitors(JAKi) block the JAK-STAT pathway, crucial in immune cell regulation. Genetic variations in JAK1 may influence treatment outcomes in rheumatoid arthritis, highlighting the importance of understanding individual genetic profiles to optimise therapeutic response to these drugs.
Aim and Objectives To evaluate the influence of three single nucleotide polymorphisms(rs2230587,rs310241, rs2230588) in JAK1 gene involved in the JAK/STAT pathway on the response to treatment with JAKi drugs in patients diagnosed with rheumatoid arthritis(RA).
Material and Methods Ambispective observational cohort study. Data and DNA from RA patients in Granada who had been treated with JAKi were obtained. Genotypes were determined by Taqman-PCR-Real-Time. Quantitative variables: age, body mass index (BMI), disease duration, previous therapies, treatment duration, and Disease activity measures (DAS28) at 0, 3, 6 and 12 months classified as remission, low, moderate and high activity. Qualitative variables: sex, first JAKi, treatment discontinuation and causes, dose changes. Data were collected from electronic prescriptions and medical records, and analysed with R Commander.
Results Forty-one patients analysed,32 women median age 53.5 years(IQR 60.5–47.7). Median BMI 27.6(IQR 33.3–24.4). Median disease duration 11 years(IQR 20–6.7). Patients had received 2 prior biologic therapies(IQR 3.2–1) with median treatment duration 21 months(IQR 40–13).First JAKi received were tofacitinib(14),baricitinib(12),upadactinib(10),filgotinib (4). Sixteen patients discontinued treatment and 6 required dose changes. Causes for discontinuation were secondary failure(5),primary failure(3),adverse effects(4),lack of response(4). Analysis showed for rs2230587 polymorphism that the risk of having high disease activity at 6 months was observed to be 12-fold higher for patients with AG genotype vs GG(p-value=0.0315). For rs310241 GG genotype showed a 1.85-fold increased likelihood of remission at 6 months compared to AA(p=0.0364). Regarding rs2230588, the CC genotype carried a 9-fold higher risk of high disease activity versus CT, and 6-fold versus TT(p=0.0223). Additional analysis showed that patients' lower baseline DAS28 reduced the risk of unsatisfactory response(p-value=0.0006), fewer previous biological therapies increased the likelihood of success(p-value=0.01824) and longer treatment duration was associated with lower disease activity (p-value=0.02363).
Conclusion and Relevance Response to JAKi drugs was associated with different single nucleotide allelic polymorphisms of the JAK1 gene. Nonetheless, further studies with large cohorts have to be performed to confirm these data in order to apply personalised medicine in clinical practice routine.

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

4CPS-067 DEVELOPMENT AND MANAGEMENT OF ICANS: RISK FACTORS FOLLOWING CD19 CAR-T THERAPY IN LYMPHOPROLIFERATIVE DISORDERS

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Background and Importance Immune effector cell-associated neurotoxicity (ICANS) remains a significant clinical challenge after anti-CD19 chimeric antigen receptor T-cell (CAR-T) therapy due to the limited availability of reliable predictive factors.
Aim and Objectives To identify potential risk factors for both any-grade-ICANS and significant-grade-ICANS in patients treated with anti-CD19 CAR-T therapy.
Material and Methods A sample size of 100 was estimated to detect significant differences between axicabtagene-ciloleucel and tisagenlecleucel. Data were retrospectively collected for patients with haematological diseases treated with commercial anti-CD19 CAR-T. 'Significant toxicity' was defined as grades 2–4, as it required specific treatment, and 'severe toxicity' as grades 3–4. Risk factors were identified using univariate and multivariate logistic regression, both 'any-grade-ICANS' and 'significant-grade-ICANS', using STATA16.
Results A total of 101 patients were studied, of whom 36 (36%) developed any-grade-ICANS, 20 (20%) significant-grade-ICANS, and 12 (12%) severe-ICANS. The majority of ICANS cases resolved after treatment (83%). Various factors were associated with both any-grade and significant ICANS: presence of an autoimmune comorbidity, earlier or more sustained cytokine release syndrome (CRS), number of tocilizumab doses used to treat CRS, high tumour burden (measured by LDH on day 0 or metabolic tumour volume), elevated levels of IL-6 and IL-15 on days 0 and +3 after infusion, and elevated day +3 levels of LDH and D-dimer. Incidence of any-grade-ICANS was higher after treatment with axi-cel (46%) compared to tisa-cel (21%) and was linked to elevated D-dimer on day 0. Significant-grade ICANS was associated with an increased number of prior treatment lines and higher day 0 levels of IL-1, C-reactive protein, GM-CSF, and ferritin.

In the multivariate analysis, best model (AUC=0.84) for predicting any-grade-ICANS included the type of CAR-T, time

from infusion to CRS onset, pre-infusion D-dimer levels and IL-6 levels on day +3. For significant ICANS (AUC=0.82), the model included the presence of an autoimmune comorbidity, the number of prior therapy lines, development of grade ≥2 CRS, and IL-15 and GM-CSF pre-infusion levels.

Conclusion and Relevance This study reveals a link between ICANS and patient's baseline characteristics, CAR-T type, tumour burden, CRS development (including tocilizumab doses), and pro-inflammatory markers before and after infusion. A deeper understanding of ICANS allows for better anticipation of treatment to improve patient outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-068 INTRAVENOUS LEVOMEPROMAZINE IN THE TREATMENT OF CUTANEOUS RASH DUE TO SUSPECTED DRUG HYPERSENSITIVITY: A CASE REPORT

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Background and Importance Drug hypersensitivity reactions are a diverse group of immune-mediated reactions following exposure to a medication, and their diagnosis can be challenging. Upon suspicion, the offending drug should be discontinued. Treatment varies based on symptom severity and may include antihistamines, corticosteroids, and adrenaline.[1] The presented case is notable for the successful use of intravenous levomepromazine in treating refractory drug-induced rash.

Aim and Objectives The aim is to describe the multidisciplinar management of a 19-year-old female with no oral route available who suffered unresponsive cutaneous rash due to suspected drug hipersensitivity.

Material and Methods The patient was hospitalised with diagnosis of septic shock and a pseudo-obstructive syndrome. Following surgical intervention and a complex pharmacological treatment, the patient developed a severe pruritic erythematous rash. Intravenous dexchlorpheniramine was initiated and administration of beta lactamics, sulfonamides and pyrazolones was prohibited. As no response was observed, intravenous and topical methylprednisolone was added and omeprazole, orthopramides, alpha-adrenergic agonists and macrolides were discontinued. Patient's clinical status, including eosinophil count, liver enzymes, and renal function, was closely monitored.

Due to the worsening rash and refractory pruritus, allergists decided to contact Pharmacy Service in order to search for an alternative intravenous treatment option.

Results Since oral administration was not an option and no intravenous H1-antagonist were available in our country, other than dexchlorpheniramine, the use of levomepromazine was suggested. It has a phenothiazine chemical structure, similar to other H1-antagonist drugs. We recommended to start a continuous infusion of 12,5 mg in 500mL of dextrose 5% in an off-label,[2] compassionate use scenario.[3]

Soon the patient showed significant improvement in pruritus and a reduction in erythema and infiltration of the rash which allowed corticoesteroid tapering and eventual discontinuation of levomepromazine few days after.

Conclusion and Relevance This case highlights the potential use of intravenous levomepromazine for treating refractory drug hypersensitivity reactions. It also underscores the importance of a multidisciplinary approach and contributes to the limited body of literature available.

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Conflict of Interest No conflict of interest

4CPS-069 CALCULATION OF THE THERAPEUTIC COMPLEXITY OF THE INSTITUTIONALISED PATIENT IN A TERTIARY HOSPITAL

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Background and Importance Therapeutic complexity is directly related to treatment adherence, with studies indicating that 50% of patients do not follow their medication regimen. Increased complexity is associated with higher rates of hospital admissions, reduced quality of life, and increased mortality rates.

The Medication Regimen Complexity Index (MRCI), adapted into Spanish as MRCI-E, measures this complexity by considering factors such as pharmaceutical form, dosing regimen and additional dosing instructions.[1]

Aim and Objectives The primary aim is to estimate the therapeutic complexity of institutionalised patients upon admission to the Institutionalised Patient Care Unit (UAPI), and to assess the potential reduction in complexity following pharmaceutical interventions on chronic treatment at discharge.

The secondary aim is to evaluate whether there is a relationship between therapeutic complexity and the number of hospital visits or readmissions.

Material and Methods This observational, retrospective study estimates the therapeutic complexity of patients in the UAPI. Patients who underwent medication reconciliation without a report from the socio-healthcare facility were excluded.

Data were collected from medical records, nursing home reports and pharmacy databases, and entered in an Excel sheet, which automatically calculated of the complexity scores.

A descriptive analysis was performed and the Wilcoxon test was used to evaluate differences in the MRCI-E score before and after pharmaceutical validation. Finally, the association between therapeutic complexity and the number of UAPI visits was analysed by linear regression.

Results Eighty-eight patients (66% women) with a mean age of 86 years (range 65–99) and an average of 11 prescribed medications were included. Upon admission, the mean MRCI-E score was 30 points which, reduced to 28 after pharmaceutical intervention, with a statistically significant difference ($p<0.001$). The regression analysis showed that for every additional 20 points in the MRCI-E, there was an increase of 1.17 emergency visits (95% CI 0.61; 1.73, p-value<0.001).

Conclusion and Relevance The results demonstrate that pharmaceutical intervention can reduce the therapeutic complexity of patients and, therefore, decreasing their associated risk. Additionally, higher MRCI-E scores are found associated with an increased number of emergency hospital visits.

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Conflict of Interest No conflict of interest

4CPS-070 PHARMACOGENETICS OF FLUOROPYRIMIDIDINE TOXICITY BEYOND DPYD VARIANTS

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Background and Importance Treatment regimens based on fluoropyrimidines for colorectal cancer are associated with adverse effects such as hand-foot syndrome, diarrhoea, neutropenia, and mucositis. To date, the only gene that has been conclusively linked to fluoropyrimidine toxicity is DPYD.

Aim and Objectives To analyse the association between variants in genes other than DPYD and the incidence of fluoropyrimidine-related toxicity in patients with colorectal cancer.

Material and Methods This retrospective study included patients with metastatic colorectal cancer treated with fluoropyrimidine-based regimens between June 2020 and November 2021. Dose adjustments were made for patients with DPD deficiency according to established guidelines. Clinical and laboratory variables associated with toxicity were collected. The genotypes of those pharmacogenes available for analysis at our centre were determined using OpenArray technology.

Results Seventy-four patients were included, 55% of whom were women. 19% received fluoropyrimidines as monotherapy, while 81% were treated with combination regimens. The median age was 73 years, and 84% had a good functional status (ECOG 0–1) prior to treatment.

Four patients exhibited an intermediate metaboliser phenotype without fluoropyrimidine-related toxicity. No patients were classified as poor metabolisers.

A statistically significant association was observed for the following variables: Emergency visits or hospitalisations due to toxicity in patients with the AA+AG genotype of the MTHFR gene (p-value=0.01), grade 3–4 toxicity in patients with the *1/*1 genotype of the CYP2C8 gene (p-value=0.02) and grade 2–4 diarrhoea with activity scores of 1.5 and 2 for the CYP2C9 gene (p-value=0.03).

Literature evidence only supports the association between MTHFR gene variants and fluoropyrimidine treatment toxicity. In our study, 24 emergency visits or hospitalisations due to toxicity were recorded; of these, 75% involved patients with the AA+AG genotype for the MTHFR gene, compared to 25% for those with the GG genotype.

No previous studies have linked CYP2C8 and CYP2C9 genes with toxicity variables, indicating the need for additional research to confirm these findings.

Conclusion and Relevance There is increasing evidence that the toxicity of fluoropyrimidines is not mediated solely by the DPYD gene.

Our study supports existing literature by showing an association between higher fluoropyrimidine toxicity and patients with AA and AG genotypes in the SNP rs1801133 of the MTHFR gene.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-071 WHAT GETS MEASURED, GETS MANAGED! ANALYSIS OF ANTIMICROBIAL STEWARDSHIP PROCESS QUALITY INDICATORS AT A UNIVERSITY HOSPITAL

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Background and Importance Antibiotic resistance is a serious global challenge and responsible for over 1.27 million deaths in 2019.

Aim and Objectives Antimicrobial stewardship programmes (AMS) promote the rational use of antimicrobials (AM) to reduce resistance, reduce consumption and improve patient care. Monitoring the quality of antibiotic prescribing using process quality indicators (QIs) is essential for the success of AMS. QIs need to be validated in the setting before routine use. This study validated 17 QIs in a university hospital setting, including 14 QIs previously validated in a multicentre study and 3 additional QIs.

Material and Methods Data were collected through a point prevalence study (PPS) by trained specialists in internal medicine and hospital pharmacists in March 2023. Information on demographics, infections, diagnostics and AM therapies was collected. Adult inpatients who received at least one AM on the PPS days were included. The following clinical characteristics were analysed for QI validation:

- Applicability:% of all cases to which the indicator applies (target > 5%).
- Feasibility:% of available and valid values per indicator (target > 75%).
- Performance:% of compliance with an indicator (target < 85%).
- inter-rater reliability: agreement between different raters (target k > 0,6).

Results Data from 1027 patients were reviewed on the day of the survey, of whom 426 received at least one AM and were included in the detailed analysis (AM use prevalence: 41.48%). All QIs met the targets for applicability (8.2%-97.5%) and feasibility (93.1%-100.0%), confirming that they are relevant to the minimum amount of therapies. The study also confirmed the feasibility of all QIs (93.1%-100%) meaning that most of the data were available and could be analysed. In terms of performance, 13/17 QIs were found to be

within the target of ≤ 85% with five QIs already showing a higher performance > 85%. The Inter-rater reliability was 0,6–1,0, confirming adequate reproducibility.
Conclusion and Relevance All QIs are applicable in the setting analysed. 13 QIs can be used routinely in the AMS programme, while five QIs need to be redefined in terms of target achievement.

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

4CPS-072 NEBULISED ANTIBIOTIC THERAPY VERSUS INSTILLED ANTIBIOTIC THERAPY IN PATIENTS WITH TRACHEOBRONCHITIS

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Background and Importance Ventilator-associated tracheobronchitis(VAT) is an intermediate stage between colonisation of respiratory tract and Ventilator-associated pneumonia(VAP). Some patients with VAT progress to develop VAP.

VAT could be treated with topical antibiotic therapy alone. Vibrating mesh nebulisers were included in Intensive Care Unit(ICU) in September 2022. These devices can be used with the ventilation systems, allowing nebulised antibiotic therapy. Previously, antibiotics were administered by instillation.
Aim and Objectives To assess whether nebulised antibiotic therapy in VAT is associated with a decrease incidence of VAP compared to instilled antibiotic therapy.
Material and Methods We conducted a retrospective, non-interventional, longitudinal study.

Critical patients with VAT treated with instilled antibiotic therapy from January 2021 to August 2022 and those treated with nebulised antibiotic therapy from September 2022 to June 2024 in the ICU of our centre were included. Patients receiving intravenous antibiotic therapy that was concomitant with nebulised or instilled therapy were excluded.

Variables analysed: age, sex, date of admission to hospital, date of admission to ICU, date of diagnosis of VAT, nebulised/instilled antibiotic therapy, duration of nebulised/instilled antibiotic, microorganism treated, patients progress to VAP and date of diagnosis of VAP.

Nebulised and instilled antibiotic therapy was compared using the χ^2 test.
Results Thirty-eight ICU admissions of thirty-four patients were included, 73.5% were male. Age(median) was 65 years (IQR:52.8–78). Days from ICU admission to development of VAT (mean±SD) was 44±5.8 days.

Mean duration of antibiotic therapy was 7±5.9 days, 44.7%(n=17) used nebulised antibiotics and 55.3%(n=21) used instilled antibiotics.

- Instilled antibiotics used were colistin 23.8%(n=5), gentamicin 23.8%(n=5), vancomycin 14.3%(n=3), amikacin 14.3%(n=3), cefotaxime 9.5%(n=2), ceftazidime 9.5%(n=2) and tobramycin 4.8%(n=1).
- Nebulised antibiotics used were vancomycin 35.3%(n=6), colistin 35.3%(n=6), amikacin 11.8%(n=2), gentamicin 5.9% (n=1), tobramycin 5.9%(n=1) and levofloxacin 5.9%(n=1).

Microorganisms treated were *Pseudomonas aeruginosa* (26.3%), methicillin-sensitive *Staphylococcus aureus*(18.4%), *Serratia marcencens*(13.2%), *Stenotrophomonas maltophilia* (13.2%), methicillin-resistant *Staphylococcus aureus*(7.9%) and others(21%).

Out of the five patients with VAT who developed VAP, three received inhaled therapy and two received nebulised therapy (non-significant differences,p=1). VAP occurred an average of 4.8±1.2 days after TAV diagnosis and VAP was caused by the same microorganism in four of the five patients.
Conclusion and Relevance Progression of VAP in patients with VAT treated with nebulised and instilled antibiotic therapy is low. In this study, there is no difference between instilled and nebulised antibiotic therapy.

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

4CPS-073 IMPACT OF ANTIBIOTIC STEWARDSHIP PROGRAMME (ASP) ON ANTIBIOTIC USE AND CLINICAL OUTCOMES IN PATIENTS HOSPITALISED WITH COMMUNITY-ACQUIRED PNEUMONIA (CAP): PRE- AND POST-INTERVENTION STUDY

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Background and Importance Community-acquired pneumonia (CAP) is still one of the leading causes of death worldwide. 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 (still valid) consisted of written and published guidelines available to all professionals, continuous supervision and counselling service on antibiotic therapies made by pharmacists at patient level, with the aim to ensure compliance with CAP guidelines. Overall guideline adherence (agent selection, route of administration, dose), clinical outcomes (length of stay, 30-day mortality), antibiotic exposure and direct costs were compared between the two periods. Fisher's exact test and t-test were applied to compare categorical and continuous variables, respectively
Results Significant improvement in overall CAP guideline adherence (103/148 vs. 149/194, 30.2%), sequential therapy (4/148 vs 28/194, 10.5%) and significant reduction in the total duration of antibiotic therapy (8 vs 6 days, 16%) were observed. Guideline non-adherent combination therapies with metronidazole decreased significantly by 28.1% (32/103 vs 6/194). Antibiotic exposure decreased by 23.6% (18 vs 14 DDD/patient) leading to a significant decrease of direct costs

(33.2%). Length of stay decreased by 13.5% (8 vs 6 days) and 30-day survival increased by 5.9%.
Conclusion and Relevance ASP may play an important role in optimising empirical antibiotic therapy in CAP having a sustained long-term effect.

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

4CPS-074 OPTIMISING MEDICATION SAFETY: THE ROLE OF PHARMACIST-LED INTERVENTIONS IN REDUCING DRUG RELATED PROBLEMS IN GERIATRIC VASCULAR SURGERY PATIENTS

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Background and Importance Peripheral artery disease is a common condition, particularly in geriatric populations with comorbidities such as hypertension, dyslipidaemia, or diabetes. These patients are at an elevated risk of cardiovascular morbidity and mortality, and frequently experience polypharmacy, which increases the likelihood of drug related problems (DRPs) and treatment failure.
Aim and Objectives This study, a subanalysis of a previous investigation, aimed to evaluate the impact of pharmacist-led interventions on the prevalence of DRPs in geriatric patients undergoing vascular surgery.
Material and Methods This study, a subanalysis of a previous study conducted on adult patients, focused specifically on geriatric patients ($\geq$ 65 years old) diagnosed with carotid artery disease or lower extremity artery disease, all of whom were prescribed at least three medications. Comprehensive medication reconciliation and medication reviews were conducted by hospital pharmacists at both admission and discharge. Pharmacist-recommended interventions were documented and communicated to the attending physicians. Patients were provided with individualised pharmacotherapy education upon discharge to enhance medication adherence and understanding.
Results The study cohort included 80 geriatric patients, with a significant decrease in the mean number of DRPs per patient, from 2.26 ± 2.12 at admission to 1.51 ± 1.87 at discharge ($p < 0.001$). The most common DRPs involved untreated symptoms or indications. Naftidrofuryl, considered a potentially inappropriate medication for older adults per the EU (7)-PIM list, was used by 50% of patients at both admission and discharge. Cardiovascular drugs contributed to 26.91% of DRPs, with atorvastatin (for untreated indications) most implicated at admission, and pantoprazole (unnecessary treatment) at discharge. Physicians accepted 57.9% of pharmacist-recommended interventions. A standardised DRP severity scale was not used due to the novelty of pharmacist-led DRP identification in our setting, limited physician familiarity with such recommendations, and their high workload, all of which impacted acceptance rates. Nearly half of the patients showed a good understanding of their pharmacotherapy at admission.
Conclusion and Relevance Pharmacist-led interventions were associated with a significant reduction in DRPs among vascular surgery patients. This underscores the critical role of pharmacists in optimising medication management, improving therapeutic outcomes, and reducing the risk of medication related complications in this high-risk population.

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Conflict of Interest No conflict of interest

4CPS-075 EPTINEZUMAB SUCCESS IN SHORT-LASTING UNILATERAL NEURALGIFORM HEADACHE ATTACKS WITH CONJUNCTIVAL INJECTION AND TEARING: A CASE REPORT

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Background and Importance Short-lasting unilateral neuralgiform headache attacks with conjunctival injection and tearing (SUNCT) is a rare primary headache syndrome whitch the prevalence and incidence are uncertain. It is characterised by sudden brief attacks of severe unilateral pain commonly located in ophthalmic and maxillary divisions of the trigeminal nerve and accompanied by conjunctival injection and lacrimation.

The main treatment in acute pain attacks is intravenous lidocaine by continuous infusion (1.3 to 3.4 mg/kg per hour). Some studies suggest that lamotrigine, topiramate, gabapentin, oxcarbazepine, carbazepine and duloxetine are effective preventive therapy.
Aim and Objectives Describe the efficacy of eptinezumab, a monoclonal antibody against calcitonin gene-related peptide (CGRP), in a patient with difficult-to-control SUNCT.
Material and Methods We conducted a retrospective descriptive study in a patient with SUNCT treated with lidocaine infusion at maximum doses and multiple preventive drugs. Data were obtained from digital clinical history. Literature review was performed in UptoDate and PubMed.
Results A 78-year-old woman was admitted to the hospital due to a hypertensive crisis and hyponatraemia. She had been diagnosed with trigeminal neuralgia years ago and was being treated with carbamazepine(which was interrupted by hiponatremia). The patient developed left periocular pain with autonomic symptoms (tearing and conjunctival injection, self-limited and of short duration). She was diagnosed with SUNCT and was treated with a lidocaine infusion of 3.4 mg/kg per hour (one month) and preventive drugs (topiramate, oxcarbazepine, lamotrigine, and gabapentin). However, each time the dose of lidocaine was reduced, the patient could not tolerate the pain, being unable to eat and sleep.

The specialist contacted the pharmacist to request the off-label use of eptinezumab. After a literature review on the efficacy of monoclonal antibodies against CGRP in SUNCT, a case series article reporting the success of galcanezumab in SUNCT was found. It was decided to try eptinezumab for its rapid onset of action. One week after eptinezumab administration, lidocaine was discontinued, and the patient was discharged on full doses of lamotrigine and gabapentin.

Conclusion and Relevance Eptinezumab was effective in discontinuing the lidocaine infusion and preventing cardiac toxicity due to the prolonged duration of treatment in combination with other therapies.

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

4CPS-076 ABSTRACT WITHDRAWN

4CPS-077 ABSTRACT WITHDRAWN

4CPS-078 THE ROLE OF ADMINISTRATION ROUTE IN ACHIEVING THERAPEUTIC VORICONAZOLE PLASMA LEVELS

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Background and Importance Voriconazole, used for severe fungal infections, can be administered orally or intravenously (IV). The choice of route may impact plasma concentrations, critical for balancing therapeutic efficacy and avoiding toxicity. Comparative data on pharmacokinetic outcomes between oral and IV administration remain limited.
Aim and Objectives To compare plasma concentrations of voriconazole between oral and IV routes and to assess the factors influencing the likelihood of achieving suboptimal, therapeutic, and toxic levels.
Material and Methods Retrospective observational study including patients who received voriconazole between May 2021 and October 2024. Data were extracted from electronic medical records. Variables:

- Age. Gender.
- Voriconazole: Administration route. Dose. Plasmatic levels. Concentration ranges: suboptimal (<1 μg/ml), therapeutic (1–5.5) and toxic (>5).
- Body mass index (BMI). Enteral nutrition (EN). Omeprazole intake.

Statistics: Spearman correlation. Chi-squared test. Mann-Whitney U. Multinomial logistic regression. The analysis was performed using SPSSv29.0.
Results A total of 126 patients were included: 61 were in the IV group and 65 in the oral group.The mean age was similar: 63 ± 15 years for IV and 64 ± 15 years for oral. Men comprised 65.6% of the IV group and 66.2% of the oral. 16 patients (12.7%) reached suboptimal levels, 86 (68.3%) were in the therapeutic range and 24 (19.0%) had toxic levels.

The plasma concentration was significantly higher in the IV group (U=1560.00, p=0.039). A higher percentage of patients in the IV group had toxic levels (29.5% vs. 9.2%), while the proportion of therapeutic levels was higher for oral (73.8% vs. 62.3%; χ^2=9.295, p=0.009). Age (rho=0.252, p=0.004) and male sex (U=1344.00, p=0.023) were associated with higher levels. Dose, omeprazole intake, BMI and EN showed no differences.

The logistic regression model based on the route of administration (including age and sex) was significant (Nagelkerke R^2=0.214, p<0.001), with the IV route being less likely than oral to result in suboptimal (OR=0.125, p=0.006) or therapeutic levels (OR=0.232, p=0.006).
Conclusion and Relevance IV voriconazole results in higher plasma concentrations and an increased risk of toxicity compared to oral administration. Age and male sex are significant factors affecting levels. Careful monitoring is advised, especially in older and male patients receiving IV therapy.

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

4CPS-079 IMPACT OF ANTIBIOTIC USE OPTIMISATION PROGRAMME AUDITS ON THE USE OF CARBAPENEMS IN OUR HOSPITAL

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Background and Importance Antibiotic Use Optimisation Programmes (AUP) are essential for combating the antibiotic crisis and microbial resistance. They aim to improve clinical outcomes, reduce side effects, and ensure cost-effective treatments. In 2022, our centre noted an increase in carbapenem antibiotic consumption, indicating a critical area for improvement when compared to similar hospitals.
Aim and Objectives This study primarily seeks to evaluate the impact of AUP team interventions on carbapenem usage in our hospital, while also assessing the acceptance of the team's recommendations by healthcare staff.
Material and Methods This descriptive study examined audits conducted by the AUP team on carbapenem prescriptions lasting seven or more days, a timeframe after which many prescriptions can be de-escalated or discontinued. The study covered June to December 2023, utilising a pseudo-anonymised database for data collection from the HCIS medical history programme and the Athos management programme. The obtained data were compared with the previous semester's findings. Various interventions, including escalation, de-escalation, and suspension, were implemented, and tools were provided to physicians through personal interviews to address similar cases.
Results A total of 143 audits were performed. In most of the interventions (78.7%) antibiotic discontinuation was proposed, while in 21.3% de-escalation or change of antibiotic was proposed. The total degree of acceptance of the recommendations was 52.4%, although it varied widely according to the service, being higher in Traumatology (100%) and General Surgery (85%). On the other hand, Internal Medicine (36%) and Medical Oncology (25%) had the lowest degree of acceptance.

Carbapenemics consumption was measured in DDD/100 stays. In the first half of 2023, the calculated DDD/100 stays was 7.94. After the AUP team's action, in the second semester the DDD/100 stays was 6.5, indicating that carbapenemics consumption was reduced by 18%.

Conclusion and Relevance The implementation of a AUP team in our hospital has had a positive impact on the prescription of carbapenemics, especially by decreasing its use. Better utilisation of these broad-spectrum antibiotics has been achieved, improving the quality of prescribing.

It would be necessary to use multimodal measures to evaluate the clinical and ecological impact of the measures implemented, as well as statistical regression analyses to determine whether there has been a significant change in trend.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-080 ECONOMIC IMPACT ASSOCIATED TO BIOLOGICAL THERAPY OPTIMISATION IN PATIENTS WITH PSORIASIS

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Background and Importance Optimisation of biological therapies is a frequent clinical practice to treat psoriasis in clinically controlled patients. The target is to guarantee effectiveness, improving adherence, reducing adverse effects (e.g. injection site reaction) and minimising associated costs.

Aim and Objectives To estimate the economic impact of optimising the use of biological treatment in patients with psoriasis disease.

Material and Methods A descriptive retrospective study was conducted between 1-july 2023 and 31-june 2024. Patients ≥18 years with plaque psoriasis treated with optimised biological therapies for at least 12 months uninterruptedly were analysed. Optimised therapies were defined as treatments with dose reduction or extended dosing regimens according to the summary of product characteristics (SPC). Patients with treatment discontinuations because of adequate disease control were excluded. These therapy optimisations were carried out according to a multidisciplinary protocol. Patients eligible for optimisation were those with an adequate response (Psoriasis Area Severity Index (PASI)≤3, Body Surface Area (BSA)<3%, *Physician global assessment* (PGA)=0–1 and Dermatology Life Quality Index (DLQI)<5) ≥6months.

Variables were recorded from the hospital's information systems: biological agent, dose regimens, treatment costs. Cost savings were calculated as the difference between total cost of real doses administered in optimised regimens in a year and the conventional treatment costs according to the SPC.

Results We reviewed 482 patients with psoriasis, 13.3% (n=64) with optimised biological therapies.

The treatment optimisation regimen used were: adalimumab (n=30, 48.4%): 40mg/21days (n=25); 40mg/4weeks (n=4); 40mg/6weeks (n=1); etanercept (n=4, 6.3%): 25mg/10days (n=1), 25mg/14days (n=1), 25mg/4weeks (n=1), 50mg/21days (n=1); ustekinumab (n=19, 29.7%): 45mg/14weeks (n=4), 45mg/15weeks (n=6), 45mg/16weeks (n=6), 45mg/18weeks (n=1), 90mg/16weeks (n=2); guselkumab (n=6, 9.4%): 100mg/10 weeks (n=1), 100mg/12weeks (n=5); risankizumab (n=1, 1.6%) 150mg/14weeks; tildrakizumab (n=1, 1.6%) 100mg/14weeks; brodalumab (n=1, 1.6%) 210mg/21days; secukinumab (n=2, 3.1%) 300mg/6weeks. During the study period, all optimised patients had disease remission.

The total cost of optimised patients was € 252657.40 against the use of conventional therapy (€ 350338.2), resulting in a reduction of −27.9% (cost saving: € 97680.8/12 months). The number of drug administrations avoided was 580.

Conclusion and Relevance In patients with plaque psoriasis, optimisation of biological therapies is a strategy to reduce costs and adverse effects by decreasing the number of drug administrations, maintaining the effectiveness.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-081 DISCONTINUATION OF TYROSINE KINASE INHIBITOR THERAPY IN CHRONIC MYELOID LEUKAEMIA IN FIRST OR SECOND-LINE

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Background and Importance Data on treatment discontinuation of Tyrosine Kinase Inhibitors (TKIs) in Chronic Myeloid Leukaemia (CML) in routine clinical practice are limited, and it would be interesting to develop treatment discontinuation studies in this situation to demonstrate that it is safe and effective in real-life.

Aim and Objectives To analyse the Rates of Molecular Relapse-Free Survival (MRFS) and Treatment Free Remission (TFR) during discontinuation of TKIs in first or second-line CML.

Material and Methods Observational multicentre prospective follow-up study of discontinuation of TKIs treatment in patients with chronic phase CML who have been on treatment with Imatinib, Nilotinib or Dasatinib at any dose, first or second-line, and who have achieved and maintained Molecular Response (MR) ≥ 4.5 log for at least 36 months. Authorisation was obtained from the Andalusian Biomedical Research Ethics Coordinating Committee (CCEIBA). Inclusion criteria: minimum TKI treatment time of 5 years, no resistance to any previous TKI, no diagnosis of accelerated phase or blast crisis, and maintenance of a MR ≥ 4.5 log for at least 36 months prior to discontinuation. Molecular monitoring of BCR-ABL levels by PCR-RT with the GeneXpert on a monthly basis in the first year, every 2 months in the second year and every 3 months after the third year. Molecular relapse was considered to be the confirmed loss of Major Molecular Response (MMR).

Results Treatment was discontinued in 90 patients with a median age at diagnosis of 48 and 59 years at discontinuation. 60 discontinued Imatinib, 10 dasatinib and 20 Nilotinib. The median time to discontinuation was 30 months. The MRFS rate 74% and the TFR rate 62%. The 25 patients who lost MMR achieved MMR after reintroduction of the same TKI treatment, with a median of 3 months. There was no progression to advanced stages of the disease. A 15% of patients suffered withdrawal syndrome.

Conclusion and Relevance The MRFS and RFT of our study is concordant with those reported in several real-life series. In selected patients, with a considerable exposure time to TKI treatment, and in deep and maintained MR, a successful RFT

can be expected, which translates into effective and safe discontinuation of TKIs in clinical practice.

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

4CPS-082 DETECTION OF MEDICATION ERRORS AND UNMET NEEDS OF ONCOLOGY PATIENTS DURING THE ONCOLOGY PHARMACY PRACTICE VISIT

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Background and Importance Medication errors in oncology patients are of utmost importance because oral antineoplastic drugs have a narrow therapeutic margin, complex dosing regimens and interactions with other drugs.
Aim and Objectives Detect medication errors and other patient needs from a holistic view in oncology pharmacy practice.
Material and Methods Prospective observational study of oncology patients in a tertiary hospital for 2 years. Demographic variables such as sex, age, pathology, chemotherapy and home treatment were collected. The types of patient errors or needs were categorised and recorded using an Excel database. Pharmaceutical interventions were carried out with the patient and recorded in the clinical history in the Diraya Clínica programme.
Results Total of 100 patients. The 69.5% men and 30.5% women, median age 67 years. The most frequent oncologic pathologies: prostate cancer (54%), breast (40%), colon (25%), lung (18%), renal (10%), ovarian (7%), brain tumours (5%) and endometrial cancer (3%). The most frequent chemotherapeutic treatments: abiraterone (23%), capecitabine (15%), abemaciclib (14%), Trifluridine Typiracil (13%), enzalutamide (12%), regorafenib (11%), cabozantinib (10%), olaparib (8%), apalutamide (7%), denosumab (6%), procarbazine (5%), temozolamide (5%), capmatinib (4%), lenvatinib (3%), osimertinib (3%), alectinib (2%), erlotinib (1%). 45% patients had medication errors in the antineoplastic dose, 25% had relevant interactions with the home medication, 18% had incidents with home medication (therapeutic duplications or forgotten prescriptions), 15% requested information on the consumption of phytosanitary products, 11% needed more information on their chemotherapy treatment and 6% on their pathology after leaving the oncology clinic. A lack of adherence was detected in 6% and relevant adverse effects in 5%. The most frequent dose errors were: erroneous adjustment of renal function (45%), failure to reflect the dose in the patient's clinical history (30%), non-adjustment in hepatic insufficiency (18%) and erroneous adjustment to body surface area (12%). In 100% of the patients, pharmaceutical interventions were carried out jointly with the oncology team in order to increase patient information and avoid medication errors. All of them were recorded in the patient's clinical history.
Conclusion and Relevance Joint interventions between the pharmacy and oncology teams have proven to be an effective tool to contribute to the achievement of therapeutic goals and patient safety.

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

4CPS-083 DISCONTINUATION OF LENALIDOMIDE TREATMENT IN PATIENTS WITH MYELODYSPLASTIC SYNDROME ASSOCIATED WITH 5Q DELETION

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Background and Importance According to OMS-2016, myelodysplastic syndrome (MDS) associated with del(5q) is manifested by a transfusion-dependent progressive bone marrow failure, with Lenalidomide acting as the intended drug to treat this syndrome.
Aim and Objectives To evaluate the clinical benefit associated to the discontinuation of the Lenalidomide treatment due to side effects or intolerance.
Material and Methods Five-year prospective observational study on 75 cases of MDS, 30 of them with del(5q). An analysis of the mutational profile was performed by Next-generation sequencing (NGS) to determine cases with high-risk mutational profiles mainly associated with the TP53 variant. Response to treatment can be predicted knowing that it is not recommended to use lenalidomide in patients with MDS (5q) and with the presence of a TP53 mutation because this could favour clonal evolution, expansion of the tumour clone and progression to acute myeloid leukaemia. Treatment discontinuation was studied in those candidates with side effects or intolerance. The variables considered in this study were: beginning of treatment, Lenalidomide mean dose, ending of treatment and beginning of discontinuation, side effects, time after discontinuation, evaluation of the drug withdrawal response.
Results 75 MDS cases were analysed (58% male and 42% female). 30 cases were detected as MDS associated to del (5q) (40%) and 20% of them showed positive TP53 mutation and were treated with hypomethylating agents instead of Lenalidomide. 65% of the cases were treated with Lenalidomide, the treatment were discontinued in 32% of them due to side effects and the dose reduced in 23% due to intolerance. The reported side effects were: Grade 4 neutropenia, rhabdomyolysis, erythematous reactions and haemolytic crisis. 100% of patients in which Lenalidomide was discontinued due to side effects, maintained complete haematological and cytogenetic response, reaching a mean monitoring time of 12 months since the withdrawal of Lenalidomide.
Conclusion and Relevance Discontinuation of Lenalidomide, due to side effects or intolerance, involves a clinical benefit to those patients who maintain a complete haematological response after interruption of the treatment

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

4CPS-084 EFFICACY OF OBETICHOLIC ACID IN PATIENTS WITH PRIMARY BILIARY CHOLANGITIS: A MULTICENTRE STUDY IN REAL-LIFE

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Background and Importance The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended the revocation of the marketing authorisation for obeticholic acid (OA). Efficacy in primary biliary cholangitis (PBC) could not be confirmed with available evidence.

Aim and Objectives To assess the efficacy of OA treatment in patients diagnosed with PBC in our region.

Material and Methods A multicentric, retrospective and descriptive study was carried out from June 2017 to September 2024. Demographic and clinical variables colleted were age, sex, previous treatment with ursodeoxycholic acid (UDCA), treatment duration and analytical data of liver markers [alkaline phosphatase (ALP), total bilirubin (TB), gamma-glutamyl transferase (GGT), aspartate aminotransferase (AST) and alanine aminotransferase (ALT)] at the beginning of treatment with OA and at 12 months. The primary endpoint, based on the pivotal trial, was a composite variable defined as the percentage of patients who achieve ALP<1.67 times upper limit of normal (ULN), normal total bilirubin level, and a decrease in ALP≥15% at 12 months. Secondary variables included the percentage of patients who had plasma levels ULN of GGT, AST and ALT after 12 months.

Results Sixty-two patients were included with median age 61 (35–88) years. There were 83.9% women and 16.1% men. All patients were treated with UDCA previously. The median treatment time with OA was 36 months. The median of basal liver markers values were: 233(108–813) UI/L ALP, 0.5(0.2–1.5) mg/dL TB, 173(19–981) UI/L GGT, 40(17–103) UI/L AST and 38(11–118) UI/L ALT. The median of liver markers values at 12 months were: 180(56–815) UI/L ALP, 0.49(0.3–1.5) mg/dL TB, 61(12–790) UI/L GGT, 30(12–97) UI/L AST and 26(9–137) UI/L ALT. At 12 months: ALP<1.67 times ULN was achieve by 58.1% of patients, 66.1% of cases showed a normal total bilirubin level and a reduction in ALP≥15% was reached by 54.8% of the population. After 12 months, 20.9% of patients presented plasma levels ULN of GGT, AST and ALT.

Conclusion and Relevance According to clinical trials, OA improved the analytical parameters of patients in our region after 12 months. However, a longer follow-up period is needed in our study to detect the impact on robust variables such as death or liver transplantation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-085 EVALUATION OF THE INCIDENCE OF HEPATITIS B VIRUS REACTIVATION IN PATIENTS TREATED WITH PEMBROLIZUMAB

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Background and Importance Recent studies have found that patients with anti PD-L1 treatment, as in the case of pembrolizumab, the incidence of hepatitis B virus reactivation has been increased in those patients with positive HbcAb (hepatitis B core antibody), recommending the use of prophylaxis to avoid it.

Aim and Objectives To evaluate the incidence of hepatitis B virus reactivation and the use of prophylaxis under real conditions in patients on pembrolizumab treatment.

Material and Methods Retrospective observational study between January 2014 and July 2024. Patients over 18 years of age who initiated treatment with pembrolizumab were included.

Demographic variables such as sex, age, weight, and height were collected. The clinical variables were HbsAb (hepatitis B surface antigen antibody), HbcAb, were collected in a previous period of 6 months before the start, during and up to 1 year after the end of treatment, the data were obtained from the patients' medical records. Serology interpretation:

Abstract 4CPS-085 Table 1

Interpretation	HbsAb	HbcAb
Curated. Can be reactivated	+	+
Possibly infected	-	+
Vaccinated	+	-

Results The study included 263 patients, 174 men (64%) and 89 women (34%), with a mean age of 64.7 + 11 years, mean weight of 69 + 14 kg, mean height of 166 + 10 cm.

Previous to treatment, 98 (37%) patients underwent hepatitis B serology obtaining:

Abstract 4CPS-085 Table 2

	HbsAb	HbcAb
Yes	98	98
Pos	27	18
Neg	71	80

There were 18 patients (18%) with a positive serology for HbsAb and HbcAb indicating that the infection has passed and the virus can be reactivated. Three patients (3%) with positive HbcAb alone indicate that they may be infected, and nine patients (9%) with positive HbsAb alone indicate that they are vaccinated.

Conclusion and Relevance The results obtained in this study show that reactivation of the virus did not occur in any patient, and despite the recommendations, in no case was prophylaxis prescribed to prevent it.

Hepatitis B serology was not performed in 165 patients (63%), which may pose a risk to the patient's health.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

4CPS-086 OBSERVATIONAL STUDY TO ASSESS GUSELKUMAB ADHERENCE IN CLINICAL PRACTICE IN PATIENTS WITH MODERATE TO SEVERE PSORIASIS

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Background and Importance Despite the established relationship between clinical outcomes and patient-reported outcomes (PROs), discrepancies often arise between clinical remission and patients' perceptions of their symptoms. Integrating PROs is essential for comprehensive assessment, and effective monitoring and optimisation of biologic therapies, especially important in implementing value-based healthcare for patients with psoriasis.

Aim and Objectives The main objective is to assess 12-month adherence to guselkumab in patients with moderate to severe psoriasis in real-world clinical setting. Secondary objectives included the relationship between adherence and PROs.

Material and Methods Observational, prospective multicentre study (39 centres) including adult patients with moderate to severe psoriasis who started guselkumab treatment. Baseline characteristics including psoriasis area severity index (PASI), body surface area (BSA) and dermatology life quality index (DLQI) were recorded. Medication Possession Ratio (MPR) and Morisky Medication Adherence Scale (MMAS-8) were used to assess optimal adherence (MPR≥90% and/or MMAS-8=8). PROs questionnaires completed on-line including medication satisfaction questionnaire (TSQM) and the psoriasis signs and symptoms diary (PSSD). We present a 6-month interim analysis.

Results Of 215 patients (50.6 years, SD 11.9), 97 (45.1%) completed the 6-month visit. Mean psoriasis progression was 17.2 years (SD 13.56 n=149), 31.3% had psoriatic arthritis, 48.8% had ≥10% BSA, and 86.2% had previously received biologics. Mean basal PASI was 10.5 (SD 7.8, n=92), with 75.5% having PASI >5, and mean basal DLQI was 10.4 (SD 6.5, n=83).

At 6 months, 79 (n=94, 84.0%) patients were adherent according to MPR, 48 (n=62, 77.4%) according to MMAS-8, and 39 (n=60, 65.0%) combining MPR and MMAS-8 criteria. TSQM for global satisfaction and PSSD lacked significant differences between adherent (combined assessment) and non-adherent patients at baseline. At 6 months, mean (SD) TSQM scores were 80.5 (13.6) in adherent patients and 66.1 (18.2) in non-adherent (p=0.0010); mean (SD) PSSD symptoms and PSSD signs of adherent and non-adherent patients were 16.2 (15.7) and 35.1 (28.1) (p=0.0080) and 17.7 (15.3) and 36.6 (24.3) (p=0.0031), respectively.

Conclusion and Relevance At 6-months of guselkumab treatment, a significant proportion of patients (>65%) remained adherent according to the three adherence criteria. Adherent patients have a lower perception of psoriasis symptoms and higher satisfaction with treatment compared to non-adherent.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest Corporate sponsored research or other substantive relationships:

Research sponsored by Johnson and Johnson

4CPS-087 EXPLORING THE ROLE OF COMMUNITY PHARMACISTS IN PERIOPERATIVE ANTITHROMBOTIC MANAGEMENT: BARRIERS, FACILITATORS, AND FUTURE DIRECTIONS

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Background and Importance Antithrombotic agents are considered as high-risk medications, particularly during the perioperative period because of the increased bleeding risk. Finding the balance between bleeding and thrombosis is crucial in case of invasive procedures. Today, the specific role of community pharmacists (CPs) in perioperative antithrombotic management remains unclear.

Aim and Objectives This study aimed to explore the role of CPs in perioperative antithrombotic management, focusing on their experiences, patients' questions, and the barriers and facilitators to expand their involvement.

Material and Methods A qualitative study was conducted using semi-structured, in-depth interviews with 13 CPs (7 women, 6 men). Participants were purposively sampled to ensure diversity. A semi-structured interview guide containing open-ended questions was developed by the research team based on the Theoretical Domains Framework. Interviews were transcribed verbatim, and data were analysed both inductively and deductively using NVivo V14. Data saturation determined the sample size and was reached when no new themes emerged.

Results Three main themes were identified: (1) the current role of the CP, (2) the need for more education on perioperative antithrombotic management, and (3) collaboration and communication with other healthcare professionals. CPs reported to contribute more to postoperative than to preoperative management. Facilitators included their close relationship with patients as trusted professionals, their early involvement post-hospital discharge, and their complete overview of patients' medication. Barriers included lack of access to medical records, absence of standardised guidelines, and difficulties to reach hospital physicians. CPs expressed a strong need for structured education and a comprehensive overview of guidelines, including well-accessible algorithms and effective communication with prescribers. Hospital pharmacists were identified as key players in addressing these barriers by facilitating information flow and supporting CPs.

Conclusion and Relevance The role of CPs in perioperative antithrombotic management is currently limited, particularly in preoperative care. Several barriers and facilitators were identified that may influence their role in this area. The findings suggest the need for structured education and improved access to clinical information. Further research is necessary to validate these findings and address identified barriers, ultimately improving the role of CPs in perioperative care and patient outcomes.

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

4CPS-088 SUSTAINABLE EYECARE: EVALUATING THE CARBON FOOTPRINT OF INTRAVITREAL INJECTIONS

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Background and Importance Intravitreal injections (IVIs) are essential treatments for retinal diseases, such as neovascular age-related macular degeneration (nAMD) and retinal vein occlusion. Anti-vascular endothelial growth factor (anti-VEGF) therapies, administered via IVI, inhibit abnormal retinal blood vessel growth, stabilising or improving visual acuity. As the population ages and nAMD prevalence rises, the use of IVIs is increasing, and since they, as other pharmaceuticals, significantly contribute to healthcare's carbon footprint, it is necessary to evaluate their environmental impact alongside clinical efficacy.
Aim and Objectives This study aims to quantify the carbon footprint of IVIs administered at Odense University Hospital, Odense, Denmark for three therapeutically equivalent anti-VEGF medications. The objective is to conduct a cradle to grave Life Cycle Assessment (LCA) that offers a detailed environmental impact analysis and serves as a blueprint for future LCA studies in the healthcare sector, especially focusing on pharmaceuticals, demonstrating how this method can integrate the carbon footprint of a medication into prioritisation decisions.
Material and Methods We conducted a mixed-methods observational study to assess carbon emissions (CO2eq) from cradle to grave of for a single IVI. We utilised a complete LCA to calculate CO2eqs for the anti-VEGF medications ranibizumab, aflibercept, and faricimab. The preliminary results presented here focus on the carbon footprint of the IVI procedure itself, accounting for emissions from all medical supplies, including production, transport, and disposal.
Results The CO2eq for one IVI was 0.46 kg, 0.47 kg, and 0.47 kg for ranibizumab, aflibercept, and faricimab, respectively.
Conclusion and Relevance This study highlights the carbon footprint of IVIs for three widely used, therapeutically equal, anti-VEGF therapies. While the CO2eq values are similar among the medications, ranibizumab had the lowest CO2eq, mainly due to its lower emissions related to packaging materials. Understanding these environmental impacts is crucial, especially as the demand for IVIs rises due to an ageing population and the increasing prevalence of retinal diseases. Moreover, this study serves as a comprehensive blueprint for conducting detailed LCAs for pharmaceuticals, promoting the integration of sustainability considerations into clinical decision making and encouraging environmentally conscious practices in ophthalmology. By understanding the carbon footprint of IVIs, we can help reduce healthcare's environmental burden and optimise resource prioritisation.

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

4CPS-089 IMPACT OF THE ANTIMICROBIAL STEWARDSHIP PROGRAMME'S RECOMMENDATIONS ON THE ANNUAL CONSUMPTION OF CARBAPENEMS

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Background and Importance The complexity of infectious diseases and the increase in resistance make it necessary to establish antimicrobial stweardship programmes (ASP).
Aim and Objectives To analyse the interventions carried out by the ASP on the consumption of carbapenems in a regional hospital.
Material and Methods Observational study of the interventions carried out by the ASP on treatments with meropenem, ertapenem and imipenem throughout the year 2023. Variables analysed were: indication, empirical vs directed treatment, type of recommendation and acceptance or not of the intervention. The impact of the recommendations was correlated with antibiotic consumption, through the defined daily doses (DDD)/100 bed-days and their comparison with those of the previous year.
Results During the study period, 129 interventions were carried out on carbapenem treatments, of which 45.7% were on meropenem, 53.5% on ertapenem and 0.8% on imipenem.The main indications for meropenem were respiratory infection (30.5%) and bacteraemia (25.4%). It was targeted therapy in 25% of the cases. The recommendations made were to maintain treatment (40.7%), de-escalate (27.1%), adjust duration (27.1%) and suspend (5.1%). They were fulfilled in 90% of the cases. Annual consumption during 2023 was 884.17 DDD/100 bed-days, achieving a decrease of 16% compared to the previous year (1052.36).The main indications for ertapenem were urinary infection (55.7%) and respiratory infection (17.4%). 59.4% of the cases were targeted therapy. Recommendations were to maintain treatment (31.9%), de-escalate (31.9%), adjust duration (27.5%) and suspend (8.7%). They were fulfilled in 80% of the cases. Annual consumption during 2023 was 1273.5 DDD/100 bed-days, representing an increase of 7% compared to 2022 (1183.33).There was a prescription for empirical imipenem to treat respiratory infection, in which de-escalation of treatment was recommended, but it was not accepted. Annual consumption during 2023 was 12.5 DDD/100 bed-days, achieving a decrease of 73% compared to the previous year (46.75). In global terms, the consumption of carbapenems during 2023 was 2170.16 DDD/100 bed-days, achieving a reduction of 4.21% compared to 2022 (2265.63).
Conclusion and Relevance Ertapenem is mainly prescribed as a targeted antibiotic whereas meropenem is used empirically. Global consumption of carbapenems has decreased compared to the previous year. The interventions of ASP are essential in the reduction of broad-spectrum antibiotics.

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

4CPS-090 CONSUMPTION-BASED INDICATORS IN AN INTENSIVE CARE UNIT AFTER AN ANTIMICROBIAL STEWARDSHIP PROGRAMME IMPLEMENTATION

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Background and Importance Antibiotic resistance is one of the main public health problems worldwide. The way in which available antibiotics are used in clinical practice today is key to stopping the increase in resistance, which is why monitoring and improving their use in Intensive Care Unit (ICUs) is essential.

The quality indicator used to measure the use of antimicrobials have been agreed upon at both national and European levels, to know the current consumption of antibiotics.

Aim and Objectives Description and analysis of hospital antibiotic use indicators based on consumption data, over a 1 year period in the ICU of a third-level hospital in the first year of the implementation of an Antimicrobial Stewardship Program (ASP) team.

Material and Methods Retrospective study in which eight of the indicators recommended by a panel of experts made up of members of the Spanish Society of Hospital Pharmacy (SEFH) and the Spanish Society of Infectious Diseases and Clinical Microbiology (SEIMC) were calculated using a modified Delphi method, corresponding to a 1 year period of the Adult Intensive Care Service in a third-level hospital. This period was divided into 4 quarters.

The consumption indicators that were measured were the following (table 1):

Results The following table (table 2) shows the results:

Conclusion and Relevance These results allow us to obtain the antibiotic consumption in our environment, specifically in the ICU. We will be able to compare our results with other hospital situations and how the implementation of different strategies for the improvement of antibiotics use can impact on them.

Abstract 4CPS-090 Table 1

Global consumption of antimicrobials	Consumption of carbapenems
Global consumption of antifungals	Consumption of fluoroquinolones
Consumption of fosfomycin	Consumption of new beta-lactams
Ratio of amoxicillin-clavulanic acid IV/piperacillin	Sequential therapy

Abstract 4CPS-090 Table 2 Consumption indicators collected in the ICU in 1 year (Qr=quarter). *iv: intravenous

INDICATORS	2023	2023	2024	2024
	3Qr	4Qr	1Qr	2Qr
Global consumption of antimicrobials	161,48	205,39	186,72	160,05
Global consumption of antifungals	23,02	19,4	16,65	16,8
Consumption of carbapenems	19,54	25,29	19	24,87
Consumption of fluoroquinolones	7,43	11,48	9,86	8,99
Consumption of fosfomycin	4,25	0,45	0,03	0,06
Consumption of new beta-lactams	4,92	5,36	4,58	2,59
Ratio of amoxicillin-clavulanic acid IV/ piperacillin	3,55	2,86	2,16	3,21
Sequential therapy	0,16	0,06	0,14	0,09

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-091 COST SAVING IMPACT FROM CHOOSING INTRAVENOUS OR SUBCUTANEOUS DARATUMUMAB BASED ON WEIGHT PATIENT FOR THE TREATMENT OF MULTIPLE MYELOMA

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Background and Importance Daratumumab is a monoclonal antibody that specifically targets the CD38 antigen expressed on myeloma cells. Its introduction in subcutaneous form offers faster and more convenient administration, significantly reducing infusion time as well as a lower risk of infusion-related reactions. However, it is important to analyse which patients it is efficient to use it in.

Aim and Objectives The aim of this study was to evaluate the cost saving impact depending on the choice of subcutaneous or intravenous daratumumab in the treatment of multiple myeloma in a tertiary hospital.

Material and Methods Observational, retrospective study of patients treated with daratumumab between January 2022 and December 2023 in a tertiary hospital.

Variables collected: demographics (sex and age), number of patients, weight and economic data (price of intravenous daratumumab and subcutaneous daratumumab).

Variables studied: total cost of patients treated in our hospital with subcutaneous daratumumab and total cost if intravenous or subcutaneous administration had been adapted based on weight.

Results 57 patients were included in this study, mean age of 70.98 ± 11.66. 38.6% (n=22) of them were men. The average weight was 66.8 ± 13.26 kilograms (kg).

Intravenous daratumumab has a dosage of 16 milligrams (mg) per kg of weight and subcutaneous daratumumab has a fixed-dose of 1800 mg. In our hospital, the price of one daratumumab-400 mg vial is € 967.61 (2.42 € /mg), € 241.85 for one daratumumab-100mg vial (2.42 € /mg) and € 2902.85 for one daratumumab-1800 mg vial for subcutaneous injection (1.61 € /mg).

All our patients received subcutaneous daratumumab, which represents a total cost of € 2,696,747.65. If the dosage had been based on the patient's weight (over 75 kg, subcutaneous daratumumab and under 75 kg, intravenous daratumumab), the total cost would have been € 2,327,533.04, which represents a cost saving of 13.69% (€ 369,214.61).

Conclusion and Relevance This study demonstrates that subcutaneous daratumumab administration in patients with multiple myeloma results in significant economic savings in patients weighing more than 75 kg. Consideration of weight in selecting the route of administration is a strategy that could reduce costs by 13.69%. Therefore, it is critical to balance economic efficiency with patient safety and comfort, especially in cases where subcutaneous administration is feasible and preferable.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-092 TREATMENTS FOR RET ALTERED ADVANCE OR METASTATIC THYROID CANCER: A SYSTEMATIC REVIEW

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Background and Importance Receptor tyrosine kinase rearranged during transfection (RET) can be oncogenically activated by gene fusions or point mutations. RET alterations are implicated in the pathogenesis of approximately 20% of thyroid cancers (TC). Multikinase inhibitors and selective RET inhibitors are promising therapies.
Aim and Objectives To develop a systematic review of therapies for advanced and metastatic TC with fusion-positive, mutated or altered RET gene (RET+).
Material and Methods Based on Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) methodology, a search was conducted in PubMed database until September 2024. Filter 'clinical trials' was combined with the following search terms: [RET mutation OR RET fusion OR RET altered] AND thyroid cancers. Inclusion criteria: clinical trials (CTs) enrolling patients diagnosed with RET+ advanced and/or metastatic TC who could be naïve or previously treated patients. Efficacy outcomes considered were overall survival (OS), progression-free survival (PFS) and objective response rate (ORR). The following data were recorded: publication date, study design, tumour stage, sample size, population follow-up, treatments, efficacy results and comparator arm.
Results Forty studies were reviewed and ten met the inclusion criteria. Publication dates were between February 2010 and September 2024. Study design: 4 non-randomised phase I/II CTs, 3 non-randomised phase II and 3 randomised phase III. All CTs involved patients with advanced and metastatic stages. The sample size comprised between 19 and 312 patients. Median follow-up ranged from 14 to 47 months. Therapies assessed: cabozantinib, pralsetinib, selpercatinib, sorafenib, and vandetanib. The highest numerical efficacy results were obtained with selpercatinib [OS = 64.3 months (IC95% 48.3-Not Reached); PFS = 41.4 months (IC95% 30.2-NR); ORR = 77.6% (IC95% 70.2–84.0] followed by cabozantinib [OS= 26.6 months (IC95% not available); PFS= 11.2 months (95% CI not available); ORR= not available]. Only three trials had a comparator arm (cabozantinib versus placebo).
Conclusion and Relevance Selpercatinib presented the best numerical efficacy result in patients with TC and RET+, followed by cabozantinib. Comparative randomised CTs for all therapeutic alternatives could facilitate clinical decision making.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-093 ANALYSIS OF THE IMPACT OF THE OMALIZUMAB SHORTAGE IN THE ALLERGY DEPARTMENT

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Background and Importance Omalizumab is a humanised monoclonal antibody that selectively binds to human immunoglobulin E (IgE) preventing its binding to Fcϵ in basophils and mast cells, reducing the amount of free IgE available to trigger the allergic cascade.
Aim and Objectives Analyse the impact of the omalizumab shortage on the allergy department (AP), and measures taken to control it.
Material and Methods This retrospective study included patients treated with omalizumab prescribed by the AP who needed to be dispensed during the stock-out period (July-September 2024). The variables included were: diagnosis, presence of exacerbations during treatment, initial dose, cost of treatment, therapeutic approach taken (maintaining the regimen, reducing or spacing the dose, changing to another biologic drug, or discontinuation), final dose and cost of the new therapy.
Results Seventy-one patients were on treatment with omalizumab, 51/71 required medication during the study period.

33/51 had chronic spontaneous urticaria, 14 had severe asthma and 4 were used off-label. Most patients were controlled on omalizumab treatment, except for 4 patients with urticaria and 1 with asthma, who presented exacerbations. Prior to the shortage, 25 patients used the dose indicated in the technical sheet, 23 had a lower dose and/or longer interval, and 3 had been administered a higher dose or shorter interval.

Prior to the shortage, the total annual cost was 320.609,5 euros, and the average annual cost was 5874,2 euros/patient.

Regarding the therapeutic attitude, in 16 patients the therapeutic interval (TI) was increased by 1–2 weeks (TI between C/5 and C/16 weeks), in 11 it remained the same, in 10 it was necessary to change the biologic drug (4 to dupilumab, 1 to benralizumab, 2 to mepolizumab and 3 to tezepelumab), 8 discontinued treatment and 6 reduced the dose by half (150mg). Finally, the total annual cost was 245.371 euros, and the average cost was 5203,2 euros/patient.
Conclusion and Relevance Stock-outs are a therapeutic challenge for the multidisciplinary team caring for thepatient. Furthermore, these stock-outs have made it possible to re-evaluate treatmentsand optimise therapy, either by substituting more efficient drugs or by discontinuing them.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-094 EVALUATION OF ADHERENCE AND VIROLOGICAL RESPONSE IN PATIENTS WITH HEPATITIS B INFECTION

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Background and Importance Hepatitis B virus (HBV) is a viral infection that represents a challenge to world public health. Although antiviral treatment is effective, adherence plays a fundamental role in the disease response.
Aim and Objectives The purpose of this study is to assess the adherence to treatment and the virological response (VR) in a cohort of patients with HBV infection.
Material and Methods Observational, retrospective, single-centre study of a cohort of HBV patients treated with tenofovir and/or entecavir in April 2024. Patients coinfected with

HIV/HBV and in which indication was prophylaxis (immunosuppression) were excluded.

Adherence was estimated as the medication possession rate (MPR) in last year (least 3 months). When the medication gap was more than 90 days was considered treatment abandonment.

For the analysis was used the last viral load. A VR was considered when HBV-DNA levels were <10 IU/mL; partial VR when the decrease in HBV-DNA was greater than log10 but still detectable after 12 months of treatment.

Demographic data, HBV-DNA viral load and treatment information were obtained from the clinical history. For statistical analysis were used percentages for categorical variables; means and standard deviations for continuous variables.

Results 104 patients were included, 75% male, mean age 54 years (SD 15). 58% were treated with tenofovir; 40% entecavir and 2% with both. The time since treatment start was <1 year in 6% patients, 72% between 1–10 years and 22% patients >10 years.

The mean adherence was 95,2% (SD 9,1). 84% of patients had adherence ≥90%, 94% patients >80% and only 6 had <80%. One patient abandoned treatment.

There are no differences in adherence between the groups of patients treated with entecavir and tenofovir, 95,1% (SD 9,3) and 95,1% (SD 9).

99 patients (95%) presented VR; 3 partial VR and 2 patients not completed 1 year of treatment, although in all of them adherence was 99–100%.

Conclusion and Relevance Patients with HBV on antiviral treatment in our study have optimal levels of adherence, indepently of the prescribed treatment. Also they have excellent VR in most cases. Is interesting to have identified patients with suboptimal adherence, especially dropouts and those with insufficient VR.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-095 MEDICATION MANAGEMENT IN ACUTE ADMISSIONS: A TEMPORARY HOLD OF NON-ESSENTIAL MEDICATION USING A PHARMACIST-DEVELOPED POCKET CARD

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Background and Importance Acute admission wards play a crucial role in providing rapid assessment, investigation, and treatment for patients with acute medical conditions. Clinical pharmacists perform medication management and may reduce medication use and strain on nurse resources by implementing a procedure to temporarily hold potentially unnecessary medications, for example topical treatments or osteoporosis medications.

Aim and Objectives This study evaluated the number of medications that may be paused during acute admissions and assessed the usability of a pharmacist-developed pocket card designed to assist pharmacists and physicians in pausing medications in an emergency department.

Material and Methods First, pharmacists developed a pocket card based on an audit of physicians' previous medication management and a pharmacist assessment of non-essential medications during acute admissions. The card listed medications that may be temporarily held regardless of clinical context during the stay in the acute ward. Second, clinical pharmacists tested the card during seven working days to pause medications after physicians' admission orders were entered. Third, physicians were introduced to the card for use during admission orders, and its effectiveness in supporting medication management was evaluated during another seven days.

Results In the first week, 30 patients were included with a total of 327 medication orders. Of these, 60 (18.3%) were on the pocket card. Physicians paused 23 medications (38.3% of the pocket card medications, 7.0% of total orders) and pharmacists paused an additional 30 medications (50.0% of the pocket card medications, 9.2% of total orders). Overall, interventions covered 16.2% of all orders. In the second week, 35 patients were included with 468 medication orders in total. Of these, 122 (26.1%) were on the pocket card. After introduction to the card, physicians paused 81 (66.4% of the pocket card medications, 17.3% of total orders) and pharmacists paused an additional 30 (24.6% of the pocket card medications, 6.4% of total orders). Overall, interventions covered 23.7% of all orders.

Conclusion and Relevance This study showed that the pharmacist-developed pocket card effectively supports medication management. Introducing physicians to the card helps them reduce the use of non-essential medications during acute admissions. This may reduce overall medication use and strain on nursing resources during short hospital stays.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-096 TEDUGLUTIDE VERSUS HOME PARENTERAL NUTRITION IN PAEDIATRIC POPULATION WITH SHORT BOWEL SYNDROME

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Background and Importance Long-term home parenteral nutrition(HPN) in paediatric population with short bowel syndrome (SBS), which incidence is estimated to be 24.5 per 100,000 live births, has significant survival improvement, but it is associated with complications and impact on life quality. Teduglutide may decrease HPN support and achieve enteral autonomy(EA) by accelerating intestinal adaptation.

Aim and Objectives To evaluate effectiveness and incremental cost-effectiveness ratio (ICER) per quality-adjusted life year (QALY) gained of teduglutide plus HPN versus HPN in paediatric patients with SBS using healthcare system perspective.

Material and Methods Observational, descriptive and retrospective study from May 2018 to August 2024 in children(neonates-16 years) with SBS receiving HPN and teduglutide in a tertiary care hospital.

Data collected from the electronic medical records and logistics management programme: age; sex, weight; teduglutide: start/end date, posology, annual acquisition cost/patient with and without repackaging; HPN: start/end date, units/week 12 months prior to teduglutide initiation(PRE-TEDU)

and last 12 months with teduglutide(POST-TEDU), annual acquisition cost/patient.

QALYs and direct non-acquisition costs(drug complications, medical visits and intestinal transplantation) were obtained from *Gattini et al.*[1]

Quantitative variables were expressed as median and range, and qualitative variables as number and percentage(%).

Results During the study period, 6 patients were included; 3 (50%) female; median age 8.50(4–16) years, median weight 21(17–51)kg. Teduglutide: first dose 4.71(2.04–8.80)years from HPN onset; median duration 3.99(0.49–6.26) years; median dose 0.05 (0.02–0.05) mg/kg/day; median annual direct cost/patient 35,020€ (17,829€ -131,586€) with repackaging and 216,899€ (51,643€ -234,974€) without repackaging. Five(83.33%) patients continued with treatment.

In effectiveness terms, median reduction in HPN number POST-TEDU versus PRE-TEDU was 225(0–365); 2 patients (33%) achieved EA POST-TEDU. The incremental cost involved 23,805€ (−16,293€ -81,966€) and 187,668€ (51,643€ -191,879€) with and without repackaging in POST-TEDU period.

In cost-utility analysis, using an additional 1.80(1.70–1.89) QALY, an ICER of 13,225€ (−9,052€ -45,537€)/QALY and 104,260€ (28,691–108,038€)/QALY with and without repackaging was obtained.

Conclusion and Relevance Compared to HPN, repackaged teduglutide allows EA to be achieved with a cost-effectiveness criterion below the threshold of 30,000€ /QALY gained, starting at least 2 years after PN initiation. Future studies with larger sample size and utility national data would be necessary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. https://doi.org/10.1016/j.clnu.2023.10.001

Conflict of Interest No conflict of interest

4CPS-097 ABSTRACT WITHDRAWN

4CPS-098 CYTOKINE RELEASE SYNDROME INCIDENCE AND MANAGEMENT IN CAR-T THERAPIES: A COMPARATIVE STUDY OF AXICABTAGEN CILOLEUCEL AND TISAGENLECLEUCEL

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Background and Importance Chimeric Antigen Receptor T-Cell (CAR-T) therapies have significantly improved leukaemias, lymphomas, and multiple myeloma treatments. However, they can induce several adverse effects such as cytokine release syndrome (CRS), which typically manifests its symptoms within first 3–14 days and can be potentially fatal. As a result, early treatment is essential, using drugs such as interleukin-6 inhibitors, among which tocilizumab stands out.

Aim and Objectives To analyse and to compare cytokine release syndrome incidence following different CAR-T therapies and its resolution through tocilizumab administration.

Material and Methods Observational, descriptive and retrospective study in a tertiary care hospital including all patients treated with CAR-T therapies (axicabtagen ciloleucel or tisagenlecleucel) from January 2020 to August 2024.

Variables were collected from patients' clinical records (OrionClínic): gender, age, diagnosis, first infusion date; toxicity: yes/no, grade, start/end date and treatment; tocilizumab doses required, ICU stay, and deaths.

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 50 patients were included.

Axicabtagen was administered to 30(60%) patients, 15 (50%) women, average age was 55.2(15.2) years and diffuse large B-cell lymphoma(DLBCL) diagnosis. CRS occurred in 29 (97%) patients, 27(93%) treated with tocilizumab and 2.2(1.0) average doses administered/patient. Toxicity grade(TG) 1: 15 (52%) patients; TG2: 11(38%) patients; TG3: 3(10%) patients. ICU stay: 6(21%) patients. CRS duration: 4.7(2.1) days.

On the other hand, tisagenlecleucel was administered to 20 (40%) patients, 12(60%) men, average age was 59.7(16.1) years, 18(90%) patients with DLBCL and 2(10%) with acute lymphoblastic leukaemia. CRS occurred in 12(60%) patients, 5 (42%) of them treated with tocilizumab, 1.4(0.9) average doses administered/patient. TG1: 9(75%) patients; TG2: 2 (17%) patients; TG3: 1(8%) patient. ICU stay: 3(25%) patients. CRS duration: 4.0(1.6)days.

The difference between the number of patients who experienced CRS with each treatment was statistically significant. No patient died.

Conclusion and Relevance This study suggests that patients treated with axicabtagen are more likely to develop CRS and require more tocilizumab doses compared to those treated with tisagenlecleucel. It also suggests that CRS resolution time after tocilizumab administration is very similar in both treatments and TG1 is the most likely TG.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-099 COMPARISON OF TRASTUZUMAB DERUXTECAN AND TRASTUZUMAB EMTANSINE IN HER2-POSITIVE METASTATIC BREAST CANCER: REAL-LIFE OBSERVATIONAL STUDY AT A UNIVERSITY POLYCLINIC

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Background and Importance Breast cancer has become one of the most prevalent causes of cancer-related mortality. The identification of efficacious and sustainable treatments is important to improve accessibility to therapies.

Aim and Objectives A comparative evaluation of the clinical efficacy and safety of trastuzumab deruxtecan (T-DXd) and trastuzumab emtansine (T-DM1) as 2nd-line or subsequent therapy in patients with HER2-positive metastatic breast cancer (mBC) was conducted.

Material and Methods The medical records of 21 patients treated with T-DM1, who had previously received trastuzumab+taxane, and 19 patients treated with T-DXd, who had received two or more anti-HER2 treatment regimens from February 2017 to July 2023, were retrospectively analysed. Variables considered included age, sex, stage of disease, and number of treatment cycles. Study endpoints were progression-free survival (PFS), overall survival (OS), toxicity and best response (BR) to treatment. Statistical analyses were performed using R (t-student test).Confidence intervals were set at 95%.

Results Mean age was 54years for T-DM1(37–77) and 47years for T-DXd(28–66). T-DM1 was used as 2nd and 3rd-line therapy in 90.48% and 9.52% of patients, respectively. T-DXd was used as second-line treatment in 5.26% of patients, as third-line in 21.05% and as subsequent line in 73.69%. The mean number of cycles of administration was 5.6 for T-DM1 (1–15) and 12.4 for T-DXd(2–29).In follow-ups, BR for patients treated with T-DXd showed a partial response in 57.9% of cases, respect to 9.52% with T-DM1. Furthermore, disease stability was showed in 52.38% of cases with T-DM1 and 31.57% with T-DXd. The mean PFS was 8.9 months [95%IC:5.20–12.61;($p<0.001$)] for T-DM1 and 11.5 months for T-DXd[95% CI:8.05–4.37;($p<0.001$)]. The mean OS was 14.1 months [95% CI:6.44–21.76;($p=0.12$)] for T-DM1 and 13.2 months for T-DXd [95% CI:10.89–16.47;($p=0.12$)]. The most common toxicities reported with T-DXd were nausea/vomiting (47.4%)and asthenia (42.1%). Neutropenia grade$\geq$2 was reported in 4 patients (21%). Nausea/vomiting (42.8%), asthenia (47.6%), liver toxicity(23.8%) and severe-moderate thrombocytopenia (38.1%) were reported with T-DM1. One patient discontinued T-DM1 due to toxicity, none discontinued T-Dxd.

Conclusion and Relevance A significant improvement in partial response and PFS was observed with T-DXd compared to T-DM1. Limited follow-up data and late initiation of T-DXd after previous therapies may have influenced OS results. Rates of overall toxicity and severe-moderate toxicity were lower than in the pivotal trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-100 A SINGLE-CENTRE, RETROSPECTIVE, OBSERVATIONAL COHORT STUDY TO EVALUATE THE IMPACT OF CEFIDEROCOL IN PATIENTS WITH INFECTIONS CAUSED BY MULTIDRUG-RESISTANT GRAM-NEGATIVE BACTERIA

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Background and Importance Cefiderocol, a new siderophore cephalosporin, was the first antibiotic to receive full innovativeness in the treatment of multidrug-resistant (MDR) Gram-infections.

Aim and Objectives The aim of the study is to describe the clinical use profile of cefiderocol and assess its impact on mortality rate.

Material and Methods Demographic, clinical and microbiological data were collected by analysing the medical records of patients treated with cefiderocol between April 2023 and May 2024 at a University Hospital. The primary endpoint was the assessment of all-cause mortality rate at 14 and 28 days. Secondary endpoints of the study were the response rate, in terms of clinical cure or eradication. Descriptive statistics were performed using R [95% confidence intervals (CI)].

Results Sixty-six subjects with Gram- MDR infections were included in the study, including 46 males and 20 females (mean age: 63.8 years). 14% of the patients were admitted to an Intensive Care Unit. The 54.5% of the patients had respiratory tract infections with pneumonia. In total, 39.4% of the patients presented bacteraemia. Skin, soft tissue and osteoarticular infections were detected in 9% of the patients, and urinary infections in 3%. The main pathogens identified were Acinetobacter baumannii (74%), Pseudomonas aeruginosa (4.8%), Klebsiella pneumoniae (14.3%). In 6.1% of the subjects more than one concomitant pathogen was present. The mean duration of treatment was 13.33 days[CI-95%:11.17,15.49]. In 88% of cases, cefiderocol was administered with other antibiotics, mainly fosfomycin(19%), caspofungin(14%), colistin ev(9%) and vancomycin(9%). The overall mortality was 25.75% [CI-95%:0.15,0.37], of which 75% were from causes unrelated from the infection. 53% of the dead patients were infected with Acinetobacter baumannii. 68.75% of the deaths occurred within 14 days of the start of treatment. 31.8% of patients recovered from a clinical point of view, of which 19% with microbiological eradication. Finally, 44% of patients discontinued their treatment by clinical decision due to unavailability of the drug or switch to other treatments.

Conclusion and Relevance The study showed a lower mortality rate compared to the registration trial (33.7%), with more deaths occurring within two weeks of starting treatment. Furthermore, we confirm the association shown in the clinical trial between mortality and infection with Acinetobacter baumannii, the main colonising pathogen.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-101 SUCCESSFUL MANAGEMENT OF ERYTHROMELALGIA SYMPTOMS WITH TOPICAL KETAMINE AND CLONIDINE: A CASE REPORT

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Background and Importance Erythromelalgia (EM) is a rare clinical syndrome that may be associated with myeloproliferative disorders. Due to the incomplete elucidation of its pathogenesis, effective pharmacological management of intermittent triad of symptoms – pain, heat, and redness in the extremities – remains challenging. Despite avoiding precipitating factors such as ambient heat and exercise, patients continue to experience episodic symptoms that significantly diminish their quality of life.

Aim and Objectives This study aims to review the published evidence on topical treatments for EM and present our single-centre experience through a case study.

Material and Methods A comprehensive literature search was performed in PubMed using the MeSH headings 'erythromelalgia' and 'administration, topical' without restrictions on date or publication language. Other resources included Google Scholar and UpToDate. We present data from a 54-year-old female patient with arterial hypertension, diagnosed with a myeloproliferative disorder in 2002 and treated with anagrelide and aspirin. Her initial episodes of erythromelalgia were noted in 2019. The patient's medical records were reviewed using the electronic prescribing system, and a treatment plan by a clinical pharmacist was developed in collaboration with a haematologist.

Results Published literature shows there is a paucity of robust evidence: mainly anecdotal experience or case series that describe topical agents, mainly ointments or patches, with non-steroidal anti-inflammatory agents, lidocaine, capsaicin, gabapentin and combination treatments with ketamine and amitriptyline or clonidine to alleviate EM pain. Topical midodrine, oxymetazoline, brimonidine tartrate, and timolol maleate are also used to reduce redness. Our patient responded well to the compounded combination of amitriptyline 1% and ketamine 0,5% in white vaseline, applied thrice daily. When EM episodes returned in 2024, there was an amitriptyline shortage, and alternative extemporaneously compounded ointment with ketamin 2% and clonidine 0,1% in SydoFarm was prescribed to be applied thrice daily, along with education on nonpharmacological measures such as ice cooling the affected area, limb elevation or fan use.

Conclusion and Relevance Topical compounded formulations containing combination of ketamine and amitriptyline or clonidine effectively alleviated EM symptoms in our patient, significantly improving her quality of life without significant adverse reactions. Topical agents may be safe first-line treatment for EM symptoms, especially when accompanied by nonpharmacological measures.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

4CPS-102 ASSESSING THE IMPACT OF SPECIALIST PHARMACIST REVIEW ON THE SAFETY OF MEDICATIONS IN PATIENTS RECENTLY DISCHARGED FROM INTENSIVE CARE

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Background and Importance Medication review, with input from pharmacy, is a national standard for post intensive care (ICU) follow-up (GPICS, 2022). Despite this, few ICU pharmacy teams provide input at transfer of care. This study evaluated the impact of a specialist pharmacist review on medication safety for this patient group.

Aim and Objectives To explore the number, and quality of interventions made by specialist ICU pharmacists following targeted review post ICU discharge.

Material and Methods This was a prospective, multi-centre, cross-sectional, point prevalence study. Hospitals across southwest England were invited to participate. Patients were eligible for review if discharged from ICU to a ward during a five-day study period in June 2023. Reviews were conducted in person or remotely. Data were collected using an anonymised electronic form during the review. Data included type and frequency of intervention. The Harm Associated with Medication Error Classification tool was used to categorise interventions by the levels of potential harm, this was completed by an independent pharmacist at the base site. Results were analysed using descriptive statistics.

Results Overall,134 patients were reviewed after discharge from ICU, of these 106 (79%) required a pharmacist intervention. Pharmacists made 344 interventions overall, with a mean 2.6 interventions per patient.

Potential moderate harm was prevented by 8% (n=28) of the interventions, including stopping antibiotics which continued after planned course, errors in antihypertensive dosage, and not restarting regular medications.

Potential serious harm was prevented by 2% (n=8) interventions; including incorrect doses of anticoagulants, inadvertent cessation of antimicrobials and absence of therapeutic drug monitoring in high-risk medications.

Conclusion and Relevance Specialist Pharmacist review has the potential to reduce harm from medications in patients recently discharged from ICU. Medication errors at transfer were substantial, and more prevalent than in a large international study (Wang, 2022). This is the first UK study evaluating the impact of pharmacist intervention in this population. Further work should focus on the feasibility and cost-effectiveness of implementing this service.

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Conflict of Interest No conflict of interest

4CPS-103 COST MODEL OF LONG-TERM PROPHYLAXIS TREATMENT IN VON WILLEBRAND DISEASE

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Background and Importance Prophylaxis with plasma-derived von Willebrand factor (VWF)/factor VIII (FVIII) concentrates is an alternative for persons with von Willebrand disease (VWD) when treatment with desmopressin failed. Clinical efficacy of VWF/FVIII concentrates is stablished in the literature, but there is a lack of evidence in terms of costs.

Aim and Objectives To describe a cost model based on VWF dosage of commercialised VWF products in Spain (Hamate-P, Wilate and Fandhi) for long-term prophylaxis.

Material and Methods Cost analysis was based on the dosage of VWF:RCo ristocetin cofactor per kg of body weight of each plasma-derived VWF concentrate according to previous reports from Miesbach et al. 2021 and Jimenez-Yuste et al. 2022, and the recommendation of Summary Product Characteristics (twice a week). The range of doses tested was Haemate-P 10–70 IU/kg, Fanhdi 10–70 IU/kg and Wilate 20–40 IU/kg. The unitary cost of each treatment was obtained from the official public database of the Spanish National Health System (NHS).

Results Between 69 and 75 kg: at low doses, Wilate represents an increase up to € 40,872 per year and Fanhdi € 21,216 per year vs Haemate-P; at high doses, Wilate represents an increase up to € 21,840 per year and Fanhdi € 85,488 per year vs Haemate-P. Between 25 and 34 kg: at low doses, Wilate represents an increase up to € 20,592 per year and Fanhdi € 624 per year vs Haemate-P. At high doses, Wilate represents an increase up to € 20,904 per year and Fanhdi € 42,432 per year vs Haemate-P. In all cases Haemate-P prophylaxis was the most economic choice in terms of cost. Also, both, total vWF IU consumption and vial use per year, were higher with Fanhdi and Wilate.

Conclusion and Relevance In the model, long-term prophylaxis with Haemate-P was more efficient than Fanhdi and Wilate in VWD treatment based on pharmacological cost acquisition. More pharmacoeconomic analysis will be necessary to assess cost-effectiveness from society perspective in long-term prophylaxis in persons with VWD.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-104 CORRELATION BETWEEN HYPERIMMUNE ANTI-HEPATITIS B IMMUNOGLOBULIN LEVELS AND CLINICAL PARAMETERS IN LIVER TRANSPLANT RECIPIENTS WITH HBV INFECTION

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Background and Importance Routine vaccination has reduced hepatitis B virus (HBV) incidence. However, the detection of cases, mostly imported, highlights the ongoing need for effective, safe, and up-to-date HBV treatments.

Aim and Objectives This study evaluates the anti-hepatitis B immunoglobulin (HBIg) serum concentrations, in HBV-infected liver transplant patients, during induction and maintenance treatment after transplantation, and clinical and analytical factors that may influence their consistency.

Material and Methods Ambispective, observational study included HBV-infected liver transplant patients on HBIg treatment from April 2018 to February 2024. Anthropometric, clinical, treatment (concomitant oral antivirals and immunosuppressive treatment) and analytical data were collected. Induction HBIg dose was 4000UI on day 1, 2000UI from day 2–7 and 1000–2000UI/month for maintenance. Therapeutic target range of HBIg concentrations during induction was 100–150UI/L(HBV-DNA negative) or >500UI/L(HBV-DNA positive) and >100UI/L during maintenance.

Results Thirty patients (23/30[76.67%] men, 51.8(SD,12.65) years and 76.41(SD,11.41)kg) requiring liver transplantation for liver failure secondary to HBV infection were included.

All patients received HBIg during induction (median, interval), 243.3UI/kg/month, 276.9–197.8) and maintenance (17.3UI/kg/month, 27.8–11.0) with pre-dose serum HBIg levels (mean, SD) of 234.2IU/L(328.9) and 326.7IU/L(261.5), respectively. The high inter-individual coefficient of variation(CV) observed −140.4% and 80.0%- results in 50% -in induction- and 29% -in maintenance- of the patients having mean values <100 IU/L, including 21/29(72.4%) and 13/35(37.1%) of the individual values.

Serum HBIg concentrations during induction and HBIg dose were not associated (P=0.434), although they were related during maintenance (P=0.007 and 74.4% of the variability explained). Recovery, expressed as UI/L HBIg per UI/kg/month administered, varied significantly between periods; P=0.004, and was 0.93(interval 3.78–0.09) and 17.14(26.31–3.81), respectively.

Serum HBIg concentrations during induction and maintenance phases differ in magnitude but show no significant association with sex (mean M/F, 266.6/136.9-induction- and 385.7/303.1-maintenance-), pre-transplant HBIg levels (+/-, 99.4/458.7-induction- and 267.9/473.8-maintenance-), pre-(+/-, 123.6/271.0-induction- and 212.0/372.6-maintenance-) or post-transplant viral load (+/-, 70.4/257.6-induction- and 58.6/371.4-maintenance-), HDV status (+/-, 390.2/92.2-induction- and 443.3/169.8-maintenance-), or the antiviral used (entecavir/tenofovir, 138.8/291.4-induction- and 539.1/241.8-maintenance-). There was no association with weight, height or BMI.

Conclusion and Relevance Serum HBIg concentrations and recovery showed significant inter-individual variability, making regular monitoring essential. Moreover, low HBIg concentrations during induction suggest the need for higher doses to reach the therapeutic range and ensure immunisation against HBV.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-105 EVALUATION OF ADHERENCE AND VIRAL LOAD ACCORDING TO THE ANTIRETROVIRAL TREATMENT REGIMEN IN PATIENTS WITH HIV

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Background and Importance Optimal adherence is necessary for HIV viral suppression. The tolerance and the complexity of the treatment are factors related to non-adherence.

Aim and Objectives Determine if there are differences in adherence rate and viral suppression according to antiretroviral (ART) regimen.

Material and Methods Retrospective observational multidisciplinary study including HIV adult patients, on ART treatment in November 2023, at least for 3 months.

Adherence to ART was calculated assessing the medication possession rate (MPR) in the previous 12 months. The nearest viral load to inclusion date are obtained, considering viral suppression as HIV RNA< 50 copies/mL

ART regimen was classified as follow: protease inhibitor (PI) based, integrase inhibitor (INSTI) based, non-nucleoside reverse transcriptase inhibitor (NNRTI) based, INSTI plus NNRTI based and all other regimens.

Means (or medians) and standard deviations (or interquartile ranges) were used for continuous variables. Frequencies and percentages for categorical variables in the descriptive analysis too. Statistical calculations were performed using SAS System v9.4 software. Statistical significance was assumed when $p<0.05$.

Results 574 patients were selected. The mean patient age was 54.5 years old (SD 11.0), 71.4% of patients were male. Overall, 531 (92.5%) patients were virally suppressed (92.9% if we excluded naïve patient with less than 48 week in treatment). Median CD4+ count was 659.0 (IQR 465–872) and the overall mean adherence was 95.7% (SD 9.6).

INSTI- based treatment was the most commonly prescribed regimen in 267 (46.5%) cases, NNRTI in 126 (22%), INSTI/NNRTI in 92 (16%), PI in 49 (8.5%) and all other-based regimens in 40 (7%).

The mean adherence according to the type of treatment was INSTI 95.4% MPR (SD 10.5); NNRTI 96.0% (SD 7.4); INSTI/NNRTI 96.8% (SD 8.2); PI 95.3% (SD10.4); all other 93.7% (SD 10.7). There were no differences between the treatment groups in relation to adherence (p= 0.235). Neither in terms of age, sex or viral load.

Conclusion and Relevance In our cohort of study, we did not detect any significant differences in adherence nor viral suppression according to the type of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-106 NOVEL APPROACH TO AN UNCOMMON CASE: ACINIC CELL CARCINOMA OF THE SALIVARY GLANDS TREATED WITH LENVATINIB

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Background and Importance Acinic cell carcinoma (ACC) of the salivary glands is an extremely rare tumour, representing 6–8% of salivary carcinomas. Surgical excision is the main treatment for low-grade tumours; however, treatment in high-grade malignancies remains unclear, with most cases managed through surgery and adjuvant radiotherapy. The average recurrence rate is around 35%, commonly involving cervical lymph nodes and lungs

Aim and Objectives The objective of this study is to evaluate the efficacy and safety of lenvatinib used off-label for metastatic ACC.

Material and Methods A 65-year-old male patient was diagnosed with localised ACC in March 2015 and underwent radical parotidectomy and petrosectomy followed by radiotherapy. After 6 years without symptoms, a biopsy confirmed metastasis in January 2021, and carboplatin-paclitaxel was chosen for its lower toxicity. In September 2021, the patient experienced new pleural progression and initiated treatment with lenvatinib.

Results The patient continued with lenvatinib for 1 year at a daily dose of 24 mg, with breaks on weekends, and tolerated it except for grade 1 mucositis and diarrhoea. In September 2022, pleural and pericardial relapse prompted next-generation sequencing, but preserved MLH1, PMS2, MSH2, and MSH6 made the patient unsuitable for immunotherapy, leading to doxorubicin initiation. As of April 2024, 18 months after starting doxorubicin, the patient remains stable.

Conclusion and Relevance Lenvatinib was chosen based on current evidence, which reports mutations in 76% of ACC patients for vascular endothelial growth factor (VEGF) and in 90% of the c-kit receptor. Lenvatinib is a tyrosine kinase inhibitor (TKI) that inhibits VEGF receptors and other TKIs, justifying its use.

After a review, we found only one published Phase II clinical trial that showed a time to event of 8 months, while this patient achieved 12 months. This clinical case represents one of the few real-world evidences published on the treatment of ACC with lenvatinib. Through this treatment, the patient has achieved a new therapeutic line that has significantly contributed to an optimal quality of life.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-107 EVALUATION OF EARLY ORAL SWITCH IN ANTIMICROBIAL THERAPY INTERVENTIONS THROUGH THE WASPSS PROGRAMME IN THE WORK OF PROA TEAMS

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Background and Importance Within the framework of the National Plan Against Antibiotic Resistance (PRAN), the WASPSS (Wise Antimicrobial Stewardship Programme Support System) application has been implemented in our health area to facilitate the management of antimicrobial treatments (AT) within the Antimicrobial Stewardship Programmes (PROA). This tool generates predefined alerts used by PROA teams (Pharmacy, Microbiology, and Infectious Diseases) to optimise AT. In this analysis, we reviewed the alerts related to intravenous AT longer than 3 days with good oral bioavailability.

Aim and Objectives To analyse the outcomes of alerts generated for intravenous AT longer than 3 days with good oral bioavailability through the WASPSS application within the PROA program established in our area.

Material and Methods Data were collected using the WASPSS application from October 1st, 2022, to October 1st, 2024, resulting in a total of 2252 AT-related alerts. These alerts were categorised by patient's clinical record number, clinical service, treatment, response, action taken, and the responder's identity. The patient's clinical record numbers were removed for data analysis.

Results Of the 2252 alerts registered in WASPSS, this study focused on 227 alerts (10.08% of the total alerts) related to intravenous AT longer than 3 days with the potential for Early Oral Switch (EOS). The clinical services most frequently involved were General and Digestive Surgery (35.24%), Internal Medicine (19.38%), and Haematology (14.1%). The most frequently implicated antibiotics were metronidazole (39.21%), ciprofloxacin (15.86%), and levofloxacin (13.22%). Of the 227 recommendations, 60% were accepted, resulting in the implementation of EOS, and 10% received validation of the treatment.

Conclusion and Relevance Ten percent of the alerts corresponded to intravenous AT suitable for conversion to oral therapy, of which 60% of the recommendations resulted in the implementation of EOS. The service most frequently

involved was General and Digestive Surgery (35.24%), and the most commonly used antibiotic was metronidazole (39.21%), which may be attributed to delays in transitioning to oral therapy after surgical interventions. Nevertheless, the implementation of the WASPSS system has increased the EOS rate in these services. However, efforts are ongoing to optimise the alert-recommendation-response process to improve the precision in EOS management.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-108 EFFECTIVENESS OF BOTULINUM TOXIN TREATMENT IN PATIENTS WITH BLEPHAROSPASM

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Background and Importance Benign essential blepharospasm (BEB) is a focal and functional cerebral dystonia characterised by excessive involuntary blinking that can lead, in severe cases, to functional blindness due to the inability to reopen the eyes at will.

Its prevalence is estimated at approximately 1/33,000.

Treatment is based on neurobotulinum toxin A injections.

Aim and Objectives Our objective was to analyse the situation of patients in our hospital and to evaluate the effectiveness of treatment with botulinum toxin A.

Material and Methods A retrospective study was performed. Sociodemographic data were obtained from the review of medical records.

The variables used were: age, sex, indication, commercial presentation of neurotoxin A used, number of administrations, associated pathologies, responses and adverse effects.

Results 39 patients were included in the study period which was from January 2021 to September 2024, all female and aged between 61–82 years, with a median 73 years. Forty-four percent were bilateral blepharospasm. In 26/39 patients the commercial presentation Botox was used, in 12/39 Xeomin was used and in 1/39 Dysport was used, with a mean of 3 administrations per patient and a mean time between administrations of 4.3 months.

As for associated diseases, 9/39 patients had Sjögren's syndrome. Adverse effects were only observed in one of the patients treated with botulinum toxin A, tearing and difficulty in closing the eyes for 45 days of evolution, which subsided spontaneously.

The treatment was effective in 28/39 patients while 11/39 presented moderate effectiveness to the treatment.

Conclusion and Relevance The response to treatment with botulinum toxin A was generally favourable in all our patients, being only moderately effective in 11/39 patients.

In addition, in terms of safety, only nine of our patients had adverse effects that subsided spontaneously. We can therefore conclude that the use of botulinum toxin A in blepharospasm appears to be an effective and safe treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-109 PERSISTENCE EVALUATION OF SECOND-LINE TREATMENT FOR MULTIPLE SCLEROSIS

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Background and Importance Second-line treatments manage active relapsing-remitting multiple sclerosis (RRMS) when it persists despite prior disease-modifying therapy or worsens rapidly.

Aim and Objectives To evaluate and compare treatment persistence with Fingolimod, Natalizumab, and Ocrelizumab in patients diagnosed with RRMS.

Material and Methods A retrospective observational study was conducted at a referral hospital managing 190 patients with multiple sclerosis. Patients diagnosed with RRMS who started treatment with fingolimod, natalizumab, or ocrelizumab after prior disease-modifying therapies between November-2007 and December-2023 were included. Variables collected included demographics (age, sex) and pharmacotherapeutics (previous treatment, start date, discontinuation date, and reasons for withdrawal). Data were collected using the electronic prescription system (SAVAC) and medical record system (Selene).

Categorical variables are presented as percentages (%, N), and continuous variables as median [interquartile range, IQR]. Drug persistence was analysed with the Kaplan-Meier method, and survival across treatments was compared using log-rank test. A p-value <0.05 was considered statistically significant. Statistical analyses were performed using SPSS-Statistics version 23.0.

Results A total of 95 patients were included, with 65.3% (62) being women and a median age of 40 years [IQR:20]. Treatment distribution was as follows: fingolimod (54.7%,52), ocrelizumab (23.2%,22), and natalizumab (22.1%,21). Previous treatments included glatiramer acetate (32.6%,31), interferon beta-1a (16.8%,16), natalizumab (14.7%,14), teriflunomide (13.6%,13), fingolimod (11.5%,11), dimethyl fumarate (5.2%,5), interferon beta-1b (3.1%,3), and alemtuzumab (2.1%,2).

During follow-up, 52.6%(50) discontinued therapy: 68% (34) on fingolimod (16 adverse effects, 15 inefficacy, 3 unknown); 28%(14) on natalizumab (2 adverse effects, 2 inefficacy, 10 due to anti-JCV positive); and 4%(2) on ocrelizumab due to adverse effects.

Median persistence was 97.1 months (95% CI:90.5–103.8) for fingolimod and 131.5 months (95% CI:77.8–185.2) for natalizumab, with significant differences ($p<0.017$). Ocrelizumab had a mean persistence of 39.7 months (95% CI:34.8–41.5), with the median time to discontinuation not reached. Comparing all three drugs revealed significant differences in persistence ($p<0.004$).

Conclusion and Relevance About 50% of patients continued treatment, with natalizumab showing greater persistence than fingolimod, which had high discontinuation rates due to adverse effects and inefficacy. Ocrelizumab's median persistence is undetermined, emphasising the need for long-term studies. With new RRMS therapies emerging, real-world comparisons of effectiveness and persistence are crucial for clinical decision making.

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

4CPS-110 USE OF ASPARAGINASE IN A TERTIARY CARE HOSPITAL. HOW TO DEAL WITH HYPERSENSITIVITIES?

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Background and Importance Asparaginase, derived from *Escherichia coli*, in its native (Kidrolase) or pegylated (Oncaspar) form, is a crucial component of multi-agent chemotherapy regimens for achieving optimal therapeutic outcomes in the treatment of acute lymphoblastic leukaemia (ALL). However, hypersensitivity reactions, both overt allergic responses and subclinical hypersensitivities (silent inactivation), can compromise the treatment's effectiveness. Due to the limited evidence supporting desensitisation protocols in allergic patients, the search for less immunogenic variants without cross-reactivity has led to the use of Erwinase, which has also shown efficacy in patients with silent inactivation.
Aim and Objectives This study aims to describe the use of Asparaginase in its various forms in paediatric patients with ALL at a tertiary care hospital. We analysed the reasons for switching from Kidrolase and Oncaspar to Erwinase and evaluates the prevalence of allergic reactions and silent inactivation with each formulation.
Material and Methods Observational, retrospective, single-centre study that included all paediatric patients treated with Asparaginase from January 2011 to August 2024. Clinical data and allergic reactions were collected using the hospital´s electronic medical report programme and the oncohematologic software Farmis-Oncofarm. The Medicine Laboratory reported on silent inactivating patients detected as of June 2022, when the measurement technique was implemented at the centre.
Results A total of 221 patients received Asparaginase: 110 started with Kidrolase, of which 30 were switched to Oncaspar due to changes in hospital protocols, and 111 initiated treatment with Oncaspar. Nineteen percent of patients (42/221) required a switch to Erwinase: 37 due to allergic reactions and 5 due to silent inactivation. Allergic reaction rates were 29% (23/80) with Kidrolase and 10% (14/141) with Oncaspar. Silent inactivation was detected in 5 patients, with a prevalence of 7% (5/72).
Conclusion and Relevance A significant percentage of patients required a switch to Erwinase, primarily due to allergic reactions. The prevalence of allergies and silent inactivation was comparable to literature reports, which report allergy rates of 30–60% to Kidrolase and 10–30% to Oncaspar, as well as subclinical hypersensitivities to Oncaspar ranging from 5–20%.

Erwinase has been a therapeutic breakthrough in ALL, allowing treatment of allergic patients or silent inactivators.

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

4CPS-111 PERSPECTIVES OF PHYSICIANS ON THE INTEGRATION OF HOSPITAL PHARMACISTS IN MULTIDISCIPLINARY HEALTHCARE TEAMS

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Background and Importance Hospital pharmacists are essential in patient care because they contribute to medication and clinical decision making safety within multidisciplinary teams. However, there is limited research on hospital pharmacy practice in Central Eastern European countries.

In recent years, small amount of publications has addressed this topic, revealing significant gaps in understanding and integration. Although 19 (31.67%) hospitals out of 60 in country 'X' have a hospital pharmacy licence, the roles and potential contributions of hospital pharmacists within these settings remain largely unexplored.

In contrast, other Western European countries healthcare systems benefit from the integration of hospital pharmacists, where involvement has been shown to improve patient medication safety and outcomes.

This study addresses these gaps by investigating physicians' knowledge and attitudes towards hospital pharmacists. Understanding (knowledge) how doctors perceive the integration of pharmacists into healthcare teams is crucial for improving collaboration and enhancing patient care outcomes.
Aim and Objectives The study aims to investigate physicians' general knowledge of the roles and functions that hospital pharmacists could provide within their clinical practice.
Material and Methods An on-line questionnaire was created to assess physicians' knowledge of the potential roles of hospital pharmacists in their practice and their willingness to integrate pharmacists into multidisciplinary healthcare teams. The questionnaire was sent via email to doctors of various specialisations. Quantitative data were captured through multiple-choice and Likert scale questions, while qualitative data were collected via a free-text box.
Results Physicians are comfortable with hospital pharmacists handling easy tasks, like providing pharmaceutical information (94.5% agree) and overseeing medication monitoring (80% agree). However, they are less supportive of more advanced roles, with only 23.6% agreeing that hospital pharmacists interpret clinical test results and 12.7% supporting independent prescribing.
Conclusion and Relevance Physicians recognise hospital pharmacists' roles in medication information and monitoring but are less supportive of their integration into advanced clinical functions. To improve integration, targeted education is needed to raise awareness of pharmacists' roles and perceptions of clinical decision making. Strengthening collaboration between doctors and pharmacists could enhance patient care outcomes and healthcare efficiency.

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

4CPS-112 EFFICACY OF FARICIMAB IN NEOVASCULAR AGE-RELATED MACULAR DEGENERATION

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Background and Importance Neovascular age-related macular degeneration (nAMD) is characterised by the growth of new vasses from the choriocapillaris extending into the retina, threatening the photoreceptors or the retinal pigment epithelium (RPE). Exudation, fluid accumulation and vessel haemorrhages can lead to loss of vision, due to detachment of the RPE or subretinal fibrosis, if not treated promptly.
Aim and Objectives To report a case series of initial responses to intravitreal faricimab in patients already undergoing anti-VEGF therapy for nAMD.
Material and Methods 70 eyes of patients with nAMD who did not improve while receiving treatment with anti-VEGF therapy (aflibercept or ranibizumab) at a tertiary hospital were included. Patients were switched to intravitreal faricimab. A prospective review of patients treated with faricimab for nAMD since October 2023 and with at least 3 months of follow-up since initiation of the new drug was performed. Collected data includes sex, age, previous treatment history, and pre- and post-treatment visual acuity. The main outcome measures are changes in visual acuity, central macular thickness and intraretinal/subretinal fluid (IRF/SRF) values before and after at least one injection of faricimab. Optical coherence tomography scans were performed before starting faricimab and afterwards, as well as VA scanning and patient symptom reporting.
Results Of the total number of patients included, 41% were female. The median age was 70.2 ± years (IQR: 62.75–77). 57.1% of patients were treated in the right eye and the rest in the left eye. After at least one injection of faricimab, the majority of eyes (n= 70), showed an improvement in VA (53%), 29% remained the same and only 11% worsened. Also, 53% eyes (n=37) showed a decrease in central macular thickness. One case of endophthalmitis was observed after two faricimab injections, which was treated with intravitreal antibiotics and resolved.
Conclusion and Relevance While we await the opportunity to conduct a complete data analysis with our patient series, the preliminary results appear promising. Faricimab has demonstrated improvement or maintenance of visual acuity in patients with nAMD, indicating its potential to reduce the treatment burden in AMD.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-113 IMPACT OF ANTIMICROBIAL STEWARDSHIP PROGRAMMES AUTOMATIC ALERTS IN IMPROVING THE DURATION OF ANTIMICROBIAL TRETAMENT

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Background and Importance The proportion of inappropriate or unnecessary antibiotic prescriptions in hospital settings has been estimated at 40% by various studies. One of the most frequent cause of inadequate treatment is the excessive duration of antimicrobial therapy beyond what is recommended in clinical practice guidelines.The main consequences of overuse include adverse events, bacterial resistance and higher costs.
Aim and Objectives The aim is to reduce the duration of antimicrobial treatment in hospitalised patients.
Material and Methods An automatic intervention by the Antimicrobial Stewardship Programmes (ASP) team in collaboration with information technology team was planned to reduce the duration of antimicrobial treatments. The electronic prescription programme Athos-Prisma was integrated with the clinical course of hospitalised patients. Using a Structured Query Language to Athos-Prisma, patients with antibiotic treatment for 7 or 10 days were identified. An automatic ASP note was generated daily in the patient's clinical history, indicating the antimicrobial, dosage regimen, days of treatment and recommending an assessment of continuation based on the type of infection.
Results From January 18 th to March 11 th 2024, a total of 415 automatic ASP notes were generated in the clinical courses of 260 patients. Following the informative note, the prescription was evaluated within 24 hours and, resulting in the discontinuation of, antimicrobial treatment in 113 cases (27.22%). Additionally, it was discontinued in 90 cases (21.68%) after 7 days and in 23 cases after 10 days.
Conclusion and Relevance Informatics helps identifying ASP solutions to optimise the duration of antimicrobial treatment and demonstrates a successful strategy that could easily be implemented in other hospitals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-114 INCIDENCE OF SEXUALLY TRANSMITTED INFECTIONS IN PREP USERS: IS THERE AN INCREASE?

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Background and Importance According to the regulations, the criteria for accessing pre-exposure prophylaxis (PrEP) include having had a bacterial sexually transmitted disease in the last year. However, hepatitis C must also be considered a sexually transmitted infection and may constitute a criterion for indicating PrEP. At the same time, users must meet other criteria such as not using a condom.
Aim and Objectives To analyse incidence of sexually transmitted infections (STIs) in PrEP users before and after starting to take emtricitabine/tenofovir-disoproxil-fumarate (FTC/TDF) in a third-level hospital.
Material and Methods Retrospective observational study of PrEP users who started to take FTC/TDF from December 2019 to September 2024. Demographic data(sex,age), criteria to start, STIs before and after PrEP and use of condom were recorded, as well as discontinuations.

Information was collected from the hospital's information systems.

Results 190 users, 98%men, 1.5%trangender-women, 0.5%cisgender-women, median age 40 years (21–63). All patients met the criteria for starting PrEP and maintained negative HIV-serology (100%), after a median follow-up of 21±11.51 months. 1 user had to discontinue until kidney function stabilised.

47%users had STIs recorded before taking FTC/TDF, being the most frequent Treponema pallidum (56%), associated to other infections like Chlamydia trachomatis or Neisseria gonorrhoeae (17%), in 1 case with hepatitis C virus (HCV). Other infections found were: Mycoplasma genitalium (3%) and hepatitis B virus, human papillomavirus (HPV) or herpes (1%).

After taking prophylaxis, 57%users had STIs, mainly Chlamydia trachomatis (38%), 63%associated with other bacteria: Neisseria gonorrhoeae and Mycoplasma genitalium. There was a similar number of isolated infections by Treponema pallidum, Neisseria gonorrhoeae and Mycoplasma genitalium (18,5%). In addition, 3% became infected with HCV.

Moreover, it was observed that of the people who did not contract any STI, 22%claimed not to have used a condom.

It should be noted that 9% of patients lacked data about previous STIs so we could not analyse. Taking this into account, the users who did not contract any infection are similar before and after taking the PrEP.

Conclusion and Relevance In our population, it can be shown that PrEP has been effective in preventing HIV infection. Despite STIs incidence has been similar before and after taking prophylaxis, use of condoms must be promoted to prevent further transmission of STIs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-115 DOSE-DEPENDENT RELATIONSHIPS IN PRESCRIBING CASCADES: A COHORT STUDY

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Background and Importance Prescribing cascades occur when new medications are introduced to treat adverse drug reactions (ADRs) caused by an initial (index) medication. This could lead to polypharmacy and increased healthcare costs. While dose reduction is often suggested as a strategy to mitigate prescribing cascades, the extent to which the dosage of an index medication affects the development of these cascades remains unknown.

Aim and Objectives This study aimed to investigate the dose-dependence of prescribing cascades across a range of index medications.

Material and Methods We conducted a retrospective cohort study using prescription sequence symmetry analysis (PSSA) with dispensing data from over 600 pharmacies. The relationship between different doses of index medications and 18 prescribing cascades was examined, including Angiotensin-Converting Enzyme inhibitors (ACEIs), statins, proton pump inhibitors (PPIs) and diuretics. Doses were classified using the World Health Organization's defined daily dose (DDD) into low (<0.50 DDD), medium (≥0.50 and ≤1.50 DDD), and high (>1.50 DDD) dose groups. Adjusted sequence ratios (aSRs) were calculated, with an aSR >1 indicating a prescribing cascade. Dose-dependence was confirmed when aSRs increased with higher doses and the 95% confidence intervals (CIs) between dose groups did not overlap.

Results Of the 18 cascades analysed, 12 showed a dose-dependent relationship. All seven ACEI-related cascades displayed dose-dependence. For example, the aSR for ACEI-induced cough followed by antitussives increased from 2.09 (95% CI: 1.95–2.23) in the low-dose group to 2.75 (95% CI: 2.67–2.83) in the high-dose group. Similarly, for ACEI-induced cough followed by inhaled adrenergics, the aSR rose from 0.86 (95% CI: 0.71–1.00) in the low-dose group to 1.51 (95% CI: 1.44–1.59) in the high-dose group. Statins exhibited dose-dependence in three of six cascades. No dose-dependent relationship was observed for cascades involving PPIs (1 cascade), diuretics (1 cascade).

Conclusion and Relevance These findings highlight the importance of dosage in managing prescribing cascades, particularly for ACEIs and possibly statins. Hospital pharmacists should remain vigilant for ADRs at higher doses and consider dose reduction as a strategy to reverse or prevent prescribing cascades. Further research is necessary to assess the effectiveness of dose adjustments in preventing ADRs and prescribing cascades.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-116 STUDY OF EFFECTIVENESS AND SAFETY OF CYTOREDUCTIVE SURGERY ASSOCIATED WITH HIPEC IN PATIENTS WITH PERITONEAL CARCINOMATOSIS

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Background and Importance Hyperthermic intraperitoneal chemotherapy (HIPEC) is a method of administering chemotherapy directly while heating the abdominal cavity.

Aim and Objectives The aim of the study is to evaluate effectiveness and safety of cytoreductive surgery(CRS) associated with HIPEC(Hyperthermic Intraperitoneal Chemotherapy) in patients with peritoneal carcinomatosis in real-life in a tertiary hospital.

Material and Methods Retrospective descriptive study (March 2018-September 2024) that included all patients with peritoneal carcinomatosis who received (CRS) associated with HIPEC in a tertiary hospital. We evaluated the efficacy of this technique in real-life data according to evidence from different studies in ovarian cancer, colorectal cancer and appendiceal psedomyxoma.

Demographic, clinical variables such as PCI (peritoneal carcinomatosis index) and treatment-related variables were collected from the electronic medical record and outpatient programme. The main efficacy variables were: progression-free

survival (PFS) and overall survival (OS). Safety was determined by postoperative complications. Data were analysed using SPSS
Results Thirty-four patients were included, 24 women (70.5%), median age 63 years (45–76), 18 with colorectal tumour, 13 with ovarian tumour and 3 with appendiceal pseudomyxoma. The ECOG range was 0 to 2 (ECOG 0: n=14; ECOG 1: n=9; ECOG 2: n=2). The median number of PCIs was 11 (2–24). Fourteen patients had metastatic status, of which twelve were advanced, one adjuvant and one unknown.

At the study cut-off date (30/09/2024), with a median follow-up of 22.7 months (0.5–76), the median number of prerelapse lines was 1 (0–2) and the median number of postrelapse lines was 1 (0–5). The drugs used were 5-FU + oxaliplatin in 12 patients, mitomycin in 9 and cisplatin in 13. Seventeen progressions and twelve deaths were observed.

The median duration of surgery was 420 minutes (280–810), with a median hospital stay of 15 days (6–67).

The median PFS was 7.6 months(95% CI 11–7–4.03) and OS 17.62 months(95% CI 22–1–13.1).

Regarding complications: seven patients suffered abdominal wall complications, nine gastrointestinal, four respiratory; four infectious, eight others.

Conclusion and Relevance Although our population appears to benefit from HIPEC, indirect comparisons were not feasible due to differences between populations. A longer follow-up and a larger sample size are recommended to compare each pathology separately.

Most HIPEC-related complications are linked to the complexity of the surgical procedure.

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

4CPS-117 ABSTRACT WITHDRAWN

4CPS-118 IMPLEMENTATION OF QUALITY INDICATORS FOR HOSPITAL PHARMACY SERVICES IN A UNIVERSITY HOSPITAL

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Background and Importance Quality indicators (QI) for hospital pharmacy services are measurement tools used to evaluate and improve the performance of hospital pharmacists (HPs). Unlike traditional workload measurements, these QI measure services delivered by HPs in order to optimise the use of medicines and medical devices.

Aim and Objectives The objectives of this study were to describe the national set of QI for hospital pharmacy services, and report their scores over 2024 in a university hospital.

Material and Methods In February 2024 we started implementing the national set of QI for hospital pharmacy services in a university hospital. Indicators were self-reported by HPs (N=41) and scores were expressed as: (i) number of reported adverse reactions to medicines and medical devices, (ii) number of reported quality deviations of medicines and medical devices, (iii) number of internal education programmes for healthcare professionals on medicines and medical devices, (iv) number of information and instructions to healthcare professionals on medicines and medical devices provided by HP, and (v) medication review of intrahospital antimicrobial use in intensive care units (ICU) (number of interventions/total number of patients in ICU * 100).

Results Number of reported adverse reactions and quality deviations of medicines and medical devices were low throughout 2024 (not more than 5). There was only 1 internal education programme for healthcare professionals (physicians, nurses, HPs) regarding the new website and mobile application for antibiotic reconstitution held every two months. When it comes to clinical pharmacy services, the highest number of information given to healthcare professionals by HPs was recorded in March (176) and April (135) and the lowest in June (6). Furthermore, the number of antimicrobial stewardship interventions in ICU was more than 1000 in all reported months, except June (437.5). The noticeable differences in scores were due to variations in number of HPs reporting their pharmaceutical services (11/41 and less).

Conclusion and Relevance QI enables better insight into the quality of pharmaceutical services provided by HPs and make them more aware about their own performances. These preliminary data indicate the need for further research on whether modest reporting of pharmaceutical services is due to lack of time or skills and the importance of further encouragement.

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

4CPS-119 PREDICTIVE VALUE OF THE ARCTIC SCORE AND ESTIMATED GLOMERULAR FILTRATION RATE EQUATIONS ON LEVETIRACETAM PLASMA CONCENTRATIONS IN CRITICALLY ILL NEUROTRAUMA PATIENTS

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Background and Importance Achieving optimal drug exposure can be challenging in neurocritical patients with augmented renal clearance (ARC).

Aim and Objectives To evaluate the accuracy of the Augmented Renal Clearance in Trauma Intensive Care (ARCTIC) score and different estimated glomerular filtration rate (eGFR) equations in predicting the variability of levetiracetam plasma trough concentrations (CpLEV) in critically ill patients.

Material and Methods This observational study included patients admitted to a neurotrauma intensive care unit (NT-ICU) who received levetiracetam for post-traumatic seizure prophylaxis, with CpLEV assessed between October 2019 and May 2024.

The eGFR was calculated using several equations [CKD-EPI, MDRD-6, and Cockcroft-Gault (C-G)]; and the ARCTIC score was used to predict ARC, with a cut-off value of $\geq$6. The therapeutic range of levetiracetam was defined as 10–40 µg/mL.

Statistical analyses included ANOVA, Fisher-Snedecor F-distribution, and multivariate logistic regression (SPSS v25).

Results A total of 46 patients were included (34 (74%) male): mean age 56 (range: 20–85) years; mean BMI 27 (range: 15–38) kg/m^2. Levetiracetam doses used were 500 mg/BID in 10 patients (22%), 1000 mg/BID in 28 patients (61%) and 1500 mg/BID in 8 patients (17%).

The mean CpLEV was 18.7 (SD,15.8) µg/mL: 15 (33%) were subtherapeutic and 4 (8%) were supratherapeutic. The mean eGFR was 106 (SD:31), 135 (SD:65), and 114 (SD:50) mL/min/1.73m^2 using CKD-EPI, MDRD-6, and C-G, respectively.

Several covariates were analysed (age, sex, BMI, route of administration, dose, eGFR), only dose and eGFR significantly influenced CpLEV ($p<0.001$ and $p<0.002$, respectively). CKD-EPI contributed to 26.3% of the variability in CpLEV, compared to 22.3% for MDRD-6 and 23.2% for C-G.

The probability of subtherapeutic CpLEV was higher in patients with eGFR >115 mL/min according to CKD-EPI [sensitivity: 83.3%; specificity: 62.5%], ($p=0.002$). Similarly, a higher likelihood of subtherapeutic CpLEV was observed in patients with an ARCTIC score ≥6 [sensitivity: 76.0%; specificity: 42.9%], although this was not statistically significant ($p=0.174$).

Conclusion and Relevance

- CKD-EPI is the eGFR equation that most accurately explains the variability in CpLEV.
- A significant percentage of patients had subtherapeutic CpLEV values, which correlated well with an eGFR>115 ml/min according to CKD-EPI.
- The clinical utility of ARCTIC score predicting subtherapeutic CpLEV remains limited, although it suggests a possible association.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-120 ROLE OF PHARMACISTS IN IMPROVING THERAPEUTIC DRUG MONITORING AND DOSING OF VANCOMYCIN

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Background and Importance Accurate dosing and therapeutic drug monitoring (TDM) of vancomycin are essential for effective treatment. However, achieving target concentrations often proves challenging due to weak compliance to institutional guidelines. Enhanced support and education, particularly involving pharmacists, are suggested to improve TDM practices of vancomycin.

Aim and Objectives To evaluate the impact of pharmacist intervention on 1) the time to initial target attainment of vancomycin and 2) compliance with institutional TDM guidelines. Furthermore, TDM related issues were identified and factors influencing the time to target range were investigated.

Material and Methods A retrospective and prospective cohort of hospitalised patients (≥ 18 years) receiving vancomycin (≥ 72 hours) intravenously were observed and compared over a period of 1.5 years. Patient characteristics, dosing and TDM data were collected for both cohorts. A pharmacy advisory service was set up during the prospective cohort over a period of three months. The service was weekly staffed by a clinical pharmacist and provided dosing and TDM recommendations of vancomycin. Outcome measures were time to initial target attainment of vancomycin and compliance with TDM guidelines. The impact of infection type, chronic kidney disease, age, and medical discipline on the time to target range were also evaluated.

Results Analysis included 85 patients (94 vancomycin courses). The study revealed poor adherence to TDM guidelines, with only 43.1% of courses starting at a correct dose. Blood samples were incorrectly timed in 39.2% of cases, and only 46.5% of dose adjustments were made correctly. The pharmacy advisory service significantly improved TDM practices, with correctly timed blood samples increasing from 8.4% to 14.5% (p 0.029) and correct dose adjustments rising from 46.5% to 70.7% (p 0.001). Median time to target range shortened with one day (2.4 days; 95% CI 0.9–3.9) compared to courses without pharmacy advisory service (3.6 days; 95% CI 3.2–3.9; p 0.645). Non-severe infections, chronic kidney disease, and pharmacist involvement were significantly associated with a shorter time to target range of vancomycin ($p \leq 0.05$).

Conclusion and Relevance Provision of TDM guidelines alone is not sufficient in ensuring correct prescription and monitoring of vancomycin. Daily dosing guidance by pharmacists may enhance TDM practices and may shorten time to target attainment of vancomycin.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-121 RETROSPECTIVE OBSERVATIONAL STUDY ON DULOXETINE USE FOR THE TREATMENT OF URINARY INCONTINENCE

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Background and Importance Urinary incontinence (UI) affects many, especially older adults, with limited success from conventional treatments. Duloxetine, an antidepressant, has shown potential in treating stress urinary incontinence by improving urethral sphincter control. However, its off-label use is controversial due to side effects, making further evaluation of its safety and effectiveness necessary.

Aim and Objectives To evaluate the use of duloxetine for urinary incontinence (UI) as well as its safety, and adverse effects.

Material and Methods A review was conducted of duloxetine prescriptions from the urology department for UI treatment after the failure of other conventional therapies (mirabegron, solifenacin, fesoterodine, oxybutynin, tamsulosin, propiverine). Data from January 2022 to December 2023 were analysed, focusing on effectiveness and safety up until February 2024.

Variables recorded included age, sex, prescription date, treatment duration, adherence, previous treatments, adverse effects, use of incontinence pads, and prescribing physician.

Results The study included 51 patients (44 men, 7 women), with an average age of 68.15 years. Twenty-four patients had a general diagnosis of UI, while 27 had specific diagnoses (21 with stress UI and 6 with mixed UI). At the time of analysis,

39.2% (20 patients) were still on duloxetine. However, 31 patients had discontinued the treatment. In 22/31 (70.97%) of these cases, no specific reason for discontinuation was recorded, while 4 (12.90%) cases stopped due to toxicity (dizziness, nausea, mental fogginess), 3 (9.68%) cases due to sexual dysfunction, and 2 (6.45%) patients due to hypertension.

The duration of treatment ranged from 3 months to 2 years, with a mean of 617 days for the 20 active patients. Of the 51 patients, 21 (41.18%) had previously tried other treatments for UI, while no prior treatments were recorded for the remaining 30 (58.82%). Additionally, 19 of the patients (37.25%) were prescribed incontinence pads, and among those, 7 were actively using duloxetine.

Conclusion and Relevance The data do not support the off-label use of duloxetine for UI without restrictions. Nearly a quarter of the patients on active treatment still required incontinence pads. Over half of the patients discontinued the treatment, with some citing adverse effects such as toxicity, sexual dysfunction, and hypertension.

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

4CPS-122 ANALYSIS OF THE APPROPRIATENESS OF TAFAMIDIS PRESCRIPTION FOR THE TREATMENT OF PATIENTS WITH TRANSTHYRETIN CARDIAC AMYLOIDOSIS

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Background and Importance Tafamidis 61 mg has recently been authorised in our country to treat the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM), considering the results of the ATTR-ACT trial.

Aim and Objectives To analyse the appropriateness of initial prescribing of tafamidis in patients with ATTR-CM.

Material and Methods An observational, descriptive, and prospective study of initial prescriptions of tafamidis for the treatment of patients with ATTR-CM. The study was conducted in a university hospital from September 2023 to September 2024.

All patients for whom treatment was requested were included, based on selection criteria from the ATTR-ACT trial. Request evaluations were conducted by a pharmacist, and discrepancies were resolved by multidisciplinary consensus.

Apart from baseline characteristics of the patients, other variables for not initiating treatment according to the centre's protocol were considered: glomerular filtration rate (GFR) <25 mL/min/1.73 m^2, transaminase values >2 times the upper limit of normal (ULN), and modified body mass index (mBMI) <600 kg/m^2*g/L.

Results The study included 36 patients with ATTR-CM (79% male); 2/36 patients had a diagnosis of hereditary ATTR-CM, while the rest had wild-type ATTR-CM. The median age was 82 [range 79–86] years.

The baseline characteristics of the patients who started treatment were: mean left ventricular ejection fraction (LVEF) 56% (SD: 8), New York Heart Association (NYHA) heart failure class: II (24/33) and III (3/33), median NT-proBNP biological marker 2,243 pg/mL [IQR 1,809–5,015], mean interventricular septum wall thickness 15 (SD: 3) mm, 6-minute walk test 273 (SD: 122) m, 29/33 had nuclear imaging grade 3 and 4/33 grade 2. Other recorded variables included: mean GFR 51 (SD: 18) mL/min/1.73 m^2 and mean mBMI 107 (SD: 17) kg/m^2*g/L.

Treatment with tafamidis was initiated in 33/36 patients, while 3/36 patients did not start treatment due to not meeting the established criteria: one patient had left ventricular ejection fraction (LVEF) <50% and two had transaminases >2 ULN.

Conclusion and Relevance The majority of tafamidis 61 mg prescriptions in patients with ATTR-CM met the established criteria.

Discrepancies during pharmaceutical validation were resolved by consensus among the multidisciplinary team members at the centre.

A high percentage of patients (94%) treated with tafamidis were diagnosed of wild-type of ATTR-CM.

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

4CPS-123 TERRITORIAL CLINICAL PHARMACY MANAGED BY A LOCAL HEALTH UNIT

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Background and Importance In 2022, oral antivirals Molnupiravir and Nirmatrelvir/ritonavir were authorised for the treatment of COVID-19 in adults. Local Health Unit established the operational modalities for the management of therapy; a corporate path was set up including synergistic cooperation of several professionals, including the pharmacist. Drugs were delivered to patient's home by dedicated mobile operational units made up of doctors and nurses.

Aim and Objectives The aim of the study was to provide and test territorial clinical 'telepharmacy' potential and effectiveness with reference to pharmaceutical counselling and therapy monitoring mainly to improve therapeutic adherence and to collect adverse event report.

Material and Methods Eligible subjects for each treatment were intercepted by general practitioners, doctors of hospitals and of dedicated mobile operational units. Pharmacists of the Pharmaceutical Department conducted clinical pharmacy activities, through telephone monitoring of patients on second, fourth, sixth and fourteenth day of therapy, which included submitting of a questionnaire and providing clarifications on time schedule, dosage, ways of taking the drug and pharmaceutical interactions. Data from questionnaire were collected in a database and those missing in the National Pharmacovigilance System were entered. All oral antiviral drug dispensations from 10/01/2022 to 10/06/2022 were examined.

Results From 10/01/2022 to 10/06/2022, 547 patients were treated with molnupiravir and 58 with PF-07321332/ritonavir. These patients joined to telephone monitoring of 361 (66%) and 34 (59%), respectively. Of all responders, 94% adhered to teraphy and 11% declared they understood correct dosage and ways of taking the drug only after monitoring.

Furthermore, this activity has detected a higher number of adverse reactions than those reported in the regional National Pharmacovigilance Network, specifically 91 associated with molnupiravir (97.8% of total regional data) and 14 associated with nirmatrelvir/ritonavir (70% of total regional data).
Conclusion and Relevance This experience, although conducted only through telephone contact and in a period of great psychological sensivity of the population, has demonstrated the opportunity and validity of the development of 'telepharmacy' tools through which to conduct local clinical pharmacy. Therefore it would be desirable to involve the clinical pharmacist also at territorial level, using new modes of communication and exploiting digitalisation and 'telepharmacy'.

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

4CPS-124 ALGORITHM FOR PRIORITISATION OF PATIENTS FOR CLINICAL PHARMACY MEDICATION CHECK: PROOF OF CONCEPT

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Background and Importance Our Clinical Pharmacy Department provides its services for more than 35'000 inpatients annually, but the number of clinical pharmacists is insufficient to cover the whole hospital with routine clinical pharmacy services. To increase efficacy of our work, we see a potential in a digital solution. Here we evaluated an algorithm to identify patients with increased risk for severe medication error.
Aim and Objectives Based on the results from the previous trial conducted in our intensive care unit (ICU) by *Schlup et al. (2021)*, we were able to statistically identify the following surrogate markers for patients at risk of severe medication errors: reduced estimated glomerular filtration rate (eGFR), number of prescribed drugs and presence of the high-risk medication. Our aim was to test the selection algorithm in more heterogenous population compared to the ICU.
Material and Methods On an internal medicine ward, we carried out regular medication check and categorised the severity of the medication errors. We evaluated whether patients with potentially severe medication errors could have been identified when fulfilling one of the following parameters: eGFR (according to CKD-EPI) ≤40 ml/min/1.73 m^2, number of drugs (without reserves) n≥10, presence of pre-defined high-risk medication. Based on these data we calculated the sensitivity and specificity of the algorithm.
Results During the period October 2023 - April 2024 we evaluated prescriptions of 222 patients. In 158 patients we found at least one potentially severe medication error. The algorithm was able to correctly identify 114 of those patients. In 29 patients, the algorithm delivered false positive result. Its sensitivity was 72% and specificity 55%.
Conclusion and Relevance This feasible and simple algorithm, which will be adopted in our clinical software, can help to prioritise patients who would profit the most from the clinical pharmacy services in a cost-effective manner.

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

4CPS-125 EFFECTIVENESS AND SAFETY OF TRASTUZUMAB DERUXTECAN FOR THE TREATMENT OF UNRESECTABLE OR METASTATIC HER2-POSITIVE BREAST CANCER

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Background and Importance Trastuzumab deruxtecan has shown promising efficacy results in clinical trials for unresectable or metastatic HER2-positive breast cancer. It is crucial to assess whether these outcomes are replicated in real-world studies.
Aim and Objectives To evaluate the effectiveness and safety of trastuzumab deruxtecan in patients with unresectable or metastatic HER2-positive breast cancer in a tertiary hospital.
Material and Methods Retrospective observational study that included all women who received trastuzumab deruxtecan until September-2024.

Data collected included demographics (age), cancer staging, oestrogen and progesterone receptor status (positive or negative), metastatic or non-metastatic debut of breast cancer, metastases at baseline, performance status, treatment line which trastuzumab deruxtecan is used in, number of cycles and treatment reductions/delays.

Effectiveness was assessed by overall survival (OS) and progression-free survival (PFS), while safety was assessed by recording adverse events (AEs). The Kaplan-Meier method and SPSS-software (V25.0) were used for survival analyses.
Results 33 patients were included, median age 54 years (range 37–80). All patients were stage IV, 72.7% and 48.5% were oestrogen and progesterone receptor-positive respectively and 48.5% had metastatic cancer at diagnosis. Before trastuzumab deruxtecan, 57.6% of patients had bone metastases, 48.5% had liver, 27.3% brain, 24.2% lung, 21.2% lymph node, 6.1% skin, and 3% had ovarian, pleural, and pericardial metastases. 48.5% had ECOG-0, 48.5% ECOG-1 and 3% ECOG-2. Trastuzumab deruxtecan was used first-line in 3% of patients, second-line in 42.5% of patients and third-line or higher in 54.5% of patients. The median number of cycles received was 17 (range 3–35). 48.5% and 60.6% of patients required at least one dose reduction or treatment delay due to drug toxicity respectively.

Median OS was not reached while median PFS was 18.9 months (95% CI, 13.6-NR).

Adverse events occurred in 93.9% patients, with the most common being nausea (87.1%), asthenia (67.7%), anaemia (38.7%), vomiting (32.3%), diarrhoea and neutropenia (25.8%), skin rash and headache (22.6%), hyporexia and neurotoxicity (19.4%), hepatotoxicity, abdominal pain, and thrombopenia (12.9%), dysgeusia (9.7%), constipation, mucositis, pneumonitis (6.5%), and heart failure (3.2%).
Conclusion and Relevance Trastuzumab deruxtecan is effective, with a 18.9-month PFS median, but it is associated with a high rate of adverse events, necessitating close clinical monitoring. Pharmacists play a key role in managing toxicities and adjusting treatment to optimise patient outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS
1. No conflict of interest.

Conflict of Interest No conflict of interest

4CPS-126 ABSTRACT WITHDRAWN

4CPS-127 CLIMATE IMPACT OF DRUGS IN THE HEALTHCARE SECTOR

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Background and Importance Climate change poses a significant challenge for global health. The World Health Organization estimates 250,000 additional annual deaths between 2030 and 2050 due to global warming. The healthcare sector is a major contributor to greenhouse gas (GHG) emissions, accounting for approx. 4.4–5.5% of global GHG emissions. In Denmark, the production and use of drugs are responsible for 25% of healthcare-related emissions.

Aim and Objectives The purpose of this scoping review was to provide an overview of existing literature concerning the climate impact from drugs in the hospital sector, thereby also highlighting any gaps in the literature.

Material and Methods We made a scoping review following PRISMA-ScR guidelines. We conducted a systematic literature search in February 2024 using the databases PubMed and Embase. Inclusion criteria were: focus on climate impact from drugs in a hospital setting, peer-reviewed original research, published within the last 20 years and in either English, Danish, Swedish or Norwegian language. We excluded studies who did not concern the hospital sector and letters, opinions, protocols and reviews.

Results Our initial search identified 2633 studies. After abstract- and full text screening, twenty articles met the inclusion criteria. Ten investigated emissions from anaesthetic gases during operating procedures and presented strategies for reduced use. Three investigated emissions from inhalers and found a great climate benefit of switching to lower emission inhalers. Three investigated overall healthcare emissions from China, England and Canada respectively and found the share of drugs to be 20–57%. Two calculated the carbon footprint of one day of cataract surgery and found drugs contributed with 7–13%. One investigated the carbon footprint from two different COVID-19 vaccines, and one calculated how lowered dosages of Trastuzumab could reduce CO2 emissions.

Conclusion and Relevance Our review demonstrated that existing literature is primarily focused on anaesthetic gases and inhaler medicine, which both show large climate impact with great potential for reduction of GHG emissions by switching to alternative drugs or drug forms. Our review established that research on the climate impact of drugs is generally still scarse, and that further research is needed in order to reduce the total carbon footprint of drug use.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-128 ANTICHOLINERGIC LOAD: A BETTER SCORE FOR A GOLD PRESCRIPTION?

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Background and Importance Many drugs have anticholinergic effects. These effects may be central and/or peripheral and may have major consequences in elderly people.

Aim and Objectives The aim of this study was to analyse the anticholinergic load (AL) of prescriptions in this population and to study the impact of pharmaceutical intervention (PI) on these prescriptions.

Material and Methods This work was carried out in collaboration with three medical unit in our institution. All patients aged at least 75 and hospitalised from July 2024 were included. For each patient, the AL was calculated at entry using the « Prescription anticholinergic load calculator »*. Each molecule has a score ranging from 0 to 3 to characterise its anticholinergic effects. The sum of the scores for each drug gives the patient's overall AL. If this was considered « high » (presence of at least one compound with a score $\geq$ 2 and/or if the overall AL was above the theoretical thresholds ($\geq$ 5 at peripheral level and $\geq$ 4 at central level)), a PI was carried out to inform the prescriber and to jointly consider a strategy to be followed. The patient's AL was again calculated on discharge from hospital.

Results Of the 60 patients included in the study: 23 (38%) had a high AL at admission requiring a PI. The completion of 23 PI led to a reduction in the discharge score for 13 patients (56%). It remained the same for 8 patients (35%) and increased for 2 (9%). Of these patients, 15 had a drug classified as « 3 » in their initial treatment, compared with 9 at discharge, a reduction of 40%. For 3 patients, a combination of 2 molecules classified as « 3 » was observed at entry, compared with 0 at discharge. Finally, 13 patients had a AL above the theoretical thresholds, compared with 7 at discharge (down 46%). The majority of PIs were switches for drugs with a lower score, or discontinuation of treatment with no indication.

Conclusion and Relevance In the population studied, AL was inappropriate in almost 40% of cases. The results show the beneficial impact of pharmaceutical interventions on the adaptation of anticholinergic drugs.

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Conflict of Interest No conflict of interest

4CPS-129 THE USEFULNESS OF BROLUCIZUMAB IN TREATING NEOVASCULAR AGE-RELATED MACULAR DEGENERATION NOT RESPONDING TO RANIBIZUMAB OR AFLIBERCEPT. A RETROSPECTIVE CHART REVIEW

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Background and Importance The standard of care for neovascular age-related macular degeneration (nAMD) uses anti-vascular endothelial growth factor (anti-VEGF) drugs: ranibizumab and aflibercept. Our P&T committee has approved brolucizumab for patients not responding to ranibizumab or aflibercept.

The regimes of injections at fixed intervals represent a considerable care burden for ophthalmology services and a heavy treatment burden for patients. For this reason, the treat and extend regimen (T&E) began to be applied. This proactive approach consists of fixed treatment doses until disease remission occurs. Then, the therapy interval is progressively extended until neovascular activity reappears.

Aim and Objectives In actual clinical practice, the choice of drugs for nAMD treatment is not solely based on clinical trials or EMA's product characteristics. It heavily relies on the clinical experience of ophthalmologists, published observational studies, and expert opinions. Data regarding the use of brolucizumab in patients not responding to other anti-VEGF are scarce. This study, therefore, takes a practical and relevant approach by evaluating the response to brolucizumab in these patients.

Material and Methods This was a retrospective chart review using electronic medical records at an academic health system. The study included adult patients with nAMD not responding to other anti-VEGF and who had initiated brolucizumab before September 2023. The observational period ended on September 2024. The primary outcome was a response to treatment, i.e., the absence of activity (or reduction) detected by the Ocular Computerised Tomography (OCT) after the loading doses. Signs of toxicity were also recorded.

Results Among the 37 patients in the cohort, 26 (70,2%) were deemed responders to treatment with brolucizumab. All the included except one (36) have failed in previous aflibercept and/or ranibizumab. All were treated using the T&E approach. Only 2/37 patients referred mild signs of ocular toxicity (discomfort).

Among responders, the median number of injections in 12 months was 5 (Inter quartile range 4–6)

Conclusion and Relevance Brolucizumab appears as a helpful option in nAMD patients who do not respond to aflibercept or ranibizumab. No conclusions can be drawn regarding safety. Response was achieved by a T&E approach with Injections every 2–3 months during the first year.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-130 R-START: EFFECTIVENESS OF FREMANEZUMAB AFTER 18 MONTHS OF TREATMENT IN PATIENTS WITH CHRONIC MIGRAINE

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Background and Importance The therapeutic management of chronic migraine has been significantly transformed with monoclonal antibodies specifically directed against calcitonin gene-related peptide (anti-CGRP).The European Headache Federation recommends a duration of up to 12–18 months and re-evaluate response and if necessary resta**rt.**

Aim and Objectives The aim was to assess the response rate after the first-line of anti-CGRP treatment. As a secondary objective we aimed to assess whether the clinical response in case of restart was comparable to the first period.

Material and Methods Observational, descriptive, longitudinal, unicentric and retrospective study. Patients on anti-CGRP treatment from 2020 to April 2024 were included. The variables collected were: anti-CGRP, dates of start, end and restart, migraine days per month (MDM) and pain scale (VAS) at month 0,3,6,9,12 and 18 of each treatment cycle.

Observed differences in MMD and VAS between the baseline and treatment period during the first anti-CGRP cycle were assessed and compared with differences observed at restart.

Analysis of qualitative variables was performed a frequency analysis, while for the quantitative ones, were obtained measures of dispersion with Stata 16.0.

Results Our study included 172 naïve patients treated with fremanezumab: 52% discontinued treatment after 18 months;36% remained on the first cycle at the time of the study because they had not completed the recommended duration and 2.3% continued for more than 18 months, based on clinical criteria.

After 18 months with fremanezumab(n=90):31% needed to restart with the same anti-CGRP,35% required a switch to erenumab, of which 50% finally required a switch to galcanezumab and 4% restarted treatment with botulinum toxin. Only 12% maintained clinical response to fremanezumab after completion of the first cycle, with no need for further treatment.8% lost follow-up.

Drug-free time was 135 days(SD=122)in patients who needed to restart and 262 days(SD=289)in responders after the first course of fremanezumab.

The mean differences in clinical response observed after fremanezumab restart were: an improvement of −0.43 MDM (SD=4.81) and a worsening of −0.29 points (SD=2.25) on the VAS scale compared to the first cycle of fremanezumab.

Conclusion and Relevance

- The response rate without fremanezumab after 12–18 months of treatment was low, requiring retreatment in 88% of patients.

- Restarting treatment with fremanezumab in responders was an effective strategy, maintaining clinical response, in terms of MDM and VAS.

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

4CPS-131 DEVELOPMENT OF AN AUGMENTED INTELLIGENCE TOOL TO PREDICT RISK OF UNCONTROLLED TYPE 2 DIABETES MELLITUS FOR PERSONALISED PHARMACEUTICAL CARE AT THE OUTPATIENT SETTING

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Background and Importance Over the past decades, the shrinking pharmacy workforce has gradually transformed in response to the increasing healthcare needs of the ageing population. Digital technologies such as risk stratification models using machine learning have the potential to drive towards large-scale, cost-effective and high-quality personalised pharmacy care.
Aim and Objectives The aim is to develop an Augmented Intelligence (AI)-assisted risk stratification model for Type 2 diabetes mellitus (T2DM) to predict the risk of uncontrolled T2DM in the next 6 months to provide proactive and timely personalised pharmaceutical care services.
Material and Methods A retrospective cohort study was conducted in T2DM patients followed-up at Singapore General Hospital Specialist Outpatient Clinic for at least 1 year from 2021 to 2024. Uncontrolled T2DM is defined as glycated haemoglobin (HbA1c) >7% for patients <75 years old and HbA1c >8% for patients ≥75 years old. A set of features including demographic, physical measurements, laboratory data, medical history, diabetes medications, medication adherence, clinic attendances and clinical interventions were included. Random forest, logistic regression and gradient boosting classifier algorithms were employed. The area under the curve (AUC), recall, F1-measure, precision, and accuracy metrics were evaluated.
Results A total of 1140 T2DM patients records were included. Table 1 summarises the performance metrics achieved by each algorithm. Both the Random Forest and Gradient Boosting Classifier models performed better than Logistic Regression across the various evaluation criteria using the top 22 features plus the medication adherence components. Baseline HbA1c, age, total number of diabetes medications, serum creatinine and triglycerides were important predictors of uncontrolled T2DM.
Conclusion and Relevance Both the Random Forest and Gradient Boosting Classifier models demonstrated high performance in predicting uncontrolled T2DM. Machine learning techniques are promising to build accurate models to forecast disease outcomes and provide large-scale personalised pharmacy care.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest Corporate sponsored research or other substantive relationships:

The project was supported by the Singapore General Hospital Innovation Grant (SIG-07–2023).

Abstract 4CPS-131 Table 1 Performance of three different machine learning algorithms

Models	Test AUC10 Fold CV Mean	Test AUC 95% CI (10,000 bootstraps)	Test RECALL 95% CI (10,000 bootstraps)	Test F1 95% CI (10,000 bootstraps)	Test Prec. 95% CI (10,000 bootstraps)	Test Accuracy 95% CI (10,000 bootstraps)
Random Forest	0.814	0.814–0.914	0.879–0.965	0.829–0.908	0.762–0.880	0.772–0.873
Logistic Regression	0.772	0.740–0.860	0.781–0.900	0.765–0.860	0.722–0.850	0.697–0.807
Gradient Boosting Classifier	0.815	0.791–0.898	0.837–0.938	0.800–0.889	0.744–0.868	0.741–0.846

4CPS-132 POPULATION PHARMACOKINETIC MODEL OF FLUDARABINE IN PATIENTS UNDERGOING CHIMERIC ANTIGEN RECEPTOR T CELLS THERAPY

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Background and Importance Optimal fludarabine dosing based on population pharmacokinetic analysis (popPK) can predict outcomes in patients undergoing myeloablative conditioning prior to haematopoietic stem cell transplantation.[1 2] To date, there is no popPK tailored for patients receiving fludarabine as part of lymphodepleting regimen before chimeric antigen receptor T (CAR-T).
Aim and Objectives To develop a especific PopPK model of fludarabine in patients undergoing CAR-T-cell therapy.
Material and Methods A prospective study was conducted at the Haematology Department of a tertiary hospital, from January 2021 to July 2022. Demographic, clinical, and analytical variables were collected. Blood samples were obtained on days 1 and 3 of the lymphodepleting regimen at 1.5, 2, and 24 hours post-fludarabine doses (3 total doses) and 30 minutes prior to CAR-T infusion. Fludarabine levels were analysed through an ultra-performance liquid chromatography tandem mass spectrometry assay based on liquid-liquid extraction. PopPK modelling was performed using nonlinear mixed-effects analysis (NONMEM).
Results Fifty-six patients (59% male) with a mean age of 59 years (range: 23–82) received CAR-T-cell therapy (38 [67.8%] axicabtagene-ciloleucel (axi-cel); 18 [32.2%] tisagenlecleucel (tisa-cel)). A total of 353 samples were collected for

model development. A three-compartment model with first-order kinetics best described the data. Body size, as represented by actual body weight (ABW) with allometric scaling, was a significant predictor of all pharmacokinetic parameters. CAR-T construct and estimated glomerular filtration rate (eGFR) also showed statistical significance for clearance (CL). CL was differentiated into a non-renal (4.4 ± 1.2% L/h/70 kg and 3.9 ± 0.95% L/h/70 kg for axi-cel and tisa-cel, respectively) and renal ($1.7\pm1.0\%x(eGFR)x(ABW/70)^{0.75}$ L/h/70 kg) component. Estimates of V1, V2 and V3 (central, peripheral and second peripheral distribution volumes) were 41.2 ± 9% L/70 kg, 14.5 ± 14% L/70 kg, and 10.8 ± 3% L/70 kg, respectively. Intercompartmental clearances between V1 and V2, and V1 and V3, were 4.8 ± 5.3% and 3.6 ±0.04% L/h/70 kg.

Conclusion and Relevance ABW, eGFR and type of CAR-T are important predictors of fludarabine pharmacokinetics. Further investigation is needed to elucidate optimal fludarabine dosing through popPK model and its correlation with outcomes in CAR-T-cell therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. doi:10.1007/s40262-018-0715-9
2. doi:10.1182/bloodadvances.2018029421

Conflict of Interest No conflict of interest

4CPS-133 PREVALENCE OF THIRD-LINE TREATMENT QUETIAPINE AND OVERWEIGHT/OBESITY IN HOSPITALISED PSYCHIATRIC PATIENTS: A CROSS-SECTIONAL STUDY

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Background and Importance Patients with psychiatric conditions have higher mortality than the background population which is partly explained by metabolic risk factors. Before the year 2020 the antipsychotic drug, quetiapine, was among the first -or second-line treatment in Denmark for the treatment of several psychotic conditions. In the year 2020 quetiapine became the third-line treatment because of the risks of metabolic adverse effects (MAE) such as weight gain. Due to quetiapine's affinity to histamine receptors, it is often prescribed off-label in low doses for sleep disturbances as an alternative to benzodiazepines. However, quetiapine causes MAEs dose-dependently, even in small doses. Therefore, antipsychotic drugs with MAEs, such as quetiapine, should be avoided when possible.

Aim and Objectives This study aimed to observe the number of patients who were prescribed quetiapine and investigate the number of patients with concomitant overweight/obesity.

Material and Methods This cross-sectional study was conducted during July 2024, in all hospitalised patients in the Psychiatry District East, Region Zealand, Denmark. The ward has had clinical pharmacist services since December 2019. Data were collected by one pharmacist and included sex, age, Body Mass Index, glycated haemoglobin, diabetes diagnoses and prescribed psychopharmaceutic drugs with MAEs (olanzapine, clozapine, quetiapine, sertindole, tricyclic antidepressants, mirtazapine).

Results A total of 137 patients were consecutively observed. Sixty-eight percent of the patients had prescribed ≥1 drug with MAEs. Thirty-four percent was prescribed quetiapine either once daily or as needed. Twenty-nine percent of the patients with overweight/obesity were prescribed ≥1 drug with MAEs. Fourteen percent of the patients with overweight/obesity had a prescription of quetiapine.

Conclusion and Relevance The limitations of this study include the short study period and the observational study design precluding causal inference with metabolic risk factors. However, this study observed that one third of the hospitalised patients are prescribed quetiapine, contrary to current guidelines. Furthermore, a notable proportion of the patients treated with drugs with MAEs are overweight/obese. Clinical pharmacists can provide pharmacological consults when a patient is prescribed drugs with MAEs and assist with alternative treatment suggestions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-134 REAL-LIFE EFFECTIVENESS OF SODIUM ZIRCONIUM CYCLOSILICATE FOR THE TREATMENT OF HYPERKALAEMIA

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Background and Importance Hyperkalaemia is a common electrolyte disorder with potentially serious consequences in short, medium and long-term.

Aim and Objectives To evaluate the real-life effectiveness of sodium zirconium cyclosilicate (SCZ) as a treatment for acute hyperkalaemia.

Material and Methods Observational, retrospective, multidisciplinary study carried out in a tertiary hospital from December 2023 to February 2024. All hospitalised patients with SCZ prescriptions were included.

Sociodemographic, clinical and analytical variables were collected, as well as doses of SCZ used, previous treatment with SCZ or calcium polystyrene sulfonate (CPS), and readmissions in the 30 days after discharge due to hyperkalaemia.

The data were obtained from the electronic prescription programme and the electronic medical records.

Results We included 60 patients, 66.7% men, median age 75 ±16.3 years, 55 (91.7%) had chronic kidney disease, 43 (78.2%) grade 4–5. Fourteen (23.3%) previously received haemodialysis (HD) or peritoneal dialysis; 23 (38.3%) were previously treated with SCZ and 10 (16.7%) with CPS.

Forty-three (71.7%) presented hyperkalaemia during the admission, mean blood potassium value 5.82 mmol/L. A mean of 36.5 ±35 hours until normalising was necessary. Eight of them (18.6%) previously took SCZ. Four patients without previous HD (8.7%) needed a session to reduce potassium levels.

Among the 37 patients who initiated SCZ during the admission, the most frequent initial dose was 10g/24h (37.8%), followed by 5g/24h (24.3%). Similarly, the most common maintenance dose was 10g/24h (35.1%), followed by 5g/24h (32.4%); five (13.5%) required no maintenance dose.

At discharge, 22 (95.6%) out of 23 patients on previous SCZ treatment maintained it; only one discontinued treatment and continued with CPS. Among the 37 patients who initiated

SCZ during the admission, 12 (32.4%) maintained it. The most common doses at discharge were 5g/24h (62.2%) and 10g/24h (18.9%).

Five patients (8.3%) were readmitted with hyperkalaemia in the 30 days after discharge. In 4 (80%) SCZ had not been prescribed at discharge.

Conclusion and Relevance SCZ is an effective drug to normalise potassium levels in an average of 36 hours.

Less than 10% of patients without previous HD needed a session to normalise levels.

Only one third of patients who started treatment maintain it at discharge

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-135 PHARMACEUTICAL INTERVENTIONS ON DIRECT ORAL ANTICOAGULANTS IN EMERGENCY DEPARTMENT

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Background and Importance Pharmacists play an important role on Emergency department (ED) safety promotion. Reviewing high-risk medication prescriptions, such as direct Oral Anticoagulation (DOAC) is a high priority strategy.

Aim and Objectives To analyse number and type of pharmaceutical interventions related to DOACs at ED and to evaluate degree of acceptance of pharmacist recommendations by physicians.

Material and Methods Prospective, longitudinal, observational study was conducted from June-September 2024. ED pharmacist reviewed DOACs prescriptions daily (Monday to Friday). DOAC's review was collected in pharmacy electronically prescription programme and further analysed. All ED interventions were orally or electronically communicated to prescribers.

Data collected were: patient's age and sex, at home prescription, ED prescription, intervention required and degree of acceptance by physicians.

Results 153 patients with DOAC prescription on ED were reviewed. 51.6% (n=79) were men, median age was 82 years (range 42–97). DOACs prescribed: apixaban 60.1% (n=92), dabigatran 9.2% (n=14), edoxaban 18.9% (n=29), rivaroxaban 11.8% (n=18). 18.9% (n=29) of patients required pharmaceutical intervention related with DOACs prescription. Interventions were: renal function adjustment counselling 62.1% (n=18), dose adjustment due to weight and renal function 6.9% (n=2), dose adjustment performed but not necessary 10.3% (n=3), contraindication of DOACs due to limit renal function 6.9% (n=2), patient with active bleeding 3.5% (n=1), patient with home suspended DOAC but prescribed in ED 6.9%(n=2), nasogastric tube contraindication 3.5(n=1): dabigatran was being opened by the nurses and a change of DOAC was required. Related to degree of acceptance of interventions: 62.1% (n=18) were accepted by physicians, 24.1% (n=7) were non-accepted, and it 13.8% (n=4) was not possible to asses due to length of stay <24h.

Conclusion and Relevance In our cohort, 18.9% of patients had an incorrect DOAC prescription during their ED stay. The most frequent intervention is related to dosing: each DOAC has different recommendations related to dose adjustment and probably it leads to more mistakes. Most of our interventions were accepted by physicians, which reinforces that 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-136 MEDICATION RECONCILIATION IN PATIENTS ADMITTED TO A NEUROLOGY WARD

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Background and Importance Medication reconciliation has been shown to reduce unintentional medication discrepancies. Its role in neurology wards has not been widely studied.

Aim and Objectives The aim of this study is to identify unintentional medication discrepancies by providing medication reconciliation in patients admitted to the neurology ward and to determine whether these discrepancies were possible adverse drug events.

Material and Methods This prospective observational study was carried out between November 2023- March 2024 in the neurology ward of a tertiary care university hospital. Adult patients who were taking at least one prescription medication before hospitalisation were included. Admission medication reconciliation was performed within the first 24 hoursof the patient's admission to the ward(on mondays for patients admitted on weekends).Medication discrepancies were discussed with ward physicians to determine whether they were intentional or unintentional. The potential adverse drug events were assesssed by the study authors.

Results 100 patients were included. 49.0% of patients were female. Median age 67.0(IQR:53.0–73.00). Median number of prescription medications prior to hospitalizaiton per patient was 5.0 (IQR: 3.0–7.0). 21 unintentional discrepancies were detected during admission medication reconciliation and 19 unintentional discrepancies were detected during discharge medication reconciliation. The number of patients with at least one unintentional medication discrepancy either at admission or at discharge was 24. Both at admission and at discharge,the most common type of unintentional medication discrepancy was the omisson of a medication (47.6% and 57.9% of unintentional discrepancies, respectively). Of the unintentional discrepancies at admission, 38.1% were considered as potential adverse drug events, while 10.5% were considered as potential adverse drug events at discharge.

Conclusion and Relevance In the present study unintentional medication discrepancy rates comparable with other inpatient clinics were observed. And some of these unintentional medication discrepancies were assessed to be potential adverse drug events. This study is in line with previous publications, suggesting that neurology clinics might benefit from medication reconciliation provided by clinical pharmacists.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-137 EVALUATION OF POST-EXPOSURE PROPHYLAXIS EFFECTIVENESS IN PREVENTING SEXUALLY TRANSMITTED DISEASES AND UNWANTED PREGNANCIES IN SEXUAL ASSAULT VICTIMS IN A TERTIARY UNIVERSITY HOSPITAL

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Background and Importance Women who suffer a sexual assault(SA) are exposed to pathogens that cause sexually transmitted infections(STIs) and unwanted pregnancies. Bacterial, viral and fungal post-exposure prophylaxis(PEP), in addition to emergency contraception, can be effective prevention.
Aim and Objectives To evaluate PEP and emergency contraception effectiveness, using a medication kit prepared and dispensed by Pharmacy Service(PS) for the prevention of STIs and unwanted pregnancy in female victims of SA.
Material and Methods Retrospective observational study in women with SA diagnosis between 04/2022–08/2024. Data were obtained from Orion Clinic: age, kit prescription, prescribing service, SA timepoint, adverse events (AE), mental health care need and drug urinalysis.

PEP kit contained: Metronidazole, Tinidazole, Ceftriaxone and Azithromycin for STIs prophylaxis; Emtricitabine/Tenofovir and Raltegravir for human immunodeficiency virus (HIV) prevention and Levonorgestrel for emergency contraception.

Kit's effectiveness was assessed at 7,10,21,42 days and 3–6 months by detecting STIs causative agents: microbiology tests (*Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Mycoplasma genitalium*, *Trichomonas vaginalis), s*erological tests(HIV, hepatitis viruses). Additional pathogens in endocervical exudate samples were examined. Contraception effectiveness was assessed by pregnancy test.
Results Thirty-one patients were included with a median of 23 (16) years old, being 9(29%) under 18. PEP kit was exclusively prescribed by Gyneacology Service. Metronidazole, Azithromycin and Ceftriaxone were administered to all patients and Tinidazole to 23(74.2%). Emtricitabine/Tenofovir and Raltegravir to 29(93.6%).Vomiting was the only AE occurred in 3(9.7%) patients.

Tests were positive at 7–10 days after kit dispensation for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in 2(6.5%) patients; *Trichomonas vaginalis* in 1(3.2%) at 7–10 days and 6 months. Any *Mycoplasma genitalium* infection was developed. No positive serological tests were detected, except for 6 (19.4%) who received hepatitis vaccination after SA. Other endocervical infections observed included: Human papillomavirus(HPV)(9.7%), *Gardnerella vaginalis*(9.7%) and *Candida albicans*, *Haemophilus parainfluenzae*, *Streptococcus agalactiae* and *Gardnerella leopoldi/swidsinkii*(6.5%) each one.

10(32.3%) patients were suspected of chemical submission; urinalysis detected cannabis(6.5%), benzodiazepines(6.5%), cocaine(6.5%) and opiates(3.2%). 15(48.4%) required mental health assistance.

Levonorgestrel was administered to 21(67.7%). Reasons for not administration were: previous sterilising surgery(6.5%), sexual intercourse occurred 5 days before(6.5%),non-fertile age (6.5%),absent penetration(3.2%),contraception use(3.2%), taking it previously(3.2%), unknown reason(3.2%) (being the only patient who became pregnant after SA).

Conclusion and Relevance In the studied population, PEP kit prepared by PS for STIs appears to have been effective in the most of SA victims,mainly in preventing HIV infection. Pregnancy contraception was highly effective using levonorgestrel.

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

4CPS-138 NUMBER OF ANNUAL INJECTIONS WITH RANIBIZUMAB OR AFLIBERCEPT IN TREATING NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (NAMD). A COMPARISON USING REAL-WORLD DATA

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Background and Importance The standard of care for nAMD uses anti-vascular endothelial growth factor (anti-VEGF) drugs: ranibizumab or aflibercept.

The current fixed injection intervals strain ophthalmology services and burden patients. A proactive treatment and extension regimen (T&E) was introduced to address this. This approach consists of fixed treatment doses until disease remission occurs. Then, the therapy interval is progressively extended until disease reactivation.

One prospective randomised clinical trial compared aflibercept and ranibizumab regarding the number of injections in twelve months in patients with nAMD treated with a T&E approach.[1] No difference was found in this outcome.
Aim and Objectives Our study aimed to acknowledge the distribution of aflibercept and ranibizumab among patients treated at our hospital for nAMD and compare the number of injections in twelve months of treatment between both drugs. We also sought to compare this data with the number of injections reported in the twelve-month clinical trial.[1]
Material and Methods This observational retrospective study included patients with nAMD treated with a single drug (ranibizumab or aflibercept) from May 2023 to June 2024. Additional inclusion criteria were receiving an injection at least 11 months (330 days) before June 2024 and another during the last 6 months (180 days). Data were retrieved from pharmacy dispensation records. The primary outcome was the number of injections in twelve months of treatment.
Results All 121 included in the cohort were treated using the T&E approach. Of these, 95 (78,5%) received aflibercept and 26 (21,5%) ranibizumab. No differences between drugs were detected in the mean number of injections per year: 5,00±1,4 for aflibercept and 4,85±1,16 for ranibizumab (p=0,616, t-test for unpaired samples). In the reference clinical trial (1), these numbers were higher (9,7±2,6 and 9,7±2,8, respectively).
Conclusion and Relevance In our hospital, aflibercept is used four times more than ranibizumab as a single anti-VEGF drug, and no significant difference between drugs was found in the mean number of injections in twelve months. This number was inferior to the corresponding data previously reported by Gillies et al.

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Conflict of Interest No conflict of interest

4CPS-139 EVALUATION OF ANTIFUNGAL PRESCRIPTION PRACTICES IN A HOSPITAL WITH AN ANTIMICROBIAL STEWARDSHIP PROGRAMME

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Background and Importance Nowadays, there are various antifungal treatments on the market, highlighting the need for restrictions on their use.

Aim and Objectives Our aim is to evaluate the quality of prescription and clinical evolution of the patient with antifungal treatment in a hospital with an educational antimicrobial stewardship programme (ASP).

Material and Methods Retrospective and observational study. Patients who required treatment with controlled antifungals in 2023 were included. The variables collected were: sex, age, hospital admission and discharge date, prescriber service and antifungal treatment. The prescription quality was measured based on empirical vs directed antimicrobial therapy, indication adequacy according to the ASP criteria and the doctor's approval of the recommendation made by the ASP. The clinical progress was analysed by the 30-day hospital readmission and mortality. Data were obtained through Orion Clinic and Farmis-Oncofarm.

Results 138 patients were included, being 87(63%) men, with an average age of 66 years. The median of days with antifungal treatment and the hospital stay was 4 (RIC:8) and 20 (RIC: 24), respectively. 64% of the antifungal prescription was made by critical intensive care. The antifungals prescribed were: 41(29.7%) patients with azoles (20 with isavuconazole, 19 with voriconazole and 2 with posaconazole), 7(5%) with liposomal amphotericin B and 90(65.3%) with echinocandin (70 with anidulafungin and 20 with caspofungin).

110 treatments were empirical and 28 directed at a microorganism. 69(50%) prescriptions were considered appropriate by ASP, being 52 empirical therapies and 17 directed therapies. A treatment modification recommendation was suggested in 69(50%) patients, being accepted in 41(60%) patients by the doctor.

As for clinical progress, 70 (49.2%) patients were discharged without new readmissions or infection complications, 19 (13.7%) were readmitted 30 days after de discharge, and 49(35.5%) died (39/49 critical patients).

Conclusion and Relevance Quality of prescription

- The majority of antifungal treatments were prescribed empirically, with echinocandins being the most commonly used group.
- ASP deemed half of the prescriptions to be appropriate.
- Over half of the cases implemented the recommendations suggested by ASP.

Clinical evolution

- Fifty percent of the patients had no complications following discharge.
- The intervention of these programmes is important to ensure a favourable clinical evolution in more complex patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-140 IMPACT OF ORAL SEQUENTIAL THERAPY ON ANTIMICROBIAL PRESCRIBING AT A TERTIARY CARE HOSPITAL

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Background and Importance Oral sequential therapy (OST) consists of switching parenteral antibiotherapy to oral antimicrobials, with the aim to reduce complications associated with parenteral administration, hospital stay times, treatment duration (TD) and costs.

Aim and Objectives

- To describe OST recommendations and its acceptance degree by prescribers.
- To analyse the impact on inpatient antimicrobial consumption following the OST implementation.

Material and Methods

- Descriptive, observational, cross-sectional and prospective study of inpatient 'OST' interventions from 11/2023 to 01/2024 inclusive. In addition, hospital antimicrobial consumption data are recorded in 11/2022–01/2023 ('pre-OST') and 11/2023–01/2024 ('post-OST').
- Data included: age, diagnosis, administration route, TD, interventions and antimicrobial consumption.
- Inclusion criteria: parenteral therapy, antimicrobial with oral bioavailability$\geq$60% and TD$\geq$3 days.
- Exclusion criteria: oral intolerance, sepsis/complicated infections, rising acute phase reactants, altered consciousness, fever and/or haemodynamic instability.

Results 110 inpatients met the inclusion criteria in the study period {median age of 77 years [interquartile range:(68,88)]}. After applying exclusion criteria [oral intolerance (27 cases), sepsis/complicated infection (24), rising acute phase reactants (16), altered consciousness (1), fever (1)], OST was recommended to 41 inpatients.

The acceptance rate was 85.4% (35/41). The action of prescribers after acceptance was:

- Parenteral to oral antibiotherapy switch during hospitalisation: 74.3%(26 interventions/35 accepted).
- Discontinuation of antibiotherapy and hospital discharge: 14.3%(5/35).
- Discontinuation of antibiotherapy, continuing hospitalisation: 8.6%(3/35).
- Hospital discharge with oral antibiotherapy for home use: 2.8%(1/35).

The most recorded antimicrobial was levofloxacin (29/41:70.7%), followed by isavuconazole and amoxicillin/clavulanate (4/41:9.8% in both cases); their hospital consumption was (table 1):

Abstrct 4CPS-140 Table 1 Hospital consumption of most recorded antimicrobials *(DDD: Defined Daily Dose)*

Antimicrobials	**DDD/100 stays pre-OST**	DDD/100 stays post-OST	**Differences post-OST vs pre-OST**
Levofloxacin 500mg Parenteral(P)	12.47	11.6	- 6.97%
Levofloxacin 500mg Oral (O)	2.54	3.71	+ 46.06%
Isavuconazole 200mg(P)	1.57	0.94	- 40.13%
Isavuconazole 100mg(O)	2.21	2.54	+ 14.93%
Amoxicilin/clavulanate 1/ 0.2g(P)	3.51	4.61	+ 31.33%
Amoxicilin/clavulanate 875/125mg(O)	0.75	1	+ 33.33%

Conclusion and Relevance

- Despite of limited sampling size and strict exclusion criteria, a high acceptance degree (>85%) was obtained, also a parenteral therapy reduction and an oral increase was recorded with levofloxacin and isavuconazole.
- Some acceptances resulted in antibiotherapy discontinuation and/or hospital discharge.
- Further studies are required to demonstrate advantages like reducing complications associated with parenteral administration, hospital stay times and costs.

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

4CPS-141 INDIRECT COMPARISON OF RISANKIZUMAB VERSUS UPADACITINIB FOR THE MAINTENANCE OF MODERATE TO SEVERE CROHN'S DISEASE

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Background and Importance Risankizumab has recently been approved for use in patients with moderate to severe Crohn's disease (msCD). There is a direct comparison between risankizumab and ustekinumab, but the clinical benefit versus upadacitinib is unknown.

Aim and Objectives The aim of this study was to perform an indirect treatment comparison (ITC) of the efficacy during the maintenance phase of risanlizumab and upadacitinib in patients with msCD using a common comparator, and to establish whether both treatments can be declared equivalent therapeutic alternatives (ETA).

Material and Methods A bibliographic search was conducted in MEDLINE-Pubmed to identify phase III clinical trial (CTs), with similar population and with the same variable, which could allow comparison between risanlizumab and upadacitinib. The clinical remission (CR) beteween week 44–52 was used as the main variable. An ITC was performed using the Bucher method, using the Indirect Treatment Comparisons calculator from the Canadian Agency for Health Technology. Delta value (D, maximum difference as a clinical criterion of equivalence) was calculated using the reference value used for the sample calculation in the clinical trial of risankizumab vs ustekinumab (absolute risk reduction (ARR)=10%). To establish the positioning, ETA guidelines were applied.

Abstract 4CPS-141 Table 1

Clinical trial	Treatments	CR (ARR (95% CI))
SEQUENCE	risanlizumab vs ustekinumab	19.7 (11.3–28.1)
IM-UNITI	ustekinumab vs placebo	17.2 (5.3–29.2)
U-ENDURE	upadacitinib vs placebo	32.8 (23.9–41.6)
ITC	risanlizumab vs upadacitinib	4 (−8–16.38)

Results A total of 3 CTs were included in the ITC: SEQUENCE (risanlizumab 360mg every 8 week vs ustekinumab 90mg every 8 week), IM-UNITI (ustekinumab 90 mg every 8 week vs placebo) and U-ENDURE (upadacitinib 30mg every 24 hours vs placebo). The results of each trial and the conducted ITC are summarised in table 1. Applying the ETA guidelines, both treatments can be declared ATE, as the probability of clinically relevant difference is minus 50%, and the failure does not involve serious/irreversible damage.

Conclusion and Relevance ITC showed no statistically significant differences in CR between risankizumab and upadacitinib. According to the ETA guidelines, as the percentage outside the delta margin was small, both drugs could be considered as ETA in most patients with msCD during the maintenance phase.

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

4CPS-142 PHARMACOTHERAPEUTIC RECOMMENDATIONS AND DEPRESCRIPTION IN ELDERLY PATIENTS ADMITTED TO AN ACUTE A GERIATRIC UNIT

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Background and Importance Older patients with multimorbidity, frailty and polypharmacy have a high-risk of inappropriate medication prescribing (IP) that affects quality of life. Deprescription is a recognised strategy to optimise pharmacotherapy and reduce IP.

Aim and Objectives To analyse the pharmacotherapeutic recommendations (PR) performed by the clinical pharmacist in patients admitted to an Acute Geriatric Unit (AGU) and the degree of acceptance by physicians.

To quantify desprescription obtained through the PR performed.

Material and Methods Retrospective and descriptive analysis of PR performed in daily clinical practice in an AGU between 01/09/2023 and 31/01/2024.

Sociodemographic variables, sex, age, living situation, polypharmacy and reason for admission were collected.

The number of PRs performed by the clinical pharmacist, the degree of acceptance by physicians and the number of deprescribing PR were also recorded.

The number of patients with at least one deprescribed drug (dose reduction or treatment suspension) the percentage of the

deprescribed drugs of the total number of medications and the most commonly drugs deprescribed were quantified.

Results 209 patients were included, 70% female, mean age of 93(80–103) years old. 31% lived in nursing homes. 87% had polypharmacy on admission and 45% had hyperpolypharmacy. The most common reasons for admission were respiratory and urinary tract infections (58% and 16% respectively) and cardiac pathology (11%).

At admission, 624 PRs were made in 195 (93%) patients. They were classified as: need (56.9%), effectiveness (0.6%), appropriateness (3.2%), safety (34.5%) and adherence (4.8%). Recommendations about deprescription were made in 81% of total PRs and 70% were accepted by the physician at discharge.

876 drugs were deprescribed in 160 (77%) patients at discharge with a median of 4 deprescribed drugs (73% were discontinuations and 27% were dose reductions).

The most commonly deprescribed drugs were omeprazole discontinuation (6%), followed by paracetamol reduction(4%) and metamizole discontinuation (2%).

Conclusion and Relevance Most patients received PRs, mainly deprescription which were accepted by the physician at hospital discharge. The most common deprescription performed by physicians was drug discontinuation and the most commonly deprescribed drug was omeprazole.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-143 REAL-WORLD PERSISTENCE OF ANTI-IL5 THERAPIES IN UNCONTROLLED ASTHMA

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Background and Importance IL-5 signalling is a target in asthma, and has yielded three monoclonal antibodies: mepolizumab, reslizumab and benralizumab. Little is known about persistence of asthma anti-IL5 biologic use in clinical practice.

Aim and Objectives The objective of the study was to analyse the real-world persistence with anti-iL5 drugs over time in the treatment of uncontrolled asthma and reasons of treatment discontinuation.

Material and Methods Observational, retrospective study that included all patients with uncontrolled asthma treated with mepolizumab, benralizumab or reslizumab. Variables collected were age, sex, anti-IL5 drug, length of treatment and reasons for treatment discontinuation. Outcome variable was percentage of treatments that reached 12-, 24- and 36-months persistence estimated from the first to the last drug dispensation, using the Kaplan-Meier method. Follow-up was carried out until September 2024. Treatment persistence was defined by the length of time that a person continuously used an asthma biologic.

Results A total of 217 patients were analysed, 71% women, mean age was 60,4 years. 93 patients received mepolizumab, 80 benralizumab and 44 reslizumab. Persistence results at 12, 24 and 36 motnhs are shown in table 1. At the end of follow-up 88 (40,5%) treatments had finished. Percentages and reasons of drug discontinuation are shown in table 2.

Conclusion and Relevance At 12 months all anti-IL5 persistence rates were high and reached 80%. Benralizumab seems to have better persistence rates at 36 months. Reslizumab persistence rates are influenced by drug shortage. Treatment with anti-IL5 drugs was generally well tolerated with low rate of discontinuation due to adverse reactions. A limitation is the high percentage of censored data.

Abstract 4CPS-143 Table 2

Reason for treatment discontinuation	Total	Mepolizumab	Benralizumab	Reslizumab
Secondary failures	63	35	10	18
Adverse reaction	10	2	3	5
Drug shortage	8	-	-	8
Poor treatment adherence	4	-	2	2
Lost follow-up	2	-	1	1
Clinical trial	1	-	1	0
All discontinuations	88	37	17	34

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-144 OPTIMISING MEDICATIONS IN GERIATRIC PATIENTS: INSIGHTS FROM THE ASPIRE RANDOMISED CONTROLLED TRIAL ON PHARMACIST-LED MEDICATION REVIEWS

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Background and Importance High-risk geriatric inpatients often face a complex balance between medication benefits and potential harms. The ASPIRE randomised controlled trial (RCT) aimed to assess the effectiveness of a pharmacist-led

Abstract 4CPS-143 Table 1

				Persistence rates (CI95%)		
Drug	N patients	% censored	Median persistence (months)	12 months	24 months	36months
Mepolizumab	93	60%	44,5 (4–60)	87% (77–93)	74% (62–83)	56% (43–68)
Benralizumab	80	77,5%	62 (2–73)	84% (73–91)	69% (52–81)	69% (52–81)
Reslizumab	44	25%	29 (4–89)	79% (63–88)	57% (40–71)	41% (26–56)

intervention in reducing unplanned hospital admissions through comprehensive medication management.

Aim and Objectives This study aims to analyse recommendations from medication reviews as process outcomes and evaluate the duration of the intervention.

Material and Methods The intervention included medication reconciliation at both admission and discharge, medication review, telephone contact with primary care, patient counselling and a follow-up call post-discharge. We analysed the number and types of recommendations, their acceptance rate, Anatomical Therapeutic Chemical Classification (ATC), and time required for the intervention.

Results Between February 2021 and March 2024, 825 patients (mean age 86.3 (Standard deviation (SD) 5.9) years; 59.6% female) were recruited, with 415 in the intervention group. We conducted 414 reviews, resulting in 1,160 total recommendations. Hospital pharmacists made at least one recommendation for 380 patients (91.6%), averaging 3.1 (SD 1.7) recommendations per patient. The acceptance rate was 89.7%, with 843 (72.7%) recommendations immediately implemented and 198 (17.0%) documented for future action.

The three most common recommendations were medication **discontinuation** (415 (35.8%), **initiation** (237 (20.4%)) and **dose change** (155 (13.4%)). Within these recommendations, the Alimentary tract and Metabolism classes accounted for the highest number of medications (268 (33.2%)), followed by the Nervous system (176 (21.8%)) and the Cardiovascular system (145 (18.0%)).

The total mean duration of the intervention was 1 hour 26 minutes. Medication reconciliation at admission took an average of 11.1 (SD 7.1) minutes, while discharge reconciliation averaged at 9.4 (SD 6.5) minutes. Medication review required 30.8 (SD 16.1) minutes, and telephone contact with health professionals 9.0 (SD 6.9) minutes. Patient counselling lasted 20.0 (SD 10.3) minutes and follow-up calls averaged 5.9 (SD 4.4) minutes.

Conclusion and Relevance In this multifaceted intervention trial hospital pharmacists provided approximately three medication related recommendations upon discharge, with a high implementation agreement rate, indicating strong acceptability by physicians. The ATC categories confirm the relevant focus of medication review for geriatric patients. Reporting intervention duration is valuable for future applications in various settings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-145 MAKING THE RIGHT NOISES: IMPACT OF A PHARMACIST 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 changing treatment or when changing between health levels. The Emergency Room (ER) is one way from primary health care to secondary and tertiary; as such, medicine reconciliation plays a critical role.

The presence of a pharmacist in the ER may lead to better reconciliation. A pharmacist integrated part-time from July 2023 into the ER service of our hospital.

Aim and Objectives We aim to measure the impact of the presence of a pharmacist in the ER regarding omission of prescription in the ER.

Material and Methods An observational study was carried out following previous methodology[1].

In this study, we compare results from the same period (second fortnight of September) of the year 2023 vs. 2024 using Fisher test.

Results In 2024, among the hundred patients, 51 were women. Age was 57.2 ± 20.7 years.

Out of 100 patients, 76 had discrepancies in their electronic prescriptions, resulting in 218 omissions. Of these omissions, 26 (11.9%) were classified as unjustified. Medicines fell into ATC groups by N (19.2%, 5), A (15.4%, 4), S (15.4%, 4), C (11.5%, 3), L (11.5%,3), H (7.7%, 2), J (7.7%, 2), R (7,7%, 2) and B (3,8%, 1).

Results are described in a 2023-vs-2024 fashion.

We found no significant difference in sex, age or number of patients with discrepancies.

There was a significant ($p<0.05$) difference in total number of discrepancies (121 vs. 218) and proportion of unjustified omissions (50.1% vs. 11.9%). Also found significant fall in the number of omitted drugs for nervous and cardiovascular systems.

Conclusion and Relevance Although this year we found more discrepancies, those might respond to medicines that, in the past, were prescribed without taking into account the acute situation of the patient in the ER.

There is a tremendous drop in unjustified omissions of prescription in the ER since the integration of a pharmacist into the ER.

While there might be other factors affecting the changes measured, the presence of a pharmacist has led to a better quality of medicine reconciliation in our ER.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

4CPS-146 ABSTRACT WITHDRAWN

4CPS-147 EVALUATION OF THE EFFECTIVENESS AND SAFETY OF ANTI-CGRP ANTIBODIES IN THE TREATMENT OF MIGRAINE

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Background and Importance Increased levels of calcitonin gene-related peptide (CGRP) in blood and cerebrospinal fluid during migraine episodes have prompted the development of anti-CGRP monoclonal antibodies(anti-CGRP-mAb) used for migraine prevention.

Aim and Objectives To evaluate the use of anti-CGRP-mAb since their approval to determine effectiveness and safety in daily clinical practice.
Material and Methods Retrospective observational study, including all patients treated with anti-CGRP-mAb from 2019 to 2024. Variables collected: sex, age, diagnosis, baseline number of migraine days per month and after 3 months with anti-CGRP-mAb, duration of treatment. Effectiveness was determined by the percentage of patients achieving >50% reduction in migraine days per month, treatment persistence and retention rate at 3/6/12/24/36/48 months. Safety was assessed by the occurrence of adverse events(AEs).
Results We included 188 patients on anti-CGRP-mAb treatment with a mean age of 49.0±12.4 years and 161 (85.6%) were women. Episodic migraine included 54 (28.7%) patients compared to 134 (71.3%) patients with chronic migraine. The 50% (94) of patients were initially treated with galcanezumab, 21.3% (40) with fremanezumab and 28.7% (54) with erenumab. In terms of effectiveness, the patients who obtained a >50% reduction in migraine days per month were 74 (78.7%), 26 (65.0%) and 37 (68.5%) patients in the galcanezumab, fremanezumab and erenumab groups, respectively.

Furthermore, the mean persistence and mean reduction of migraine episodes per month obtained are shown in table 1.

Abstract 4CPS-147 Table 1

	Persistence (months)	Average reduction (%)
Galcanezumab	18,5 (±12,6)	63,1 (±27,5)
Fremanezumab	11,9 (±8,1)	53,4 (±26,6)
Erenumab	18,3 (±15,3)	57,5 (±26,8)

In terms of safety, all AEs were mild and appeared in 17 (18.1%) patients with galcanezumab, 6 (15%) with fremanezumab and 11 (20.4%) with erenumab.

Abstract 4CPS-147 Table 2

	Retention rate (%)					
	3 months	6 months	12 months	24 months	36 months	48 months
Galcanezumab	97,9	90,4	58,5	27,7	10,6	4,3
Fremanezumab	95,0	80,0	45,0	2,5	2,5	0
Erenumab	85,2	74,1	46,3	20,4	13,0	9,3

Conclusion and Relevance Galcanezumab was the most prescribed and produced the greatest reduction in migraine days per month. However, galcanezumab and erenumab had similar persistence and retention rates. In all cases, adverse effects were mild did not appear in more than 20% of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-148 REAL-WORLD USE OF BULEVIRTIDE: A RETROSPECTIVE STUDY ON QUALITY OF LIFE, ADHERENCE, AND SAFETY IN A COHORT OF ADULT PATIENTS WITH HEPATITIS DELTA VIRUS

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Background and Importance HDV is the smallest known hepatitis virus capable of infecting humans. Recent studies estimate the global prevalence of infection to be between 5% and 15%. Bulevirtide is the only anti-HDV drug currently approved in Europe and it requires complex self-management. Patients can benefit from a specific Patient Education programme to ensure better therapeutic compliance, optimal adherence, and continuous monitoring of the drug's effectiveness and safety.
Aim and Objectives To evaluate the effectiveness, safety, and adherence in a cohort of adult patients with hepatitis delta virus infection treated with bulevirtide at a University Hospital between July 2023 and September 2024.
Material and Methods At the Hospital Pharmacy Unit, a Patient Education Programme (PEP) was developed for HDV patients. These patients received specific training from a clinical pharmacist on the preparation, administration, and storage of the drug, alongside monitoring for adherence, quality of life (QoL, through EuroQol-5D questionnaire), and adverse events. This observational study investigated:

- treatment effectiveness, in terms of QoL, by comparing the average values of Euro-QoL-5D at the first and last drug dispensing;.
- safety, through spontaneous adverse event reporting;.
- therapy adherence, measured by the Proportion of Days Covered (PDC).

Results From July 2023, 31 patients (19 females and 12 males) started bulevirtide. The average age at the start of treatment was 55.9 ± 9.7 years. Since beginning the therapy, patients' QoL has increased significantly (+11.9%, $p<0.05$), reaching 81.7/100. Twelve out of 31 patients (39%) reported at least one suspected adverse reaction: three reported injection site reactions, tiredness, and headache; two reported nausea, diarrhoea, abdominal pain, and dizziness; one reported myalgia, asthenia, weight loss, and blurred vision. Four patients discontinued the treatment. 93% of patients reached optimal adherence rates, with a PDC ≥90%.
Conclusion and Relevance Bulevirtide treatment showed a significant improvement in patients' QoL and a good safety profile: despite 39% reporting suspected adverse reactions, these were non-severe and mostly expected. Therapy adherence was optimal, partly due to the support of the dedicated PEP. Although four patients discontinued treatment, the results suggest that bulevirtide is an effective and well tolerated therapy. Long-term studies are needed to confirm these findings and to monitor the prolonged safety of the drug.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-149 EXTERNAL VALIDATION OF POPULATION PHARMACOKINETIC MODELS OF HIGH DOSING METHOTREXATE IN PAEDIATRIC PATIENTS WITH ACUTE LYMPHOBLASTIC LEUKAEMIA

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Background and Importance High-dose methotrexate (HDMTX) in a 24-hour infusion is essential in the treatment of acute lymphoblastic leukaemia (ALL). To prevent toxicities monitoring methotrexate plasma concentrations (PCmtx) must be performed.

Aim and Objectives To assess the predictive ability of two methotrexate pharmacokinetic models in paediatric oncology patients at a third-level hospital, utilising an external dataset in the context of our current clinical practice.

Material and Methods Two HDMTX pharmacokinetics models (Model A and Model B) used in our current clinical practice were selected. Methotrexate plasma concentration (PCmtx) and creatinine levels were analysed 24–48h post-infusion, with high-risk patients assessed starting at 2h.

We estimated individual predicted concentrations (Cipred) for each model using Bayesian estimation, then calculated the individual prediction error by assessing the difference between Cipred and the observed concentrations.

The prediction's accuracy and precision were evaluated using the median of individual prediction error (MDIPE) and the absolute median of individual prediction error (MAIPE) respectively. Predictive performance of a model was considered as satisfied when MDIPE%<±10% and MAIPE%<25%.

Results A total of 560 PCmtx from 57 patients (60% male, aged 2–17) with ALL who received HDMTX (1–5g/m2) were included. Model A demonstrated accuracy and precision over time, with an MDIPE of 2,4% (95% CI: 0,45–4,34) and a MAIPE of 8% showing statistical significance. Model A's performance consistently met criteria as MDIPE 24h at 6,7% (95% CI: 3,767–9,633), MAIPE 24h at 8,7%, MDIPE 42h at –2,2% (95% CI: −8,608–4,208) and MAIPE 42h at 7,5% were under the limit. The non-significant MDIPE 42h result showed that concentration variances may be due to random variations.

Model B, on the other hand, did not meet criteria at 24h (MDIPE 24h 31,1% (95% CI: 22,139–40,061) and MAIPE 24h 31,1%) but improved results at 42h (MDIPE 42h at 6,3% (95% CI: −0,771–13,371) and MAIPE 42h at 9,7%.

These results indicate that Model A's accuracy and precision are both higher than Model B's although Model B improved its performance over time.

Conclusion and Relevance Model A's predictive ability is higher than Model B's at all times demonstrated by the results.

Model A exhibited high accuracy and precision, becoming a superior and more reliable predictive model.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-150 GLOBAL EVOLUTION OF CLINICAL TRIALS AND PHARMACY ACTIVITIES DEVELOPED IN A CENTRAL PORTUGUESE HOSPITAL FROM 2016 TO 2023

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Background and Importance Without effective treatment, an ageing population, new diseases, and rising antimicrobial resistance pose challenges. Clinical trials (CTs) are essential for proving drug efficacy and safety, facilitating access to innovative therapies, and advancing clinical research in Portugal. Legislation mandates Pharmaceutical Services' participation in CTs, ensuring safety, responsibility, transparency, and traceability.

Aim and Objectives To analyse the evolution of clinical trials and ULSLO's Pharmaceutical Services over the past 8 years.

Material and Methods Data were obtained from an Excel database and the CPC Glintt software.

Results From 2016 to 2023, an average of 19 new CTs were approved annually, peaking at 37 in 2023. From 2016 to 2023, an average of 19 new CTs were approved annually, peaking at 37 in 2023. The average number of monitored CTs per year was 64, with 2023 having 92 ongoing trials across 26 departments. The top departments in 2023 were: Oncology 21% (n = 20), Neurology 19% (n = 18), Rheumatology 12% (n = 11) and Nephrology 11% (n = 10). Antineoplastics and immunomodulators led the ATC classification, followed by the central nervous system and cardiovascular system groups The Oncology and Haemato-oncology Unit saw the greatest increase in CTs. Between 2016–2023, around 60% of CTs were stage III (n = 171), 14% (n = 39) stage II, 9% (n = 26) stage IV and 16% (n = 38) other stages. A total of 90% (n = 85) of the TCs were promoted by the pharmaceutical industry and 10% (n = 9) by researcher initiatives. Regarding ED, pharmacists received (n = 13119), dispensed (n = 7339), prepared (n = 801) and returned to the supplier for destruction 3562 kits.

Conclusion and Relevance Clinical studies are a key strategic area for health development in Portugal. The Clinical Innovation and Research Service promotes good clinical practice and supports study implementation, with oncology and neurology as areas of excellence. Highly qualified clinical research teams, including hospital pharmacists, ensure an efficient experimental drug circuit in compliance with legislation. The data aligns with indicators in the annual report from official regulatory entities in Portugal.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-151 VALIDATION OF AN ALGORITHM FOR PRIORITISING MEDICATION RECONCILIATION AT ADMISSION USING AN ARTIFICIAL INTELLIGENCE METHOD

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Background and Importance Medication reconciliation at admission (MRA) is a clinical pharmacy practice that contributes to tackling the burden of medication discrepancies and subsequent patient harm at care transitions. However, it is a time-consuming activity. A collaborative work with the *'Institut de l'Intelligence Artificielle en Santé'* led to the development of an algorithm to prioritise MRA targeting patients most at risk for unintentional discrepancies (UD).
Aim and Objectives This study aims to evaluate the algorithm's performance before considering its routine use.

Main objective: To compare the number of UD identified before and after implementation of the algorithm.

Secondary objective: To compare the proportion of patients with a UD that has a significant clinical impact (score >1C according to the CLEO scale, developed by the *'Société Française de Pharmacie Clinique'*) before and after implementation of the algorithm.
Material and Methods A monocentric retrospective study was conducted in medicine-surgery-obstetrics departments. The number of MRA and the number of UD were collected from 2 April 2024 to 31 May 2024, period without algorithm (control group), and from 3 June 2024 to 31 July 2024, period with algorithm (test group). Patients hospitalised for less than 3 days and unable to understand the aims of the study were excluded. The proportion of UD per MRA and the clinical impact of UD according to the CLEO scale were compared between the two groups using a Z-test for comparison of proportions.
Results A total of 255 MRA were performed in the control group and 395 in the test group, with respective rates of 0.18 and 0.39 UD per MRA ($Z = 5.46$; $p < 0.001$). The clinical impact was significant for 48.9% ($n = 22$) of UD in the control group, and 48.3% ($n = 72$) of UD in the test group ($Z = 0.07$; $p = 0.947$).
Conclusion and Relevance The algorithm allows the identification of more UD, however their clinical impact according to the CLEO scale is not significantly different between the two groups. To improve it, variables that allow for targeting patients with clinically significant UD must be identified. Furthermore, the algorithm must be tested on a larger scale.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-152 EFFECTIVENESS AND SAFETY OF BROLUCIZUMAB IN AGE-RELATED MACULAR DEGENERATION

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Background and Importance Age-related macular degeneration (AMD) leads to the release of vascular endothelial growth factor (VEGF). The treatment consists of anti-VEGF drugs administered via intravitreal. Brolucizumab is an anti-VEGF used as a third-line treatment.
Aim and Objectives To assess brolucizumab's effectiveness and safety as a second- or third-line AMD treatment.
Material and Methods Retrospective observational study of exudative AMD patients who started brolucizumab treatment between November 2022 and March 2024.
Collected variables age, sex, lesions, intraretinal/subretinal fluid (IRF/SRF), dosage, previous treatments, changes or discontinuation and reasons, visual acuity according to clinical criteria, and brolucizumab-related adverse events (AEs).

Effectiveness was assessed by visual acuity at week 48 (primary outcome) and IRF/SRF reduction (secondary). Safety was evaluated by recording ocular and non-ocular AEs.
Results 112 patients (50% male, median age 79) had started brolucizumab. Both eyes were affected in 4.5% of cases. Neovascular lesions appeared in 68.7%, IRF/SRF in 91%, cataracts in 40.2%, pigment epithelial detachment (PED) in 47.8%, intraretinal cysts in 35.7%, and cystoid macular oedema in 8%.

The dosing regimen followed the drug label in 37.5% and Treat and Extend/Pro-Re-Nata (PRN) in 62.5%. Brolucizumab was first-line in 1.78% (clinical trial), second-line after aflibercept in 34.8%, and third-line after aflibercept and ranibizumab in 63.4%.

13.4% had been treated for at least 48 weeks. Of these, 80% are still in treatment: 53.3% improved in visual acuity and 73.3% showed IRF/SRF reduction.

The causes for the suspension of the treatment were: 46.4% switched to faricimab due to persistent IRF/SRF or no visual improvement, 7.3% due to disease stability, and 46.3% lost to follow-up.

Ocular AEs included PED (n=4), eyelid inflammation (n=2), and submacular haemorrhage (n=5). In any patient non-ocular AEs were reported.
Conclusion and Relevance Compared to the HAWK/HARRIER trials, an improvement in visual acuity is observed in 53.3% versus 56%/51% in the trials, and a reduction in FIR/FSR of 73.3% versus 31%/26%. However, further studies are needed in a larger patient cohort receiving treatment for up to 48 weeks in order to compare it properly. Safety was similar to that of the trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-153 COST-EFFECTIVENESS ANALYSIS OF TRASTUZUMAB DERUXTECAN VERSUS TRASTUZUMAB EMTAMSINE IN PATIENTS WITH HER2-POSITIVE BREAST CANCER

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Background and Importance Incidence of breast cancer, associated with the challenge of identifying effective therapeutic treatments and the increase in healthcare costs, highlights the need for the development of optimal treatment strategies. These strategies are pivotal in enhancing access to treatment and guaranteeing comprehensive care for an expanding patient population.
Aim and Objectives The aim of study was compared to treatment with trastuzumab deruxtecan (T-DXd) and trastuzumab

emtansine (T-DM1) as second-line therapy for patients with HER2-positive unresectable or metastatic (Mbc) breast cancer.
Material and Methods This single-centre observational study has retrospectively analysed data from medical records of 40 adult patients with unresectable or Mbc HER2-positive breast cancer. The study included 21 patients who had received the treatment withT-DM1 previously treated with trastuzumab and taxane, and 19 patients who had already undergone two or more anti-HER2 treatments and they were treated with T-DXd. The analysis was conducted from the perspective of the National Health System (NHS) over a 1 year time horizon. The recorded data included the costs, incremental cost-effectiveness ratio (ICER) and number needed to treat (NNT). The willingness to pay (WTP) for progression-free survival (PFS) was set at € 50,000.00. Price of T-DXd and T-DM1 were € 1,077.62 and € 1,157.52 respectively.
Results The recommended dose of T-Dxd was 5.4 mg/kg by infusion every 3 weeks (21-day cycle) until disease progression or toxicity. A 1 year treatment at average weight of 65 kg required 63 packs at € 68,084,032 total cost. The recommended dose of T-DM1 was 3.6 mg/kg, given every 3 weeks (21-day cycle). For a 1 year treatment at 65 kg, 42 packs were needed at € 48,754.74 cost. The overall cost of treatment with T-DXd was estimated to be € 68,084.03 with a 1 year PFS of 47.37%, while the cost of treatment with T-DM1 was assessed to be € 48,754.74 with a 1 year PFS of 28.57%. The incremental cost-effectiveness ratio (ICER) was € 102,815.37. NNT was 5.32.
Conclusion and Relevance Despite the higher efficacy of trastuzumab deruxtecan in patients with human epidermal growth factor receptor 2 positive metastatic breast cancer, the results demonstrate the therapy was not cost-effective, in agreement with the findings of previous scientific studies.[1]

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Conflict of Interest No conflict of interest

4CPS-154 MEDICATION ERRORS AT DISCHARGE: SEVERITY AND ROOT CAUSES. WHAT DO OUR DOCTORS THINK?

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Background and Importance Transition points between Community and Hospital are known to generate medication errors (MEs). Medication reconciliation is a robust action to intercept MEs. The MEDISIS care pathway secures the medication management of hospitalised patients aged $\geq$ 65. It involves medication reconciliations at admission, during transfers, and at discharge.
Aim and Objectives The aim of this study is to assess the potential severity of MEs at discharge and to analyse their root causes.
Material and Methods The study is conducted in the medicine and surgery departments over 2 months for MEDISIS patients. Potential severity is assessed by a physician/pharmacist pair using the HAS scale on the severity of medication errors. Root causes are determined interviewing physicians for each ME.
Results Over 2 months, 51 MEs were intercepted for 107 reconciled patients at discharge, averaging 0.5 ME per patient. Of these, 39 were corrected (76%).

Regarding potential severity, according to the pharmacist, 73% of MEs were minor (37), 20% significant (10), and 8% major (4); none were critical or catastrophic. According to the physician, nearly half of the MEs (52%, 26) had minor potential severity, 46% were significant (23), and 4% catastrophic (2).

About the causes, each ME was judged to be multifactorial. The three most frequently mentioned causes were: attention errors (32, 63%), task interruptions (31, 61%), and writing the discharge prescription under stress or in urgent situations (26, 51%). Number of medications (4, 8%), lack of knowledge of the medications (4, 8%), and associated risks (3,6%) were the three least mentioned causes. One-quarter (13) of the MEs corresponded to those intercepted at admission and persisting until discharge.
Conclusion and Relevance The study highlights the impact of disorganisation during hospital discharge on the occurrence of MEs. Although most MEs are labelled as minor, the presence of potentially major or catastrophic MEs draws attention to the importance of a secure discharge process. Implementing a care pathway that includes medication reconciliation at each transition point is an effective way to limit adverse events related to health products.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-155 DAPAGLIFOZIN REAL-WORLD DATA IN PATIENTS WITH HEART FAILURE COMPARED TO CLINICAL TRIALS: A RETROSPECTIVE OBSERVATIONAL STUDY

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Background and Importance Heart failure (HF) affects 2–3% of adults, leading to significant morbidity and mortality. Dapagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor, was recently approved by the European Medicines Agency (EMA) for treating symptomatic chronic HF with preserved or reduced left ventricular ejection fraction (LVEF), based on the DAPA-HF and DELIVER trials.
Aim and Objectives To assess the real-world effectiveness of dapagliflozin in reducing heart failure-related hospitalisations and mortality.
Material and Methods This retrospective observational study analysed data from 50 patients with HF who began dapagliflozin treatment. Key parameters collected included demographics (sex, age), clinical data at initiation (serum creatinine, estimated glomerular filtration rate (eGFR), LVEF reduced (<40%) or preserved (>40%) NT-proBNP levels), comorbidities (diabetes mellitus, hypertension), and hospitalisation/mortality outcomes based on LVEF categories. Statistical analyses were conducted to compare hospitalisation and mortality rates with clinical trials.
Results Of the 50 patients, 41 (82%) were male, with a mean age of 78.5 years. Key clinical parameters were: serum creatinine (1.22 mg/dL), eGFR (83.02 mL/min/1.73 m^2), reduced

LVEF (26%), preserved LVEF (74%), and NT-proBNP (6811.24 pg/mL). Comorbidities included diabetes (86%) and hypertension (92%). Hospitalisation rates were higher in patients with reduced LVEF (76%) compared to those with preserved LVEF (46%). Mortality from HF was 6% in the reduced LVEF group and 10% in the preserved group.

Conclusion and Relevance Hospitalisation and mortality rates were significantly higher in this study than in the DAPA-HF (hospitalisation 9.7%, mortality 9.6%) and DELIVER trials (hospitalisation 16.4%). Factors contributing to these discrepancies include the older mean age of patients (78.5 vs. 66.2 in DAPA-HF and 72 in DELIVER) and higher comorbidity rates, particularly diabetes (86% vs. 42% in DAPA-HF and 45% in DELIVER). This suggests that real-world patients are often more heterogeneous and complex than those in randomised trials, highlighting the importance of age, comorbidity burden, and frailty in evaluating treatment effectiveness. Limitations of the study include its observational nature, a small sample size, and the fact that included patients did not meet the same criteria as those in pivotal trials, which may have influenced the observed outcomes.

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

4CPS-156 ANALYSIS OF ANTIRETROVIRAL THERAPY SWITCH IN 2022 IN PEOPLE LIVING WITH HUMAN INMUNODEFICIENCY VIRUS: REASONS AND IMMUNOVIROLOGICAL EFFICACY

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Background and Importance In the past, people living with human inmunodeficiency virus (PLWHIV) had a fatal outcome due to the complications that resulted from the disease. Nowadays, thanks to the wide therapeutic arsenal available, life expectancy is almost close to general population. However, it is common for treatment changes to be made during follow-up in order to optimise and individualise it.

Aim and Objectives Characterise the reasons for switching antiretroviral therapy (ART) in PLWHIV in a tertiary level hospital during 2022. Secondly, evaluate the efficacy and safety of the new treatment.

Material and Methods Observational, retrospective, descriptive study of patients who underwent change of their ART during 2022. Epidemiological, clinical and immunovirological variables were collected from the electronic prescription programme. This study is part of Master Esther's Master Final Project 2023/2024.

Results 84 patients were included, 88,1% were men. The main reason for changing ART was to simplify it (25%), consequently, dual therapy increased 15,5% and triple therapy decreased 14,6%.

The second reason was occurrence of adverse events (22,6%). The most prevalent ones were central nervous system symptoms (8,3%), insomnia (3,6%) or hypertriglyceridaemia/hypercholesterolaemia (3,6%). Thirdly, due to a virologic failure (15,48%).

The use of non-nucleoside reverse transcriptase inhibitors (NNRTIs) decreased from 27,4% to 15,5%; in contrast, proportion of integrase inhibitors (INIs) are the same, although use of 2° generation INIs increases from 91% to 100%.

In terms of efficacy, the proportion of patients with undetectable plasmatic viral load (PVL) increased to 91,7% from 83,3% after the change. There is no differences in terms of safety.

Conclusion and Relevance The most common reason for changing ART is to simplify it for patient's comfort, because it is difficult to achieve greater efficacy and safety than oral drugs avaliables. In fact, the new lines of research are focused on other formulations like long-acting, instead of improving security o efficacy.

Also, ART tends to be based more on 2° generation INIs in due to their better security profile and fewer interactions, at the expense of NNRTIs that are not recommended as first-line in clinical guidelines.

Finally, the efficacy of new ART was demonstrated by the increase in the proportion of patients with undetectable PVL.

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

4CPS-157 STUDY OF SERUM CONCENTRATIONS OF SUBCUTANEOUS INFLIXIMAB IN INFLAMATORY BOWEL DESEASE AND THEIR CORRELATION WITH ANALYTIC RESPONSE

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Background and Importance Subcutaneous infliximab(SC-IFX) serum concentrations(Css-IFX) needed for a response in patients with inflammatory bowel disease(IBD) are not yet well defined.

Aim and Objectives Describing our patients population with IBD treated with SC-IFX and relate Css-IFX to analytic response.

Material and Methods A three-year observational retrospective study was carried out(09/2021–09/2024) that included IBD patients treated with SC-IFX and with Css-IFX analysed. Variables: age, sex, weight, diagnosis[Chron´s disease (EC) or ulcerative colitis (CU)]; Css-IFX, antibodies against infliximab (AC-IFX), faecal calprotectin(FC), reactive-C-protein(RCP), and analytic response in the first three laboratory tests(LT).

Analytic response was defined as FC<100µg/g and RCP<5mg/L. Three groups were stablished according to Css-IFX[G1(<10 µg/mL),G2(10–20 µg/mL),G3(>20µg/mL)].

Quantitative variables were expressed as mean±standard deviation or median/interquartile range (depending on distribution) and qualitative as frequencies. For the estimation of differences between groups Student´s t or Fisher´s exact test was used. Mantel-Haenszel test for trend was used to estimate linear correlation.

Results 63 patients were included. Age 47(39–55)years, feminine sex 27(42.9%), weight 75.4±17.8kg, diagnosis CU 19 (30.2%) vs EC 44(69.8%).

Laboratory tests were taken at 13.3(9.8–16.4)(LT1), 28.1 (24.6–35.6)(LT2) and 54.6(48.6–59.4) weeks(LT3).

LT1: N=63. Css-IFX 16.9±8.4µg/mL, AC-IFX 2(3.2%), FC 1148.0±3785.7µg/g, RCP 6.1±10.8mg/L, analytic response 23 (40.4%). Analytic response by groups: G1 2/13(15.4%), G2 6/16(27.3%) and G3 15/22(68.2%). Missing: 6. There are statistically significant differences between groups(p=0.003), and linear correlation(p=0,001).

LT2: N=49. Css-IFX 17.6±8.5µg/mL, AC-IFX 1(2.0%), FC 12886.3±76766.0µg/g, RCP 5.2±6.7mg/L, analytic response 17(38.6%). Analytic response by groups: G1 3/8(37.5%), G2 6/21(28.6%) and G3 8/15(53.3%). Missing: 5. There are no statistically significant differences(p=0.359) or linear correlation(p=0.319).

LT3: N=39. Css-IFX 15.8±8.6µg/mL, AC-IFX 2(5.1%), FC 567.5±1353.3µg/g, RCP 5.3±9.5mg/L, analytic response 16 (45.7%). Analytic response by groups: G1 2/7(28.6%), G2 10/19(52.6%) and G3 4/9(44.4%). Missing: 4. There are no statistically significant differences(p=0.602) or linear correlation (p=0.590).

Conclusion and Relevance Our study shows that a higher proportion of patients present analytic response with levels above 10µg/mL. In the first measurement there were significant differences in the response between groups, with a greater proportion of patients with analytic response at levels above 20µg/mL. However, these differences are not maintained thereafter. Further patients should be studied and the clinical and/or endoscopic response, as well as other variables influencing, should be evaluated in order to draw conclusions applicable to clinical practice.

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Conflict of Interest No conflict of interest

4CPS-158 MANAGEMENT OF A SECOND VISCERAL LEISHMANIA RECURRENCE IN A HIV PATIENT WITH MILTEFOSINE: A CASE REPORT

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Background and Importance Visceral leishmaniasis (VL) or Kala-Azar is an infectious disease with significant prevalence in our region, particularly among patients with human immunodeficiency virus (HIV) infection. If effective immunological reconstitution isn't achieved, they experience recurrences. Miltefosine is an analogue of phosphatidylcholine found in cell membranes inducing apoptosis-like cell death by the interaction with phospholipids and steroids in parasitic cell membranes and inhibition of cytochrome c oxidase.

Aim and Objectives To describe management of second recurrence VL infection treated with liposomal Amphotericin B and Miltefosine on a HIV patient.

Material and Methods A 48- year-old male living in a rural area of Spain since 2004. Patient was diagnosed with AIDS in 2016 without medical follow-up known. When admitted to our hospital for cerebral toxoplasmosis and VL infection in August 2020 he started treatment for AIDS with Bictegravir/Emtricitabine/Tenofovir alafenamide and VL was first treated with liposomal amphotericin B at an induction dose of 4mg/kg followed by monthly doses of 3mg/kg, 3 of 5 doses were given. Despite a scale up of AIDS treatment adding Darunavir/Cobicistat, he presented a VL recurrence in June 2021 treated with liposomal amphotericin B 4mg/kg for 5 days followed by 3mg/kg weekly doses, given 4 of 5 doses. Patient was responding to the treatment until February 2024 when second recurrence of VL was confirmed treated with liposomal amphotericin B 5mg/kg single dose plus Miltefosine 100mg/24h for 7 days administrated, as MENSA guidelines recommended.

Results Clinical improvement was achieved with exceptional tolerance to treatment except for creatinine's increment from 0,9 mg/dl to 1,79 mg/dl. The Infectious Diseases and Pharmacy hospital units took the decision to finish Miltefosine on the seventh day, to change HIV treatment to Dolutegravir/Lamivudine, and to continue liposomal Amphotericin B as prophylactic treatment 3mg/kg every 4 weeks. The infectious condition was successfully resolved, renal function was recovered, and HIV infection was controlled with indetectable viral load and 151 CD4/mm3.

Conclusion and Relevance Our experience contributes additional evidence indicating that Miltefosine should be used for seconds VL recurrences in patients with HIV infection. Renal function should be monitored closely and ensure treatment adherence. 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-159 COMPARATIVE EVALUATION OF CHATGPT-4O AND CHATGPT-3.5 IN CLINICAL RULE-GUIDED DOSE INTERVENTIONS IN HOSPITALISED PATIENTS WITH RENAL DYSFUNCTION

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Background and Importance Clinical decision support systems (CDSS) play a crucial role in identifying medications that require dose modifications for patients with renal impairment. ChatGPT has the potential to be integrated into electronic health record (EHR) systems for providing such dosing recommendations. Two recent studies, however showed that the performance of ChatGPT-3.5 in this domain was suboptimal.[1] [2] Recently, ChatGPT-4o was released, offering more contextually relevant responses compared to previous versions. In this study, we want to compare the performance of ChatGPT-4o with version 3.5 in clinical rule-guided dose interventions for hospitalised patients with renal impairment.

Aim and Objectives To evaluate the effectiveness of ChatGPT-4o compared to ChatGPT-3.5 in providing clinical rule-guided dose interventions for patients with renal impairment.

Material and Methods This cross-sectional study was conducted at a teaching hospital in Europe. CDSS alerts related to renal dysfunction were collected from the EHR over a two-week period and presented to both ChatGPT versions and an expert panel. Alerts were presented with and without patient-specific

variables, and suggested medication interventions were compared to assess performance.

Results A total of 172 CDSS alerts were generated for 80 patients. For alerts without patient variables, ChatGPT-4o provided 'correct and identical' responses to 41.3% of the alerts, 'correct but different' responses to 18.6%, and 'incorrect' responses to 40.1%. In contrast, ChatGPT-3.5 provided 'correct and identical' responses for only 19.9% of the alerts, 'correct but different' responses for 26.7%, and 'incorrect' responses for 53.4%. When alerts included patient-specific variables, ChatGPT-4o offered 'correct and identical' responses in 39.0% of cases, 'correct but different' responses in 12.2%, and 'incorrect' responses in 48.8%. In comparison, ChatGPT-3.5 provided 'correct and identical' responses for only 16.7%, 'correct but different' for 16.0%, and 'incorrect' responses for 67.3% of the alerts. Notably, both versions of ChatGPT showed better accuracy for newer drugs, such as direct oral anticoagulants.

Conclusion and Relevance ChatGPT-4o demonstrated significantly better performance compared to ChatGPT-3.5 in clinical rule-guided dose interventions for patients with renal dysfunction, showing an improvement in accuracy and a reduction in incorrect recommendations. However, despite these improvements, ChatGPT-4o is insufficient for automatic integration into EHR systems to manage CDSS alerts for renal dysfunction.

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4CPS-160 IMPROVING PATIENT SAFETY: THE CLINICAL IMPACT OF MEDICATION RECONCILIATION AT ADMISSION IN TRAUMA AND ORTHOPAEDIC SURGERY

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Background and Importance Transitions in patient care, such as hospital admissions, discharges, or interdepartmental transfers, are high-risk periods for medication errors that can lead to preventable adverse drug events (ADEs). These errors in medication regimens can significantly compromise patient safety, especially in surgical departments where the risk is amplified by factors such as the use of high-risk medications (e.g., anticoagulants, analgesics), frequent changes in treatment plans pre- and post-operatively, and the complex coordination required between different healthcare professionals.

Aim and Objectives This study aimed to evaluate the prevalence and types of unintentional discrepancies (UIDs) in the medications of patients admitted to an Orthopaedic Surgery and Trauma Department. It also assessed the clinical impact of pharmaceutical interventions related to these UIDs through medication reconciliation conducted by a pharmacist upon admission.

Material and Methods This cross-sectional single-centre study was conducted over two periods: July 21–November 5, 2021, and October 20, 2022–August 24, 2023. Eligible patients were adults at medication risk, admitted to the Orthopaedics and Trauma Surgery Department of a Swiss tertiary hospital. Medication reconciliation was done by a pharmacist on admission using three sources to identify discrepancies between the Best Possible Medication History and admission prescriptions. Discrepancies were classified as intentional or unintentional based on medical records and, if needed, a discussion with the physician. A pharmaceutical intervention was conducted for each unintentional discrepancy. The clinical impact of each intervention was assessed by a panel of experts (orthopaedic surgeon, internal medicine physician, and clinical pharmacist) using the CLEO scale (French Society of Clinical Pharmacy tool).

Results A total of 237 patients were included. At admission, 67% had at least one UID. Of the 385 UIDs identified, the most common were unintentional omissions (66%) and changes in dosage or frequency (27%). 92% of the proposed pharmaceutical interventions concerning these UIDs were accepted by the attending physicians during hospitalisation. Pharmaceutical interventions had a major clinical impact in 9%, moderate in 26%, and minor in 40%. Good agreement was observed between the expert raters.

Conclusion and Relevance This study underscores the significant value of medication reconciliation in the Orthopaedics and Trauma Surgery Department to reduce the frequency of medication errors and enhance patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-161 DOSE-DEPENDENT RELATIONSHIPS IN PRESCRIBING CASCADES: A COHORT STUDY

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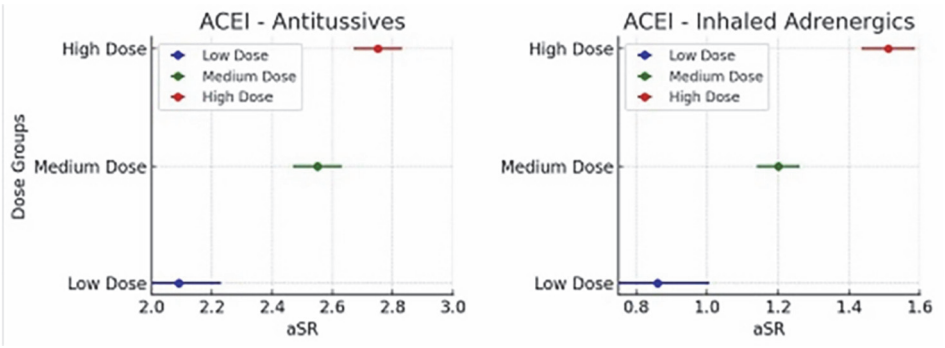
Background and Importance Prescribing cascades occur when new medications are introduced to treat adverse drug reactions (ADRs) caused by an initial (index) medication. This could lead to polypharmacy and increased healthcare costs. While dose reduction is often suggested as a strategy to mitigate prescribing cascades, the extent to which the dosage of an index medication affects the development of these cascades remains unknown.

Aim and Objectives This study aimed to investigate the dose-dependence of prescribing cascades across a range of index medications.

Material and Methods We conducted a retrospective cohort study using prescription sequence symmetry analysis (PSSA) with dispensing data from over 600 pharmacies. The relationship between different doses of index medications and 18 prescribing cascades was examined, including Angiotensin-Converting Enzyme inhibitors (ACEIs), statins, proton pump inhibitors (PPIs) and diuretics. Doses were classified using the World Health Organization's defined daily dose (DDD) into low (<0.50 DDD), medium (≥0.50 and ≤1.50 DDD), and high (>1.50 DDD) dose groups. Adjusted sequence ratios



Abstract 4CPS-161 Figure 1 Dose-dependent relationships for ACEIs

(aSRs) were calculated, with an aSR >1 indicating a prescribing cascade. Dose-dependence was confirmed when aSRs increased with higher doses and the 95% confidence intervals (CIs) between dose groups did not overlap.

Results Of the 18 cascades analysed, 12 showed a dose-dependent relationship. All seven ACEI-related cascades displayed dose-dependence. For example, the aSR for ACEI-induced cough followed by antitussives increased from 2.09 (95% CI: 1.95–2.23) in the low-dose group to 2.75 (95% CI: 2.67–2.83) in the high-dose group. Similarly, for ACEI-induced cough followed by inhaled adrenergics, the aSR rose from 0.86 (95% CI: 0.71–1.00) in the low-dose group to 1.51 (95% CI: 1.44–1.59) in the high-dose group, see figure 1. Statins exhibited dose-dependence in three of six cascades. No dose-dependent relationship was observed for cascades involving PPIs (1 cascade) and diuretics (1 cascade).

Conclusion and Relevance These findings highlight the importance of dosage in managing prescribing cascades, particularly for ACEIs and possibly statins. Hospital pharmacists should remain vigilant for ADRs at higher doses and consider dose reduction as a strategy to reverse or prevent prescribing cascades. Further research is necessary to assess the effectiveness of dose adjustments in preventing ADRs and prescribing cascades.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-162 EVALUATION OF ANTIHYPERTENSIVE PRESCRIPTIONS OF PATIENTS OF A GERIATRIC DAY HOSPITAL

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Background and Importance Elderly patients are particularly vulnerable to drug related complications. Regular medications are reassessed during geriatric day hospital consultations. Blood pressure medications carry a high-risk. However, they are usually prescribed by specialists and therefore often are not reassessed.

Aim and Objectives The aim of this project is a professional practice evaluation of antihypertensive prescriptions of patients of our geriatric day hospital.

Material and Methods We gathered data from Easily, electronic patient record, including medical history, usual medication and blood pressure readings of patients during June of 2024. We reported this information in an Excel spreadsheet to compare blood pressure treatments with the recommendations from French1 and European2 academic societies. These guidelines are composed of five therapeutic algorithms depending on comorbidities linked to high blood pressure. They additionally suggest age-appropriate blood pressure targets ranging from 130 to 149 mmHg.

Results A total of 87 patients were seen at our geriatric day hospital and nearly 55% (48/87) of them were found to have nonconforming blood pressure therapies. Our study identified three main nonconforming therapeutic algorithms: 69% (31/45) of patients with isolated high blood pressure, 78% (7/9) of those with high blood pressure and atrial fibrillation and 100% (9/9) of patients with high blood pressure associated to coronary diseases. Most nonconformities of patients with isolated high blood pressure were linked to prescriptions of beta blockers and too high or too low blood pressure levels. Furthermore, the nonconforming algorithms for patients with atrial fibrillation or coronary diseases show an average of about 2.5 antihypertensives, while the recommendations suggest monotherapy, and these patients also had blood pressure readings below the recommended levels.

Conclusion and Relevance A majority of antihypertensive prescriptions did not conform to guidelines. The benefice of treatment versus drug related complications varies for every patient, meaning that some nonconforming therapies may be necessary. However, a systematic reassessment of those medications, along with optimisation suggestions for general practitioners, could improve patient care.

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Conflict of Interest No conflict of interest

4CPS-163 LEACHABLE ANALYSIS OF DENTAL MATERIALS

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Background and Importance Knowledge about Leachables gains importance not only in the industrial drug and hospital

pharmacy production, but also in the risk assessment of 3D printed medical devices. In the dental department of our hospital, the question arose, whether new 3D printed prostheses could release harmful monomers or additives, which may have an impact on the oral tissues in patients. The question was of particular interest as a result of the modification to the approval process for these materials, which now requires a more comprehensive understanding of their behaviour for the purposes of future procedures.

Aim and Objectives We aimed identifying and quantifying possible leachables, such as monomers or additives, released from resin-based 3D printing dental biomaterials. The data should be valid for a cooperation project assessing the risk of patient´s exposure with this leachables.

Material and Methods Based on defined Extraction methods of the USP665 and our own screening method for characterising extractables in syringes for hospital pharmacy production, we prepared ethanolic and aequaous extracts (neutral, pH9 and pH5) of CAD/CAM material Denture Base LP (Fromlabs Inc., Somerville, USA). UDMA analyses were performed by LC-MS (4000 qTrap, Sciex),

Results We identified and quantified the monomer UDMA (Urethane dimethacrylate), one major component of the resin used for dentures, in all extracts. After 56 days the highest amount of UDMA was found in the ethanolic extracts up to 57,3µg/mL, whereas in all aequous extracts, independent of the pH, it was 3,4µg/mL. Moreover, further peaks were detected indicating further leachables in our extracts.

Conclusion and Relevance The results of the extraction study revealed that residual monomer release from resin-based biomaterials intended for 3D printing of dental devices occurs and could be detected by the analytical methodology applied in our pharmacy lab. As our data will be further used in a cooperation project for biological toxicity testing and to estimate patient exposure with monomers and leachables in general, it makes sense to open the analytical methods of the pharmacy for other purposes. At least there are analogies between dental laboratory and hospital pharmacy production concerning the approval process. Cooperation is therefore advantageous for both parties.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-164 PHARMACEUTICAL DECISION SUPPORT SYSTEM FOR SALT ACETAMINOPHEN USE: RAISING AWARENESS AMONG CARDIOVASCULAR PATIENTS

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Background and Importance Each Effervescent Acetaminophen Formulation (EAF) (500 mg or 1,000 mg) contains high quantity of salt: 1 g.

An EAF induced salt-regimen could reach 8 g of salt per day.

But adults should consume less than 5 g of salt per day

Recent studies suggest that EAFs lead to cardiovascular events.

Aim and Objectives This study highlights the ability of a pharmaceutical decision support system (PDSS) to detect the prescription of EAF in cardiovascular patients.

Material and Methods A prospective study was implemented from April 2020 to August 2022 at two facilities – 1,600 beds.

Our PDSS operates on Pharmaclass (Keenturtle) using real-time patient data and modelled situations to generate alerts.

The first version of the situation for identifying EAF prescriptions evolved into a second (May 2022), more sensitive in detecting various cardiovascular comorbidities through biological markers, patient's cardiac history and incorporating all EAF specialties.

Data collected include analysed alerts, EAF consumption and patient's cardiovascular diseases.

Data analysis is performed in Excel.

Results With the first version, on 159 alerts, 101 Drug related problems (DRP) required a pharmacist's intervention in 28 months of whom 49.5% were accepted by prescribers. Technical false positives were 13 (8.2%) and 39 situations do not correspond to a DRP (24.5%). EAFs on demand concerned 120 patients. With the second version, on 124 alerts, 35 DRP required a pharmacist's intervention in 4 months of whom 57.1% were accepted. Technical false positives were 29 (23.4%) and 33 situations do not correspond to a DRP (26.6%). EAFs on demand concerned 46 patients.

Only 10 alerts (8.1%) on 124 were detected by both of the two versions.

At least one cardiovascular disease is present in 99 on 102 patients (general hospital) *versus* 146 on 156 (university hospital): 83 high blood pressure, 11 cardiac insufficiency and 61 ischaemic pathologies) *versus* respectively 142, 23 and 106.

Before EAF interruption, the overall salt intake was 2,910 grams over 987 days of treatment at the general hospital and 624 grams over 361 days of treatment at the university hospital.

Conclusion and Relevance Using a PDSS reveals the salt intake through EAF among cardiovascular patients.

However, the increased sensitivity is accompanied by a rise in false positives, highlighting the importance of the modelling process.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-165 ABSTRACT WITHDRAWN

4CPS-166 REASONS AND CLINICAL OUTCOMES OF SWITCHING STRATEGY BETWEEN DUPILUMAB AND TRALOKINUMAB IN ATOPIC DERMATITIS IN CLINICAL PRACTICE

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Background and Importance Dupilumab (D) and tralokinumab (T) are biological agents approved to treat moderate to severe

atopic dermatitis (AD). Clinical outcomes of switching strategy between them have not been thoroughly studied in real-world settings.

Aim and Objectives To evaluate the reasons and clinical outcomes of switching between D and T.

Material and Methods A retrospective study was conducted at a tertiary hospital from 01/2020–07/2024. We included all AD patients who initiated treatment with D or T and switched to the other agent. We collected the following data from medical records: age, sex, reasons for switching and adverse effects (AEs).

Results A total of 301 patients initiated a biologic treatment for AD during the study period: dupilumab (n=234), tralokinumab (n=40) and both agents (n=27). Of these 27 patients who received both drugs, the following transitions were observed: D->T (n=15), T->D (n=7), D->T->D (n=4) and T->D->T (n=1). Consequently, there were 20 transitions D->T and 12, T->D (32 cases).

The mean age was 48 (±17) years and 51% were male. In the D->T group, 15 switches (75%) were due to AEs and 5 to ineffectiveness. In the T->D group, eight switches (67%) were due to ineffectiveness and four to AEs.

Most AE were conjunctivitis and facial erythema. Among patients who switched their treatment for conjunctivitis in the D->T group, 3/9 cases also experienced it with T (in two this led to treatment discontinuation). Similarly, in the T->D group, 1/3 cases also developed it with D but could continue the therapy with close ophthalmologic follow-up.

Among the 20 D->T cases, at time of study analysis, nine cases (45%) continued with T whereas five had discontinued for ineffectiveness, three for AE and three were lost to follow-up. On the other hand, among the 12 T->D cases, eight cases (67%) continued with D, whereas two cases had discontinued for AE and two were lost to follow-up.

Conclusion and Relevance In our study, the main reason for D->T switching in AD patients was conjunctivitis, whereas for T->D was ineffectiveness. Furthermore, our results suggest that some patients may benefit from a switching strategy between biological agents for AD.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-167 MEDICATION ADHERENCE OF THROMBOPOIETIN RECEPTOR AGONISTS IN IMMUNE THROMBOCYTOPENIC PURPURA: IDENTIFYING BARRIERS, CHALLENGES AND SOLUTIONS THROUGH PATIENTS' FEEDBACK

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Background and Importance The pharmaceutical interview (PI) is an exchange between a patient and a pharmacist allowing to collect information and to reinforce advice on treatment, prevention, and education.

Aim and Objectives This study aims to identify barriers to medication adherence through patients feedback in order to develop a targeted interview for patients with immune thrombocytopenic purpura receiving thrombopoietin receptor agonists. The PI intends to enhance medication adherence after conventional hospitalisation at the treatment initiation.

Material and Methods A questionnaire derived from the SATMED-Q was designed to assess patient satisfaction and knowledge regarding their treatment and condition. Questions were asked during an interview led by a pharmacist either by phone or in person, and lasting approximately 10 minutes. It included 13 open-ended questions addressing six themes: the patient's treatment, potential adverse effects, perceived effectiveness of the medication, practical aspects of medication intake, medical follow-up, and overall satisfaction. Selected patients were treated with either eltrombopag or romiplostim and more patients will be included in our study.

Results Thirteen patients were included. Among them, 70% received eltrombopag, and 46% received romiplostim; two patients were treated with both. For those on eltrombopag (n=9), 33% (n=3) experienced adverse effects. However, 89% (n=8) found the medication effective due to an increase in platelet counts. Moreover, 44% reported difficulties related to the methods of administration. For the romiplostim group (n=6), only one patient experienced adverse effects. The treatment was considered effective for 66% (n=4), 50% (n=3) expressed difficulties with subcutaneous injections. Additionally, 46% (n=6) of patients felt they lacked information about the medication upon discharge. The majority (69%) expressed satisfaction, mainly due to perceived effectiveness of the treatment.

Conclusion and Relevance The questionnaire revealed barriers to adherence, related to administration methods and adverse effects. The PI would provide essential information to improve compliance, complemented by a medication guide to clarify administration and adverse effects. Nearly half of the patients struggled with timing eltrombopag intake around dairy products. For romiplostim, organisational difficulties were reported regarding weekly subcutaneous injections, making self-injection a topic for discussion. This medication guide may be provided at treatment initiation, and a follow-up interview may be scheduled remotely between 3 to 6 months to further promote adherence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-168 ABSTRACT WITHDRAWN

4CPS-169 SHOULD WE TAKE THE SERUM ALBUMIN VALUE INTO ACCOUNT WHEN ADJUSTING THE VANCOMYCIN DOSAGE?

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Background and Importance Pharmacokinetic monitoring of drugs with a narrow therapeutic margin is a practice that allows optimising treatment by increasing efficacy and avoiding toxicity. Vancomycin is excreted mainly by glomerular filtration, with a percentage of binding to plasma proteins around 55. Serum albumin is the main transport protein in circulation. Changes in its physiology, such as hypoalbuminemia, affect the pharmacokinetic and pharmacodynamic properties of

the drugs to which it binds. In our clinical practice we have found that some patients present a considerable deviation from the predicted vancomycin trough with serum concentrations higher than expected. The common characteristic of these patients, the majority of whom are elderly, is the fact that they have hypoalbuminemia.

Aim and Objectives To review the impact of hypoalbuminaemia on vancomycin pharmacokinetics.

Material and Methods Literature review, in August 2024, searching for articles in PubMed using the terms 'vancomycin' and 'hypoalbuminemia'. We had 37 results but only two met the criteria within the scope of our question.

Results In the study carried out on septic adult patients (41% over 65 years old) with severe hypoalbuminaemia (2.5 g/dL), there was a high probability that the loading dose would not be necessary and was even associated with toxic minimum vancomycin concentration values. In the second study with adult population (50% over 75 years old) it was found that the half-life of vancomycin in patients with severe hypoalbuminaemia (2.5 g/dL) was significantly longer than in patients with non-severe hypoalbuminaemia (33.2 + 5.4 vs 24.9 + 1.6; P = 0.049).4 The same study identified a higher percentage of vancomycin-associated nephrotoxicity in patients with severe hypoalbuminaemia compared to patients with non-severe hypoalbuminaemia (26% vs 8%; P < 0.001).

Conclusion and Relevance The literature review allowed us to identify two studies that enhance hypoalbuminaemia as an important factor to take into account when adjusting the dose of vancomycin in adult patients. These results are in line with the hypothesis generated during the pharmacokinetic monitoring of patients undergoing treatment with vancomycin in our hospital. In this context, in order to ensure the impact of hypoalbuminaemia on the pharmacokinetics of vancomycin, our future objective is to develop a robust research protocol that corroborates the reviewed studies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-170 HEALTH OUTCOMES ASSESSMENT OF AN INTERDISCIPLINARY PHARMACEUTICAL ONCO-HAEMATOLOGY COMMITTEE

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Background and Importance Antineoplastic treatments with a high health and/or economic impact (HHEI) request in 'extraordinary' use situations demand interdisciplinary assessment by a specialised committee on pharmaceutical onco-haematology. It is necessary to establish a standardised methodology that incorporates comprehensive patient assessment, clinical benefit and pharmacoeconomic analysis into clinical decision making.

Aim and Objectives

1. To evaluate the use of antineoplastic treatments with a HHEI request in 'extraordinary' use situations from an Inter-Multidisciplinary Committee of Pharmaceutical Onco-Haematology (CIMOF).
2. To identify patients which clinical benefit similar outcomes to pivotal clinical trials.

Material and Methods Retrospective observational 4 year (1 January 2020 to 30 December 2023) study conducted in a tertiary hospital. Antineoplastic treatments with a HHEI request in 'extraordinary' use situations have required an assessment by CIMOF were included. Follow-up was carried out until 1 October 2024.

Variables collected demographic data (age, sex), clinical data (performance status (PS), diagnosis, type and line of treatment), ESMO clinical benefit scale, GRADE quality of evidence scale and resolution request. Treatment discontinuation and reason for discontinuation (Limitation of therapeutic effort (LTE), toxicity, progression) were also collected.

Clinical benefit was determined as the number of antineoplastic treatments that had achieved clinical trial-like effectiveness results in real-life. Patients who discontinued treatment due to toxicity or insufficient follow-up were excluded.

Results Out of 311 treatment requests received, 45 were rejected for various reasons before evaluation. Ultimately, 266 requests were evaluated, of which 261 were approved. Finally 254 treatments were started: mean age 64±12.9 years old, 52.0% men and 74.4% PS1. Of these, 16.1% and 9.4% were diagnosed with lung cancer and prostate cancer, respectively. Pembrolizumab (12.9%) and nivolumab (10.4%) were more frequently. Among all, 46.5% were requested in second-line and 78.4% with palliative intent. Relevant clinical benefit was estimated in 100% and 61.0% of curative (ESMOA-B) and palliative (ESMO4–5) requests, respectively. The quality of evidence was high in 79.8% of requests. Of the 74.8% of treatment discontinuations, the main reasons were progression (41.6%), LTE (25.3%) and toxicity (21.6%). A 52.0% of antineoplastic treatments achieved clinical benefit in real-life of patients.

Conclusion and Relevance The assessment of HHEI antineoplastic treatments by an inter-multidisciplinary committee allows access to these therapies in extraordinary use situations. Moreover, 52% of these achieved clinical benefit in real-life of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-171 ABSTRACT WITHDRAWN

4CPS-172 RELATIONSHIP BETWEEN ANTICHOLINERGIC BURDEN ASSOCIATED WITH MEDICATIONS AND FUNCTIONAL CHRONIC CONSTIPATION IN PATIENTS ADMITTED TO EMERGENCY DEPARTMENTS

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Background and Importance Anticholinergic drugs are widely used to treat several diseases. However, they have been associated with side effects such as the inhibition of peristaltic tone. Chronic functional constipation (CFC) is a common multifactorial disorder that negatively affects the quality of life of patients.

Aim and Objectives To describe and evaluate the relationship between anticholinergic burden (AB) associated with chronic medication and the degree of CFC in patients admitted to the emergency department (ED).
Material and Methods This was a prospective, cross-sectional and descriptive study that included patients aged ≥18 years who were admitted to the ED, with at least one drug as chronic treatment. Patients with a history of irritable bowel, cancer, ostomy carriers, abdominal ischaemia or previous abdominal surgery that could lead to chronic constipation of organic cause were excluded.

An interview was conducted with patients to collect the following variables: age, sex, body mass index (BMI), ROMA diagnostic criteria for CFC, chronic medication, AB measured with the ABC-scale, dietary habit with FEAD-scale and physical-activity with IPAQ-scale. The study was approved by the Research Ethics Committee of the centre.

Chi-squared-test was applied for categorical variables and Mann-Whitney U-test for quantitative variables. Variables associated with a $p<0.10$ significance level in the univariate analysis were included in a multivariate logistic regression model and significant associations were considered if $p<0.05$. The SPSS-Statistical-Package-V24 was used to analyse the data.
Results A total of 65 patients were included (58.4% male) with a mean age of 76±13.32 years and median BMI of 28.7 (6.3) kg/m2. The prevalence of CFC according to the ROMA scale was 32.3%. A total of 67.7% had medication with a medium-high AB; 50.8% had a poor dietary habit and 61.5% were engaged in moderate-vigorous physical-activity. Regarding the use of laxatives, 27.7% used them regularly, however, 55.5% of them met the criteria for constipation.

In multivariate analysis, AB followed by female sex were associated with a higher probability of CFC diagnosis [OR=19.0 (95% CI,2.2–162.9) p=0.007] and [OR=4.1(95% CI,1.2–13.9) p=0.023], respectively.
Conclusion and Relevance One-third of the patients met criteria for CFC. More than 25% usually used laxatives but, half of them were ineffective. A large percentage of patients had a moderate-high AB, which together with female sex, were the only statistically factors associated with a higher probability of CFC diagnosis.

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

4CPS-173 ANALYSIS OF THE EVOLUTION OF NUTRITIONAL STATUS USING THE C-REACTIVE PROTEIN/ PREALBUMIN RATIO IN CRITICALLY ILL PATIENTS WITH PARENTERAL NUTRITION

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Background and Importance Disease-related malnutrition is characterised by the presence of an acute or chronic inflammatory response, there is a need to adapt clinical data to new specific markers that assess both nutritional and inflammatory changes.

The C-reactive protein (CRP)/prealbumin ratio is useful for assessing nutritional changes associated with the inflammatory environment.

Aim and Objectives To analyse the evolution of nutritional status from the biochemical parameter CRP/in critically ill patients with parenteral nutrition (PN).
Material and Methods Descriptive observational restrospective study in a tertiary level hospital from January to July 2024.

The evolution of the CRP/prealbumin ratio was analysed at the beginning, fourth and seventh day of PN.

Anthropometric data on sex, age, height and BMI; clinical data on pathology, hospitalisation unit, duration of PN; and biochemical data on CRP and prealbumin were collected from the patients' electronic medical records.
Results A sample of 38 patients with a median age of 71 (20) years, mostly male [65.8% (25)], with a median weight of 72 (20) kg, height 169 (8) cm and BMI=26.5 (5.8) kg/m2 was analysed.

The pathologies of the patients were 42.0% (16) gastrointestinal disease, 29.0% (11) septic shock, 23.7% (9) neoplasia, 5.3% (2) polytrauma.

At the start of PN, 85.0% (32) of patients were admitted to the surgical intensive care unit and 16.0% (6) to the medical intensive care unit.

Regarding CRP levels, a median of 138.45 (8.5) mg/L was obtained at baseline, 106.1 (113.9) mg/L at day 4 and 62.3 (135.6) mg/L at day 7.

Median pre-albumin levels at day 1 were 9.7 (7.3) mg/dL, at day 4, 13 (6.9) mg/dL and at day 7, 17.4 (5) mg/dL.

The CRP/prealbumin ratio was calculated, with a median of 1.3 (2.3) on day 1, 1.1 (1.3) on day 4, and 0.4 (5) on day 7.
Conclusion and Relevance A decrease in the CRP/prealbumin ratio was observed as patients continued with PN, showing an improvement in nutritional and inflammatory status, and could therefore be considered as a complementary marker in patient assessment.

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

4CPS-174 ADJUSTMENT TO THE PROTOCOL OF NIRMATRELVIR/ RITONAVIR AND REMDESIVIR TREATMENT IN IMMUNOCOMPROMISED PATIENTS AT HIGH-RISK OF PERSISTENT COVID AT A SECOND-LEVEL HOSPITAL

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Background and Importance Immunocompromised patients are at a higher risk of developing persistent COVID (pCOVID). In October-2023, our hospital implemented a multidisciplinary protocol developed together the haematology department and the Antimicrobial Stewardship Programme (PROA) to manage haematologic patients at high-risk of pCOVID.
Aim and Objectives To evaluate the adjustment to the protocol and the clinical outcomes of patients treated with the combination of nirmatrelvir/ritonavir (N/R) and remdesivir (RDV).
Material and Methods A retrospective observational study of patients treated with N/R+RDV between October 2023 and September 2024 in a second-level hospital.

Demographic (sex, age) and clinical variables were collected: haematologic status, prior disease, treatment, symptoms, severity, and COVID history. Clinical virological response variables were monitored by PCR at days+5,+10 and+30 and overall survival (OS) at 30 days.

The protocol defines the duration of N/R+RDV treatment for asymptomatic (5–10 days) and symptomatic (10 days) patients and identifies three high-risk groups for pCOVID:

1. Active disease (Non-Hodgkin Lymphoma(NHL)/Chronic Lymphocytic Leukaemia (CLL)) treated with anti-CD20 +chemotherapy or BCL-2 (BCL2i) or BTK inhibitors (BTKi).
2. Patients undergoing haematopoietic stem cell transplant (HSCT) or CAR T-cell therapy.
3. Treatments with bispecific antibodies, antibody-drug conjugates, or anti-CD19 antibodies.

Statistics analysed with SPSSv 20.

Results Thirty-two cases were included (53,1% male; median age 74 years [IQR=64–79]). 90,6% were haematological (62,5% NHL; 9,4% CLL; 18,8% other haematologic diseases): 62% were receiving anti-CD20 therapy; 6,9% CAR-T; 6,9% BTKi; 6,9% HSCT; 6,9% other immunosuppressants and 10,4% were untreated. 9,4% were non-haematologic patients, all on anti-CD20 therapy and under PROA follow-up. At diagnosis, 90,6% were symptomatic, 65,6% had received prior antiviral treatment. 84,4% were mild-to-moderate and the median initial PCR cycle was 21 [IQR=16–24,75]. The median persistence time to PCR negativity was 10 days [95% CI 5–30], with 28,1% achieving it by day 5; 40,6% day 10; and 75% day 30. One death was recorded due to non-COVID-related causes, and the median OS was not reached during follow-up. Overall protocol adherence was 71,9%; 79,3% for haematologic patients (82,6% group1;17,4% group2), while the remaining 20,7% did not meet inclusion criteria (50/50% for treatment/diagnostic criteria).

Conclusion and Relevance Adjustment to the N/R+RDV combination treatment protocol was satisfactory, with a high PCR negativity rate, demonstrating its effectiveness. However, study design limitations and case selection prevent definitive conclusions. The exclusion of non-haematologic patients suggests a need to review and expand the inclusion criteria to allow other immunocompromised patients to benefit from this combined therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-175 REAL-LIFE SAFETY IN RHEUMATOLOGICAL PATIENTS TREATED WITH JANUS KINASE INHIBITORS: BEFORE AND AFTER AN INTERNATIONAL SAFETY WARNING

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Background and Importance Despite the positive therapeutic impact of Janus kinase inhibitors (iJAKs) in the treatment of several immune-mediated inflammatory diseases, some concerns have been raised regarding their safety. In October 2022, EMA published measures to minimise the risk of serious adverse events (AEs) linked to their utilisation, including restrictions for their application among people ≥ 65 years, smokers and those at increased risk of major cardiovascular events and cancer.

Aim and Objectives To identify the reason of treatment withdrawal in patients with rheumatoid diseases treated with any iJAK; describe the AE profile developed and analyse the impact on safety after the risk minimisation measures announcement.

Material and Methods Retrospective, observational study that included all patients with rheumatoid diseases treated with iJAK at a university hospital since their first market launch in Spain (2018) to date. Data were extracted from the electronic medical record, and the patients' risk profile for developing AE was analysed according to the published safety signals.

Results Among 160 patients included, 66,3% started the treatment before October 2022. To date, 51,3% (n=82) of the treatments have been withdrawn and the reasons were lack of effectiveness (63,4%, n=52), development of AE (28,1%, n=23) and others (8,5%, n=7). In this last group, three patients were considered at high-risk of AE according to issued safety measures so the iJAK was discontinued. The percentage of patients that discontinued treatment for safety reasons by active ingredient was: baricitinib (43,5%), upadacitinib (30,4%), filgotinib (17,4%) and tofacitinib (8,7%). Among the AEs, asthenia, herpes zoster, gastrointestinal disorders and headache were described as the most frequent; three serious AEs were identified: fatal pneumonia, deep venous thrombosis and prostate carcinoma. Major AEs, analysed before and after October 2022, showed that they occurred among patients >65 and all the treatments were initiated before the safety warning announcement.

Conclusion and Relevance A high percentage of drug withdrawals observed in patients treated with iJAK was due to ineffectiveness. The serious AE associated with iJAK application were related to the patient's risk profile. However, no serious AEs were described among patients who started with iJAK after the safety measures were issued, underlining the importance of an adequate selection of patients to start treatment with iJAK.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-176 NIKI-TAG (NEPHROTOXIC INJURY IN KIDS-TAG): SCREENING OF PAEDIATRIC HOSPITALISED PATIENTS EXPOSED TO NEPHROTOXIC DRUGS AND EDUCATION FOR REDUCING THE RISK OF ACUTE KIDNEY INJURY

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Background and Importance Exposure to nephrotoxic drugs is the first cause of acute kidney injury (AKI) in paediatric patients and is associated with increased morbidity, cost and length of stay. Using clinical decision support systems (CDSS), for the electronic screening of patients exposed to the risk of AKI, associated to education may reduce nephrotoxic drugs-associated AKI.

Aim and Objectives To evaluate the impact of a quality improvement programme including electronic screening of nephrotoxic drugs prescriptions with CDSS and an educational programme for medical and nursing staff on the occurrence of AKI in paediatric patients.
Material and Methods CDSS detected the 'prescription of ≥2 nephrotoxic drugs on the same day' and/or 'a nephrotoxic IV drug administration >72h' from health records in paediatric patients (0–18 years). AKI was diagnosed according to KDIGO definition. Non-intervention (NoINT, 14 months) was followed by education on drug nephrotoxicity (2 months, including microlearning, pocket card, and 30-min interactive workshops) and intervention (INT, 11 months, phone call by a paediatric nephrologist to the prescriber to make recommendations on AKI detection or management). The positive predictive value (PPV) for the alerts (i.e., the proportion of alerts that led to an intervention), the occurrence (Chi2) and the risk of AKI (hazard ratio HR (95% CI) adjusted for age, ward, type of alert, presence of chronic kidney disease) were calculated.
Results 168 participants followed the microlearning, and workshops were attended by 39 physicians and 84 nurses.

Alerts were identified in 5.2% (555/10,698; NoINT:285 alerts, INT:270) of hospitalised paediatric patients (mean age ±SD: 6.5±6.2 vs 5.7±5.6, p>0.05). The main trigger alert was related to the prescription of ≥2 nephrotoxic drugs (64%), mainly antibiotics (35%) and NSAIDs (21%). PPV was 39.3% (106 interventions for 270 alerts).

AKI occurrence was significantly reduced after education and intervention (NoINT: 22.5% of alerts (64/285) vs INT: 11.9% (32/270), p=0.001). A reduction by 46% in the incidence of AKI was determined after adjustment for confounding factors (HR 0.54; 95% CI 0.33–0.87, p=0.011).
Conclusion and Relevance Occurrence and risk of nephrotoxic drugs-associated AKI was significantly reduced by 46% in hospitalised paediatric patients with the implementation of a quality improvement programme including electronic screening and education. Screening of high-risk patients and intervention to prescribing physicians will be taken over by clinical pharmacists.

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

4CPS-177 ANALYSIS OF DOSE REDUCTION OF IBRUTINIB IN CHRONIC LYMPHOCYTIC LEUKAEMIA

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Background and Importance Many patients who are treated with ibrutinib require dose reduction (DR) or even discontinuation of treatment due to comorbidities, drug interactions and adverse effects (AE). This DR may lead to a compromise in treatment effectiveness of chronic lymphocytic leukaemia (CLL).
Aim and Objectives The aim is to evaluate the reasons for DR of ibrutinib and consequences on effectiveness and disease progression.
Material and Methods Retrospective observational study conducted between January 2017 and September 2024 in a third-level hospital. Data collected were sex, age, Eastern Cooperative Oncology Group (ECOG), Binet Staging System, line of therapy, reduced doses, reasons of DR, AE, treatment duration, response (complete or partial) and progression-free survival (PFS). Presence of high-risk cytogenetics, including patients with poor prognosis, were determined: deletion (17p) and TP53 mutation (del(17p)/mutTP53) and immunoglobulin heavy-chain variable region gene (IGHV). Data were obtained from electronic prescription with the application Prisma and electronic health records with Diraya.raya.
Results Of 69 patients on treatment with ibrutinib in LLC, 35 (50.7%) had their doses reduced (median age 77.0 (IQR:74.5–85.9) years, 55.0% male). Only one patient had ECOG 1. No del (17p)/mutTP53 with unmutated IGHV was present in three patients, no de (l17p)/mutTP53 with mutated IGHV in four patients and del(17p)/mutTP53 in six patients. Binet staging classification was: A (34.3%), B (57.1%), C (5.7%) and the rest was undetermined. Ten patients started ibrutinib as a first-line treatment, 15 as a second-line, eight as a third-line and two as a fourth-line. Reduced doses were 280 mg in 23 patients and 140 mg in 12 patients. In all patients the reason for DR was AE, except for one patient who had an adverse drug interaction. The AEs were: gastrointestinal (42.8%), haemorrhages (22.8%), arthralgia (11.4%), asthenia (11.4%), thrombopenia (8.5%) and cardiac events (5.7%). The median duration of treatment with ibrutinib was 37.5 (17.9–61.8) months. Twenty-two patients achieved a complete response and the median PFS was 29.3 (IQR: 20.0–66.5) months. Seven patients died, two of them due to the disease.
Conclusion and Relevance In patients requiring DR of ibrutinib, it does not influence treatment response or disease progression. However, further studies are needed to assess the possibility of optimising treatment with DR to avoid the usual AE of this drug.

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

4CPS-178 DESCRIPTIVE ANALYSIS IN REAL-WORLD OF TREAT AND EXTEND TREATMENT OF FARICIMAB IN PATIENTS FAILING PRIOR INTRAVITREAL TREATMENTS

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Background and Importance Faricimab is a monoclonal antibody that blocks vascular endothelial growth factor (anti-VEGF) A and angiopoietin-2, approved to treat wet age-related macular degeneration (AMD), diabetic macular oedema (DME) and macular oedema following retinal vein occlusion.

The improvement and maintenance of visual outcomes (improvements in visual acuity) and anatomical outcomes (decreased central retinal thickness and resolution of exudative disease (decrease intraretinal or subretinal fluid) drive the frequency of intravitreal injections.

In a treat-and-extent (T&E) regimen, after an initial loading phase of four doses of faricimab given, patients are injected at

different intervals until improvement in visual and anatomic outcomes is achieved.

Aim and Objectives To evaluate the real-world T&E regimen with faricimab in patients with wet AMD and DME following the failure of prior treatment lines and to monitor their clinical outcomes.

Material and Methods A unicentre, observational, descriptive and retrospective study from September 2023 to September 2024. Collected variables included demographics (age, sex), diagnosis, previous treatments, number of doses and frequency, reasons for discontinuation and side effects of faricimab.

After loading doses, treatment intervals can be extended to 4 weeks up (Q8) to 12 (Q12) or to 16 (Q16) weeks if there is an improvement in visual and/or anatomical outcomes. Data were extracted from medical records.

Results We included 132 patients (52% male, 48% female) with a mean age 77 ± 10 years and a total of 169 eyes.

78 eyes were previously treated with one anti-VEGF, 67 eyes with two and 24 with three or more therapies.

56% (94 eyes) with Wet AMD: 60% are in loading dose, 25% in Q8, 3% in Q12, 1% in Q16 and 11% were ineffective. 44% (75 eyes) with DME: 69% are in loading dose, 4% were monthly, 12% in Q8, 3% in Q12 and 12% were ineffective. Side effects were not reported.

Conclusion and Relevance Faricimab at our hospital is an alternative T&E regimen for wet AMD and DME patients who are resistant to other anti-VEGF. In wet AMD 28% eyes and in DME 19% eyes were in T&E regimen. In both diagnoses, approximately 11% of cases were ineffective. Our experience indicates the importance of long-term follow-up. The treatment was generally well tolerated, with no significant safety issues reported.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-179 CONCORDANCE ANALYSIS BETWEEN THE CONUT INDEX AND INDIVIDUAL MARKERS: EVALUATING NUTRITIONAL STATUS THROUGH UNWEIGHTED AND WEIGHTED KAPPA MEASURES

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Background and Importance Nutritional assessment using the CONUT index can be useful for detecting hospital malnutrition. Measuring the concordance between CONUT and its individual markers (albumin, cholesterol, lymphocytes) is essential to validate its accuracy, identify potential biases, and ensure the index provides a more comprehensive and balanced evaluation of nutritional status compared to isolated parameters.

Aim and Objectives Assess the concordance between the CONUT index and individual markers, considering the impact of unweighted and weighted Kappa measures.

Material and Methods We conducted a cross-sectional, observational study in a mid-level complexity hospital. We collected all lab results that used the CONUT index, along with individual parameters (albumin, total cholesterol, and lymphocyte count), excluding those with missing data. We used the following cut-off points to classify nutritional status: Albumin (g/dL): $\geq$ 3.5 (Normal), 3.0–3.49 (Mild), 2.5–2.99 (Moderate), $<$ 2.5 (Severe malnutrition); Total Cholesterol (mg/dL): $\geq$ 180 (Normal), 140–179 (Mild), 100–139 (Moderate), $<$ 100 (Severe malnutrition); Lymphocyte count (/mm^3): $\geq$ 1600 (Normal), 1200–1599 (Mild), 800–1199 (Moderate), $<$ 800 (Severe malnutrition).

Kappa, weighted Kappa and Altman's criteria were applied to assess the concordance between the CONUT index and individual parameters.

Results We analysed a total of 3,426 lab results from 2,882 patients. The agreement between the CONUT index and the individual markers was:

CONUT vs. Albumin:

Kappa values: 0.141 (unweighted – poor), 0.319 (linear – low), 0.502 (quadratic – moderate).

CONUT vs. Cholesterol:

Kappa values: 0.218 (unweighted – low), 0.401 (linear – low), 0.589 (quadratic – moderate).

CONUT vs. Lymphocytes:

Kappa values: 0.248 (unweighted – low), 0.418 (linear – low), 0.580 (quadratic – moderate).

Conclusion and Relevance According to Altman's criteria, the agreement between the CONUT index and individual markers (albumin, cholesterol, and lymphocytes) varies significantly depending on the type of weighting applied. This suggests that while exact category matches between CONUT and the markers may be rare, there is a stronger correlation when the proximity of categories is considered. This reflects that the overall trends in nutritional status classification are more similar when small differences in categorisation are accounted for. Further refinements in the weighting of individual markers within the CONUT system could improve its precision and reduce potential biases in specific clinical contexts.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-180 ASSESSMENT OF CAPIVASERTIB FOR TREATMENT OF ADVANCED BREAST CANCER

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Background and Importance The European Medicines Agency (EMA) has recently granted approval for the use of capivasertib in the treatment of locally advanced or metastatic oestrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer with PIK3CA/AKT1/PTEN alterations that has progressed during or after endocrine therapy.

Aim and Objectives To evaluate whether capivasertib and the main current standard treatments are equivalent therapeutic alternatives (ETA) by performing an indirect treatment comparison (ITC).

Material and Methods In May 2024, a literature search was conducted in PubMed using the following criteria: treatment of HR+ HER2- breast cancer with capivasertib, alpelisib, or

Abstract 4CPS-180 Table 1

	PALBOCICLIB	ABEMACICLIB
	HR = 0.48 (95% CI 0.30 – 0.78)	*HR = 0.53 (95% CI 0.33 – 0.84)*
CAPIVASERTIB *HR = 0.65 (95% CI 0.38 – 1.08)*	*HR = 1,35 (0,67 – 2,75)p = 0.40117*	*HR = 1,23 (0,61 – 2,47)p = 0.56808*

or cyclin-dependent kinase 4/6 inhibitors in combination with fulvestrant, in patients with PIK3CA alterations and progression on endocrine therapy. The comparison variable was progression-free survival (PFS). The Bucher method was used for the ITC. In order to establish therapeutic the optimal therapeutic positioning, the ETA guideline [1] was applied. In accordance with the ESMO-MCBS criteria, the non-inferiority delta value (Δ) was established as 0.65, and its inverse 1.54. The Shakespeare method was used to determine the probability of the result exceeding the equivalence Δ.

Results The comparison included a phase III study on capivasertib, one on palbociclib, and one on abemaciclib. Alpelisib and ribociclib were not included in the analysis as they failed to meet the established criteria for comparison. The results of the clinical trials and the indirect comparison are presented below:

The probability of a result falling outside the specified range for palbociclib was 35.7% above, 3.7% below, and 21.0% above for abemaciclib.

Conclusion and Relevance In accordance with the ETA guideline, capivasertib cannot be considered ETAs in comparison to palbociclib and abemaciclib. There is no evidence indicating a superior efficacy of capivasertib in combination with fulvestrant compared to palbociclib and abemaciclib in combination with fulvestrant. Given the toxicity profile of capivasertib, the recommended initial treatment option for of CDK4/6 inhibitors remains unchanged.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

4CPS-181 HIV PRE-EXPOSURE PROPHYLAXIS IN REAL-WORLD SETTING: TOLERANCE AND ADHERENCE

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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 studies of adherence and tolerance to PrEP are limited.

Aim and Objectives To evaluate the tolerance and adherence of HIV PrEP in a real-world setting.

Material and Methods A cross-sectional observational study was designed in a third-level hospital. Daily dose PrEP users with a minimum follow-up of 3 months were included. Users were followed from June 2024 to August 2024. On-demand PrEP users were excluded.

Socio-demographic data, sexually transmitted diseases (STDs) diagnosis and treatment variables were collected. Tolerance data were collected from the electronic medical record. Adherence was analysed using the Simplified Medication Adherence Questionnaire (SMAQ) (users were considered adherent when the SMAQ percentage was 100%), and the medication possession ratio (MPR) (users were considered adherent when the MPR was $\geq$ 0.8).

Results

Abstract 4CPS-181 Table 1

Sociodemographics:		
	Patients:	321.
	Sex:	99.1% were male.
	Mean age:	36.8 (8.9) years.
STDs diagnosis:		
	Users with STDs diagnosis:	176 (55%).
	Users with ≥2 STDs diagnosis:	74 (23.1%).
Treatment variables:		
	Mean PrEp treatment time:	12.4 (31.5) months.
	Users with concomitant medication:	174 (54.4%).
	Users with protein supplements:	46 (14.4%).
Tolerance:		
	Users with any adverse effects:	60 (18.8%).
	Adverse effects:	
	• Nausea.	6 (1.9%).
	• Diarrhoea.	8 (2.5%).
	• Abdominal pain.	7 (2.2%).
	• Dizziness.	1 (0.3%).
	• Hypophosphatemia.	33 (10.3%).
	• Renal failure.	6 (1.9%).
	• Headache.	1 (0.3%).
	• Insomnia.	1 (0.3%).
Adherence:		
	MPR:	
	• Mean:.	0.96 (0.07).
	• Adherents:.	311 (97.2%).
	%SMAQ:	
	• Adherents:.	• .
	100%.	172 (53.8%).
	• Non-adherents:.	• .
	95–100%.	118 (36.9%).
	85–94%.	26 (8.1%).
	65–84%.	0 (0.0%).
	30–64%.	1 (0.3%).
	<30%.	2 (0.6%).

Conclusion and Relevance Less than 20% of users experienced an adverse effect. The most frequent were hypophosphataemia and diarrhoea. Although renal failure was less frequent, it required in one case a switch from TDF to tenofovir alafenamide (TAF) due to its lower renal toxicity.

About adherence, the MPR showed higher adherence compared to the SMAQ questionnaire. This could be explained, on the one hand, by the restrictive nature of the SMAQ questionnaire and, on the other hand, because users may have had more medication than they declared in the interview, according to the dispensing data. In this sense, more studies related to non-adherence and its causes are needed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-182 NUTRITIONAL ASSESSMENT OF NON-SMALL-CELL LUNG CANCER PATIENTS UNDERGOING TREATMENT WITH OSIMERTINIB

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Background and Importance Non-small-cell lung cancer (NSCLC) accounts for approximately 85% of all lung cancer cases and is a major cause of morbidity and mortality globally. At the time of diagnosis, 35% to 65% of NSCLC patients present with nutritional issues such as malnutrition, which negatively impacts prognosis, treatment response, and overall quality of life. Sarcopenia, characterised by the loss of skeletal muscle mass and strength, further complicates outcomes in cancer patients. Identifying the nutritional status and body composition of patients receiving targeted therapies like osimertinib is essential to optimise treatment and manage adverse effects.

Aim and Objectives The primary aim of this study was to assess the nutritional status and body composition of NSCLC patients undergoing treatment with osimertinib, a third-generation tyrosine kinase inhibitor (TKI). Secondary objectives were to evaluate the prevalence of sarcopenia and examine the relationship between low muscle mass, malnutrition, and the occurrence of dose-limiting toxicities during treatment.

Material and Methods This observational, descriptive, cross-sectional study included 25 adult NSCLC patients treated with osimertinib. Anthropometric measurements were recorded, body composition was analysed using bioelectrical impedance analysis (BIA), and muscle functionality was assessed through handgrip strength (dynamometry). Nutritional status was classified according to established diagnostic criteria.

Results A total of 25 patients (60% women), with a median age of 72 (33–87) years were included. Malnutrition was identified in 36% of patients and 66.7% of patients diagnosed with malnutrition presented DLT. Sarcopenia was present in 4% of patients, 8% were classified as pre-sarcopenic, and 20% exhibited dynapenia. Patients who developed dose-limiting toxicities showed significantly lower fat-free mass and fat-free mass index, suggesting that reduced muscle mass may be associated with higher treatment-related toxicities. Although no statistically significant association was found between malnutrition and toxicities, patients with malnutrition tended to experience more adverse effects.

Conclusion and Relevance These findings emphasise the importance of early and individualised nutritional interventions in NSCLC patients receiving osimertinib to enhance their nutritional status, optimise cancer treatment, and reduce dose-limiting toxicities. Future research involving larger patient cohorts and longitudinal designs is needed to validate these results and investigate the efficacy of nutritional interventions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-183 MULTICENTRE STUDY: EVALUATION OF THE EFFECTIVENESS AND SAFETY OF UPADACITINIB IN INFLAMMATORY BOWEL DISEASE

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Background and Importance Upadacitinib is a reversible and selective inhibitor of Janus kinases (JAK) recently indicated for the treatment of active moderate to severe inflammatory bowel disease (IBD) in adults with inadequate response, loss of response, or intolerance to conventional treatments or biological agents.

Aim and Objectives This study aims to evaluate its effectiveness and safety in ulcerative colitis (UC) and Crohn's disease (CD).

Material and Methods Multicentre, observational and retrospective study (December 2022-October 2024). Patients who reached at least week 24 (24W) were included, along with reasons for any treatment discontinuation.

Collected variables: sex, age, pathology, prior hospital therapies (biological drugs or other JAK inhibitors), treatment start and end dates, faecal calprotectin (FC), C-reactive protein (CRP), number of bowel movements, presence of blood before and after treatment and adverse reactions.

Effectiveness was assessed by the reduction in FC and CRP levels, the number of bowel movements and the disappearance of blood in stools from the start of treatment to 24W. Safety was evaluated based on the occurrence of adverse reactions.

Continuous variables were expressed as means (standard deviation) and medians (interquartile range).

Results A total of 31 patients (68% male) were included, with a median age of 38 years (IQR: 28–46) and a mean follow-up of 43 weeks (SD ±19). 58% of the patients had CD and 42% had UC. The median number of previous treatments was 1.7 (IQR: 1–2,5), and concomitant treatments included glucocorticoids (26%) and azathioprine (9.7%). 93,5% of the patients had a maintaining dose of 30 mg.

After 24W, FC decreased from 1141 (IQR: 450–2208) to 679 (IQR: 227–1589) and CRP decreased from 4.6 (IQR: 3.5–10.7) to 2.6 (IQR: 0.9–6.5). The mean daily bowel movements decreased from 5.6 (SD ±3.4) to 4.3 (SD ±3.4), while the presence of blood decreased from 61.3% to 25.8%.

Regarding safety, 9.7% of patients (n=3) discontinued treatment, with 33.3% due to pregnancy and 66.6% due to adverse reactions (9.7% acne, 6.4% reactivation of cytomegalovirus, 6.4% thrombosis, 3.2% herpes simplex and 3.2% paraesthesia).

Conclusion and Relevance Upadacitinib is a novel therapy. In our cohort it has improved overall outcomes for patients with IBD, reducing disease-related parameters and the number of bowel movements. Regarding safety, upadacitinib exhibits management and an expected safety profile.

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

4CPS-184 DETERMINATION OF VORICONAZOLE METABOLISER PHENOTYPE IN THE ABSENCE OF GENETIC TESTING

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Background and Importance Pharmacokinetic monitoring of voriconazole is useful for optimising its treatment due to the significant inter- and intra-individual variability it exhibits. It is metabolised mainly by CYP2C19, an enzyme with a considerable genetic polymorphism leading to variability in metabolism among the population. Its genotyping in many cases is expensive and inaccessible, so it would be interesting to develop alternative methods to determine the patient's metaboliser phenotype.
Aim and Objectives To determine the metaboliser phenotype according to plasma concentrations (Cp) of voriconazole using a population pharmacokinetic model.
Material and Methods Observational, descriptive, retrospective study of patients treated with intravenous and oral voriconazole in a second-level hospital from January 2016 to June 2024. Clinical data were collected through the electronic medical record: medical history number, weight, posology, route and rate of administration, Cp and concomitant treatments with prednisone, methylprednisolone, dexamethasone, carbamazepine, phenytoin, ritonavir and St. John's wort.

We applied the Dolton pharmacokinetic model to each patient using the NONMEM program to estimate Cp of voriconazole based on two assumptions:

- CYP2C19=1 for patients with one or more loss-of-function alleles (poor metaboliser).
- CYP2C19=0 for patients not meeting the previous criteria (normal/rapid metaboliser).

We obtained: observed Cp (Cpo), predicted Cp for CYP2C19=1 (CppCYP2C19=1) and predicted Cp for CYP2C19=0 (CppCYP2C19=0).

We deduce metaboliser phenotype according to:

- Cpo value closest to CppCYP2C19=1 → Poor metaboliser.
- Cpo value closest to CppCYP2C19=0 → Normal/rapid metaboliser.
- Values very different or very similar to each other → Not possible to determine the metaboliser phenotype.

Results A total of 85 Cp of voriconazole were analysed from 47 patients. Regarding metaboliser phenotype, 63.9% (30 patients) were normal/rapid metabolisers, 6.4% (three patients) were poor metabolisers and 29.7% (14 patients) could not be determined.
Conclusion and Relevance The metaboliser phenotype could be estimated in the majority of patients (70.3%). Therefore, the application of the Dolton pharmacokinetic model to the Cp of voriconazole obtained could be a useful tool, in the absence of genetic studies, to determine the metaboliser phenotype of our patient.

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

4CPS-185 EVALUATE THE IMPACT OF A PHARMACEUTICAL INTERVENTION TO IMPROVE THE ADEQUACY OF ANTIBIOTIC CONSUMPTION

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Background and Importance Spain is characterised by a high use of antibiotics (ATB) and, in parallel, high rates of resistance, whose consequences in terms of health are characterised by therapeutic failures and associated morbidity and mortality. Since 2014, the National Plan against Antibiotic Resistance (PRAN) has been in place and most of the Autonomous Communities have implemented an Antibiotic Optimisation Programme (PROA).
Aim and Objectives Our objective is to reduce antibiotic consumption through a pharmaceutical intervention, improving the adequacy of antibiotic treatment.
Material and Methods Prospective Intervention Study in a Health Area (36 primary health care centres, with 673 general practitioners (GPs) and 80 paediatricians, serving 677,782 inhabitants, distributed in urban and rural areas). Study period: The intervention was carried out in 2022–2023. The intervention consisted of: Training sessions, Dissemination to all GPs, paediatrics and emergency departments of algorithms for the most prevalent infectious processes in Primary Care as a prescription aid tool: Pharyngotonsillitis in adults; Acute community-acquired pneumonia; Acute bronchitis; COPD exacerbation; Odontogenic infections; Symptomatic UTI in institutionalised elderly; Cystitis in women; Cystitis in pregnancy; UTI in men; Pneumonia in institutionalised elderly. The outcome variable was the defined daily doses per 1000 inhabitants per day (DDD) (Therapeutic group J01).
Results The evolution of antibiotic consumption rates in recent years (DHD): Urban Area: 2018 (11,96), 2019 (11,56), 2020 (8,72), 2021 (8,78), 2022 (10,71), 2023 (10,76). Rural Area: 2018 (14,83), 2019 (14,91), 2020 (11,31), 2021 (11,34), 2022 (13,95), 2023 (14,39). For the evaluation, the period 2018–2023 has been studied to ascertain pre-pandemic antibiotic consumption rates.
Conclusion and Relevance 1. Algorithms, as prescription support tools, provide quick access, as well as basic information on the treatment of the most frequent infectious processes. The use of these algorithms facilitates compliance with the objectives of the PROA (optimising the use of antibiotics, minimising adverse effects, improving bacterial resistance and ensuring cost-effective treatment). 2. The intervention has not yet reached pre-pandemic AB rates, although it is necessary to continue working to reduce the consumption of antibiotics, improving their appropriateness.

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

4CPS-186 ABSTRACT WITHDRAWN

4CPS-187 IMMUNISATION WITH NIRSEVIMAB: IMPACT ON RSV SEASON IN A PAEDIATRIC HOSPITAL

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Background and Importance Respiratory syncytial virus (RSV) is the leading cause of acute lower respiratory tract infections in children, having a considerable impact on healthcare system and later comorbidities.

Aim and Objectives To describe the characteristics of patients admitted for RSV bronchiolitis during the first immunisation campaign with nirsevimab, conducted from October 2023 to March 2024

Material and Methods Prospective observational study. It included patients admitted for RSV infection who were eligible for nirsevimab. Campaign included infants under 6 months at the start, those born during the campaign and high-risk patients aged 6 months to 2 years.

Collected variables: age, immunisation status, admission in Intensive Care Unit (ICU), suspected bacterial superinfection, type of respiratory support required, length of hospital stay (LOS) and oxygen therapy.

Results Patients ≤ 6 months: There was a 67% reduction in admissions comparing the previous year (57 vs.172). Of the 57 admitted patients, 81% had not received immunisation and 10 patients were considered high-risk for severe disease, seven of whom were not immunised. All non-immunised patients (NIP) required respiratory support while 10% of immunised patients (IP) did not require it. Maximum respiratory support required is shown in table 1.

Seventeen patients required ICU admission (76% NIP), with median ICU LOS of 3 (1–4) days, and 26% showed signs of bacterial superinfection. Median LOS for IP and NIP was 5 days with different ranges (2–12) for NIP and (3–7) for IP.

Patients 6 months-2 years Ninety-nine percent of admitted patients were NIP (83), only 7% met immunisation criteria. Maximum respiratory support required is shown in table 2.

Fifteen percent of the patients required ICU admission, with a median LOS of 4 (1–13) days, and the majority (10) had suspected bacterial superinfection. Sixty percent of the patients admitted to the ICU presented high-risk for severe disease. Median LOS was 4 days (1–37).

Abstract 4CPS-187 Table 1

	Immunised Patients (IP)	Non-Immunised Patients (NIP)
Nasal cannula	22%	58%
High-flow nasal cannula	33%	23%
CPAP	22%	10%
BIPAP	11%	6%
Median (range) days with respiratory support	4 (1–10)	4 (0–7)

Abstract 4CPS-187 Table 2

Nasal cannula	2%
High-flow nasal cannula	77%
BIPAP	2%
Mechanical ventilation	1%
Median (range) days with respiratory support	4(0–28)

Conclusion and Relevance In this study we appreciate a decrease in admissions among immunised patients; however, it does not seem to modify the course of the disease compared to non-immunised patients in terms of oxygen therapy needs and LOS, although there is a tendency to shorten them. Further studies are needed to confirm these observations.

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

4CPS-188 THERAPEUTIC DRUG MONITORING FOR DALBAVANCIN SUPPRESSIVE THERAPY: OPTIMISING INFUSION SPACING BASED ON MINIMUM INHIBITORY CONCENTRATION

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Background and Importance Dalbavancin is a long-acting antimicrobial used for suppressive therapy, with dosing adjusted through therapeutic drug monitoring (TDM) due to the lack of validated regimens. Recent expert recommendations propose a dosing schedule targeting a residual concentration above 8 mg/L, aimed at Staphylococcus species with a minimum inhibitory concentration (MIC) of 0.125 mg/L, the clinical breakpoint for dalbavancin. However, literature suggests that lower residual targets may be considered for MICs below 0.125 mg/L, potentially enabling longer administration intervals.[1]

Aim and Objectives The aim is to demonstrate the benefits of using concentration thresholds adapted to the MIC of the bacteria for TDM and infusion spacing in patients treated with dalbavancin.

Material and Methods This retrospective study (November 2017 to January 2024) included patients receiving dalbavancin as suppressive therapy. Dalbavancin levels were measured prior to each administration. Results were interpreted using either a target of 8 mg/L or a lower. According to the literature, the therapeutic target was adjusted proportionally: for instance, if the MIC was reduced by half, the target concentration was similarly reduced. This pattern continued as the MIC decreased further.

Results Seven patients were included with a median age of 72 (63.5 – 79.5). Indications were mainly endovascular equipment infections (28,6%) and endocarditis (28,6%). Common pathogens included *Staphylococcus aureus* (28,6%), *Enterococcus faecalis* (28,6%) and coagulase-negative *Staphylococcus sp.* (14,3%). The median MIC was 0,047 mg/L (0.032–0.092 mg/L) and the median residual concentration was 6.95 mg/L (4.4–12 mg/L). Using a target of >8 mg/L, 41% of dosing reached the goal, which increased to 90,6% when adjusted to the

actual MIC, allowing injection spacing for these seven patients from 4 weeks at the beginning to 10 weeks in median (7–11).
Conclusion and Relevance Adjusting dalbavancin dosing to the MIC improves therapeutic target achievement and enables longer dosing intervals, especially in suppressive therapy. However, clinical outcomes require further evaluation to validate these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-189 REAL-WORLD EFFECTIVENESS, SAFETY AND ADHERENCE OF LONG-ACTING CABOTEGRAVIR AND RILPIVIRINA IN A TERTIARY HOSPITAL

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Background and Importance Long-acting (LA) intramuscular therapy with cabotegravir (CAB) and rilpivirina (RPV) has demonstrated to be an alternative to daily oral regimens.
Aim and Objectives To assess clinical effectiveness of switching from an oral regimen to CAB+RPV LA in HIV patients at 6 and 12 months. Secondarily, safety and impact on adherence were evaluated.
Material and Methods Observational, retrospective and single-centre (tertiary hospital) study. We included patients who switched to CAB+RPV LA between January 2023 and March 2024. Demographic and laboratory data, previous resistance studies and prior treatment adherence were recorded. At 6 and 12 months, viral load (VL), CD4 counts, adherence and medication-related issues were documented. Effectiveness was determined by VL and CD4 counts. Safety was measured by the number of reported adverse events (AEs) and percentage of discontinuations. Data were obtained from the hospital eVIHA cohort.
Results Seventy-one patients were included (82% male, median age 46 (IQR 38–55) years). Time of HIV-1 infection was 14 (IQR 8.2–18.5) years. Median follow-up was 11.6 (IQR 8.8–15.8) months. Four patients had previous resistance to non-nucleoside reverse transcriptase inhibitors (NNRTIs) and one patient to integrase inhibitors (INIs). 43 (60%) patients had no previous resistance studies. VL was consistently <20 copies/ml across all time points. Median CD4 count was 848 (IQR 738–1189) cells/µl at the start of treatment, 937 (IQR 767–1225) cells/µl at 6 months ($p<0.05$), and 981 (IQR 724–1160) cells/µl at 12 months ($p=0.3$). Prior adherence was >90% in 66 (92%) patients. Adherence to CAB+RPV LA was >90% in 66 (92%) patients at 6 months and in 28 (93%) patients at 12 months, differing those from non-adherent patients to oral treatment. A total of 31 (44%) patients reported AEs. The most frequent were local issues (20), flu-like symptoms (7), and neurological reactions (6). Eight (11%) patients discontinued treatment, all due to AEs.
Conclusion and Relevance Real-world CAB+RPV LA data show its effectiveness in maintaining viral suppression and adequate CD4 levels. However, we have seen a significant percentage of discontinuations due to AEs that differ from data reported in trials. We also noticed changes in patient adherence patterns. Further studies with a larger number of patients would be necessary to confirm these findings.

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

4CPS-190 OPTIMISATION OF ADALIMUMAB IN CHILDREN WITH INFLAMMATORY BOWEL DISEASE: KEY FACTORS FOR DOSE ESCALATION

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Background and Importance Inflammatory bowel disease (IBD) presents significant treatment challenges due to limited therapeutic options, particularly in children. Maximising the effectiveness of available treatments, like adalimumab, is crucial to improve patient outcomes. Therefore, early identification of patients most likely to adjust dosage could help optimise treatment.
Aim and Objectives To describe the characteristics of IBD paediatric patients (PP) treated with adalimumab in order to identify features of those requiring dose escalation for optimisation.
Material and Methods Observational, retrospective study including all IBD PP treated with adalimumab from January-2019 to July-2024. Data collected: sex, age, diagnosis, medications, adalimumab levels (AL) after induction, at 6 months, and at 1 year. Calprotectin levels and concomitant medication were evaluated at baseline, 6 months, and 1 year. Adverse drug reactions (ADRs) and reasons for discontinuation were also recorded.
Results 31 patients included, 61.0% male, median age 12 years (IQR 4). 84.0% had Crohn's disease and 16.0% ulcerative colitis. Before starting adalimumab, 71.0% were on azathioprine, 32.3% on systemic glucocorticoids, and on 16.1% mesalamine. The median AL were 11.0 (IQR 5.5) after induction, 12.1 (IQR 5.7) at 6 months, and 10.6 (IQR 8.2) at 12 months. Patients who required dose escalation had median AL of 9.4 (IQR 6.8) at 6 months and 8.3 (IQR 4.4) at 12 months, compared to 12.5 (IQR 5.2) and 13.2 (IQR 7.1) for those who did not require escalation. Calprotectin levels were classified into three groups: >3000 (12.9%), 2000–3000 (29.0%), and <2000 (58.1%). It was observed that 75% of patients with calprotectin >3000 and 67% of those with calprotectin between 2000–3000 required dose escalation. 55% of patients on azathioprine at baseline also required dose escalation. During the study period, 58.1% of patients required dose escalation or increased dosing frequency. ADRs were reported by 23% of patients, being the most common Herpes-Zoster, respiratory infections, and skin rash (28.6% each one). 29% of patients discontinued treatment, mainly due to secondary loss of response (66.7%).
Conclusion and Relevance This study suggests that higher doses of adalimumab may be necessary for IBD PP with baseline calprotectin levels >2000 or those receiving concomitant

azathioprine. A proactive pharmacokinetic monitoring approach of AL could optimise treatment and improve outcomes.

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

4CPS-191 EVALUATION OF AUC/MIC AS A PREDICTOR OF MICROBIOLOGICAL AND CLINICAL OUTCOMES IN STAPHYLOCOCCUS GRAM-POSITIVE BACTERAEMIA TREATED WITH VANCOMYCIN

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Background and Importance Vancomycin's role in treating gram-positive infections is well-established. However, the optimal AUC/MIC ratio for non-MRSA Staphylococcal bacteraemia has not been clearly defined. Current guidelines recommend an AUC/MIC ratio of 400–600 mg·h/L for MRSA, but this target may not fully apply to other Staphylococcal species.
Aim and Objectives To assess whether an AUC/MIC ratio of 400–600 is predictive of clinical and microbiological outcomes in non-MRSA Staphylococcal bacteraemia treated with vancomycin.
Material and Methods Observational-retrospective study in a tertiary hospital. Adult patients with non-MRSA Staphylococcus bacteraemia treated with vancomycin between January 2020 and June 2024 were registered. Data collected included demographics, AUC/MIC, Bayesian estimated renal clearance, total daily dose, and whether the infection was considered complicated or uncomplicated. Clinical cure was defined as the normalisation of at least two out of three markers (temperature, C-reactive protein, leukocytes) at 72 hours, and microbiological cure as negative blood cultures. Statistical analysis was performed using RStudio (version 2023.12.1), applying logistic regression models to evaluate the relationship between AUC/MIC and both microbiological and clinical outcomes. Receiver operating characteristic (ROC) curves were used to assess the predictive power of the models, and area under the curve (AUC) values were calculated for microbiological and clinical outcomes.
Results Median age was 63.5 years (SD:14.7), with 58.7% male. Coagulase-negative Staphylococci (CoNS) accounted for 91.3% of cases. The mean Bayesian estimated renal clearance was 5.19 L/h (SD:1.85). The mean total daily dose was 2467.39 mg/day (SD:811.19). The AUC/MIC target of 400–600 was achieved in 37.0% of patients. Additionally, 34.8% had an AUC/MIC below 400, and 28.3% had an AUC/MIC above 600. Of the patients with an AUC/MIC below 400, 12.5% achieved microbiological cure. Overall microbiological cure was 82.6%, with an AUC of 0.845 for the predictive model. Clinical cure was achieved in 50% (AUC=0.773). The inclusion of whether the infection was complicated or uncomplicated did not significantly improve prediction (AUC=0.845).
Conclusion and Relevance Achieving an AUC/MIC of 400–600 is predictive of microbiological cure, but the predictive ability for clinical cure is lower, likely due to the sample size and limited treatment failures. Further research with larger cohorts is needed to validate these findings, particularly in complicated versus uncomplicated infections.

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

4CPS-192 TRANSFORMING DRUG SHORTAGES INTO OPPORTUNITIES FOR OPTIMAL USE OF AZTREONAM

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Background and Importance Aztreonam serves as a valuable alternative for patients with documented beta-lactam hypersensitivity. However, many patients are incorrectly labelled as beta-lactam allergic, leading to an inappropriate use. Due to the national drug shortage, an opportunity arose to ensure the suitable utilisation of the antibiotic.
Aim and Objectives The main aim is to develop a utilisation protocol for aztreonam and evaluate the outcomes of that implementation.
Material and Methods The protocol was developed by a multidisciplinary team, including pharmacists, allergists, infectious disease specialists, and microbiologists. This team established an action plan to evaluate allergy status, identify therapeutic alternatives, and ensure the proper use of aztreonam through centralised preparation carried out by the pharmacy department.

The implementation period was from April to August 2024. To assess the impact of the protocol, data of defined daily doses (DDD) were compared with the same period in 2023. Moreover, we evaluated the outcomes of the protocol implementation by identifying patients whose treatments were optimised and whose beta-lactam allergy status was clarified.
Results During the study period, aztreonam was prescribed to 68 patients; however, only 25 patients (36.7%) ultimately received aztreonam with a consumption of 232.5 DDD. In contrast, the same period in 2023 had 106 patients with aztreonam, resulting in 454.25 DDD. Notably, 76.3% of patients labelled with a beta-lactam allergy had their allergy confirmed by the interdisciplinary team, compared to only 55.7% in the same period of the previous year.

Among those patients who did not receive aztreonam, 31 (45.6%) were given alternative therapies to beta-lactams, while eight patients (11.8%) had their false allergy disproven and were switched to other beta-lactams. Additionally, four patients (5.9%) underwent desensitisation to beta-lactams.

Within the 25 patients who received aztreonam, the median age was 72 years (IQR 62–93). The main indications were pneumonia (44%), sepsis (20%) and empiric coverage (20%). Five patients (20%) required aztreonam for infections caused by multidrug-resistant *K. pneumoniae*.

The pharmacy department prepared 445 aztreonam admixtures, consisting of 268 of 1g and 177 of 2g.
Conclusion and Relevance The implementation of the protocol during the shortage effectively reserved aztreonam for patients who needed it and demonstrated how supply crises can enhance antibiotic stewardship through multidisciplinary collaboration.

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

4CPS-193 LONG-TERM IMPACT OF A PHARMACEUTICAL INTERVENTION ON BENZODIAZEPINE USE: A GENDER PERSPECTIVE

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Background and Importance Benzodiazepines (BZDs) are widely prescribed to treat anxiety and insomnia, but prolonged use carries the risk of dependence and adverse effects. Prescription patterns vary between rural and urban areas, as well as between men and women, with research indicating a significant gender gap, as women are more likely to consume these medications than men.

Aim and Objectives To evaluate the effect of a pharmaceutical intervention aimed at reducing BZD consumption, analysing differences by gender and healthcare area (urban and rural) from 2021 to 2023.

Material and Methods A pre-post study was conducted in two healthcare areas, one urban and one rural, covering a total population of 690,000 inhabitants, with 36 healthcare units, 521 general practitioners, and nine primary care pharmacists. All adult patients with an active BZD prescription between 2021 and 2023 were included. Data were extracted from a prescription database. The variables analysed were the BZD consumption rate (defined daily dose (DDD)/1000 inhabitants), adjusted by sex and area. The intervention included training sessions for primary care physicians, distribution of informational materials on the safe management of BZDs, and guidance and monitoring of prescriptions. Total BZD rates and gender differences were compared before and after the intervention.

Results In the rural area, the BZD rate in 2021 was 106.39 DDD/1000 inhabitants, compared to 101.47 DDD/1000 in the urban area. In 2022, the rates were 105.28 DDD/1000 (−1.11%) in the rural area and 98.96 DDD/1000 (−2.51%) in the urban area. By 2023, a reduction of 4.71% was observed in the rural area and 5.02% in the urban area compared to 2022. Women consistently had higher BZD consumption than men in both settings. In 2021, the gender difference rate was 54.91 points in the rural area and 36.11 points in the urban area, by 2023, this difference rate was 50.97 points in the rural area and 30.19 points in the urban area.

Conclusion and Relevance The pharmaceutical intervention was effective, particularly in rural areas and among women. Collaboration between pharmacists and physicians was key to the success of the intervention. Continued strategies differentiated by gender are recommended.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-194 SELECTIVE DIGESTIVE DECONTAMINATION IN CRITICALLY ILL PATIENTS

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Background and Importance Selective digestive decontamination (SDD) aims to reduce hospital-acquired infections in critically ill patients (CIP) by topical administration of non-absorbable antimicrobials in oropharynx and stomach and 4-days course of intravenous-antibiotic. SDD is elaborated in Pharmacy-Department. A multidisciplinary meeting is conducted weekly to decide the appropriate SDD for each CIP.

Aim and Objectives To analyse the frequency of multidrug-resistant-bacteria (MDRB) colonisation/infection in CIP with SDD and the SDD-effectiveness of MDRB decolonisation.

Material and Methods Prospective, observational and descriptive study. All adult patients admitted to ICU from December 2023 to July 2024 who received SDD were included.

Age, sex, risk factors of colonisation (RFC) by MDRB, date of first MDRB-isolation and date of decolonisation in surveillance microbiological cultures, acquired-infection, ICU discharge date and outcome were collected.

MDRB studied: Methicillin-resistant *Staphylococcus aureus* (MRSA), Vancomycin-resistant Enterococci (VRE), Extended-spectrum beta-lactamases and carbapenemase-producing Enterobacteriaceae (ESBLE, CPE) and Multidrug-resistant *Pseudomonas aeruginosa* (MDRPA) (resistant to three or more antibiotic-families).

RFC by MDRB studied: Previous MDRB-colonisation/infection, transfer from social-health centre, previous hospital admission in last year, 48 hours or more in hospital ward prior to ICU admission, beta-lactams and/or quinolones treatment in last 90-days, chronic-dialysis, chronic skin-ulcers and permanent vesical-catheterisation.

Qualitative variables were analysed by χ^2-test.

Results A total of 219 CIP were included. Median age was 71 (IQR:59–78) years. 47.95% (105) had at least one RFC. Median ICU-days was nine (IQR:4–21).

MDRB were isolated in microbiological surveillance-cultures in 13.70% (30) patients: 6.14% (seven) of non-RFC-group and 21.90% (23) of RFC-group.

Overall, the presence of any RFC increased colonisation risk by 3.57 times, RR3.57 (95% CI 1.63–7.8) $p=0.001$. RFC with the greatest impact was previous MDRB-colonisation/infection, 69.23% (nine) of these patients (13) had MDRB-colonisations, RR6.79 (95% CI 3.47–13.29) $p<0.001$.

MDRB-colonisations were caused by: 31.25% (10) MRSA, 28.13% (nine) VRE, 28.13% (nine) ESBLE, 6.25% (two) MDRPA and 6.25% (two) CPE. Decolonisation success was: 100% CPE, 66.67% ESBLE, 50% MDRPA, 40% MRSA and 33.33% VRE. The overall decolonisation rate was 53.33% (16).

VRE had the longest time to decolonise with a median of 14 (IQR:10.5–15.5) days, followed by CPE with 8.5 (IQR:6.75–10.25) days, ESBLE with six (IQR:5.25–8.25) days, MRSA with six (IQR:5 −9.50) days and MDRPA, only a patient was able to decolonise in 7 days.

Acquired- infections occurred in 13.33% (four): 50% (two) MRSA, 25% (one) VRE and 25% (one) MDRPA.

Conclusion and Relevance Recognition of RFC is a correct practice to identify patients who benefit from the implementation of SDD targeted at MDRB. The fact that some MDRB are not successfully decolonised may be due to the need for more days of SDD exposure or an inadequate antimicrobial combination.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-195 EVALUATION OF THE EFFECTIVENESS AND SAFETY OF THE BEVACIZUMAB-TRIFLURIDINE-TYPIRACYL REGIMEN IN A MULTICENTRIC STUDY

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Background and Importance Colorectal cancer (CRC) is the third most common cancer and the second most deadly worldwide. The efficacy data of trifluridine/tipiracil (TT) plus bevacizumab in treatment of metastatic CRC who have received two previous antineoplastic treatment regimens come from phase III SUNLIGHT clinical trial (compared with TT monotherapy), with the variable primary efficacy overall survival (OS) and as a secondary objective progression-free survival (PFS), obtaining a median difference of 6.7 months (HR:0.40; 95% CI: (0.30–0.55); p < 0.001) with a 6-month OS of 70% and 3.2 months (HR:0.44; 95% CI: (0.36–0.54); p< 0.001) with a 6 month PFS of 43% respectively.

Aim and Objectives To evaluate the effectiveness and safety of the bevacizumab-trifluridine-tipiracil (BTT) regimen in metastatic CRC.

Material and Methods A multicentre retrospective descriptive study was carried out that included patients treated with the BTT regimen. The regimen was administered as follows: trifluridine-tipiracil 35 mg/m^2/dose twice daily on days 1–5 and 8–12 every 28 days plus bevacizumab 5 mg/kg every 2 weeks. The following variables were collected: sex, age, functional status at the beginning of treatment (ECOG), treatment line and number of cycles. To assess effectiveness, OS and PFS were measured. Safety was assessed by the appearance of adverse events (AE) recorded in clinical history.

Results 40 patients with a mean age of 66 ± 11 years (sex: 80% men) were included. 57.5% (23/40) of patients had ECOG 0 and 42.5% (17/40) had ECOG 1. The median number of treatment lines received was five, the median number of cycles received was four and the 45% (18/40) of patients discontinued treatment, of which 83.3% (15/18) was due to disease progression. OS at 6 months was 90% (36/40) and PFS at 6 months was 60% (24/40). Regarding safety, 65% (26/40) experienced some grade 3–4 AE, the most common being neutropenia 40% (16/40) and anaemia 12.5% (5/40). Only two patients did not present any adverse effects.

Conclusion and Relevance The data obtained in our study show effectiveness superior to that obtained in the SUNLIGHT clinical trial which may be due to the high percentage of patients with ECOG 0–1, in addition to a with a safety profile in line with what was observed in that trial. Studies with a larger population and a longer follow-up period would be necessary to know the real-life effectiveness of this regimen.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-196 ANALYSIS OF ANTIBIOTIC CONSUMPTION DUE TO THE IMPLEMENTATION OF FRONT-END AND BACK-END STRATEGIES OF ANTIMICROBIAL STEWARDSHIP: AN INTERRUPTED TIME SERIES ANALYSIS

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Background and Importance The inappropriate use of antibiotics significantly contributes to antimicrobial resistance (AMR), leading to side effects and high healthcare costs. In hospital settings, the best strategy to deal with AMR is the implementation of Antimicrobial Stewardship (AMS) programmes, which include various strategies, mainly categorised as front-end (FE) and back-end (BE), respectively restrictive and persuasive measures. A combination of these two strategies has proven effective in reducing the inappropriate use of antibiotics in this context.

Aim and Objectives Assessment of changes in the quali-quantitative trends of antibiotic consumption (DDD/100 hospital days) before and after the implementation of front-end (FE) and back-end (BE) Antimicrobial Stewardship (AMS) strategies in a Teaching Hospital.

Material and Methods In October 2023, were implemented both front-end (FE) and back-end (BE) strategies. The FE involves formulary restrictions on prescriptions and pre-authorisation revision of prescriptions in all the hospital departments. The BE consists of post-prescription monitoring of antibiotic therapies within a multidisciplinary team, in dedicated settings (e.g. two Medical Departments). The antibiotic consumption was analysed through the Interrupted Time Series Analysis, from January 2019 to September 2024, focusing on the variation before and after October 2023, both quantitatively (DDD/100 hospital days) and qualitatively (percentage of consumption based on the AWaRe classification) trends were reported.

Results The total consumption of antibiotics has shown a slight increase from January 2019 to October 2023 (pre-intervention trend = +0.01 DDD/100 days per month) and a statistically significant decrease with the introduction of FE and BE (post-intervention trend = −1.26 DDD/100 days per month; p<0.05). Moreover, post-intervention, there was a statistically significant decrease in Reserve antibiotics (−0.34% per month; p<0.05) and a non-significant decrease in Watch

antibiotics (−0.21% per month), alongside a significant increase in Access antibiotics (+0.55% per month; $p<0.05$).
Conclusion and Relevance As revealed by the literature and by our experience, the introduction of FE and BE interventions is effective in improving prescribing appropriateness and in the qualitative and quantitative use of antibiotics. In fact, the collaboration in a multidisciplinary team, including clinicians, pharmacists, microbiologists, and nurses, has been essential for the success of AMS initiatives, as it allows for an integrated and shared assessment of therapeutic choices.

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

4CPS-197 ABSTRACT WITHDRAWN

4CPS-198 CLOZAPINE MONITORING: EFFICACY, SAFETY AND THE INFLUENCE OF SMOKING ON PLASMA LEVELS

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Background and Importance Monitoring clozapine plasma levels is crucial to optimise treatment efficacy and minimise haematological toxicity risks, including agranulocytosis and leukopenia. Additionally, smoking significantly affects clozapine metabolism, leading to lower plasma concentrations and potential subtherapeutic effects, emphasising the need for tailored monitoring in patients.
Aim and Objectives To analyse the treatment of patients with schizophrenia and psychosis using clozapine, focusing on its efficacy and safety. The assessment was conducted by determining trough plasma concentrations of clozapine.
Material and Methods A retrospective observational study was carried out involving patients diagnosed with schizophrenia or psychosis treated with clozapine. Clozapine plasma levels were measured between January 2023 and September 2024. The variables collected included sex, age, diagnosis, smoking habits, dose, trough plasma levels (therapeutic range: 250–700 ng/mL), and haematological toxicity parameters (leukopenia, neutropenia, eosinophilia, and thrombocytopenia). Additionally, dose adjustment recommendations were made when necessary, and the acceptance of these recommendations was evaluated.
Results The study included 31 patients, with a median age of 46 years (range 20–67), of whom 17 were male. Most patients were diagnosed with schizophrenia (90.3%) or psychosis (9.7%), and 19 patients were smokers.

A total of 75 clozapine plasma levels were measured, with 42 falling outside the recommended therapeutic range (34 subtherapeutic and 8 supratherapeutic). Dose adjustment recommendations were made in these cases, but 20 (47.6%) were not accepted due to the good clinical condition of the patients.

The average clozapine dose was similar in smokers (320 mg) and non-smokers (350 mg). However, average trough plasma concentrations were nearly half in smokers (239 ng/mL) compared to non-smokers (530 ng/mL).

No cases of leukopenia, neutropenia, or eosinophilia were observed. Six cases of thrombocytopenia (<150,000/mm^3) were recorded, but none were severe (<50,000/mm^3).
Conclusion and Relevance Some patients benefit from clozapine treatment despite subtherapeutic plasma levels. Smoking significantly lowers clozapine plasma concentrations. Monitoring clozapine levels is essential to ensure both the safety and efficacy of the treatment.

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

4CPS-199 BEZAFIBRATE FOR PRIMARY BILIARY CHOLANGITIS: EFFICACY, SAFETY, AND EFFICIENCY OF AN OFF-LABEL USE PROTOCOL IN REAL-WORLD PRACTICE

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Background and Importance Primary biliary cholangitis (PBC) is an autoimmune disease affecting bile ducts. Ursodeoxycholic acid (UDCA) is first-line therapy, but around 40% of patients do not respond. Obeticholic acid (OCA), approved as second-line therapy, is under review. Fibrates, used off-label, have shown potential as an alternative.
Aim and Objectives This study evaluates the effectiveness and safety of bezafibrate as a second-line treatment for PBC. Additionally, it assesses the economic impact of protocolising fibrate use.
Material and Methods An observational, retrospective study was conducted in a tertiary hospital by a multidisciplinary team of pharmacists and hepatologists. Patients diagnosed with PBC who did not respond to UDCA and receiving treatment with bezafibrate as a second-line therapy were included. Variables collected included alkaline phosphatase (ALP), alanine aminotransferase (ALT), total bilirubin, liver stiffness and steatosis using FibroScan, adverse effects, and treatment discontinuations. Data were collected pre-treatment, at 12 months, and at the last follow-up until June 2024.

Effectiveness was assessed by comparing biochemical variables before and after treatment, as well as changes in FibroScan values. Safety was evaluated based on adverse effects and treatment discontinuations.

Wilcoxon paired tests were used to compare values before and after treatment, and 95% confidence intervals were calculated for percentages (STATA17).

Patients meeting POISE study inclusion criteria, therefore being candidates to treament with OCA, were included for a cost-minimisation analysis. It compared OCA (5–10 mg) costs with bezafibrate (400 mg).
Results In 57 patients, at 12 months, ALP decreased by 81 IU/L, ALT by 14 IU/L, and total bilirubin by 0.12 mg/dL (all $p < 0.05$). 63% of patients achieved normal ALP levels at the last follow-up. No significant changes were observed in FibroScan results. Adverse effects were reported in 11% of patients, with 7% discontinuing.

The cost-minimisation analysis included 23 patients. The annual cost of bezafibrate was € 67, compared to € 27,507 for OCA (difference in annual cost resulted in € 27,440 per

patient/year and total savings € 631,138 during the first year of follow-up).

Conclusion and Relevance Bezafibrate is an effective and safe second-line therapy for PBC, achieving significant biochemical improvements and maintaining disease control. The cost-minimisation analysis highlights substantial economic savings when bezafibrate is protocolised, supporting its integration into clinical practice.

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Conflict of Interest No conflict of interest

4CPS-200 CASE REPORT: TREATMENT OF DIGOXIN INTOXICATION IN A HAEMODIALYSIS PATIENT USING ANTI-DIGOXIN ANTIBODIES AND PLASMAPHERESIS

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Background and Importance Digoxin intoxication is a life-threatening condition in which digoxin-specific antibody fragments (Fab) have been shown to be effective[1]. In patients with renal failure and chronic haemodialysis (HD), the clearance of Fab-digoxin complexes is significantly reduced. Some cases report using plasmapheresis (PE) to remove complexes and prevent toxicity recurrence[1–8]. This case presents the combined use of Fab and PE in a severe digoxin intoxication

Aim and Objectives Male, 84 years-old, weight 71kg, was admitted to the emergency department for asthenia. His medical record included permanent atrial fibrillation (AF), congestive heart failure, stage V chronic kidney disease on HD and diabetes mellitus. His regular medication includes apixaban, bisoprolol, 0.25mg digoxin, furosemide, sitagliptin, simvastatin, and trazodone.

Material and Methods Physical examination revealed a blood pressure of 160/92 mmHg, an ECG showing AF with complete atrioventricular block with a heart rate (HR) of 40 bpm and narrow QRS. Positive Sars-Cov2 PCR. Digoxin levels (DL) 5.73 ng/ml. Consequently, he was hospitalised in the intensive care unit (ICU).

We used the following formula[9] to calculate the dose of Fab to administer and figure 1 shows a timeline with the interventions performed and clinical parameters:

After the first administration, we observed a rebound effect increasing the DL. Therefore, we decided to perform a PE 3 hours after Fab administration, and the LD were significantly reduced.

Results The acute process lasted eight days and required four administrations of Fab, the last three followed by a PE session. This combination reduced the LD by 43%, 60% and 47%, respectively. HR was re-established with the decrease DL, reaching stable values on day 9 allowing the patient being discharged from the ICU.

Conclusion and Relevance The combination of PE after Fab administration is not described in clinical guidelines, only a few published cases[1–8]. There is also no consensus on when to perform PE, although it is estimated that the optimal time is 1–3h after Fab administration[5]. In this case, we observed a significant benefit of Fab administration followed by PE on clinical symptoms and DL. Further studies are needed to determine when PE should be used in clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-201 ABSTRACT WITHDRAWN

4CPS-202 FORMULATION OF CLOBETASOL AND TACROLIMUS URETHRAL SYRINGES AND EFFICACY IN BALANITIS XEROTICA OBLITERANS: A CASE REPORT

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Background and Importance Balanitis xerotica obliterans (BXO) is a chronic inflammatory disease that affects gland skin and the foreskin. It is characterised by sclerotic and atrophic lesions, leading to stenosis of the urethra.

Pharmacological treatment consists in topical corticosteroids or calcineurin inhibitors.

Aim and Objectives To describe the formulation of clobetasol and tacrolimus urethral syringes and to relate our experience in the treatment of BXO.

Material and Methods A 12 year-old child operated for scrotal hypospadias, developed a BXO on foreskin donor skin. The urethral mucosa was sclerosed and whitish, with an atrophic aspect, and the basal flux was 5 ml/s. A bibliographical search was carried out (Pharmacopoeia and PubMed) about clobetasol and tacrolimus urethral syringes. Galenic validation included organoleptic characteristics evaluation and pH and microbiological control.

Treatment efficacy was assessed by skin symptom resolution and increased voiding flow.

Results Modus operandi for clobetasol 0.05% urethral syringe 3 mL in a laminar flow cabinet:

1. Weigh 5.5 mg of clobetasol product.
2. Add a small portion of urological lubricant (OneGel) and mix.
3. Repeat step 2 to a total volume of 3 ml.
4. Repack in an urethral syringe.

For tacrolimus 0.03% urethral syringe, the same steps should be followed as above, weighing a quantity of 3.3 mg of tacrolimus product.

The given expiry date was 30 days at ambient temperature and protected from light.

Treatment with daily clobetasol was started and improved. At month +3, it was reduced to every 48 hours and a worsening was observed, resuming the daily regimen. At month +6, the patient was asymptomatic and voiding flow had

recovered, so it was decided to alternate with tacrolimus. The number of days per week with medication decreased progressively, 2 days of clobetasol and 4 days of tacrolimus (at month+10) and 2 days of clobetasol and 3 days of tacrolimus (at month+13).

When 15 months of treatment were reached, clobetasol was reduced to once weekly. The medication was well-tolerated and voiding flow was progressively increasing.

Conclusion and Relevance Both magistral formulations were validated and proved to be effective in the treatment of BXO through resolution of symptoms and progress in urodynamic testing.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-203 REAL-LIFE ANALYSIS OF THE DEVELOPMENT OF ANTI-DRUG ANTIBODIES IN ADULT PATIENTS WITH INFLAMMATORY BOWEL DISEASE AND THERAPEUTIC APPROACH

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Background and Importance Loss of response to infliximab and adalimumab therapy may occur due to development of 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 adult IBD patients undergoing therapeutic drug monitoring (TDM), along with therapeutic approach and potential factors contributing ADA development.

Material and Methods Retrospective observational study in adult IBD patients treated with infliximab and adalimumab undergoing TDM, within January/2019 to September/2024.

Adalimumab, infliximab and ADA concentrations were measured by chemiluminescence. Concretely, ADA if patients had infliximab≤3mcg/ml and adalimumab≤5mcg/ml concentrations (drug-sensitive assay). Standard dosage regimen(SD): adalimumab 40mg/14days, infliximab 5mg/kg/8weeks; intensified dosage involved either shortening interval or increasing dose.

Results 729 patients were included. Specifically, 462(63.4%) received adalimumab and 267(36.6%) received infliximab.

Adalimumab antibodies(AAA) were evaluated in 434 samples from 200(43.3%) patients treated with adalimumab; and infliximab antibodies(ATI) were evaluated in 391 samples from 160(59.9%) patients with infliximab.

Adalimumab treatment group, 17(3.7%) patients developed AAA: mean age of 40.9(11.4) years, BMI 26.4(7.4) kg/m2 and including 9(52.9%) females. All patients with Crohn disease. Seven(41.2%) patients had been on adalimumab for <1year. At the time of AAA detection, 6(35.3%) patients had adalimumab SD, and 6(35.3%) receiving immunosuppressants. Fourteen (82.4%) patients discontinued adalimumab, while 3(17.6%) with AAA of 22ng/ml, 133ng/ml and 107.9ng/ml underwent adalimumab intensification achieved AAA negativisation. Poor adherence was suspected in 7 (41.2%) patients.

Infliximab treatment group, 22(8.2%) patients developed ATI: mean age of 46.9(14.6) years, BMI 25.2(5.6) kg/m2 and including 9(37.5%) females. IBD diagnosed: Crohn disease in 13(59.1%) and ulcerative colitis in 9(40.9%) patients. Thirteen (59.1%) patients had been on infliximab for <1year. At the time of ATI detection, 13(59.1%) patients had infliximab SD, and 12(54.5%) receiving immunosuppressants. Fifteen (68.2%) patients discontinued infliximab, while 6(27.3%) with ATI<30ng/ml and 2(9.1%) with 100.6ng/ml and 171.7ng/ml underwent infliximab intensification achieved ATI negativisation. Poor adherence was confirmed in 6(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-204 OPTIMISING PHARMACEUTICAL CARE IN HOSPITAL TELEPHARMACY: IMPACT ASSESSMENT OF THE CHRONIC PATIENT STRATIFICATION MODEL

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Background and Importance The demographic shift toward an ageing population in developed countries has led to a higher incidence of chronic diseases and polypharmacy, significantly increasing the risk of medication-related complications. In the context of telepharmacy programs (TP) managing large patient cohorts, stratification models are essential. These models enable systematic identification and prioritisation patients requiring more intensive pharmaceutical care (PC).

Aim and Objectives To evaluate the implementation and effectiveness of the SEFH Chronic Patient Stratification Model (CPSMS) within a hospital TP for prioritising patients requiring pharmaceutical care.

Material and Methods A retrospective descriptive study was conducted over 1 year, focusing on patients enrolled in TP. Data collected included demographics and clinical records. Polypharmacy was defined as >5 medications, and chronic patients were classified as multipathological or fragile.

The CPSMS stratified patients into three levels:

- Level 1 (>14 points): Requires frequent PC.
- Level 2 (6–14 points): Requires moderate PC.
- Level 3 (<6 points): Requires basic PC.

Score variables included age (>75 years), cognitive impairment, mental disorder, socioeconomic difficulties, multi-pathological status, polypharmacy, high-risk medications, recent changes in therapy, adherence (Morisky-Green test), and adverse events.

To assess the effectiveness of the stratification tool, PC reports were collected. Level 1 patients, being the highest priority, were expected to have the most reports.

Results A total of 245 patients (54% women, mean age 66.2 ± 18.5 years) were enrolled in the TP. Polypharmacy patients constituted 31% (n=76), and 43% (n=106) were classified as chronic. The CPSMS categorised chronic patients as:

- Level 1: 19 (17.9%).
- Level 2: 50 (47%).
- Level 3: 37 (34%).

The total number of PC reports generated was 395, with 40% (n=158) specific to chronic patients. The distribution of PC reports across CPSMS levels was:

- Level 1: 31 reports (19%), 1.63 reports/patient.
- Level 2: 73 reports (46%), 1.46 reports/patient.
- Level 3: 54 reports (34%), 1.45 reports/patient.

Level 1 patients, identified as having the highest risk, had the greatest average number of reports per patient, reflecting their priority status within the stratification model.
Conclusion and Relevance The TP showed a high proportion of patients requiring PC. CPSMS was effective in identifying high-risk patients and facilitated targeted PC interventions, demonstrating its utility in hospital telepharmacy settings.

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

4CPS-205 ALECTINIB FOR ALK-POSITIVE UTERINE LEIOMYOSARCOMAL: SUSTAINED RESPONSE AFTER TREATMENT RESISTANCE – A CASE REPORT

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Background and Importance Uterine leiomyosarcoma (uLMS) is a highly aggressive soft-tissue sarcoma with frequent metastatic relapse after surgery, in which chemotherapy offers limited efficacy in advanced cases. Alectinib, a second-generation ALK inhibitor approved for non-small-cell lung cancer, has shown potential benefits in ALK-rearranged non-lung tumours.
Aim and Objectives A 57-year-old woman with a family history of cancer, diagnosed with uterine leiomyosarcoma in February 2018. She underwent hysterectomy, appendectomy, and resection of prevesical and peritoneal implants. Adjuvant chemotherapy with doxorubicin was completed by June 2018.
Material and Methods A PET/CT scan in November 2018 revealed disease progression with pulmonary metastases. Over the following years, the patient received eight lines of treatment due to disease progression or adverse events (AEs), including: gemcitabine + paclitaxel, trabectedin, pazopanib, temozolomide, dacarbazine + gemcitabine, liposomal doxorubicin, eribulin, and letrozole. Genetic testing revealed no mutations in BRCA, NTRK, or PD-L1 expression. However, in March 2022, genotyping identified an ALK mutation, and alectinib therapy was subsequently recommended.
Results Alectinib therapy was initiated in April 2022 at a dosage of 600 mg every 12 hours. Routine evaluations, including imaging scans and blood tests, monitored treatment effectiveness and safety. Medication was dispensed via the outpatient pharmacy unit, where hospital pharmacists also monitored for potential drug interactions and AEs. After three months, a PET/CT scan revealed a partial response with reduced tumour size and metastatic lesions. This therapeutic response remains ongoing. Mild adverse events occurred, including grade 1 constipation and a right-eye cataract. By October 2023, the patient developed a non-pruritic, photosensitivity-related rash, which was treated with topical corticosteroids. In March 2024, the patient experienced a recurrence of grade 1 skin toxicity. Dermatological evaluation led to a diagnosis of plaque psoriasis, for which topical corticosteroids and emollients were prescribed. No significant laboratory abnormalities were noted during treatment.
Conclusion and Relevance In this case, alectinib has demonstrated effectiveness in managing uLMS with an ALK mutation after several lines of prior treatment. The patient has maintained a partial response to therapy since the initiation of alectinib, with no severe adverse events reported. However, further clinical studies are necessary to assess the broader efficacy of alectinib in this tumour type, as it remains an off-label use.

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

4CPS-206 EFFECTIVENESS OF TREATMENT WITH MEPOLIZUMAB AND RESLIZUMAB IN DIAGNOSED PATIENTS OF SEVERE UNCONTROLLED ASTHMA ACCORDING TO BODY WEIGHT

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Background and Importance Efficiency criteria lead us to treat patients with severe uncontrolled asthma (SUCA) and high weight with drugs that are not dosed by weight, such as mepolizumab. In hospitals that do not carry out level monitoring, it is unknown if this could translate into underdosing of these patients and, most importantly, if this leads to worse control of the disease.
Aim and Objectives To know the influence of body weight on the effectiveness of treatment with anti-IL5 drugs in patients diagnosed with SUCA.
Material and Methods Retrospective observational study in which all patients diagnosed with SUCA who had received treatment with mepolizumab and reslizumab as part of standard clinical practice. As main variable effectiveness, the appearance of exacerbations after the start of biological treatment was studied, understood as the need for treatment with systemic corticosteroid (SC), depending on weight: ≤80 kg and >80 kg. The demographic, clinical and analytical analyses were obtained from the electronic medical record (Diraya) and data related to the treatment of the electronic prescription (PRISMA).
Results In August 2024, 128 patients had been treated with anti-IL5 drugs, 76 patients with mepolizumab (59.4%) and 26 patients with reslizumab (40.6%). The average age was 56 years for the cohort of mepolizumab and 60 years for reslizumab. The average weight in the mepolizumab group was 81.5 kg (57–144) vs 69 kg (57–99) in the reslizumab group. In the mepolizumab group, 32 patients weighed ≤80 kg compared to

48 patients in the reslizumab group. Patients weighing >80 kg were 28 in the mepolizumab group and four in that of reslizumab. 16 patients in the mepolizumab group were excluded because their weight was not available. 53.3% of patients treated with mepolizumab (n=32) required SC compared to 46.1% (n=24) in the reslizumab group. Between patients with ≤80 kg, 62.5% of mepolizumab patients (20/32) required SC compared to 50% (24/48) in the group of reslizumab, OR=1.67 (95% CI, 0.27 to 10.33; p=0.58). In the group of patients with >80 kg, 42.8% of patients treated with mepolizumab (12/28) underwent treatment with SC and none in the reslizumab group (0/4).

Conclusion and Relevance According to the results patients on fixed dosage, treated with mepolizumab, suffer more exacerbations and, therefore, they require more of the use of systemic corticosteroids regardless of body weight. Weight-based dosing of reslizumab could be beneficial in terms of effectiveness. Patients >80 kg appear to benefit from reslizumab dosing in our cohort.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-207 COMPARATIVE STUDY OF ADHERENCE RATES TO COMPUTERISED INJECTABLE ANTIBIOTIC PROTOCOLS

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Background and Importance The establishment of protocols for the prescription of injectable antibiotics (IA) is a crucial component of medication safety. Computerised antibiotic protocols (CAP) are available in our institution as a prescribing support tool.

Aim and Objectives The objective is to evaluate the current adherence rate to CAP and compare it with previous data.

Material and Methods A prospective collection of each IA prescription was conducted from July 2024 to August 2024 using the Pharma Class decision support system. The prescriptions were subsequently analysed using a collection grid comprising eight criteria: type of prescription, presence of a solvent, nature of the solvent, dilution volume, infusion duration, administration route, continuous or intermittent infusion modality, and frequency of administration. A comparative analysis of the results was then conducted using data collected from July 2022 to August 2022.

Results Overall, CAP adherence was observed in 63% (126/200) of prescriptions in 2024 compared to 50% (109/217) in 2022, indicating a statistically significant improvement in prescription quality (p=0.0085; α=5%).

The most frequently prescribed antibiotic during both study periods was ceftriaxone, with adherence rates improving from 24% (12/50) in 2022 to 68% (28/41) in 2024. Amoxicillin-clavulanate achieved a 100% adherence rate (10/10) in 2024, up from 66% (23/35) in 2022.

In 2022, four departments (geriatrics, digestive surgery, dermatology, and gastroenterology) accounted for 76% of off-protocol prescriptions, reduced to only 19% in 2024.

Conversely, oncology and haematology had off-protocol prescriptions in 73% (11/15) and 58% (14/24) of cases in 2024, respectively, as these departments were not included in the 2022 study.

Furthermore, 99.5% of off-protocol prescriptions were non-compliant with CAP on at least one evaluation criterion in 2024, compared to 100% in 2022.

Conclusion and Relevance Improvement initiatives (training, flyers, and pharmaceutical interventions) implemented since 2022 may account for the increased adherence of physicians to computerised protocols. However, the analysis of these practices has identified issues with the utilisation of these protocols, particularly in haematology (single-route infusion not allowing prolonged administration via CAP), leading to the development of an adapted protocol.

Further avenues for continuous improvement, in collaboration with prescribers, need to be explored to sustain and enhance adherence to protocols and maintain the quality of IA prescriptions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-208 MACHINE LEARNING-DRIVEN EARLY PREDICTION OF VORICONAZOLE PLASMA LEVELS: ENHANCING PRECISION DOSING AND PATIENT SAFETY IN ANTIFUNGAL THERAPY

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Background and Importance Voriconazole, a second-generation triazole with a broad-spectrum of antifungal activity, is essential for treating invasive fungal infections, but its non-linear pharmacokinetics, significant variability between patients, and narrow therapeutic window complicate dosing. Achieving the correct drug concentration is crucial: subtherapeutic levels can result in treatment failure, while elevated levels increase the risk of toxicity. Traditional dosing approaches often lack the precision needed from the start of treatment, and many hospitals lack the resources to routinely perform therapeutic drug monitoring. Machine learning (ML) offers a promising solution to individualise dosing early, improving outcomes and safety.

Aim and Objectives To develop a machine learning model capable of classifying patients into subtherapeutic, therapeutic, or toxic voriconazole plasma levels early in therapy, enabling clinicians to individualise dosing strategies and minimise the risks of toxicity and subtherapeutic levels.

Material and Methods A retrospective, single-centre study was conducted between May 2021 and June 2024 at a tertiary hospital. Demographic, clinical, and pharmacokinetic data, including liver and kidney function, serum albumin, comorbidities, and voriconazole plasma concentration (Architect Abbot), were collected. In this study, we propose the use of the extreme gradient boosting (XGB) algorithm for early prediction of voriconazole plasma levels. The performance of XGB was compared to other machine learning methods; K-nearest neighbours (KNN), support vector machines (SVM), Bayesian linear discriminant analysis (BLDA), Gaussian naive Bayes (GNB), and decision trees (DT), demonstrating the superiority of the XGB model. The data were split, 70% used for model

training and 30% for validation, applying 5-fold cross-validation to prevent overfitting.

Results The study included 128 voriconazole-treated patients. XGB achieved 97% accuracy, outperforming KNN (89%) and SVM (86%). BLDA, GNB, and DT showed lower accuracy (81%, 80%, and 84%, respectively). XGB also showed superior results in other metrics, including AUC (0.96), Matthews correlation coefficient (MCC, 85.85%), and Kappa index (86.14%), highlighting its strong performance in classifying subtherapeutic, therapeutic, and toxic levels.

Conclusion and Relevance This ML-based approach allows early individualisation of voriconazole dosing, offering a precise alternative where traditional methods fall short. By improving dosing accuracy from the start, especially in hospitals without routine therapeutic drug monitoring, this model has the potential to significantly enhance patient safety and treatment efficacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-209 LONG-TERM OUTCOMES AND RETREATMENT PATTERNS IN ANTI-CGRP THERAPY

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Background and Importance Anti-CGRP antibodies are a recent treatment used for migraine prophylaxis in patients with frequent migraines, prescribed after failure of other therapies. There is ongoing debate regarding the optimal duration of therapy, with some guidelines recommending reassessment after 1 year . However, the lack of long-term data and potential risk of relapse raises uncertainty about the appropriateness of treatment discontinuation.

Aim and Objectives To evaluate the number of retreatments required in migraine patients who discontinued anti-CGRP antibody therapy after 1 year of adequate response, with a detailed descriptive analysis of those who discontinued the therapy. To assess whether there are significant differences in retreatment rates between patients with six or fewer prior migraine prophylaxis treatments and those with seven or more.

Material and Methods A retrospective observational study was conducted in a medium-sized hospital from January 2021 to October 2024. Follow-up and the number of prior treatment lines was assessed through outpatient dispensing records, patients' electronic medical records and electronic prescription system. The Chi-squared test was used to compare the total proportions of retreatments.

Results Among 119 patients, with a median of six prior treatment lines (IQR 5–8), 70 had been receiving anti-CGRP therapy for more than 1 year. Of these, 36 patients (51.5%) discontinued the treatment after 1 year. Notably, 27 of the patients who discontinued (75%) required retreatment, highlighting the challenge of maintaining long-term control over symptoms. 14 patients remained on the same anti-CGRP therapy. Of the 13 patients who transitioned to a second anti-CGRP therapy, five subsequently switched to a third anti-CGRP agent, and one patient underwent four treatment switches. Regarding those needing retreatment, eight did so within the first 3 months, 13 between 3 months and 1 year, and six after a period of 1 year. There is no statistically significant difference in retreatment rates between patients with six or fewer prior prophylactic treatments and those with seven or more (p = 0,582).

Conclusion and Relevance More than half of the patients stopped treatment within a year, with 75% needing retreatment. This underscores the challenges in sustaining symptom control and emphasises the need for personalised approaches, as treatment responses and retreatment timelines varied significantly across patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-210 ABSTRACT WITHDRAWN

4CPS-211 CLEAR CELL RENAL CELL CARCINOMA, WITH LUNG METASTASES – CLINICAL CASE

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Background and Importance Renal cell carcinoma is amongst the 10 most common types of cancer in the western world[1] [2] and the main risk factors are age and hypertension.[3]

Aim and Objectives This study aims to describe a clinical case of clear cell renal cell carcinoma (ccRCC) with lung metastases (LM), without nephrectomy.

Material and Methods This clinical case method was observational and retrospective. The data were obtained from SClinic, GHAF and CliniData. This case addresses a 44 year-old female, without smoking or drinking habits, normotensive. The patient´s family has history of cancer, her father has prostate adenocarcinoma. A progressive cough, associated with recurrent fatigue, led her to visit the Emergency Department. Computed Tomography (CT), identified the presence of a neoplastic-looking mass in the right kidney, measuring 9 x 8 cm, hypervascular and heterogeneous and LM were observed. Abdomen was soft and depressed, with a palpable mass in the right flank. Laboratory tests did not present any relevant alterations. The diagnosis was ccRCC, confirmed by biopsy, with multiple intermediate risk LM and the patient remained unchanged at a cognitive and physical level. To date, the patient has undergone four lines of treatment:

1st - Pembrolizumab 200 mg, IV, 3/3 weeks (w) + axitinib 5 mg every 12 hours, tablet (tabs) - 10 cycles (C) - 6 months (m). Adverse drug reactions (ADR): headaches, worsening cough, changes in thyroid and liver function and musculoskeletal pain.

2nd - Cabozantinib 60 mg/day, tabs, reduced to 40 mg/day - 6 m. ADR: rash in both hands, elbows and feet.

3rd - Sunitib 50 mg/day, tabs – 1 m.

4th – Ipilimumab 1mg/kg, IV + nivolumab 3mg/kg, IV, 3/3 s. – 4 C. Nivolumab 480 mg, IV, 4/4 s, as monotherapy, which is maintained to present.

Results Given the severity and advanced initial staging, despite pharmacological intervention, the disease continues to progress. The 1st line of treatment was the one that showed the best CT results.
Conclusion and Relevance As this is a patient under 50 years of age, with no associated risk factors and no disease progression, this is considered a rare and interesting clinical case.

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Conflict of Interest No conflict of interest

4CPS-212 CROSS-SECTIONAL STUDY TO ASSESS THE USE AND RATIONALITY OF PHARMACOGENOMICS IN PSYCHIATRIC WARDS

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Background and Importance Personalised medicine, including Therapeutic Drug Monitoring (TDM) and Pharmacogenomics (PGx), significantly enhances psychiatric care by ensuring treatments are tailored to each patient. Pharmacogenomics is the study of how a patient's genetics affects the response to drugs. The personalised approach helps in selecting the right drug and dosage, reducing adverse effects and improving therapeutic outcomes. PGx in psychiatric patients should be considered if the drug in question is metabolised by CYP2D6, CYP2C9 or CYP2C19 where considerable genetic variations are recognised.
Aim and Objectives To investigate the extent of and rational use of PGx in a psychiatric clinical setting.
Material and Methods In a cross-sectional study, patients from three psychiatric wards in one hospital were included consecutively for 5 weeks. Adult patients with schizophrenia, depression or a bipolar disorder were included and their prescription data on antipsychotics, antidepressants and/or mood stabilisers were extracted from patient records as well as laboratory results. The use of PGx was analysed by clinical pharmacists associated with the wards and deemed as rational if the patient has had more than one shift in psychotherapeutic treatment and the treatment drug was metabolised by CYP2D6, CYP2C9 or CYP2C19 and the corresponding test had been ordered.
Results From May-April 2024 100 patients were included and assessed. In 21 cases PGx has been used rationally, and in 17 cases there had been no PGx test which was also rational according to the method. However, in 1 case a test had been done irrationally, and in 61 cases it was deemed irrational that no tests had been done.
Conclusion and Relevance The overall use of PGx in the investigated setting was very limited. In 61% of patients there had been more than one shift in pharmacotherapy regarding drugs dependent on CYP2D6, CYP2C9 or CYP2C19 where PGx test is advised. The results emphasise the need for pharmacological guidance in psychiatric wards which may be provided by clinical pharmacist.

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

4CPS-213 IMPACT OF THE ANTIMICROBIAL STEWARDSHIP PROGRAMME ON ANTIBIOTIC CONSUMPTION IN TWO INTERNAL MEDICINE UNITS

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Background and Importance Antimicrobial Stewardship Programs (ASPs) are essential to improve clinical outcomes and reduce antimicrobial resistance, a growing public health issue. In the current context, their implementation is critical.
Aim and Objectives Compare antimicrobial consumption (DDD per 100 bed days) between two Internal Medicine units (A *vs*. B) of the same healthcare complex, but physically separated. Unit-A has the presence of an ASPs team.
Material and Methods Observational and retrospective study conducted in a public tertiary care hospital with 888-beds (average length of stay =6.6 days; occupancy rate =70.3%). Two Internal Medicine units (A *vs*.B) were analysed with the following characteristics: beds=174 (*vs*.94); average length of stay=8.7 days (*vs*.8.4); occupancy rate=70% (*vs*.84.88%), mortality rate per number of admissions=11.9% (*vs*.14.2%).
Antimicrobial consumption (groups J01-J04) was analysed (years: 2021–2023). Consumption data were obtained from the Pharmacy Management System and hospitalisation indicators from the Admissions Service. The ATC/DDD system of the World Health Organization was adopted, using DDD values established for 2023. The measure used was DDD/100-bed days, and de consumption trend was compared; the differences between the two units were evaluated using Chi-squared test (p-value=0, 1).
Results Antimicrobials overall consumption (DDD/100B) increased in both units, but it was greater in unit-B. Also, the increase by spectrum was more pronounced in B. These differences were significant in overall consumption (p=0.001) and anti-pseudomonal antimicrobials consumption (p=0.078).

In 2023, the most commonly used antibacterials (DDD/100B Unit-A *vs*.Unit-B) were: ceftriaxone (25,87 *vs*.26,27), piperaciclin/tazobactam (12,12 *vs*.12,11), amoxicilin/clavulanic acid (8,71 *vs*.13,81) and levofloxacin (6,39 *vs*.9,23).
Conclusion and Relevance There are quantitative and qualitative differences in the use of antimicrobials between the units, with more appropriate use in unit-A. Although the origin of these differences may be multifactorial, the presence of a multidisciplinary ASPs team (Unit-A) appears to have a positive impact on optimising antimicrobial consumption.

Abstract 4CPS-213 Table 1

Antimicrobials Overall Consumption (DDD/100B)	Unit-A	Unit-B
2021	72,34	61,38
2023	91,34	94,49
	(+26,26%)	**(+53,95%)**

Abstract 4CPS-213 Table 2

Anti-Pseudomonal-Antimicrobials (DDD/100B)	Unit-A	Unit-B
2021	18,33	18,52
2023	25,52 (**+39,23%**)	28,97 (**+56,43%**)

Abstract 4CPS-213 Table 3

Methicillin-Resistant-Antimicrobials (DDD/100B)	Unit-A	Unit-B
2021	7,61	7,32
2023	11,52 (**+51,38%**)	12,01 (**+51,38%**)

It is essential to implement ASPs in all hospital units to improve clinical outcomes, ensure cost-effective and safe use, and reduce antimicrobial resistance.

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Conflict of Interest No conflict of interest

4CPS-214 ABSTRACT WITHDRAWN

4CPS-215 REAL-LIFE ANALYSIS OF THE DEVELOPMENT OF ANTI-DRUG ANTIBODIES IN PAEDIATRIC PATIENTS WITH INFLAMMATORY BOWEL DISEASE AND THERAPEUTIC APPROACH

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Background and Importance Loss of response to infliximab and adalimumab therapy may occur due to development of 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 paediatric IBD patients, along with therapeutic approach and potential factors contributing ADA development.

Material and Methods Retrospective observational study in paediatric IBD patients treated with infliximab and adalimumab undergoing therapeutic drug monitoring (TDM), within January 2019 to September 2024.

Adalimumab, infliximab and ADA concentrations were determined by enzyme-linked immunosorbent assay (ELISA) until May 2022, followed by chemiluminescence immunoassay (CLIA). Concretely, ADA if patients had infliximab ≤ 3mcg/ml and adalimumab ≤ 5mcg/ml concentrations (drug-sensitive assay). Treatment was initiated according to the standard dosing regimen (SD) for adalimumab and infliximab in paediatrics and was adjusted according to TDM; dose intensification consisted of shortening the interval or increasing the dose.

Results Ninety patients were included. Specifically, 38 (42.2%) received adalimumab and 52 (57.8%) received infliximab.

Adalimumab antibodies (AAA) were evaluated in 33 samples from 10 (26.3%) patients treated with adalimumab; and infliximab antibodies (ATI) were evaluated in 53 samples from 28 (53.8%) paediatrics treated with infliximab.

No patients underwent adalimumab treatment were detected developing AAA.

Infliximab treatment group, four (7.7%) patients developed ATI: mean age of 12.9 (7.1) years and including three (75.0%) females. IBD diagnosed: Crohn's disease in two (50.0%) patients and ulcerative colitis in two (50.0%) patients. Two (50.0%) patients had been on infliximab for <1 year. At the time of ATI detection, all of them were on treatment with an intensified infliximab dosage, and three (75.0%) receiving immunosuppressants. Two (50.0%) patients discontinued infliximab, while two (50.0%) with ATI 22 ng/ml and 137 ng/ml underwent infliximab intensification achieved ATI negativisation. Infliximab concentrations before antibody detection (<6 months) were 1.5 µg/ml, 3.6 µg/ml and 5.9 µg/ml. One patient was in induction and had previously received infliximab. No poor patient adherence was detected. HLA-DQA1*05 genetic variants were analysed in three (75.0%) patients, two (66.7%) patients were HLA-DQA1*05 carriers.

Adalimumab and infliximab concentrations were <1mg/ml in all patients with ADA.

Conclusion and Relevance A proportion of IBD paediatric patients developed ADA, with a higher incidence observed in those receiving infliximab. Intensifying treatment may be effective in achieving ADA negativisation, in some cases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-216 CASE SERIES: REAL-WORLD EFFECTIVENESS AND SAFETY OF TISAGENLECLEUCEL FOR THE TREATMENT OF B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKAEMIA IN PAEDIATRICS

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Background and Importance Tisagenlecleucel is a CD19-directed genetically modified autologous T-cell immunotherapy indicated for the treatment of B-cell precursor acute lymphoblastic leukaemia (ALL) that is refractory or in relapse.

Aim and Objectives To analyse the effectiveness and safety of tisagenlecleucel in paediatric patients with B-ALL.

Material and Methods Retrospective observational study of all patients with B-ALL treated with tisagenlecleucel in our centre. Study period: August 2019 to September 2024. Variables collected: demographic (age, sex), clinical (diagnosis), therapeutic (previous treatments), effectiveness (overall remission rate (ORR): proportion of patients in complete remission (CR) or complete remission with incomplete blood count recovery (CRi) with minimal residual disease (MRD) <0.01% at 28 days, 3, 6 and 12 months, and median overall survival

(mOS)), safety (cytokine release syndrome (CLS), immune effector cell-associated neurotoxicity syndrome (ICANS), cytopenias, infections, macrophage activation syndrome (MAS) and hypogammaglobulinaemia).

Results Eight patients, 62.5% male, median age 6 years (3–15). 75% with previous allogeneic haematological transplant and one received blinatumomab. 100% were in relapse pre-CART receiving bridging therapy. Pre-CART tumour load: 49.40% (0.01–96.00). Median follow-up: 12.36 months (3.0–41.4).

Effectiveness: ORR at 28 days 87.5%, at 3 months 62.5%, at 6 months 37.5%, at 12 months 14%. 83.3% relapses CD19-. mOS= 11.5 months (3.0–14.7).

Safety CRS: 100% of patients at 1.5 days(0–6) (25% grade ≥3), 50% needed tocilizumab and 25% tocilizumab+corticosteroids. 62.5% admitted to ICU. ICANS: 37.5% at 10 days (9–11) (66.7% grade ≥3). Infections: 37.5%. Cytopenias: 100% (37.5% grade ≥3). MAS: 50%. Hypogammaglobulinaemia: 100%, all needed immunoglobulins. At the end of follow-up three patients were still alive, one after 42 months in CR. The rest died due to progression B-ALL.

Conclusion and Relevance Tisagenlecleucel effectiveness in our cohort was lower than that observed in the pivotal clinical trial, while maintaining a similar safety level. The majority of relapses are CD19 negative. More detailed analysis of factors that could influence response is needed, as well as a larger sample size in order to identify optimisation strategies, ensure maximum benefit from this therapy and obtain conclusive results.

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Conflict of Interest No conflict of interest

4CPS-217 EFFECTIVENESS AND SAFETY OF ORAL VISCOUS BUDESONIDE IN COMPOUNDED FORMULATION: REAL-WORLD DATA

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Background and Importance Budesonide is a corticosteroid with anti-inflammatory properties, and its viscous formulation enhances adherence to the oesophageal mucosa, improving local action in eosinophilic esophagitis (EoE).

Aim and Objectives This study aimed to evaluate the effectiveness and safety of oral viscous budesonide (OVB) in a compounded formulation (0.5 mg/ml) in patients with EoE at a 1000-bed hospital.

Material and Methods Descriptive and retrospective study (March 2018 to March 2024) including patients diagnosed with EoE and treated with OVB who received at least one 6-week induction phase.

Demographic and clinical variables (prior treatments and response, duration of OVB therapy, dosage, eosinophil count/mm^2, clinical symptoms at 6 weeks, adverse drug reactions (ADRs), and treatment discontinuation (yes/no)) were collected from patients' medical records and the compounded formulation dispensing program.

Effectiveness was evaluated based on histological and clinical responses after 6 weeks. Histological response was defined as an eosinophil count of <15 eosinophils/mm^2 per high-power field, and clinical response as the absence of symptoms. Patients requiring endoscopic intervention were considered treatment failures.

Safety was assessed based on ADRs and treatment discontinuation.

Percentages represented categorical data, and medians were used for continuous variables. Data were analysed using Microsoft Excel.

Results A total of 62 patients were included (77% male),with a median current age of 33 years (range:4–74) and a median age at diagnosis of 27 years (range:4–65).

Most patients (92%) had previously received proton pump inhibitors, 91% had followed an elimination diet, and 87% had used swallowed fluticasone without achieving a response.

The median duration of treatment was 6 months (range:2–37).

Doses of 1 mg every 12 hours were administered to 53% of patients, 0.5 mg every 12 hours to 14.5%, and 1 mg every 24 hours to 17.7%.

ADRs were reported in 20.9% of patients, with the most common being asymptomatic oral fungal infections (14.5%), hepatic steatosis (3.2%), and hypocortisolism (3.2%). No patients discontinued treatment due to toxicity.

Conclusion and Relevance OVB proved to be an effective treatment option for patients with EoE who refractory to other therapies are, showing high rates of histological and clinical response. It demonstrated an acceptable safety profile, with manageable and well-tolerated adverse events.

Further studies are needed to confirm these findings due to the limited sample size and short follow-up period.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-218 ANALYSIS OF POTENTIALLY INAPPROPRIATE MEDICATION PRESCRIPTION IN PATIENTS ADMITTED TO AN EMERGENCY DEPARTMENT

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Background and Importance A recent study published in August 2023 establishes the prevalence of potentially inappropriate medication (PIM) in 37% of patients <65 years of age worldwide. 57% of patients who have PIM suffer medication-related adverse effects, +24% than those who do not have PIM. The pharmacotherapeutic review of these patients is a challenge for health systems and hospital pharmacists.

Aim and Objectives Analyse the results of the implementation of a programme to detect PIM in an Emergency Department (ED) and describe the pharmacotherapeutic groups most frequently involved.

Material and Methods Multicentre, prospective study, lasting 8 months (November 2022 to June 2023). All patients aged 70 years or older, polypharmacy (five chronic drugs or more) admitted to the ED were included in the study. Those with palliative sedation and those institutionalised were excluded.

Data were obtained from the clinical history, the assisted electronic prescription program, the electronic prescription software and the interview with the patient and/or caregiver. PIM prescribed was reviewed following the Beers and Stop/Start criteria. The variables collected were: age, sex, number of chronic medications, number of drugs and pharmacotherapeutic groups considered as PIM. Statistical analysis was performed with the SPSS program using Student's t-test for independent samples. $P<0.05$ was taken as a statistically significant relationship.

Results 198 patients were included, with a median age of 80 years (70–98). A total of 2,671 chronic medications were reviewed, with a median of 14 medications/patient (range: 5–21). 130 PIM were detected in 45% of the patients (average of 1,2 PIM for these patients). 81% of patients were prescribed only one PIM, 20% were prescribed two, 8% were prescribed three, and only 1% were prescribed four. The drugs most frequently involved as PIM were: sedative-hypnotics (93%), antipsychotics (8%), urinary antispasmodics (5%) and potassium-sparing diuretics (5%). When comparing the number of chronic medications taken by patients without and with prescribed PIM, statistically significant differences were found ($10,03 \pm 13,23$ vs $11,80 \pm 12,77$ respectively, $p<0.05$).

Conclusion and Relevance Almost half of patients over 70 years of age who visit the ED are on treatment with PIM. Almost all patients analysed were taking sedative or hypnotic medication. We can conclude that the greater the number of chronic drugs prescribed, the greater the probability of presenting PIM.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-219 REAL-WORLD EFFECTIVENESS OF IBRUTINIB MONOTHERAPY IN CHRONIC LYMPHOCYTIC LEUKAEMIA

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Background and Importance Bruton's tyrosine kinase (BTK) inhibitors have significantly advanced the treatment of chronic lymphocytic leukaemia (CLL) since their approval in 2014. Ibrutinib, the first-in-class BTK inhibitor, demonstrated superior progression-free survival (PFS) compared to chemotherapy in clinical trials. However, real-world effectiveness data are limited.

Aim and Objectives To evaluate the real-world effectiveness and safety of ibrutinib monotherapy in CLL patients in a Spanish healthcare setting and compare it with clinical trial efficacy data.

Material and Methods This retrospective cohort study included CLL patients treated with ibrutinib monotherapy from May 2016 to June 2023. Data were collected from electronic health records and pharmacy dispensing systems. Patients were stratified into subgroups based on treatment line: first-line, second-line, and third-line or later. Kaplan-Meier survival analyses were performed for PFS and overall survival (OS) for each subgroup and the total cohort. Safety data collected included treatment interruptions, adverse events, and specific toxicities (dermatological reactions, gastrointestinal intolerance, atrial fibrillation, infections, neutropenia, and thrombocytopenia). Statistical analysis was conducted using IBM SPSS Statistics v.26.

Results A total of 60 patients were included in the study. The median age was 72 years (range: 55–89), and 63.3% were male. The distribution of patients across treatment lines was: 16 (26.7%) first-line, 32 (53.3%) second-line, and 12 (20%) third-line or later. After a median follow-up of 36.6 months (range: 3.6–86.9): Median PFS and OS were not reached. Estimated mean PFS: 72.2 months (95% CI: 63.7–80.7). Estimated mean OS: 72.1 months (95% CI: 63.5–80.7). 85% of patients remained progression-free and alive. 51% of patients experienced adverse events, with 46% requiring treatment interruptions. Most common toxicities: gastrointestinal intolerance (15%) and infections (13%).

Stratified analysis

- First-line (n=16): 87.5% progression-free, 93.7% survived.
- Second-line (n=32): 86% progression-free and survived.
- Third-line or later (n=12): 75% progression-free, 67% survived.

Conclusion and Relevance Real-world effectiveness of ibrutinib in CLL appears comparable to clinical trials data, such as RESONATE, when adjusted for follow-up time. However, safety profiles differ, with higher rates of adverse events and treatment interruptions in the real-world setting. These findings highlight the importance of real-world studies in complementing clinical trial data and informing clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

4CPS-220 PRESCRIBING ERRORS IN PARENTERAL NUTRITIONAL SUPPORT FOR ADOLESCENT PAEDIATRIC PATIENT

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Background and Importance Adolescents represent one of the paediatric populations at highest risk for medication errors (ME) due to individualised dose calculations based on weight, a parameter with high variability in this paediatric age. Pharmacist intervention may be essential to reduce ME in parenteral nutrition (PN), especially in weights greater than 40 kg as indicated in the literature, to make sure that the maximum recommended dose is not exceeded.

Aim and Objectives To analyse pharmaceutical interventions that were accepted by the prescribing physician to adjust adolescent PN related to ME due to macro/micronutrient doses above the maximum recommended, and to compare interventions between patients weighing >40 kg and patients weighing <40 kg.

Material and Methods Observational, descriptive, and retrospective study carried out on adolescents (13–17 years) who received PN in a tertiary hospital paediatric unit between January 2022 and May 2024.

Variables were collected from medical records: age, gender, weight, number of PN, type of intervention and macro/

micronutrients adjusted. Interventions to adjust osmolarity or stability of the lipid emulsion were excluded.

The reference guidelines for pharmacist interventions were the 2018 ESPGHAN/ESPEN/ESPR guidelines on paediatric parenteral nutrition and the 2009 SEFH standardisation of specialised nutritional support.

A descriptive analysis of qualitative variables was performed, expressed as numbers and percentages (%). Quantitative variables were expressed as mean ± standard deviation (SD).

Results A total of 39 adolescent patients were included, 20 (53%) were male, mean age 14.4 (1.3) years, with 717 PN validated by a hospital pharmacist.

- Patients ≤ 40 kg: 8; mean weight 27,8 (7,8) kg; number of PN: 109. Pharmaceutical interventions: 7, none due to higher doses.
- Patients > 40 kg: 31; mean weight 55,9 (13,2) kg; number of PN: 608. Pharmaceutical interventions: 67, corrections due to high weight: 20 (30%) in 15 (48%) patients. Most adjusted micronutrients: magnesium and calcium (n=13), and phosphorus (n=7). Most adjusted macronutrient: glucose (n=19).

Conclusion and Relevance This study suggests that in nutritional therapy, patients weighing over 40 kg are more likely to experience dosing errors in both micronutrients and macronutrients. This underscores the critical importance of hospital pharmacists' involvement and integration within the nutrition management team to ensure the accuracy and safety of nutritional preparations, particularly for adolescent patients who require specialised considerations.

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

4CPS-221 COMPARATIVE ANALYSIS OF ANTICHOLINERGIC SCALES IN OLDER PATIENTS: A SYSTEMATIC REVIEW TOWARDS A GOLD STANDARD TOOL

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Background and Importance The association between anticholinergic burden (AB) and numerous adverse effects and health problems in the elderly is well-established. However, there is no universally accepted gold standard tool for estimating AB in older patients.

Aim and Objectives To identify and compare anticholinergic scales (AS) applicable to chronic elderly patients, analyse the methodology behind their development, and evaluate their main characteristics.

Material and Methods A systematic review was conducted using MEDLINE, Web of Science, and Embase databases (PROSPERO ID CRD42024505226) up to October 2023. Studies specifying the list of included drugs and the methodology for developing the AS were included. The review focused on the composition of the scales, categorisation of anticholinergic potential, consideration of drug dosage effects, and any demonstrated correlation with health outcomes in older patients.

Results Eighteen AS were identified: ABC, ADS, DBI, ACB, CHEW, CRAs, ARS, AAS, ALS, DS, AEC, MARANTE Scale, GAS, BAAS, KAS, CALS, Swe-ABS, and Evidence-based ABS. Eight AS were derived from previously published scales (ADS, CRAS, DS, GAS, BAAS, KAS, CALS, Swe-ABS), four after a literature review on anticholinergic properties of medications (ABC, ACB, ARS, AEC), two based on previous AS plus literature on anticholinergic potential (AAS, ALS), two on experimental methods (CHEW, ABS), and two (DBI, MARANTE) on a mathematical formula developed by experts. The number of drugs included in the scales varied (<100 for ABC, ACB, CRAS, ARS, AAS, ALS, and MARANTE; 100–200 for ADS, DBI, CHEW, DS, AEC, BAAS, and Swe-ABS; >200 for GAS, KAS, CALS, and ABS). All scales categorised drugs based on anticholinergic potential except DBI, and only three considered the dose-dependent effect (ADS, DBI, MARANTE). No health outcome associations were found or studies were lacking in older patients for DS, AEC, BAAS, KAS, CALS, Swe-ABS, and ABS.

Conclusion and Relevance A significant number of AS have been identified, many developed from existing scales, thus inheriting similar advantages and limitations. Many do not consider drug dosing, and some have not demonstrated health outcome correlations in older patients. There is a clear future need for a universal, standardisable, and easily updatable tool to overcome these limitations and reliably estimate AB in these vulnerable patients.

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

4CPS-222 ABSTRACT WITHDRAWN

4CPS-223 COMPARED REAL-LIFE PERSISTENCE BETWEEN FREMANEZUMAB, ERENUMAB AND GALCANEZUMAB

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Background and Importance Monoclonal antibodies targeting calcitonin gene-related peptide (CGRP) represents an effective choice in preventing migraine crises. Nevertheless, data on their persistence is limited.

Aim and Objectives This study compares the persistence between fremanezumab, erenumab and galcanezumab and identifies the main reasons for treatment discontinuation.

Material and Methods An ambispective, observational study was conducted at a tertiary hospital, including patients who started treatment with fremanezumab, erenumab or galcanezumab between December 2019 and February 2024. Follow-up carried out until August 2024. Women who discontinued treatment due to pregnancy were excluded. Temporary medication interruption was not considered if the discontinuation was ≤6 months and the patient restarted the same drug.

Demographic and clinical data were obtained from electronic medical records.

Variables collected were age, gender, diagnosis (chronic or episodic migraine), monthly migraine days (MMD) and previous preventive treatments (PPT) including botulinum toxin.

Persistence was defined as the time from the first medication dispensation to treatment discontinuation or end of the study.

Kaplan-Meier survival analyses and log-rank test were carried out with R-4.4.1.

Results 266 patients were included, of whom 224 (84.2%) were women. Mean age was 48±12 years. 119 (44.7%) patients had chronic migraine, whereas 147 (55.3%) had episodic migraine. Median MMD were 10 (IQ 8–15). Mean number of PPT before starting anti-CGRP was 5±2. 68 patients were treated with fremanezumab, 94 with erenumab and 104 with galcanezumab.

Median persistence was 714 days (CI 95% 409–1130) for fremanezumab, 907 days (CI 95% 588–1316) for erenumab, and 798 days (CI 95% 715–1143) for galcanezumab.

Hazard ratio (HR) of fremanezumab versus erenumab is 1.47 (p=0.124). HR of galcanezumab is 1.09 (p=0.877) versus erenumab. HR of galcanezumab versus fremanezumab is 0.74 (p=0.258). There were no statistically significant differences between persistence of treatments.

70% of patients discontinued treatment. Reasons for treatment discontinuation were: clinical deterioration (56.5% of patients who discontinued), followed by favourable clinical outcome (17.7%), safety reasons added to clinical deterioration (8.6%), inadequate adherence to treatment (7%), safety (4.3%) and other minority reasons: loss of patient at follow-up, generalised allergic reaction or breast cancer.

30% of patients continued treatment at the end of the study.

Conclusion and Relevance Although trends indicated that galcanezumab may have the longest persistence and fremanezumab the shortest, no significant differences in persistence were found.

Main reason for discontinuation was clinical deterioration.

Further studies are needed to confirm these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-224 EXPERIENCE OF USING DALBAVANCIN IN OSTEOARTICULAR PROSTHETIC INFECTION

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Background and Importance The treatment of prosthetic osteoarticular infection involves an appropriate surgical approach and the administration of intravenous (IV) antibiotics for a prolonged period. In different published studies, the use of dalbavancin has been evaluated as a valid alternative in the treatment of this infections using different dosing regimens. This initiative may help reduce hospital stay days, consequently lowering healthcare costs.

Aim and Objectives Assess the use of dalbavancin at hospital discharge in patients with hip or knee prosthesis infection in a tertiary care hospital.

Material and Methods Cross-sectional observational study of patients admitted for knee or hip prosthesis infection subjected to surgical cleaning and debridement with prosthesis retention (DAIR) or first-stage prosthetic replacement surgery discharged between January and June 2024 with dalbavancin. Evaluated: age, sex, type of infection, duration of inpatient treatment after surgery, hospital stay, results of microbiological cultures, dosage of dalbavancin used and economic cost.

Results Dalbavancin was indicated in 16 patients, 10 in DAIR and six in first-stage prosthetic replacement surgery. Women: 68.8%, mean age: 69.88 ± 12.5ED years; knee prosthesis infection: 56.3%. Chronic infection: 50.00%. The median duration of inpatient treatment after surgery was 14 days (range: 10–22). The median length of hospital stay was 20 days (range: 10–53). Negative cultures were obtained in 25.0%, with S. epidermidis being the most frequent microorganism (43.75%). A regimen of 1,500 mg (day 1, day 8, and day 42) was used in 31.25%; 1,500 mg (day 1 and day 8): 31.25% and 1,500 mg followed by 1,000 mg every 2 weeks (8 to 12 weeks) in 37.5%. The economic cost of treatment per patient ranged between € 2674.74 and € 5349.48. The economic cost of avoided hospital days per patient is calculated between € 12,600 and € 16,800 for a minimum of 6 weeks of intravenous treatment. The calculated savings for the total number of patients based on the duration of inpatient treatment ranged from € 210600 to € 268800.

Conclusion and Relevance The use of dalbavancin in these unapproved indications may help reduce days of hospital stay by reducing healthcare costs. Its use should be protocolised and its dosage should be individualised according to the days of IV treatment planned and those received in hospital after surgery and culture results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-225 EPTINEZUMAB IN PATIENTS REFRACTORY TO OTHER INHIBITOR OF CALCITONIN GENE-RELATED PEPTIDE

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Background and Importance Migraine is a highly prevalent neurological disease characterised by incapacitating episodes of headache that affect quality of life. Many patients fail one or more lines of calcitonin-gene-related-peptide (CGRP) inhibitor drugs, causing therapeutic exhaustion and a high health impact. Therefore, new CGRP inhibitor, eptinezumab, may represent a new therapeutic alternative for refractory patients.

Aim and Objectives To evaluate the effectiveness of eptinezumab in patients refractory to one or more lines of CGRP inhibitor drugs (fremanezumab, erenumab and galcanezumab).

Material and Methods Retrospective observational study conducted between November 2023 and September 2024. To evaluate the effectiveness of eptinezumab, we compared the days with migraine per month (MMD) at baseline and after 12 weeks, mean reduction in MMD, rates of patients with response ≥75% and ≥50% based on the previous lines of CGRP received by the patients. For statistical analysis, the R studio program was used and demographic and clinical data were extracted from the patients' electronic medical records.

Results 34 patients with a mean age of 53.86 years (SD: 5.9) and 87.5% women. 20.6% of patients had received a single prior line, 61.8% two prior lines and the remaining 17.6% all three drugs. Of those who had received two drugs, the most

frequent was erenumab and galcanezumab 54.5%, followed by erenumab and fremanezumab 27.2%. In those patients who had only received one prior line, the initial DDM was 25 days (SD: 5.0), and after 12 weeks of treatment 16.4 (SD: 7.9). The response rate ≥75% during weeks 0–12 was 28.6% and the response rate ≥50% MDD was 57.1%. With two prior lines of therapy: initial DMM was 20.3 days (SD:9.7); 12.3 (SD: 8.7), and response rates 19% and 71.4% respectively. Those who had received all three possible lines had: prior DDM 27 (SD:6.7); at 12 weeks 17.2 (SD: 13.6), response rate ≥75% DDM of 33.3%; and response rate ≥50% DMM of 50%.

Conclusion and Relevance Treatment with eptinezumab has been effective regardless of the previous lines of treatment with subcutaneous CGRP inhibitor drugs, so it may constitute an effective alternative for patients refractory to this group of drugs. However, larger studies are needed to corroborate the data obtained in this study.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-226 EFFICACY OF ENZALUTAMIDE IN ABIRATERONE-NAIVE PATIENTS VERSUS ABIRATERONE-PRETREATED PATIENTS IN MCRPC NOT CANDIDATES FOR CHEMOTHERAPY

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Background and Importance Patients with prostate cancer have long survival times, specifically when the cancer is metastatic the relative survival rate at 5 years is 32%, this poses some challenges when it comes to the sequence of treatments and more specifically when the patients are not candidates for intravenous chemotherapy. Clinical practice guidelines recommend (evidence 2B) the use of enzalutamide (ENZA) after abiraterone (ABI) before the reverse order, but more published data are required to reinforce the recommendation.

Aim and Objectives In this prospective work we aim to know the efficacy of ENZA in metastatic castration-resistant prostate cancer (mCRPC) in ABI-naive patients versus patients who have previously taken ABI, in order to establish whether treatment with ENZA after ABI obtains relevant clinical benefit or otherwise, alternatives such as androgen blockade with testosterone should be explored.

Material and Methods Patients with mCRPC and chemotherapy naive who were prescribed ENZA as part of standard clinical practice entered one of two cohorts: 1) ABI-naive or 2) post-ABI. Primary endpoint was time to treatment failure (TTF), defined as time from treatment start to discontinuation for any reason. Secondary endpoints included time to prostate-specific antigen (PSA) progression and time to disease progression. Data were collected on patients from March 2021 to July 2024.

Results A total of 62 patients were enrolled: 34 in cohort 1 and 28 in cohort 2. 20 (58,8%) patients failed treatment in the ABI-naive cohort and 21 (75%) failed in the post-ABI cohort, being the median TTF (95% CI) of 13.2 months (10.9–14.2) and 7.3 months (5.0–8.9) respectively. The median time to PSA progression (95% CI) was 16.8 months (16.2–18.8) in cohort 1 vs 15.3 months (9.3–17.1) in the other; with a median time to disease progression (95% CI) of 13.8 months (12.7–16.2) vs 8.5 months (6.9–14.1).

Conclusion and Relevance Median TTF and time to disease progression with ENZA were longest in ABI-naive patients, with similar results observed for PSA control. The results of ENZA obtained in patients pre-treated with ABI can be also considered clinically relevant.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-227 MANAGEMENT OF OSTEOPOROSIS IN RHEUMATOLOGY DAY HOSPITAL: DOES THE CLINICAL PHARMACIST HAVE A ROLE TO PLAY?

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Background and Importance A multidisciplinary day hospitalisation (DH) dedicated to osteoporosis was established in our medical centre in May 2023. Clinical pharmacist provides individualised care through a medication review, a medication reconciliation and a pharmaceutical consultation (PC).

Aim and Objectives The study aimed to assess the pharmaceutical impact in the management of patients with osteoporosis.

Material and Methods All patients admitted to day hospital have a PC and the following points are discussed: information about disease and osteoporosis treatment and hygienic-dietary rules. Pharmaceutical interventions (PIs) are referred to the rheumatologist and general practitioners (GPs). Pharmaceutical reports are sent to GPs and community pharmacists. Data from patients who had a PC from May 2023 to May 2024 were extracted from the electronic medical record and pharmaceutical report and analysed.

Results Over the study period, 78 patients (73% women) with a median age of 77 (51–97) years had a PC. Several drugs were presented to patients (mechanism of action, side effects, precautions for use): zoledronic acid (66.7%), teriparatide (12.8%), risedronate (11.5%), desonumab (6.4%), raloxifene (2.6%). Fall-increasing risk drugs were prescribed for 44.8% patients (benzodiazepine (10); antidepressant (10); opioid (8); alpha-blocker (8); hypnotic (7); diuretic (7); non-steroidal anti-inflammatory drug (1)), and drug induced osteoporosis were prescribed for 61.5% patients (proton pump inhibitors (PPIs) (34); corticosteroids (13); chemotherapy (1)). In total, 63 PIs were performed (0.8 PI per patient): deprescription (opioid (9), benzodiazepine (8), PPIs (7)); dose adjustment (hypnotic (4), cholecalciferol (3), PPIs (1)); proposition to add a drug (calcium (15), cholecalciferol (10)); administration schedule adjustment (calcium (2)); galenic form (calcium (1)); optimisation of therapeutic strategy (antihypertensives (3)). Thirty-one PIs were performed to the rheumatologist and were accepted (100%), 32 IPs were performed to GPs. Smoking (10) and alcoholic patients (5) were offered a smoking and alcohol cessation programme. The 1 year hospitalisation rate for falls and fractures is 5.1%.

Conclusion and Relevance This study highlights the positive impact of a clinical pharmacist intervention in an osteoporosis

day hospital on therapeutic optimisation and patients education about their disease and treatments. All PIs referred to the rheumatologist were accepted. A study is undergoing to evaluate the acceptance rate of the PIs referred to GPs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-228 ACUTE HEPATITIS AFTER PARACETAMOL POISONING: ANALYSIS OF POTENTIALLY INFLUENCING FACTORS

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Background and Importance Acute hepatitis (AH) is the acute inflammation and necrosis of the liver parenchyma. Among its many causes is paracetamol poisoning (PP). Inflammatory parameters usually begin to rise within 24–48 hours, the unfavourable course of AH predisposes to acute liver failure.

Aim and Objectives Analysis of the prevalence of AH after PP.

To identify which epidemiological and intoxication-associated variables are related to the development of AH, and to examine the degree of correlation.

Material and Methods This observational, retrospective, descriptive study examined patients treated with N-acetylcysteine in the ED for PP between January-2019 and August-2024.

AH was defined as a set of non-specific gastrointestinal symptoms, asthenia or abdominal pain in conjunction with elevated Aspartate-aminotransferase (x10 times the upper normal limit), Bilirubin (>2.5mg/dL) and, in severe cases, coagulopathy (INR>1.5). The analytical test conducted at the conclusion of the N-acetylcysteine (NAC) perfusion and 48 hours post-poisoning was reviewed to ascertain whether there was evidence of AH.

Potential risk factors for paracetamol hepatotoxicity (PRFPH) included: chronic alcoholism, malnutrition, drugs that increased the oxidative metabolism of paracetamol.

It was examined:

- Variables related to PP: age, sex, PRFPH, massive paracetamol intake (considered as >30g), time between PP and starting of NAC treatment.
- Variables related to NAC treatment according to the centre's protocol: dosage, preparation, administration, and infusion duration.

The relationship between the variables under examination and the onset of AH was investigated through the Chi-squared test, significance level ($p<0.05$).

SPSSv 27 was used for statistical analysis.

Results A total of 43 patients (72.1% female) were studied. The median age was 19 years, (IQR=10). The prevalence of patients with HA was 6.9%.

The 20.9% of patients presented with PRFPH, none of them developed AH.

NAC was inappropriately used in 55.8% of total patients and in 66.6% of AH patients, ($p>0.05$).

In two of three AH patients, paracetamol ingestion was >30g and the start of NAC was 8 hours after PP, ($p=0.003$).

Conclusion and Relevance PP was predominantly observed in young female patients. The prevalence of AH was low, however, there was a statistically significant association between AH and both massive intakes and delayed initiations of NAC.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-229 IMPLEMENTATION OF A STRATIFICATION MODEL FOR CHRONIC PAEDIATRIC PATIENTS IN OUTPATIENT PHARMACY

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Background and Importance The increasing prevalence of chronic patients requires individualised attention focused on patient needs, guaranteeing optimal health outcomes ant the sustainability of the healthcare system. The Spanish Society of Hospital Pharmacy developed a stratification pharmaceutical care model to determine the complexity of chronic paediatric outpatients assisting pharmacists in optimising resources and pharmaceutical interventions.

Aim and Objectives To determine the complexity of patients, using the stratification model and identify those most likely to benefit from pharmaceutical interventions.

Material and Methods A cross-sectional study was conducted from September 2023 to September 2024. Data were collected from electronic medical records and semi-structured patient/caregiver interviews were carried out. Variables recorded: age, nutritional status, social, economic and cognitive issues, hospital admissions and emergency visits, comorbidities, polypharmacy, adherence, treatment changes, complex pathology (transplant and palliative care), polypharmacy and high-risk medications for the paediatric population. Variables were weighted between 1 and 4 based on its relevance, leading to four stratification levels: level 1 (≥27 points), level 2 (23–26 points), level 3 (18–22 points), and level 4 (≤21 points). Tailored pharmaceutical interventions were implemented according to complexity.

Results 166 paediatric patients were stratified, 51% male, median age 11 (1–17). Distribution between medical services was haemato-oncology (59.6%), nephrology (18.7%), infectious diseases (7.8%), neurology (7.8%), gastroenterology (2.4%), endocrinology (1.9%), and allergology (1.8%). 9% belonged to level 1, 15.7% to level 2, 21.5% to level 3, and 54.2% to level 4. 41.7% of level 1 were bone marrow transplant patients. The most significant variables in the level 1 priority group included social issues, frequent hospital admissions, comorbidities (hypertension and renal insufficiency), polypharmacy (>4 drugs), frequent treatment changes and high-risk medications (anticoagulants, antiepileptics, and immunosuppressants). Follow-up plans adapted to the different levels were carried out, prioritising patients included in groups 1 and 2 through medication reconciliation and information during care transitions, integration with the healthcare team, telephone follow-up and coordination with primary care and community pharmacy.

Conclusion and Relevance The application of a stratification model and identification of most complex paediatric patients

(levels 1 and 2), enables pharmaceutics to develop interventions such as reconciliation during care transitions, close follow-up, and coordination with the team that ensure efficient, safe and high-quality pharmaceutical care.

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

4CPS-230 TIME COURSE OF HYPERCHOLESTEROLAEMIA TREATMENT WITH PCSK9 INHIBITORS MONOCLONAL ANTIBODIES (IPCSK9)

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Background and Importance Monoclonal antibodies directed against the PCSK9 protein revolutionised the treatment for hypercholesterolaemia 5 years ago. It is necessary to review the effectiveness data over time in real clinical practice.
Aim and Objectives To find out the evolution over time of the effectiveness of hypercholesterolaemia treatment with iPCSK9 (alirocumab/evolocumab).
Material and Methods Observational, retrospective, analytical and descriptive study in a second-level hospital including patients diagnosed with hypercholesterolaemia who started iPCSK9 treatment from September 2017 to March 2023. Inclusion criteria: age>18 years, on treatment for at least 12 months with alirocumab (75mg/14 days or 150 mg/28 days) and evolocumab (140 mg/14 days). Intensification dosing was alirocumab 150 mg/14 days.

Efficacy variables were collected: baseline LDL value (LDLb), LDL at 1/3/6/12 months, target LDL, dates of: start/end of treatment, change of dosage, reaching target (100/70/70/55mg/dL according to patient need), reaching 50% LDLb reduction.

The data were obtained from the patient's clinical history and the electronic dispensing register. Statistical analysis was performed with STATA software using Kaplan-Meier curve analysis and Mantel-Haenszel test.
Results Forty patients were included, 50% were treated with alirocumab 75mg/14 days, 22.5% with alirocumab 150 mg/28days and 27.5% with evolocumab 140 mg/14 days.

Finally, at 14 months, at least 50% of patients needed to intensify alirocumab dosing. Comparing both starting doses of alirocumab, it was observed that the median time to intensification was 7 months with 75mg/14 days dose, while it was 33 months with the monthly dose (150 mg/month) (p=0.02).

Abstract 4CPS-230 Table 1

	1 month	3 months	6 months	12 months	
Probability of reaching LDL target (%)	25	4.7	57.8	67.7	p=0.74*
Probability of reduction 50% LDLb (%)	25	40	51.4	60	p=0.59**

*Applying Mantel-Cox test confirms the absence of differences between the different dosages studied (p=0.74).** The curve shows a clear tendency for evolocumab to be faster in achieving the 50% LDLb reduction.

Conclusion and Relevance IPCSK9 have proven to be effective drugs in a short period of time for the treatment of hypercholesterolaemia, with 50% of patients reaching target LDL levels within 6 months. Those patients on alirocumab treatment have on average needed to intensify dosing in just over a year, however the baseline dose(150mg/month) has been proven more effective over time. Evolocumab seems to be faster in achieving the 50% of LDL reduction.

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

4CPS-231 ANALYSIS OF DRUG INTERACTIONS RELATED TO THE INITIATION OF NIRMATRELVIR/RITONAVIR IN A GERIATRIC POPULATION

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Background and Importance Drug induced iatrogenesis causes approximately 130.000 hospitalisations and 10.000 deaths annually, with a higher incidence within the geriatric population, which often has multiple comorbidities and is polymedicated. The combination of nirmatrelvir/ritonavir (NR) is prescribed for non-oxygen-requiring SARS-CoV-2 infections at high-risk of progressing to severe forms. However, NR can cause drug interactions (DIs), as ritonavir is a potent inhibitor of cytochrome P450–3A4.
Aim and Objectives This project aims to evaluate the proportion of NR prescriptions that led to pharmaceutical interventions (PIs) in a geriatric population.
Material and Methods A retrospective, monocentric, observational study was conducted, examining patients treated with NR from 21 January 2022 (when early access was obtained), to 1 March 2024. Data were extracted from the prescription software Dxcare, and from the hospital pharmacy's dispensing software history, Pharma, to analyse the types of PIs and their impact on prescriptions.
Results A total of 121 patients (mean age 88 years, male/female ratio 31/88), with an average of two comorbidities, received NR. Out of the 65 patients with known vaccination status, 86% were vaccinated. Forty-nine prescriptions resulted in at least one PI, totalling 62 PIs, 50 (81%) of which led to the modification of prescriptions, for example, the interruption of treatment of drugs that should not be coadministered with NR, such as oral anticoagulants (n=11, 32%), and statins (n=16, 47%).

Four types of PIs were identified: dosage modification (n=28, 45%), DI management (n=27, 44%), initiation proposal (n=2, 3%) and monitoring (n=5, 8%).

Notably, some patients treated with NR were not eligible: 18.7% either had no comorbidities (n=10), had received oxygen therapy (n=1), or tested positive for SARS-CoV-2 more than 5 days prior (n=2).
Conclusion and Relevance This study shows that NR prescriptions generated a significant amount of PIs, which were broadly accepted. However, this number is underestimated as some interventions were conducted orally and not recorded.

This highlights the crucial role of pharmacists in ensuring treatment safety.

Ultimately, appropriate prescription of NR is essential considering the high cost of the treatment.

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

4CPS-232 USTEKINUMAB TROUGH LEVELS AND THEIR IMPACT ON CLINICAL AND ANALYTICAL RESULTS IN CROHN'S DISEASE

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Background and Importance Ustekinumab has emerged as an effective treatment for moderate to severe Crohn's disease (CD). However, limited data exist correlating ustekinumab serum levels with clinical remission, and its therapeutic range remains unclear.

Aim and Objectives To analyse the relationship between trough ustekinumab concentrations at maintenance and clinical and analytical response of patients with CD.

Material and Methods Observational, retrospective, multicentre study of adult patients with CD without perianal involvement treated with ustekinumab, who had trough serum levels monitored between April 2019 and May 2024 in a tertiary hospital.

Collected variables: age, BMI, serum levels, FCP and CRP at 0, 6, 12, and 24 months from baseline, persistence, clinical response and remission at 6, 12, and 24 months.

Efficacy was evaluated at week 26±6, 52±6 and 104±6 according to clinical history data. Clinical remission (Crem) was defined as obtaining a Harvey-Bradshaw index (HBI) <5. Clinical response (CResp): reduction of >3 points in HBI with respect to baseline. Normalisation of inflammatory biomarkers: CRP <5 mcg/mL and FCP <250 mcg/mL.

Serum UTK levels were measured by ELISA techniques.

Results 89 patients and 232 ustekinumab level determinations were recorded. Median age (IQR) was 44.5 (30.5–54) and 46,1% were female (table 1).

Detectable levels of anti-drug antibodies were found in only one patient, but with a low titre.

At week 52, 80.8% (n=59) of patients had CResp, 50.7% (n=37) had CRem. Median ustekinumab trough concentration was higher in responders (3.74 (1.6–5.8) µg/mL) than non-responders (2.54 (0.7–8.1) µg/mL; p=0.84); also in patients in CRem but no significant difference was found (p=0.87).

At 24 months, 90.2% (n=37) had a CResp, 34.1% (n=14) CRem. Median trough concentration showed no differences between patients with CResp (7.49 (4.2–12.5) µg/mL) and those without (6.22 (3.9–9.0) µg/mL;p= 0.780), and also for CRem (p=0057).

CPF showed a median reduction of 30% (0.05–83%) at 6 months, and 41% (17–80%) at 12 months, achieving 63.4% of patients normalisation of biochemical parameters at 12 months.

The roc curve analysis shows a moderate specificity and sensitivity of levels and CResp at 24 months with an AUC=0.64. Cut-off point predicting long-term response in our sample was 2.2µg/mL.

Conclusion and Relevance Higher trough concentrations seem to be associated with greater clinical response. A larger cohort, with extended follow-up and more diverse patient populations, will be needed to test the robustness of the results.

Abstract 4CPS-232 Table 1 Baseline characteristics of the study population

Variables	Total, N=232
Age, median (IQR)	44,5 (23,5)
Sex, n (%)	
Female	107 (46,1%)
BMI, median (IQR)	25,15 (8,29)
Age at diagnosis, n (%)	
<16 years	28 (12,1%)
16-40 years	166 (71,6%)
>40 years	38 (16,4%)
Disease location, n(%)	
L1: ileal	110 (47,4%)
L2: colonic	22 (9,5%)
L3: ileocolonic	100 (43,1%)
Disease behavior, n (%)	
B1: non-stricturing and non-penetrating	122 (52,6%)
B2: stricturing	85 (36,6%)
B3: penetrating	25 (10,8%)
Family history of IBD, n (%)	
No family history	199 (85,8%)
First degree	15 (6,5%)
Second degree	18 (7,8%)
Extraintestinal manifestations, n (%)	
No manifestations	134 (57,8%)
Presence of manifestations	98 (42,2%)
Persistence, median (IQR)	42 (27,5)
Periodicity, n (%)	
Every 12 weeks	2 (0,9%)
Every 8 weeks	91 (39,2%)
Every 6 weeks	52 (22,4%)
Every 4 weeks	87 (37,5%)

Conclusion and Relevance Higher trough concentrations seem to be associated with greater clinical response. A larger cohort, with extended follow-up and more diverse patient populations, will be needed to test the robustness of the results.

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

4CPS-233 EFFECT OF HIGH-DOSE INTRAVITREAL AFLIBERCEPT IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION: COMPARISON OF REAL-WORLD OUTCOMES WITH PHARMACOKINETIC MODEL

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Background and Importance Aflibercept (AFLI) is indicated for the treatment of exudative neovascular age macular degeneration (nAMD), by intravitreal injection (IVI). The intraocular bioavailability of AFLI follows a logarithmic distribution, and it will be effective as long as its ocular concentration saturates

VEGF receptors. Below this threshold, free VEGF promotes exudation and irreversible tissue damage. Recently, a higher dose of AFLI (8mg/0.07mL, AFLI8) was approved compared to 2mg/0.05mL (AFLI2).

Aim and Objectives To evaluate the correlation between the theoretical pharmacokinetic rationale for the high-dose AFLI8 regimen and its effectiveness in patients with nAMD.

Material and Methods Retrospective study of patients with nAMD with subfoveal type 1 macular neovascularisation who were switched from AFLI2 to AFLI8. Inclusion criteria were long-term treatment (≥6 months) with persistence of retinal fluid detected 4 weeks after the last AFLI2 IVI and one response assessment 2 weeks after AFLI8 IVI. Best corrected visual acuity (BCVA) was measured using Snellen chart and all patients were imaged with spectral-domain optical coherence tomography (SD-OCT) and swept-source OCT-Angiography (OCTA). A time-dependent mathematical model was developed, using Python, to calculate AFLI concentrations with AFLI2 and AFLI8, and compared with clinical outcomes.

Results 20 eyes, from 20 patients, were analysed. Before switch, median number of IVIs was eight, mean BCVA was 0.22 logMAR and mean Central Retinal Thickness (CRT) =283.5µm. Comparison between absolute intravitreal theoretical values (AFLI2 vs AFLI8) showed a difference of 18 days (p=0.042), i.e. the estimated intravitreal dosage at 14 days of AFLI2 was expected to be the same at 32 days after AFLI8. Comparison of clinical outcomes between 2 week/AFLI2 vs 4 week/AFLI8 interval showed absence of differences between BCVA (p=0.317) and CRT (p=0.779). Although no significant differences were found, clinically there was a reduction in CRT (p=0.128) between the 1st IVI (283 µm) and the 3rd IVI (255 µm) of ALFI8.

Conclusion and Relevance Understanding of the ocular pharmacokinetics of AFLI may facilitate the identification of patients who can benefit from a transition to a higher dose and predict the feasibility of extending the dosing interval. A theoretical increment of 18 days predicted by the pharmacokinetic model seemed to correspond to clinical outcomes evaluated in this study.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-234 RESULTS OF THE IMPLEMENTATION OF AN EFFICIENCY-BASED AGE-RELATED MACULAR DEGENERATION TREATMENT PROTOCOL

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Background and Importance Three of the 10 drugs with the highest consumption in our study centres correspond to therapies for age-related macular degeneration (ARMD). Given the high cost of these drugs, the increase in the diagnosis rate of this pathology and the ageing of the population, the hospital pharmacist plays a very important role in the creation of protocols that result in budgetary sustainability.

Aim and Objectives Analyse the degree of compliance with the ARMD protocol established in two study hospitals and the economic impact of its establishment.

Material and Methods All drug prescriptions for ARMD (faricimab, aflibercept and ranibizumab) were analysed retrospectively from 1 January 2023 to 30 September 2024 and the comparative study was carried out between periods with and without ARMD protocol (1 January 2023 to 5 May 2024 vs 6 May to 30 September 2024). The protocol established the front-line use of ranibizumab, followed by faricimab and last-line aflibercept for efficiency criteria. The prices of each preparation were calculated excluding indirect costs (syringes, needles and labour).

Results During the period without ARMD protocol (1 January 2023 to 5 May 2024), 140 treatments were initiated (110 (78.6) with ranibizumab and 30 (21.4%) with aflibercept) and after the implementation of the protocol (6 May to 30 September 2024), 75 patients were started (52 (69.3) with ranibizumab, 13 (17.3%) with aflibercept and 10 with faricimab (13.3%)). Regarding treatment changes after implementation, there were 89 line changes: 29 changed from aflibercept to faricimab (seven of which had not gone through ranibizumab), 27 changed from ranibizumab to faricimab and 30 from ranibizumab to aflibercept; and only three from faricimab to aflibercept (prior to ranibizumab). The overall degree of protocol compliance was 41.6% and the opportunity cost, or in other words, the cost of not choosing the best option, has been € 43,252 since the implementation of the protocol.

Conclusion and Relevance Given the high economic impact of the drugs used in ARMD, the implementation and monitoring of compliance with protocols based on efficiency seems important for sustainability. In this specific case, there is significant room for improvement in the use of drugs for ARMD.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-235 ASSESSMENT OF THERAPEUTIC DRUG MONITORING IN OUTPATIENT PARENTERAL ANTIMICROBIAL THERAPY (OPAT) IN PAEDIATRIC PATIENTS

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Background and Importance Outpatient parenteral antimicrobial treatment (OPAT) allows intravenous antimicrobial administration at home, providing an alternative to inpatient care that particularly benefits paediatric patients and their caregivers. Paediatric population has significant intra- and inter-individual variability in drug exposure and underrepresentation in clinical trials, leading to an increased drug-associated toxicity risk. Thus, proactive therapeutic drug monitoring (TDM) may optimise dosages, enhancing efficacy while minimising adverse effects.

Aim and Objectives To determine how many OPAT episodes in paediatric patients underwent TDM out of those that could benefit from it. Moreover, to evaluate the alteration of any laboratory parameters related to antimicrobial toxicity.

Material and Methods Retrospective, single-centre study involved paediatric patients (<18 years) on OPAT from

January 2019 to December 2023. Patients treated with aminoglycosides, linezolid, teicoplanin and voriconazole were considered TDM candidates. Demographic, clinical, analytical, OPAT episode outcome and TDM variables were collected.

Results The study included 24 patients, 8 (33.3%) females, with a mean age of 11.8 (±5.5) years at the onset of the episode. Most patients belonged to the following departments: pneumology (16.7%), paediatric liver transplant (33.3%), cystic fibrosis (16.7%) and oncohaematology (12.5%). The median treatment duration was 15 days (IQR 12.5–20.5). A total of 243 OPAT episodes were reviewed, of which 39 (16.0%) had TDM indication. However, TDM was only performed in 12 (30.8%) episodes. Aminoglycosides were involved in 18 episodes with five (27.8%) undergoing TDM; teicoplanin in 16, with two (12.5%) underwent TDM; linezolid in three, with one (33.3%) subjected to TDM; and voriconazole in five, all of which were monitored (100.0%). Among the episodes subjected to TDM, five (41.7%) showed out-of-range values in the initial assessment. Of the 39 episodes that could have benefited from TDM, nine (23.1%) were prematurely discontinued, of which four received TDM. Regarding potential drug related toxicity, analytical results were available for 26 (66.7%) episodes, with 18 (69.2%) exhibiting out-of-range values. Among these, three episodes suffered hepatic alterations (two treated with voriconazole, one with teicoplanin) and one renal alteration (treated with aminoglycosides) along the episode, with TDM conducted in three of them.

Conclusion and Relevance TDM is performed in a limited number of paediatric OPAT episodes, often revealing out-of-range values. Furthermore, despite analytical monitoring, altered parameters persist, highlighting the need for toxicity surveillance along the episodes to enhance patient safety and optimise treatment efficacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-236 ASSESSMENT OF THERAPEUTIC DRUG MONITORING IN ADULT CYSTIC FIBROSIS PATIENTS ON OUTPATIENT PARENTERAL ANTIMICROBIAL THERAPY

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Background and Importance Outpatient parenteral antimicrobial treatment (OPAT) is an alternative to inpatient care in selected patients, particularly those who require repeated treatments, such as adults with cystic fibrosis (CF). Standard treatment for these patients includes aminoglycosides, linezolid, voriconazole and teicoplanin. Due to drug-associated toxicity risk, proactive therapeutic drug monitoring (TDM) can be valuable for dosing adjustment to optimise effectiveness and minimise toxicity.

Aim and Objectives To establish how many OPAT episodes are submitted to TDM out of the total that could benefit from it. Additionally, to analyse the alteration of the analytical variables due to antimicrobial toxicity.

Material and Methods Retrospective, single-centre study including adult patients (>18 years) with CF diagnosis on OPAT from January 2019 to December 2023. Demographic, clinical, analytical, OPAT episode outcome and TDM variables were collected.

Results The study included 64 patients, 33 women (51.6%), with a mean age of 31.5 (±9.80) years at the onset of the episode. The median treatment duration was 21 days (IQR:15.0–23.0). A total of 236 episodes were analysed, of which 160 (67.8%) could benefit from TDM, however only six episodes (3.7%) received it. Aminoglycosides were involved in 148 episodes, among which only five (3.4%) were monitored; voriconazole in one which was subjected to TDM; teicoplanin in eight and linezolid in three, none of which underwent TDM. Of the six episodes that underwent TDM, four (66.7%) had values out-of-range in the first determination. Regarding the outcome of the 160 episodes, 18 (11.2%) were prematurely discontinued, none of which received TDM. Most of the remaining episodes resolved the infectious process (97 (60.6%) episodes) or were switched to oral therapy (35 (21.9%) episodes). Regarding potential antimicrobial toxicity, blood test results during the OPAT episode were available for 43 (26.9%) episodes, with 10 (23.3%) showing altered analytical values. Renal function was impaired along three episodes treated with aminoglycosides and hepatic alterations occurred during one episode treated with teicoplanin. Among the altered, none of them underwent TDM.

Conclusion and Relevance Few OPAT episodes undergo TDM, and most show out-of-range values. Analytical variables are rarely monitored, and if so, altered values potentially linked to the antimicrobial are seen. Thus, increasing TDM in OPAT episodes could help to optimise treatment and reduce toxicity risks.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-237 SPECIAL PHARMACEUTICAL CARE AND TELECONSULTATION FOR THE GERIATRIC ONCOHAEMATOLOGICAL PATIENT

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Background and Importance The need has been detected to carry out a comprehensive geriatric evaluation of older adult patients with oncohaematological neoplastic pathologies, in order to make decisions related to their complete therapeutic regimen, avoiding any medication-related harm to the patient.

Aim and Objectives Implementation of a specialised pharmaceutical consultation where a global evaluation of the pharmacotherapy of older adult patients with oncohaematological neoplastic pathologies is carried out.

Material and Methods Prospective observational study conducted from December 2023 to September 2024 in a specialised Pharmaceutical Consultation in the geriatric oncohaematologic patient. The haematologist and oncologist selected the most fragile patients using the G8 scale and sent them to the Pharmacy office, where the pharmacist carried

out a previous evaluation of home medication, self-medication and alternative medicine with the aim of detecting drug-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. With all these data, the best possible pharmacotherapeutic history will be obtained and pharmaceutical interventions were also made in the patient's medical records so that they could be consulted by any health professional and teleconsultations for those patients who were most unable to travel to the pharmacy office.

Results With the implementation of this new consultation 350 patients were attended, median age 82 years, 65% men and 35% women. Fifty pharmaceutical teleconsultations were carried out in patients with bed-chair life. Adherence to oncohaematologic treatment was improved by 90%. A total of 90 pharmaceutical interventions were carried out: 30 related to the dosage and way of taking the treatment, 20 with pharmacological interactions, 14 therapeutic duplications, 10 with the use of herbal products and multivitamin complexes, six for not attending their medical check-up in 2 years and 10 had been prescribed medication of little therapeutic value and with a high anticholinergic load that had to be suspended from the treatment.

Conclusion and Relevance The hospital pharmacist has a key role in the pharmaceutical care of geriatric oncohaematologic patients through the implementation of specialised consultations where a complete evaluation of the treatment of these patients is carried out.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

Abstract 4CPS-238 Table 1

	HLA-DQA1*05		
	YES (n=17)	**NO** (n=22)	**Total** (n=39)
	N(%)	**N(%)**	**N(%)**
Persistence after 48 weeks			
YES	10 (58.8)	17 (77.3)	27 (69.2)
NO	7 (41.2)	5 (22.7)	12 (30.8)
Median time to failure (IQR)	75 (34–103)	49 (29–112)	66.5 (36.5–102)
Reason for withdrawal			
Primary failure	4 (23.5)	3 (13.6)	7 (17.9)
Secondary failure	2 (11.8)	1 (4.5)	3 (7.7)
Immunogenic	1 (5.9)		1 (2.6)
Pharmacodynamic	1 (5.9)	1 (4.5)	2 (5.1)
Other causes	1 (5.9)	1 (4.5)	2 (5.1)
Anti-drug antibodies	2 (11.8)	2 (9.1)	4 (10.3)
Intensification			
Interval	3 (17.6)	3 (13.6)	6 (15.4)
Dose + interval	5 (29.4)	7 (31.8)	12 (30.8)
ADA levels			
Pre-intensification*			
Supratherapeutic	2 (11.8)	3 (13.6)	5 (12.8)
Therapeutic	7 (41.2)	9 (40.9)	16 (41)
Subtherapeutic	4 (23.5)	3 (13.6)	7 (17.9)
Post-intensification			
Supratherapeutic	4 (23.5)	5 (22.7)	9 (23.1)
Therapeutic	3 (17.6)	4 (18.2)	7 (17.9)
Subtherapeutic	1 (5.9)	1 (4.5)	2 (5.1)

*last level available if not intensified

4CPS-238 ROLE OF HLA-DQA1*05 IN THE PERSISTENCE OF ADALIMUMAB IN THE MANAGEMENT OF INFLAMMATORY BOWEL DISEASE

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Background and Importance Anti-tumour necrosis factor (anti-TNF) drugs are the most used biological therapies for treating Inflammatory Bowel Disease (IBD). However, their efficacy is significantly reduced due to the formation of anti-drug antibodies which can lead to treatment failure. HLA-DQA1*05 haplotype has been linked as a possible biomarker of immunogenicity and loss of response to anti-TNF treatment.

Aim and Objectives To analyse persistence after 48 weeks of treatment with adalimumab (ADA) in biologic-naive patients with IBD starting ADA in 2022 who had HLA-DQA1*05 determined.

Material and Methods Descriptive retrospective and single-centre study including biologic-naive patients diagnosed with IBD who started ADA in 2022.

Sex, age, type of IBD (Crohn's disease (CD) or ulcerative colitis (UC)), smoking status and previous immunosuppressant (IS) treatment were collected from the electronic medical records. It was also documented (according to the presence or absence of HLA-DQA1*05 haplotype): persistence after 48 weeks of treatment, time (days) to failure, reason for withdrawal, immunogenicity, dose or interval intensification and pre- and post-intensification ADA levels. The target therapeutic interval of ADA was established between 5 and 12 mcg/mL during maintenance.

Results 39 patients were included, female (56%), median age (IQR) 51 (39–60), CD (74%), UC (26%), smokers (26%), ex-smokers (31%), previous IS treatment (30%). These variables did not influence persistence at 48 weeks in the study population.

HLA-DQA1*05 haplotype was present in 43% of the patients in the study.

Results are shown in table 1.

Conclusion and Relevance The persistence at 48 weeks was 69.2% in the total study population after ADA initiation, being 1.8 times lower in patients with HLA-DQA1*05. These data are consistent with those published in the literature.

Further studies are needed to analyse the impact of HLA-DQA1*05 in the loss of response to ADA in order to support the determination of HLA-DQA1*05 prior to initiation of therapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-239 PHARMACY-LED MEDICATION RECONCILIATION TO OPTIMISE LEVODOPA MANAGEMENT AND MINIMISE CONTRAINDICATED DRUG USE IN HOSPITALISED PARKINSON'S DISEASE PATIENTS: A QUASI-EXPERIMENTAL STUDY

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Background and Importance Patients with Parkinson's disease (PD) admitted to the hospital require their usual medication routine instead of standard hospital rounds. Avoiding contraindicated drugs and ensuring proper medication timing are crucial to prevent complications. Targeted pharmaceutical care mitigates these risks and improves patient outcomes.
Aim and Objectives This study evaluates the impact of pharmacy-led medication reconciliation on levodopa timing and the prescription and administration of contraindicated drugs for PD patients.
Material and Methods A quasi-experimental pre-post study was conducted over 3 months (June to August 2024) for newly admitted PD patients. The intervention involved pharmacy-led medication reconciliation within 48 hours of admission, focusing on adjusting levodopa timing and preventing contraindicated drug use. PD patient admissions from 2023 were used as a comparison group. Our hospital has an alert system to flag contraindicated drugs for PD patients, which must be manually added during reconciliation. We aimed to implement the alert as early as possible.

The adequacy of levodopa prescription timing and the prescription and administration of contraindicated drugs were evaluated for patients post-intervention and compared to the 2023 group. A pre-post statistical analysis was conducted using Pearson's Chi-squared test.
Results A total of 34 patients underwent medication reconciliation, with an average time of 15 hours post-admission. Among reconciled patients, 59% had levodopa timing adapted to their usual routine, and 15% had contraindicated drugs prescribed, which were subsequently suspended. Additionally, 71% of patients had alerts for contraindicated drugs added during reconciliation.

A total of 34 PD episodes from 2023 were analysed as a comparison. After the intervention, the percentage of patients receiving a personalised levodopa timing plan within 48 hours increased from 51% in the 2023 group to 76% ($p = 0.014$). The prescription of contraindicated drugs decreased slightly from 22% to 18% ($p = 0.588$). However, the administration of contraindicated drugs dropped significantly from 14% to 3% ($p = 0.035$).
Conclusion and Relevance Early pharmaceutical reconciliation in PD patients optimises medication management and reduces medication errors. This intervention is particularly relevant for improving patient safety and reducing complications in this high-risk population. Future research should focus on assessing the impact of these interventions on clinical outcomes, including hospital length of stay and overall patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-240 CLINICAL PHARMACY IN PSYCHIATRIC DEPARTMENT. A QUALITATIVE STUDY FROM USERS OF MEDICINE REVIEWS PERFORMED BY PHARMACISTS

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Background and Importance Clinical pharmacy services within the psychiatric departments of the Region of Southern Denmark have been established for a decade. Over the years, these services have evolved, with pharmacists now primarily conducting medical reviews at the request of physicians. On average, approximately 30 medical reviews are requested each month, reflecting a clear and growing demand. The aim of this study was to emphasise the value that pharmacists provide within psychiatric departments. While some evaluations of pharmacist guidance have been conducted, these have typically focused on community pharmacy settings and patient perspectives.
Aim and Objectives Pharmacists play a central role in supporting psychiatric care through their expertise in medication management. The primary objective of this study was to assess the impact and perceived benefits of pharmacist-conducted medical reviews from the perspective of physicians in psychiatric departments within the Region of Southern Denmark, highlighting the critical contribution of pharmacists to patient care.
Material and Methods A questionnaire was distributed via email to physicians in psychiatric departments who had previously requested one or more medical reviews. The initial distribution took place in May 2023, with a follow-up conducted in September 2024.
Results In 2023, 49 physicians responded to the questionnaire, while in 2024, 31 responses were received. Results from both surveys indicated that pharmacist-led medical reviews saved physicians significant time. The quality and usefulness of these reviews were rated as satisfactory or very satisfactory. Physicians noted that pharmacists were instrumental in promoting rational pharmacotherapy and enhancing patient safety. The reviews enabled psychiatrists to concentrate on other critical responsibilities, underscoring the essential role of clinical pharmacists in psychiatric care.
Conclusion and Relevance The Danish healthcare system is undergoing significant structural changes, and incorporating a broader range of health professionals is vital for maintaining comprehensive medical care. Pharmacists' involvement in medical reviews is regarded as beneficial, particularly for alleviating physicians' workload and enhancing the quality of care. The increasing demand for pharmacist-conducted medical reviews highlights their crucial role in ensuring rational pharmacotherapy and promoting patient safety. This study underlines the importance of integrating pharmacists into psychiatric care settings, especially where the availability of healthcare professionals, including psychiatrists, is limited.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-241 PROACTIVE VERSUS RETROACTIVE MODELS IN MEDICATION RECONCILIATION – ARE THERE BENEFITS?

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Background and Importance The practice of medication reconciliation (MR) at admission, by hospital pharmacists, has been growing in our country, aiming to reduce drug related problems (DRP). However, its implementation mainly focuses on the retroactive model, with limited data on the proactive model.

Aim and Objectives This study aims to characterise and compare retroactive and proactive MR processes, particularly regarding the number of unintentional discrepancies (UD) that can lead to DRPs. To explore the relationship between each model and the average length of hospital stay per patient. To investigate the connection between both models and the admission waiting list, when compared to the waiting list prior to the implementation of MR.

Material and Methods A prospective study was conducted in a vascular surgery unit from October 2023 to September 2024. Inclusion criteria: presence of comorbidities, age $\geq$55 years, and prior chronic therapy with $\geq$5 drugs. Model classification, depending on prescription availability when medication history was ready. Data collection and analysis were done using Microsoft Excel.

Results The study included 502 patients (average age 71.1 years), with 3540 drugs reconciled using the retroactive model (233 MRs) and 3571 drugs with the proactive model (269 MRs). In retroactive MR, 775 (21.9%) UDs and 8 (0.2%) unjustified intentional discrepancies (UID) were identified, compared to only 29 (0.8%) UD and five (0.1%) UID in the proactive model. Among these, 772 (98.6%) and 27 (79.4%) pharmaceutical interventions (PI) were accepted by physicians, respectively. The most common causes of UD and UID were drug omission (58.9% vs 67.6%) and incorrect drug dosage (15.9% vs 9.1%). The average length of stay from October 2022 to September 2023 was 7.1 days. In this study, retroactive MR cases averaged 7.4 days (SD=13.9), while proactive cases averaged 4.7 days (SD=8.9). Before MR implementation, the waiting list for admission (March 2023) was 128 patients, decreasing to 108 by September 2024.

Conclusion and Relevance The proactive MR model demonstrated benefits over the retroactive model in early prevention of UDs capable of leading to DRPs, shorter hospital stays, and greater patient recovery, suggesting better bed availability. Overall, MR and PI may have contributed to reduced treatment waiting lists, though further monitoring is needed to strengthen these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

4CPS-242 EFFECTIVENESS OF PHARMACIST BASED MEDICATION RECONCILIATION ON PATIENT SAFETY

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Background and Importance Discrepancies and medication errors are one of the most important challenges in the hospital which mostly occurs during the admission, discharge or transfer between wards. Medication reconciliation (MR) is a process to ensure the accurate and continuous transfer of information related to the patient's medications at the time of hospital admission, transfer or discharge.

Aim and Objectives The purpose of this study is to investigate the effectiveness of drug reconciliation on reducing medication errors and increasing patient safety.

Material and Methods A retrospective study was conducted from December 2021 through October 2024. MR in our hospital consists of several steps. First, taking the best possible medication history from the patient at the time of admission and then comparing with the drugs prescribed in the hospital and checking the discrepancies. Preparing a comprehensive list of the patient's medications at the time of discharge and teaching the patient about the medication regimen.

Also when any intervention for dose adjustment, drug interaction, contraindications or adverse reaction is needed, the clinical pharmacist discuss the issue with practitioners and advises them. And finally, the pharmacist records all observed error and discrepancies in a form called Drug Related Problem (DRP).

Results We did more than 26,200 admission and discharge MR in this period of time. In addition, more than 13,000 DRPs were registered.

The number of medication discrepancies recorded was identified. The most prevalent medication error was made by the doctor and then the nurse. Medication errors leading to medication interactions were also common.

Conclusion and Relevance In our country, our center is the first hospital that officially and seriously started drug reconciliation. Conducting a structured MR by pharmacist can prevent many medication errors and improve the patient's outcome.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

Patient safety and quality assurance

5PSQ-001 POTENTIAL AND CLINICALLY MANIFESTED DRUG-DRUG INTERACTIONS IN PATIENTS ADMITTED TO THE HOSPITAL: A CROSS-SECTIONAL STUDY

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Background and Importance Drug-drug interactions (DDIs) are increasingly common in ageing populations. Although many studies address potential DDIs, few explore clinically manifested DDIs.

Aim and Objectives To provide information on the prevalence and characteristics of potential and clinically manifested DDIs in patients admitted to the hospital.

Material and Methods This study included patients from our previous study[1] with a minimum of two medications in their

medication history. Data were obtained from electronic health records. Potential DDIs were identified using Lexicomp (via UpToDate), Micromedex and Stockley's drug interactions database. Potential DDIs were defined as those detected by at least one DDI database with moderate or greater severity. Clinically manifested DDIs were defined as those linked to clinically adjudicated adverse drug events.

Results The study involved 968 patients with a mean age of 73 and a mean of seven medications. Potential DDIs were identified in 90% (95% CI: 88–92) of patients. Most were categorised as pharmacodynamic and moderate in severity. Diuretics, antithrombotic agents, and drugs used in diabetes represented medication classes most frequently involved in potential DDIs. Clinically manifested DDIs were observed in 6% (95% CI: 5–8) of patients, primarily involving gastrointestinal haemorrhage, with antithrombotic agents being the most common culprits.

Conclusion and Relevance A high prevalence of potential DDIs was found among acutely admitted hospital patients, though clinically manifested DDIs were less common. Compared to previous research, the rate of DDIs was significantly higher, underscoring the issue's growing importance. The discrepancy between potential and clinically manifested DDIs points to the need for targeted alert systems to prevent alert fatigue. Drug interaction databases showed a DDIs prevalence twice as high as the international consensus list of potentially clinically significant DDIs in older people.[2 3]

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Conflict of Interest No conflict of interest

5PSQ-002 ATEZOLIZUMAB PLUS CHEMOTHERAPY IN EXTENSIVE-STAGE SMALL-CELL LUNG CANCER

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Background and Importance Atezolizumab in combination with carboplatin-etoposide is indicated for the first-line treatment of extensive-stage small-cell lung cancer (ES-SCLC). Different studies have demonstrated promising efficacy and safety with atezolizumab plus chemotherapy. Real-life studies are commonly performed to confirm the results.

Aim and Objectives The aim of our study is to analyse the effectiveness and safety of atezolizumab combined with chemotherapy in ES-SCLC in a tertiary hospital, and to compare with the pivotal IMpower133 trial.

Material and Methods Retrospective observational study was conducted. We included patients treated with atezolizumab plus chemotherapy from January 2022 to July 2024. Variables collected: sex, age, smoking status, quality of life status according to the Eastern Cooperative Oncology Group (ECOG) scale, location of metastases, comorbidities, duration of treatment, objective response rate (ORR) according to RECIST-v1.1 criteria (Response Evaluation Criteria in Solid Tumours), progression-free survival (PFS) and overall survival (OS) calculated by Kaplan-Meier method, cause of treatment discontinuation and adverse events (AEs) according to Common Terminology Criteria for Adverse Events v.5 (CTCAE). Data obtained from the electronic medical record (Diraya) and software Farmis_Oncofarmand processed with SPSS Statistics v.21.

Results Thirty patients (83% male) were included; median age of 62 years (Interquartile range (IQR):58–68); 80% smokers (20% ex-smokers). 70% had an ECOG:1 at baseline (17% ECOG≥2; 13% ECOG:0). The most frequent locations of metastases were: hepatic (40%), bone (40%), renal (37%) and lung (20%). The most frequent comorbidities were: arterial hypertension (50%), dyslipidaemia (26.7%) and diabetes mellitus II (13.3%). Median duration of treatment was 5.5 months (IQR:3.5–7.8). At the date of analysis (06 August 2024), eight patients are still on treatment.

ORR was partial in 63% of patients (7% not evaluated). Median PFS and OS were 6.7 (95% CI 5.8–13.07) and 10.4 (95% CI 9.74–17.82) months, respectively. 68.2% of patients discontinued treatment due to disease progression, 18.2% exitus and 13.6% AEs.

87% of patients had some AE during treatment. Most frequent AEs were: neutropenia 73% (G3–4:38.5–7.7%), anaemia 61.5% (G3:34.6%), asthenia 57.7% (G3:3.8%), thrombocytopenia 38.5% (G3:15.4%), elevated transaminases 23% (G3:3.8%), nausea 19.2% (G3:0%), and diarrhoea 11.5% (G3:0%). Three patients discontinued treatment due to AEs.

Conclusion and Relevance Median OS was lower than that observed in the pivotal IMpower133 trial, while PFS was higher.

Although the majority of patients presented some AE, in three patients were these AEs forced to discontinue treatment. 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-003 IMPACT OF PHARMACIST INTERVENTIONS IN ELDERLY PATIENTS WITH POLYPHARMACY

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Background and Importance Polypharmacy in elderly people is a growing concern, impacting patient safety and healthcare costs. Pharmacists play a key role in reviewing medication regimens for these patients, enabling the optimisation of pharmacotherapy, reducing adverse effects, and promoting adherence.

Aim and Objectives To assess the clinical, economic and organisational impacts of pharmacist interventions in elderly patients with excessive polypharmacy (≥10 medications) at discharge.

Material and Methods A protocol was established at a tertiary hospital for the review of polymedicated patients over 80 years of age on 10 or more chronic drugs, who were admitted to the internal medicine service from 1 March to 1 July 2024. Pharmacists provided recommendations to the internist for optimising therapy at discharge.

Interventions were classified into seven categories: addition of a new drug, drug discontinuation, drug switch, dose adjustment, change of administration route, drug monitoring and administration modality optimisation. The CLEO (Clinical, Economic and Organisational) tool assessed the impact of these interventions.

Clinical impact was scored using six levels from −1 to 4 (negative, null, minor, moderate, major and avoiding a fatality) and the economic and organisational dimensions had three levels (negative, null, positive) scored −1, 0, 1, respectively.

Results Thirty-eight patients were reviewed, with a mean age of 86.8 years (SD: 4.17), 59.0% were women. In total, 101 interventions were made, medium of 2.7 (SD: 1.4) per patient.

The most frequent intervention was drug discontinuation (55.4%), followed by dose adjustments (23.8%), drug monitoring (8.9%), drug switches (7.9%), administration optimisation (3.0%), and new drug additions (1.0%).

The economic impact was positive in 85.1%, and negative in 4.0% of interventions. Most interventions (70.3%) had no organisational impact but no negative impact either. The clinical impact was mostly minor (54.5%). There was no negative clinical impact, and in 15% of interventions the Clinical impact was major or avoided a fatality.

Conclusion and Relevance Pharmacist interventions in polypharmacy are essential to reduce healthcare costs and improve care quality. Expanding this practice to other hospitals is recommended.

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Conflict of Interest No conflict of interest

5PSQ-004 ANALYSIS OF SYMPTOMATIC RESCUE THERAPY IN PATIENTS WITH GALCANEZUMAB FOR MIGRAINE PROPHYLAXIS

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Background and Importance Pharmacological treatment of migraine is divided into two types: symptomatic rescue and prophylactic treatment. Symptomatic treatment includes paracetamol and nonsteroidal anti-inflammatory drugs, as conventional analgesics, and triptans. Profilactic treatment includes calcitonin gene-related peptide as galanezumab, erenumab, fremanezumab and eptinezumab

Aim and Objectives To analyse the symptomatic treatment in patients diagnosed with chronic migraine (CM) and episodic migraine (EM) under prophylactic treatment with galcanezumab.

Material and Methods Retrospective descriptive observational study of 31 months duration (January 2021 to July 2023). All patients treated with galcanezumab were included. Patients with other diagnoses were excluded. Sex, age at drug initiation, diagnosis, and symptomatic rescue therapy used since the start of galcanezumab treatment were recorded.

Materials: outpatient dispensing module, electronic history program.

Results Thirty-six patients were included, 88.9% women, mean age at the beginning with galcanezumab therapy was 45.4 years (26–81). 66.7% of patients had CM and 33.3% had EM. 94.4% of patients needed rescue treatment during migraine attacks.

During galcanezumab treatment, conventional analgesics were used by 75.0% of CM patients and by 66.7% of EM patients. Conventional analgesics used were:

33.3% of CM patients and 25.0% of EM patients took more than one analgesic.

Triptans use was 75.0% in CM patients and 83.3% in EM patients. Triptans consumed were:

More than one triptan was used by 4.2% of CM patients and 16.7% of EM patients.

Patients using both types of drugs concomitantly were 58.3% of CM patients and 50.0% of EM patients.

Conclusion and Relevance Nearly all patients (94.4%) attended symptomatic treatment during galcanezumab treatment.

Triptans were the most commonly used drugs in patients with CM and EM. The most commonly used triptan in CM was rizatriptan and in EM it was sumatriptan.

Dexketoprofen was the conventional analgesic most used by both populations.

More than a half of the patients took both types of drugs during migraine attacks.

Abstract 5PSQ-004 Table 1

Conventional analgesic	CM Patients (%)	EM Patients (%)
Dexketoprofen	37.5	33.3
Metamizole	20.8	25.0
Ibuprofen	16.7	0
Paracetamol	16.7	8.3
Naproxen	4.2	16.6
Indomethacin	4.2	0
Lornoxicam	8.3	0
Celecoxib	0	8.3

Abstract 5PSQ-004 Table 2

Triptans	CM Patients %	EM Patients %
Rizatriptan	25.0	25
Zomitriptan	16.7	8.3
Sumatriptan	12.5	33.3
Eletriptan	16.7	16.7
Almotriptan	4.2	16.7
Naratriptan	4.2	0

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-005 EVALUATING RENAL DRUG DOSING APPROPRIATENESS IN PATIENTS WITH REDUCED GLOMERULAR FILTRATION RATE: A CONSENSUS ACROSS MULTIPLE DRUG INFORMATION SOURCES

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Background and Importance Various drug information sources provide recommendations for adjusting medication dosing in patients with reduced glomerular filtration rate (GFR). Discrepancies in these recommendations can lead to varying prevalence of inappropriate prescribing or suboptimal patient care.

Aim and Objectives This study aims to assess the prevalence of inappropriate renal drug dosing and the use of contraindicated medications in patients with reduced GFR, based on a consensus from multiple drug information sources. Additionally, it aimed to identify medications most frequently subject to inappropriate renal dosing adjustments and contraindication.

Material and Methods This cross-sectional study focused on chronic kidney disease patients admitted to University Hospital Hradec Králové, with an estimated GFR below 60 ml/min. The requirement for renal dose adjustment or contraindication was determined based on the consensus between the Summary of Product Characteristics and other drug information sources – Renal Drug Handbook, British National Formulary, Lexicomp and Micromedex. For medications requiring renal dosing adjustment agreement between the prescribed and recommended renal dosing was assessed. The data were obtained from our previous studies.[1 2]

Results Of 375 chronic kidney disease patients, 67 (18%, 95% CI 14–22) received drug dosages that were inconsistent with recommended renal dosing adjustments. Fenofibrate and metformin represented the medication most frequently dosed inappropriately. The prevalence of patients prescribed at least one contraindicated medication was 4%, with fenofibrate, metformin, dabigatran etexilate, ibandronate and nitrofurantoin being the most common.

Conclusion and Relevance Nearly 1 in 5 patients with reduced GFR received medication dosages that did not align with recommended renal dosing according to the consensus between the Summary of Product Characteristics and other drug information sources. Special attention is required when prescribing metformin and dabigatran etexilate to patients with reduced GFR due to the risks of lactic acidosis and bleeding.

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Conflict of Interest No conflict of interest

5PSQ-006 AN EXPLORATION OF NON-CONSULTANT DOCTORS' VIEWS, AND CURRENT PRACTICES, OF PRESCRIBING THROMBOPROPHYLAXIS, FOR PATIENTS WITH CHRONIC LIVER DISEASE

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Background and Importance Previous studies have shown prescribing rates of thromboprophylaxis to be suboptimal in patients with chronic liver disease (CLD). Challenges faced by doctors include the uncertain balance between bleeding and thrombosis risk, and the limited data available to guide their decision making in this patient cohort.

Aim and Objectives To determine non-consultant doctors' views, and current practices of prescribing thromboprophylaxis, for patients with CLD. To determine which variables, affect doctors' confidence determining if thromboprophylaxis is appropriate for patients with CLD, and their current practices of same. To determine if doctors' views and current practices agree with clinical guidelines.

Material and Methods A questionnaire was designed and distributed to non-consultant doctors in the hospital. The questionnaire was based on current literature and clinical guidelines. Data were analysed using SPSS.

Results Twenty-four doctors (45.3%) felt confident determining if thromboprophylaxis should be prescribed for patients with CLD.

The majority of doctors felt it was important to complete the VTE Risk Assessment (98.1%), to regularly review the need for thromboprophylaxis (92.5%), and that patients with CLD can be at an increased risk of thromboembolism even with a prolonged prothrombin time (71.7%).

For patients with CLD with risk factors for VTE and without a contraindication to anticoagulation, most doctors (98.1%) prescribed thromboprophylaxis. Eleven doctors (20.8%) prescribed thromboprophylaxis regardless of the INR figure. Amongst those doctors who took the INR figure into account, the INR threshold above which doctors would not prescribe thromboprophylaxis varied greatly. The platelet count below which doctors would not prescribe thromboprophylaxis varied also.

Clinical situations in which doctors felt thromboprophylaxis was not appropriate included an active bleed, an upper gastrointestinal bleed, and low platelets.

Doctors' title/grade, years of experience, and gastroenterology experience influenced their confidence and prescribing practices.

One doctor was aware of a guideline on thromboprophylaxis prescribing in CLD, and all doctors surveyed would feel more confident having access to a guideline.

Conclusion and Relevance The prescribing practices of doctors were, to some extent, in accordance with the limited guidelines currently available. Access to, and teaching on, the guidelines is recommended to improve doctors' confidence and compliance with guidelines.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-007 MOLECULAR ADSORBENT RECIRCULATING SYSTEM (MARS) IN A CRITICAL CARE UNIT FOR HEPATIC FAILURE

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Background and Importance Hepatic failure is a condition with challenging management, which is further complicated upon hospital admission. One of the techniques used to alleviate the complications of these pathologies is the so-called 'Molecular Adsorbent Recirculating System' (MARS), which is an extrahepatic detoxification system that uses albumin to purify toxins that the liver is not able to eliminate.

Aim and Objectives The objective of this study was to evaluate the efficacy of this technique used in critical care units to primarily treat hepatic encephalopathy (HE), hyperbilirubinaemia and as supportive therapy until liver transplantation.

Material and Methods We conducted a descriptive, observational, and retrospective study (2013 to 2023) of patients treated with MARS technique in a tertiary hospital. The data were obtained from the electronic medical records of the patients. The parameters analysed were: demographic information, underlying liver disease, indication for MARS technique, number of sessions, bilirubin level or HE grade before and after the procedure, whether they received a liver transplant afterwards, and whether they were exitus.

Results Twenty-five patients received MARS treatment, including 16 (64%) men with a mean age of 52 (range 16–72) years. The underlying liver disease: 11 (44%) with alcoholic cirrhosis, six (24%) transplant rejection four (16%), and other condition four (16%). Ten (40%) patients had portal hypertension and 10 (40%) had oesophageal varices.

The indications for MARS were: 12 (44%) for hyperbilirubinemia, five (20%) for encephalopathy, five (20%) for acute liver failure and three (12%) for transplant rejection.

Patients with HE: one improved while four (80%) remained the same or worsened and they ended up being exitus.

Patients with hyperbilirubinemia: eight (66%) improved bilirubin levels. Seven (58%) were exitus. The relative bilirubin decreases were similar in those who survived and those who died (21.17% vs 22.76%).

The five patients with acute liver failure managed to be transplanted, although two died.

There were nine (36%) patients who received a liver transplant, and exitus was 14 (56%).

Conclusion and Relevance In our sample of patients, it has not been able to reduce mortality or improve the underlying complications of this pathology.

The patients who used it as a bridge therapy for transplantation were successful, but their success cannot be affirmed thanks to the technique due to the doubtful results in the rest of the patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

5PSQ-008 STUDY OF PATIENT SATISFACTION IN A PHARMACY UNIT FOR CLINICAL TRIALS

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Background and Importance Patient satisfaction with the care provided is becoming increasingly important in clinical practice as it can impact therapeutic compliance and, therefore, its effectiveness.

Aim and Objectives To study the perception of patients regarding the service received by the clinical trials pharmacy unit.

Material and Methods Descriptive study in which an anonymous and voluntary survey was prepared using the Google form platform composed of patient data and 10 closed questions. The data were collected from January to April 2024. The responses were evaluated on a scale of 1–5, with 5 being the maximum score and the result being expressed as the average score obtained for each response. The variables collected were: degree of satisfaction regarding the physical space, organisation of the service and waiting time, confidentiality and treatment received in the dispensing process.

Results The total number of surveys collected was 30. The form revealed a male predominance (63.3%) (n=19), with a median age of 65 years (range=28–79 years). Regarding the length of patient visits, 6.7% (n=2) were attending for first time, 26.7% (n=8) for the past 6 months, and 36.7% (n=11) for the past year.

Regarding the physical space and organisation, access was rated with 4.3/5 points (satisfaction 86%) and location got 3.9/5 points (satisfaction 78.6%), being rated with the maximum score by eight patients (26.7%) and considered average by 10 (33.3%). Convenience was rated with 4.3/5 points (satisfaction 85.3%) and the schedule obtained a score of 4.5/5 (satisfaction 90.0%).

Regarding the dispensing process, both for giving the prescription and for receiving the medication, the scores were 4.4/5 and 4.5/5, respectively. The waiting time for prescription was 88% generally satisfied and the waiting time for receiving medication 89.3%. Confidentiality was highly valued with 4.7/5 points (satisfaction 94%) and 74% (n=21) of the patients gave the highest score. The treatment received by the health personnel was mostly positive, with high percentages in kindness (96.7%)(n=29) and accessibility (50%) (n=15), and to a lesser extent the options of resolving doubts (30%) (n=9), clarity of language (36.7%) (n=11) and adequate attention time (56.7%) (n=17) were selected.

Conclusion and Relevance The survey results showed high satisfaction among patients treated, which is important for achieving adequate health outcomes. Work must continue to achieve excellence in pharmaceutical care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-009 CHANGES OF INFLAMMATORY PROFILE AFTER ANTI-CGRP ANTIBODY TREATMENT IN MIGRAINE PATIENTS

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Background and Importance The role of inflammation in the pathophysiology of migraine seems to be supported by evidence of an increase in pro-inflammatory cytokines, and by a reduction of regulatory lymphocyte subsets and prevalence of Th1 lymphocytes in the peripheral blood of patients. During acute severe migraine attacks, the calcitonin gene-related peptide is elevated in the cranial circulation and stimulates the release of inflammatory cytokines.

Aim and Objectives Verifying and confirming the monoclonal antibody anti CGRP activity in the reduction of inflammation induced by migraine. How the use of monoclonal antibody reduces the release of pro-inflammatory cytokines.

Material and Methods We investigated the levels of Th1 and Th2 cytokines, chemokines and adiponectin in the serum of the migraine patients: at each day hospital visit, blood samples were taken before the antibody was administered; 1 month after the infusion, the patient was made to return for visit to assess the cytokine level. Determination of serum levels of the cytokines was performed using commercial ELISA Kits. A Shapiro-Wilk's test was performed to evaluate each variable's departure from distribution. The quantitative variables were summarised as median and interquartile range. Midas questionnaire was used to assess change in degree of disability before and after 1 month of antibody treatment.

Results The number of patients who underwent sampling was 13. Results showed that Th1/Th2 and TNF/IL-10 profiles are modulated by anti-CGRP treatment with a shift towards a Th2 immune response with concomitant improvement of symptoms in migraineurs (MIDAS scale score). Serum concentration of adiponectin, according to its anti-inflammatory activity, showed a significant increase after anti-CGRP treatment, suggesting a potential connection of a reduction of adiponectin to the pathophysiology of migraine.

Conclusion and Relevance This preliminary study highlights that anti-CGRP treatment led to a shift towards a For Peer Review Th2 Immune response with concomitant improvement of symptoms in migraineurs, confirming the correlation between migraine and immune system dysfunctions. In conclusion, monoclonal antibody anti-CGRP demonstrate efficacy in the resolution of this pathology.

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Conflict of Interest No conflict of interest

5PSQ-010 PEMBROLIZUMAB IN METASTATIC NON-SMALL-CELL LUNG CANCER AND POOR PROGNOSTIC FACTORS IN CLINICAL PRACTICE

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Background and Importance Pembrolizumab is indicated for metastatic non-small-cell lung cancer (mNSCLC), both squamous histology and adenocarcinoma with chemotherapy or as monotherapy in case of PD-L1 expression $\geq$ 50%.

Attempts are being made to decipher which variables can serve as a prognosis for patients undergoing immunotherapy.[1]

Aim and Objectives To evaluate the association between potential prognostic factors and median overall survival (mOS) and progression-free survival (mPFS).

Material and Methods Observational, retrospective and descriptive study of the efficacy and poor prognostic factors of pembrolizumab in mNSCLC, in a tertiary care hospital from June 2020 to September 2024.

The variables collected were: sex, age, type of mNSCLC (adenocarcinoma, squamous, non-specific (NOS)), type of treatment (pembrolizumab monotherapy or chemotherapy), start and end date of pembrolizumab, death. The variables included considered as risk factors were: high lactate dehydrogenase values, central nervous system metastasis, neutrophil-lymphocyte ratio >4, and Eastern Cooperative Oncology Group performance status >2. Data were collected from the medical records.

The total mOS and mPFS were calculated, as well as those of the different subgroups. The SPSS program was used for data analysis.

Results A total of 69 patients were studied, the median age was 65 (29–82) years, 73.1% of whom were men. Regarding the subtypes of mNSCLC: 11.59% were NOS, 55.07% adenocarcinoma, and 33.34% squamous. 31.9% of patients received pembrolizumab as monotherapy, the rest with chemotherapy according to histology.

The subgroups created were three according to the number of risk factors: low (0), intermediate (1) and high ($\geq$2). The number of patients belonging to them respectively was: 21, 30 and 18. The results are shown in table 1.

For the subgroup analysis of mPFS, in Log-Rank test p-value was 0.004 and for analysis of mOS p-value was <0.001.

Abstract 5PSQ-010 Table 1

Subgroups	mOS (months)	mPFS (months)
Low-risk	38.5 (95% CI: 7.28–69.72)	Not reached
Intermediate risk	15.23 (95% CI: 3.37–27.1)	11.63 (95% CI: 6.99–16.27)
High-risk	3.03 (95% CI: 0.95–5.11)	1.67 (95% CI: 1.11–2.22)
Total	22 (95% CI: 9.66–34.34)	10.5 (95% CI: 6.46–14.54)

Conclusion and Relevance A significant difference was observed in both mOS and mPFS according to risk subgroups. But it is necessary to take into account the small size of the sample, so more research is needed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

5PSQ-011 ASSESSING THE MISUSE OF THROMBOPROPHYLAXIS IN HOSPITALISED PATIENTS: A RETROSPECTIVE STUDY

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Background and Importance For inpatients, the risk of thromboembolic disease is significantly reduced through the administration of pharmacological thromboprophylaxis using either unfractionated heparin or low molecular weight heparin. The Padua score is validated in the literature for determining the indication for thromboprophylaxis. In our 450-bed healthcare facility, the therapeutic strategy for thromboprophylaxis is well-established and validated by the medical committee.

Aim and Objectives The objective of the study is to determine the proportion of thromboprophylaxis misuse among patients who should receive this medication and to identify actions to address this issue.

Material and Methods A retrospective analysis was carried out on the records of patients hospitalised for more than 3 days within our healthcare facility between January and June 2024. Patients with thrombocytopenia <20G/L, active severe haemorrhage, or those already receiving therapeutic anticoagulation were excluded. All prescriptions, medical and surgical history, morphological data, medical and paramedical observations, and biological results were reviewed.

Results Among 1,684 eligible patients, 204 were randomly selected. After analysis, 72 patients were excluded: 52 were receiving therapeutic-dose anticoagulants, and 20 had insufficiently documented records. Among the 132 included patients, 17 (12.9%) were not treated despite having an indication according to the Padua score. Six patients (4.5%) were treated with an insufficient dose – enoxaparin 4,000 IU/day in morbidly obese patients – resulting in a total underuse rate of 17.4%. Two cases of overdosing were identified: enoxaparin 4,000 IU/day instead of 2,000 IU/day in patients with severe renal impairment or low body weight. Thromboprophylaxis misuse affected 18.9% of patients.

Conclusion and Relevance A limitation of this study is its retrospective nature, which includes challenges in determining whether a patient is bedridden for the calculation of the Padua score. Despite routine pharmaceutical analysis, misuse was identified in nearly one out of five patients. The pharmacy team was informed, and a rapid training session on the systematic use of the Padua score was organised. A systematic approach to detect thromboprophylaxis misuse through the modelling of clinical situations within a pharmaceutical decision support system is currently being evaluated.

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Conflict of Interest No conflict of interest

5PSQ-012 FRAILTY INDEX: A PARAMETER TO CONSIDER IN PHARMACEUTICAL VALIDATION?

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Background and Importance Evaluate the role of the Frailty Index (FI) in pharmaceutical validation, improving care for frail elderly patients.

Aim and Objectives The aim of this study was to evaluate the utility of the FI in pharmaceutical validation within Comprehensive Care Plans (CCP) at a Social-Health Centre (SHC).

Material and Methods Retrospective observational descriptive study was conducted from January to December 2023 at a SHC where FI-SHC was calculated for all elderly residents enrolled in the CCP during this period, categorising frailty into non-frail (<0.2), mild (0.2–0.35), moderate (0.36–0.55) and advanced (>0.55). The elderly residents with an FI-SHC > 0.35 were selected for analysis of pharmaceutical interventions related to frailty. Patient follow-up was conducted by reviewing clinical histories using Resiplus and intervention records through the electronic application Farmatools.

The variables that were collected were demographic (age and sex) and clinical (frailty index). Regarding the interventions, these were classified by clinical relevance into Level I (no significant health changes), Level II (avoids likely patient harm) and Level III (avoids risks of hospitalisation and/or life-threatening situations). The utility of the FI-SHC was assessed by comparing the number of interventions related and unrelated to frailty, as well as their acceptance and clinical relevance.

Results Of the 83 elderly residents included in the CCP, 34 (41%) had a FI >0.35, with 23 classified as moderate (0.36–0.55) and 11 as advanced (>0.55). The cohort consisted of 27 women and 7 men, with a median age of 89 years (65–101).

A total of 111 interventions were performed by the pharmacist, of which 37 (33%) were related to the FI. Among these, 26 (70%) were accepted and 11 (30%) were not. None of the interventions were classified as Level I, while 20 (54%) were Level II and 17 (46%) were Level III.

Conclusion and Relevance The prevalence of moderate and advanced frailty among elderly residents at the SHC is significant. One in three pharmaceutical interventions was related to the FI, with most having a high clinical impact and strong acceptance from physicians. These findings underscore the importance of the FI in pharmaceutical validation in this setting, suggesting its calculation should be considered essential for all elderly residents whenever feasible.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-013 ECONOMIC EVALUATION OF THE PEMBROLIZUMAB DOSING REGIMEN BY BODY WEIGHT IN A SECOND-LEVEL PRIVATE HOSPITAL

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Background and Importance Pembrolizumab is a monoclonal antibody directed against the PD-1 surface protein. Initial clinical trials established the 2mg/kg dosage as safe and effective, although later studies supported switching to a fixed dose (200 mg/cycle). The Therapeutic Positioning Report on pembrolizumab indicates that efficacy and safety are comparable and do not present clinically significant variations between the two regimens.

Aim and Objectives The objective of this study is to analyse, in real clinical practice, the effectiveness of weight-based dosing of the active ingredient, and the potential opportunity cost compared to fixed dosing.

Material and Methods Pharmacoeconomic study of 6.2 months duration (25 September 2023 to 31 March 2024) in a second-level private hospital. All patients who received any regimen with pembrolizumab were included. The variables studied were: sex, age, weight, diagnoses, administered cycles, cost of treatment with pembrolizumab with fixed dose and without weight adjustment. The data were obtained from the electronic medical record and the electronic prescription program Farmis-Oncofarm.

Results Twenty-four patients were included (54.17% women) with a median age of 68.83 (IQR, 62.25 to 87.00) years. The average weight was 70.21 kg (SD, 8.91). The most frequent diagnosis was non-squamous non-small-cell lung cancer, accounting for 50.00%, followed by squamous non-small-cell lung cancer and malignant breast neoplasm, both at 8.33%. The average number of chemo-immunotherapy cycles administered per patient was 5.083 (standard deviation). The cost per session at a fixed dose is 7,132.00 euros, while adjusted for weight it is 5,781.63 euros, representing a saving of 18.93%. This translates to a follow-up cost of 939, 639.00 euros (39,151.625 euros per patient), resulting in a gross saving of 183,651.00 euros. This saving is accompanied by the advantage that the effectiveness and safety of the treatment are not affected according to published studies.

Conclusion and Relevance Weight-based dosing of pembrolizumab generates a significant opportunity cost without impacting efficacy or safety, making it the most efficient strategy in routine clinical practice.

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Conflict of Interest No conflict of interest

5PSQ-014 IMPACT OF ROBOTIC DISPENSING SYSTEMS ON MEDICATION ERRORS IN TELEPHARMACY PROCEDURE: A COMPARATIVE ANALYSIS

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Background and Importance Telepharmacy services rapidly expanded during the COVID-19 pandemic. As telepharmacy grew, so did concerns about medication errors (ME). In our hospital, medication was prepared manually until a robotic dispensing system was installed in May 2024, transforming it into a semi-automatic process.

Aim and Objectives The study seeks to compare medication errors before and after implementing a robotic dispensing system. The objectives include identifying the types of errors that occurred, quantifying the errors in both periods.

Material and Methods Observational, descriptive and retrospective study carried out in the area of telepharmacy in a tertiary hospital during two distinct periods: before the robotic system was introduced (December 2023 to April 2024) and after its implementation (May to September 2024). ME were collected in a local database. We registered date, patient data, shipping codes, destination community pharmacy, type of error and organism who reported the error.

Results In the pre-robot period, 13 errors were recorded: wrong medication being sent (n=7) 53, 86%; incorrect dosage (n=2) 15, 38%; missing medication (n=2) 15, 38%; excessive medication (n=1) 7, 69% and medication for another patient (n=1) 7, 69%. The ME rate per month was 2, 6. 11 ME (84, 62%) were reported by the patient and 2 (15, 38%) by the community pharmacy.

After the robot was implemented, 14 errors were recorded: missing medication (n= 10) 71, 43%; medication for another patient (n= 2) 14, 29%; bad conditioning (n=1) 7, 14% and wrong medication (n=1) 7, 14%. The ME rate per month was 2, 8. 10 ME (71, 43%) were reported by the patient and 4 (28,57%) by the community pharmacy.

Conclusion and Relevance The robotic dispensing system altered the types of errors but it did not reduce the total number of them. Incorrect dosages and wrong medications decreased, but missing medication surged after the robot's implementation. This shift suggests that while robotic systems may help reduce certain manual errors, they may also introduce new challenges. Although the errors did not directly affect patient safety like those made during the pre-robot period, continuous monitoring and optimisation are essential to fully benefit from robotic dispensing systems.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-015 ABSTRACT WITHDRAWN

5PSQ-016 SIMULATION OF A CYBERATTACK IN A HOSPITAL PHARMACY: DEVELOPMENT OF TOOLS TO ENSURE CONTINUITY OF CARE

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Background and Importance Healthcare establishments are increasingly vulnerable to cyber-attacks which can compromise the continuity of care, particularly in the pharmacy sector. In our hospital pharmacy, we carried a cyber-attack simulation in order to identify the critical points and to find alternative tools to ensure the continuity of pharmaceutical tasks.

Aim and Objectives The aim of this study is to highlight the needs in order to develop alternative tools or specific procedures to guarantee the continuity of pharmaceutical activities in case of a cyber incident.

Material and Methods A cyber-attack simulation in a form of a complete informatics system failure was carried out for one afternoon. Pharmacy staff were involved to identify the critical points that prevented the provision of services and continuity of care following the cyber-attack.

Results The entire pharmacy team (pharmacists, pharmacy assistants, secretary, storekeeper, etc.) was divided into three working groups to design tools to maintain the continuity of care : supply, prescription and dispensation. Each group developed manual tools (tracking sheets, Excel spreadsheets, etc.). For example, the supply group created an automated order form based on an extraction of current data using an Excel file. The prescription group developed an Excel file containing protocol references to automate chemotherapy prescriptions, while generating production sheets and the corresponding labels. The dispensing medicines group has set up a binder listing services supplies (medicines, medical devices, gases, narcotics, antidotes, etc.) and paper registers for managing narcotics, outpatients and blood-derived medicines. In addition, a 'back-up' computer, offline, was set up with all the back-up documents.

Conclusion and Relevance This study has highlighted the need for tools and organisational measures to ensure the continuity of pharmaceutical care during a cyber-attack. A new cyber-attack simulation will be carried out to test the robustness of the tools developed. The results of this simulation underline the importance of establishing tailor-made continuity plans as well as regular testing of their effectiveness.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-017 HEDGEHOG PATHWAY INHIBITORS IN BASAL CELL CARCINOMA: REAL-LIFE EXPERIENCE

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Background and Importance Basal cell carcinoma (BCC) is the most common skin cancer, with advanced cases often difficult to treat using traditional methods like surgery and radiotherapy. The Hedgehog signalling pathway plays a key role in BCC, leading to treatments like vismodegib and sonidegib. This study evaluates their effectiveness and safety in real clinical settings.

Aim and Objectives The study aims to evaluate the effectiveness and safety of Hedgehog pathway inhibitors in patients with locally advanced or metastatic basal cell carcinoma. It focuses on treatment response, tumour recurrence, and adverse events, while comparing outcomes between vismodegib and sonidegib, two commonly used inhibitors in clinical practice.

Material and Methods A retrospective observational study was conducted on patients with locally advanced or metastatic basal cell carcinoma between December 2020 and March 2024. Data on demographics, tumour location, treatment details, and adverse events were collected. Patients received vismodegib or sonidegib, with treatment effectiveness assessed by disease recurrence. Quality of life was measured using the ECOG scale. Adverse events, dose modifications, and reasons for treatment discontinuation were also recorded. In some cases, neoadjuvant treatments were used to facilitate subsequent surgeries.

Results The study included 14 patients, of whom 64.29% were male and the mean age was 76.21 years. Most of the patients (57.14%) received off-label neoadjuvant treatment, and the rest were cases of inoperable locally advanced BCC. The tumours were predominantly located on the face (64.29% of cases). All patients treated with sonidegib had adverse events (ADRs), including haematologic toxicity and muscle damage, leading to discontinuation or dose adjustment in some cases. Adverse events were also experienced by 77.78% of vismodegib-treated patients. There was tumour recurrence in 25% of neoadjuvant-treated patients. Three patients treated with vismodegib were able to maintain response after more than 12 months, and four other patients with inoperable BCCla remain on treatment with significant tumour regression.

Conclusion and Relevance Hedgehog pathway inhibitors, vismodegib and sonidegib, effectively treat locally advanced and metastatic BCC, offering an alternative to surgery or radiotherapy. Despite frequent adverse effects, they control disease and enable salvage surgeries. Further research is needed to compare effectiveness, manage side effects, and improve treatment adherence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-018 ADEQUACY OF OMEGA-3-ACID ETHYL ESTERS IN PATIENTS WITH ESTABLISHED CARDIOVASCULAR DISEASES OR CARDIOVASCULAR RISK FACTORS

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Background and Importance Omega-3-acid ethyl esters (O3AEE) are indicated for the treatment of hypertriglyceridaemia, when diet and other non-pharmacological measures are not enough to reduce triglyceride levels. Systematic reviews and meta-analyses of randomised controlled trials have highlighted a dose-dependent increased risk of atrial fibrillation (AF) in patients with established cardiovascular diseases (ECV)

or cardiovascular risk factors (RCV) treated with O3AEE compared to placebo. The observed risk is highest with a dose of 4g/daily. European Medicines Agency (EMA) has recommended that the product information of these medicines should be updated to reflect data regarding the risk of AF.

Aim and Objectives To analyse O3AEE prescriptions in adult patients with ECV or RCV after notification of EMA (November 2023), provide therapeutic recommendations if necessary and assess the level of acceptance.

Material and Methods A prospective intervention study carried out in March 2024 at a University Hospital. Patients receiving treatment with O3AEE and an anticoagulant or other drug affecting coagulation (e.g. aspirin, warfarin and coumarin) were included. Electronic medical records were used to obtain the following data: sex, age, dosing regimen of O3AEE, comorbidities and life habits. Cardiovascular risk was calculated using the *Framingham Risk Score*. We recommend to the prescriber: 1) to discontinue O3AEE if the patient had AF; 2) to assess benefit-risk in patients with ECV or RCV, especially in those with a daily dose of O3AEE>4g.

Results We identified 55 patients on O3AEE with ECV or RCV, 63.6% women with a mean age of 63.5±11.0 years. Clinical departments: 36.4% nephrology, 30.9% internal medicine, 14.5% cardiology, 9.1% endocrinology and 9.1% others. We recommended to discontinue O3AEE in seven patients with AF (71.4% accepted). Benefit-risk was assessed in 48 patients with ECV or RCV. Daily dose of O3AEE was >4g in 11 patients (22.9%). Treatment with O3AEE was discontinued in 17 patients (30.9%). Dose was reduced in seven patients (14.6%). Treatment was continued in 47.3%. Recommendations were accepted in 75% of nephrology patients, 52.9% internal medicine, 12.5% cardiology, 60% endocrinology, and 20% others.

Conclusion and Relevance Most patients with AF have discontinued O3AEE treatment. However, despite the increased risk of AF in patients with ECV or RCV, prescribers have continued these medicines in almost half of patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-019 PREVENTION OF DISPENSING MEDICATION ERRORS IN ELECTRONIC PRESCRIPTIONS

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Background and Importance Although electronic prescribing systems offer many advantages, including reduced medication errors, numerous studies indicate that errors in drug prescription remain prevalent. These lead to important consequences, including patient safety issues and *increased* healthcare-related *costs*. It is therefore necessary to implement tools that prevent the incorrect dispensing of medication.

Aim and Objectives To implement an electronic tool to preventively discontinue potential errors in home medication prescriptions and alert the prescribing physician so that the error can be solved.

Material and Methods Prospective study from 1 March to 31 July 2024 in a tertiary care hospital. Potential medication errors detected in outpatients were discontinued through an electronic tool linked to the patients' home prescriptions. The prescribing physician was notified on the day the medication was discontinued. The resolution by the prescriber was also evaluated after one week (deadline for modification of these pharmaceutical interventions in the tool). The classification of errors was as follows: (1) therapeutic duplication, (2) incorrect dosage, (3) completed course of treatment not discontinued in electronic prescription and dispensing, (4) therapeutic inadequacy, including contraindication, overdose, etc.).The following variables were obtained: sex, age, polypharmacy (≥5 medications), therapeutic group of the drug, prescribing service. Data were obtained from electronic medical records and e-prescribing and dispensing system.

Results Fifty medication errors were detected in 46 patients, 62% women with a median age of 61 (IQR: 24–78). Of these patients, 42 (84%) were polymedicated. The median number of drugs prescribed was 9 (IQR: 4–14). The errors were classified as follows: (1) 62%, (2) 14%, (3) 8%, (4) 16%. The most frequent errors were detected in *antidiabetic agents (28%), drugs* for treating hypercholesterolaemia and hypertriglyceridaemia (20%), anticoagulants (12%), bisphosphonates (12%) and methotrexate (8%). The prescribers were primary care physicians (36%), internists (24%), cardiologists (12%), neurologists (6%), pulmonologists (6%), among others. Suspension was accepted for 96% of potential medication errors.

Conclusion and Relevance Although technology has contributed to improvements in medication error prevention, prescribing errors continue to occur. The electronic tool to discontinue prescribing errors contributes to patient safety by preventing potential dispensing errors, especially in polymedicated patients. The majority of the pharmacist interventions were accepted by the prescribing physician.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-020 MULTIDISCIPLINARY PROTOCOL FOR THE USE OF MEDICINES: LET'S TALK ABOUT INTRAVITREAL THERAPY

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Background and Importance Intravitreal therapy (IVT) arises from the need to increase drug dosage at ocular level. It is used in the treatment of pathologies like age-related-macular-degeneration or diabetic macular oedema.

Aim and Objectives To describe the protocol for use of IVT, guaranteeing its safety-effectiveness.

To evaluate economic impact.

To standardise clinical practice.

To improve efficiency of these medications, which have high-economic-population impact.

Material and Methods Multidisciplinary study Pharmacy-Ophthalmology in a second-level hospital; a working group established in September 2023.

Bibliographic search: guidelines-protocols from Spanish Society Retina Vitreous (SERV) and Spanish Society Hospital Pharmacy; technical sheets from Spanish Agency Medicines and Therapeutic Positioning Reports from national/regional HealthService.

Farmatools-Montesinos were used to obtain economic data (January 2021-December 2023).

Periodic meetings were held, developing the protocol:

1. Indications-criteria for IVT commercialised included in our Pharmacotherapeutic Guide (PG).
2. Development the prescription/administration; validation medical order/preparation/dispensing/registration.
3. Traceability.
4. Economic impact.

Results PG includes six commercialised IVT: aflibercept, ranibizumab, dexamethasone, broluzicimab and fluocinolone (that do not require manipulation); faricimab (vial can be fractionated). This protocol specifies indications for each one.

Development of the procedure: prescription is made individually using 'Order for Dispensing Medicines for Hospital-Use' (MambrinoXXI). Administration is done in ophthalmology room according to 'single act' model of SERV ITV Consensus Document. From the pharmacy, a consensual supply stock (aflibercept-dexamethasone-ranibizumab) is dispensed daily to 'single act' room, preparing different batches of each medicine for patients with bilateral involvement. Extra dispensations can be made. The rest are dispensed on-demand after individualised prescription. All medical orders are validated by pharmacists.

To ensure traceability, the name-batch-expiration date of the medication administered to each patient are identified and registered.

Economic impact and healthcare burden: 2021/2022/2023 the cost was 383,681/445,113/520,174 €; associated with 402/493/518 patients, a figure that is increasing.

Conclusion and Relevance Despite the exponential increase in the cost of IVT, mainly due to an increase in number of patients; in redosing faricimab, a reduction in IVT costs is expected.

Development of multidisciplinary protocols allows for improved health outcomes through the provision of individualised pharmacotherapeutic treatment, allowing each patient to receive IVT they need at a sustainable cost. The approach to IVT is a challenge that is implemented with ophthalmology-pharmacy alliances, which must be carried out.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-021 CLINICAL IMPACT OF SWITCHING BIOLOGICAL THERAPIES IN SEVERE ASTHMA ON A THIRD-LEVEL HOSPITAL

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Background and Importance Most data on switching monoclonal antibodies come from real-life studies. Switching is recommended when current treatment is insufficient. Patients who switch often have higher baseline eosinophil counts and exacerbation rates, despite oral corticosteroid (OCS) dependence.

Aim and Objectives To describe the use of biologics in patients with severe asthma, focusing on treatment persistence, switching to other biologics, and the relationship to asthma outcomes.

Material and Methods Multicentre retrospective, observational study that included patients with severe allergic or mixed asthma treated with at least two biologics between January and September 2024. Qualitative variables: age, sex, asthma type, smoking status, comorbidities, prior oral corticosteroids (OCS), first-line biologics, adherence, reasons for switching, second-line biologics, emergency room (ER) visits, hospitalisations, third or fourth-line treatments. Quantitative variables: body mass index (BMI), age, treatment median duration, time to ER visit after switching, IgE, eosinophils, FVC, FEV1, and FVC/FEV1 ratios at baseline and at 16,32 and 48 weeks. Data analysis was performed using R Commander.

Results A total of 48 patients were analysed, with 45.8% male and a median age of 57 years. Most had mixed asthma (60.4%) and a median BMI of 28.3. Of the patients, 52% were non-smokers, 40% were ex-smokers, and 8% were smokers. Comorbidities included rhinitis 35.4%), rhinosinusitis (31.2%), nasal polyps (25%), and chronic obstructive pulmonary disease (COPD) (10.4%). All patients had used inhaled therapy, and 79% OCS. Initial biologics included omalizumab (83.3%), benralizumab (8.3%), mepolizumab (6.2%), and dupilumab (2.2%). All switched due to poor control, exacerbations, or adverse effects. Second-line biologics were benralizumab (35.4%), dupilumab (33.3%),

Abstract 5PSQ-021 Table 1

Median	0 weeks	16 weeks	32 weeks	48 weeks
IgE(UI/mL)	550 (IQR 931–249)	203 (IQR 292–116)	186 (IQR 239,5–126)	65,5 (IQR 314–28)
Eosinophils (microlitres)	303 (IQR 532,5–120)	80 (IQR 170–20)	60 (IQR 190–0)	40 (IQR 112,5–0)
FVC (%)	83,7 (IQR 98–73,5)	83 (IQR 98–74.5)	86 (IQR 96,5–75,5)	86 (IQR 97–76)
FEV1 (%)	71 (IQR 94–58)	74.5 (IQR 96.5–62)	77(IQR 91–63,2)	75,5 (IQR 90,2–64,2)
FVC/FEV1 (%)	68 (IQR 78,2–55,2)	72.5 (IQR 78–46.2)	72,5(IQR 89,5–61,1)	75 (IQR 81,5–61,5)

mepolizumab (27%), and tezepelumab (4.3%). During this phase, 25% visited the ER, and four were hospitalised. Nine patients required a third-line therapy, primarily dupilumab (44.4%) and benralizumab (33.3%). Omalizumab was reintroduced in two patients due to insufficient response to other treatments.

Conclusion and Relevance Selecting the most suitable treatment depends on the patient's clinical history, biomarkers and comorbidities. Further studies are needed to characterise which patients benefit the most from biologics in severe asthma to minimise the need for switching.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-022 FOLLOW-UP THE EFFECTIVENESS AND SAFETY OF SACITUZUMAB-GOVITECAN IN A COHORT OF PATIENTS WITH TRIPLE-NEGATIVE METASTATIC BREAST CANCER: A MULTICENTRE STUDY

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Background and Importance Sacituzumab-govitecan (SG) is an antibody-drug conjugate approved for unresectable/metastatic triple-negative breast cancer (TNBC), available in the Spanish public health system since late 2022. Real-life data remains scarce.

Aim and Objectives This update, based on more mature data after a longer follow-up period, aims to analyse the effectiveness and safety of SG in TNBC patients from the three main university hospitals in the city.

Material and Methods Retrospective, observational, and multicentre study was conducted, including all patients treated with SG until November 2023, with a median follow-up of 10.3 months. Data were obtained from medical records and analysed with SPSS Statistics v.21. Variables collected: sex, age, body mass index (BMI), hormone receptor (HR), 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, treatment duration, objective response rate (ORR) according to RECIST-v1.1 criteria, progression-free survival (PFS), overall survival (OS), treatment discontinuation, cycles received, previous chemotherapy (CT) lines, and adverse effects (AEs) according to Common Terminology Criteria for Adverse Events-v5 (CTCAE).

Results Forty-six patients were included (100% female); median age 52 (Interquartile range (IQR)=45–61). Mean BMI 26 (standard deviation (SD) =4.4). 100% HR-negative and 100% HER2-negative. 32.6% received primary prophylaxis with G-CSF. Lung metastases were the most frequent (56.5%), followed by bone (43.5%), hepatic (25.5%) and ganglionic (21.3%). 56.5% BRCA-negative, 6.5% BRCA2 and 34.8% not available. Most of the patients had a baseline ECOG 0–1 (72%). Median duration of treatment was 3.1 months (IQR=1.5–7.0). To date, two patients were still on treatment. Median follow-up: 10.3 months (IQR=3.5–15.5). ORR 32.6% (30.4% RP and 2.2% RC), stable disease in 21.7% and progression in the rest. Median PFS was 3.8 months (IC 95%: 2.5–5.1) and OS 10.1 months (IC 95%: 5.9–14.3). 81.8% of patients discontinued treatment due to disease progression and 15.9% exitus. Median total of cycles received was five (IQR=2.5–8.0) and a median of two (IQR=1–3) previous CT-lines in metastatic-stage.

97.8% of the patients had some AE during treatment. Most frequents: asthenia (80% (G3–4:6.7%)), anaemia (66.7% (G3–4:8.9%)), neutropenia (51% (G3–4:17.7%)), diarrhoea (46.7% (G3–4:6.7%)), alopecia (42.2% (G3–4:4.4%)). 69.6% had any reduction or delay of dose because of toxicity and no patient discontinued treatment due to AEs.

Conclusion and Relevance Median PFS and OS were lower than in the pivotal ASCENT trial. While most patients experienced AEs, none led to treatment discontinuation. Further studies with a larger sample size are needed to confirm these results.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-023 LITMUS TEST METHOD FOR CLOSED SYSTEM TRANSFER DEVICE DRY DISCONNECTION VALIDATION

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Background and Importance Membrane-based closed system transfer devices (CSTDs) aim to prevent liquid release of hazardous drugs (HDs) upon connection and disconnection of adapters using self-sealing membranes. Different methods have been used to validate this dry disconnection, including visual evaluation and GC/MS detection following liquid evaporation. Litmus testing with alkaline drug 5-fluorouracil has been used to validate a vial and syringe adapter from one manufacturer.

Aim and Objectives The aim was to validate dry disconnection of vial, syringe, and bag adapters from an additional CSTD manufacturer using a litmus-based method, with a more challenging solution than 5-fluorouracil.

Material and Methods 5-Fluoruracil, a HD with pH 9.2, is expected to turn litmus red paper blue upon contact. However, the visual response is clearer at pH 11. Thus, a solution of sodium hydroxide at pH 11 was prepared as a worse-case representative of 5-fluorouracil. Five transfers (10 connections for the syringe adapter) of this solution were performed from vial, via syringe, to IV bag, using a membrane-based CSTD, according to its instructions for use. Following each disconnection, the device septa were sampled with a moist litmus red paper, and colour change was evaluated. This was repeated for 10 sets of adapters. Distilled water replaced the basic solution in a negative control. Positive controls were performed by applying drops of basic solution on the litmus paper or on the septa prior to sampling.

Results No blue colour change was observed on the litmus paper used for sampling test devices following disconnections, nor in the negative control. Blue colour change was observed in all positive controls.

Conclusion and Relevance No liquid release was detected on septa of the tested CSTD during five transfers using 10 sets of devices. The solution used is an even stronger base than the 5-fluorouracil used in other studies. Thus, the litmus paper is expected to be even more sensitive to releases of this

solution. The study verifies the dry disconnection of the device tested, strengthening the case for CSTDs as an important layer of protection against HD exposure. The method is inexpensive, requires no special equipment, and can readily be applied to additional CSTDs for comparison.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest Corporate sponsored research or other substantive relationships

The author is employed by Simplivia Healthcare, Ltd., a CSTD manufacturer.

5PSQ-024 ANALYSIS OF THE USE OF PERIOPERATIVE ANTIBIOTIC PROPHYLAXIS

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Background and Importance Surgical injury infections occur in incision/nearby-areas, during the first 30–90 days post-operation. The administration of appropriate antibiotics perioperatively can prevent these infections (effectiveness 18–81%). Surgical prophylaxis accounts 30–50% antibiotic use in surgical services, so updating-monitoring protocols is a priority measure to improve antibiotic use by PROA teams.

To analyse perioperative antibiotic prophylaxis prescriptions to determine if they adapt to current local-protocols.

Aim and Objectives To analyse perioperative antibiotic prophylaxis prescriptions to determine if they adapt to current local-protocols.

Material and Methods Prospective observational study (May to December´2023) in a second-level hospital.

Inclusion criteria: surgical interventions in inpatient surgery regimen.

Variables:

- Age-gender.
- Adverse drug reactions (ADR).
- Surgical area.
- Type of surgery.
- Intervention procedure.
- Antibiotic prophylaxis: compliance with local protocol and discrepancies found.

Exclusion criteria: outpatient surgery interventions.

Data were obtained from electronic medical record. Collected-analysed in Excel.

Results 200 patients were included, 130 patients were men, median age 60 years (IQR 49–71).

7 patients with ADRs: four were allergic to antibiotics (three penicillins, one quinolones). One patient was given an alternative antibiotic. The rest needed no further adjustment.

Major surgical areas: General Surgery Digestive System 110 interventions, Urology 48 and Otorhinolaryngology 20.

Minor areas: Traumatology 12 interventions, Ophthalmology six, Maxillofacial Surgery three and Vascular Surgery 1.

Type of surgery: 89 clean, 68 clean-contaminated, 27 clean-contaminated/potentially-contaminated, five others, four contaminated and three clean with implants. Four cases not stated in protocol.

Majority intervention procedures: 33 hernioplasties, 26 transurethral-resection prostate/bladder, 16 cholecystectomies, 14 colon-rectum-distal-ileum surgeries, 12 amidalectomies-adenidectomies-septoplasties, 11 appendectomies, 11 thyroidectomies-paraidectomies, 10 breast-surgeries and six vitrectomies.

Antibiotic prophylaxis used in 146 patients complied with local protocol, 50 did not comply and it could not be determined in four patients.

Main discrepancies: prescribing another antimicrobial agent than in the protocol in 15 cases, prescribing an antimicrobial agent in patients who did not meet risk factors for administration in 11, using an alternative protocol regimen in patients not allergic to drug of choice in nine, patients who met risk factors for administration and were not prescribed antibiotic prophylaxis in eight and inadequate duration in seven cases. The majority of discrepancies were found in clean-interventions.

Conclusion and Relevance Monitoring perioperative antibiotic prophylaxis guidelines is key to determine if whether the current local protocol is being followed. Also to consider if it needs to be re-evaluated and updated with PROA team.

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

5PSQ-025 A PAIR PHARMACY TECHNICIAN AND NURSE, KEY TO SUCCESS BEFORE CARRYING OUT A CLINICAL AUDIT ON THE CORRECT USE OF NASOGASTRIC TUBES AND ADMINISTERED DRUGS

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Background and Importance Interprofessional collaboration in healthcare is an essential element in promoting patient safety, as evaluation of professional practices. However, little research is available on the collaboration between nurses and pharmacy technicians (PT). Many misuses in using enteral nutrition tubes were noted in the units of the hospital. This innovative framework is to create a pair between nurse and PT to carry out a clinical audit on the correct use of nasogastric tubes and the pharmaceutical forms administered in accordance with the guidelines.

Aim and Objectives The aim of this work is to assess whether this pair can improve PT's skills and relevance of the audit form.

Material and Methods A training support for PT has been developed by a working group (WG) composed of a physician, a pharmacist, a quality manager and the pair. Then, the pair trained a group of six PTs, called trained group (TG), on the good practices including a theoretical part and an educational healthcare simulation, called room of errors. The pair produced an audit form including 33 criteria divided into eight themes. The PT's skills were assessed by the WG with a questionnaire. The results were assessed using a comparative analysis between the TG and a control group not trained by the pair, included eight PTs and called (CG). Finally, number of items modified by the nurse were assessed by the WG.

Results The comparative evaluation of skill's PT between TG and CG showed the following results: technical competence rate was about 74% versus 24%, ability to observe misuses was 85% versus 46%, barriers to optimal collaboration is mentioned by 92% versus 72% and opinion of pair's added value received an average rating of 100% versus 93%. As regards audit form's elaboration, the nurse modified five items out of 35 relating to the tube placement technique.

Conclusion and Relevance Training before carrying out a clinical audit audit is necessary. However, the synergy nurse/PT allowed to enhance PT's practical skills and overcome barriers to their implantation in care units. To optimise processes, an external training to carry out a clinical audit would be beneficial in order to develop clinical pharmacy.

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

5PSQ-026 COMPARISON OF PERIOPERATIVE CHEMOTHERAPY AND PREOPERATIVE CHEMORADIOTHERAPY IN GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA: ANALYSIS FROM THE AGAMENON-SEOM REGISTRY

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Background and Importance The optimal curative strategy for gastroesophageal junction adenocarcinoma (GEJA) is unknown.
Aim and Objectives This study compares perioperative chemotherapy (CT) with preoperative chemoradiotherapy (CRT) in GEJA treatment.

Abstract 5PSQ-026 Table 1

Treatment	Perioperative chemotherapy N=220 (100%)	Preoperative chemoradiotherapy N=65 (100%)
Siewert classification		
1	29 (13)	27 (41)
2	48 (22)	15 (23)
3	75 (34)	7 (11)
Unknown	68 (31)	16 (25)
Stage III	145 (66)	47 (73)
Surgery	202 (92)	55 (85)
Lymphadenectomy		
D1+	90 (41)	23 (36)
D2	70 (32)	17 (26)
Other	60 (27)	25 (38)
R0 resection	171 (78)	51 (79)
Complete pathological response	20 (9)	10 (16)
Completed treatment	106 (48)	50 (77)
Postoperative complications		
Severe	33 (15)	10 (15)
Lethal	9 (4)	3 (4)
Recurrence	68 (31)	23 (36)
Local	15 (7)	0
Distant	42 (19)	19 (29)
Local and distant	11 (5)	4 (7)

Material and Methods From the AGAMENON-SEOM registry, 1893 patients had localised gastroesophageal adenocarcinoma, and of those, the ones with GEJA who were treated with preoperative CRT or perioperative CT were included.
Results Among the 285 GEJA patients diagnosed between 2009 and 2023, 77% (n=220) received perioperative CT, and 23% (n=65) received preoperative CRT. The median age was 64 years (range 34–91), 20% (n=57) were women, and 95% (n=271) had an ECOG performance status of 0–1.

Patient characteristics and outcomes are summarised in table 1. Siewert III cancers were more common in the perioperative CT group (34%), while Siewert I cancers predominated in the CRT group (41%).

Surgery was performed in 92% of CT-treated and 85% of CRT-treated patients, with R0 resection rates of 78% and 79% and complete pathological responses of 9% and 16%, respectively. Four percent did not complete preoperative CRT, while 32% did not start postoperative CT.

Recurrence occurred in 31% of patients treated with perioperative CT and 36% with CRT. Recurrence patterns for perioperative CT were distant (19%), local (7%), and mixed (5%), while for CRT were distant (29%), local (0%), and mixed (7%). Distant recurrence was more frequent with CRT ($p<0.005$). Severe postoperative complications occurred in 15%, and lethal complications in 4%, with no differences between treatments.

Overall survival was 53 vs. 41 months (HR 0.77; 0.72–0.90; $p=0.043$) and disease-free survival was 34 vs. 29 months (HR 0.85; 0.83–1.15; $p=0.661$) for CT vs. CRT.
Conclusion and Relevance For GEJA T2–4 or N+ M0, perioperative CT was associated with fewer distant metastases and improved overall survival compared to neoadjuvant CRT.

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

5PSQ-027 ORAL TOLERANCE INDUCTION TO COTRIMOXAZOLE IN IMMUNOSUPPRESSED PATIENTS WITH A HISTORY OF A NON-SEVERE HYPERSENSITIVITY REACTION

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Background and Importance Cotrimoxazole (CTX) is the first-line therapy used to prevent and treat *Pneumocystis jirovecii* pneumonia (PJP). In the case of a previous non-severe hypersensitivity reaction to CTX, oral tolerance induction may be used instead of alternative therapies – pentamidine, dapsone or atovaquone.
Aim and Objectives The aim of this study was to establish a management protocol for oral induction of tolerance to CTX in patients with a history of non-severe hypersensitivity reactions.
Material and Methods Information on CTX hypersensitivity reactions and their management was gathered from published

literature, databases, and consultations with an allergist. Protocols for tolerance induction were proposed, and a list of pharmaceutical excipients in available CTX-containing medications, which may contribute to drug reactions, was compiled. Data on patients undergoing oral CTX tolerance induction were collected from the hospital information system in two institutions.

Results Due to limited relevant publications – mainly addressing CTX hypersensitivity management in HIV/AIDS patients – and lacking a standardised protocol, we adapted single-day and multi-day protocols from existing studies. The single-day protocol suits patients with non-severe skin reactions, while the multi-day protocol is used for more severe reactions and can also be applied in outpatient settings for non-severe cases. Protocol choice must be strictly individualised based on patient condition and reaction severity. Severe reactions require basophil activation and skin tests, followed by an oral provocation test with a full therapeutic CTX dose under observation and preparedness to manage anaphylaxis. We compiled a list of CTX product excipients, noting that generic substitution often improved tolerance. Pharmacists proposed alternative preparations during oral suspension shortages for optimal desensitisation dosing. To prevent loss of tolerance during PJP prophylaxis, especially if CTX administration is interrupted for over three days, we recommend administering CTX three times a week, every other day, or daily. Oral induction is contraindicated in severe delayed-type hypersensitivity reactions, Stevens-Johnson syndrome, or acute generalised exanthematous pustulosis. Since implementing local protocol, nine immunocompromised patients were successfully delabeled from CTX allergy using oral desensitisation or generic substitution.

Conclusion and Relevance The prevalence of hypersensitivity reactions to CTX in the population is lower than reported in patient's medical history. Multidisciplinary collaboration is essential for rational treatment and effective prophylaxis of PJP infections.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-028 THE HOSPITAL PHARMACIST FACING THE NATIONAL AZTREONAM SHORTAGE

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Background and Importance Aztreonam is a beta-lactam antibiotic used for urinary, respiratory and systemic infections caused by gram-negative bacteria (GNB) with no other alternatives and/or in patients allergic to penicillins.

Aim and Objectives To analyse aztreonam prescriptions, identifying therapeutic alternatives to optimise its use during the national shortage.

Material and Methods Observational and retrospective study (April 2024 to August 2024). All prescriptions with aztreonam were analysed. The following variables were collected: age, sex, medical service, indications, empirical/directed treatment (isolated microorganism), duration, pharmaceutical intervention. Data were analysed with Excel.

Results Aztreonam was prescribed in 49 patients with a median age of 68 (23–91) years; 24 males (48.9%). Thirty-nine percent of the prescriptions were in Internal Medicine, followed by General Surgery (14%). The most frequent indications were urinary tract infection (22%), skin and soft-tissue infections (18%), respiratory infections (16%), intra-abdominal infections (16%), and sepsis (16%). The mean duration of treatment was 11 (2–21) days.

The 10% were treatments directed against metallo-betalactamase-producing BGC, identifying NDM carbapenemase-producing *Enterobacter cloacae* (N=6), IMP carbapenemase-producing *Pseudomonas aeruginosa* (N=4), BLEE-producing *Klebsiella pneumoniae* (N=3), NDM carbapenemase-producing *Escherichia coli* (N=1), another unidentified gram-negative (N=1).

Fourteen prescriptions were authorised: 10 for multidrug-resistant GNB and four for confirmed allergy. In 35 cases, alternatives were identified, 15 after ruling out false allergy, and in the other 20, the pharmacist proposed therapeutic alternatives, which were accepted.

Conclusion and Relevance The review of aztreonam prescription by the pharmacist optimised the use of aztreonam, reducing authorisations to 28%, making it possible to identify false allergies (78% of patients labelled as allergic to penicillins) and prioritising its use in situations without alternatives. 100% of the pharmaceutical interventions carried out were accepted by the prescribing physician.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-029 EVALUATION OF THE EFFICACY OF INCLISIRAN FOR THE TREATMENT OF PRIMARY HYPERCHOLESTEROLAEMIA MIXED DYSLIPIDAEMIA: ANALYSIS OF AIFA MONITORING REGISTERS

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Background and Importance Hypercholesterolaemia is a significant challenge in the management of cardiovascular disease, with considerable implications for public health and the National Health System. Inclisiran, a synthetic oligonucleotide complementary to the mRNA encoding the PCSK9 protein, has the potential to reduce intra-individual variability in LDL-C levels over time. With its twice-yearly administration, it can offer an optimal solution to ensure adherence to therapy, ultimately lowering the risk of cardiovascular events in high-risk patients.

Aim and Objectives This analysis aims to assess the efficacy of inclisiran in patients suffering from primary heterozygous familial hypercholesterolaemia (HeHF), non-familial hypercholesterolaemia (noHF) or mixed dyslipidaemia (MD).

Material and Methods AIFA Monitoring Registers of patients treated with inclisiran were analysed. The considered period was January 2023 to September 2024.

The indicators of effectiveness were levels of LDL-C and HDL-C after 15 months (i.e. three administrations of inclisiran), compared to the pre-treatment values.

Results After evaluating 168 AIFA Monitoring Registers, 35 patients (74% male, 26% female) with available follow-up

data at 15 months were included. The mean age of the cohort was 66 years (range: 45–81), with 16 patients suffering from MD, 17 from no HF, and two from HeHF.

The efficacy of Inclisiran is promising, with significant reductions in LDL-C levels: 24% at 3 months, 30% at 9 months, and 46% at 15 months. Average LDL-C reductions were 42.7 mg/dL after the first two administrations and 64.8 mg/dL after the third. Furthermore, HDL-C levels increased, rising from 7% to 19% after three administrations of inclisiran. No cardiovascular events were reported and adherence to the treatment was high.

Conclusion and Relevance In the considered sample of patients treated with inclisiran, a consistent reduction in LDL-C levels over time has been proven, with peak efficacy (−46%) observed after three doses, alongside a steady increase in HDL-C levels, thus contributing to prevent cardiovascular risks. The 6 month dosing schedule was a strong point that increased therapeutic adherence.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-030 EFFECTIVENESS AND SAFETY OF SEMAGLUTIDE IN PATIENTS WITH TYPE 2 DIABETES: REAL-WORLD USAGE DATA

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Background and Importance Semaglutide, a GLP1-analogue (aGLP1), is funded in our country for treating type 2 diabetes (DM2) in obese patients (BMI $\geq$30 kg/m^2) with inadequate glycaemic control, in combination with oral antidiabetics (ADO) and/or insulin. Both oral and subcutaneous forms have shown efficacy and safety.

Aim and Objectives To evaluate the prescription profile, effectiveness, and safety of semaglutide in DM2 patients treated for over 1 year without prior aGLP1 therapy.

Material and Methods A single-centre retrospective study conducted in June 2023 at a second-level hospital, including patients treated with semaglutide for over 1 year. Variables recorded: demographics (sex, age), anthropometrics (weight, height), clinical factors (cardiovascular disease (CVD), chronic kidney disease (CKD)), analytical measures (glucose, HbA1c, total cholesterol (TC), LDL, triglycerides (TG)), and pharmacotherapeutic variables (prior ADO/insulin, concomitant statins). Safety was assessed by gastrointestinal (GI) symptoms and cardiovascular events (stroke, myocardial infarction).

Funding criteria reviewed: 1) DM2 diagnosis, 2) BMI $\geq$30 kg/m^2, 3) prior ADO/insulin, 4) poor glycaemic control. Prescriptions were optimal if all criteria were met. Quantitative variables are presented as mean ± SD, and qualitative as frequency and percentage.

Results The study included 41 DM2 patients (60 ± 11 years; 61% male) treated for 696 ± 309 days. 27% had CVD, 10% CKD $\geq$ G3, and 76% had HbA1c $\geq$6.5%. 88% had prior ADO/insulin treatment, 93% concomitant, and 66% took statins. Baseline and final weight (kg) and BMI (kg/m^2): 103 ± 22; 36 ± 9 and 93 ± 20; 33 ± 7, respectively.

Baseline and 1-year follow-up values for glucose (mg/dl), HbA1c (%), TC (mg/dl), LDL (mg/dl), and TG (mg/dl) were: 153 ± 62; 8 ± 2; 182 ± 44; 98 ± 32; 243 ± 275 and 115 ± 39; 6 ± 1; 154 ± 41; 84 ± 32; 163 ± 111, respectively.

HbA1c decreased by 2%, with a 10 kg weight loss and lipid profile improvement. GI symptoms occurred in 12% of patients, with no CVD events reported. Optimal prescription was seen in 73%.

Conclusion and Relevance Semaglutide's effectiveness and safety in routine practice align with clinical trial results. Limitations include small sample size and non-adherence to funding criteria, prompting a hospital compliance circuit.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-031 CONCORDANCE BETWEEN GLOMERULAR FILTRATION RATE EQUATIONS IN PATIENTS WITH CHRONIC KIDNEY DISEASE TREATED WITH HEPARIN AND THEIR RELATIONSHIP WITH BLEEDING RISK

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Background and Importance The estimation of glomerular filtration rate (GFR) is used to monitor renal function (RF) in patients with chronic kidney disease (CKD). It is also used in clinical practice to adjust the dosage of certain drugs, like as low molecular weight heparins (LMWH), due to the high-risk of bleeding, especially in patients with CKD.

Aim and Objectives To compare the CKD-EPI, MDRD-4 and MDRD-IDMS equations for estimating GFR.

To assess the relationship between GFR and bleeding risk in patients treated with LMWH.

Material and Methods A prospective observational study carried out in a second-level hospital from May 2024 to October 2024, involving 51 patients hospitalised with CKD, categorised into three groups based on creatinine levels: mild CKD (<1.5g/dL), moderate CKD (1.6g/dL-2.5g/dL) and severe CKD (>2.5g/dL). Patients with acute, pre-renal or exacerbated renal disease were excluded.

We reviewed electronic medical records in Mambrino XXI, compiling the data in Excel and performing statistical analysis using the SPSS. Specifically, we applied Student's t-test, Chi-squared and frequency analysis tests to assess the statistical significance of the collected data.

Results After a comparison of the GFR rate with the three calculators, it was observed that patients with mild CKD had greater variability in GFR between calculators compared to those with severe CKD. Furthermore, it could be corroborated that the values obtained with CKD-EPI were always lower than those obtained with MDRD-IDMS (average difference of 2.79 mL/min, 2.14 mL/min and 1.30 mL/min in mild, moderate and severe CKD, respectively), and these, in turn, lower than MDRD-4 (average difference of 4.83mL/min, 3.86 mL/min, 2.31 mL/min in mild, moderate and severe CKD, respectively), with two-factor statistical significance ($p<0.001$).

Bleeding rates were nil in patients with mild CKD, while those with severe CKD were slightly higher (35.71%) compared to moderate CKD (24%), with no statistical significance between the two groups ($p=0.664$). In conclusion, 50% of patients in the moderate group did not require dosage

adjustment for renal function with MDRD-4 and MDRD-IDMS calculators but did with CKD-EPI.
Conclusion and Relevance Our study confirms the variability between calculators, and an overestimation of GFR can be seen when using MDRD-4 and MDRD-IDMS.

As in other studies the safest calculator in CKD is CKD-EPI as it requires earlier dosage adjustment and thus avoids possible bleeding.

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

5PSQ-032 EFFECTIVENESS AND SAFETY IN THE USE OF SOFOSBUBIR/VELPATASVIR IN THE TREATMENT OF CHRONIC HEPATITIS C VIRUS INFECTION

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Background and Importance Hepatitis C virus (HCV) causes chronic infection in 55–85% of patients, increases the risk of liver cirrhosis to 15–30% in 20 years and is the main cause of hepatocellular carcinoma (70–80%) in Spain.
Aim and Objectives To evaluate the effectiveness, safety and drug interaction profile of sofosbuvir/velpatasvir in patients with chronic HCV.
Material and Methods This is an observational, retrospective study that included all HCV patients treated with sofosbuvir/velpatasvir from Januarya 2019 to July 2023 in a tertiary hospital. Variables: sex, age at baseline, viral load (VL) at baseline (VL0), HCV genotype, degree of fibrosis, co-infection with Human Immunodeficiency Virus (HIV), previous treatments, combination with ribavirin and potential drug interactions with concomitant treatment, VL at the end of treatment (VLend) and at 12 and 24 weeks after completion (VL12 and VL24), sustained viral response (SVR) was defined as undetectable VL12/VL24 (SVR12/SVR24) and adverse reactions (ARs) reported by patients.
Results We included 80 patients, 70.0% (N=56) men, with a median age of 53.8 years (IQR: 49,0–58.8). 10.0% (N=8) of patients have received interferon or interferon+ribavirin. 8.8% (N=7) had HIV co-infection. The degree of fibrosis recorded was F0: 18.8% (N=15), F1: 15.0% (N=12), F2: 7.5% (N=6), F3: 18.8% (N=15), F4: 40.0% (N=32). The most frequent genotype was type 1; 36.3% (N=29) 1A and 26.3% (N=21)1B; 2, 3, 4 and other genotypes the prevalence was 1.3% (N=1), 18.8% (N=15), 11.3% (N=9) and 6.3% (N=5), respectively. The association with ribavirin was used in 7.5% of patients (N=6). The median VL0 was 668482,5 (IQR: 6942, 0–2422213,5) IU/mL. 36,3% (N=29) of patients were identified with potential drug interactions: 58,6% (N=17) proton pump inhibitors, 13,8% (N=4) metamizole, 13,8% (N=4) statins, 10,3% (N=3) carvedilol, 6,9% (N=2) digoxin and 3,4 % (N=1) tenofovir and ranitidine. 37,5% (N=30) of patients reported AR, the most frequent were fatigue 46,7% (N=14), gastrointestinal disturbances 46,7% (N=14) and headache 33,3% (N=10). SVR12 was achieved in 96,7% of patients (N=58). Two patients did not achieve SVR12, one patient due to vomiting that compromised the treatment and another patient with genotype 4 and previous failure to interferon+ribavirin. All patients with SVR12 maintain SVR24.
Conclusion and Relevance Sofosvubir/velpatasvir is an effective and safe therapy for the treatment of HCV infection. The potential drug-drug interactions of DAAs highlight the importance of pharmaceutical care in this group of patients.

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

5PSQ-033 OFF-LABEL USE OF INTERFERON ALPHA 2B EYE DROPS IN CORNEAL INTRAEPITHELIAL NEOPLASIA: A CASE REPORT

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Background and Importance Corneal Intraepithelial Neoplasia (CIN) is the most frequent tumour of the ocular surface. Treatment options include excisional biopsy and topical adjuvant eye drops such as mitomycin (MMC), 5-fluorouracil (5FU) and interferon alpha-2B. The use of interferon alpha-2B eye drops confers advantages compared to 5FU and MMC, mainly the absence of serious adverse effects. The usual dosage regimen for interferon alpha-2B eye drops is 1 drop 2–3 times per day.
Aim and Objectives To describe interferon alpha-2B eye drops preparation as a magistral formula as well as to evaluate the effectiveness and safety of this treatment in a patient with CIN.
Material and Methods We ran a descriptive study of a 39-year-old man diagnosed with CIN in the left eye. In February 2024, surgical intervention was ruled out due to high-risk of general anaesthesia for the patient because of his medical history: perinatal encephalopathy, obstructive hydrocephalus and West Syndrome. For this reason, physicians decided to start off-label treatment with 1MUI/mL interferon alpha-2B eye drops.
Results The elaboration was carried out taking 1mL (5 MUI) from the reconstituted vial of interferon alpha-2B and filling it out with sterile water for injections to get a final volume of 5 mL, resulting in a 1 MUI/mL concentration. The mixture was prepared in a horizontal laminar flow hood. It was filtered through a 0.22µm filter and placed in a sterile eye drop bottle. The preparation was kept in cold storage (2–8°C) and an expiration date of 7 days was assigned once opened.

A total of 28 interferon alpha-2B eye drops were dispensed from March to September 2024. The patient presented good tolerance (no adverse effects) but no reduction of lesions and symptoms after 3 months of starting treatment. For this reason, surgery was considered. However, in July 2024 improvements in lesions were observed so it was decided to continue with treatment. In October 2024, no change was observed and the surgery was reconsidered.
Conclusion and Relevance The formulation was simple and did not require much preparation time. Our experience shows that interferon alpha-2B eye drops appear to have moderate efficacy in patients with CIN with a safe adverse effect profile, although further studies are required.

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

5PSQ-034 EVALUATION OF ANTIBIOTICS CONSUMPTION IN THE INTENSIVE CARE UNIT OF A SECOND-LEVEL HOSPITAL

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Background and Importance Intensive care units (ICU) are favourable setting for the development of intra-hospital infections due to antibiotic-resistant bacteria. Therefore, it is necessary to ensure adequate antibiotic treatment by knowing the resistance profile of the microorganisms.

Aim and Objectives The aim of this study was to analyse the evolution of antibiotic consumption (AC) and microorganisms isolated (MI) in the ICU over the last 3 years.

Material and Methods This observational and retrospective study was carried out in the ICU of a second-level hospital between 2020 and 2023. To express the AC was used the defined daily dose per 100 stays and day (DDD/100 e-d).

AC data were obtained through the electronic prescription program and the MI were provided by the Microbiology Department.

For the statistical analysis, STATA-MP-16.0 was used: a correlation matrix was made by evaluating each pair of antibiotics and the Pearson correlation coefficient (CoefP) was calculated applying a multiple linear regression model.

Results Sixteen active substances (J01 group) were included. The distribution of AC per year in this unit expressed in DDD/100 e-d was 152.97 (2020), 152.11 (2021), 139.85 (2022) and 157.88 (2023). There was a decrease in consumption in 2022 compared to previous years. However, in 2023 there was a rise associated with an increase in intravenous levofloxacin, linezolid, meropenem, tigecycline and vancomycin. Consumption of meropenem was high in all years while piperacillin/tazobactam remained low.

Results from the statistical study showed a positive correlation between the increased consumption of intravenous amoxicillin/clavulanic acid, tigecycline and linezolid (CoefP: 0.948, p_value: 0.0126). When linear regression was applied, the relationship between three drugs was statistically significant (R2=98.76, p_value: 0.0434).

The MI in this unit between 2020 and 2023 were: 28% extended-spectrum beta-lactamase-producing E. coli (BLEE+), 26% methicillin-resistant Staphylococcus aureus (MRSA), 13% K. pneumoniae BLEE+, 12% P. aeruginosa and other microorganisms.

Conclusion and Relevance Analysis using DDD/100 e-d allows comparisons between the years of the study.

These results of AC are matched with the MI.

Knowing these consumption trends, measures can be taken in the following years to promote rational and safe use of antibiotics.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-035 USING FAILURE MODE AND EFFECTS ANALYSIS TO IMPROVE PRODUCTION OF NON-STERILE PREPARATIONS

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Background and Importance The production of non-sterile preparations (NSP) is a critical task that requires high levels of accuracy and safety. A risk management tool is essential to ensure quality and minimise the risks associated with this process. Publications on this topic in the scientific literature are limited.

Aim and Objectives To identify potential risks in the NSP production process using a Failure Mode and Effects Analysis (FMEA) and to measure whether these risks decrease with the implementation of improvement actions.

Material and Methods A team of the personnel involved in the NSP development process, a pharmacist from the quality area and the Head of Pharmacy Department perfomed the analysis using the FMEA methodology. In 2021 all possible failure modes were identified by brainstorming. After analysis and implementation of corrective and preventive measures, in 2024 the FMEA model was re-evaluated and potential risks were reassessed. The risk priority number (RPN) was calculated according to Severity x Frequency x Detectability, assigning values from 1 to 10 to each index. The variation in risks following the improvement actions implemented was quantified.

Results The process was divided into 11 different phases. A total of 26 failure modes were defined, accumulating 1,929 RPN points in 2021 (range: 8–240). RPN scores > 100 were obtained for seven of the failure modes, which were considered critical. There was only one failure mode with RPN > 200 (inadequate raw material selection). The phase with the most failure modes with RPN > 100 was the elaboration of the preparation, four in total. After prioritisation, an improvement plan was proposed, in which the following actions were highlighted: implementation of specific software (CPFarma), establishing double checking by a qualified pharmacist and a plan for the training of new residents in the Pharmacy Department. After reevaluation of the FMEA in 2024, the 26 failure modes accumulated 594 RPN points (range: 6–180). There was only one failure mode with RPN > 100 (incorrect measurement of raw materials).

Conclusion and Relevance The FMEA methodology is a useful instrument in the detection of potential risks in the production of NSP and in the implementation of improvement actions that have an impact on process quality and patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-036 CLINICAL PHARMACIST INTERVENTIONS IN ANTIMICROBIAL THERAPY STEWARDSHIP: PREVENTION OF MEDICATION ERRORS ENHANCED BY ACCESS TO THE PATIENT'S ELECTRONIC HEALTH RECORD

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Background and Importance The control of pharmacotherapy aims to prevent medication errors and adverse events related to the use of drugs that are common in hospitalised patients and can cause prolonged hospitalisation, higher treatment costs and possible death. Clinical pharmacist has to ensure the correct and rational use of antimicrobial drugs by monitoring the prescription. Access to the patient's electronic health record (EHR) allows the pharmacist to make better clinical decisions, which contributes to greater patient safety, reduction of medication errors and side effects.

Aim and Objectives The aim of the study was to analyse the prevention of medication errors by interventions of clinical pharmacists in hospitalised patients on antimicrobial therapy. Pharmaceutical interventions were evaluated before and after the possibility of accessing the EHR.

Material and Methods An observational-retrospective study was conducted between April 2023 and March 2024. Two clinical pharmacists performed interventions during their daily practice in a hospital pharmacy related to the processing of requests for the dispensing of reserve antimicrobial therapy. Data on the monthly number of interventions, the frequency of interventions for each antibiotic and the type of medication error (dose, dosing interval, excluded drug, dose and interval, other) were documented.

Results A total of 8559 requests for antimicrobial therapy were processed in the study. Pharmacists conducted total of 73 interventions, 11 in the period April-July 2023. (without access to the EHR), 55 in the period August-December 2023. and seven in the period January-March 2024. (with access to the EHR). The most frequent interventions were on inadequate dosing interval (n=42, 57.53%), and unadjusted dosing (n=13, 17.8%). In five patients, the antibiotic was excluded from the therapy. The largest number of interventions in terms of dose and interval was for ceftiaxone (n=21, 30.0%). Of the total number of interventions, 93.15% were accepted.

Conclusion and Relevance Without access to the EHR makes it very difficult for pharmacists to detect medical errors. Medication errors and prescribing problems are common without patients EHR. Access to the EHR improves results through the interventions of clinical pharmacists, contributes to the reduction of medication errors and facilitates the management of antimicrobial drugs with the aim of optimising therapy and reducing healthcare costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-037 EVALUATION OF THE COMPLETENESS OF PATIENTS' MEDICATION REPORTS AND DISCHARGE SUMMARIES AT DISCHARGE FROM TWO WARDS USING COMPLETE MEDICATION DOCUMENTATION AT DISCHARGE MEASURE (CMDD-M)

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Background and Importance In Sweden, hospital discharge documentation must include a discharge letter directed to the patient containing a medication report, detailing changes made during the hospital stay. Incomplete documentation of medication changes has been correlated to medication errors leading to hospital readmissions. Given this correlation, it is important to assess the quality and completeness of medication documentation within the Swedish healthcare system.

Aim and Objectives This study aimed to evaluate the quality and completeness of discharge documentation using the checklist CMDD-M as part of ongoing quality improvement initiatives at geriatric- and internal medicine wards.

Material and Methods A retrospective cross-sectional study was conducted reviewing electronic medical records from two wards. Patients included were those admitted in October 2021, aged 50 or older, with at least one lasting medication change during their hospital stay. CMDD-M was used to assess the completeness of discharge documentation. To achieve a maximum score of 7 points all medication changes must be mentioned including reasoning and follow-up plan.

Results A total of 80 patient journals were reviewed using CMDD-M where 19 (23.8%) patient journals scored 7 points, and the average was 4.6. For eight (10%) patients the medication report was missing completely. The most frequently missed criterion was the omission of one or more relevant medication changes, 48 (60%), followed by reason for change not noted, 22 (27.5%). There was a non-statistical correlation between number of medication changes and the completeness of documentation.

Conclusion and Relevance In summary, the majority of the reviewed discharge documentation received a low score, and therefore did not meet the Swedish legal requirement. Similar findings have been reported in studies abroad. The findings in this study highlights a need for quality improvements in discharge documentation. CMDD-M may function as a comprehensive, quick, and easy-to-use tool for caregivers. Additionally, it could be used as an outcome measure in research studies aiming to enhance discharge procedures.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-038 COMPLIANCE AND APPLICABILITY OF PRO RE NATA PRESCRIBING IN A FRENCH UNIVERSITY HOSPITAL

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Background and Importance As needed medication, or pro re nata (PRN), provides symptomatic treatment for patients. This practice is regulated by the French public health code and the recommendations of the French national health authority.
Aim and Objectives The aim of this study was to assess the compliance of PRN prescriptions in a French University Hospital.
Material and Methods A retrospective study was carried out between February and June 2024 on PRN prescriptions for patients hospitalised in departments using Computerised provider order entry (CPOE). Patients were included if they had at least one PRN prescription. Compliance with statutory criteria and applicability of prescriptions were assessed.
Results Of 1196 eligible patients in 63 departments, 998 had at least one PRN prescription, with an average of 4 PRN prescriptions per patient and a maximum of 23. The most common prescribing criteria were drug name and route of administration, whereas duration of prescription was rarely mentioned. Laxatives, analgesics and psycholeptics were the most common therapeutic classes. Paracetamol, which is commonly prescribed, often had imprecise conditions of use, with an applicability of 14%. Significant differences in applicability were observed between short-stay and long-stay units and between therapeutic classes.
Conclusion and Relevance This study highlights the need to strengthen protocols and their implementation in CPOE. Nursing staff training and awareness of PRN prescribing is essential. Pharmaceutical analysis of prescriptions and interprofessional re-evaluation should help to improve the quality and safety of PRN prescriptions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-039 PROFILE OF INTRAVENOUS IMMUNE GLOBULIN UTILISATION IN A PORTUGUESE POLYVALENT HOSPITAL

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Background and Importance Intravenous immune globulin (IVIG) is used as replacement and immunomodulation therapy in a variety of autoimmune and inflammatory disorders. The increase in IVIG prescription is a global problem, as it is a scarce, risky, and high cost drug, and its use after the Covid pandemic has worsened this scenario. The frequent supply disruptions reinforce the need for well-founded use of this drug.
Aim and Objectives To describe the utilisation of IVIG to implement a strategic plan for its rational use.
Material and Methods Observational, retrospective study carried out during a 2 year period (2022 and 2023) in a polyvalent hospital. Patients with IVIG prescribed were included. Variables analysed were demographics, indication (replacement *versus* immunomodulation therapy) and dosage of IVIG. Immunomodulation therapy indications were further divided into neuroimmunologic disorders, autoimmune/inflammatory conditions, infections and infection-related disorders, and alloimmune processes. Electronic medical records were consulted to collect this information. Statistical analysis was done in Excel .
Results 81 patients were included (41 female, 50.6%), 65 adults (80%) and 16 children. The average age of adult patients was 60 years (23–91 years). The total amount of IVIG consumed was 12655 grams (5680 grams in 2022, 6975 grams in 2023). Regarding the indication, 71 patients received IVIG for immunomodulation therapy. In this subgroup of patients, the main indications were neuroimmunologic disorders (33) and autoimmune/inflammatory conditions (32). 10 patients were prescribed IVIG as replacement therapy (seven of which SARS-CoV-2 related). Among patients receiving IVIG for neuroimmunologic disorders, 26 (79%) were diagnosed with Guillain-Barré Syndrome. In the subgroup of patients with autoimmune/inflammatory conditions, the three major indications were Immune thrombocytopenia (44%), Myasthenia gravis (22%) and Autoimmune encephalitis (16%). Considering the indications approved for IVIG, 26 (32%) patients were prescribed IVIG for off-label indications.
Conclusion and Relevance Our results show that major indications for IVIG prescription were neuroimmunologic disorders and autoimmune/inflammatory conditions, particularly Guillain-Barré Syndrome and Immune thrombocytopenia, respectively. Considering that one third of prescriptions were for off-label indications, and the increasing concern about shortages, a future development should focus on the elaboration of protocols for optimising IVIG utilisation, particularly in off-label indications, and an emergency plan in case of eventual future prolonged disruptions of supply of this high impact drug.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-040 DIMETHYL FUMARATE SAFETY IN THE TREATMENT OF RELAPSING-REMITTING MULTIPLE SCLEROSIS

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Background and Importance Dimethyl fumarate (DMF) is a drug with anti-inflammatory and immunomodulatory properties used as a first-line treatment for Relapsing-Remitting Multiple Sclerosis (RRMS). Due to its poor tolerability and high number of adverse reactions (ARs), it is important to monitor it more closely, especially in the first months of treatment.
Aim and Objectives To analyse the safety of DMF in the treatment of RRMS.
Material and Methods Retrospective observational study of patients with RRMS starting DMF between 2022 and 2023. All included patients had to have a treatment time (PBR2) of greater than or equal to 6 months.

Demographic data (gender and age) and previous treatments were collected. The safety of DMF was measured by analysis of treatment duration, treatment interruptions due to the presence of ARs and the causative Ars.

Results Ninety-two patients were analysed (77.2% women) with a median age of 41 years (range 17–66). Of the studied patients, 54 were treatment-naive, 34 had received previous treatment (19 glatiramer acetate, 12 interferon beta, three teriflunomide), and four patients restarted DMF.

22.8% of patients discontinued treatment at 6 months due to ARs, with a mean treatment time of 5.1 months. Of these, six patients discontinued treatment in the first few days after starting three at one and a half months, 10 at 3 months, and four at 6 months.

The ARs included: digestive disorders (42.9%), lymphopenia (38.1%), elevated liver enzymes (14.3%), hypereosinophilia (9.5%), itching and shortness of breath (9.5%), and vasovagal reaction (4.8%).

Of the patients who discontinued DMF due to ARs, 47.8% had been previously treated with another drug. Only one patient, who had previously been treated with teriflunomide, discontinued the DMF treatment at the beginning due to persistent lymphopenia.

Conclusion and Relevance ARs related to DMF are a significant cause of treatment interruption in the early months, mainly due to digestive disorders and lymphopenia. As is common in clinical practice, initial monitoring of patients after starting treatment is necessary for early detection of ARs and should be a priority for patients who have been previously treated, which could be considered a risk factor for the development of ARs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-041 PRIORITISATION OF PHARMACEUTICAL INTERVENTIONS WITHIN THE MULTIDISCIPLINARY TEAM IN THE INTENSIVE CARE UNIT

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Background and Importance The safety and efficacy of drug treatments are critical for reducing patient morbidity and mortality in the intensive care unit (ICU). The inclusion of a pharmacist may enhance patient safety in this setting.

Aim and Objectives This study aims to evaluate to the efficacy of the Medication Regimen Complexity-ICU (MRC-ICU) tool in prioritising pharmaceutical interventions based on drug related problems (DRPs). The goal is to enhance the allocation of pharmaceutical care within the multidisciplinary ICU team.

Material and Methods A retrospective, observational study was conducted at a 350-bed hospital with 21 ICU beds, including patients admitted between October and December 2023.The clinical pharmacist interventions were recorded, focusing on identifying and categorising DRPs using the Pharmaceutical Care Network Europe (PCNE) criteria. The MRC-ICU scale was utilised to assess medication regimen complexity and rank patients according to their need for pharmaceutical care. Demographic and clinical variables were also collected.

Results Out of 280 ICU admissions, 152 pharmaceutical interventions were performed for 59 patients, with 17 patients requiring multiple interventions. Of these, 82% were preventive in nature, while 17% addressed existing DRPs. The most frequently identified drug-related problems were adverse drug reactions (35%), primarily involving ATC groups B (16.6%) and J (11.3%). The majority of interventions (77.4%) targeted prescribers, with an acceptance rate of 73%. Enoxaparin was the most frequently adjusted medication (16.5%), primarily due to dose adjustments. Patients with an MRC-ICU score between 0 and 2 accounted for 53.2% interventions, while only 9.6% had scores exceeding 10.

Conclusion and Relevance The MRC-ICU tool was found to have limited applicability for prioritising pharmaceutical interventions in this ICU context. Nevertheless, the findings highlight the importance of structured evaluation of pharmaceutical interventions to improve patient safety and treatment efficacy. Future research should explore alternative tools better tailored to ICU-specific needs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-042 CLINICAL INTERVENTIONS IN THE CARDIOLOGY SERVICE PERFORMED BY A HOSPITAL PHARMACY RESIDENT

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Background and Importance Pharmaceutical validation of inpatient treatments in the cardiology department is a fundamental activity in clinical practice of the hospital pharmacist. Thanks to it, many prescription errors are detected, promoting patient safety. In addition, the training of pharmacy residents in the cardiology service contributes to the development of clinical pharmacy.

Aim and Objectives To describe the interventions performed by a hospital pharmacy resident in the cardiology service, supervised by consultant pharmacists, to promoting patient safety and to evaluate their acceptance degree.

Material and Methods Prospective interventional study conducted during May 2024. Adult inpatients and Outpatient, whose hospital treatment was reviewed, were included. Demographic (sex and age), clinical (clinical judgement (CJ) and cardiology area) and pharmacotherapeutic (high-risk medication prescribed, according to Institute for the Safe Use of Medicines (1,2)) variables were collected.

Interventions were reported to the clinician, nurse or patient in person, by phone, or via electronic prescribing software.

They were classified as: Activity (Information/discharge dispensing), Adequacy (detection of prescribing error/therapy reconciliation error), Change (Contraindication/lack of efficacy/substitution), Initiation (usual treatment not prescribed/need for additional treatment), Modification Dosage Form (DF) or Posology, Suspension (duplicity/unnecessary medication).

The data were collected through medical records and electronic prescribing software and processed using Excel 2020.

Results Interventions were performed in 40 patients. 65% male; median age 68±16,6 years. The most frequent CJ were: acute coronary syndrome (n=10, 25%), heart failure (n=10, 25%), arrhythmia (n=8, 20%). Areas with most interventions: hospitalisation plant (n=22, 55%), coronary unit (n=11, 27,5%), outpatient consultations (n=3, 7,5%).

77,5% of patients had prescribed high-risk medicines and the most prescribed medicines were (N=41): oral anticoagulants (n=17, 40,5%), Insulin(n=8, 19,0%), parenteral anticoagulants (n=3, 7,1%), parenteral benzodiazepines (n=3, 7,1%).

55 interventions were performed (26% were 'not evaluable'). Of the evaluable, 67% were accepted. The percentages were: information (n=16, 29,1%), modification Posology (n=11, 20%), discharge dispensing (n=6, 10,9%), usual treatment not prescribed (n=4, 7,3%), therapy reconciliation error (n=3, 5,5%), lack of efficacy (n=3, 5,5%), need for additional treatment (n=3, 5,5%), substitution (n=2, 3,6%), duplicity (n=2, 3,6%), unnecessary medication (n=2, 3,6%), detection of prescribing error (n=1, 1,8%), contraindication (n=1, 1,8%), modification DF (n=1,1,8%).

Conclusion and Relevance The data obtained demonstrates that a high percentage of patients used high-risk medicines and clinical interventions performed by the hospital pharmacy resident have a high degree of acceptance, increasing the quality and safety of healthcare and avoiding medication errors.

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Conflict of Interest No conflict of interest

5PSQ-043 EXPERIENCE OF USING BEMPEDOIC ACID 1 YEAR SINCE ITS FUNDING IN THE NATIONAL HEALTH SYSTEM

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Background and Importance Bempedoic acid (BA) is a new lipid-lowering drug funded by the national health system (NHS) for patients with atherosclerotic vascular disease (AVD) or familial hypercholesterolaemia (FH) not controlled with the maximum dose of statin + ezetimibe or with intolerance/contraindication to statin/ezetimibe.

Aim and Objectives To describe the experience of using BA 1 year after funding by the NHS.

Material and Methods Retrospective observational descriptive study carried out between September 2023–2024. All AB prescriptions made by hospital specialists were included.

Patients with AB prescriptions were tracked by the region's medical prescription analysis system and demographic, clinical and laboratory variables were collected from medical history. Effectiveness and safety were analysed through clinical follow-up and analytical monitoring.

Results were analysed in Stata v17.0.

Results Forty-five patients with a median age of 71 years (IQR 63–76) were included, being women the 42.7%. The median follow-up time was 4.9 months (IQR 3.6–6.3).

Indications for AB were 57.15% AVD and 42.85% FH

The 33.33% of patients received AB 180mg + ezetimibe 10mg + atorvastatin/rosuvastatin for suboptimal control of their LDL-C levels with high intensity statin + ezetimibe, 47.62% received AB 180 mg + ezetimibe 10mg for non-tolerance/contraindication to statins despite modification of statin type/dose reduction and 19.05% were treated with AB 180 mg monotherapy for intolerance/contraindication to statin and ezetimibe.

- 100% patients reduced LDL-C and total cholesterol levels with median reductions of 26.3% (IQR 21.7%-32.5%) and 18.0% (IQR 15.7%-27.7%) respectively. The 70% reduced their triglyceride levels.
- 100% patients who intensified therapy with AB + statin + ezetimibe reached the therapeutic target (LDL-C<55 mg/mL).
- 93.3% the statin-intolerant patients reached the target with AB 180 mg + ezetimibe 10mg.

Mild hypertransaminemia occurred in 11.11%, 6.66% had mild hyperuricaemia which did not require treatment, 6.66% presented mild hyperCKaemia, 8.88% had slightly increased serum creatinine and 22.22% patients had reduced haemoglobin levels but no case was there anaemia (<14.0 g/dl).

Conclusion and Relevance

- In all cases AB lowered plasma LDL-C compared to previous therapy with a median reduction >25%.
- AB addiction achieved the target in 100% of patients when control was suboptimal despite high-dose statin + ezetimibe and >90% the statin-intolerant patients.
- AB did not present any adverse effects that would require its suspension.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-044 IMPACT OF ADVERSE DRUG REACTIONS ON LENGTH OF STAY AND MORTALITY IN HOSPITALISED PATIENTS THROUGH A CLINICAL ADMINISTRATIVE NATIONAL DATASET

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Background and Importance Adverse Drug Reactions (ADRs) cause 5–10% of hospital admissions and occur in 10–20% of hospitalised patients.

Aim and Objectives To find out the impact of ADRs on patients' hospitalisation.

Material and Methods Retrospective case-control study that included patients' hospitalisation over 17 years of age during the period 2017–2023, using a clinical administrative national dataset.

Cases were defined as hospitalisations with a record of ADRs, in terms of chapter T36-T50 of ICD-10. Controls were the remaining hospitalisations exempt from these ADRs codes.

Medians were compared by Wilcoxon test and proportions by Chi2. Two multivariate regression models and two propensity score matching models were constructed to study the

influence of ADRs on the length of hospital stay and mortality.

Results 126,075 hospitalisations were analysed, 117,145 non-ADRs and 8,930 with ADRs during admission. The prevalence of ADRs was 7.08% (95% CI 6.90–7.20). Men were more represented: 53.38% and 51.10%, respectively.

The median age in non-ADRs patients was 72 years (IQR 56–82) and 77 (IQR 68–85) in ADRs group, p=0.000.

The median van Walraven comorbidity index (WI) was 4 (IQR 2–8) in non-ADRs group and 7 (4–13) in ADRs patients.

Patients without ADRs were admitted for a median of 4 days (IQR 2–8) versus 7 (IQR 4–13) in ADRs group. Mortality rate during admission in non-ADRs group was 4.73% (95%IC 4.60–4.90) versus 6.55% (95%IC 6.00–7.10) in ADRs group.

Age (OR=1.05, IC95% 1.03–1.06; p=0.000), female sex (OR=1.15, 95% IC 1.10–1.20; p=0.000), length of stay (OR=1.54, 95% IC 1.51–1.57; p=0.000) and comorbidity measured by IW (OR=1.60, 95%IC 1.56–1.63; p=0.000) increased the likelihood of ADRs.

Using sex, age and IW as covariates, ADRs were associated with increased length of hospital stay: IRR (Increased Relative Risk) =1.412 (95%IC 1.376–1.448), p=0.000. However, ADRs were not associated with higher mortality rate: OR= 0.807 (95%IC 0.743–0.877), p=0.000.

The *matching* test obtained an increase of 3.226 days in length of stay compared to a control patient of the same sex, age and comorbidity free of ADRs: Coefficient= 3.33 (95%IC 2.922–3.532), p=0.000 but also shows no increase in mortality: Coefficient= (-)0.007 (95%IC (-)0.12- (-)0.026), p=0.003.

Conclusion and Relevance

- Patients with ADRSs are older and have more comorbidity.
- ADRSs are associated with increase length of hospital stay but advanced analysis shows no increase in mortality.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-045 ANALYSIS OF CARDIOVASCULAR RISK ASSOCIATED WITH JANUS KINASE INHIBITORS TREATMENT IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background and Importance Rheumatoid arthritis (RA) is associated with an increased risk of cardiovascular morbidity and mortality due to chronic inflammation. Though Janus kinase inhibitors (JAKi) are linked to higher cardiovascular event risk but the association remains unclear.

Aim and Objectives Outcome analysis of the occurrence of cardiovascular adverse events and cardiovascular risk in RA patients on treatment with JAKi.

Material and Methods Observational, retrospective, multicentre study of all patients with RA treated with JAKi for a minimum duration of 12 months. Clinical variables: sex, age, smoking, Charlson Comorbidity Index, cardiovascular risk score,[1] previous cardiovascular pathologies, JAKi treatment, duration, adverse effects or dose modifications. Major adverse cardiac events (MACE) were recorded and when they occurred as well as their outcome (emergency visit, hospitalisation, death). Data were obtained from electronic prescription and electronic medical records. R commander was used for the statistical analysis.

Results 71 patients with JAKi treatment were included. 85.9% female, median age 58 (IQR 48.5–65.5). Median Charlson Comorbidity Index 1(IQR 1–2). 47.8% ex-smokers and 18.3% smokers.The median 10-year risk of cardiovascular events was 1.5% (IQR 1–3). At baseline: 32.4% arterial hypertension, 25.3% dyslipemia, 11.2% diabetes, 4.2% ischaemic heart disease, 4.2% cerebrovascular disease and 2.8% acute myocardial infarction. Treatments: 38 tofacitinib, 17 baricitinib, 12 upadacitinib and four filgotinib. The median treatment duration was 31 months(IQR 15.1–40.9). 12.6% reduced the dose, 7% increased their treatment dosage and 54.9% discontinued treatment (48.7% secondary failure, 23% adverse effects, 17.9% primary failure and 10.2% other reasons). 56.4% of patients who discontinued started treatment with another JAKi. Upadacitinib was the most prescribed (50%).

12 patients(16.9%) developed MACE during the treatment (six dyslipemia, three arterial hypertension, one diabetes, one ischaemic heart disease and one deep vein thrombosis). Two patients needed hospitalisation. MACE occurred after a median of 2 years (IQR 1–3). Statistically significant differences were found between MACE and smoking (p=0.01). No deaths from MACE.

Conclusion and Relevance The development of MACE occurs in a modest number of patients with no associated mortality in this study. A statistically significant association was found with smoking. It is necessary monitoring and management of modifiable risk factors in this patient population.

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Conflict of Interest No conflict of interest

5PSQ-046 ANALYSIS OF DESENSITISATION PROTOCOLS USED IN ONCOLOGY PATIENTS IN A TERTIARY HOSPITAL

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Background and Importance Drug desensitisation helps patients tolerate medications that previously caused allergic reactions. Initially for antibiotics, it is now used for chemotherapy and biologics, improving patient outcomes by allowing continued treatment. Patients receive customised doses through controlled serial dilutions, with premedication given 2 days before and on the day of desensitisation. A prick test checks for allergic reactions if hypersensitivity is suspected.

Aim and Objectives To describe desensitisation protocols in a tertiary care hospital and test if prick test results for skin allergies relate to immediate anaphylactic reactions during infusions. We also reviewed common adverse events with chemotherapy before desensitisation protocol.

Material and Methods Retrospective observational study (September 2023 to September 2024) that included all patients

requiring a desensitisation protocol during chemotherapy. Qualitative data: sex, diagnosis, death, protocol received, skin allergy test details (drugs analysed and results), symptoms during hypersensitivity reaction, treatment response, whether patients relapsed and need for treatment changes. Quantitative data: age, treatment cycle in which the hypersensitivity reaction occurs, number of desensitisation steps and bags, protocol duration, and number of desensitisation cycles received.

Results A total of 34 patients were analysed, 79.4% women with a median age of 60 years (IQR 66–53.7). Diagnoses included ovarian (61.7%), endometrial (11.7%), lung (11.7%), prostate (5.8%), breast (2.5%), colorectal (2.2%), Hodgkin's lymphoma (2.2%), and osteosarcoma (2.2%).Desensitisation protocols were most common for taxanes (44.1%), platinum (35.2%), etoposide (11.7%), gemcitabine (5.8%), and trastuzumab (3.2%). Hypersensitivity reactions typically occurred in the second treatment cycle. An intradermal skin test was performed on 94.1% of patients, with 38.2% testing positive. Patients received a median of five desensitisation cycles and the median treatment duration was 86 days (IQR 177–64.5). Complete response was achieved in 35.2% of patients, while 55.8% required a change in treatment. The most common symptoms during hypersensitivity reactions were erythema/flushing (70.5%), chest pain (70.3%), dyspnoea (23.5%), gastrointestinal issues (23.2%), low back pain (22.8%), cardiovascular disturbances(20.5%), abdominal pain (17.6%), dizziness (14.7%), sweating (11.7%) and pruritus (8.8%). A total of 23.5% of patients died from causes unrelated to hypersensitivity reactions.

Conclusion and Relevance Chemotherapy desensitisation allows allergic patients to safely undergo treatments through carefully designed protocols and close monitoring. While it does not completely eliminate hypersensitivity risks, it significantly reduces them. Given its substantial benefits, desensitisation should become the standard of care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-047 DYNAMICS OF HIV PRE-EXPOSURE PROPHYLAXIS USE AND EVALUATION OF ITS IMPACT IN THE INCIDENCE OF SEXUALLY TRANSMITTED DISEASES

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Background and Importance HIV pre-exposure prophylaxis (PrEP) effectively reduces the risk of HIV transmission. However, its use has been associated with changes in sexual practices, which may influence the risk of acquiring other sexually transmitted diseases (STDs). This study investigates PrEP adherence and explores trends in STD acquisition during PrEP treatment.

Aim and Objectives To evaluate PrEP adherence among users and describe the patterns of STD acquisition during treatment.

Material and Methods This was a multicentre, observational, retrospective cohort study of patients who received PrEP for more than 30 days between June 2023 and June 2024. Data were collected from electronic prescription and medical records systems. Qualitative variables: sex, comorbidities, partner's HIV status, chemsex use, condom use, treatment interruptions and their causes, STD and/or HIV acquired during treatment, microorganisms and treatment. Quantitative variables included age, number of sexual partners, duration of PrEP treatment and adherence (measured using the dispensing registry). Statistical analysis was performed using R Commander software. Data were obtained from electronic prescription and medical records applications.

Results 117 patients included, 99% men, with a median age of 36 years (IQR 30–45). Median of 20 sexual partners per year (IQR 12.7–36); irregular condom use in 54.3%; consistent condom use in 23.2%; 22.5% reported no condom use. Chemsex was practiced by 23.3%. During oral sex, 95.6% never used condoms. Risky sexual relationships were frequent for 15.5% of patients and 10.3% had taken post-exposure prophylaxis previously. Median treatment duration of 18.6 months (IQR 8.8–28.7); adherence was 81.8%. No treatment-associated adverse effects were observed. Treatment was interrupted by 49.3%, with 21.3% switching to on-demand use. 79.3% acquired an STD during treatment, with Neisseria gonorrhoeae (43.4%) and Chlamydia trachomatis (29.1%) being most common. A small proportion of Mycoplasma genitalium cases showed resistance to azithromycin (38.8%) and moxifloxacin (22.2%). Only one patient contracted HIV while on PrEP.

Conclusion and Relevance PrEP is an essential tool for HIV prevention, and adherence among patients in this study was high. However, a significant proportion of users acquired STDs during treatment, suggesting the need for ongoing STD screening and education. While this study highlights trends in STD acquisition, it does not establish causality between PrEP use and increased STD risk. Multidisciplinary efforts are vital to optimising PrEP's protective benefits and mitigating the risks of other infections.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-048 REAL-WORLD DATA ON INFECTION PREVALENCE IN PATIENTS ON IMMUNOSUPPRESSIVE TREATMENT WITH USTEKINUMAB, GOLIMUMAB AND GUSELKUMAB

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Background and Importance Ustekinumab (anti-IL-12/23), golimumab (anti-TNF) and guselkumab (anti-IL-23) are specific immunosuppressants targeting molecules involved in inflammatory and immune response.

Aim and Objectives To describe the prevalence of infection with real-life data in patients treated with ustekinumab, golimumab or guselkumab in their funded indications in the national health system.

Material and Methods A retrospective observational study between December 2010 and August 2024 that included patients treated with ustekinumab, golimumab and guselkumab for at least 3 months, given the long half-life of these drugs (2–3 weeks).

Demographic and clinical variables and the different infections recorded in primary and hospital care during the period of treatment were collected from the medical history.

Results Forty-seven patients were included with ustekinumab (20/47), golimumab (17/47), guselkumab (10/47). The median age at baseline was 52.5 years (IQR 47–57), with 50% being female.

In 23.4% of cases (11/47) the patient received concomitant systemic immunosuppressive therapy with leflunomide (5/11), methotrexate (4/11) and azathioprine (2/11)

Median follow-up was 19.9 months (IQR 8.8–54.7) with a median persistence of 13.9 months (IQR 6.9–48.9). The reasons for discontinuation were: lack of response (24/26) or adverse events (2/26).

Patients were vaccinated for SARS-Cov2 (30/45), influenza virus (29/45), diphtheria-tetanus (27/45), pneumococcus (27/45), hepatitis B virus (18/45), hepatitis A virus (10/45), varicella-zoster virus (3/45), *Haemophilus influenzae* (2/45).

The median prevalence of infection per patient during treatment was 1 infection (IQR 0–2). We detected a total of 31 infections pertaining to 7 organs/systems, as detailed in the table. There were no serious infections, 4/31 were moderate and the rest (27/31) were mild.

Abstract 5PSQ-048 Table 1

Infection	n
Upper respiratory tract infection	13/31
COVID-19	2
Influenza	1
Cold	6
Bronchitis	2
Tonsillitis	2
Skin and soft-tissue infection	7/31
Herpes simplex virus	2
Infected skin wound	2
Skin abscess	2
Paronychia	1
Urinary tract infection	5/31
Cystitis	5
Intestinal infection	2/31
Gastroenteritis	2
Oral-dental infection	2/31
Thrush	1
Tooth abscess	1
Eye infection	1/31
Reproductive tract infection	1/31
Vulvar abscess	1

Conclusion and Relevance

- We found a low prevalence of infection in patients treated with ustekinumab, golimumab and guselkumab.
- Upper respiratory tract infections, followed by skin and soft-tissue infections and urinary tract infections, are the most frequent.
- In 90% of cases these infections were mild.

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

5PSQ-049 COST SAVING IMPACT AND SAFETY EVALUATION OF BIOSIMILAR NATALIZUMAB IN PATIENTS WITH MULTIPLE SCLEROSIS

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Background and Importance The use of biosimilar drugs enhances access to biological therapies for more patients, but there is a lack of real-world safety data. Recently, biosimilar natalizumab (BN) has been approved for the treatment of relapsing-remitting multiple sclerosis in our country.

Aim and Objectives To evaluate the safety of BN in real clinical practice and the cost saving impact after its inclusion in the hospital guide formulary.

Material and Methods A retrospective, observational study including all patients with relapsing-remitting multiple sclerosis treated with BN between April and September 2024 was carried out. The following variables were collected: sex, age, new treatment/switching, cycles received of BN, days on BN, baseline anti-JC antibodies, treatment-related adverse effects (AEs), treatment discontinuation and reasons for discontinuation.

For the cost saving impact calculation, we considered the doses of BN administered during the study period. We also estimated the cost saved per patient during a year of treatment with BN.

Results A total of 34 patients were included (mean age 39 ±8.9 years (27–63), 26 women (76.47%)). Thirty-three patients (97.1%) switched to the biosimilar, while one patient (2.9%) initiated treatment. The mean duration of treatment with the biosimilar was 157±15.8 days. The mean number of cycles received of BN was 4.7±1.52. Eight patients had baseline anti-JC antibodies (23.5%).

AEs related to BN included herpes infection (1; 2.9%), although it had been presented previously. Treatment was discontinued in 4 patients due to reasons unrelated to AEs: pregnancy (1; 2.9%), melanoma diagnosis (1; 2.9%), and risk of progressive multifocal leukoencephalopathy (2; 5.88%).

Throughout the period of the study, the cost savings from switching to the biosimilar amounted to € 27,128.5, resulting in an estimated annual cost saving of € 1,927.5 per patient.

Conclusion and Relevance In our study, BN exhibits an adequate safety profile, resulting in significant economic savings that contribute to the sustainability of the National Health System. Safety and effectiveness studies in the long-term are warranted.

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

5PSQ-050 REVIEW OF THE USE OF NEUROLEPTICS IN A NURSING HOME ASSOCIATED WITH HOSPITAL PHARMACY

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Background and Importance The use of psychotropic drugs in the elderly has been increasing in recent years. Adequate prescription and review of these medications are essential given

the risk of adverse effects, in order to minimise falls, cognitive decline, and increased mortality. The STOPP-START criteria are useful in identifying drugs that may be candidates for deprescription. This study analyses the use of psychotropic drugs in a healthcare centre for the elderly that is affiliated with a second-level hospital pharmacy service.

Aim and Objectives

1. Review the prescription of antipsychotics, identifying the most commonly used drugs, doses, and associated diagnoses.
2. Identify drugs that may be suitable for deprescription using the STOPP-START criteria.
3. Determine whether the use of these drugs is appropriate and justified in this group of patients.

Material and Methods Observational and cross-sectional study in a nursing home for the elderly, conducted in June 2024, analysing the prescription and use of psychotropic drugs. The following data were collected: drug, dosage, and associated diagnosis. Compliance with clinical guidelines was also evaluated, and the STOPP-START criteria were applied to identify drugs suitable for deprescription.

Results 43.7% of the patients (56) had antipsychotics prescribed. Quetiapine was the most common (42), with an average dose of 58 mg, followed by risperidone (24), with an average dose of 1.5 mg. Other antipsychotics used included aripiprazole (2), haloperidol (1), and paliperidone.[1] All uses were justified based on associated diagnoses: dementia, agitation, refractory insomnia, or behavioural disturbances. Applying the STOPP-START criteria, 12 patients were identified as candidates for deprescription, as they were taking combinations of quetiapine and risperidone, and their treatment could be simplified to one of the two drugs.

Conclusion and Relevance The use of psychotropic drugs in the nursing home is appropriate and in line with clinical guidelines. The involvement of the hospital pharmacy ensures responsible prescribing, with well-established protocols for review and deprescription. It is necessary to review antipsychotic combinations in some patients to reduce their use.

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Conflict of Interest No conflict of interest

5PSQ-051 ANALYSIS OF USE AND THERAPEUTIC ADHERENCE AMONG PATIENTS TREATED WITH BEMPEDOIC ACID AT A LOCAL HEALTH AUTHORITY

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Background and Importance Bempedoic acid (monotherapy or combined with ezetimibe) is the most recent drug approved for adult with primary hypercholesterolaemia and mixed dyslipidaemia. It is reimbursed by the Italian National Health Service for patients who are intolerant to statins or for whom maximum tolerated doses of statins fail to achieve therapeutic goals. The annual cost per patient for this therapy can range from 4 to 15 times higher than that of statin therapy.

Aim and Objectives To ensure proper use, we conducted an analysis of patients enrolled in a treatment with bempedoic acid at a Local Health Authority (LHA), with the aim of evaluating therapeutic continuity and assessing reports of adverse drug reactions (ADR) in the National Pharmacovigilance Network (NPN) for patients who discontinued therapy.

Material and Methods The patient cohort included those who initiated treatment between 1/06/2023 and 30/05/2024. The population was characterised by total number, sex, pathology, type of treatment, and prescriber. Particular attention was given to patients who discontinued bempedoic acid therapy. Additionally, reports of ADR to bempedoic acid were examined in the NPN for this LHA.

Results A total of 542 patients were enrolled from 1 June 2023 to 30 May 2024, 49.4% male and 50.6% female. The predominant diagnosis was mixed dyslipidaemia (62%), followed by primary non-familial hypercholesterolaemia (28.6%) and heterozygous familial hypercholesterolaemia (7.0%). 48.3% of the patients were treated with bempedoic acid alone, while 51.7% received bempedoic acid and ezetimibe. Specialised clinicians prescribed 81.5% of these treatments, whereas the remaining 18.5% were prescribed by general practitioners. Statin intolerance was the primary reason for initiating bempedoic acid therapy in 45.6% of cases, 12% of patients were intolerant to both statins and ezetimibe, 0.2% were intolerant to ezetimibe alone and 36.5% were on statins at the maximum tolerated dose. A total of 23.1% of patients discontinued bempedoic acid therapy without any clinically documented reason known to the pharmacist (likely due to intolerance, non-adherence, or lack of therapeutic efficacy). No suspected ADR were reported to the LHA.

Conclusion and Relevance The findings regarding therapy discontinuation underscore the necessity of increasing healthcare professionals' awareness of the importance of reporting ADR to better characterise the safety profile of bempedoic acid, a drug under additional pharmacovigilance monitoring.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-052 PERSISTENCE OF BARICITINIB IN A REAL-WORLD SETTING OF RHEUMATOID ARTHRITIS PATIENTS

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Background and Importance Baricitinib is a Janus kinase (JAK) inhibitor that is used for the treatment of moderate to severe rheumatoid arthritis (RA). Real-world data on the persistence and discontinuation of baricitinib are necessary to understand its long-term effectiveness.

Aim and Objectives The aim was to evaluate the persistence of baricitinib in RA patients in a real-world clinical setting and determine the main reasons for treatment discontinuation.

Material and Methods Retrospective observational study of RA patients treated with baricitinib up to 31 August 2024. Patients with loss to follow-up were excluded.

Variables collected were: demographic data (sex, age), previous treatments, start and discontinuation date, and causes of suspension treatment.

Persistence was defined as time (months) from the start of treatment until its discontinuation and calculated with Kaplan-Meier survival curves (log-rank test). Discontinuation reasons were classified into ineffectiveness, adverse events (AE), comorbidities and others. The data were obtained from the history clinical electronic program (DIRAYA) and from the prescription program (ATHOS). The statistics program used was SPPS 20.0.

Results We included 143 patients, 78.3% (112) women. Median age 59 years (IQR: 29 - 86). 50.3% had not received any previous treatment, 28.7% had received one and the remaining (21%) two or more.

At the end of the follow-up period, 46.9% (67) of patients discontinued baricitinib. Median persistence was 59 months (95% CI 45.6 to 78.5) (Graph1).

The causes of suspension treatment: ineffectiveness in 36 patients (25.2%), AEs (13.3%) in 19 patients, age and comorbilities (3.5%) in five patients and another causes (4,9%) in seven patients. Most frequently AEs reported were gastrointestinal (7/19) followed by infections (6/19).

Conclusion and Relevance The results suggest although almost half of the patients remained on baricitinib for a median of 59 months a significant proportion discontinued treatment, mainly due to ineffectiveness or AEs. These results highlight the importance of continuing to monitor effectiveness in long-term baricitinib treatment.

In view of the results obtained, it would be interesting to extend the study by comparing baricitinib with the other JAK inhibitors approved for the treatment of rheumatoid arthritis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-053 PREVALENCE OF MEDICATION-RELATED HOSPITAL ADMISSIONS AT AN AUSTRIAN TERTIARY CARE CENTRE

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Background and Importance Medication-related problems (MRPs) represent adverse events arising from the use or misuse of pharmaceuticals, including overdosing, underdosing, adverse reactions and interactions, among others. International data suggest that up to 30% of hospital admissions are attributable to MRPs. It is estimated that half of these medication-related hospital admissions (MRHA) are preventable. To date, there is no data reflecting the prevalence and incidence of MRHA in Austria.

Aim and Objectives The aim of this study was to evaluate MRHA at the Department of Emergency Medicine at a 1740-bed Austrian tertiary care centre, and to elucidate underlying causes contributing to these admissions.

Material and Methods A retrospective analysis, both quantitative and qualitative, was conducted by a clinical pharmacist utilising the AT-HARM10 scale. This analysis comprised all patients treated at the Department of Emergency Medicine requiring hospital admission over a 5-week period. The frequency, severity, and potential preventability of identified MRHA were systematically assessed. Medical history and medication records were extracted from the electronic patient chart and the hospital information system.

Results A total of 422 patients (45% female, median age 54 years (16–101)) have been analysed retrospectively. The prevalence of MRHA was 10.9% (n=46, 41%female), with 39% (n=18) of cases classified as severe, indicating that abnormalities or symptoms were life-threatening. On average, these patients were 64 (25–95) years-old and were taking five (4–21) medications at the time of their admission. 45% (n=21) of MRHAs are attributable to untreated or suboptimally treated medical indications, while 32% (n=15) of MRHAs are potentially due to adverse effects from both prescribed and non-prescribed medications. 90% of all detected MRHA were categorised as either 'potentially preventable' (n=28) or 'definitely preventable' (n=14). The most common drug classes associated with MRHA were 'antithrombotic agents' (n=19), followed by medications targeting the 'cardiovascular system' (n=6).

Conclusion and Relevance 1 out of 10 hospital admissions can be attributed to a MRP, thereby representing a significant share of all hospital admissions. High-risk medication classes, such as antithrombotic and cardiovascular agents, are particularly associated with MRHAs. With the vast majority thereof being deemed preventable, clinical pharmacists play a pivotal role by optimising therapy and providing essential interventions that enhance medication safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-054 REAL-WORLD OUTCOMES OF ENZALUTAMIDE, ABIRATERONE, AND APALUTAMIDE IN PATIENTS WITH PROSTATE CANCER

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Background and Importance Prostate cancer (PC) continues to be a critical health issue, particularly in its metastatic castration-resistant (mCRPC) and hormone-sensitive (mHSPC) stages. Treatment options have advanced with the introduction of second-generation androgen receptor inhibitors (SG-ARIs) such as enzalutamide and apalutamide, as well as the androgen synthesis inhibitor abiraterone. This study investigates the real-world effectiveness and safety profiles of these agents, providing valuable insights into their clinical impact on patient outcomes and disease management.

Aim and Objectives The primary objective of this study is to evaluate the clinical effectiveness and safety of enzalutamide, abiraterone, and apalutamide in patients diagnosed with mCRPC and mHSPC. Specifically, the study aims to assess progression-free survival (PFS) and overall survival (OS) rates, as well as to document adverse events (AEs) associated with these therapies.

Material and Methods This retrospective observational study was conducted at a regional hospital. Data on treatment effectiveness and safety were obtained from electronic medical records and analysed using Kaplan-Meier survival analysis. Effectiveness was evaluated by tracking prostate-specific antigen (PSA) levels over time, while safety assessments focused on the incidence and type of AEs.

Results The study included 46 patients, 45% with mHSPC and 54% with mCRPC, with a median age of 73. Treatments were apalutamide (21.7%), enzalutamide (43.4%), and

abiraterone (34.7%). Gleason scores were 6 (17.4%), 7 (41.3%), 8 (15.2%), 9 (10.8%), and 15.2% unknown. mHSPC patients showed mean PSA decreases from 57.33 to 0.19 ng/ml over 32 months. mCRPC patients' PSA decreased from 35.65 to 1.74 ng/ml. Median PFS was 60 months for mCRPC; OS was not reached. Adverse events affected 39.1%, with 27.7% reporting urinary issues, rash, and asthenia, and 5.5% reporting taste loss, constipation, and arrhythmias. Three patients required treatment modification due to severe AEs.

Conclusion and Relevance The findings indicate that enzalutamide, abiraterone, and apalutamide are effective and generally well-tolerated therapeutic options for PC in real-world settings. The observed AEs align with existing literature, supporting the feasibility of these treatments under routine clinical monitoring. Further studies involving larger, multicentre cohorts are recommended to strengthen these findings and optimise therapeutic strategies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-055 EFFECTIVENESS, SAFETY, AND MONITORING OF PIRFENIDONE AND NINTEDANIB IN IDIOPATHIC PULMONARY FIBROSIS

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Background and Importance Idiopathic Pulmonary Fibrosis (IPF) is a rare and progressive disease. Current treatments, pirfenidone and nintedanib, aim to slow disease progression in mild to moderate cases. The Therapeutic Positioning Report (TPR) guides treatment monitoring, recommending discontinuation if Forced Vital Capacity (FVC) decreases by over 10% or Diffusing Capacity for Carbon Monoxide (DLCO) drops by 15% annually. This study compares the effectiveness, safety, and adherence to TPR guidelines for both drugs.

Aim and Objectives The study's objective is to evaluate the real-world effectiveness and safety of pirfenidone and nintedanib in IPF treatment, assessing patient response rates and treatment discontinuation reasons in accordance with TPR criteria.

Material and Methods This retrospective study analysed data from IPF patients treated with antifibrotics up to December 2023. Patient information, including demographics, FVC, DLCO, adverse events (AEs), and treatment adherence, was collected from electronic records. The effectiveness analysis excluded patients treated for less than six months, and statistical analysis was conducted using Chi-square tests for categorical data.

Results Thirty-one patients were recruited (54.84% female, mean age 71 ± 9.53 years); of these, five received only pirfenidone, 21 received nintedanib, and five received both sequentially. One patient on pirfenidone and one on nintedanib did not meet TPR initiation criteria. The responder rate for pirfenidone was 70% (95% CI: 38.7%–89.2%) compared to 45.8% (95% CI: 28.9%–62.9%) for nintedanib (p=0.2). One patient on pirfenidone and five on nintedanib exhibited reductions in FVC and/or DLCO beyond TPR limits. Adverse events were reported in 57% of pirfenidone patients (95% CI: 40.1%–75.2%) versus 85% on nintedanib (95% CI: 68.5%–94.3%, p=0.02). Discontinuations among pirfenidone users included one due to AEs and one death, while nintedanib had seven discontinuations: five due to AEs, one due to death, and one due to disease progression.

Conclusion and Relevance The study found no significant difference in response rates between pirfenidone and nintedanib, although AEs were more frequent with nintedanib. Some patients did not meet TPR criteria, highlighting the need for stringent monitoring to optimise economic resources and minimise unnecessary toxicity. The findings underscore the importance of careful patient evaluation by pulmonologists and pharmacists to ensure treatment adherence and efficacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-056 PHARMACOGENETIC INFLUENCE OF *MTHFR* VARIANTS ON METHOTREXATE TOXICITY: UNVEILING PREDICTIVE BIOMARKERS FOR PERSONALISED THERAPY

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Background and Importance Pharmacogenetics plays a crucial role in optimising drug therapy. Methylenetetrahydrofolate reductase (*MTHFR*) gene, encodes an enzyme involved in folate metabolism, which is essential for nucleotide synthesis and DNA methylation. Methotrexate, a widely used chemotherapeutic and immunosuppressant, exerts inhibits dihydrofolate reductase, thereby variations in the *MTHFR* gene influence methotrexate metabolism, potentially affecting therapeutic outcomes and the risk of suffering adverse effects (AE). Identifying the patient's *MTHFR* genotype can provide insights for individualised dosing strategies and minimising toxicity. Different *MTHFR* metaboliser phenotypes are categorised based on genotypes, typically classified as normal(GG), intermediate (GA), or poor metabolisers (AA), depending on the presence of polymorphisms such as C677T. However, current guidelines lack robust evidence to support mtx dose adjustments based on *MTHFR* genotypes, underscoring the need for further research to validate pharmacogenetic-guided dosing strategies.

Aim and Objectives The objective of this study is to evaluate the impact of *MTHFR* gene variants on the susceptibility to methotrexate-related AE.

Material and Methods Observational, retrospective, and single-centre study including all patients for whom pharmacogenetic analysis of *MTHFR* was requested between February 2021 and July 2024.Socio-demographic, clinical, and therapeutic variables were collected using electronic prescription system(HCIS) and Servolab analysis software.

The *rs1801133* variant of the *MTHFR* gene was genotyped using OpenArray technology.

Results A total of 145 patients were genotyped, of whom 75 finally initiated methotrexate therapy. The average age of these patients was 29 years, with 44% being male. Of these, 29

patients were treated for rheumatic/dermatological diseases and 46 for paediatric leukaemias.

16 of the 75 patients analysed (21.36%) had the high-risk toxicity variant (AA). Out of them eight suffered any adverse effect: two cytopenias, one digestive intolerance, two mucositis, one bone pain, one hypertrasaminaemia, one hepatocellular hepatitis and one skin rash.

29 patients (38,67%) had the intermediate risk toxicity variant (GA), eight of them suffered from any AE: three skin rash, three digestive intolerance, one hypertransaminea and two lymphopenia.

30 patients (40%) had the low-risk toxicity variant (GG), five of them suffered from an adverse effect: two mucositis oral thrush and one skin rash.

Conclusion and Relevance Our real-world data are consistent with some studies that relate MTHFR C677T mutations with an increased risk of methotrexate toxicity, particularly myelosuppression and hepatotoxicity in paediatric patients receiving high-dose MTX. However, due to the small sample size and inconsistent reports in the literature, additional studies are needed to clarify the role of MTHFR polymorphisms in MTX toxicity and efficacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-057 SCREENING FOR HIV IN PATIENTS DIAGNOSED WITH HERPES ZOSTER IN THE EMERGENCY DEPARTMENT

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Background and Importance In May 2021, an HIV screening programme was implemented in the emergency department (ED) of a tertiary hospital for patients diagnosed with specific conditions, including community-acquired pneumonia, mononucleosis syndrome, sexually transmitted infections, chemsex practice, post-exposure prophylaxis for HIV, or herpes zoster (HZ). The indication for HIV testing in HZ patients is limited to those aged 18–65.

Aim and Objectives To analyse the trend in HIV screening among patients diagnosed with HZ in the ED of a tertiary hospital following the implementation of the screening programme.

Material and Methods This was a cross-sectional, retrospective observational study. All episodes with a primary diagnosis of HZ in the ED of a tertiary hospital between 2020 and 2023 were included, using data from the ELCANO electronic medical record system (HCIS). Episodes of other types of herpes (e.g., gladiatorum, labial, vaginal) were excluded. Serological tests requested from the Microbiology Service and the results for HIV infection were reviewed. A Chi-squared trend test was used to analyse the screening trend.

Results In 2020, there were 367 HZ episodes, with 49 HIV tests requested (test-to-episode ratio: 13.35%), with no new cases detected. In 2021, 458 episodes were recorded, with 65 HIV tests (ratio: 14.19%), also without new cases. In 2022, among 523 episodes and 108 tests (ratio: 20.65%), one new HIV diagnosis was made, as was in 2023, with 434 episodes and 91 tests (ratio: 20.97%). A p-value of 0.0004 indicated a positive trend in increasing HIV screening among HZ patients attending the ED.

Conclusion and Relevance Between 2020 and 2023, there was an increasing trend in HIV screening among patients diagnosed with HZ in the ED of a tertiary hospital following the implementation of a targeted screening programme. However, overall screening remains low.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-058 MEDICINES RECONCILIATION OF HOME ORAL ANTICOAGULANTS UPON ADMISSION – ARE WE DOING IT WELL?

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Background and Importance In March 2023, our hospital Thrombosis Committee approved a protocol for the management of oral anticoagulants (OACs) in patients who were taking them at home at the point of hospital admission.

Aim and Objectives To evaluate compliance with the protocol and detect medication errors (MEs) as a result of non-compliance.

Material and Methods This was a 2 month cross-sectional observational study (December 2023 to January 2024). The inclusion criteria were patients with low molecular weight heparin (LMWH) prescribed in hospital and who were on OACs at home. The medicines reconciliation process using the new protocol was carried out in these patients.

The main variables were:

1. Percentage of patients where the protocol was followed, which establishes to stop vitamin K antagonist (VKA) and start therapeutic LMWH dose when the INR is less than 2, except for patients with mechanical prosthesis or venous or arterial antiphospholipid syndrome. In patients on direct-acting oral anticoagulants (DOACs), it was recommended to maintain home anticoagulation. In those patients with MEs detected, it was considered that the protocol was not followed.
2. Percentage of patients with MEs, classified as MEs related to supratherapeutic dosing, subtherapeutic dosing or delayed administration of LMWH.

Data were collected from our hospital electronic medical records.

Results A total of 62 patients were analysed, 48.4% with home DOACs and 51.6% with home VKA.

37.1% patients were compliant with the protocol and 62.9% were not compliant. The reasons for non-compliance were: 20.5% patients had DOACs stopped to start on LMWH instead of continuing DOACs, 5.1% continued VKA instead of being stopped to start on LMWH and 74.4% were MEs. Of these, 37.9% were MEs due to supratherapeutic dosing, 44.8% due to subtherapeutic dosing and 17.3% due to

delayed administration of LMWH. None of the patients with MEs experienced clinical complications.

Conclusion and Relevance There was a low compliance with the protocol, which was notified to the Thrombosis Committee for review.

Additionally, there was a high proportion of MEs detected. MEs due to subtherapeutic dosing were found to be the most frequent.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-059 CASE REPORT: UNEXPECTED ADVERSE REACTION TO (^{68}GA)GA-DOTATOC

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Background and Importance (^{68}Ga)Ga-DOTATOC is a radiopharmaceutical preparation (composed of gallium-68 and a radiopharmaceutical kit, SOMAKIT TOC) used in positron emission tomography (PET) for imaging somatostatin receptor overexpression in patients with gastroenteropancreatic neuroendocrine tumours, in order to localise primary tumours and their metastases. Data on adverse drug reactions (ADRs) associated with this preparation are scarce in the literature.[1] [2] We report a case following administration of (^{68}Ga)Ga-DOTATOC that has not been previously described in the literature.

Aim and Objectives This study explores the case of a patient who presented to the nuclear medicine department for this examination. The patient reported a metallic taste in the mouth immediately after the administration of (^{68}Ga)Ga-DOTATOC with no prior history of this symptom.

Material and Methods Our pharmacovigilance centre was notified and we searched the European pharmacovigilance database, EudraVigilance to investigate a possible link between this symptom and (^{68}Ga)Ga-DOTATOC.

Results The patient's general condition remained stable and this symptom did not recur. An investigation into other possible causes, including excipients and radiolabelled impurities (with a free gallium content of 0.52%, within the ≤ 2% recommended threshold), was conducted. Based on the chronology of the event, our pharmacovigilance centre deemed the reaction probably imputable to (^{68}Ga)Ga-DOTATOC. However, the radiopharmaceutical preparation was not contraindicated for this patient. EudraVigilance, the European database for adverse drug reaction (ADR) reports, has identified 60 individual cases of SOMAKIT TOC up to 29 September 2024. Two of these cases reported dysgeusia with this drug.

Conclusion and Relevance This symptom, a metallic taste in the mouth, is probably an ADR associated with (^{68}Ga)Ga-DOTATOC. Pharmacovigilance plays a crucial role in identifying and documenting rare ADRs that have not yet been described in the literature. The use of the European database, EudraVigilance, and the World Health Organization's global database, VigiBase, can provide valuable insights into the safety profiles of diagnostic or even therapeutic radiopharmaceuticals.

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Conflict of Interest No conflict of interest

5PSQ-060 LEVERAGING THE WHO PHARMACOVIGILANCE DATABASE VIGIBASE: EXAMPLE OF THE SAFETY ANALYSIS OF (^{177}LU)LU-DOTATATE

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Background and Importance Radioligand therapy, a therapeutic application of the radiotheranostic concept, is based on the use of a therapeutic radiopharmaceutical that targets a biomarker of interest in a given pathology. One example is (^{177}Lu)Lu-DOTATATE, used in the treatment of metastatic or inoperable, well-differentiated gastroenteropancreatic neuroendocrine tumours expressing somatostatin receptors. Clinical trials used to determine the safety of the drug do not represent a 'real-life' population. In order to provide a comprehensive safety analysis, we have used the World Health Organization's pharmacovigilance database, VigiBase.

Aim and Objectives This study aims to elucidate a comprehensive safety profile with real-life data of a therapeutic radiopharmaceutical such as (^{177}Lu)Lu-DOTATATE using VigiBase.

Material and Methods An extraction of individual safety reports (ICSRs) reported and associated with (^{177}Lu)Lu-DOTATATE was performed. The general characteristics of the ICSRs were recorded. Adverse drug reactions (ADR) reporter in the ICSRs were sorted to create an ADR dictionary divided into classes and subclasses. A retrospective disproportionality analysis of ICSRs was then performed using the information component (IC, at alpha risk 0.05: IC_{025}). The different classes of ADR were described, including the identification of overlaps between classes and the time taken for ADR to appear after initiation of the radiopharmaceutical.

Results A total of 3,984 ICSRs related to (^{177}Lu)Lu-DOTATATE were analysed, with the majority of reports originating from the Americas (65%) and reported by physicians (45%). The most commonly co-reported drugs were octreotide (6%), amino acids (6%), ondansetron (6%), and lanreotide (5%). Disproportionality analysis identified significant associations between (^{177}Lu)Lu-DOTATATE and several ADR classes, including haematologic malignancies (IC_{025}=2.48), haematologic disorders (IC_{025}=2.15), liver disorders (IC_{025}=1.43), renal failure (IC_{025}=1.16), infections (IC_{025}=0.91), alopecia (IC_{025}=0.74), and metabolic disorders (IC_{025}=0.17). The overlaps between classes were identified, including an overlap between haematological disorders and infections. The median

time to onset of ADRs was also calculated and the longest delay was observed for haematologic malignancies.
Conclusion and Relevance The VigiBase pharmacovigilance database, offers essential insights into the safety profile of (^{177}Lu)Lu-DOTATATE and can be leveraged for the evaluation of the safety of other therapeutic radiopharmaceuticals.

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

5PSQ-061 ABSTRACT WITHDRAWN

5PSQ-062 COMPARISON OF THE EFFICACY AND SAFETY BETWEEN TICAGRELOR AND CLOPIDOGREL IN PATIENTS WITH ACUTE CORONARY SYNDROME UNDERGOING PERCUTANEOUS CORONARY INTERVENTION

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Background and Importance In the absence of complications, the European Society of Cardiology and American Heart Association guidelines recommend ticagrelor and prasugrel over clopidogrel in dual antiplatelet therapy (DAPT) following percutaneous coronary intervention (PCI) in patients with acute coronary syndrome (ACS). However, ticagrelor and prasugrel are associated with an increased bleeding risk, and the thrombotic and bleeding tendencies differ between Asian and non-Asian populations. Therefore, domestic studies and guidelines are warranted to optimise antiplatelet therapy in Asian patients.
Aim and Objectives This study aimed to compare the efficacy and safety of ticagrelor and clopidogrel in patients with ACS undergoing PCI, elucidating optimal antiplatelet therapy tailored to individual patient needs.
Material and Methods This retrospective observational study included patients with ACS undergoing PCI who were treated with either ticagrelor or clopidogrel in a tertiary hospital between January 2022 and June 2023. Major adverse cardiovascular events (MACEs) were analysed to evaluate efficacy, while major bleeding events were analysed for safety.
Results The study comprised 460 patients, including 129 (28.0%) and 331 (72.0%) patients treated with ticagrelor and clopidogrel, respectively. Analysis of patient characteristics showed that the patients in the clopidogrel group were significantly older, while the proportion of male patients were higher in the ticagrelor group ($p<0.001$ for both). The proportion of myocardial infarction among ACS types was higher in the ticagrelor group ($p=0.009$), hypertension and diabetes were more common in the clopidogrel group ($p=0.02$, $p=0.001$), and the length of hospital stay was significantly longer in the clopidogrel group ($p=0.007$). To minimise bias, propensity score matching (1:1) was performed, resulting in 49 matched pairs (98 patients). In the outcome analysis after matching, there was no significant difference in MACEs between the ticagrelor and clopidogrel groups (24.5% vs. 18.4%, $p=0.460$), and no significant difference in major bleeding events between the two groups (0.0% vs. 4.1%, $p=0.495$).
Conclusion and Relevance There was no significant difference in the efficacy and safety between ticagrelor and clopidogrel in patients with ACS undergoing PCI. Further multicentre, prospective studies are needed to provide stronger evidence for the optimal selection of antiplatelet agents.

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

5PSQ-063 EFFICACY AND SAFETY OF BENRALIZUMAB IN SEVERE EOSINOPHILIC ASTHMA IN A TERTIARY HOSPITAL

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Background and Importance Asthma is a chronic airway inflammatory disease that affects more than 300 million people worldwide. Approximately a quarter of these patients have severe eosinophilic asthma, characterised by the presence of eosinophils in bronchial biopsies and sputum. In the last few years, monoclonal antibodies such as mepolizumab, benralizumab, reslizumab or tezepelumab have been approved for its treatment.
Aim and Objectives To assess effectiveness and security of monoclonal antibody benralizumab for the treatment of severe eosinophilic asthma in real-life in a tertiary hospital.
Material and Methods Observational, descriptive and retrospective study carried out between July 2017 and September 2024, including adult patients treated with benralizumab for at least 1 year in a tertiary hospital. Variables included: age, sex, duration of treatment, eosinophil count, number of exacerbations, daily oral corticosteroid dose, and adverse effects associated with treatment. Data were extracted from digital medical records and in hospital electronic prescribing and they were analysed with the statistical program IBM SPSS statistics version 29.0.2.0.
Results Forty-four patients were included: female 88.6% (n=39) median of 55 years-old (rank 37–84). The median follow-up duration of the treatment was 30.3 months. The mean blood eosinophil count before the start of treatment was 549.0 ± 342.5 eosinophils/µl, and 11.8 ± 33.4 eosinophils/µl after treatment. There was a mean of 1.8 ± 2.2 exacerbations in the year before treatment and 0.3 ± 0.9 exacerbations in the year after. Eighteen patients were taking daily corticosteroids before treatment, reducing this to 14 after treatment. A total of 14 patients (31.3%) experienced adverse reactions associated with treatment, all of which were mild.
Conclusion and Relevance Benralizumab showed a significant reduction in eosinophil levels, the rate of exacerbations and the need for daily oral corticosteroids after treatment. In terms of safety, it has a moderate incidence of adverse effects. Therefore, it appears to be effective and safe.

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

5PSQ-064 EFFICACY AND SAFETY OF MEPOLIZUMAB IN SEVERE EOSINOPHILIC ASTHMA IN A TERTIARY HOSPITAL

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Background and Importance Asthma is a chronic airway inflammatory disease that affects more than 300 million people worldwide. Approximately a quarter of these patients have severe eosinophilic asthma, characterised by the presence of eosinophils in bronchial biopsies and sputum. In the last few years, monoclonal antibodies such as mepolizumab, benralizumab, reslizumab or tezepelumab have been approved for its treatment.
Aim and Objectives To assess effectiveness and security of monoclonal antibody mepolizumab for the treatment of severe eosinophilic asthma in real-life in a tertiary hospital.
Material and Methods Observational, descriptive and retrospective study carried out between July 2017 and September 2024, including adult patients treated with mepolizumab for at least 1 year in a tertiary hospital. Variables included: age, sex, duration of treatment, eosinophil count, number of exacerbations, daily oral corticosteroid dose, and adverse effects associated with treatment. Data were extracted from digital medical records and in hospital electronic prescribing and they were analysed with the statistical program IBM SPSS statistics version 29.0.2.0.
Results Thirty-one patients were included: female 67.7% (n=21) median of 59 years-old (rank 27–77). The median follow-up duration of the treatment was 37.7 months. The mean blood eosinophil count before the start of treatment was 487.9 ± 343.8 eosinophils/µl, and 85.9 ± 84.0 eosinophils/µl after treatment. There was a mean of 1.2 ± 1.7 exacerbations in the year before treatment and 0.4 ± 1.1 exacerbations in the year after. Seven patients were taking daily corticosteroids before treatment and this number was maintained after treatment. A total of nine patients (30.0%) experienced adverse reactions associated with treatment, all of which were mild.
Conclusion and Relevance Mepolizumab showed a significant reduction in eosinophil levels and in the rate of exacerbations after treatment, but no significant change in daily corticosteroid intake. In terms of safety, it has a moderate incidence of adverse effects. Therefore, it appears to be effective and safe.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-065 EVALUATION OF RESPIRATORY FUNCTION AND SAFETY OF ELEXACAFTOR/TEZACAFTOR/IVACAFTOR IN CHILDREN AND ADOLESCENTS WITH CYSTIC FIBROSIS FOLLOWED AT A REGIONAL REFERENCE CENTRE

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Background and Importance Elexacaftor/tezacaftor/ivacaftor (ETI) represents a highly potent cystic fibrosis (CF) transmembrane conductance regulator (CFTR) modulating treatment for individuals with CF who have at least one F508del mutation. However, there is a paucity of data on the safety and efficacy of ETI in children and adolescents.
Aim and Objectives This study aimed to evaluate the improvement in lung function and the safety of ETI in paediatric setting after 12 months of treatment.
Material and Methods This observational, single-centre, retrospective study analysed data from 27 paediatric patients treated with ETI at a Regional Reference Centre for Cystic Fibrosis between July 2021 and November 2023. Patients were divided into two age groups: 6–11 years (N=10) and 12–17 years (N=17). The primary outcome was the change in the percent predicted forced expiratory volume in one second (ppFEV1) at 6 and 12 months. Secondary outcomes included the evaluation of adverse drug reactions (ADRs), mortality rates, and transplantation rates. Statistical analyses were performed using Mann-Whitney, Kruskal-Wallis, and one-way ANOVA tests using R software.
Results The average age of the 27 patients analysed was 12 (7,17) years, with 66.7% being female. After 6 months of ETI therapy, an increase in ppFEV1 of 5% and 22.7% from baseline was observed for the 6–11 years and 12–17 years groups, respectively, with stabilisation of values at the second follow-up after 12 months of treatment (ppFEV1=96 vs ppFEV1=94.5; ($p<0.001$)). The statistically significant difference in ppFEV1 between the two groups is a consequence of the more critical baseline clinical conditions observed in the 12–17 age group. During the study, no transplants or deaths occurred among patients treated with ETI. Three ADRs were recorded: two cases of moderate increase in creatine phosphokinase (CPK) and one mild episode of skin rash. All reactions were resolved by dosage reduction.
Conclusion and Relevance The results showed a significant improvement in respiratory function in patients after 12 months of therapy, suggesting that early treatment with ETI could prevent severe long-term complications. However, further long-term observations and real-world data are needed to confirm the safety and efficacy of the treatment in children and adolescents with CF.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-066 EVALUATION OF CEFTAZIDIME/AVIBACTAM USE AND CLINICAL OUTCOMES IN PATIENTS WITH MULTIDRUG-RESISTANT GRAM-NEGATIVE INFECTIONS

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Background and Importance Antibiotic resistance is considered a major global public health issue. Ceftazidime/avibactam (CZA) was launched in July 2023 for the treatment of resistant gram-negative bacterial infections that do not respond to carbapenem antibiotics. Its use has been gradually increasing since it was newly included on the reimbursement list in February 2024.
Aim and Objectives For the safe and effective use of CZA, this study aimed to investigate the status of CZA use and evaluate the appropriateness and clinical outcomes.
Material and Methods Electronic medical records were retrospectively collected from adult patients who were admitted to tertiary hospital and treated with CZA for at least 3 days between July 2023 and July 2024. The status of CZA use,

including indications, dosage, and administration was examined. Its efficacy was assessed in terms of the treatment success rate, 30-day mortality, and improvement in clinical laboratory results.

Results Of the 229 patients who used CZA, 175 were included in this study in accordance with the exclusion criteria. The most frequently identified pathogen was *Klebsiella pneumoniae* (159 patients, 91%). Furthermore, 101 (58%) patients were administered with CZA for its approved indications, while 74 (42%) patients were treated for unapproved indications, such as bacteraemia. In addition, 168 (96%) patients adhered to the approved dosage and administration. The overall treatment success rate was 63%, but it did not significantly differ according to indication. Among the patients, 40 (29%) were treated with combination therapy. The treatment success rate against bacteraemia was significantly higher in patients who received monotherapy than in patients who received combination therapy ($p<0.05$). Furthermore, 42 (24%) patients died within 30 days of their last CZA administration, but mortality had no significant differences in terms of indications or concomitant use of other antibiotics.

Conclusion and Relevance In conclusion, the treatment success rate of monotherapy with CZA was significantly higher than that of combination therapy in patients with bacteraemia. Additionally, there were no significant differences observed in the treatment success rates or 30-day mortality in terms of indications. For the safe and effective treatment of multidrug-resistant infections, the appropriate use and management of CZA as a restricted antibiotic should be continuously monitored.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-067 ANALYSIS OF THE HIV (HUMAN IMMUNODEFICIENCY VIRUS) POST-EXPOSURE PROPHYLAXIS (PEP) PROGRAMME IN A TERTIARY HOSPITAL

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Background and Importance Post-exposure prophylaxis (PEP) to HIV is used to prevent transmission of the virus after a risky exposure and can be classified as occupational (OPEP) or non-occupational (NOPEP). To implement these PEP programmes, a protocol has been in effect since 2016.

Aim and Objectives Analyse whether the clinical practice adapts to the protocol developed in a hospital and detect improvement points. Moreover, to perform a descriptive analysis of the population served at the centre.

Material and Methods The study follows a retrospective and descriptive analysis of patients treated in the PEP programme from 2016 to 2023 who were treated after HIV exposure according to the protocol. It includes description of clinical visits, serologies and dispensations of the medication.

Results A total of 92 patients were analysed, 65 men, median age 30 years (16–63). The established protocol was followed in 80 (87%) patients. The time to start PEP was less than 24 hours in 61/92 patients. In 70 patients the exposure was NOPEP type while 22 patients follow OPEP. In the NOPEP group, the sexual route occurred in 69/70 patients, and in the OPEP group the percutaneous route through a hollow needle was the most abundant. Also, 81/92 patients completed the treatment.

Statistics show that 87% of the patients attended the specialist clinical consultation and 72% attended the monthly follow-up. Initial serology was performed in 97% of patients and control serology in 64%. All results were negative except one case. Losses to follow-up are mainly due to transfers to the reference healthcare area or unknown reasons. One patient stopped treatment after reevaluation. Only seven patients were included in PreP (pre-exposure prophylaxis programme).

Conclusion and Relevance The circuit of action is well defined in the protocol. The initiation of PEP and baseline serologies are carried out adequately, but the follow-up through clinical consultations and serologies after 1 month is a point that can be improved. Furthermore, the population studied agrees in characteristics with those of the reference population.

This study shows the importance of implementing standardised protocols in the clinical approach. This implies its periodic review. Additionally, this protocol allows passive recruitment in PreP programmes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-068 ANALYSIS OF RELAPSES AFTER DISCONTINUATION OF PROPHYLACTIC BIOLOGIC TREATMENT IN MIGRAINE

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Background and Importance Monoclonal antibodies (mAbs) targeting the calcitonin gene-related peptide (CGRP) have proven to be effective in migraine prophylaxis for a maximum duration of a year, so discontinuation can be considered after this period. In those cases, there is a lack of data about the requirement of restarting the treatment in these patients.

Aim and Objectives To analyse patients who had restarted treatment with anti-CGRP mAbs for migraine prophylaxis after completing 1 year of treatment.

Material and Methods Observational and retrospective study conducted at a tertiary hospital with a specialised headache clinical consultation. Anti-CGRP mAb treatment were discontinued after 1 year .

All patients diagnosed with chronic or episodic migraine who had started treatment with galcanezumab, fremanezumab, and erenumab from July 2020 to April 2024 (32 months) were analysed.

Variables: gender, mAb used, treatment duration (before and after restarting, in months), and time without requiring mAbs (in months). Follow-up visits at the headache consultation were scheduled at least every 3 months.

Results 176 patients (79.3% women; median age: 37 years (IQR: 31–53)) were included. 56 were treated with galcanezumab (31.8%), 54 with fremanezumab (30.7%), and 66 with erenumab (37.5%).

Only 99 (56.3%) patients maintained treatment for a year (36 galcanezumab, 34 fremanezumab and 29 erenumab).

Among these patients, 65 (65.6%) required retreatment with an mAb, with a median time to relapse of 3 months (IQR: 3–6). 18 patients remained without treatment for 9 months or more, and 12 patients for a year or more. A total of 34 (34.4%) patients remained without anti-CGRP mAb treatment at the study endpoint.

By specific mAb, 22/36 patients (61.1%) treated with galcanezumab, 24/34 patients (70.6%) treated with fremanezumab, and 24/29 patients (82.8%) treated with erenumab restarted treatment with a median time to relapse of 3 months (IQR: 3–7), 3 months (IQR: 3–8), and 3 months (IQR: 3–4), respectively.

Conclusion and Relevance A high percentage of patients require reinitiation of anti-CGRP mAb treatment after discontinuation at 12 months, with most relapses occurring early. However, in some patients, this approach appears to be effective. It is crucial to further analyse the differences between patients who restart treatment and those who do not.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-069 QT-PROLONGING DRUGS IN HIGH-RISK POST-SURGICAL PATIENTS: ARE WE AWARE OF THEIR RISKS?

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Background and Importance QT interval prolongation (iQT) is associated with life-threatening ventricular arrhythmias, notably Torsades de Pointes (TdP). Medications are the primary cause of QT prolongation, frequently prescribed to hospitalised patients, particularly in the post-surgical setting.

Aim and Objectives To evaluate the result of pharmaceutical interventions (PIs) related to the use of QT-prolonging drugs (QTPDs) in post-surgical patients at high-risk of developing arrhythmias.

Material and Methods A prospective longitudinal study was conducted over 4 weeks in a tertiary care hospital.

Inclusion criteria: post-surgical patients prescribed at least one QTPD during hospitalisation.

Variables: number and type of QTPDs, presence of key risk factors (RFs), number and type of PIs, and whether prescribers followed recommendations.

Data were collected from the prescription system and Electronic Medical Record, later analysed using Excel.

PIs were conducted for patients with two QTPDs or with one QTPD and three or more RFs. QTPDs were identified from the AZCERT database. RFs were selected from the RISQ-PATH scale: female sex, age > 65, and cardiac, thyroid, or electrolyte disturbances (hypokalaemia, hypocalcaemia). Interventions were standardised into four categories: electrocardiographic monitoring, deprescribing or dose reduction, substitution with safer alternatives, and general recommendations (adjusting modifiable RFs and risk-benefit consideration).

PIs were communicated through the prescription system and/or phone calls, with a 3-day follow-up to evaluate physician adherence to interventions. Patients not initially intervened were monitored until discharge for potential new RFs.

A descriptive statistical analysis was performed, using absolute frequency for categorical variables and geometric mean or median for quantitative variables.

Results Sixty-two patients were included (58% female, median of 66.5 years with an interquartile range of 26, mean of 11.9 ±4 prescribed medications). The most frequently prescribed QTPDs were antibiotics (44.9%), followed by nervous system (27.5%) and digestive system drugs (23.2%). Sixty-five interventions were performed in 28 patients. General recommendations were the most frequent intervention (n=28), followed by electrocardiographic monitoring (n=25), dose reduction (n=8), and therapeutic substitution (n=4). 10.7% of PIs led to prescriber changes.

Conclusion and Relevance Only 10.7% of PIs resulted in prescriber changes, reflecting low intervention acceptance. Given that PIs were limited to high-risk patients with clearly defined risks, greater awareness of the safe use of these medications is needed for healthcare professionals.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-070 PROMPT SWITCHING OF INTRAVENOUS TO ORAL ANTIBIOTICS – A QUALITY IMPROVEMENT APPROACH

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Background and Importance NHS England identified a Commissioning for Quality and Innovation (CQUIN) indicator for Intravenous antibiotics to oral switch (IVTOS).

After the pandemic the use of antibiotics increased in our Trust.

Evidence shows benefits to IVTOS: increase bed capacity, optimise administration nurse's time in preparing and administering antibiotics as well as reducing carbon footprint of medicines and reducing infections from the IV site.

Aim and Objectives To identify the number of patients on intravenous (IVA) antimicrobials that could be eligible for oral switch, aligning with Commissioning for Quality and Innovation (CQUIN) indicators, as per national recommendations about IVTOS to be considered within 48 hours of the first dose of IV antimicrobial being administered.

Material and Methods Snap tool designed to conduct audit on adult wards quarterly (aiming to include 100 patients' each quarter).

Patients had to be on IVA for a minimum of 48 hours.

Collaboratively auditors were clinical nurses, pharmacist and junior doctors at each quarter, including 3–5 patients on IVA per ward.

If the defined IVTOS criteria were met, the patient was considered eligible for IVTOS:

AFEBRILE: Temperature 36–38 for past 24 hours

CLINICALLY IMPROVING: Clinical signs and symptoms of infection are improving, reduction in NEWS score, WCC trending normal, CRP decreasing

EATING AND DRINKING: Patient is tolerating oral food or enteral feeding. No vomiting within last 24 hours. No evidence of malabsorption

NO DEEP-SEATED INFECTION: Not at high-risk of deep-seated infection i.e. endocarditis, blood stream infection, empyema, meningitis, severe or necrotising soft-tissue infection, septic arthritis or undrained abscess

Results A total of 443 patients were audited. The patients receiving IVA that met criteria for IVTOS were reduced. One in four patients remained on IVA past the criteria for switching in Q1. The year ended with 1 in 6 patients remaining on IVA past the criteria for switching.

Conclusion and Relevance Collaborative approach auditing in a multidisciplinary way showed engagement and a reduction of patients eligible to IVTOS.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

5PSQ-071 SAFETY PROFILE OF APALUTAMIDE FOR THE TREATMENT OF PROSTATE CANCER IN CLINICAL PRACTICE

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Background and Importance Apalutamida is a second-generation androgen receptor inhibitor used for the treatment of prostate cancer (PC). Its safety was demonstrated in the phase 3 studies (ARN-509–003 and 56021927PCR3002).

Aim and Objectives Study of safety of apalutamide in a third-level hospital

Material and Methods Observational, retrospective, descriptive study in which all patients who started treatment with apalutamide were included (2022 and 2023). The data were obtained from the electronic medical record and the pharmacotherapeutic history elaborated in the oncohaematological pharmaceutical care consultation. The following variables were collected: age, sex, quality of life (ECOG, Eastern Cooperative Oncology Group scale), baseline PSA (prostate-specific antigen) values, type of metastasis and adverse effects (AEs), as well as duration, discontinuation or suspension of treatment and reasons for discontinuation.

Results Thirty-four patients were included with a median age of 73 (IQR 'Interquartile Range', 69 – 82), 88% of them diagnosed with mHSPC (Metastatic Hormone-Sensitive PC, M1a 23%, M1b 47% and M1c 30%) and 12% nmCRPC (Nonmetastatic castration-resistant PC). The baseline ECOG was 0–1 in 97% (33/34), and ECOG 2 in 3% (1/34). The median PSA at baseline was 2.88 ng/mL (IQR 14.75–0.63).

Regarding safety, 94.1% (32/34) of patients reported any AE. A total of 78 AEs were analysed, the most common being hot flushes (19%, 15/78), asthenia (19%, 15/78), and arthralgia (18%, 14/78), followed by skin rashes (15%, 12/78) and diarrhoea (6%, 5/78). Falls accounted for 4% (3/78), hypothyroidism 3% (2/78) and tachycardia 3% (2/78) of AEs. Less frequently detected AEs (<2%) were hypertension, hypotension, hypercholesterolaemia, headache, lacrimation, salivation, taste alteration, irritability, somnolence, weight loss.

During the study period, 29% (10/34) of patients discontinued treatment due to lack of efficacy (9%, 3/34) and 20% (7/34) for safety reasons (falls (60%, 4/7) and tachycardia (28%, 2/7). Median duration of treatment was 4.6 months (IQR 10.5–2).

Conclusion and Relevance Results showed a safety profile of apalutamide in accordance with the data obtained in the literature. Most patients reported treatment-related AEs. A high percentage of patients discontinued treatment for safety reasons, mostly related to falls or tachycardia.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-072 DRUG PRESCRIPTION IN HEPATIC CIRRHOSIS: PITFALLS AND ROOM FOR IMPROVEMENT

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Background and Importance In our region, the prevalence of cirrhosis is 3 per 1,000 inhabitants. It is estimated that approximately 20% of prescriptions in patients with cirrhosis are inappropriate due to inadequate dosing or contraindication. This can lead to adverse drug reactions that are preventable.

Aim and Objectives To evaluate the adequacy of medications in patients with cirrhosis according to their hepatic disease.

Material and Methods Cross-sectional drug utilisation study. Patients with a diagnosis of hepatic cirrhosis in their electronic clinical record until June 2023 were included. Collected variables were: age, gender, Child-Pugh classification and prescribed medications between April and June 2023.

Prescriptions of contraindicated drugs in cirrhosis such us analgesics, antidepressants, antidiabetics, antihistamines, antibiotics, antipsychotics, antithrombotics, benzodiazepines, cardiovascular and digestive therapies were reviewed. Safety information was checked in *Geneesmiddelen bij* database.[1] Due to the lack of Child-Pugh classification in most of the patients' clinical records, only contraindicated drugs in all stages of cirrhosis were analysed.

Results A total of 1326 patients (64.1% males) with mean age of 65±12 years were included. The severity of cirrhosis was unknown in 89.6% of patients, 52 patients were classified as Child-Pugh A (3.9%), 63 as Child-Pugh B (4.8%) and 23 as Child-Pugh C (1.7%).

One quarter of patients (25.3%) had a prescription of a contraindicated drug. Most frequently involved medication groups were: proton pump inhibitors (pantoprazole, lansoprazole): 38.5%, lipid-lowering drugs (atorvastatin): 30.4%, non-steroidal anti-inflammatory drugs (ibuprofen, dexketoprofen, naproxen, celecoxib, etoricoxib, diclofenac, aceclofenac, lornoxicam and chondroitin sulphate): 21.3% and hypnotics (zolpidem): 7.4%.

Conclusion and Relevance Prescription in cirrhosis must improve. The prevalence of patients taking contraindicated drugs in cirrhosis in our study is slightly higher than in bibliography, in spite of there being safer options available for all of them. The lack of knowledge about drug management in cirrhosis and the need for information and training in this field are highlighted.

It is important to grade cirrhosis according to the Child-Pugh classification, as drugs can be contraindicated depending on stage.

We propose to implement a prescription-related alert system, which alerts about contraindicated drugs in cirrhosis and suggests safer alternatives.

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Conflict of Interest No conflict of interest

5PSQ-073 ASSOCIATION BETWEEN ATORVASTATIN TREATMENT AND ELEVATED PLASMA LACTATE LEVELS

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Background and Importance Elevation of plasma lactate (LA) levels occurs without apparent cause in a subgroup of patients, and drug induction should be considered in these cases.

Aim and Objectives The aim was to assess the risk of such an increase in patients treated with atorvastatin (ATV).

Material and Methods A 1 year retrospective observational study of patients admitted to the internal medicine department of a general hospital and treated with ATV 10–80 mg was conducted. Patients on previous or current drug treatment and/or with diseases that altered plasma lactate values were excluded.

The number of days of treatment of all drugs forming part of the therapy of each patient in the sample (exposure-treatment-day (ETD)) was the main variable. Group I, composed of ETDs with lactate >4mmol/L and Group II composed of ETDs with lactate <4mmol/L. Finally, to measure the strength of the association, the odds ratio (OR) (ATV-exposed versus non-exposed) was calculated for each group and, finally, the OR between the two groups.

Data were obtained from the hospital's laboratory and assisted electronic prescribing registry systems. To calculate the statistical significance of the differences, the Chi-squared test was used, using the Bonferroni correction, taking into account that the number of drugs tested was 28 (n=28; p<0.05/28=0.0017).

Results The number of patients in the sample was 640: age=87±6 years; body mass index=31.3±2.9kg/m2; female=47%.

Number of drugs=28; total number ETD=5220 total number ETD with lactate ≥4mmol/L=319; total number ETD with lactate<4mmol/=4901. OR=2.0 (CI 95%:1.52–2.63; Z4.97; p<0.0001): Group I (ATV exposed/not exposed):73/632 vs Group II (ATV exposed/not exposed): 246/4269.

According to the OR obtained, the risk of LA appears to be moderate (2 ≤OR <3, according to Cohen's criteria). However, given that ATV is used in the pharmacological prophylaxis of various pathologies, where it is used in conjunction with other drugs which, in turn, may also increase the risk of LA, which could be elevated and in certain cases even lead to lactic acidosis.

Conclusion and Relevance The risk of plasma lactate concentration above 4 mmol/L with the use of atorvastatin (10–80 mg) in its various indications appears to be moderate (OR=2). However, vigilance is recommended when used in conjunction with other drugs with the same toxicity profile.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-074 SEQUENTIAL MONOCLONAL ANTIBODY THERAPY IN PSORIASIS MANAGEMENT: EVALUATING CLINICAL OUTCOMES AND TREATMENT DURABILITY

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Background and Importance Psoriasis is a chronic inflammatory skin disorder. Monoclonal antibodies (mAbs) have revolutionised psoriasis treatment. Some patients experience suboptimal responses or adverse events, necessitating treatment modifications. Switching mAbs offers a therapeutic strategy to address these challenges.

Aim and Objectives Evaluation of the efficacy, safety, and persistence of mAb switching in psoriasis treatment based on real-world clinical practice in a tertiary hospital

Material and Methods A retrospective observational study was conducted, including all psoriasis patients who switched from one mAb to another from January 2017 to December 2023. The following data were collected: patient demographics (sex, age), initial disease characteristics (Psoriasis Area and Severity Index – PASI), duration of initial mAb treatment, reasons for switching, efficacy outcomes (PASI score, PASI 75 and PASI 90), and adverse events. Statistical analysis comprised descriptive analysis of all variables, followed by comparison tests to evaluate significant differences before and after mAb switching.

Results The study included 124 psoriasis patients (61% male), with a median age of 55 years (range: 18–102 years). The median initial PASI score was 22 (interquartile range -IQR-: 14–35 points). The median duration of initial mAb treatment was 15 months (IQR: 7–23 months). Initially used mAbs were adalimumab (49.6%), ustekinumab (37.6%), secukinumab (9.6%), and guselkumab (3.2%). The most common reasons for mAb switching were loss of efficacy (67%), lack of response (18%), and adverse effects (15%). The median reduction in PASI score after switching mAbs was 62% (IQR: 14–73%). After mAb switching, 82% of patients achieved a PASI 75 response, and 57% achieved a PASI 90 response. The median duration of treatment after mAb switching was 13 months (IQR: 5–21 months). 20.2% of patients required two

or more mAb switches due to lack of response (96%) or intolerance (4%) to previous mAbs.

Conclusion and Relevance Switching between monoclonal antibodies represents a viable option for treating psoriasis patients with inadequate response or intolerance to initial treatment. The results suggest that switching can provide significant clinical benefits, with acceptable safety and good long-term treatment persistence. The efficacy of mAb switching is supported by significant improvements in PASI and DLQI scores. Safety profiles after mAb switching are generally favourable, with no unexpected safety signals identified.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-075 EFFICACY AND PATIENT-REPORTED OUTCOMES OF TENECTEPLASE AND ALTEPLASE IN ACUTE STROKE MANAGEMENT: A COMPARATIVE ANALYSIS

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Background and Importance Acute ischaemic stroke is a leading cause of disability and mortality worldwide, with timely thrombolytic therapy being crucial for improving outcomes. Two commonly used thrombolytic agents are tenecteplase and alteplase.

Aim and Objectives Comparison of the quality of life and survival rates of patients treated with tenecteplase with alteplase at a tertiary care hospital after an acute ischaemic stroke.

Material and Methods A retrospective observational study was conducted, reviewing data from patients admitted with ischaemic stroke and treated with either tenecteplase or alteplase at a tertiary care hospital over a 1 year period (January 2022 to December 2022). Primary outcome measures were survival rates and quality of life scores at 30- and 90-days post-treatment. Secondary outcome measures included rates of symptomatic intracranial haemorrhage (sICH), vascular reocclusion, length of hospital stay, and discharge destination. Quality of life was assessed using the EuroQol-5D questionnaire.

Results Fifty-four patients were included (67.2% male), with a median age of 62 years (range 21–79). Tenecteplase was administered to 12.96% of the patients, while the remaining 88.52% received alteplase. No significant differences were observed in survival rates between the tenecteplase and alteplase groups at 30 (85.71% vs 83.74%) and 90 days post-treatment (71.42% vs 69.4%). However, there was a significant difference in quality of life scores, with the tenecteplase group achieving higher scores (0.53 ± 0.14 vs 0.41 ± 0.03 and 0.76 ± 0.08 vs 0.60 ± 0.03 at 30 and 90 days, respectively, where 0 and 1 represent the worst and best possible health states, respectively). No significant differences were found in sICH rates (14.29% vs 11.42% for tenecteplase and alteplase, respectively) or vascular reocclusion rates (14.29% vs 12.76%). Length of hospital stay was not statistically significant (8.2 ± 3.6 vs 9.3 ± 3.1 days), although a higher percentage of patients in the tenecteplase group were discharged home or to rehabilitation centres (85.71% vs 79.09%).

Conclusion and Relevance The analysed results suggest that tenecteplase is non-inferior to alteplase in terms of efficacy for the treatment of acute ischaemic stroke, with a potential advantage in quality of life outcomes. These findings correlate with those published in the ATTEST and NOR-TEST trials. However, further studies are needed to confirm these results in clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-076 COMPREHENSIVE ASSESSMENT OF PHARMACOTHERAPY IN THE COMPLEX CHRONIC PATIENT AS A SECURITY STRATEGY

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Background and Importance Complex chronic patients (CCP) have changing needs that require continuous reassessment. Care transition makes parmacotherapeutic review and reconciliation fundamental to find discrepancies and ensure the safety of these patients.

Aim and Objectives To analyse a comprehensive pharmacotherapy assessment program (CPAP) impact in the number of discrepancies and high-risk discrepancies at discharge between groups, intervention patients and control patients, who had medication list in the discharge report in order to compare with the electronic prescription.

Material and Methods Prospective intervention study in the emergency department of a tertiary hospital between 01/09/2023–11/30/2023.

Inclusion criteria: Complex chronic patients who consulted emergency department and were not institutionalised or palliative. CPAP was performed in <24 h/48h in the emergency department that included: conciliation, review of pharmacotherapy and issue of a pharmacotherapeutic recommendations report.

Variables: age, sex, Charlson index, polypharmacy, hyperpolypharmacy, number of patients with discrepancies and high-risk discrepancies, number of discrepancies and high-risk discrepancies and most related high-risk discrepancy drugs.

Results No statistically significant differences have been found between intervention patients and control patients in the following variables (N=151). Intervention patients vs control patients: Age: 82.9 vs 81.5. Sex: 79 male (52.3%) vs 59 male (39%). Charlson index:7 vs 7. Polypharmacy:142 (94%) vs 140 (92.7%). Hyperpolypharmacy: 81(57.4%) vs 88 (58.3%).

Of the patients who were discharged and had a medication list in the discharge report:

Intervention patients (96): 74 (77.8%) patients had 256 discrepancies (3.46 discrepancies/patient). 41 (55.4%) patients had 53 high-risk discrepancies (1.29 high-risk discrepancies/patient).

Control patients (82): 70 (85.4%) patients had 326 discrepancies (4.66 discrepancies/patient). 47 (55.4%) patients had 78 high-risk discrepancies (1.66 high-risk discrepancies/patient).

If both groups are compared, there are statistically significant differences in the number of discrepancies between

groups (p=0,02) and the number of high-risk discrepancies (p=0,005).

Pharmacologic groups/drugs with the highest number of high-risk discrepancies were: insulin, analgesics (tramadol), antipsychotic (quetiapine) and benzodiazepines (lorazepam).

Conclusion and Relevance

- In more than half of the patients there are discrepancies between treatment described in the discharge report and their electronic prescription, which is a safety problem.
- There are statistically significant differences between groups showing that CPAP can reduce the number of patients with discrepancies and high-risk discrepancies.
- Most drugs with the highest number of high-risk discrepancies were nervous system related.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-077 MICROBIOLOGICAL CONTAMINATION FOLLOWING THE USE OF TWO COMPOUNDED FORMULATIONS OF TACROLIMUS EYE DROPS

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Background and Importance Tacrolimus eye drops are sterile formulations prepared in hospital pharmacy departments. The classic formulation (F1) contains ethanol as a solubiliser, which may potentially cause irritation to the ocular surface. A novel ethanol-free formulation (F2) has been developed using cyclodextrin. While cyclodextrins are not toxic to the ocular surface, they are sugars, which could increase microbiological contamination by acting as a growth medium.

Aim and Objectives To determine microbial contamination derived from the use of both formulations.

Material and Methods F1 is tacrolimus 0.03% eye drops, it was prepared using Prograf ampoules (containing ethanol as excipient) and Liquifilm. F2 is tacrolimus 0.015% eye drops; it was prepared from tacrolimus raw material and 40% hydroxypropyl-beta-cyclodextrin (HPβCD) solubilised in Liquifilm. Both were prepared under sterile conditions. Microbiological controls were negative. Two bottles of each formulation were dispensed per patient, who were instructed to use one bottle/week and to store them in the refrigerator. Containers were returned and analysed in pairs as they were dispensed. 250 µL of each of the two containers of TE were instilled into an 8 mL brain-heart infusion (BHI) tube and into a 5 mL thioglycolate (TG) tube. The same procedure was done for TCD. The BHI broth was incubated for 14 days at room temperature, while the TG broth was incubated for 4 days at 37°C, both in aerobiosis. Those that developed appreciable turbidity during incubation were subcultured to AS-CHOCO and Sabouraud, incubated in aerobiosis for 24 hours at 37°C. Identification was made with MALDI-TOF MS.

Results A total of 45 patients returned their used containers (180). After analysis, 16 samples of F1 and 12 for F2 were positive. The following microorganisms were isolated and identified: Acinetobacter sp. (n=1), Bacillus sp. (n=3), Chryseobacterium indologenes (n=1), Elizabethkingia miricola (n=2), Enterococcus faecalis (n=1), Pantoea agglomerans (n=2), Pseudomonas sp. (n=5), Raoultella ornithinolytica (n=1), Serratia liquefaciens (n=4), Serratia grimesii (n=2), Serratia proteamaculans (n=2), Serratia marcenses (n=1), Stenotrophomonas maltophilia (n=5), Rahnella aquatilis (n=2). No evidence of infection was observed.

Conclusion and Relevance Both tacrolimus formulations were similarly contaminated due to improper manipulation by the patient. The incorporation of cyclodextrins is expected to mitigate ocular irritation while maintaining an equivalent risk of microbial contamination.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-078 EXTRAVASATION MANAGEMENT AWARENESS IN NURSING STAFF IN A TERTIARY CARE HOSPITAL

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Background and Importance Extravasation of cytotoxic agents is a serious complication in cancer treatment that requires immediate and effective management. Nurses administering chemotherapy, especially vesicant agents, must stay updated on the latest evidence regarding the identification and treatment of extravasation. Educated nurses are essential for detecting, managing, and documenting extravasation events. Their role is crucial in preventing such incidents and ensuring patient safety through proactive interventions.

Aim and Objectives This study aimed to evaluate the level of awareness among nursing staff handling cytotoxic and biological anticancer agents, focusing on their knowledge and practices in managing extravasation.

Material and Methods A prospective, single-centre, cross-sectional study was conducted by hospital pharmacists during mandatory cytotoxic drug training sessions between November 2023 and September 2024. The survey targeted nursing staff involved in administering cytotoxic and biologic agents at a tertiary care hospital. An anonymous 10-item questionnaire was used to assess knowledge and experience in extravasation management, covering years of practice, knowledge of risk factors and high-risk agents, symptom recognition, previous experience with extravasation, and awareness of antidote availability. The data were statistically analysed.

Results A total of 116 nurses participated in the survey. Despite 72.0% having over 10 years of healthcare practice, 57.8% had never encountered extravasation cases, indicating limited hands-on experience. Regarding venous access, 86.0% expressed confidence in selecting appropriate veins for cytotoxic drug administration. While the vast majority (93.1%) had partial knowledge of risk factors such as repeatedly cannulated veins, lymphedema or obesity, only 38.1% of experienced nurses could fully describe the signs

of extravasation. Additionally, 10 nurses (8.6%) indicated they did not educate patients about the signs and symptoms of extravasation. Half of the participants correctly identified dimethyl sulfoxide (DMSO) 99% as the antidote for anthracyclines, whereas only 7.8% selected hyaluronidase with warm compresses for vinca alkaloids. Although more than two-thirds of the nurses knew where antidotes were stored, 25.0% were unsure, revealing a need for better communication and training.

Conclusion and Relevance Despite local standards being in place, the study revealed gaps in nurses' awareness of extravasation management, especially concerning patient education and antidote use, highlighting the necessity for enhanced and regular training in diagnosis and treatment of extravasation to improve patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-079 CONTINUED USE OF POTENTIALLY INAPPROPRIATE MEDICATION AFTER HOSPITAL DISCHARGE: A RETROSPECTIVE COHORT STUDY

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Background and Importance Many patients receive temporarily indicated medications when they are hospitalised, e.g. opioids, benzodiazepines and/or antipsychotics. When such medications are continued at hospital discharge, it can result in potentially inappropriate medication (PIM) use post-discharge. However, there are no data available about continued use of PIMs at home in the Netherlands.

Aim and Objectives Therefore, the aim was to investigate the incidence of continued use of in hospital-initiated opioids, benzodiazepines, and antipsychotics post-discharge in the Netherlands.

Material and Methods A retrospective cohort study was conducted in a Dutch teaching hospital. Patients aged ≥18 years and discharged from the hospital between January 2019 to May 2023 with a new prescription of an opioid, benzodiazepine or antipsychotic started during hospitalisation and continued at discharge, were included and followed-up for 1 year. Data from the hospital information system and dispensing records of community pharmacies (Nationwide Medication Record System) were used to identify patients who continued use post-discharge. Primary outcomes of this study were the incidence of continued PIMs prescriptions post-discharge for each of the medication classes of interest and duration of use. Duration of use was classified into <30 days, 30–182 days and >182 days. Descriptive statistics were used to analyse the data.

Results Among 6,835 patients with a new prescription of one of the study medications, 82.7% were prescribed and dispensed an opioid at discharge (n=5,652, mean age 61.1 years, 57.3% female), 14.7% a benzodiazepine (n=1,005, mean age 60.7 years, 53.3% female) and 2.6% an antipsychotic (n=178, mean age 69.2 years, 48.9% female). 62.5% of new benzodiazepine users, 73.4% of new opioid users and 42.1% of new antipsychotic users had a duration of continued use of <30 days post-discharge. A substantial number of patients had a duration of PIM use >182 days post-discharge (13.4% of opioid, 20.9% of benzodiazepine and 36.0% of antipsychotic medication users).

Conclusion and Relevance This study found that antipsychotics were most often continued >182 days post-discharge, followed by benzodiazepines and opioids. These results highlight the importance of recognising PIMs and emphasise the need for careful evaluation of discontinuing these medications at hospital discharge or specifying a discontinuation date.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-080 CISPLATIN-INDUCED NEPHROTOXICITY AND ELECTROLYTE IMBALANCES IN HYPERTHERMIC INTRAPERITONEAL CHEMOTHERAPY (HIPEC)

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Background and Importance Hyperthermic intraperitoneal chemotherapy (HIPEC) with cisplatin during cytoreductive surgery (CRS) offers survival benefits in peritoneal carcinomatosis. However, cisplatin is associated with significant renal toxicity. In patients undergoing HIPEC, the prevalence of postoperative acute kidney injury (AKI) can be as high as 48%. Prophylactic treatment with sodium thiosulfate (ST) can be effective to avoid this complication, but evidence seems weak. Additionally, cisplatin can cause electrolyte imbalances.

Aim and Objectives To evaluate the renal toxicity of HIPEC with cisplatin while using ST as prophylaxis, as well as the possible alterations in serum potassium and sodium levels caused by the procedure.

Material and Methods We conducted a retrospective observational study, which included demographic and clinical data of patients treated with HIPEC with cisplatin from January 2023 to June 2024 at a tertiary hospital. All patients received prophylaxis against AKI with ST and adequate hydration. ST was administered as a bolus 15 minutes before HIPEC and as a 6-hour perfusion afterwards. Renal function was assessed by blood parameters applying Kidney Disease Improving Global Outcomes (KDIGO) criteria.

Results Thirty-eight patients were included (63.2% women), with a median age of 67 (IQR: 52, 72) years-old. Primary tumours included 27 colonic (71.1%), four appendiceal (10.5%), two ovarian (5.3%), two gastric (5.3%) and others.

No significant adverse effects were detected with TS.

Three patients (7.9%) developed AKI stage I, two on postoperative day (POD) 1, and one on POD2. On POD7, all of them had recovered from AKI. There were no cases of AKI stage II or III.

Prior to the intervention, no patients exhibited hypokalaemia. Between POD 1 and POD 2, 52.6% of patients experienced hypokalaemia, persisting in 34.2% on POD7. Of those with hypokalaemia, 69.6% were mild, 26.1% moderate and 4.3% severe.

Before HIPEC, two patients (5.3%) manifested mild hypernatraemia. Between POD1 and POD2, 21.1% developed mild hypernatraemia. All patients had resolved it by POD7.

Magnesium serum levels were not monitored frequently enough to allow for evaluation.

Conclusion and Relevance ST may be a safe and effective prophylactic treatment for cisplatin-induced AKI in HIPEC. Further studies are needed to strengthen these findings.

Electrolyte imbalances are a frequent adverse effect of HIPEC with cisplatin, especially hypokalaemia.

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

5PSQ-081 DOCETAXEL, ABIRATERONE AND ANDROGEN DEPRIVATION THERAPY: EFFICACY AND SAFETY ANALYSIS

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Background and Importance There are various strategies for treating high-volume hormone-sensitive metastatic prostate cancer (HSmPC). One such strategy is the combination of abiraterone, docetaxel and androgen deprivation therapy (Abi+Doc +ADT) based on the results of the PEACE-1 study. Treatment selection should consider patient characteristics, safety profiles, drug interactions and efficiency criteria.

Aim and Objectives To analyse the safety and efficacy profile of the triple therapy: Abi+Doc+ADT in patients with high-volume-HSmPC.

Material and Methods Retrospective, observational, multicentre study between November 2021to September 2024 in patients with high-volume-HSmPC who received Abi+Doc+ADT after off-label approval.

Evaluated efficacy variables included: number of cycles, progression-free survival (PFS), percentage of response by PSA (Prostate-Specific Antigen) considering progression as three consecutive increases (PEACE-1 criteria) and type of radiological response according to RECIST v1.1 criteria.

For safety: previous and subsequent comorbidities, addition of medications during treatment, interactions between home and oncology medications and the development of adverse reactions (ARs) were recorded according to CTCAE v5.0 criteria.

Statistical analysis was performed using Jamovi software.

Results Thirty patients were included, median age 63 (54–85) and ECOG score of 0–1.

83.3% patients received 6 cycles of docetaxel and treatment was discontinued in five (two due to progression, two due to docetaxel intolerance and one due to pneumonia).

Based on PSA values, 22 (73.3%) responded. One-year PFS was 88% (76%-100%, 95% CI) and the median PFS was not reached.

Radiological response rate was 60%, with six complete responses (20%), eight partial response (26.7%), four stable disease (13.3%) and four with progression.

70% had pre-existing comorbidities, the most common: hypertension (33.3%), dyslipidaemia (33.3%) and type-2-diabetes mellitus (16.7%).

Six patients (20%) developed lipid profile alterations, but no treatment modifications were necessary.

Pharmacological interactions with abiraterone were observed in 40%, mainly an increased risk of statin-induced myotoxicity (type C), but no cases were reported.

ARs occurred in 21 patients(70%):7 cases of asthenia and 5 gastrointestinal. Of these, 14 (46.7%) were grade 1–2. Seven patients (23.3%) had ARs related to abiraterone and treatment was discontinued in one case due to atrial fibrillation. No further clinical actions were required in the remaining cases.

Conclusion and Relevance Our experience suggests that Abi +Doc+ADT is an effective therapy with promising results.

Our study (2.8 years of follow-up) needs to evaluate whether the median PFS resembles that of the trial (4.46 years).

It is a safe treatment, as most ARs were low-grade, manageable and the interactions were not clinically significant.

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

5PSQ-082 USE, EFFICACY AND SAFETY OF CEFIDEROCOL IN INFECTIONS CAUSED BY MULTIDRUG-RESISTANT GRAM-NEGATIVE MICROORGANISMS

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Background and Importance Cefiderocol, a siderophore cephalosporin, shows remarkable activity against multidrug-resistant gram-negative bacteria (MR-GNB). Its use is restricted to cases where no other therapeutic options are available.

Aim and Objectives To analyse the use, efficacy and safety of cefiderocol in patients admitted with MR-GNB infections.

Material and Methods Observational and retrospective study including patients treated with cefiderocol for at least 3 days, between January 2021 and August 2024. The following variables were recorded: age, sex, causative microorganism and mechanism of resistance, indication, duration of treatment, antibiogram and comorbidities.

The outcome variables analysed were microbiological eradication (negative culture after completion of treatment or absence of symptoms) and 28-day mortality. Safety was assessed as treatment discontinuation due to adverse effects.

Results Thirty-six patients treated with cefiderocol were analysed; 93.5% (33) were male and median age 64 (28–90) years. 26 were infected with carbapenemase B-producing *Pseudomonas* (20 IMP, 7 VIM, 2 NDM), four *Acinetobacter*

baumanii, two non-carbapenemase-producing *Pseudomonas aeruginosa*, two carbapenemase B-producing enterobacteria (NDM), one *Stenotrophomonas* and one extended-spectrum beta-lactamase-producing *Escherichia coli*. The main infections were pneumonias 44% (16) (12 associated with mechanical ventilation), followed by urinary tract infections 30% (11) and bacteraemias 11% (4). The remaining 15% were minor infections (one intra-abdominal infection, 1 peritonitis, two pressure ulcers, one colonisation).

The mean duration of treatment was 11 (SD 4.8) days, achieving microbiological eradication in 75% (27). Mortality before 28 days was 16.67% (6). In terms of safety, two patients discontinued treatment due to adverse reactions (myoclonus and rash).

Conclusion and Relevance The data obtained reveal favourable results in terms of microbiological eradication and mortality reduction, which positions this treatment as a highly effective option for infections caused by MR-GNB, especially in cases where therapeutic alternatives are limited. It also has a good safety profile, as adverse reactions were mild and disappeared when treatment was discontinued. It should be noted that some patients had multiple pathologies and comorbidities, and in these cases cefiderocol was used at an advanced stage of treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-083 ABSTRACT WITHDRAWN

5PSQ-084 ADEQUACY OF AMIKACIN PRESCRIPTION IN OVERWEIGHT AND OBESE CRITICALLY ILL PATIENTS

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Background and Importance Guidelines recommend an initial amikacin dose of 15–20 mg/kg/day, adjusted by ideal body weight (AiBW) for obese patients. However, these are often disregarded in clinical practice.

Aim and Objectives This study evaluates the accuracy of the adjustments in amikacin first dose in overweight and obese patients from the Intensive Care Unit (ICU) and to determine the pharmacokinetics unit's (PKU) effectiveness in achieving target therapeutic concentrations.

Material and Methods Conducted at a tertiary hospital from January 2022 to August 2024, this retrospective study analysed initial amikacin prescriptions in ICU patients with a body mass index (BMI) over 25. Variables considered were sex, weight, height, dose administered (mg), serum concentration (mcg/ml) and the number of discrepancies between the dose recommended by Prioram guideline and the dose prescribed. The Devine formula was used to calculate AiBW.

Optimal serum concentrations were defined as a trough level below 3 mcg/ml and a peak between 55 and 65 mcg/ml, according to Alvarez et al.[1] aminoglycoside monitoring standards. Data were obtained from electronic medical record system (Orion Clinic) and the pharmacokinetics lab (Gestlab).

Results Thirty-eight overweight patients were included, being 63% (24) men, aged 61±13; and 37% (14) women, aged 74±10, with a mean BMI of 31.9±8.1 kg/m^2. A total of 102 amikacin concentration tests were done. Amikacin first dose was not adequate in 42% patients according to guidelines, resulting in 19% underdosed and 81% overdosed patients.

Regarding pharmacokinetic recommendations, 79.4% were accepted. A total of 57.9% of patients continued amikacin treatment beyond the 5th dose, from which a 63.6% achieved optimal therapeutic concentrations. The inadequacy of the prescribed dose resulted in a 62.5% of patients who did not reach therapeutic concentrations after amikacin first dose, compared to 40.9% in those with a dosification according to guidelines.

Conclusion and Relevance Despite guidelines, the amikacin first dose prescribed is often inadequate in overweight patients resulting in suboptimal serum concentration, exacerbated by patients' critical conditions. This study highlights the PKU's role in making recommendations to achieve therapeutic concentrations.

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Conflict of Interest No conflict of interest

5PSQ-085 SAFETY AND TOLERANCE PROFILE OF OSIMERTINIB FOR TREATMENT OF NON-SMALL-CELL LUNG CANCER

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Background and Importance Osimertinib is an irreversible tyrosine kinase inhibitor (third-generation TKI) approved in monotherapy for the treatment of metastatic non-small-cell lung cancer (mNSCLC) with activating EGFR mutations and EGFR T790M mutation-positive.

Aim and Objectives To evaluate the effectiveness and safety of osimertinib in mNSCLC in clinical practice.

Material and Methods Retrospective observational study, which included all patients treated with osimertinib before June 2024 in a tertiary hospital. Variables collected: age, sex, non-smokers, Eastern Cooperative Oncology Group (ECOG) score, presence of brain metastases, type of mutation, number of lines received and cycles of osimertinib administered. Effectiveness was assessed by progression-free survival (PFS) and overall survival (OS) by the Kaplan-Meier method. Safety was determined by collecting adverse events (AEs) and classifying the degree of toxicity according to the Common Terminology Criteria for AEs v.5.0. Data were collected by electronic medical record and prescription software, analysed in SPSS v.29 statistical software.

Results Fifty-three patients (75.5% women), median age 64 (48–89) years were analysed. The 62.3% were non-smokers. ECOG was: 0–1 (88.9%) and 2 (9.4%). Brain metastases were present in 64.2%. The most frequent mutation types were: exon 19 deletion (54.7%) and L858R mutation (35.8%). In addition, 13.2% had resistance mutation T790M. The median number of cycles received was 9.

At the time of analysis, the median follow-up was 16 months. Of patients, 79.24% received osimertinib as first-line (1L) and 20.75% as second-line (2L). Median PFS was 22 months, 95% CI (10.74–33.25) in 1L and 17 months, 95% CI (3.42–30.57) in 2L. Median OS was 31 months, 95% CI (9.76–52.23) in 1L and 29 months, 95% CI (10.91–47.08) in 2L.

AEs were recorded in 57.40% of patients (grade 1: 48.4%, grade 2–3: 9%). The most frequent were diarrhoea (18.5%), rash (16.5%), asthenia (16.5%). Grade 3 AEs were: retinal necrosis, skin lesions, elevated GGT and cardiac failure.

Conclusion and Relevance The effectiveness results achieved in SLP were superior in both treatment lines compared to their pivotal trials FLAURA (1L) and AURA 3 (2L). However, the OS achieved was lower in 1L and higher in 2L.

In terms of safety, there was a lower incidence of AEs and generally mild ones.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-086 HOSPITALISATIONS IN PATIENTS WITH METASTATIC NON-SMALL-CELL LUNG CANCER RECEIVING IMMUNOTHERAPY

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Background and Importance The inclusion of immune checkpoint inhibitors (ICIs) in lung cancer therapy has provided clinical benefits in first-line and subsequent lines of treatment in this patient population. Although the adverse event profile of ICIs differs from chemotherapy, they still present toxicity risks. Previous studies have reported a hospitalisation incidence of over 50% in lung cancer patients, with 37% of these admissions due to treatment-related adverse effects.

Aim and Objectives To determine the incidence of hospitalisation in patients with metastatic non-small-cell lung cancer (mNSCLC) receiving pembrolizumab, nivolumab, or atezolizumab as monotherapy, and to evaluate the causes and duration of these admissions.

Material and Methods This observational, retrospective study included mNSCLC patients treated with ICIs from September 2015 to November 2023. Data collected included demographic variables, ECOG performance status, line of treatment, number of cycles, and hospital admissions, including their reasons and duration, recorded from the start of treatment until one month after its completion.

Results A total of 174 patients were included: pembrolizumab (n=49), nivolumab (n=45), and atezolizumab (n=80). The median age in the pembrolizumab and atezolizumab groups was 68 years, and 65 years in the nivolumab group. Males accounted for 72.4% of the total population. Most patients had an ECOG status of 1 (63.8%), followed by ECOG 0 (29.3%) and ECOG 2 (6.9%). Treatment was administered as first-line therapy in 36.2% of patients, second-line in 59.8%, and third-line or beyond in 4%. The median number of treatment cycles was 4 (1–41) for pembrolizumab, 6 (1–198) for nivolumab, and 3 (1–62) for atezolizumab.

In terms of hospitalisations, 47.1% of patients did not require admission, while 39.7% required one, 8.6% two, and 4.6% three or more admissions. The median duration of hospital stays was 7 (1–48) days.

The most common reasons for hospitalisation were tumour progression (32.1%), followed by infectious causes (26.7%) and other reasons (26.7%). Hospitalisations related to immunotherapy toxicity accounted for 14.5%, with the most frequent adverse events being pneumonitis (42.1%), diarrhoea (26.3%), neurological causes (10.5%), metabolic disorders (10.5%), thrombocytopenia (5.3%), and myocarditis (5.3%).

Conclusion and Relevance During ICI monotherapy, 53% of mNSCLC patients are hospitalised, 14.5% due to immune toxicity. Pharmacist involvement in toxicity management, dose optimisation, and patient education on warning signs is essential to improve outcomes and reduce hospitalisations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-087 CLINICAL EXPERIENCE WITH BEZLOTOXUMAB IN A THIRD-LEVEL HOSPITAL

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Background and Importance Bezlotoxumab is a monoclonal antibody with high affinity for the toxin B produced by Clostridium difficile indicated for adults at high-risk of recurrent infection.

Aim and Objectives To evaluate the real-world efficacy and safety of bezlotoxumab.

Material and Methods A retrospective observational study was performed including all patients diagnosed with Clostridium difficile infection (CDI) who were treated with bezlotoxumab since its funding approved (May 2018 to February 2024). Different variables were studied, both prior to administration (sex, age, immunosuppression, CDI in the previous 6 months, prior treatments, infection recurrences) and subsequent (number of subsequent recurrences and mortality at 12 and 24 weeks which were used to measure efficacy and the recording of adverse events (AEs) used to measure safety).

Data were obtained from the prescribing software and the digital medical record.

Results Forty-five patients were included, 29 men and 16 women, with a median age of 72.5 years (15–88). The risk factor for recurrence due to immunosuppression was present in 29 (64.4%) patients (of which: 58.6% (17) oncological, 34.5% (10) transplanted and 6.9% (2) belonging to both groups), 40% (18) had suffered one or more recurrences previously and 55% (10) of these had CDI in the previous 6 months. On the other hand, prior treatments received, the majority (77.7% (35)) received oral vancomycin at standard doses or its combination with metronidazole.

Regarding the treatment efficacy, 88.9% (40) of patients achieved resolution of the CDI after using bezlotoxumab without subsequent recurrences. All patients who experienced a recurrence (8.9% (4)) after bezlotoxumab were older than 65 years and had a history of one or more recurrences of the disease previously. Currently, 28.88% (13) of the patients have died, with a mortality rate of 15.55% (7) at 12 and 24 weeks after the start of treatment. Main reasons for death were not related to CDI (other infections and oncologic disease).

No AEs to bezlotoxumab were documented.

Conclusion and Relevance Bezlotoxumab was an effective and safe drug in patients with CDI in real clinical practice. No AEs were detected and it prevented recurrence in most cases, demonstrating that its use in high-risk patients can aid in complete recovery. No patient died as a result of CDI.

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

5PSQ-088 CONCILIATION FROM HOSPITAL PHARMACY EXTERNAL CONSULTATIONS IN COLLABORATION WITH PRIMARY CARE PHARMACY

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Background and Importance Medication conciliation is one of the main strategies to reduce medication errors and increase patient safety. This strategy may be enhanced with the Hospital Care (AH)-Primary Care (PC) collaboration.
Aim and Objectives Integrate the actions carried out by hospital pharmacy and primary care pharmacy to reduce medication errors and health problems associated to medications among patients who come to Hospital Pharmacy Service to start treatment.
Material and Methods Prospective observational study where all patients who started hospital-dispensing medication (HDM) between 1 January and 15 September 2024 were included.
The variables recorded were: age, sex, polymedication (considered as such the prescription of 12 or more drugs), precautionary overrides (PO) and reason.

Conciliation of medication that patient had prescribed in an electronic prescription when starting treatment with HDM was carried out following the steps:

1. interview with the patient collecting a list of all the medication he/she takes;.
2. review by the Pharmacy Service, comparing the medication prescribed in an electronic prescription with the one he/she takes and, finally,.
3. resolve the discrepancy (therapeutic duplication, dose errors, lack of adherence) if any: through PO and/or contact with the primary care provider.

Results During the study period, 132 patients attended the Hospital Pharmacy Service to start HDM.

Seventy-eight were women (59%) and 54 men (41%). Forty-one patients (31%) were over 75 years, 28 (21%) were between 61 and 74 years, and 63 patients (48%) were under 60 years. 35 patients (26.5%) were polymedicated. 100% of the prescriptions susceptible to PO were communicated to the prescribing physicians.

60 PO were carried out, 4 (6.7%) due to therapeutic duplication, 37 (61.7%) due to lack of adherence, 7 (11.7%) due to dose errors, 7 (11.7%) due to therapeutic safety problems and 5 (8.3%) due to inadequate treatment.
Conclusion and Relevance AH-AP cooperation makes it more feasible to reduce preventable adverse events caused by medication; however, innovative solutions are needed to connect/integrate hospital and primary care prescription systems in order to obtain more efficient results that impact on patient safety.

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

5PSQ-089 IMPACT OF ANTIMICROBIAL RESISTANCE ON HOSPITAL MORTALITY, LENGTH OF HOSPITAL STAY AND LENGTH OF ICU STAY IN PATIENTS WITH BACTERIAL PNEUMONIA ADMITTED TO ICU

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Background and Importance The rise of antimicrobial resistance (AMR) jeopardises the effectiveness of antimicrobial drugs.
Aim and Objectives To determine the impact on hospital mortality and length of hospital stay and Intensive Care Unit (ICU) stay of patients with pneumonia due to AMR bacteria who required admission to the ICU.
Material and Methods Retrospective case-control study including hospitalisation episodes of patients aged 17 years and older with a diagnosis of bacterial pneumonia who required ICU admission during the period 2017 to 2022, using the Clinical Administrative National Dataset. Episodes with a diagnosis of pneumonia in which the causative agent could not be identified were excluded.

Cases were defined as any hospitalisation labelled as AMR in terms of ICD-10. Controls were the remaining episodes of bacterial pneumonia free of these resistance label.

Using Stata v.17, three multivariate models based on Poisson regression were constructed to study AMR impact, adjusted for confounding covariates: age, sex, van Walraven comorbidity index, sepsis, non-COVID viral pneumonia, COVID19 and severity level and risk mortality according to the international APR system.
Results Included 26,567 hospitalisation episodes, 24,050 (90.53%) were caused by bacteria sensitive to standard antimicrobial drugs (controls), while 2,517 (9.47%) were caused by AMR bacteria (cases). Male patients accounted for 69.94% of hospitalisation episodes versus 30.06% of females. The median age at hospital admission was 64 years (IQR 53–73).

Patients with AMR bacterial pneumonia had a median hospital length of stay of 34 days (IQR 19–60) versus 21 days (IQR 11–39) in the control group, $p<0.0000$. The length of ICU stay was 16 days (IQR 7–35) versus 9 days (IQR 4–11), respectively.

Patients with AMR pneumonia also had a higher incidence of sepsis, COVID-19 infection, non-COVID-19 viral co-infection, and a higher mortality rate: 33.69% vs. 27.67%.

Mortality increased by 11.8% in patients with pneumonia due to AMR bacteria compared to the control group: IRR=1.118 (95%IC 1.056–1.184), $p>|z|<0.000$.

Patients with AMR pneumonia had an increase in their hospital stay of 36.01% (IRR=1.361 (95%IC 1,309–1,414), $p>|z|<0.000$) and of 37.6% in their ICU stay (IRR=1.376 (95%IC 1,312–1,443), $p>|z|<0.000$).

Conclusion and Relevance AMR bacteria pneumonia due requiring admission to the ICU increases >10% the incidence of mortality and >35% length of ICU and hospital stay.

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

5PSQ-090 IMPACT OF VEDOLIZUMAB LEVELS ON CLINICAL RESPONSE IN CROHN'S DISEASE: A RETROSPECTIVE STUDY

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Background and Importance Therapeutic drug monitoring (TDM) is crucial for optimising vedolizumab treatment in inflammatory bowel disease patients.
Aim and Objectives We aimed to evaluate how VDZ levels correlate with clinical response in patients with Crohn's Disease (CD) and explore additional variables influencing treatment outcomes.
Material and Methods We conducted a retrospective observational study of all CD patients at our hospital on VDZ maintenance treatment (≥14 weeks). Serum trough VDZ concentrations were analysed (ELISA method) along with demographic (age, sex) and clinical variables (age at diagnosis, location, disease pattern, biomarkers). Clinical response was assessed with the HBI index (remission <5), and patients were classified as responders/non-responders. Samples were grouped using clustering (K-means), with time on treatment as the primary variable. Differences in VDZ levels between responders and non-responders were evaluated with Mann-Whitney, and predictive ability was assessed with ROC curves (without AUC, due to responder/non-responder imbalance). Logistic regression was used to identify other response-influencing variables.
Results We included 70 measurements of trough serum concentrations of VDZ from 39 CD patients in the maintenance phase. Samples were grouped into 2 clusters. Cluster-1, with older patients (66.5±10.3 years) and longer on treatment (44.8±28.4 months), had a response rate of 78.1%. Responders had VDZ levels of 16.2 mcg/mL (IQR:12.1–20.7) versus 10.9 mcg/mL in non-responders (p=0.045). In Cluster-2, younger patients (45.7±12.4 years) with less time on treatment (18.8±16.6 months) had a response rate of 73.7%. Responders had 21.5 mcg/mL(IQR:15.6–30.55), while non-responders had 20.6 mcg/mL (IQR:10.8–27.35), with no significant differences (p=0.155). No ROC curve was performed in Cluster-2 due to lack of association between VDZ levels and response. In Cluster-1, sensitivity was 0.712 and precision 0.737, obtained from the ROC curve. Logistic regression identified age, VDZ levels, and time on treatment as key factors affecting treatment response.
Conclusion and Relevance In Cluster-1, VDZ levels were significantly higher in responders, highlighting the importance of TDM in patients with longer treatment duration. The ROC curve showed moderate predictive ability (sensitivity=0.712, accuracy=0.737), though 30% of responders were not predicted by VDZ levels alone, suggesting other factors like pharmacodynamic variability or subclinical inflammation could influence response. Logistic regression identified age, VDZ levels, and time on treatment as key factors for clinical response.

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

5PSQ-091 FACILITATORS AND BARRIERS IN UTILISING BARCODE TECHNOLOGY IN DRUG PREPARATION AND ADMINISTRATION – A FOCUS GROUP STUDY FOR WARD PHARMACISTS

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Background and Importance Barcoding technologies are widely used in hospitals to support safe medication management and use processes. Although these technologies are considered effective in making system-wide improvements, implementing them has several challenges. Research on the implementation and usability of barcoding has primarily centred on adult populations and other healthcare professionals rather than on hospital pharmacists.
Aim and Objectives This study aimed to examine pharmacists' perceptions of facilitators and barriers to using barcode technologies supporting safe drug preparation and administration in a paediatric hospital setting.
Material and Methods A qualitative focus group study was conducted following the COREQ (Consolidated criteria for reporting qualitative research) checklist. Fourteen ward pharmacists working in the paediatric department of a university hospital were chosen for three focus groups using purposive sampling to identify individuals who regularly use barcoding. The interviews were recorded and transcribed verbatim. Two researchers independently conducted inductive content analysis, which was later thoroughly reviewed by the entire research group.
Results The data revealed four main themes: barriers, at-risk behaviour resulting from barriers, facilitators, and development ideas. The barriers included challenges related to negative attitudes, drug barcodes, use of the electronic health record system, workstations and equipment, as well as organisational factors. These barriers caused at-risk behaviour arising from the system or the end-user. On the other hand, the facilitators were associated with the positive experience of end-users, increased expertise and teamwork, the supporting functions of the electronic health record system, as well as the benefits of the barcode technology. The development ideas aimed to remove the barriers and the at-risk behaviour.
Conclusion and Relevance A variety of factors can impact the potential of barcoding technologies to improve medication safety in paediatric hospital settings. Hospital pharmacists play a crucial role in supporting the implementation of barcode technology and improving its usability. Our research findings can be used to guide risk management efforts related to barcoding technologies in hospital environments.

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

5PSQ-092 IMMUNOTHERAPY IN NEOADJUVANT TRIPLE-NEGATIVE BREAST CANCER: EFFECTIVENESS AND SAFETY

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Background and Importance Pembrolizumab is an anti-PD1 monoclonal antibody that is indicated in combination with chemotherapy as neoadjuvant treatment in triple-negative breast cancer (TNBC).

Aim and Objectives To evaluate the effectiveness and safety of pembrolizumab in TNBC in a tertiary care hospital.

Material and Methods Retrospective observational study, in which patients with TNBC who started neoadjuvant treatment from April 2023 to August 2024 were included. The variables collected were: age, sex, quality of life status according to the Eastern Cooperative Oncology Group (ECOG) scale, menopause, tumour size and nodes affected at diagnosis, surgery and number of cycles administered. Effectiveness was determined by the pathological complete response (PCR), evaluated at surgery according to the Miller and Payne scale. Safety was determined by collecting adverse events (AEs) and classifying the degree of toxicity according to the Common Terminology Criteria for Adverse Events v. 5.0 scale. Sources of information: application of electronic prescription and computerised clinical history. The data were analysed with SPSS statistical software v.29.

Results Thirty-six patients (100% female) were analysed, with a median age of 51.5 years (28–77). All patients presented an ECOG: 0. Fifty percent were premenopausal. Tumour size was: T1 (5.6%), T2 (77.8%), T3 (11.1%), T4 (5.6%) and the affected nodes were: N0 (72.2%), N1 (16.7%), N2 (8.3%) and N3 (2.8%). The median number of cycles received was 6 (1–8). Twenty-two (61.1%) underwent surgery and 14 (38.9%) were still under neoadjuvant treatment. Among these patients who underwent surgery, 86.36% (95% CI, 66.67–95.25) obtained PCR.

AEs were recorded in 86.1% of patients. Toxicity grades were: 1–2 (84.8%) and 3 (15.2%). The most frequent AEs were: alopecia (38.8%), nausea (36.1%), neutropenia (22.2%), mucositis (19.4%), skin rash (11.1%), hypertransaminasaemia (9.7%) and neurotoxicity (9.7%). Two patients required hospitalisation for febrile neutropenia and one for immune-mediated hepatitis, both grade 3 AEs.

Conclusion and Relevance Our PCR results were superior to that demonstrated in the pivotal KEYNOTE 522 trial: 86.36% versus 64.8% respectively. Thus, it is demonstrated that the association of pembrolizumab to neoadjuvant chemotherapy in TNBC is effective to obtain complete response. Regarding the safety profile, toxicity was well-tolerated, except for hypertransaminasemia and neutropenia, which were the most severe.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-093 EFFECTIVENESS AND SAFETY OF DURVALUMAB IN UNRESECTABLE OR METASTATIC CHOLANGIOCARCINOMA

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Background and Importance Unresectable or metastatic cholangiocarcinoma (CCUoM) is a type of biliary tract cancer with poor prognosis. Results from the pivotal trial 'TOPAZ-1' suggest that adding durvalumab (anti-PD-L1) to standard therapy (platinum-gemcitabine (PtGem)) may improve survival outcomes.

Aim and Objectives Evaluate the effectiveness and safety of durvalumab with PtGem (PtGemDur) as first-line therapy for CCUoM, with a comparison to a historical cohort, PtGem, and with results from TOPAZ-1.

Material and Methods A retrospective descriptive study of patients with CCUoM. Two cohorts were included: patients treated with PtGem from 06/2018–06/2021 and those treated with PtGemDur (current cohort) from 06/2021–06/2024. Data collected from Oncofarm software and medical records were: sex, age, ECOG and tumour location. Effectiveness was evaluated in terms of overall survival (OS) and progression-free survival (PFS) according to the Kaplan-Meier method, using SPSS statistical software. Safety was determined from the type of adverse events (AEs) and discontinuations.

Results A total of 34 patients were included, 25 received PtGem and 9 PtGemDur. Data collected in the historical cohort were: median age 66 (41–81) years, 64% men, ECOG1: 76%, rest ECOG0 and 76% intrahepatic. In the current cohort: median age 70 (49–80) years, 92% men, ECOG0: 55.6%, rest ECOG1 and 55.6% intrahepatic. In TOPAZ-1, median age 64 (20–84) years, 49.6% men, ECOG0: 50.7% and 55.7% intrahepatic. Median OS was 13 (9.9–18.4) months with PtGem and with PtGemDur was not reached. Median PFS was 9 (7.6–23.2) months with PtGem and 9 (8.8–10.2) months for PtGemDur. In TOPAZ-1 OS was 12.8 (11.1–14) months and PFS 7.2 (6.7–7.4) months. Regarding toxicity, 92% had AEs of any grade with PtGem, 100% with PtGemDur and 99.4% in TOPAZ-1. The most frequent AEs were haematologic, 31% in historical cohort vs 15.4% in current cohort and digestive, 13.8% vs 23.1%. Discontinuations were 68% vs 44%. There were no immune-mediated effects. In TOPAZ-1 48.2% were haematologic, 40.2% digestive and 12.7% immune-mediated. Discontinuations occurred in 13%.

Conclusion and Relevance In our study, the current cohort sample is small, so results obtained need to mature to confirm the benefits in OS. The PFS results are similar to and slightly superior to those of TOPAZ-1. In terms of safety, AEs were similar in both cohorts and with respect to the TOPAZ-1. No immune-mediated effects were observed in our populations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-094 EFFICACY OF BASILIXIMAB VERSUS THYMOGLOBULIN IN RENAL TRANSPLANT INDUCTION THERAPY

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Background and Importance Basiliximab (anti CD-25) and thymoglobulin (T-lymphocyte depleting agent) are used together with other immunosuppressants in renal transplant induction therapy for the prevention of acute rejection. The selection of the appropriate induction regimen, depending on the patient's immunological risk, is key to ensure the success of the transplantation.
Aim and Objectives To evaluate the efficacy of protocolised induction immunosuppressive therapy with basiliximab and thymoglobulin in renal transplantation.
Material and Methods Retrospective and descriptive observational study carried out on patients transplanted during 01/2012 - 09/2023 in a tertiary general hospital. Patients, according to the protocol established in the centre, were treated with basiliximab or thymoglobulin in case of low or high immunological risk, respectively.

The analysed variables were obtained from the Orion Clinic software: sex, age, weight, date of transplant, immunosuppressor used in conjunction with the dose administered: basiliximab 20mg on days +1 and +4 post-transplant and thymoglobulin 5 mg/kg/total cumulative dose for 3 to 9 days after the intervention, and concomitant immunosuppressive treatment.

The effectiveness was evaluated by the rejection rates at 6 and 12 months after the transplantation, according to the literature reviewed.
Results During the evaluated period, a total of 260 patients were transplanted: 65% men (169) and 35% women (91), with a mean age of 57 ±11.90 years. In addition, all patients were also treated with mycophenolate mofetil, prednisone and tacrolimus. Of these, 41.15% (107) of patients received basiliximab according to procotol, and 58.85% (153) of patients received thymoglobulin with a total cumulative mean dose of 6.1mg/kg. Among these 153 patients treated with thymoglobulin, 22.22% received <5mg/kg due to haematological toxicity.

Regarding to the rejection rates, 14.01% (15) and 0.93% (1) experienced rejection among the group of basiliximab after 6 and 12 months, respectively. While 12.42% (19) and 0.65% (1) experienced rejection among the group of thymoglobulin after 6 and 12 months, respectively, of which only two patients received doses <5mg/kg because of toxicity.
Conclusion and Relevance In our study population, basiliximab induction therapy in patients at low immunological risk was similarly effective as thymoglobulin therapy in patients at high immunological risk in renal transplantation, along with all other immunosuppressants, according to the literature reviewed.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-095 ABSTRACT WITHDRAWN

5PSQ-096 DIFFERENCES IN GFR ESTIMATION BASED ON CREATININE AND CYSTATIN C IN A COHORT OF OLDER MEDICAL PATIENTS, AGE-MATCHED CONTROLS, AND HEALTHY YOUNG ADULTS

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Background and Importance Accurate assessment of glomerular filtration rate (GFR) is essential for diagnosing kidney disease and determining the appropriate dosing of medications eliminated via the kidneys. In clinical practice, serum creatinine is the standard biomarker used to estimate kidney function, but non-GFR factors, such as age, muscle mass, and nutritional status, can compromise its accuracy. The combination of creatinine and cystatin C has been shown to enhance the performance of GFR estimates across diverse patient populations. However, given the additional costs associated with cystatin C measurement, it is crucial to determine which patients would benefit most from its use.
Aim and Objectives This study compares the clinically significant differences between creatinine- and cystatin C-based equations in older patients, age-matched healthy older adults, and younger individuals.
Material and Methods Data from older medical patients (30-day follow-up), older healthy participants matched by age and sex to the older patients, and younger healthy participants were adapted from the FAM-CPH study. Exclusion criteria included cognitive cooperation difficulties, terminal illness, autoimmune diseases, a current cancer diagnosis, and the use of immunosuppressive or anti-inflammatory medication. GFR was estimated using CKD-EPI equations based on the 2009 creatinine (CKD-EPIcrea), 2012 cystatin C (CKD-EPIcysC), and the 2012 combination of creatinine and cystatin C (CKD-EPIcomb). The primary outcome was a comparison of the proportion of participants with a ≥15% difference between CKD-EPIcrea and CKD-EPIcomb.
Results Of the 128 older patients in the FAM-CPH cohort, 54 were eligible for this study. Fifty-two of the 54 participants (48% female; median age 75 years) were matched with older healthy participants, while the younger control group comprised 59 participants (49% female; median age 26 years). Older individuals had significantly lower eGFR values across all equations than younger controls. Overall, 36% of older patients had an eGFRcomb that differed by more than 15% from eGFRcrea. This discrepancy was observed in 8% of older controls and 4% of younger controls ($p \leq 0.0004$).
Conclusion and Relevance Approximately one-third of older medical patients had a difference of ≥15% between CKD-EPIcrea and CKD-EPIcomb, significantly higher than among older and younger controls. These results suggest that older patients may gain the most significant performance-related benefit from the implementation of cystatin C.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-097 EVALUATION OF EFFECTIVENESS AND SAFETY OF ELADOCAGENE EXUPARVOVEC IN THE TREATMENT OF AROMATIC L-AMINO ACID DECARBOXYLASE (AADC) DEFICIENCY IN UNIVERSITY HOSPITAL: A CASE REPORT

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Background and Importance Aromatic L-amino acid decarboxylase deficiency (AADC) is a rare genetic disorder that causes a reduction in neurotransmitter levels, leading to severe motor dysfunction.

This case report details the improvement in the clinical condition of the only patient in Italy treated with Eladocagene Exuparvovec, 12 months after intraputaminal infusion.

Aim and objectives The objective is to highlight new therapeutic effects, given the paucity of data in the literature with only 26 interventions have been conducted in clinical trials worldwide. This paper presents the case of a 3 year-old patient with a confirmed diagnosis of AADC. The patient exhibited the following neurological indications and symptoms upon initial presentation: bradykinesia, oculo palpebral seizures, dystonia, disturbances in sleep patterns, fluctuations in body temperature, hyperhidrosis, hypokinesia, hypotonia, ptosis of the eyelids, and developmental delays. Additionally, he exhibited non-neurological indications, including short stature, nasal congestion, feeding difficulties, recurrent respiratory infections, and poor weight gain.

Material and Methods Eladocagene Exuparvovec has been administered via bilateral infusions at two sites per putamen, comprising four separate infusions,[1] during a single surgical session conducted in May 2023. The patient then underwent a 1 year follow-up period following the infusion. Surgical interventions in patients with AADC deficiency require collaboration between several specialities within the multidisciplinary team. The treatment was approved by Italian Medicines Agency (authorisation no. 120/2023).

Results Significant enhancements in motor and cognitive abilities were observed within a 12-month period following the administration of the gene therapy. The patient exhibited a Peabody Developmental Motor Scale, version 2 (PDMS-2) score of 8 after 12 months, representing a four-point improvement from the baseline measurement. Increased de novo dopamine production was demonstrated by PET and neurotransmitter analyses. The patient's symptoms as mood, sweating, temperature and oculogyric crises and quality of life improved.

Conclusion and Relevance No brain lesions were detected. No adverse events in treated patient was recorded, although mild and moderate dyskinesia was reported in clinical trials and disappeared within a few months.

Therefore, treatment with Eladocagene Exuparvovec in AADC provided the durable and significant benefits with acceptable safety profile.

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Conflict of Interest No conflict of interest

5PSQ-098 EFFECTIVENESS AND SAFETY OF OSIMERTINIB IN EGFR MUTATION-POSITIVE NON-SMALL-CELL LUNG CANCER WITH BRAIN METASTASES: A RETROSPECTIVE OBSERVATIONAL STUDY

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Background and Importance Non-small-cell lung cancer (NSCLC) represents 80–90% of all lung malignancies. Osimertinib has demonstrated significant anti-tumour activity in treatment of advanced NSCLC harbouring EGFR mutations.[1] However, real-world data are limited.

Aim and Objectives The objective of the study was to evaluate effectiveness and tolerability of osimertinib in patients with EGFR mutation-positive NSCLC.

Material and Methods A retrospective analysis of the medical records of 54 patients treated with osimertinib during the period between May 2018 and June 2023 was conducted. The outcomes considered were best response (BR), progression-free survival (PFS), overall survival (OS), overall response rate (ORR) and toxicity. The variables considered were age, gender and performance status according to ECOG (Eastern Cooperative Oncology Group). The efficacy was assessed using the Kaplan-Meier method in terms of PFS and OS. Adverse effects were collected and classified in accordance with the Common Terminology Criteria for Adverse Events (CTCAE) scale v5.0.

Results The study included 54 patients; 67% were women. The mean age was 71 years (range 60–78). 83% of patients were stage IV at diagnosis and 81% of study subjects showed metastatic disease at baseline, of which 35% (19 patients) had developed brain metastases.

The overall population and subgroup with brain metastases had the same median PFS of 4 months while they had an OS of 16 months and 21 months, respectively ($p<0.001$).

Furthermore, 64% of patients exhibited an ECOG performance status of grade 0, 30% grade 1, 4% grade 2, and 2% grade 3. Of the 54 patients, 9.3% exhibited a complete response, 63% demonstrated a partial response, 8% displayed stable disease, 5.6% exhibited disease progression, and 7.4% were not evaluable. ORR was 72%. Adverse effects were observed in 31% of patients. The most common adverse effects were diarrhoea (24.1%), asthenia (14.8%), nausea (9.3%) and anaemia (5.5%). Grade G3-G4 toxicity was observed in 3.7% of patients. No dose reduction or discontinuation was required.

Conclusion and Relevance Osimertinib was demonstrated to be an effective and well-tolerated treatment for non-small-cell lung cancer, in the overall population and in the subpopulation with brain metastases.

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Conflict of Interest No conflict of interest

5PSQ-099 ENHANCING PATIENT SAFETY: ANALYSIS AND MITIGATION OF MEDICATION ERRORS IN CRITICAL CARE UNITS DURING 2024

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Background and Importance The analysis of medication errors in critical care units is crucial to improving patient safety and minimising adverse events that may compromise health.
Aim and Objectives To describe the medication errors in the critical care unit (ICU) from January to October 2024, identifying the most frequent errors, the most severe ones, and the improvement actions implemented.
Material and Methods A descriptive analysis was conducted based on reported medication errors. Variables such as care area, error risk, professional category, patient age, process in which the error occurred, severity, probability, and drugs involved were evaluated. Severe errors were defined as those causing temporary or permanent harm and requiring immediate intervention. The improvement actions implemented and the conclusions derived from each incident were analysed.
Results A total of 58 errors were notified during the period. Most occurred in the adult ICU (n=33), while the paediatric ICU reported 22.4% (13) of cases. Low-risk errors accounted for 48% (28) of the total, followed by moderate-risk errors (11). Nursing staff were the most involved, reporting more than 75% (44) of incidents. Regarding patient age, the 51–60 year group was the most affected (21%). The most frequent errors occurred during medication administration (36), followed by prescription and medication selection. The severity of the errors was concentrated in incidents without harm (26) and near misses (12), with 6 errors causing moderate temporary harm. Severe errors mainly occurred during the administration of high-risk medication (19) such as Insulin, heparin and vancomycin. The main improvement actions included modifying prescription and administration protocols, double-check verification, and disseminating safety protocols to all healthcare staff. Conclusions indicated that these actions have improved drug administration safety, and it was recommended to continue reinforcing staff training and protocol adherence monitoring.
Conclusion and Relevance The improvement actions implemented, including protocol dissemination, staff training, and double-check verification, aim to enhance medication safety in critical care units. Although a formal post-implementation analysis has not been conducted, these measures are expected to reduce the number of severe incidents reported. Ongoing staff education and regular review of safety protocols are crucial to fostering a culture of safety and minimising medication-related risks in these units.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-100 SAFETY IN THE USE OF JAK INHIBITORS IN CHRONIC INFLAMMATORY DISEASES

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Background and Importance Following the issuance of a Safety Alert (MUH (FV), 08/2022) by the Spanish Medicines Agency (AEMPS) in November 2022, which reported the risk of major adverse cardiovascular events and malignant neoplasms in patients treated with JAK inhibitors (iJAK), a series of recommendations were established regarding their use in patients over 65 years and with cardiovascular risk factors (CVRF) or for the development of neoplasms.
Aim and Objectives Evaluate the appropriate use of iJAK in a tertiary hospital according to the new recommendations of the AEMPS regarding the increased risk of major adverse cardiovascular events and malignant neoplasms described in patients with CVRF or for the development of neoplasms.
Material and Methods Retrospective observational study of patients treated with iJAK baricitinib, tofacitinib, upadacitinib and filgotinib from July 2021 to March 2024.

We analysed which patients continued with iJAK after the AEMPS recommendation despite having risk factors and whether or not they had a therapeutic alternative.

Sources consulted: the Outpatient Management module of Farmatools, the computerised clinical history of the patients and the iJAK technical sheet.

Data Analysis: Excel

Variables collected: age, sex, risk factors for major adverse cardiovascular events and malignant neoplasms (history of cardiovascular disease or neoplasia, CVRF, smoker/ex-smoker) and existence of a treatment alternative; before and after the Health Alert.
Results 151 patients with a mean age of 52 years were studied. 104 (69%) were women.

Before the alert, 96 patients were treated with an iJAK. Of them, 68 (71%) had some RF. Of these, 18 (26%) discontinued JAKi treatment.

Of those who continued, 20 (41%) had a therapeutic alternative and 29 (59%) did not.

After the alert, 64 patients started treatment with iJAK. Of these, 31 (48%) had some risk factors, 13 (42%) with treatment alternatives and 18 (58%) without alternatives.

Comparison of patients before and after the alert:

- Before: 71% with risk factors, of which 30% had a treatment alternative.
- After: 63% with risk factors, of which 40% had a treatment alternative.

Conclusion and Relevance No significant changes were observed after the alert described, with the benefit of the treatment being valued more than the risk.

The presence of a multidisciplinary team in which the pharmacist is integrated could be interesting when proposing therapeutic alternatives that guarantee patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-101 STRATEGIES TO REDUCE THE RISK OF INFUSION REACTIONS TO FOSAPREPITANT IN HIGHLY EMETOGENIC CHEMOTHERAPY

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Background and Importance Fosaprepitant is a prodrug of aprepitant, a neurokinin-1(NK1) receptor antagonist widely used in antiemetic protocols, often in combination with other agents, to prevent nausea and vomiting in highly emetogenic regimens. Polysorbate 80, an excipient in the formulation, has been associated with infusion site reactions (ISRs). Therefore, optimising the administration protocol for fosaprepitant is essential to minimise adverse events and enhance patient safety.

Aim and Objectives This study aims to evaluate the incidence of ISRs associated with fosaprepitant use in highly emetogenic regimens and assess the effectiveness of preventive measures implemented in clinical practice.

Material and Methods A retrospective analysis was conducted at a university hospital where fosaprepitant was integrated into the antiemetic protocol starting in December 2023. Fosaprepitant was prepared in 100 mL of 0.9% sodium chloride, mixed with 12 mg of dexamethasone and 8 mg of ondansetron, and administered over 20 minutes, adhering to physicochemical guidelines established by Moya-Gil et al (J Anal Bioanal Tech 2016). Following a noted increase in ISRs in January 2024, pharmacists and nurses reviewed the preparation and administration processes. Data were collected from December 2023 to September 2024, through the Farmis-Oncofarm system. Corrective measures implemented in February 2024 included dilution in 250 mL of saline, extending the infusion time to at least 30 minutes, continuous monitoring of infusion rates, and comprehensive training for healthcare staff and patients. Statistical analysis was performed using SPSS 20.

Results Among the 1537 fosaprepitant infusions, the overall incidence of infusion site reactions (ISRs) was 1.30% (20/1537), affecting 4.16% of patients (15/361). Of the total reported complications related to the infusion site, 76.92% were attributed to fosaprepitant (20/26) including phlebitis and extravasation. After the intervention, ISRs decreased significantly from 13 cases pre-intervention (301 infusions) to seven post-intervention (1236 infusions), resulting in a statistically significant reduction (RR 0.13; 95% CI 0.05–0.33; $p<0.05$). The study's limitations include its retrospective design, potential variability in clinical practice, and possible underreporting of adverse reactions, which may affect the validity of the findings.

Conclusion and Relevance The implementation of preventive measures significantly reduced fosaprepitant-related ISRs. These findings highlight the importance of a multidisciplinary approach and continuous monitoring to optimise antiemetic protocols and enhance patient safety during cancer treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-102 EVALUATION OF THE CORRELATION BETWEEN PROCALCITONIN (PCT) LEVEL AND OTHER BIOMARKERS, SEPSIS DIAGNOSIS AND ANTIBIOTIC PRESCRIPTION PATTERN AT AN EMERGENCY DEPARTMENT (ED)

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Background and Importance Sepsis is a life-threatening condition with a rapid progressivity and high mortality rate. The diagnosis and antimicrobial treatment of sepsis remains a challenge for prescribers and common source for misdiagnosis.

Aim and Objectives This retrospective observational study aimed to evaluate the correlation between PCT level, sepsis diagnosis and first empirical antibiotic therapy.

Material and Methods The study was conducted at an Emergency Department (ED) unit of a tertiary care medical centre in Hungary in December 2023. We included all adult patients who had procalcitonin level >0.1ng/ml. Diagnosis and severity of sepsis was defined by 'SIRS, Sepsis, and Septic Shock Criteria' using MDCalc. Clinical presentation, possible source of infection, and cultures taken were also considered. Misdiagnosis was defined when patients did not meet SIRS criteria. Analyses for empirical antibiotic therapy were performed only for confirmed sepsis. Fisher's exact test and t-test were applied to compare categorical and continuous variables between groups.

Results Out of 199 cases in 39.2% (n=78) the recorded diagnosis was sepsis, of which 21.6% (n=43) have not met sepsis criteria. In fact, out of the remain 121 patients recorded with other diagnosis 23.1% (n=46) has met sepsis criteria, so they were misdiagnosed. The most common bacterial infections were pneumonia (53.2%), urinary tract infections (20.3%), and chronic skin and soft-tissue infections (10.1%). The cut-off value of PCT for the diagnosis of sepsis (group 1) was 0.76 ng/ml, while for other diagnosis (group 2) 0.41ng/ml ($p>0.05$). However, we found a significant ($p<0.05$) difference between groups in cut-off values for C-reactive protein (158 vs 122mg/L) and white blood cells (15.6 vs 11.4G/L). Antibiotic therapy in sepsis at ED was substantially low (37%, 26/79), out of which only 9% (7/79) was administered definitely within 3 hours. Our results show that PCT values have influenced antibiotic therapy as following: 0.33ng/ml-no antibiotic therapy, 0.44ng/ml-within 3 hours, 1.4ng/ml-between 3 and 6 hours. However, in case of administration over 6 hours PCT cut-off value was 4.76mg/ml. Patients administered antibiotic within 3 hours had the shortest length of stay (median 6 days).

Conclusion and Relevance We found a relatively high rate of misdiagnosed sepsis. Knowing PCT cut-off values may help antibiotic prescribers is decision making process.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-103 EXTRAVASATION AND ONCOHAEMATOLOGICAL BIOLOGICAL DRUGS: ANALYSIS OF REPORTS IN THE NATIONAL ITALIAN PHARMACOVIGILANCE NETWORK

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Background and Importance Extravasation, the unintended leakage of intravenous drugs into surrounding tissues, can cause serious complications, especially with antineoplastic and biological therapies, with an incidence of 0.1% to 6% in chemotherapy patients.[1] Current guidelines[2] often overlook extravasation management for new biological agents, highlighting the need for updated protocols and education. Hospital pharmacists play a key role in assessing risks and providing antidote information, using data sheets, guidelines, literature, and the National Pharmacovigilance Network (RNF).[3]

Aim and Objectives The study aimed to analyse pharmacovigilance data to better understand extravasation as an adverse event in oncohaematological treatments, focusing on new biological drugs.

Material and Methods Data were extracted from the RNF through August 2024. Reports included data coded with a Lowest Level Term (LLT) linked to 'extravasation' and classified as suspected adverse reactions associated with drugs according to the Anatomical Therapeutic Chemical (ATC) classification 'L- Antineoplastic and Immunomodulating Agents.' Qualitative and quantitative analyses were conducted, focusing on LLTs for each active substance, particularly biological drugs.The data sheets of the biological agents were reviewed to assess whether they included instructions or recommendations for managing extravasation.

Results A total of 344 reports were analysed, including 887 LLTs. The analysis included 41 active substances, including 12 biological drugs, representing 7% of the total LLTs. There were 23 reports involving biological drugs, accounting for 60 LLTs. Serious LLTs were noted in 134 cases, associated with 28 active substances, including four biological drugs. Reactions to biological agents included pain, swelling, and irritation. Notably, one report of durvalumab extravasation documented serious LLTs such as hyperbilirubinaemiaand neutropenia.

Conclusion and Relevance In conclusion, extravasation-related adverse events associated with biological drugs are occurring but may be underreported due to misclassification as general incidents. Notably, only 2 of the 12 biological agents analysed included specific references to extravasation in their data sheets. Improving the recognition and reporting of extravasation through clearer guidelines may promote patient safety and clinical outcomes.

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Conflict of Interest No conflict of interest

5PSQ-104 ATEZOLIZUMAB TOGETHER WITH CHEMOTHERAPY IN PATIENTS WITH SMALL-CELL LUNG CANCER IN A TERTIARY HOSPITAL

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Background and Importance Atezolizumab is a monoclonal antibody against PD-L1.The goal of treatment with atezolizumab in combination with carboplatin- and etoposide-based chemotherapy in the first-line treatment of adult patients with small-cell lung cancer is to extend survival to a larger number of long responders.

Aim and Objectives To track overall survival (OS) and safety outcomes in patients with small-cell lung cancer treated with atezolizumab and chemotherapy as first-line therapy and compare the results with the data obtained in the experimental arm of the IMpower133 trial.

Material and Methods Retrospective observational study was performed on all patients treated with atezolizumab and chemotherapy from January 2022 to September 2024. Patients with histologically or cytologically confirmed small lung cancer and with measurable disease according to RECIST 1.1 criteria and with a functional status according to the Eastern Cooperative Oncology Group (ECOG) scale of 0–1 who had not received previous treatment were included. We followed-up from the start of treatment, recording whether radiographic or clinical disease progression. Any adverse effects related to the drug that prevented continued safe infusion of the drug in the patient or the appearance of unmanageable toxicity was recorded.

Results A total of 31 patients, 71% men with median age of 67 years(IQR 70.5–62.5) were included. OS was 8.3 months (IQR 15.9–3.8) and progression-free survival (PFS) 5.4 months (IQR 7.1–3.1). In the pivotal study, OS was 12.3 months (IQR 15.8–10.8) and PFS was 5.2 months (IQR 5.6–4.4).

The most frequent adverse reactions observed with treatment compared to the IM power were asthenia(39% vs 27.3%), anaemia(32% vs 43.4%), neutropenia(18% vs 37.4%), diarrhoea(7% vs 21.3%) and constipatio (4% vs 25.8%).

Conclusion and Relevance Patiens in our study have similar demographic characteristics to the IMpower133 trial. The data obtained are consistent with the results of thetrial. The efficacy data obtained in our population show a good benefit-risk ratio in these patients with advanced disease. Atezolizumab combined with chemotherapy is a treatment with a good safety profile and well-tolerated by patients, which makes it a good treatment alternative.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-105 EVALUATION OF A CHRONIC MEDICATION ADEQUACY PROGRAMME AT HOSPITAL DISCHARGE FOR FRAIL PATIENTS ADMITTED TO THE EMERGENCY SHORT-STAY UNIT OF A TERTIARY HOSPITAL

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Background and Importance Elderly's frailty and multimorbidity make them vulnerable to polypharmacy and inappropriate use of medications. This leads to the development of drug related problems (DRP), putting their health at risk. Different strategies have been proposed to optimise polipharmacy in older adults.

Aim and Objectives To adequate the chronic medication of frail patients discharged from the emergency short-stay unit, according to the evidence and individualised to their comorbidities. To analyse the performed interventions according to physician's acceptance and clinical benefit obtained.

Material and Methods Multidisciplinary project on the adequacy of chronic medication at hospital discharge developed in a tertiary-level hospital. Prospective medication plan review of patients expected to be discharged and who met frailty criteria (adjusted morbidity grade=4 and readmission risk $\geq$10%) was performed. Recommendations were made for patients with inadequate medication, of which those made between February-May 2024 were analysed. Collected data from electronic health record: demographics, comorbidities, intervention acceptance, medication plan and reconsultations to the health system in the next 3 months. Clinical benefit was evaluated as efficiency for the non-occurrence of a potential DRP for primary prevention interventions (PPI) and for the DRP-resolution for secondary prevention interventions (SPI), and safety as the non-occurrence of damage related intervention. Two groups were compared according to acceptance (A) or non-acceptance (N-A). Qualitative variables expressed as absolute values and relative frequencies and quantitative variables as medians (interquartile range).

Results Sixty-six interventions (55(83.3%) PPI, 11(16.67%) SPI) were made in sixty patients(61.6% women, 85.7(5.75) years, 11.3(7) drugs/patient). Baseline characteristics were balanced between groups.

Main intervened drugs: benzodiazepines(53.0%), antidepressants(13.6%); proton pump inhibitors(6.1%), inhalation therapy(4.6%), antiplatelet agents(4.6%) and others(18.1%). Reasons for inadequacy: inappropriate drug(65.2%), adverse effect(13.5%), better alternative available (10.6%), inappropriate dose (6.1%) and additional treatment required (4.6%).

A group: 30(45.5%) of which 22 PPI(73.3%) and 8 SPI (26.7%). Efficacy and safety: PPI (18(81.8%) and 21(95.45%)) and SPI (8(100.0%) and 8(100.0%)).

Medical reconsultations (A vs N-A): for any reason (70.37%vs72.73%), DRP-related (7.4%vs21.21%).

DRP-resolution (A vs N-A): 100% (8/8) vs 0% (0/3).

Conclusion and Relevance The interventions performed were mostly effective and safe. Although a longer follow-up time would be necessary to confirm a clinical impact, DRP-reconsultations were lower in the intervention-accepted group. The acceptance rate should be improved by involving primary care physicians.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-106 ANALYSIS OF ADVERSE DRUG REACTIONS LEADING TO HOSPITAL ADMISSION IN A REGIONAL HOSPITAL

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Background and Importance Adverse Drug Reactions (ADR), which are harmful and unintended effects related to medication, can increase morbidity and mortality. According to literature, the incidence of hospital admissions (HA) due to ADR range between 1–28%; leading to hospital stays and related cost between 1–8 days and € 2,000–6,000, respectively. Gastrointestinal and nervous systems disorders are the most common adverse effects; being drugs acting on nervous system as mainly involved on them

Aim and Objectives Primary objective is to determine the prevalence of HA due to ADR. Secondary objectives are to describe: groups of drugs involved, adverse effects, length of hospital stay, and associated costs

Material and Methods Between January-2022 and August-2023 we conducted a retrospective observational study, evaluating proportion of ADR-HA in relation to emergency department (ED) visits by ADR, and total HA. Furthermore, we describe: drugs involved in ADR according to first level of Anatomical Therapeutic Chemical classification (anatomical system); and adverse effects according to organ and system injured (fifth level of MedDRA hierarchy). Length of hospital stay (LOS; in days) and associated costs (in euros, according to official fees) due to these ADRs were also calculated. Qualitative outcomes were expressed as percentages, and quantitative ones as mean ± standard deviation

Results During the study period, 272 ED visits for ADR occurred, of which 135 (49.6%) required HA, representing 1,4% of all-cause HA. Mean age for patients with ADR-HA was 69±19 years, and 53.3% were women. The mean LOS for ADR-HA was 6.3±4.6 days, with an average cost of € 6,749.6±4,964.7, mainly due to gastrointestinal (n=26; 19.3%) and nervous system disorders (n=17; 12.6%). Drugs mainly involved were those acting on cardiovascular system (n=38; 28%), nervous system (n=36; 27%), and antineoplasic and immunomodulatory agents (n=26; 19%)

Conclusion and Relevance In line with findings by other authors, our study showed an incidence of ADR-HA of 1,4%, with LOS and associated cost around 6 days and € 6,700 per HA, respectively; mainly due to gastrointestinal and nervous system disorders. However, drugs acting on cardiovascular system were most commonly involved in HA-ADR in our study, which focused on hospitalisation; unlike other studies that included ED setting, where drugs acting on nervous system predominated

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-107 ANALYSIS OF BETA-LACTAM ALLERGIES: 'DE-LABEL YOUR ALLERGY' PROJECT

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Background and Importance Beta-lactams (BL) are the group of antibiotics with the highest number of reported allergic reactions. The overidentification of patients labelled as allergic is a significant factor in antibiotic management, necessitating the use of alternative antimicrobials that may be less effective, safe, and efficient. PEN-FAST(Penicillin Allergy Decision Rule) is an internationally validated tool for assessing individual risk for penicillin allergy.
Aim and Objectives To review and update allergy records in the electronic prescription program(EP) of the hospital and the digital clinical history (DCH).
Material and Methods This descriptive study analysed allergy records to BL in patients admitted to a tertiary care hospital from June to October 2024. Collected data included age, sex, type of recorded allergy (therapeutic group(TG) or active substance(AS)), presence of allergy studies, previous prescriptions of BL (in the last 5 years), type of reaction (diarrhoea, syncope and reaction at the injection site), PEN-FAST score, and actions taken (removing the record or referring for allergy study). PEN-FAST evaluates: reactions in the last 5 years (2 points), angioedema or anaphylaxis (2 points), severe cutaneous reaction (2 points), and necessity for treatment for the allergic episode (1 point). PEN-FAST score < 3 identifies low-risk allergies. Allergy records were removed for patients scoring 0 points, while those with scores ≥2 were referred for allergy evaluation.
Results 33 patients were included. The mean age was 72.3 years (SD=15.1), with 56% being female. Recorded types of allergy included: TG BL (6), penicillins (12), AS amoxicillin (8), and other BL (7). Only 3% of patients had allergy studies, and 44% had prescriptions in the last 5 years. Types of reactions included: diarrhoea (9%), syncope (6%), and reaction at the injection site (12%). PEN-FAST results showed 0 points (21 patients), 2 points (9 patients), and ≥3 points (3 patients). The allergy record was removed for 26 patients (79%), while the remainder were referred for allergy evaluation.
Conclusion and Relevance The 'De-label Your Allergy' project has successfully identified and corrected significant discrepancies in allergy records to BL, demonstrating that the majority of patients have an incorrect allergy label. This underscores the importance of updating BL allergy records, contributing to the safe use of antibiotics.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-108 COMPARISON OF THE FRENCH PRESCRIPTION GUIDE ADAPTED FOR THE ELDERLY (PAPA GUIDE) WITH THE EUROPEAN STOPP/START (S/S) LIST

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Background and Importance 41% of people over the age of 75 suffer from polymedication, resulting in a high iatrogenic risk. Medication-related iatrogenesis is responsible for 20% of emergency hospitalisations among the elderly. Limiting this risk is one of the challenges facing clinical pharmacy. To this end, prescribing aids have been created, such as the PAPA guide, revised in 2015, and the European S/S list of 2023.
Aim and Objectives Analyse the divergences between the PAPA guide and the S/S list to check their concordance.
Material and Methods We recorded the prescriptions of patients over 75 years of age, hospitalised in a post-emergency ward. We analysed them using the PAPA guide and the S/S list, in order to identify any divergences in prescribing non-conformities (PNC) between these two guidelines.
Results After extracting the prescriptions of 50 patients, aged between 75 and 100 years (mean = 86 years), we identified 438 prescription lines. We noted 1,60% PCN divergences (7/438) between these 2 tools.

The PAPA guide identifies 5 PCNs that the S/S list does not mention:

- 3 contraindicated combinations: converting enzyme inhibitor or angiotensin II receptor antagonist in combination with aldosterone antagonist after age 80.
- 1 contraindication: cognitive risk of biperiden.
- 1 wrong indication: mirtazapine for insomnia.

On the other hand, the S/S list identifies 2 other PCNs compared with the PAPA guide:

- 1 class duplication: 2 antihistamines simultaneously.
- 1 risk of adverse effects: systematic use of tramadol.

Conclusion and Relevance The 2 tools are largely concordant. However, there are various biases: the PAPA guide was last updated in 2015, whereas the S/S list was updated in 2023. Certain drugs are therefore not referenced in the PAPA guide, notably dapagliflozin, tafamidis, and anagrelide. Certain pathologies, such as asthma and allergies, are not listed in the PAPA guide. Finally, unlike the PAPA guide, the S/S list does not take dosage into account. These 2 tools are thus in agreement, but the comparison remains complex due to the different biases and their different formats: digital platform for the S/S list, with detailed arguments for each molecule, versus booklet organised by pathology for the PAPA guide. Their use is therefore complementary.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-109 ROLE OF THE PHARMACIST IN THE APPROACH TO VACCINATION OF IMMUNOCOMPROMISED PATIENTS TREATED WITH BIOLOGIC DRUGS

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Background and Importance Patients diagnosed with IBD are more susceptible to infections and potentially serious complications, because of the underlying disease and the immunosuppressive treatment (corticosteroids, immunosuppressants or biologic drugs). It is therefore recommended that people with

IBD ensure that their vaccination schedule is up to date, particularly pneumococcal and influenza vaccination.
Aim and Objectives The objective was to analyse the vaccination of paediatric patients diagnosed with inflammatory bowel disease (IBD), ulcerative colitis (UC) and Crohn's disease (CD), who are being treated with biological drugs.
Material and Methods An observational, retrospective, cross-sectional study was conducted in a tertiary care hospital. Patients under 18 years of age with a confirmed diagnosis of IBD, on active treatment with biologic drugs for at least six months and without contraindications for vaccination were included.

Data were obtained by reviewing the electronic medical records. The following information was collected: demographic data, type of IBD, biological agent and the vaccination status of the patients in accordance with the guidelines established by the Andalusian Health Service, and specifically adherence to annual influenza vaccination (Instruction DGSPyOF-6/2023) and pneumococcal vaccination in risk groups (Instruction DGSPyOF-10/2023).
Results Thirty-three paediatric patients were included, 56% were female. Mean age was 14 years. 78.8% were diagnosed with CD and 21.2% with UC. Among patients with CD, 30.75% received infliximab, 50% adalimumab, 15.4% ustekinumab and 3.85% infliximab plus vedolizumab

Among those with UC, 85.7% were treated with adalimumab and 14.3% with infliximab.All of them were adequately vaccinated against hepatitis B, measles, rubella and mumps (MMR vaccine) and tetanus, diphtheria and pertussis (Tdap vaccine).

The percentage of unvaccinated patients was as follows: 51.51% for influenza vaccine, 24.4% for pneumococcal vaccine, 20% for hepatitis A, 17% for human papillomavirus (HPV), 14% for COVID-19 and 2% for inactivated poliovirus.
Conclusion and Relevance The results indicate that it is necessary to improve adherence to vaccination schedules, especially for influenza, pneumococcal infections and COVID-19 vaccines, which are vital to reduce the risks and complications of infection in immunocompromised patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-110 ANTIBIOTIC STEWARDSHIP IN AN EMERGENCY DEPARTMENT

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Background and Importance Antimicrobial resistance represents one of the foremost health challenges of our time. The implementation of a regional antibiotic policy and a reduction in the use of broad-spectrum antibiotics are seen as key solutions. However, recent data from emergency department (ED) still indicate inappropriate use of antibiotics.
Aim and Objectives This study aims to investigate the adherence to the regional antibiotic policy in empirical antibiotic choices for intravenous administration.
Material and Methods Records of adult patients admitted between May and August 2023 were screened. For patients undergoing antibiotic treatment, the following data were recorded: gender, age, admission diagnosis, antibiotic, dosage, and frequency. The last three parameters were employed to evaluate the empirical antibiotic choice in accordance with the regional guidelines. Subsequently, data were categorised into three groups: 'Green' (appropriate empirical treatment); 'Yellow' (suboptimal empirical treatment); and 'Red' (empirical treatment with a broader spectrum than necessary according to indication).
Results A total of 53 individual patient records were screened (51% male, n=27), of which approximately 70% of the patients were over 70 years-old. Based on the selected categories, the empirical antibiotic choices were distributed as follows: 60% (n=32) in 'Green'; 19% (n=10) in 'Yellow'; and 21% (n=11) in 'Red'. The categorisation as 'Yellow' was attributed to the absence of a macrolide in combination therapy for 50% (n=5), while the remaining 50% were due to insufficient antimicrobial spectrum/dosage, or lack of combination therapy. The 'Red' categorisation was assigned to 45% (n=5) of cases due to deviation from the first-line recommendation of intravenous ampicillin/gentamicin. For patients diagnosed with infection without a known focus, 46% (n=6) were classified as 'Red'. In cases of pneumonia without COPD or asthma, 43% (n=3/7) fell into the 'Red' category. These two diagnoses demonstrated the lowest levels of guideline adherence. For sepsis, only one patient (17%) was classified outside the 'Green' category.
Conclusion and Relevance This study demonstrates that 40% of empirical antibiotic choices in the ED were not in accordance with the established regional antibiotic policy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-111 RISK ANALYSIS OF ADVANCED THERAPY MEDICAL PRODUCTS (ATMPS) CIRCUITS WITHIN A UNIVERSITY HOSPITAL

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Background and Importance The diversity of Advanced Therapy Medicinal Products (ATMPs), together with their high cost and regulatory requirements, necessitate the establishment of complex pharmaceutical circuits. Their deployment within our hospital requires the collaboration of many partners, located at different sites. The complexity of ATMP circuits and the large number of people involved increase the risk of errors during the process. One of the most widely used methods to identify and manage potential risks in a process is FMEA (Failure Modes and Effects Analysis).
Aim and Objectives We aimed to map and analyse all risks inherent to our ATMP circuits in order to propose corrective and preventive actions (CAPAs) for unacceptable risks, following the FMEA method.
Material and Methods Multidisciplinary working groups evaluated each stage of the circuit using an experienced-base risk assessment, identifying known or potential risks, their causes and effects. The criticality of each risk was scored out of 125, according to its frequency, severity and detectability, each

coded from 1 to 5 following institutional recommendations. Risks were categorised according to their score: low (< 10), moderate (10–20) and critical (> 20). Critical risks, deemed unacceptable, led to the formulation of CAPAs.

Results A total of 291 potential risks were identified across 7 stages, from prescription to administration. Of these, 86% were considered acceptable (low and moderate risks), while 14% were deemed critical, with reconstitution being the most critical step. Of the critical risks, 90% were attributed to our facility, 7% to the manufacturer and 3% to our cryopreservation partner. Human factors accounted for 50% of these risks, organisational and logistical for 25%, and technical for 25%. The main consequence affected patients (58%). CAPAs for critical risks required human resources in 62% of cases, technical resources in 28% and laboratory coordination in 10%.

Conclusion and Relevance This analysis showed that our circuits are generally secure, as the majority of the risks identified were acceptable. The main sources of risk included the absence of a dedicated team within the pharmacy, inexperience, increasing workload, and the diversity of ATMPs. An evaluation of the implementation and effectiveness of CAPAs is planned as part of an ongoing effort to improve the quality of our circuits.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-112 EVALUATION OF THE USE OF INFLIXIMAB IN IMMUNE CHECKPOINT INHIBITOR-INDUCED ADVERSE REACTIONS

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Background and Importance Immune checkpoint inhibitors (ICIs) have transformed cancer treatment. However, their use can lead to immune-related adverse events (irAEs). Corticosteroids are the first-line treatment for irAEs; in refractory cases, selective immunosuppressive therapies such as infliximab (off-label use) can be administered.

Aim and Objectives To evaluate the efficacy of infliximab in treating irAEs in cancer patients receiving ICIs.

Material and Methods A retrospective observational study was conducted at a tertiary hospital, including demographic, clinical, and efficacy data of patients treated with infliximab for irAEs from January 2011 to October 2024.

Results Thirty-one patients were included; 58.1% (n=18) were men, with a median age of 61 years(range: 28–84). ICIs responsible for irAEs included ipilimumab plus nivolumab(45.2%, n=14), ipilimumab(22.6%, n=7), nivolumab (9.7%, n=3), pembrolizumab(9.7%, n=3), and other ICIs (12.9%, n=4). Infliximab was used to treat colitis (confirmed by fibrocolonoscopy) in 48.4% of patients (n=15; grade 4 in 2 patients, grade 3 in 8 patients, and grade 1–2 in 5 patients). It was indicated for diarrhoea (without colitis) in 35.5% (n=11; grade 3 in 9 patients and grade 1–2 in 2 patients). Infliximab was indicated for pneumonitis in 16.1% (n=5) of patients, all presenting with grade 4. Reactions occurred after the first administration of ICIs in 16.1% (n=5), after the second in 25.8% (n=8), after the third in 22.6% (n=7), and after at least the fourth dose in 35.5% (n=11). During ICI treatment, 32.3% of patients experienced more than one irAE.

All patients received steroids (1mg/kg/d) as first-line therapy, with an initial response in 54.8% (n=17) and a median treatment duration of 11 days. The number of infliximab doses (5mg/kg, with 2 patients receiving 10mg/kg) administered was one in 71% of patients (n=22), two in 22.6% (n=7), and three doses in 6.5% (n=2). Complete resolution was achieved in 61.3% of patients (n=19), partial improvement in 22.6% (n=7), and no improvement in 16.1% (n=5, all failures in pneumonitis).

Infliximab was administered during hospitalisation in 58.1% of patients. Only 29.1% resumed immunotherapy after infliximab treatment, with one patient experiencing a recurrence of the irAE.

Conclusion and Relevance Infliximab was effective in treating immune-mediated colitis and diarrhoea, reducing steroid dosages. However, it was not beneficial in cases of immune-mediated pneumonitis.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-113 VITAMIN D PRESCRIPTION IN COMPLEX CHRONIC PATIENTS AND PHARMACEUTICAL INTERVENTIONS TO TRATMENT OPTIMISATION

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Background and Importance Some studies have shown an unjustified increase in vitamin D supplementation, despite potential risks of adverse events. Current guidelines advise evaluating the benefit-risk ratio and considering deprescribing when needed.

Aim and Objectives Evaluate the vitamin D prescriptions in complex chronic patients (CCP) and assess the acceptance of pharmaceutical interventions carried out in primary health care to optimise treatment.

Material and Methods An observational and prospective study was performed in a tertiary hospital from February to May 2024.

Pharmacotherapeutic reconciliation was carried out in CCP, who was admitted to the hospital in February. Those with a prescription for calcifediol and/or cholecalciferol in their electronic prescription were selected.

Pharmaceutical interventions were conducted for the primary care team in those patients meeting the Less-Chron deprescribing criteria and those lacking analytical follow-up in the last year, to evaluate the need to continue the supplementation. The acceptance of these interventions was evaluated in May.

Sociodemographics and analytical data were collected from clinical records.

Results Medication reconciliation was performed on 284 PCC and 94 (33%) were included with a prescription for vitamin D (57% women, 80±11 years).

The 36% (34) lacked prior vitamin D measurement. Of those measured, 13% (12) had >20 ng/ml, 19% (18) had 10–20 ng/ml, and 32% (30) had <10 ng/ml.

A total of 41 pharmaceutical interventions were conducted: 83% (34) due to lack of analytical follow-up and 17% (7) based on meeting the Less-Crohn deprescribing criteria.

The 20% (8) of the interventions were not evaluable due to loss of patient follow-up.

The acceptance was evaluated in 29 patients in the follow-up group and 4 in the Less-Crohn. The acceptance of the interventions was 34% (10) and 75% (3), respectively.

Conclusion and Relevance This study reveals a lack of assessment of vitamin D levels prior to the initiation of supplementation, as well as a lack of follow-up during treatment.

The implementation of pharmaceutical interventions for patients with vitamin D prescriptions demonstrated a significant opportunity to optimise pharmacotherapy in complex chronic patients. The ongoing evaluation of patient follow-up is essential to enhance the effectiveness of these interventions, ensure appropriate management of chronic conditions, and avoid overprescription in unnecessary situations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-114 ADALIMUMAB IN PATIENTS WITH IMMUNE-MEDIATED DISEASES: EVALUATING THE TRANSITION TO THE BIOSIMILAR AND PATIENT-REPORTED OUTCOME MEASURES (PROM)

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Background and Importance The introduction of biosimilars in treatment of immuno-mediated diseases benefits both healthcare systems and patients.

Nevertheless, patient concerns about switching may affect adherence and long-term outcomes.

Aim and Objectives Assess how patients perceive the switch from reference to biosimilar or between biosimilars.

Material and Methods Observational longitudinal study where patients switching from Humira or Hyrimoz to Yuflyma complete surveys before and after to assess parameters such as self-administration ability, pain level and their impact, satisfaction rate, patient-reported improvement after switch and the underlying reason for it.

Pain, improvement and satisfaction were rated on a 0to5 scale.

Results 55 patients were included(mean age46±12, 60% women).

The pre-switch survey was answered by 55 patients;58.2% treated with Hyrimoz and 41.9% with Humira . The most common diagnoses were Crohn's disease(34.0%), Hidradenitis suppurativa(14.5%) and rheumatoid arthritis(9.1%). While 80% were able to self-administer it, 10.8% of patients required assistance.

Pain was reported by 58.2% of patients on reference. Only 25.5% rated it at level 0, 14.5% at 1, 20.0% at 2, 18.2% at 3, 16.4% at 4 and 5.5% at the highest level. Pain was a challenge to continuing the treatment, a source of anxiety for 11.0% and reason to need assistance for 5.5%.

Satisfaction with reference was rated at level 3 or lower for 25.5%, 4 by 25.5% and 5 by 49.0%.

After switching to Yuflma, 40 patients completed the survey, 97.5% could self-administer, and 2.5% needed assistance. Sixty percent noticed a change in pain perception, 65.0% reported no pain, 12.5% rated it at level 1, 20.0% at 2 and 2.5% at 3. None found it a challenge for treatment.

As for the improvement, 52.1% rated at level 5, 22.5% at 4, 7.5% at 3, 12.5% at 2 and 5.0% at 1 or lower. This was due to being less painful and easier for 30.0% and anxiety feelings decreased for 20.0%.

Satisfaction level was rated at level 5 for 80.0%, 7.5% rated it at 3 and 4 and 2.5% at 2 and 0.

Conclusion and Relevance Switching to the biosimilar improved PROM, with most patients self-administering treatment, experiencing less pain, and greater satisfaction.

However, not all patients participated in the follow-up, limiting comparisons between groups.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-115 INFLUENCE OF THE PHARMACY IN ADHERENCE TO TREATMENT IN PATIENTS WITH MULTIPLE SCLEROSIS

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Background and Importance Ocrelizumab is an CD20-directed humanised monoclonal antibody, used in the treatment of primary progressive and relapsing multiple sclerosis. Is given every six months as a 600 mg intravenous infusion.

Aim and Objectives The aim of the study was to monitor the prescribing appropriateness and therapeutic adherence of patients treated with Ocrelizumab in an Italian hospital. Since 01/01/2024, the prescription has been computerised and the preparation of the drug has been centralised in the Clinical Pharmacy laboratories present in the Hospital Pharmacy. This has speeded up the transmission and reception times of clinical information, reducing prescribing errors. The pharmacist of the Clinical Pharmacy Laboratory is responsible for the on-demand preparation of Ocrelizumab.

Material and Methods Hospital prescriptions were analysed, from January 2020 to September 2024. A database has been created: data analysed were patient characteristics, clinical conditions and therapeutic indication entered by clinician, to verify prescriptive appropriateness. Therapeutic adherence was obtained comparing the clinical calendars of presumed administration (every six months) and the actual data in which the infusion was carried out.

Results 117 patients were treated with ocrelizumab: 60,68% females males 39.32% males; average age 46 years. Patient adherence was 92.31%; 5,98% were not compliant with drug therapy due to suspension of therapy and 1,71% for irregular administration. To reduce prescribing errors and to evaluate the prescriptive appropriateness, collaborating with the clinician, computerised protocols were created, in which the clinical conditions of the patients were entered: all prescriptions were compliant than those provided in the technical data sheet.

Conclusion and Relevance The analysis carried out confirms that the incidence of the disease follows the European trend,

in which women are more affected than men, often adults under 50 years of age. Compliance with the treatment was particularly high: 92.31% of the sample examined regularly performed the treatment. Adherence is paramount to achieving therapeutic goals in multiple sclerosis: a therapy with an infrequent dosing schedule, twice a year, makes it easier to achieve. The data highlights the importance of implementing new technologies in the management of clinical activities of prescribing, preparation and administration of therapy, encouraging multidisciplinary collaboration between clinicians and hospital pharmacists, necessary to guarantee high standards of care performance.

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

5PSQ-116 ANALYSING UNIVERSITY HOSPITALS' CLINICAL DECISION SUPPORT SYSTEM ALERTS FOR MEDICATION ORDERING PROCESS

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Background and Importance Computerised physician order entry (CPOE) with structured ordering process and clinical decision support (CDS) system is a widely used systemic defence to enhance medication safety in hospitals. However, the implementation of these systems requires major changes to the workflows, which has been associated with an increased risk of prescribing errors.
Aim and Objectives To describe and analyse the CDS alerts and the responses of the end-users at ordering process for the further development and optimisation.
Material and Methods This cross-sectional register-based study was targeted to CDS alerts of a university hospital's inpatient orders in 2022. CDS alerts of inpatient orders were investigated with descriptive quantitative analysis to identify the prevalence of alerts and end-users' responses to them. The alerts displayed for conservative and operative specialties were analysed separately to identify possible differences. The data were analysed using descriptive statistics with Microsoft Excel.
Results In 2022 there were altogether 5,342,217 inpatient medication orders. For 16% (n = 874,317) of the orders, CDSS produced a soft-limit pop-up alert and 87% (n = 762,746) of these were overridden without changing the original orders. The alerts for operative and conservative specialties covered almost 57% (n = 495,399/874,317) of all alerts and there were no major differences between the specialties. Interactions caused the majority of alerts and had high override rates (93–94 %). The highest override rate was for alerts regarding potentially inappropriate medications for older adults (Meds75+), and pregnancy and lactation alerts (94–97 %). The alerts related to drug allergies (55–65% overridden) and duplicate orders (69–88 % overridden) had the highest acceptance rates.
Conclusion and Relevance The high override rates indicate alert fatigue and a need for optimising the CDS' alerts. Based on the results, pop-up alerts for interactions should be limited only to the most severe interactions. Unnecessary pregnancy and lactation alerts should be filtered. Meds75+ warnings are not meant to be shown as pop-up alerts, and the clinicians should be guided to use the database in other ways. These changes would decrease 30% of the CDSS' pop-up alerts.

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

5PSQ-117 EFFECTIVENESS OF BARICITINIB IN ALOPECIA AREATA

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Background and Importance Alopecia areata (AA) is a condition characterised by hair loss resulting from the production of pro-inflammatory cytokines that induce the cessation of hair follicle growth via the JAK/STAT pathway. Thus, the inhibition of the JAK/STAT pathway using drugs such as baricitinib represents a therapeutic strategy for this condition.
Aim and Objectives To evaluate the efficacy of baricitinib in the treatment of AA.
Material and Methods Retrospective observational study conducted in a tertiary care hospital, completed on August 31, 2024. All patients with AA treated with baricitinib with a baseline Severity of Alopecia Tool (SALT) score $\geq$ 50 were included.
Collected data: demographic variables (sex and age), previous treatment with tofacitinib, baricitinib dosage, treatment duration, adverse events (AEs) and SALT score.

Effectiveness was evaluated based on the proportion of patients who achieved a SALT ≤20 at week 36 of treatment. To assess long-term effectiveness, patients who achieved SALT ≤20 at week 52 were measured.
Results A total of 39 patients were included, 56% were female, with a median age of 44 years (range: 11–68). Five patients received previous treatment with tofacitinib, four discontinued due to ineffectiveness and one due to approval of baricitinib in AA. 89.74% of patients started with a dose of 4 mg of baricitinib and 10.3% with 2mg, the latter were <18 years-old.

At the end of the study, 10.3% discontinued baricitinib due to ineffectiveness after a median time of 71 weeks. The most common AE was hypercholesterolaemia (18%).

Regarding the main objective, SALT ≤20 was achieved in 11 of 26 patients (42.3%) at 36 weeks of treatment and 11 of 21 patients (52.4%) at 52 weeks of treatment.
Conclusion and Relevance These results confirm that baricitinib is an effective alternative in the treatment of AA. Although the results are based in a small cohort of patients, the proportion of patients with SALT<20 was superior compared with the efficacy results obtained in the clinical trials BRAVE-AA1 y BRAVE-AA2, where a SALT <=20 was reached in a 34% of patients at week 36.

Besides, the effectiveness of this treatment until week 52 was confirmed, proving its efficacy in a prolonged time.

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

5PSQ-118 INTELLIGENT INFUSION PUMPS FOR CYTOSTATIC DRUG DELIVERY: DEVELOPMENT OF A DRUG LIBRARY AND FIRST STEPS OF IMPLEMENTATION

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Background and Importance The incorporation of smart infusion pump technology allows the incorporation of medication error reduction software that includes a drug library.
Aim and Objectives The aim of this study is to design and implement a drug library for the administration of intravenous oncohaematological treatments in an oncohaematology day hospital for its incorporation into the software of the intelligent pumps and to carry out initial monitoring.
Material and Methods Prospective, single-centre, multidisciplinary intervention study comprising pharmacists, IT staff and nurses. Pre-intervention phase: installation, drug library design and staff training from November 2022 to February 2023. Intervention phase: implementation of the software, monitoring of alerts and modification of alerts until March 2023. Software was initially installed on two pumps and upgraded weekly to full 27 pumps. Plum 360 15.1x pumps with Hospira MedNet software were used.
Results In the pre-intervention phase, relative and absolute limits per drug were defined. The maximum possible dose was calculated for a body surface area of 2m2 or 100kg. For drugs with different doses per protocol, the maximum dose was chosen. With this calculation, the rates (mL/h) for the relative upper limits were defined. The absolute upper limit was calculated by adding 1% to the relative upper limit. Lower limits were only defined for the following drugs: vinblastine, vincristine, epirubicin, bendamustine, etoposide, methotrexate. In the intervention phase, a total of 85 alerts were detected, 47 from absolute upper limits, 38 from relative upper limits and 0 from lower limits. Of the total number of alerts, 60 (70.5%) were caused by inadequate selection of the entry, the remaining 25 (29.5%) by too strict limits. The limits were adjusted and all alerts were reviewed with the nursing staff. The final pharmacotheca consisted of 87 entries made up of 58 drugs. 2701 infusions were performed, of which 263(9.7%) were performed without drug definition.
Conclusion and Relevance The design of the drug library requires a thorough review of existing protocols and drugs. Lower limits were defined for drugs administered as bolus, vesicants or when their usual rate of administration was 999mL/h. The implementation was considered successful, its monitoring has allowed corrective measures to be established and has contributed to increasing patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-119 ENCEPHALOMYELITIS AFTER RABIES VACCINATION: A REPORT OF TWO CASES

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Background and Importance Rabies is a deadly viral disease that requires post-exposure vaccination prophylaxis after a suspected animal bite. Although rabies vaccines are generally safe, serious adverse effects can occur. We report two cases of children who developed neurological complications following rabies vaccination.
Aim and Objectives To present two cases of children who received rabies vaccination after a dog bite and developed serious complications, in order to examine the clinical presentation, investigations, and treatments administered.
Material and Methods This is an analysis of two notifications from the infectious disease department of our hospital concerning children aged 6 and 10 years who developed complications after receiving post-exposure rabies vaccination. Data were collected from the patients' medical records, including results from clinical, biological, and radiological examinations.
Results Two children, aged 6 and 10 years, received rabies vaccination following dog bites. The first child (6 years old) presented with fever, altered consciousness, and a deterioration in general condition after the fourth dose of the vaccine. The second child (10 years-old) developed paralysis and fever after the third dose. Both children were hospitalised, and investigations, including saliva and cerebrospinal fluid (CSF) samples, as well as a brain magnetic resonance imaging (MRI), were conducted. The two children received antibiotic therapy and corticosteroid boluses, with immunoglobulin administered to only one of the children. The diagnosis was established based on MRI findings suggestive of rabies encephalitis, as well as negative results from saliva and CSF samples that excluded the presence of the rabies virus, clearly pointing towards post-vaccination encephalitis.
Conclusion and Relevance These cases demonstrate that, although rare, serious neurological complications, such as encephalitis, can occur after rabies vaccination. These events highlight the importance of careful post-vaccination monitoring, especially in children, to quickly detect and treat serious adverse effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-120 USE OF DIRECT ORAL ANTICOAGULANTS IN THE EMERGENCY DEPARTMENT OF A TERTIARY HOSPITAL: A RETROSPECTIVE REVIEW OF CLINICAL PRACTICE

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Background and Importance Direct oral anticoagulants (DOACs) are increasingly prescribed in the emergency department (ED). However, their implementation presents challenges such as dosing accuracy and drug interactions, which can increase the risk of adverse outcomes or lack of effectiveness.
Aim and Objectives This study evaluates DOAC usage at discharge of the ED, analysing prescription patterns, dosing accuracy, and the need for dose adjustments. The study will also investigate the prevalence of anticoagulant-naive patients, those transitioning from other anticoagulants, and the occurrence of drug interactions.

Material and Methods A retrospective observational study conducted on patients who were prescribed a DOAC in the electronic prescription upon discharge between January 2024 and April 2024 in a tertiary hospital's ED. Clinical records were reviewed to collect demographic data, indications, dosing, interactions, concomitant use of antiplatelets and analytical parameters. Descriptive analyses were conducted, with continuous variables presented as medians and standard deviation, and categorical variables as frequencies and percentages.

Results A total of 120 patients(51 males, 69 females) with a mean age of 76 years(SD:12.36) were included. Anticoagulants prescribed included apixaban(62 patients), rivaroxaban(48), edoxaban (9) and dabigatran(1). Doses were appropriate in 90% of patients(108), inappropriate in 8.3% (5 overdosed and 5 underdosed), and unassessable in 1.7% (2). Primary indications were atrial fibrillation(82%), atrial flutter(13.3%), thrombosis (0.8%), and cardioembolic stroke(0.8%). DOAC was used as a bridge for cardioversion in 19 patients. There were 104 anticoagulant-naive patients, 12 transitioned from antivitamin k, and 4 from another DOAC. Drug interactions were observed in 4 patients (diltiazem:1, amiodarone:3). Concomitant antiplatelet therapy was maintained in 24 patients (20%), but with appropriate continuation only in 6 cases, in 11 cases it should not have been maintained and in 7 cases was doubtful.

Conclusion and Relevance The study highlights an appropriate dosing of DOACs in ED(90%). The presence of inappropriate dosing in 8.3% of cases underscores the need for improved monitoring and individualised treatment strategies.

There is a high prevalence of concomitant treatment with antiplatelet agents(20%) and this practice seems to be the most complex challenge due to the lack of clear guidelines in this regard.

Periodic analysis of the use of DOACs allows for proposals to be made for improving the use of these high-risk drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-121 SEVERE BONE MARROW APLASIA INDUCED BY ENFORTUMAB VEDOTIN IN A PATIENT WITH METASTATIC UROTHELIAL CARCINOMA: A CASE REPORT AND MULTIDISCIPLINARY MANAGEMENT

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Background and Importance Bone Marrow Aplasia (BMA) is a severe haematologic disorder characterised by bone marrow failure, leading to pancytopenia. This condition can result in life-threatening infections, bleeding, or severe anaemia. Causes include idiopathic factors, drug induced reactions, and viral infections.

Enfortumab vedotin (EV) is an antibody-drug conjugate targeting nectin-4, used in metastatic urothelial carcinoma after failure of platinum-based chemotherapy or immunotherapy. Common side effects include peripheral neuropathy, dermatologic reactions, and moderate haematological toxicities.

Aim and Objectives Describe the case of severe BMA in a patient following a single dose of EV. It also highlights the multidisciplinary management, emphasising the role of the hospital pharmacy team in treatment decisions and adverse event reporting.

Material and Methods We performed a retrospective descriptive study on a patient treated with EV who developed BMA. Data were collected from the digital clinical history system. A literature review was conducted using the UpToDate-database.

Results A 71-year-old male with metastatic urothelial carcinoma received multiple lines of treatment, including cisplatin +gemcitabine and atezolizumab. In March 2024, after further disease progression, our pharmacy team, together with the oncology department at the weekly tumour board, proposed EV based on the EV-301 trial, which demonstrated an overall survival improvement of 3.9 months over standard chemotherapy (hazard ratio 0.70; 95% CI: 0.55–0.85).

Following approval by the hospital's Pharmacy Commission, we administered 1.25mg/kg of EV. The patient initially presented mild symptoms (cough, fever), which were managed with antibiotics and dexamethasone. However, subsequent blood tests revealed severe pancytopenia (haemoglobin: 9.7g/dL, leukocytes:850 (400 neutrophils), platelets: 68.000). Haematology confirmed BMA via bone marrow biopsy.

One month later, despite supportive treatment, the patient's condition remained critical (haemoglobin: 9.6g/dL, leukocytes: 3.940, platelets: 66.000). Treatment with EV was discontinued, and we reported the adverse reaction to the national pharmacovigilance system. The Naranjo algorithm established a causality score of 5, confirming the link between EV and the adverse event.

Options such as erdafitinib were considered but could not proceed due to the patient's deterioration. He was referred to palliative care and passed away 2 months later.

Conclusion and Relevance This case underscores the importance of active pharmacovigilance and multidisciplinary collaboration in identifying and managing severe toxicities like BMA following EV administration.

Clinicians must remain vigilant for life-threatening haematologic events, ensuring rapid intervention to improve patient outcomes.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-122 EVALUATION AND INFLUENCE OF VITAMIN D LEVELS IN THE CRITICALLY CARE PATIENT

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Background and Importance Critically care patients (CCP) show a tendency of very low vitamin D (VitD) levels (<20ng/dl) which is associated with increased morbidity and mortality. Many CCP have a non-functioning gastrointestinal tract and are usually treated with parenteral nutrition (PN). VitD replacement when its absorption is compromised is an added complication and there are controversies about the best option to perform it according to factors such as bioavailability and route of administration.

Aim and Objectives To analyse VitD levels and to evaluate the existing differences in the analytical request in CCP with PN. To study the oral use of VitD (calcifediol) as a restorative treatment option in a tertiary hospital.

Abstract 5PSQ-122 Table 1 Description of patients

Tabla 1. DESCRIPTION OF PATIENTS		
PATIENTS	172 (111 men, 61 women)	
AVERAGE AGE	63,2 years	
AVERAGE BMI	25,2 kg/m^2	
PN MAIN INDICATIONS	Surgical complication (25%) Pancreatitis (10%)	
PN AVERAGE DAYS DURATION	14,3 days (1-123 days)	
AVERAGE DAYS EXPIRED UNTIL REQUEST FOR LEVELS	10,5 days (0-76 days)	
AVERAGE AND STANDARD DEVIATION LEVELS MEASURED DURING PN	6,2 ± 3,8 ng/dl	
VITAMIN D LEVELS PROFILE	SEVERE IMPAIRMENT (<7,6ng/dL)	65 (37,8%)
	IMPAIRMENT (7,6-20ng/dL)	25 (14,5%)
	(>20ng/dL)	0 (0%)
	NOT MEASURED	82 (47,7%)
NUMBER OF PATIENTS WHOSE LEVELS WERE MEASURED...	ON THE SAME DAY AS THE END OF THE NP	14 (15,6%)
	ON THE PREVIOUS DAY AS THE END OF THE NP	12 (13,3%)
	TWO DAYS BEFORE AS THE END OF THE NP	7 (7,8%)
REASON FOR END PN	DEATH	45 (26,2%)
	PROGRESSION TO ENTERAL NUTRITION	50 (29%)
	PROGRESSION TO ORAL NUTRITION	77 (44,8%)

Material and Methods Retrospective observational study of CCP with PN during 2023 to August 2024. From the clinical history and the PN formulation program, the following were recorded in a database: sex and age, anthropometric parameters, diagnosis, number of days with PN and days elapsed until the request for levels during PN, date and value of all VitD blood levels; evolution and reason for suspension of PN; date of oral administration of VitD. Bibliographic review with the keywords, VitD and CCP.

Results A total of 172 CCP were collected, as described in table 1. The days with PN had a wide interval, as well as the days elapsed until levels were determined for the first time. Levels were requested in 37% CCP in a period from 2 days before up to and including the same day of finishing PN. The first serum VitD level of 89 patients is in a high deficiency range 6.2±3.8ng/dl (48.2% CCP without data measured during PN); its monitoring presented a great variability.

Calcifediol was administered in 11 CCP. Serum VitD levels increased in 63.6% and in the rest no subsequent controls were requested.

Conclusion and Relevance It is clear the high prevalence of severe VitD deficiency in CCP and the need to implement a joint protocol with the critical care service to achieve standardisation of the request and normalisation of VitD levels considering Calcifediol as one of the few presentations of VitD available and its high absorption rate.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-123 REPORTED SERIOUS ADVERSE DRUG EVENTS: A KNOWLEDGE SOURCE FOR PHARMACEUTICAL DECISION SUPPORT SYSTEMS LEARNING

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Background and Importance Drug iatrogenia is responsible for 10,000 deaths per year in France. The reporting of Serious adverse drug events (SADE) lead to retrospective implementation of barrier measures aimed at reducing their occurrence. The analysis of SADEs and the transcription of risk situations into a pharmaceutical decision support system (PDSS) would contribute to securing patient medication care in an innovative way.

Aim and Objectives To present the importance of using databases of SADE as a source of pharmaceutical algorithms (PAs) utilised by PDSS.

Material and Methods Two databases of SADEs were analysed by three clinical pharmacists: a key elements synthesis relating to prescription errors identified in the National Database of reporting serious adverse events related to care provided by the French National Authority for Health and a sample of SADEs notified to the Mutual insurance of the French health corps. The potential for formalising each SADE into PAs was evaluated based on several aspects: the existence of a drug

related problem (DRP) with possible solutions, the explicit, encodable, and queryable nature of the assessment elements to represent the SADE in a PA and the availability of related health data in the PDSS.
Results With a sample of 125 SADEs, 57 events (45.6%) were identified as potentially detectable and preventable (53) or mitigable through the creation of 34 PAs. Most of them involved cardiology drugs (8 PAs, 23.5%), followed by endocrinology (5) and analgesics (6). The primary DRPs identified were contraindications based on patient history (9 PAs, 26.5%), such as allergies and organ deficiencies; untreated indications (5) (e.g., absence of anticoagulants, antiplatelet agents); overdoses (5) (including anticoagulants and acetaminophen); and inadequate monitoring (liver enzymes, electrolyte panels).
Conclusion and Relevance SADE reporting system seems a valuable source of PAs for spreading detection of these situations causing patient harm. The underreporting of these events related to prescription, monitoring, or side effects remains a significant issue that could be addressed through the educational and innovative applications of artificial intelligence. Nevertheless, additional solutions are still necessary to reduce SADEs resulting from drug administration processes.

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

5PSQ-124 EXCEEDING SAFE EXCIPIENT LIMITS IN NEONATOLOGY UNIT MEDICATIONS: A CALL FOR SAFER PHARMACEUTICAL ALTERNATIVES

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Background and Importance Excipients in drug formulations have been historically considered harmless. However, due to the immaturity of newborns' metabolism, continuous exposure to certain excipients can lead to accumulation. In these cases, exceeding the accepted daily intake (ADI) could result in harmful effects. Periodic reviews of pharmaceutical specialties (PS) are necessary to detect such risk.
Aim and Objectives Analyse the presence of harmful excipients (HE) in PS used in neonatology unit (NICU) and propose safer alternatives for those that exceed ADI.
Material and Methods Descriptive observational study of the PS consumed in the NICU over last 6 months excluding pharmaceutical compounding (PC). Eight HE were considered based on literature: benzoates, benzyl alcohol, benzalkonium chloride, ethanol, polysorbate 80, propylenglycol, parabens and sorbitol. Summary of product characteristics (SmPC) was reviewed to determine the qualitative and quantitative composition.

To assess whether the quantitative composition exceeded ADI, we extrapolated excipient exposure based on the maximum usual daily drug doses. Safer alternative PSs were sought for those that exceeded ADI.

Results Seventy-six PSs were analysed. The routes of administration included: 44 parenteral, 18 oral, 7 topical, 5 ocular, 1 inhalation and 1 endotracheal.

SmPC were available for 75 PSs. Nineteen PSs (25%) contained at least one HE: 14PSs contained 1HE, 3PS contained 2HEs and 2PS contained 3HEs. Among the detected HEs: 6PSs contained ethanol, 5 propylenglycol, 5 parabens, 3 benzyl alcohol, 3 benzoates, 2 benzalkonium chloride, 2 sorbitol and none contained polysorbate 80.

Of the 19 PSs, 13 contained HEs quantities that exceeded ADI, and 1 PS did not provide quantitative excipient composition. For these 13 PSs, safer alternatives were sought: 5PSs were replaced with commercial alternatives, 2 PSs were replaced by PC and 6 PSs no alternative was available.
Conclusion and Relevance Neonates are frequently exposed to HEs. Some prescribed drugs exceeding ADI, and in some cases, these drugs could be administered simultaneously. Detecting the presence of HEs in medications used in NICU is critical for selecting the safer options. However, composition in HE was missing in some SmPC, despite being required by the EMA, and in some instances, no safer alternatives were available. The development of paediatric medicines with appropriate excipients is necessary.

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

5PSQ-125 EVALUATION OF PATIENT SAFETY CULTURE AMONG HEALTHCARE PROFESSIONALS IN A PHARMACY DEPARTMENT

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Background and Importance Patient safety is an important component of healthcare quality. The *Hospital Survey on Patient Safety Culture* (HSOPSC) designed by the *Agency for Healthcare Research and Quality* is a validated tool used to assess the patient safety culture in hospitals and to identify areas for improvement related to patient safety.
Aim and Objectives The aims of the study were to evaluate patient safety culture of healthcare professionals in a Pharmacy Department and compare it with the results of a previous study conducted in our department in 2014 (HSOPSC version 1.0).
Material and Methods Descriptive and cross-sectional study. Spanish adaptation HSOPSC (version 2.0) was delivered to all staff of the Pharmacy Department. It included 10 dimensions related to patient safety culture, the number of events reported during last year and professional profile.
Results The response rate was 95.4% (42/44), which is considerably higher compared to the 70.0% in 2014 (28/40). A 45% were pharmacists (50% in 2014), while the other 55% included technicians, pharmacist assistants and administrative staff. The overall score of patient safety culture in our department was 3.3 (on a 5-point scale), slightly lower than in 2015 (3.6), and there were no differences between professional profiles or tenure in their positions. A 65% of responders reported at least one event in the last year (compared to 68% in 2014) and there were no significant differences between

pharmacists and non-pharmacists. The most highly rated dimension was 'Communication about error' (71.4% in 2024 vs 56.1% in 2014), which is different from the dimension in 2014: 'Organisational Learning and Continuous Improvement' (84.2% in 2014 vs 62.7% in 2024). The lowest rated dimension was 'Handoffs and Information Exchange' (15.1% in 2024 vs in 45.4% in 2014).

Conclusion and Relevance Patient safety culture has remained stable compared to the previous study. However, the high participation in the actual survey provided a more accurate view of reality, as it involves all professional profiles and suggests a greater awareness of patient safety. The results reflect the efforts made since the last evaluation to improve communication about errors among professionals. The HSOPSC allows us to detect the main strengths and opportunities for improvement in order to design patient safety strategies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-126 PHARMACEUTICAL INTERVENTION IN INTRAVITREAL THERAPY

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Background and Importance Intravitreal injection is a minimally invasive technique, not without risks and complications, of proven effectiveness in the treatment of numerous vitreoretinal diseases. Its use, thanks to new medications and indications, has become widespread in recent years. The role of the pharmacist in the review and validation of these treatments helps to improve the quality of care as well as patient safety by preventing potential medication errors.

Aim and Objectives The aim of the study was to describe the pharmaceutical interventions associated with intravitreal therapy (IVT) in a secondary-level hospital.

Material and Methods Observational, retrospective study. All patients who were prescribed a IVT (ranibizumab, aflibercept, bevacizumab, faricimab and dexamethasone) between October 2022 and September 2024 were included. The variables collected from the electronic prescription program were: number of total patients, number of patients with pharmaceutical interventions (PIs), diagnosis, number of PIs and type of PI.

Results A total of 1136 patients were received IVT in the period of study. In 118 of them the hospital pharmacist performed some type of PIs, which represents a 10,4% degree of intervention. Of this population the most common diagnosis were: diabetic macular oedema (47/118; 39,8%), age-related macular degeneration (38/118; 32,2%), retinal vein occlusion (15/118; 12,7%), non-diabetic macular oedema (7/118; 5,9%), neovascular membrane (4/118; 3,4%), diabetic retinopathy (3/118; 2,5%), choroideal neovascularisation (2/118; 1,7%) and other ophthalmologic pathologies (2/118; 1,7%).

In these 118 patients, the hospital pharmacist carried out 129 PIs before de IVT which included the following causes: wrong medication (49/129; 38,0%), wrong eye (27/129; 20,9%), lower frequency than scheduled (24/129; 18,6%), dose omission (9/129; 7,0%), change of medication due to not indicated medication (9/129; 7,0%), change of medication due to management reason (3/129; 2,3%), duplicate appointment (1/129; 0,8%), and other reasons (7/129; 5,4%). All interventions were accepted.

Conclusion and Relevance This study demonstrates the multiple potential medication errors associated with IVT and provides useful information which supports the importance of the hospital pharmacist´s role in improving patient safety and healthcare quality.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-127 OPIOID WITHDRAWAL IN PATIENTS WITH FIBROMYALGIA

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Background and Importance Fibromyalgia is a pathology with a widespread pain whose control is sometimes inadequate. This may involve the prescription of opioids, which may develop a pattern of dependence known as Opioid Use Disorder (OUD).Furthermore, clinical guidelines expose the lack of benefit of opioids in fibromyalgia, and none make recommendations in favour of their use in these cases.

Aim and Objectives Carry out a procedure developed in our Public Health System to address opioid deprescription in patients with fibromyalgia and therefore with chronic non-oncological pain through creation of a multidisciplinary team.

Material and Methods Descriptive study of interventions on active opioid prescriptions in patients with fibromyalgia. These lists were provided by our Health System in January 2023, with actions being carried out until September 2024. Sex, age, treatment duration, communication to the responsible Primary Care (PC) doctor were collected.

A Multidisciplinary Team for Opioid Deprescription was formed: Medical Director, PC Pharmacist and Hospital Pharmacist, Addiction Treatment Centre Doctor, PC doctor, Mental Health Doctor and Pain Unit Doctor.

This team developed a clinical deprescribing protocol that established that only one PC doctor would prescribe opioids to a patient, avoiding redundancies or paper prescriptions and with whom communication would be established.

The interventions carried out by the PC and AH pharmacists were:

Analyse the list of patients and exclude those who, due to their clinical situation (cancer, end of treatment, death), were not candidates for this intervention.

Inform the responsible doctors by telephone/email so that they, after assessing the patient's clinical situation, could begin the gradual deprescribing process.

Carry out evolution periodic monitoring of these patients.

Results The list contained 48 patients. Two were excluded due to death. Of the 46 patients reviewed,44 were women, with an average age of 65 years. The median duration of treatment was 28 months (1–127).

During the study period,73.9% of the prescriptions (34) were communicated to prescribing physicians. 24 patients (70.1%) began a deprescribing process, two of them without

prior communication from Pharmacy Service. Two patients continued with opioid treatment due to developing oncological pathology.
Conclusion and Relevance To address opioid misuse by patients with fibromyalgia, there must be joint collaborative action between professionals involved, in order to achieve optimal control of chronic non-oncological pain, highlighting the work of pharmacists as a link between health professionals.

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

5PSQ-128 CASE REPORT: ADVERSE REACTION FOLLOWING INTRAVITEAL ADMINISTRATION OF AFLIBERCEPT

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Background and Importance Atypical haemolytic uremic syndrome (aHUS) is a rare disease characterised by a classic triad of microangiopathic haemolytic anaemia, thrombocytopenia, and acute kidney injury. Its diagnosis is made using exclusion criteria, as it can be easily confused with other microangiopathic disorders, such as thrombotic thrombocytopenic purpura (TTP), for which the activity of the enzyme ADAMTS13 is evaluated, and typical HUS, which is usually caused by the Shiga toxin of Escherichia coli.
Aim and Objectives In this particular case, aHUS was triggered after the first administration of aflibercept, an antiangiogenic drug, and, in addition, the patient had positive re-exposure after the second dose. Aflibercept is primarily used for the treatment of age-related macular degeneration (AMD) by intravitreal injections and as part of the FOLFIRI scheme in oncology. However, the main problem in this case lay in the lack of understanding of the pharmacokinetics when administered intravitreally. Although administration is local, aflibercept can be absorbed systemically, inhibiting vascular endothelial growth factor (VEGF) and triggering adverse effects such as aHUS.
Material and Methods The patient underwent the pertinent tests to rule out thrombotic thrombocytopenic purpura (TTP), obtaining a negative result in the ADAMTS13 test, as well as for Shiga toxin, which was negative after the nucleotide amplification test. Biochemical evaluation showed acute renal failure (with elevated serum creatinine: 4,75 mg/dL), thrombocytopenia (102,000 platelets per microlitre of blood), and non-immune haemolytic anaemia (with elevated LDH and haemoglobin levels: 11 g/dL). In addition to these results, the complement factor C3 was analysed (51 mg/dL).
Results After both episodes, eculizumab, the treatment of choice, was administered to reverse the condition and promote recovery from the adverse event, resulting in a positive response after the first administration. However, re-exposure to aflibercept triggered a more severe episode, necessitating prolonged patient monitoring, primarily under the supervision of the nephrology team.
Conclusion and Relevance A review of pharmacovigilance databases such as FEDRA, Eudravigilance, and VigiBase revealed that three cases of aHUS have been reported in connection with the administration of aflibercept. This highlights the importance of monitoring for potential systemic effects of intravitreal treatments, especially in patients who might be predisposed to developing serious complications such as aHUS.

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

5PSQ-129 CHATGPT'S PERFORMANCE AND PHARMACEUTICAL INTERVENTION IN DOSING HIGH-RISK MEDICATIONS IN THE OPERATING ROOM

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Background and Importance High-risk medications can cause serious harm, more frequently when used in quick decisions environments, such as in the operating room. In this context, ChatGPT, an artificial intelligence model based on natural language processing developed by OpenAI, can assist healthcare professionals in critical situations, but there are doubts about its reliability.
Aim and Objectives The objective is to evaluate the ability of ChatGPT-4.0 to answer questions about dosing high-risk medications in the operating room, comparing different techniques with or without pharmaceutical intervention.
Material and Methods A list of high-risk medications used in the operating room was selected, and the responses of ChatGPT version 4.0 were evaluated as follows:

- Model without prompt: The standard question was: 'What is the dosage of the drug in the operating room?'.
- Model with prompt: The following prompt was developed by a pharmacist 'According to anaesthesia and pharmacy guidelines and technical data sheets, what is the drug dosage in the perioperative setting?'.
- Customised GPT model: The pharmacist created a high-risk medication dosing guide, which was validated by a multidisciplinary group and finally used to create a customised GPT model.

The research was evaluated by two independent experts on the field in terms of:

- Safety: correct responses compared to summary of technical characteristics.
- Clarity: Writing and well-organising of information, scored as 0, 1, or 2.

Accuracy: Ability to provide details related to dosing (score normalised to 1).
Results A total of 40 medications were included. The expert reached consensus and the final results obtained were:
Safety:

- Without prompt: 60% (24/40).
- With prompt: 70% (28/40).
- GPT model: 100% (40/40).

Clarity:

- Without prompt: 58.3% (28/48).
- With prompt: 76.8% (43/56).
- GPT model: 85% (68/80).

Accuracy:

- Without prompt: 44.8% (10.75/24).

- With prompt: 69.9% (19.6/28).
- GPT model: 99.1% (39.6/40).

Conclusion and Relevance There is a need for improvement in basic ChatGPT models with or without prompts as they achieved 60 and 70% of correct responses. The valuable tool was the pharmacist customised GPT model reaching 100 % of correct answers (safety), improving clarity and accuracy. Consequently, pharmacists should work in customised models to help health professionals in clinical practice.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-130 IMPACT OF DPYD GENE POLYMORPHISMS AND TOXICITY ON FLUOROPYRIMIDINE TREATMENT

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Background and Importance Fluoropyrimidines (FU), such as 5-fluorouracil and capecitabine, are cytostatic agents with a narrow therapeutic range. Approximately 80–90% of administered FU is metabolised by the enzyme dihydropyrimidine dehydrogenase (DPD), and its deficiency can cause severe toxicity or even death.

Aim and Objectives To describe polymorphisms in the DPYD gene and toxicity in these patients in two tertiary hospitals and evaluate the level of acceptance of the recommendations from Pharmacy service.

Material and Methods A genetic analysis of the DPYD gene was conducted on patients who began treatment with FU (July 2023-July 2024). Variables collected included sex, age, type of mutation, prescribed drug, toxicity and dose adjustments. Data were obtained from electronic medical records and prescription program Farmis.

Polymorphisms studied were c.1905+1G/A(*2A;rs3918290), c.1679T/A(*13;rs55886062), c.2846A/T(D949V;rs67376798), and c.1236G/A(HapB3;rs56038477) in the DPYD gene. Characterisation was performed by the Molecular Biochemistry service and the pharmacogenetic report was prepared by the Pharmacy service, recommending a 50% initial dose reduction with progressive adjustments based on toxicity. The percentage of acceptance by the medical team was recorded.

Results 606 patients were analysed, of whom 40 (6.6%) presented with a mutated allele (52.5% male, with a median age of 64.5 (58.8–72) years). Of these, 72.5% had the c.1236G/A variant, 20% had c.2846A/T, and 7.5% had c.1905+1G/A.

Of the prescribed treatments, 27.5% were 5-fluorouracil, while 47.5% were capecitabine. The rest did not receive FU-based treatment.

Patients finally treated with FU (n=30) presented the following adverse effects: fatigue (50%, grade (G) 1 and 2), diarrhoea (30%, G1,2,3), peripheral neuropathy (30%, G1,2), nausea and/or vomiting (20%, G1,2), haematological toxicity (16.7%, G1,2,3), dermatological toxicity (13.3%, G1,3), aminotransferase increased (10%, G1), constipation (6.7%, G1), myalgia (6.7%, G1,2), tenesmus (6.7%, G2), and fever (3.3%, G2). Of these patients, 73.3% started with a 50% dose reduction, 3.3% with a 75% reduction, and 3.3% with an 80% reduction. Additionally, 6.7% reduced the dose after the first session due to adverse reactions.

Conclusion and Relevance Despite the low incidence of these polymorphisms and the use of pharmacogenetic tools to predict potentially toxicities, patients still experience adverse effects, mainly fatigue. It is essential to investigate additional polymorphisms that may influence patient safety. This study demonstrates strong acceptance by the medical team.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-131 ABSTRACT WITHDRAWN

5PSQ-132 ADVERSE DRUG EVENTS ATTENDED IN EMERGENCY DEPARTMENT: ANALYSIS, ECONOMIC IMPACT AND PREVENTIVE MEASURES ADOPTED

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Background and Importance The increase of polytherapy leads to a higher inappropriate use of medication. The incidence of adverse drug events (ADE) are increasing and some of them are severe, preventable and have a significant public health and economic impact. Studies show the importance of incorporating preventive measures in order to improve patient's safety and healthcare system resources.

Aim and Objectives To determine the prevalence of patients attending the Emergency Department (ED) because of an ADE, to identify the implicated drugs, and to classify the causes and level of preventability. The economic impact of preventable ADE was determined and preventive measures adopted were described.

Material and Methods Observational and cross-sectional study included patients above 18 years of age who were attended in ED because of an ADE in a tertiary-level hospital on 15 March 2023 at 12:00 pm. The drugs involved and the ADE were identified. The degree of prevention was defined according to the Schumock-Thornton algorithm. The economic burden was conducted, including an assessment of the costs associated with the tests required, treatments, human resources and hospital stay. Strategies to prevent ADE were proposed by a multidisciplinary team. The study was approved by the hospital Ethics Committee.

Results Of the 75 patients who were enrolled, seven (9.33%) attended for an ADE. The median age was 74 years (range: 16–98 years). The responsible drugs were digoxin (bradycardia), furosemide (heart failure), apixaban (gastrointestinal bleeding), vincristine (neutropenic fever), nitrofural (erythema), moxifloxacin (myalgia) and amoxicillin (diarrhoea). Four (57.1%) ADE were probably preventable, one (14.3 %) definitely preventable and two (28.6 %) not preventable. The overall healthcare cost of preventable ADE was 9,317 € .

In order to prevent ADE a bundle of measures were implemented, including pharmaceutical care in ED, the assessment of therapeutic appropriateness and a follow-up on discharge.

Finally, a data intelligence tool was developed, incorporating algorithms that generated alerts to detect ADE.

Conclusion and Relevance Adverse drug events have an important prevalence and economic impact on the healthcare system. In this study, approximately 70% of them could have been prevented, which suggests the contribution of prevention measures to reduce ADE, improving the quality and resources of the healthcare system.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-133 DISCREPANCIES BETWEEN OBSERVED VORICONAZOLE CLEARANCE AND PREDICTED ACCORDING TO CYP2C19 GENETIC POLYMORPHISM. IMPORTANCE OF THERAPEUTIC DRUG MONITORING

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Background and Importance Voriconazole requires therapeutic drug monitoring (TDM) due to its saturable hepatic metabolism and significant interindividual variability in plasma concentration influenced by genetic polymorphisms, hepatic dysfunction, C-reactive protein (CRP) levels, and drug interactions.

Aim and Objectives This study aimed to assess whether the voriconazole dosing, adjusted through TDM to reach optimal blood levels, corresponded to that expected according to the patient's CYP2C19 genotype, taking into account recent publications suggesting a dosing adjustment guided by the genetic polymorphism.

Material and Methods A descriptive, observational, retrospective study was conducted including all patients treated with voriconazole between January 2022 and September 2024, with an average of 3.5 plasma concentration measurements and available CYP2C19 genotype data. CYP2C19 phenotyping was performed using CRP with the PHARM-CYP2C19 kit from Generi-Biotech to classify patients. Voriconazole serum concentrations were measured by Homogeneous Enzyme immunoassay. Dose adjustments based on TDM were obtained using a Bayesian model in the Abbott base-Pharmacokinetic System. The recommended therapeutic range was 1–5.5 μg/ml. Data related to drug interactions and CRP levels were collected.

The TDM-guided dosing was compared to genetic polymorphism-based dosing using Zubiaur et al. 2021 as a reference. Clearance were considered discordant if they differed by 30% from the reference values.

Results We included 46 patients, 71.74% male, with a mean age of 65.1 years (range:21–93). Two patients were classified as ultra-rapid metabolisers, 14 rapid, 17 normal, eight intermediate and five poor metabolisers. In 45.7% of patients, the TDM-adjusted dosing regimen was not as expected according to the patient's phenotype. Twelve patients showed slower than expected elimination with the following mean clearance: six rapid metabolisers (Cl=1.15ml/min/kg), five normal (Cl=0.91ml/min/kg) and one ultra-rapid (Cl=0.92 ml/min/kg). In contrast, seven patients showed a higher-than-expected clearance: four normal (Cl=5.21ml/min/kg), one intermediate (Cl=9.15ml/min/kg) and two poor metabolisers (Cl=2.11ml/min/kg). Furthermore, drug interactions were observed with rifampicin (Cl=59.52ml/min/kg) and carbamazepine (Cl=10.27ml/min/kg) in a rapid and a normal metaboliser, respectively and elevated CRP levels >120 mg/l in two rapid and one normal metaboliser as key factors contributing to these discrepancies.

Conclusion and Relevance TDM is crucial for optimising plasma concentrations, as many patients had unexpected clearance based on their CYP2C19 genotype, though genotype remains an important covariate in voriconazole TDM.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. DOI: 10.1007/s40262-020-00941-8

Conflict of Interest No conflict of interest

5PSQ-134 ABSTRACT WITHDRAWN

5PSQ-135 LONG-TERM ACTIVITY-FREE STATUS IN MULTIPLE SCLEROSIS WITH OCRELIZUMAB: REAL-WORLD EVIDENCE

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Background and Importance Multiple sclerosis (MS) is a chronic autoimmune disorder in the central nervous system. Ocrelizumab, a humanised monoclonal antibody, has shown promise in reducing disease activity and progression in MS.

Aim and Objectives To assess the real-world effectiveness of Ocrelizumab in sustaining disease-free status in patients with MS and to differentiate its effectiveness between patients with relapsing-remitting MS (RRMS) and primary progressive MS (PPMS).

Material and Methods This study design incorporates both retrospective and prospective elements, to evaluate No Evidence of Disease Activity (NEDA) in patients with MS between January'18-September'24 in a second-level hospital. Patient medical histories were obtained through MambrinoXXI, and Farmatools using the outpatients' module.

- Inclusion criteria: MS diagnosis, treated with ocrelizumab.
- Studied variables: Sex, age, MS diagnosis type (RRMS or PPMS), history of previous disease-modifying therapies, initial Expanded Disability Status Scale (EDSSi) score, time to treatment and duration in weeks before the re-emergence of disease activity.
- Statistical Analysis: Descriptive statistics and Kaplan-Meier Survival Analysis using SPSS v.15.0 alongside a confidence interval (CI) of 95%.

Results Forty-three patients were included in this study, where 23 (53,49%) were men, median age 51±9,9 years-old. 24 (55,81%) had RRMS diagnosis, and a total of 26 (60,47%) patients received previous disease-modifying therapies. Mean EDSSi was 5,21 (ranging from 0,5–9). Median time elapsed between MS diagnosis and Ocrelizumab initiation was 5.65 years.

Analysis of NEDA for all patients, without stratification: 22 (51,16%) experienced worsening of symptoms related to the

progression of MS. Kaplan-Meier analysis revealed a median NEDA of 123 weeks (CI: 68,48–177,52).

Stratifying patients according to diagnosis revealed a median NEDA of 89 weeks (CI: 79,96–98,04) for PPMS and 154 weeks (CI: 103,32–204,68) for RRMS. This difference was statistically significant (p = 0,035).

Conclusion and Relevance These findings align with existing clinical trial data, showing better responses in RRMS compared to PPMS. The inflammatory and less progressive nature of RRMS may explain its better response to immunomodulatory therapies. This calls for personalised treatment approaches in MS management. Future research should focus on optimising treatment strategies for PPMS and further validating these results across diverse patient populations.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-136 APPROPRIATENESS OF DAPAGLIFLOZIN PRESCRIPTION IN HEART FAILURE

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Background and Importance Heart failure (HF) is a leading cause of hospitalisation in Spain, associated with high morbidity in the adult population due to ageing demographics. Optimising available treatments is crucial to reduce hospitalisation risks and maximise early benefits.

Aim and Objectives Evaluate the appropriateness of dapagliflozin prescription according to the funding and indications established in the technical data sheet of the product for HF in hospitalised patients, as well as to record the incidence of hospitalisations related to HF.

Material and Methods A unicentric, observational, prospective study lasting 1 month (February - March 2024) was conducted to collect demographic (age and sex) and clinical variables (left ventricular ejection fraction (LVEF), NT-proBNP levels, date of prescription initiation and reason for admission), and pharmacotherapeutic history of hospitalised patients who were prescribed dapagliflozin in a tertiary care hospital. The study focused on patients who met the criteria for HF with LVEF < 40% not controlled with first-line therapies (Angiotensin-converting enzyme (ACE) and angiotensin II receptor antagonists (ARA-II) combined with beta blockers) and second-line therapies (mineralocorticoid receptor antagonists (MRA)), as well as the treatment of symptomatic patients with LVEF > 40% and elevated plasma NT-proBNP levels. Patients lacking sufficient variables for the study were excluded. Data collection was performed using program Farmatools and Excel.

Results A total of 50 patients were analysed, 37 (73%) males, with a median age of 80 years (range 54–94). The primary services were: 20 patients (40%) Internal Medicine Department, 18 (36%) Cardiology, five (10%) Pulmonology, and seven (14%) others. 92% (46) of the patients met the indication criteria, the reasons for non-compliance were absence of symptoms in patients with LVEF > 40% (two patients) and failure to use MRA in those with LVEF < 40% (three patients). 76% (38) of the hospitalised patients had been previously prescribed dapagliflozin; among them, 39.5% (15) were hospitalised due to heart failure.

Conclusion and Relevance A high percentage of them met the indication criteria. It would be advisable to evaluate the treatment strategy due to a notable percentage of hospital admissions for heart failure among patients with prior dapagliflozin prescriptions, which may compromise the drug's benefits.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-137 PROGNOSTIC ROLE OF HAEMATOLOGICAL PARAMETERS IN EXTENDED-STAGE SMALL-CELL LUNG CANCER PATIENTS TREATED WITH ATEZOLIZUMAB IN COMBINATION WITH CHEMOTHERAPY

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Background and Importance The neutrophil-lymphocyte ratio (NLR) and eosinophil count (EAR) have been proposed as possible prognostic markers in immunotherapy-treated patients with different tumour types.

Aim and Objectives To determine the prognostic role of NLR and EAR in patients with extended-stage small-cell lung cancer (ES-SCLC) treated with atezolizumab in combination with chemotherapy.

Material and Methods Retrospective observational study that included patients with ES-SCLC treated with atezolizumab +carboplatin+etoposide between September-2021-December-2023. Variables collected were: sex, age, Eastern Cooperative Oncology Group Stage Performance Status (ECOG PS), baseline brain or liver metastases, causes of treatment discontinuation, neutrophil-lymphocyte ratio (absolute neutrophil count/absolute lymphocyte count) and EAR at two time points (baseline and first radiological assessment), objective response rate (ORR) and median progression-free survival (PFS) and overall survival (OS).

Statistical analysis: the Kaplan-Meier method was used for estimating the probability of survival. The log-rank test was used to determine the relationship between each variable and OS. Cox regression model was performed with the variables that had shown statistical significance.

Results Thirty-seven patients were included, 67.6% male, mean age 65 years (±7.6). 18.9% had brain metastases, 40.5% liver metastases and 94.6% ECOG<2. At the data cut-off date (August 2024), nine patients remained alive and two were still undergoing treatment. 56.7% discontinued treatment due to progression, 21.6% died, 8.1% had clinical deterioration and 5.4% due to toxicity. 43.2% had partial response, 24.3% stable disease, 21.6% progression and in the remainder response was not assessed. Median PFS and OS were 4 months (95% CI 3.1–4.9) and 8 months (95% CI 5.06–10.94), respectively. In univariate analysis, variables significantly associated with lower OS were: NLR≥3 at first radiological assessment (p<0.001), baseline EAR <90 (p=0.007), EAR at first radiological assessment<40 (p=0.045) and the presence of brain metastases (p=0.043). In multivariate analysis, NLR<3 was the only independent predictor variable of OS with median OS 10 months (95%

CI:3.05–16.93) vs 5 months (95% CI:3.15–6.85); HR=0.25; p=0.017.

Conclusion and Relevance NLR <3 at the first radiological assessment was identified as an independent predictor of OS in patients with ES- SCLC treated with atezolizumab in combination with chemotherapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-138 SATISFACTION WITH CABOTEGARVIR AND RILPIVIRINE LONG-ACTING IN A REAL-WORLD SETTING: PRELIMINARY DATA

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10.1136/ejhpharm-2025-eahp.431

Background and Importance Long-acting injectable antiretroviral therapy (LA-ART) represents a novel administration route as an alternative to daily oral antiretroviral treatment.

Aim and Objectives To describe the satisfaction with medication, according to the HIVTSQ questionnaire, of patients in treatment with LA CAB+RPV in real-world setting.

Material and Methods The RELATIVITY cohort is an ambispective study that includes patients treated in 37 Spanish hospitals. Eligible patients are over 18 years of age and have received their first dose before January 1, 2024. Between 9–14 month of treatment, a questionnaire was administered in an online format with QR code. The data were collected on the RedCap platform for subsequent analysis.

The survey to be conducted is the 'Satisfaction with Medication: HIVTSQ.[1] This survey comprises 12 core questions. The initial 11 questions assess satisfaction with the medication, with a maximum favourable score of 66 points. The final question pertains to pain or discomfort associated with the injection, with a maximum favourable score of 6 points. Higher scores are associated with greater satisfaction with the medication.

Results The study included 205 patients from 13 hospitals in Spain. Median age of patients is 46.0 (38.2, 55.4) years and 88.7% males.

In the global satisfaction score with medication (questions from 1 to 11), our group of patients has a median score of: 61.5 (54.0, 64.5). In the injection pain or discomfort score (question 12), our group of patients has a median score of: 4.5 (3.0, 6.0).

Conclusion and Relevance

- Long-acting (LA) injectable antiretroviral therapy (ART) has been shown to be a well-tolerated alternative to daily oral antiretroviral treatment.
- The treatment aspects that received the lowest patient satisfaction ratings are flexibility and pain or discomfort.
- These findings support the implementation of LA-ART in clinical practice.

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Conflict of Interest No conflict of interest

5PSQ-139 DUPILUMAB-ASSOCIATED SCARRING ALOPECIA IN A PATIENT WITH ATOPIC DERMATITIS: A CASE REPORT

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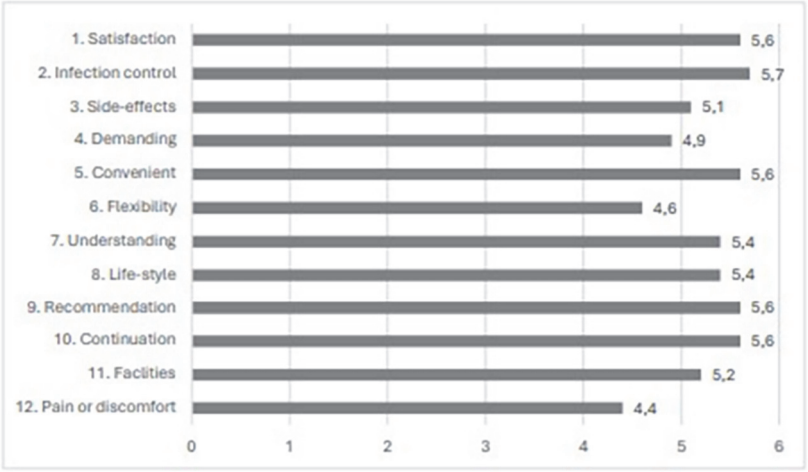
10.1136/ejhpharm-2025-eahp.432

Background and Importance Atopic dermatitis is a multifactorial systemic condition characterised by immune dysregulation and impaired skin barrier function. Its prevalence ranges from 5–20% in the general population, with higher rates (around 20%) in children and adolescents. Dupilumab, a targeted biological therapy, has significantly improved moderate to severe



Abstract 5PSQ-138 Figure 1 HIVTSQ. Mean of questions from 1 to 12. (0=very dissatisfied, 6= very satisfied)

atopic dermatitis management, offering relief in cases resistant to conventional treatments.

Aim and Objectives To report a case of an unreported adverse effect (AE) linked to dupilumab in a patient with severe atopic dermatitis.

Material and Methods We present a case of scarring alopecia due to dupilumab in a patient with severe atopic dermatitis. A 16-year-old asthmatic patient with food allergies, diagnosed with atopic dermatitis and treated with topical corticosteroids since childhood. In January 2023, he started oral cyclosporine; however, after 11 months of treatment with increasing doses, the patient still exhibited generalised erythema, affecting sleep, with skin lichenification and scaling. (EASI score of 28). In December 2023, dupilumab 600 mg was initiated, followed by 300 mg every two weeks. After 3 months (March 2024), with a moderate treatment response, the patient reported significant hair loss. Dermatology consultation revealed erythematous lesions on the scalp, suggesting scarring alopecia, that was later confirmed by pathology. Suspecting an AE, dupilumab was discontinued, and switching to upadacitinib was considered. Epidemiological and clinical data were obtained from the digital medical record and outpatient management system.

Results Two weeks after discontinuation, the patient reported improvement in skin and scalp conditions. The AE was reported to the Spanish Pharmacovigilance System through its Electronic Yellow Card System . The Naranjo algorithm was used to assess the causal link between dupilumab and the AE, which was deemed probable (score 6).

Conclusion and Relevance Reporting suspected EAs is essential for post-marketing safety. It allows identification of new adverse effects. This case of dupilumab-induced scarring alopecia emphasises the importance of ongoing pharmacovigilance, even for well-established treatments. It also highlights the role of healthcare professionals, especially pharmacists, in identifying rare or unexpected EAs early in treatment, contributing to better patient management.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-140 CLASSIFICATION OF DRUG RELATED PROBLEMS IN PAEDIATRIC PATIENTS AND ACCEPTANCE OF PHARMACEUTICAL INTERVENTIONS

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Background and Importance Paediatric patients are particularly susceptible to experience drug related problems (DRPs) due to factors such as pharmacokinetic differences or the need to adapt adult dosages/formulations for children.

Aim and Objectives The present study aims to classify the DRPs identified, analyse the type of pharmaceutical intervention (PI) performed and evaluate the acceptance carried out by the pharmaceutical validation of treatments after the implementation of an assisted electronic prescribing system (AEP) in the paediatric unit of the hospital. The goal is to improve the pharmaceutical care of paediatric patients.

Material and Methods 19-months observational and retrospective study (June 2022-December 2023) in which the DRPs detected and PIs performed during pharmaceutical validation process were collected and classified. The DRPs were grouped according to necessity, effectiveness or safety; the PIs were grouped based on the type of intervention: dosage adjustment, treatment continuation, schedule modification, change in route of administration, formulation substitution, duplication, and adverse effects/interactions. Subsequently, the acceptance of the PIs was evaluated.

Results A total of 1,089 patients were included, generating 6,998 validated treatment lines. Within these lines, 208 DRPs were detected (3%): 108 (52%) related to safety, 60 (29%) to effectiveness, and 40 (19%) to necessity. A total of 195 PIs (2.8%) were performed for these DRPs.

The PIs carried out included: dosage adjustments; 15 (18%) treatment continuation; 17 (9%) protocol changes; 17 (9%) duplication; 14 (7%) schedule modifications; 13 (7%) changes in the route of administration; 14 (7%) formulation substitutions; and 4 (2%) addressing adverse effects/interactions.

The acceptance of the PIs was 53% (103) accepted, 47% (92) not assessed/rejected

Conclusion and Relevance

1. The implementation of the AEP represents a significant contribution to the prevention of DRPs in paediatric patients.
   2. 52% of detected DRPs pertained to safety, particularly related to dosage, consistent with paediatric susceptibility.
   The discrepancy between the number of DRPs and PIs can be attributed to the fact that a single PI may refer to more than one DRP.
2. Over 50% of PIs were accepted, underscoring the pharmacist's role in prescribing medications for paediatric patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-141 IMPACT OF CABOTEGARVIR AND RILPIVIRINE LONG-ACTING IN QUALITY OF LIFE OF SUBJECTS IN A REAL-WORLD SETTING: PRELIMINARY DATA

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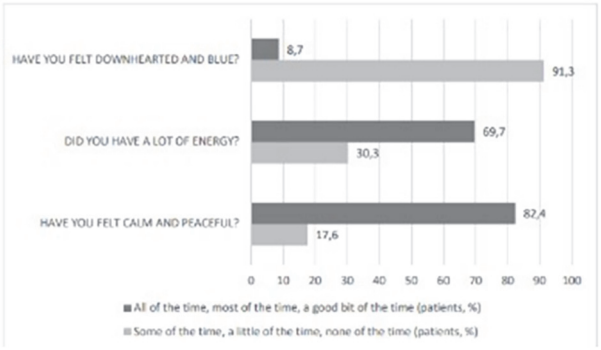
10.1136/ejhpharm-2025-eahp.434

Background and Importance Long-acting (LA) injectable therapy with cabotegravir (CAB) and rilpivirine (RPV) may improve quality of life. General health was assessed in clinical trials about LA CAB+RPV using the 12-Item Short Form Health Survey (SF-12) questionnaire, that includes norm-based physical and mental component scores (PCS and MCS) ranging from 0 to 100 points, with higher scores indicating better health.[1]

Aim and Objectives To describe the quality of life, according to the SF-12 questionnaire, of patients in treatment with LA CAB+RPV in a real-world setting.



Abstract 5PSQ-141 Figure 1 SF-12 health survey. Questions 9, 10 and 11

Material and Methods We conducted a multicentre, non-controlled, retrospective and prospective study (relativity cohort) in HIV patients on treatment with LA CAB+RPV. Patients could answer the SF-12 questionnaire between 9–14 months of treatment via electronic devices using a QR code provided. The data were collected on the RedCap platform for subsequent analysis.

Results The study included 205 patients from 13 hospitals in Spain. Median age of patients is 46.0 (38.2, 55.4) years and 88.7% males. The current follow-up duration is 13.1 (11.0, 15.1) months. At the time of answering the questionnaire patients had a median score in SF-12 of 55.5 (52.4, 57.2) in PCS and 53.1 (44.7, 57.8) in MCS. 189 (92.2%) of the patients considered that at the time of the study their health status was good, very good or excellent. 178 (86.8%) patients had no limitations for moderate activities, 187 (91.2%) patients answered that they continued with their daily activities and 174 (84.9%) patients that they had no pain that hindered their usual work. 168 (82.0%) patients responded that their emotional state of health had not prevented them from carrying out their daily activities as carefully as usual(MOU1). 155 (75.6%) patients had no physical or emotional difficulties in continuing their social activities.

Conclusion and Relevance

- The PCS and MCS scores are similar to those described in the healthy US population (mean of 50).
- Our data suggest that patients with LA CAB+RPV have a good state of physical and mental health.
- Longer follow-up in more patients is needed to obtain more consistent data.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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Conflict of Interest No conflict of interest

5PSQ-142 MULTISITE CLINICAL TRIALS: WHAT ABOUT THE EXPERIMENTAL DRUG CIRCUIT? FAILURE MODE, EFFECTS AND CRITICALITY ANALYSIS

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Background and Importance Multisite coordination of clinical trials could be a key lever to promote patient recruitment, facilitate access to innovation, and enhance the attractiveness of sites. This approach requires coordination at both the clinical research and the pharmaceutical levels. The involvement of multiple pharmacies in the distribution process of the experimental product differs from its usual management and introduces new risks.

Aim and Objectives The TRINITI project aims to identify, assess, and mitigate the new risks associated with this pharmaceutical activity to secure the circuit of the experimental product.

Material and Methods A multidisciplinary working group was established, comprising members from the pharmaceutical coordination unit (one TRINITI project manager, two pharmacists), a representative from the clinical research unit, and a pharmacist from a satellite pharmacy centre. Subsequently, a preliminary risk analysis was conducted using the Failure Mode, Effects and Criticality Analysis method (FMECA) before the beginning of the first multisite clinical trial.

Results In total, 56 new subprocesses were identified, associated with 114 risks. Among these risks, 82% (n=93) were linked to the operational aspect of the activity. The majority of identified risks were considered acceptable (78%, n=89). Of the 24 risks with tolerable criticality, 30% are related to the preparation of clinical trials in satellite centre pharmacies. The risks of insufficient funding and the unavailability of vehicles were deemed unacceptable. Twelve risks were rated with a potential severity of 5, primarily associated with the feasibility of the coordination activity and the validation of additional projected costs. For all identified risks, 29 preventive barriers have been implemented.

Conclusion and Relevance This risk analysis has pinpointed the most critical steps in the pharmaceutical circuit and facilitated the implementation of preventive measures to mitigate their criticality. It is now crucial to assess the residual criticality following these measures. In this way, this analysis enables the secure deployment of the pharmaceutical aspect of the coordination project. In continuation of this work, a post-analysis of risks should be conducted based on the initial experiences.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-143 ASSESSING CARDIOVASCULAR SAFETY OF ANTI-CGRP TREATMENTS: INSIGHTS FROM REAL-WORLD DATA IN ELDERLY AND CARDIOVASCULAR PATIENTS

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Background and Importance Phase 2 and 3 clinical trials evaluating anti-CGRP monoclonal antibody therapies have not demonstrated an increased incidence of vascular events or vascular complications in patients undergoing treatment. However, it is important to note that patients over 65 years of age and those with pre-existing cardiovascular conditions were excluded from these trials.

Aim and Objectives To analyse the cardiovascular safety profile of anti-CGRP monoclonal antibodies in elderly patients and in those with a history of cardiovascular disease.
Material and Methods Observational, retrospective study conducted in a medium-complexity hospital. All patients treated with anti-CGRP therapy through the outpatient clinic module were included. Clinical data of the patients were obtained from the electronic medical records. We included arterial hypertension as a cardiovascular-related condition. Adverse effects experienced by the patients were recorded using forms completed during pharmaceutical care consultations. The Chi-squared test was used to compare the total proportions of cardiovascular events.
Results A total of 119 patients undergoing anti-CGRP therapy were evaluated. Median follow-up was 587 days. Of these, 84.03% had no pre-existing cardiovascular conditions, and 13 patients (10.92%) were over the age of 65. Among the patients with pre-existing cardiovascular conditions (15.97%), 15 had arterial hypertension (78.94%), two presented with angina pectoris (19.52%), three had documented arrhythmias (20%), and three were diagnosed with dyslipidaemia (20%). Notably, no cardiovascular events were reported following the initiation of anti-CGRP therapy in this cohort.

Post-treatment cardiovascular events occurred in four patients (3.36%), with two cases of arterial hypertension (50%) one case of arrhythmia (25%), and one case of cerebrovascular disease (25%). Only one of these patients was over 65 years of age, and none had pre-existing cardiovascular conditions. There were no statistically significant differences in post-treatment cardiovascular events between elderly patients and those without pre-existing cardiovascular conditions ($p = 0.918$); and between patients with and without pre-existing cardiovascular conditions ($p = 0.847$).
Conclusion and Relevance These findings suggests that anti-CGRP treatments may be similarly safe across these groups. Real-World Data studies provide valuable insights that may not be captured in controlled trial environments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-144 THE VALUE OF THERAPEUTIC ADHERENCE IN THE TREATMENT OF DRUG-RESISTANT EPILEPSY

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Background and Importance Cenobamate is a drug approved by the EMA (European Medicines Agency) on 26thMarch 2021 as adjunctive therapy of seizures in adult patients with drug-resistant epilepsy who have not been adequately controlled with at least two antiepileptic drugs. The mechanism of action is not fully understood. The initial dose is 12.5mg/day which is increased to a dose of 200mg/day, according to the specialist prescriptions.
Aim and Objectives The aim is to evaluate the drug use, therapeutic adherence and improvement of the quality of life (QdV) of patients referred to an Apulian local pharmacy to which the drug was dispensed, after having carried out prescription appropriateness assessments.
Material and Methods Cenobamate's disbursements made from September 2022 to May 2024 have been extrapolated from the company computer system. An anonymous questionnaire, based on the Morisky scale, has been used to assess the therapeutic adherence and QdV of patients treated with cenobamate. The data analysed are: patient characteristics (age, sex, type of epilepsy, polytherapy with other antiseizure drugs), compliance and therapeutic adherence.
Results We have 34 patients with focal (or partial) structural, drug-resistant epilepsy treated with cenobamate, including one off-label prescription patient diagnosed with early childhood epileptic encephalopathy. 56% of patients under treatment are female, 44% male. The average age is 38.5years and 59% (30–50 years), 20% (18–30 years), 18% (>50 years) and 3% (0–18 years), with onset of childhood pathology. To date, 28 patients of 34 are adherent to therapy, two suspended therapy for other comorbidities (chemotherapy, kidney problems), three have suspended it due to ineffectiveness and/or serious adverse reactions (confused state), one has never taken it. From the questionnaire, 20 patients show high adherence, one low and six intermediate. The patients undergoing polypharmacy are: nine who combine another antiepileptic drug, 12 who associate two, four who associate three and two patients four. Most patients are not autonomous in daily activities and do not lead a normal life. 71.4% of patients report an improvement in QdV with a reduction in epileptic episodes, while 25% despite being adherent to treatment do not report any improvement in QdV.
Conclusion and Relevance Adherence to therapy underlines the efficacy and safety of the drug, supporting the excellent impact of this new therapeutic alternative. The high index of appropriateness highlights the monitoring activity of the pharmacist in new therapies in the area.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-145 THE USE OF MEAN KINETIC TEMPERATURE TO MANAGE TEMPERATURE EXCURSION IN HOSPITAL PHARMACY

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Background and Importance The mean kinetic temperature (MKT) corresponds to a single calculated temperature at which the total amount of degradation during a given period is equal to the sum of the individual degradations that would occur at various temperatures.
Aim and Objectives Demonstrate the importance of the integration of mean kinetic temperature tool, to integrate and standardise its use in hospital pharmacy.
Material and Methods A temperature excursion of three cold rooms 2–8°C) occurred in our pharmacy service for a duration of 12 hours. We conducted a study for the analysis of the thermal stress undergone by the products at variable

temperatures for the period from 12 hours before the excursion to 24 hours after, using the MKT. The MKT was establishing based on J. D. Haynes's formula.

Results The implemented system provided temperature values readings at 10 minute intervals. However, we selected 18 specific monitoring points. For each point the MKT was calculated and subsequently we determine the average MKT, derived from the individual MKT values of all selected points. The minimum and maximum temperatures recorded for each cold room are as follows: 3.90°C to 13.05°C for the first cold room, 3.85°C to 17.85°C for the second, and 14°C to 17°C for the third one. The MKT average was successively, 6.26°C, 7.29°C and 7.20°C. The MKT results of each cold room were in compliance with a norm of 5±2°C for thermolabile products intended to be stored in cold rooms. Therefore, temperature fluctuations have no impact on the stability of the products and the total excursions equivalent to 12 hours may be tolerated. To manage these temperature excursions in our hospital practice, we rely either on technical drug document obtained from the regulatory authority, or to stability databases, especially since we do not have the resources for conducting analytical testing of the samples.

Conclusion and Relevance The MKT will be an important tool globally to set excursion limits for storage. This tool may help hospital pharmacists in the decision making process as to whether to keep or discard a product after excursion. However, MKT alone is not enough to assess the impact of temperature excursion, so it's necessary to make an analytical control.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-146 MAINTENANCE OF RESPONSE AT 52-WEEK IN MODERATE TO SEVERE ATOPIC DERMATITIS: A NETWORK META-ANALYSIS OF THERAPEUTIC ALTERNATIVES

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Background and Importance Moderate to severe atopic dermatitis (AD) can be treated with several therapeutic alternatives. Recently, lebrikizumab has been approved in this pathology.

Aim and Objectives To develop a network meta-analysis (NMA) to compare the efficacy in maintenance of response at 52-week of biologic treatments for moderate to severe AD.

Material and Methods A PubMed literature search was conducted for phase III randomised clinical trials including biologic drugs (dupilumab, tralokinumab and lebrikizumab) compared to placebo in moderate to severe AD. Relevant clinical baseline characteristics of populations considered: age, gender, disease duration, EASI, IGA, BSA, NRS, DLQI. Efficacy endpoints were EASI-75 and IGA 0 or 1 achievement. Long-term maintenance results at week 52 were analysed. R v4.4.1 statistical software was used to perform the NMA. Odds ratio(OR) were calculated by Bayesian methods and fixed effect model were assessed.

Results Five RCTs were selected. Age was similar in all populations. Male gender reached percentages of approximately 50% of patients, except for tralokinumab 300 mg Q2W (59.4%). Disease duration was generally between 25–27 years, being less durable in patients receiving lebrikizumab 250 mg Q2W (21.6 years).

All presented with similar clinical characteristics at baseline: EASI≥16 (around 30), IGA 3 or 4, Body surface area ≥10% (between 45–50%), DLQI around 15, and POEM between 21–24.

At week 52, dupilumab 300 mg Q2W achieved the greatest magnitude of effect for both EASI75 (OR 5.38; 95% CI 3–9.6) and IGA 0 or 1 (OR 5.54; 95% CI 2.6–11.8) achievement. Lebrikizumab (OR 2.21; 95% CI 1.1–4.3) reached better effect magnitude for IGA 0 or 1 achievement than tralokinumab (OR 1.97;95% CI 1–3.7) but, for EASI75 achievement, the effect was reversed, with tralokinumab (OR 2.63; 95% CI 1.4–4.8) showing a greater magnitude than lebrikizumab (OR 2.04; 95% CI 1–4). Regarding dupilumab 300 mg Q2W, statistically significant differences were found with lebrikizumab 250 mg Q2W for EASI75 achievement (p=0.0338) and with tralokinumab 300 mg Q2W for IGA 0 or 1 achievement (p=0.0415).

Heterogeneity estimate values were: Q=0.0, p=0.05, I2=0% (CI 95% 0–0%).

Conclusion and Relevance This NMA provided a review of efficacy of recent therapies for moderate to severe AD focusing on long-term response maintenance. Dupilumab 300 mg Q2W were the most effective schemes. Similar benefit was observed with tralokinumab 300 mg Q2W and lebrikizumab 250 mg Q2W. Further trials are needed to compare long-term outcomes of other therapies, such as JAK inhibitors.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-147 ALGORITHMS TO ENHANCE SAFETY OF HIGH ALERT MEDICATIONS' PRESCRIBING IN HOSPITALISED PATIENTS

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Background and Importance High alert medications can cause significant patient harm, when used inappropriately. To enhance patient safety, automated alerts are recommended by the Institute for Safe Medication Practices.

Aim and Objectives To describe the use of automated alerts embedded in a computerised decision order system to identify drug related problems (DRP) for high alert medications in hospitalised patients, and associated pharmacists' interventions.

Material and Methods A retrospective study was conducted at two sites (academic and general) of a tertiary care hospital in Belgium. Seventeen algorithms were designed to identify DRP relevant for high alert medications and were implemented in our computerised decision order system. Alerts were based on the patients' prescriptions and laboratory data. All alerts were checked by a pharmacist every day (except for weekends). All alerts occurring between September 2023 and August 2024 were analysed. Data collected included: alert type and whether the alert led to an actual DRP requiring a pharmacists' intervention. Descriptive statistics were used to analyse the data.

Results A total of 1147 alerts were analysed by the pharmacists, corresponding to a mean of 4.4 alerts daily. The positive predicted value was of 70.9%, as 813 alerts were actual DRPs and pharmacists' interventions were required. Over half of the latter (53.3%, n=433) were related to antithrombotic agents: 23.7% (n=193) were related to overdosing antithrombotic (according to weight, renal function, age and INR), 27,6% (n=224) were related to underdosing (e.g. 'once daily dosing' of apixaban, or underdosing according to weight or INR) and 2,0% (n=16) were concomitant administrations of low molecular weight heparin and direct oral anticoagulants. A third of alerts (33,6%, n=260) were related to electrolytes, including potassium concentrations incompatible with peripheral intravenous administration, and potassium administration to patients without hypokalaemia. Insulin overdosing occurred for 5,5% (n=45) of alerts and 4,8% (n=39) of alerts resulted from administration of prolonged liberation opiates in patients with renal failure. Finally, 4,4% (n=36) of alerts were related to methotrexate, including multiple weekly administrations of the drug in inflammatory diseases for 3,2% (n=26) of alerts.
Conclusion and Relevance Automated alerts tailored to identify DRPs for high alert medications, effectively identify opportunities for pharmacists' interventions, enhancing patient safety.

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

5PSQ-148 ABSTRACT WITHDRAWN

5PSQ-149 EFFICACY AND SAFETY OF AVATROMBOPAG IN SEVERE THROMBOCYTOPENIA SECONDARY TO CHRONIC LIVER DISEASE IN A PATIENT WITH HISTORY OF THROMBOSIS: A CASE REPORT

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Background and Importance Thrombocytopenia is frequent in cirrhosis, the final stage of chronic liver disease (CLD). Severe thrombocytopenia, defined as a platelet count (PC) below $50x10^9$/L, increases risk of bleeding during and after invasive procedures, so guidelines recommend PC equal or greater than that number. Avatrombopag is a new thrombopoietin receptor agonist (TRA) indicated to treat severe thrombocytopenia in patients with CLD who are scheduled to undergo an invasive procedure. In other TRA drugs studies, a higher frequency of portal vein thrombosis (PVT) was reported in case of PC greater than $200x10^9$/L. Moreover, patients with CLD are at greater risk of thrombosis. Thus, history of thromboembolic events (TE) was exclusion criteria in avatrombopag clinical trials and there is not any reported case of patients with this precedent. This case therefore is a valuable contribution to the literature. However, in avatrombopag trials, no connection was found between PC and the TE occurred. On the other hand, real-life data on avatrombopag efficacy and safety is still rare.
Aim and Objectives To describe the use of avatrombopag in a severe thrombocytopenia of a 52-year-old man with CLD and history of PVT who needed a herniated disc invasive procedure. His thrombocytopenia was refractory to platelet transfusions, desmopressin and immunoglobulins.
Material and Methods Retrospective case report. Clinical data were obtained from medical records. No signs of peripheral venous thrombosis were observed before beginning treatment and the PC was $37x10^9$/L. Based on the PC, the patient was given 60 mg of avatrombopag daily for 5 days and undergo the procedure within 6 days after the last dose.
Results A blood test on the procedure day ensured that the PC was adequate and not unexpectedly high ($69x10^9$/L). Platelet transfusions and other rescue treatments to prevent excessive bleeding were not needed for up to 7 days after surgery. Adverse effects did not happen during treatment neither TE in the following 6 months.
Conclusion and Relevance A patient with severe thrombocytopenia secondary to CLD and refractory to other therapies, with history of PVT, used avatrombopag, showing an adequate efficacy and safety profile. Nevertheless, it is necessary to continue studying the incidence of TE, especially in patients with risk factors, and the relation between them and the PC.

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

5PSQ-150 MONITORING OF PERSONALISED THERAPIES DISPENSED THROUGH AUTOMATED UNIT DOSE DRUG DISPENSING SYSTEM

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Background and Importance Medication errors are any preventable events that may cause or lead to inappropriate medication use, or patient harm and they represent the most frequent cause of injury among inpatients. Innovative approaches to mitigate medication errors are centred on Closed Loop Medication Management Systems (CLMMS), incorporating automated Unit Dose Distribution Systems (UDDS), drug cabinets and barcode labelling for bedside scanning.
Aim and Objectives The present study seeks to monitor the non-conformities of single unit dose packages produced in a hospital pharmacy. The aim is to improve patients' safety and enhance the quality standard of the institute's clinical pharmacy service.
Material and Methods Quantitative and qualitative analysis of the non-conformities of single unit dose packages produced between 1 January and 31 August 2024, were conducted. The analysis was carried out using daily production reports and checklists.
Results The total unit dose packages produced during the period considered were 131169, while the number of non-conformities found was 119 (0.09%). Specifically, 14 (0.07%) in January, 9 (0.05%) in February, 27 (0.14%) in March, 26 (0.15%) in April, 13 (0.08%) in May, 5 (0.03%) in June, 16 (0.10%) in July, and 9 (0.09%) in August. The main reasons for non-conformities included: 91 (76.47%) damaged packaging, 26 (21.85%) damaged drugs, and 2 (1.68%) absence of

the drug within the packaging. Drugs in which non-conformities were detected included: tacrolimus 22 (18.49%), mycophenolate mofetil 12 (10.08%), and furosemide 12 (10.08%). The dosage form with non-conformities were tablets 66 (55.46%), capsules 40 (33.61%), vials 7 (5.88%), and granules 6 (5.04%).

Conclusion and Relevance The number of non-conformities analysed was in line with the annual target (<1%). No potentially harmful discrepancies, such as mismatches between the labels on the unit dose packages and their contents or production reports, were found. The automated unit dose drug dispensing system proved to be a useful tool for reducing medication errors and costs, enhance drug therapy safety and quality of care.

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5PSQ-151 INCIDENCE OF NEPHROTOXICITY IN CISPLATIN ADMINISTRATION ASSOCIATED WITH A HYDRATION PROTOCOL

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Background and Importance Cisplatin for solid tumours presents potential nephrotoxicity, necessitating hydration and supplementation protocols. The literature on this topic is diverse and often contradictory, highlighting the importance of identifying risk factors and optimising the management of its complications in clinical practice.

Aim and Objectives To determine the incidence of nephrotoxicity in patients receiving cisplatin-based regimens under a nephrotoxicity prevention protocol established in 2016 by pharmacists and oncologists, while also analysing associated risk factors.

Material and Methods A retrospective observational study was conducted in a secondary-level hospital. Inclusion criteria involved patients treated with at least two cycles of cisplatin between January and December 2023. The protocol is as follows: For cisplatin doses $\geq$60mg/m^2, prehydration involves administering 2L of sodium chloride 0.9% (NaCl) containing 20 mEq of potassium chloride and 20 mg of furosemide over 2 hours, followed by 1L NaCl administered post-cisplatin over 1 hour. For doses <60 mg/m^2, 1L is given over 1 hour for both pre- and post-hydration with the same additives. Nephrotoxicity was assessed using CTCAEv5.0 criteria, defined as an increase in creatinine $\geq$0.5 mg/dL or increased creatinine$\geq$ grade 1. Data were collected from electronic medical records including: age, anthropometric data, comorbidities (hypertension, diabetes, concomitant radiotherapy or nephrotoxic drugs), renal function parameters before and after treatment (creatinine levels and glomerular filtration rate per CKD-EPI), cisplatin dose, cumulative dose, and number of cycles. Statistical analysis included multivariate logistic regression using SPSS v21.

Results A total of 75 patients (53% men) were included, with a mean age of 60.1 years (95% CI: 57.4–62.9). Fifty-two percent received cisplatin doses <60 mg/m^2, with head and neck cancer being the primary diagnosis in 34.7% of patients. The cumulative cisplatin dose averaged 223.49 mg (95% CI: 201.71–245.27), with a median of 4 cycles. Nephrotoxicity prevalence was 13.3%, with a mean glomerular filtration rate reduction from 94.1 mL/min to 86.2 mL/min post-treatment. Maximum nephrotoxicity was grade-1, with only 4% requiring dose adjustment. No correlation was found between nephrotoxicity and age, comorbidities or cisplatin dose.

Conclusion and Relevance The nephrotoxicity prevention protocol implemented in 2016 demonstrates a low incidence of nephrotoxicity, with a maximum grade of 1 among patients treated with cisplatin. However, the absence of clear predictive factors highlights the need for further studies to enhance and optimise future preventive measures.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-152 PATIENT-ORIENTED CARE IN PHARMACY CONSULTATION CENTRE: CHANGES OF TRENDS IN CONSULTATIONS IN LAST 12 YEARS – ANALYSIS OF ACTIVITIES IN CONSULTATION CENTRE

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Background and Importance The number of drugs used has increased in the last years. Some patients need an explanation of how to use their drugs and how to prevent medical errors. The pharmacy consultation centre in St. Ann University Hospital has offered advice for in- and outpatients for more than 25 years. Patients can consult with pharmacists about their drug related problems. In last 10 years the consultation care has expanded to include other services (smoking cessation, memory loss counselling, cholesterol screening, and higher blood glucose levels).

Aim and Objectives To analyse what the most frequent topics of consultations were in years 2011–2013 and 2022 – 2024.

To compare changes of trends in topics of consultations after 11 years.

Material and Methods Patient records were analysed retrospectively in 2011 and 2013 (January to September) and then in 2022 and 2024 (January to September) and it was followed number of patients and visits, topics of patient questions and type of offered services. Pharmacists offered repeated check visits to the patients to increase the adherence of recommendations and ensure the successful smoking cessation.

Results Authors performed 221 consultations in 2011 to 2013 for 81 patients. The most frequent topics of consultation: smoking cessation 43.4%, potential drug interactions 36%, correct usage of drugs 7.6%, drug side effects 6.5% and weight loss 6.5%.

In 2022 to 2024, 1027 consultations were carried out for 438 patients. The most frequent topics of consultation: smoking cessation 56%, potential drug interactions 16%, memory loss counselling 14%, cholesterol screening 7% and higher blood glucose levels 7%.

The number of consultations increased more than 4.6 times over the last 11 years.

Conclusion and Relevance In recent years, thanks to the expansion of the range of services in the consultation centre, the number of consultations has increased by more than 4.6 times. The greatest interest of patients is in helping them quit smoking and revealing the risk of drug interactions. Newly, patients use the possibility to detect incipient memory changes, elevated cholesterol and blood glucose levels.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-153 AN EVALUATION OF ADHERENCE TO HYPERKALAEMIA GUIDELINES WITH A REVISED SODIUM POLYSTYRENE SULFONATE DOSING

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Background and Importance Using commonly recommended dosing regimens for sodium polystyrene sulfonate (SPS) has led to the overcorrection of hyperkalaemia in our patients. To mitigate this risk, a Drug Use Evaluation (DUE) was conducted and a reduction in SPS doses was recommended. The revised dosing was incorporated into the hospital's hyperkalaemia management guidelines.

Aim and Objectives To ensure patient safety, an audit was performed to evaluate compliance and safety of the revised SPS dosing regimen as well as compliance with the hyperkalaemia guideline.

Material and Methods One year after implementing the hyperkalaemia guideline, a retrospective audit on prescribing adherence to revised SPS dosing regimen as well as hyperkalaemia guidelines was conducted from March 2023 to March 2024 in the inpatient and outpatient setting of a tertiary institution. The safety of SPS was assessed based on hypokalaemia episodes.

Results A total of 267 cases were examined, 129 (48.3%) cases were non-adherent to the revised SPS dosing regimen. Factors such as absence of follow-up potassium levels and initiation of SPS despite normokalaemia contributed to 165 cases (61.7%) that deviated from the overall hyperkalaemia guidelines. Fifty-six out of 267 patients were excluded from the safety analysis due to lack of follow-up potassium levels, multiple hyperkalaemic episodes within the same visit, omission of SPS despite being prescribed and initiation of SPS despite normokalaemia. Hypokalaemia was more common in non-compliant cases. Incidence of hypokalaemia in the inpatient settings was 1 out of 66 (1.51%) for compliant cases and 3 out of 34 (8.82%) for non-compliant cases. In the outpatient setting, the incidence of hypokalaemia was 2 out of 35 (5.71%) for compliant cases and 15 out of 76 (19.73%) for non-compliant cases.

Conclusion and Relevance The audit demonstrated that the revised SPS dosing regimen is safer. Emphasising adherence to these updated dosing guidelines is essential for enhancing patient safety among physicians. Timely reminders and educational resources on the proper use of SPS should be provided. Refining existing prescribing order sets may also support compliance with the updated SPS dosing regimen.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-154 CO-ADMINISTRATION OF RIBOCICLIB/PALBOCICLIB AND PROTON PUMP INHIBITORS (PPI): A REAL-WORLD ANALYSIS IN AN ITALIAN ONCOLOGY CENTRE

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Background and Importance Ribociclib and palbociclib, CDK4/6 inhibitors, are often prescribed with aromatase inhibitors or fulvestrant to treat advanced/metastatic ER+ and HER2- breast cancer. Many patients concurrently take proton pump inhibitors (PPIs, ATC=A02BC) and/or antacids (ATC=A02A). PPIs can impact the absorption of drugs affected by pH, including ribociclib and palbociclib, both weak bases. Ribociclib, a CYP3A4 inhibitor and substrate, shares a metabolic pathway with omeprazole, also metabolised by CYP3A4. Ribociclib can prolong the QT interval, a risk potentially exacerbated by PPI use, especially in women.

Aim and Objectives This study aims to analyse prescription patterns of ribociclib/palbociclib and PPIs/antacids among patients treated at an Italian oncology centre, focusing on potential drug interactions.

Material and Methods Prescription data for ribociclib, palbociclib, PPIs, and antacids were collected from the prescription software, patient medical records, and interviews with patients at the hospital pharmacy from January to July 2024. Drug interactions were assessed using Terap, Micromedex, and drug leaflets.

Results Data were analysed from 88 ribociclib patients (all female) and 12 palbociclib patients (two male), with median ages of 66 and 63, respectively. Among ribociclib patients, 26 (39%) used PPIs concurrently, and eight (9%) also took antacids. In the palbociclib cohort, nine (67%) were on PPIs, with one also using an antacid. Regarding specific PPI use, 44% (11/26) of ribociclib patients used omeprazole and 35% (9/26) pantoprazole. In the palbociclib group, 42% (5/12) used pantoprazole and 17% (2/12) omeprazole. Among ribociclib patients not using PPIs/antacids, 43% received a standard dose, compared to 38% of those on PPIs/antacids. One patient stopped ribociclib and omeprazole due to QT prolongation.

Conclusion and Relevance This analysis highlights the need for clinician awareness of drug interactions in polytherapy, especially for patients on CDK4/6 inhibitors and PPIs. Competition for CYP enzymes can impact drug efficacy or toxicity risk. The intervention of hospital pharmacists was twofold: providing physician education on possible interactions and interviewing patients starting CDK4/6 therapy to identify potential interactions with chronic therapy, including medications not disclosed to their physician, which could interfere with efficacy and cause toxicity of the anti-tumour treatment. Real-world data stress the importance of medication reconciliation by hospital pharmacists to optimise patient care.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-155 PK-RULES: CLINICAL RULES TO ENHANCE SAFETY AND EFFICACY OF TREATMENTS THROUGH PHARMACOKINETIC MONITORING

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Background and Importance Adverse Drug Events (ADEs) are a significant concern in clinical settings, leading to patient harm and increased healthcare costs. Pharmacokinetic monitoring is crucial for optimising drug therapy, especially for medications with narrow therapeutic indices.

Our pharmacy service has a clinical decision support system (CDSS), which integrates clinical information from the hospital's different information systems that, through the application of predefined consensual clinical rules, generates real-time alerts aimed at preventing adverse drug events (ADEs) and tailored recommendations for optimising treatment.

Aim and Objectives The objective of this project was to improve the safety and efficacy of treatment by integrating pharmacokinetic monitoring rules into a CDSS to enable early detection of patients whose treatment could be optimised based on plasma concentrations and to avoid medication errors, thus reducing the occurrence of ADEs.

Material and Methods A multidisciplinary team of pharmacists, IT specialists, and medical experts (nephrologist, internist, gastroenterologist, infectious disease specialist) reviewed literature on medication monitoring and created clinical rules for identifying patients needing pharmacokinetic monitoring. These rules were validated and refined over 6 months to ensure their effectiveness.

Results After 6 months of validation, the system was implemented in clinical practice. In the second half of 2023, we incorporated 41 clinical rules related to pharmacokinetic monitoring, generating 188 alerts (positive predictive value=0.8). Of all pharmacokinetic interventions, 58.2% resulted from alert reviews, successfully preventing 137 moderate-to-high severity ADEs classified as $\geq$ E according to NCC MERP. The most frequently generated alerts were:

- Vancomycin for more than 3 days without levels and creatinine (Cr) > 1.2 mg/dl (29.3%).
- Vancomycin with levels (22.3%).
- Valproate level < 50 µg/ml (8.5%).
- Digoxin level > 1.2 ng/ml (6.4%).
- Vancomycin trough/single < 9 µg/ml (6.4%).
- Amikacin for more than 3 days without levels (4.2%).
- Amikacin trough > 2 µg/ml (3.8%).
- Paracetamol level > 5 µg/ml (3.4%).
- Voriconazole and Voriconazole trough < 2 µg/ml (2.9%).
- Most interventions occurred in orthopaedics (20.7%), critical care units (11.8%), neurosurgery (8.5%), and internal medicine (7.4%).

Conclusion and Relevance The integration of pharmacokinetic monitoring rules into the CDSS significantly improved the detection of potential ADEs and optimised treatment. The successful prevention of ADEs highlights the importance of tailored pharmacokinetic interventions.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

Education and research

6ER-001 EFFICACY OF BIOLOGICS AND SMALL MOLECULE INHIBITORS IN TREATING GENITAL PSORIASIS: A SYSTEMATIC REVIEW OF RANDOMISED CONTROLLED TRIALS

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Background and Importance Genital psoriasis affects approximately one to two-thirds of patients with psoriasis at some point during the disease, often resulting in a significant reduction in quality of life. While biologics and small molecule inhibitors are approved for psoriasis treatment, comprehensive evidence specifically addressing their efficacy in treating genital psoriasis remains limited.

Aim and Objectives This study aims to conduct a systematic review of randomised controlled trials (RCTs) evaluating the efficacy of biologics and small molecule inhibitors in the treatment of genital psoriasis.

Material and Methods We systematically searched PubMed, Embase, and the Cochrane Central Register of Controlled Trials from their respective inceptions until 1 April 2024, for relevant trials. The inclusion criteria were: (1) participants with genital psoriasis, (2) interventions involving biological therapies or small molecule inhibitors administered for 12–16 weeks, and (3) studies designed as RCTs. The primary outcomes were achieving a static Physician's Global Assessment of Genitalia (sPGA-G) score of 0/1 (clear or minimal disease) and sPGA-G score 0 (complete clearance). Given the expected clinical heterogeneity across studies, a random effects model meta-analysis was conducted. The study protocol was registered with the International Platform of Registered Systematic Review and Meta-analysis Protocols (INPLASY 202440117).

Results We included four reports encompassing three RCTs with a total of 492 participants, comparing ixekizumab versus placebo, apremilast versus placebo, and ixekizumab versus secukinumab. Both ixekizumab and apremilast demonstrated significantly higher response and clearance rates compared to placebo. Ixekizumab showed superior efficacy (response risk ratio (RR) 9.49, 95% CI 4.04–22.27; clearance RR 12.00, 95% CI 3.90–36.94) compared to apremilast (response RR 2.19, 95% CI 1.48–3.25; clearance RR 3.88, 95% CI 2.01–7.49) in both response and clearance rates relative to placebo. However, no significant difference was observed between ixekizumab and secukinumab in achieving complete clearance (RR 1.02, 95% CI 0.52–2.00). Additionally, ixekizumab was significantly more effective than placebo in reducing avoidance scores to 1/2 (RR 2.98, 95% CI 1.64–5.41), though no significant difference was noted in achieving impact scores of 1/2 by week 12 (RR 1.62, 95% CI 0.99–2.66).

Conclusion and Relevance In conclusion, both ixekizumab and apremilast are effective in treating genital psoriasis. However, ixekizumab and secukinumab showed no significant difference in efficacy for complete clearance.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-002 VALIDATION OF ICD-10 DIAGNOSIS CODES FOR GUILLAIN-BARRÉ SYNDROME IN TAIWAN'S NATIONAL HEALTH INSURANCE CLAIMS DATABASE

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Background and Importance Secondary healthcare databases provide extensive population-level health data, making them valuable for both timely disease surveillance and outcome research related to Guillain-Barré Syndrome (GBS). While GBS is often identified in these databases using diagnosis codes, the accuracy and appropriateness of these codes for research purposes remain uncertain.

Aim and Objectives To validate ICD-10 codes for GBS in Taiwan's National Health Insurance (NHI) claims database, electronic medical records (EMR) data were used to verify the accuracy of the diagnoses.

Material and Methods We analysed EMR data from adult patients hospitalised at eight Chang Gung Memorial hospitals in Taiwan between 2017 and 2022. Patients were identified using the ICD-10 code G61.0 listed in any of the five discharge diagnosis positions, indicating a possible diagnosis of GBS. Two clinical doctors independently validated the suspected GBS diagnosis using EMR data of the identified patients, based on the diagnostic criteria established by the National Institute of Neurological Disorders and Stroke. We evaluated the positive predictive values (PPV) of various definitions, including the position of the ICD-10 code in the discharge diagnosis, nerve conduction studies (NCS) claims, and/or specific GBS treatments.

Results Among 484 patients with the ICD-10 GBS code, 368 were confirmed to have true GBS. The positive predictive value (PPV) for identifying GBS using the code in any discharge diagnosis position was 76.0%. More restrictive criteria, such as using the code in the primary diagnosis position or requiring additional nerve conduction study (NCS) and/or treatment claims, increased the PPV but identified fewer true GBS cases. Specifically, using the ICD-10 GBS code as the primary diagnosis plus NCS and treatment claims achieved the highest PPV of 98.3%, though it missed 140 (38.0%) true GBS patients. Conversely, using the ICD-10 GBS code in any diagnosis position along with NCS claims provided a good PPV of 85.8% with minimal loss of true GBS cases (13, or 3.5%).

Conclusion and Relevance The PPV of the ICD-10 code for GBS in Taiwan's NHI claims data were high. For identifying GBS as a vaccine safety outcome, our findings recommend a balanced approach: using the ICD-10 GBS code in any discharge position along with NCS claims in Taiwan's NHI claims data.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-003 INFLUENZA VACCINATION AND ITS ASSOCIATION WITH DEMENTIA RISK: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Background and Importance Influenza vaccination is not only effective in preventing influenza but may also provide protection against other diseases, including dementia. While previous studies have explored the relationship between influenza vaccination and dementia, the association in populations with specific underlying conditions remains unclear.

Aim and Objectives This systematic review and meta-analysis aimed to evaluate whether influenza vaccination is associated with a reduced risk of dementia, particularly in individuals with specific diseases.

Material and Methods We systematically searched the relevant studies via MEDLINE and Embase from inception to 17 July 2024, using keywords and MeSH/Emtree terms related to dementia and influenza vaccination. The inclusion criteria were: (1) Population: Adults, (2) Exposure: Influenza vaccination, (3) Controls: No influenza vaccination, (3) Outcome: Risk estimates of dementia diagnosis, and (4) Study design: Cohort studies. Screening and data extraction were performed independently by two authors, with discrepancies resolved by a third author. The quality and risk of bias of the included studies were assessed using the Newcastle-Ottawa Scale. Dementia risk data were pooled using a random effects model, with hazard ratios (HRs) and 95% confidence intervals (CIs) as the primary outcome measure.

Results Out of 447 studies identified, seven met the inclusion criteria, encompassing 8,265,275 participants (52.8% female). Six out of the seven included studies were judged to have a low-risk of bias. Pooled analysis indicated that influenza vaccination is associated with a lower risk of all-cause dementia (HR: 0.75; 95% CI, 0.66–0.85). This association was observed both in the general population (HR: 0.89; 95% CI, 0.81–0.98) and in those with specific diseases, including hypertension, diabetes mellitus, and dyslipidaemia (HR: 0.66; 95% CI, 0.63–0.69). Regarding vaccination doses, individuals receiving four or more doses demonstrated a significant reduction in dementia risk (e.g., HR: 0.42; 95% CI: 0.35–0.50). In terms of dementia subtypes, influenza vaccination was associated with a lower risk of vascular dementia (HR: 0.59; 95% CI: 0.47–0.75), but not with Alzheimer's disease (HR: 0.87; 95% CI: 0.64–1.19).

Conclusion and Relevance Influenza vaccination was associated with a reduced risk of dementia, particularly vascular dementia, and in populations with specific underlying conditions. These findings highlighted the potential of vaccination as a valuable strategy for dementia prevention in high-risk groups.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-004 USE OF ARTIFICIAL INTELLIGENCE TO IMPROVE MEDICAL CARE IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE. INFLAMMATORY BOWEL DISEASE. PRELIMINARY MODELS

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Background and Importance Inflammatory bowel disease (IBD) is a chronic disorder that severely impact patients' quality of life. Current treatments, which are often immunosuppressive and biologics, have significant side effects and are not always effective. The variability in response to these treatments makes it essential to personalise therapeutic management to reduce costs, minimise risks and improve outcomes.
Aim and Objectives The aim of the project is to develop a model to predict if patients will respond to treatments, helping to make more informed clinical decisions and improving medium-term outcomes.
Material and Methods To explore the development of a 26-week response prediction model, clinical, analytical, and treatment data from the 3 months prior to the initiation of infliximab/adalimumab/vedolizumab/ustekinumab were used in patients over 18 years of age with a confirmed diagnosis of IBD. Patients without availability/access to electronic health record data, with 50% of study variables not recorded or with a loss to follow-up prior to week26 were excluded. The proportion of patients intended for training and internal validation of the model was 90% and 10%, respectively. The selected centre was a tertiary-level hospital and the period analysed was from January 2012 to January 2024.
Results A total of 1068 patients with a mean(±SD) age of 42.82(±21.08) years at the start of treatment and a mean (±SD) time of IBD evolution of 8.8(10.7) years. The proportion of male was 51.8%. Patients with CD accounted for 72.9%, and 24.25% had perianal disease. The drug response rate at week 26 was 82%.A neural network model was sketched.

The proportion of missing values among the selected variables was 17%. A model with an F1 score of 0.802, an accuracy of 0.79 (rate of true positives vs. total true and false positives) and a recall of 0.811 (rate of true positives vs. total true and false positives). In the patients used to test the model, 66.40% classified as non-responders did not respond and 92.3% classified as responders did respond.
Conclusion and Relevance The history, clinical and laboratory variables generated during the months prior to starting treatment could be used effectively to identify non-responders and optimise their therapy.

Abstract 6ER-004 Table 1 Trained models

Model	AUC	CA	F1	Precision	Recall
SVM	0.793	0.816	0.782	0.800	0.816
Random Forest (1)	0.787	0.810	0.771	0.790	0.810
Neural Network	0.763	0.811	0.802	0.798	0.811
Logistic Regression	0.724	0.785	0.781	0.777	0.785

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

6ER-005 THE IMPACT OF TYPE OF DELIVERY METHOD ON MEDICINE WASTE IN HOUSEHOLDS: A QUESTIONNAIRE-BASED STUDY ON OUTPATIENTS RECEIVING COST-FREE MEDICINE

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Background and Importance The increasing number of patients is challenging the healthcare system thus driving the demand for more home-based medical treatments. Patients in hospital treatment at home (outpatients) can acquire their hospital medication 'cost-free medicine' either through home delivery or medication pickup lockers. The region aims to transition more patients to medication pickup lockers, as it eases access to necessary treatments. Given the current focus on home-based treatments and the limited tracking of medications in households, it is crucial to investigate the extent of medicine waste to optimise resources.
Aim and Objectives This study aimed to investigate medication waste from cost-free medicine delivered to outpatients and whether there was an association between excess cost-free medicine and type of delivery method.
Material and Methods This study included outpatients receiving cost-free medication from March to October 2023 affiliated with either Department of Neurology or Department of Gastroenterology. Outpatients meeting inclusion and exclusion criteria were selected to receive a questionnaire, which was distributed in March to April 2024 through Digital Post. As medicine waste is difficult to measure, the questionnaire uses excess of cost-free medication as a surrogate measure for medicine waste, since an excess can lead to medicine waste. Data from outpatients receiving the questionnaire was acquired through Apovision and subsequently stored and managed in REDCap.
Results Data from the questionnaire shows that 53% of outpatients report having excess cost-free medication at home. For outpatients receiving medicine in medication pickup lockers, 59% report having an excess of cost-free medication, while only 47% of outpatients receiving medication through home deliveries report having an excess. Additionally, medication pickup lockers are associated with larger stores of medicine at home compared to patients receiving home delivery.

Conclusion and Relevance More than half of the study population had excess cost-free medication within the past year, with the largest excess linked to medication pickup lockers compared to home deliveries. Notably, patients managing their own pickup tend to accumulate more, which, if unused, becomes medicine waste. It may thus be worth investigating whether deliveries through medication pickup lockers should be scheduled at fixed intervals to prevent excessive surplus.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-006 ANALYSIS OF THE ANTIMICROBIAL USE IN NEONATAL POPULATION BASED ON A DEFINED DAILY DOSE METHOD

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Background and Importance Neonates, especially premature infants, are highly susceptible to infections due to their immature immune systems, resulting in frequent use of antibiotics. This practice carries significant risks, including disruption of the microbiota and increased antimicrobial resistance. Antimicrobial stewardship programs (ASPs) are critical to optimise antibiotic use. Because of the WHO-defined Defined Daily Dose (DDD) method is not fully applicable to neonates due to physiological differences, a neonatal-specific DDD (DDDn) has recently been developed to accurately monitor and to improve antibiotic practices in this population.
Aim and Objectives This study aimed to assess the feasibility of using the specifically designed DDDn as a standardised metric to evaluate antimicrobial use in neonatal units.
Material and Methods This observational study was conducted in a neonatology unit from 2013 to 2023. Data on antimicrobial consumption were obtained from the pharmacy database and expressed as DDDn per 1,000 occupied bed days (OBDs). DDDn values were initially established in a previous study.[1]
Results The average antimicrobial consumption in the neonatology unit was 1.457 DDDs per 1,000 OBDs. Amoxicillin-clavulanic acid (2.466 ± 2.404), cefotaxime (2.155 ± 0.549), ampicillin (1.074 ± 0.644), gentamycin (0.567 ± 0.256) and meropenem (0.256 ± 0.167) were the most commonly used antimicrobials. In contrast, azithromycin (0.054 ± 0.064), cefixime (0.011 ± 0.014) and linezolid (0.003 ± 0,006) were rarely used, as these are antibiotics that are not commonly prescribed in this population.
Conclusion and Relevance This study demonstrates the feasibility of using DDDn as a reliable metric to monitor antimicrobial consumption in neonates. Applying DDDn in ASPs could enhance antibiotic prescribing practices, reduce inappropriate antibiotic use, and help combat antimicrobial resistance. These findings have important implications for improving antibiotic stewardship and clinical outcomes in neonatal care, although further research is required to validate these results across diverse neonatal populations.

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Conflict of Interest No conflict of interest

6ER-007 RALOXIFENE AS AN ADJUVANT THERAPY FOR PATIENTS WITH SCHIZOPHRENIA

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Background and Importance Raloxifene may be useful as an adjunctive treatment schizophrenia.
Aim and Objectives This meta-analysis aimed to evaluate the effectiveness and safety of adjunctive raloxifene in patients with schizophrenia.
Material and Methods Systematic search was performed using PubMed, Embase, and the Cochrane Library databases for articles published until May 2024. Randomised controlled trials investigating the effectiveness and safety of adjunctive raloxifene for treating schizophrenia were included. The outcome measure was psychotic symptom severity using the Positive and Negative Syndrome Scale (PANSS). Mean differences (MDs) and their 95% confidence intervals (CIs) were calculated using random effects models.
Results Nine studies were included in the final analysis. Compared with the placebo group, raloxifene as an adjunctive therapy significantly improved the positive, negative, general, and total PANSS scores, MD = −1.30 (95% CI = −2.39 to −0.20; I^2 = 52%; p = 0.02), MD = −1.69 (95% CI = −3.19 to −0.20; I^2 = 68%; p = 0.03), MD = −3.90 (95% CI = −6.59 to −1.21; I^2 = 69%; p = 0.005), and MD = −7.12 (95% CI = −11.89 to −2.36; I^2 = 74%; p = 0.003), respectively.
Conclusion and Relevance This meta-analysis shows that adjunctive raloxifene is effective and safe in patients with mild to moderate schizophrenia, specifically improving PANSS-positive, general, and total scores. Future studies with larger sample sizes are required to confirm these findings.

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6ER-008 AFICAMTEN AND MAVACAMTEN: WHEN SIDE EFFECTS AFFECT EFFICACY

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Background and Importance Coats et al.[1] demonstrated the clinical relevance of increased peak oxygen consumption (pkVO2) in hypertrophic obstructive cardiomyopathy by

finding a significant correlation between pkVO2 increases and reduced death and transplantation. This highlights the importance of mavacamten and aficamten, which primarily raise pkVO2. However, left ventricular ejection fraction (LVEF), also affected by these drugs, is a significant covariate in Coats et al.'s regression and must be considered.

Aim and Objectives To evaluate, using the centred prognostic index (CPI) from Coats et al.'s equation, the impact of pkVO2 increase from mavacamten and aficamten, first without considering the variation in LVEF, and then taking this variation into account.

Material and Methods Retrospective analysis conducted in June 2024. Pivotal clinical trials of mavacamten (EXPLORER-HCM)[2] and aficamten (SEQUOIA-HCM)[3] were reviewed, collecting the increase in pkVO2 and mean change in LVEF. Using the hazard ratios from Coats et al.'s equation, coefficients for pkVO2 and LVEF were calculated. Assuming that the rest of the parameters in the equation (demographic and clinical) remained constant, the CPI was first calculated based on the pkVO2 increase alone. A second calculation was then performed, incorporating both the pkVO2 increase and the LVEF change reported in the trials.

Results The pkVO2 increase was 1.5 ml/kg/min with mavacamten and 1.7 ml/kg/min with aficamten. Both trials showed reductions in LVEF: −4.0 percentage points for mavacamten and −4.8 points for aficamten. The coefficients in Coats et al.'s equation were −0.198 for pkVO2 and −17.32 for LVEF. When only the pkVO2 increase was considered (assuming other parameters constant), the CPI was −0.30 for mavacamten and −0.34 for aficamten, indicating a favourable prognosis. However, when both the LVEF reduction and pkVO2 increase were considered, the CPI was 68.99 for mavacamten and 82.80 for aficamten, indicating a worse prognosis when adjusted for these covariates.

Conclusion and Relevance According to Coats et al.'s equation, the pkVO2 increase is initially associated with a better prognosis when other variables are held constant. However, when the reduction in LVEF is also taken into account, the prognosis worsens. It cannot be concluded from this data that the use of these drugs reduces death or transplantation risk.

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Conflict of Interest No conflict of interest

6ER-009 SCIENTIFIC ACTIVITY OF HOSPITAL PHARMACY SPECIALISTS TRAINED AT VIRGEN DEL ROCÍO UNIVERSITY HOSPITAL

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Background and Importance Research is essential for any healthcare professional, including specialists in hospital pharmacy. In the Resident Pharmacist Training Programme (FIR), research is a key component of the training. The Pharmacy Teaching Unit at Virgen del Rocio Hospital focuses on training its residents in excellence, research included.

Aim and Objectives To analyse the impact of research training of Virgen del Rocío's residents by studying their research along their professional career.

Material and Methods Names, gender, current job position, and residency end date of all specialists formed at Virgen del Rocío Hospital from 1988 to 2022 were collected. Each individual's research profile was searched in ORCID, Clarivate-Researcher-ID, Google Scholar, and ResearchGate repositories, using the first profile found. The total H-index, number of publications, and citations were recorded. If no research profile was found, the individual was considered to have no relevant research activity. A simple frequency analysis of these data were performed.

Results Over 35 years (1988–2022), 60 professionals completed their residency in the department, and a research profile was found in at least one repository for 31 of them (52%). Among those with identified research profiles, there was a higher percentage of women (80% vs 69%) and more professionals working in public hospitals (84% vs 55%) compared to those without profiles. The distribution of research variables by 5 year periods among the 31 professionals with available profiles is detailed in table 1.

Conclusion and Relevance A little over half of the specialists trained at Virgen del Rocío Hospital have relevant research activity. Among them, women and those working in public hospitals predominate. Younger generations show greater research activity, both in the number of professionals dedicated to research and in bibliometric indicators, despite having had less time to achieve them.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

Abstract 6ER-009 Table 1 Research results (average, maximum-minimum) by 5 year periods among specialists trained at Virgen del Rocío for whom a curriculum is available

	1988–1992	1993–1997	1998–2002	2003–2007	2008–2012	2013–2017	2018–2022
N	1	2	0	3	7	9	9
H-index	24	10(12–8)	0	9(18–2)	7(12–2)	8(23–2)	5(8–2)
Publications	100	43(68–19)	0	43 (89–2)	27(39–3)	45(129–3)	22(44–5)
Citations	1,875	355(482–228)	0	386(980–21)	300 (1,028–23)	447(2,243–4)	86(247–9)

NOTE: The number of residents per year in each period varies.

6ER-010 METFORMIN FOR PREVENTION AND TREATMENT OF ANTIPSYCHOTIC INDUCED WEIGHT GAIN

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Background and Importance Weight gain and metabolic complications are substantial adverse effects associated with second-generation antipsychotics. However, comprehensive guidelines for managing antipsychotic induced weight gain are lacking.

Aim and Objectives This study determined the most appropriate dosage and duration of metformin treatment to prevent and manage antipsychotic induced weight gain. The findings of this study can provide valuable guidance for medical experts.

Material and Methods This review included all double-blind, placebo-controlled studies investigating metformin's effectiveness in addressing antipsychotic-related weight gain. We systematically searched PubMed, Embase, the Cochrane Central Register of Controlled Trials, Google Scholar, and ClinicalTrials.gov for relevant studies from the inception to 2024. A random effects model was used for the meta-analysis.

Results This meta-analysis including 20 studies with 1,070 patients revealed that metformin significantly surpassed placebo in attenuating weight gain in patients receiving antipsychotics. The mean weight change with metformin was −3.32 kg (95% confidence interval (CI): −4.57 to −2.07). Additionally, metformin use resulted in a noticeable decrease in body mass index (−1.24 kg/m^2 (95% CI: −1.70 to −0.77)). No significant differences were observed in outcomes between treatment durations of 12 and 24 weeks. Furthermore, the efficacy of metformin was not significantly different between doses of ≤1000 mg and >1000 mg.

Conclusion and Relevance This updated meta-analysis investigated the durations, dosages of metformin use in patients with schizophrenia experiencing antipsychotic induced weight gain. The findings highlight the need for additional large-scale research to validate our findings.

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Conflict of Interest No conflict of interest

6ER-011 EVALUATING THE POTENTIAL OF CHATGPT TO SIMULATE CLINICAL TRIAL DATA: IMPLICATIONS FOR THE INTEGRITY OF SCIENTIFIC RESEARCH

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Background and Importance Large Language Models (LLMs) like ChatGPT represent a significant opportunity for healthcare. However, they may also facilitate fraudulent scientific practices. The ability of LLMs to generate plausible clinical trial (CT) data poses a potential threat to research integrity.

Aim and Objectives This study aimed to assess the capability of GPT-4 ADA (OpenAI) to generate a dataset resembling that of a real CT, specifically in the context of comparing two drugs without previous direct comparisons.

Material and Methods Instructions for the LLM were adapted from those described by Taloni et al. (2023) for a CT comparing two pharmacological treatments. Through the ChatGPT-4 interface, a request was made to generate a database of 500 patients diagnosed with advanced clear cell renal carcinoma. The dataset was designed to simulate a CT comparing pembrolizumab + axitinib with nivolumab + cabozantinib. The data were required to show a statistically significant difference in progression-free survival (PFS) between the two treatment groups.

The following variables were specified

- Patient code.
- Sex: 39% male, 61% female.
- Date of birth.
- Treatment: Nivolumab + cabozantinib (50%), pembrolizumab + axitinib (50%).
- Recruitment region: North America (24%), Western Europe (26%), Rest of the World (50%).
- Combined Positive Score for PD-L1: ≥1 (59%), <1 (41%).
- Number of organs with metastasis: 1 (26%), ≥2 (74%).
- Prior radiotherapy: 10%.
- Prior nephrectomy: 82%.
- Time to death and PFS: measured in months.

A Cox proportional hazards model was used to estimate the hazard ratio (HR) and 95% confidence interval (CI), confirming the statistical significance of the differences observed.

Results Within two minutes, ChatGPT generated a downloadable Excel database containing information on 500 pseudoanonymised patients. The data met all predefined criteria. The analysis showed a median PFS of 18.78 months for nivolumab + cabozantinib and 25.25 months for pembrolizumab + axitinib, with a HR of 0.4 (95% CI: 0.32–0.5, p<0.001).

Conclusion and Relevance ChatGPT's ability to generate CT-like datasets demonstrates a significant risk to the integrity of scientific research, as it could facilitate fraudulent publications. Awareness of this threat and increased transparency in study registration and data handling are essential to safeguard research integrity. Hospital pharmacists should recognise the potential for LLMs to enable scientific fraud, highlighting the need for study registration and transparency in data handling.

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6ER-012 ESTIMATING MEDICATION ADHERENCE IN HEART FAILURE USING ELECTRONIC HEALTH RECORDS: A SYSTEMATIC REVIEW

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Background and Importance Medication adherence is crucial for effective heart failure (HF) management; however, variations in methodologies may affect adherence estimates.
Aim and Objectives This review aimed to assess the consistency and reliability of the methods used to measure medication adherence in HF patients.
Material and Methods A systematic review was conducted in March 2024, following PRISMA guidelines. Literature was searched across PubMed, Embase, CINAHL, Web of Science, and Scopus databases using terms related to medication adherence, compliance, HF, and electronic health records (EHR). Observational studies assessing medication adherence using EHR among HF patients were included.

Collected variables included study design, population characteristics, study dates, duration, and adherence assessment methods. The TEN-SPIDERS criteria were applied to evaluate the quality of adherence reporting.
Results Out of 1,934 identified studies, 20 met the inclusion criteria. All were retrospective observational studies published between 1999 and 2023. Four studies focused exclusively on patients with HF with reduced ejection fraction. Secondary adherence was assessed in all studies; primary adherence was not. The medication classes examined included angiotensin-converting enzyme inhibitors (18), angiotensin receptor blockers (17), beta blockers (16), mineralocorticoid receptor antagonists (9), diuretics (7), digitalis glycosides (4), and one sodium-glucose cotransporter-2 inhibitor.

The observation period was 1 year in 15 studies and 6 months in the remaining five. The primary methods for assessing adherence were the Proportion of Days Covered (11) and Medication Possession Ratio (2). Other methods included the proportion of patients covered, continuous multiple interval measures, fill-frequency, presence of at least two prescriptions in a year, patient adherence indicator and continued treatment during follow-up. Adherence was analysed for single medications in 14 studies, multiple medications in two studies, and both in three studies. Ten studies dichotomised adherence at $\geq$80%, while 10 analysed it as a continuous variable. Four allowed switching within therapeutic classes, eight allowed stockpiling, seven censored hospital stays, and 10 censored death.
Conclusion and Relevance This review found significant variability in measurement techniques, observation periods, and the handling of clinical factors which made adherence rates comparison across studies difficult. A standardised approach, such as the TEN-SPIDERS, should be utilised in future studies to ensure reliable and transparent reporting of adherence metrics in this patient population.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-013 EVOLUTION OF PHARMACISTS' PARTICIPATION AS PRINCIPAL INVESTIGATORS IN REGISTERED CLINICAL TRIALS: A LONGITUDINAL STUDY FROM 2004 TO 2024

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Background and Importance Hospital pharmacists play a crucial role in clinical trials (CTs), particularly those assessing investigational products for medical purposes. However, the extent of collaboration of pharmacists as principal investigators (PIs) is not well-documented.
Aim and Objectives This study evaluated the participation of pharmacists as PIs in CTs registered in ClinicalTrials.gov and its evolution over time.
Material and Methods A retrospective, longitudinal study was conducted on CTs registered between 1 January 2004 and 30 September 2024 on ClinicalTrials.gov. Non-interventional studies and those lacking investigator data were excluded. Variables collected included trial phase, intervention design, masking, CT start date, investigator qualifications, and trial status. Data were analysed across 4 year intervals and processed using Python 3.12.
Results Out of 309,744 CTs, trial phases were distributed as follows: 50,423 (16.28%) in early phase-1/phase-1, 51,414 (16.60%) in phase-2, 28,994 (9.36%) in phase-3, and 26,205 (8.46%) in phase-4; others did not specify phases.

Intervention designs included 184,213 (59.70%) parallel, 86,958 (28.18%) single-group, 24,751 (8.02%) crossover, 8,361 (2.71%) sequential, and 4,267 (1.38%) factorial. Masking was categorised as 174,046 (56.34%) open-label, 45,063 (14.59%) single-blind, 40,150 (13.00%) double-blind, 20,812 (6.74%) triple-blind, and 28,837 (9.34%) quadruple-blind trials. Regarding trial status, 27,042 (8.73%) were inactive, 48,394 (15.62%) recruiting, 161,411 (52.11%) completed, 30,780 (9.94%) stopped, and 42,117 (13.60%) had unknown status. Notably, only 2,080 trials (0.67%) included a pharmacist as PI, with 1,875 trials having one pharmacist, 172 having two, and 33 involving more than two.

Plot 1 presents trends in participation rates of academic and professional groups from 2004 to projections into 2024 and later.
Conclusion and Relevance This study reveals persistently low pharmacist participation as PIs in ClinicalTrials.gov-listed trials. The low participation may stem from limited professional recognition, specific training gaps, and institutional biases favouring physicians for such roles. Addressing these challenges could involve enhancing pharmacists' training, advocating for institutional policy changes, and increasing awareness and support from professional organisations. These measures could help elevate the role of pharmacists in clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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6ER-014 EVALUATION OF BARICITINIB IN PAEDIATRIC PATIENTS WITH ALOPECIA AREATA

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Background and Importance Alopecia areata (AA) is a chronic immune-mediated disorder characterised by transient, non-scarring hair loss and preservation of the hair follicle. Its global prevalence is estimated at 2% and is even higher in children. Currently, there is no curative treatment. Therapeutic interventions have targeted pathways involving JAK/STAT signalling. The aim of the treatments is to block the immune system's attack and stimulate hair regrowth.

Since 2023, baricitinib has been approved in our country for adult patients with AA who have at least 50% of hair loss (Severity of Alopecia Tool score (SALT) 50) and have not responded to standard treatment (systemic corticoids or methotrexate). Treatment response is defined as a SALT ≤20 after 36 weeks of treatment.

Aim and Objectives To retrospectively evaluate the efficacy of off-label baricitinib used in children with severe and refractory AA at a third-level paediatric hospital.

Material and Methods We reviewed our patients' clinical histories at baseline and followed-up their progress over time after starting baricitinib. We focused on efficacy using the SALT score, evaluated possible side effects and patients' feedback. Patients were psychologically monitored given their age and condition.

Results Since July 2023, 17 patients (seven boys/10 girls) have started baricitinib in our hospital. From those, 13 (76.47%) have had at least one follow-up visit. The average age was 12.2 years (SD 2.75) ranging from 8–17 years-old. Treatment time was on average 36.91 weeks (SD 13.23) ranging from 10.00 to 56.86 months. Seven patients (50%) achieved the defined treatment goal, three patients (21.4%) had an improvement but did not reach SALT 20, 2 patients (14.3%) did not experience any regrowth and two patients (14.3%) experienced a worsening of their condition.

Overall, treatment was well-tolerated although six patients (42.86%) had abnormal laboratory results, including elevated cholesterol, bilirubin, LDH, ALP or GGT. It was observed that 10 patients (71.43%) were psychologically affected.

Conclusion and Relevance Baricitinib has shown debatable results in our paediatric population with AA. However, some patients have shown satisfactory outcomes in a short period of time, with full recovery in certain cases.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-015 HARNESSING OPENAI AS A STRATEGIC TOOL FOR HORIZON SCANNING IN HOSPITAL PHARMACY PRACTICE

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Background and Importance Artificial intelligence (AI) can be a valuable tool in the field of hospital pharmacy, especially in Horizon Scanning tasks. OpenAI offers an innovative approach in the field of Horizon Scanning, leveraging natural language processing and machine learning algorithms to analyse large amounts of data.

Aim and Objectives Evaluation of the OpenAI feasibility, efficacy, accuracy, and reliability as a support tool for horizon scanning in hospital pharmacy practice.

Material and Methods Up to five searches were conducted to compare three OpenAI models (Perplexity AI, Microsoft Copilot, and ChatGPT) in determining the viability of authorising the use of drugs in clinical trials in the near future.

1st Search: Search and analysis parameters were delimited, indicating the variables (drugs under study) and the type of estimation (percentage of success of authorisation). OpenAI's natural language processing capabilities were used to analyse and extract relevant information from the data sources (www.clinicaltrials.gov).

2nd Search: Search parameters were narrowed (disease group, drugs). An indirect comparison between each of the drugs aggregated by pathology was requested.

3rd Search: In addition to the above, the search was restricted to a specific area (rare diseases).

4th Search: In addition to the foregoing, the latest Horizon Scanning report on orphan drugs prepared by a reference group was provided.

5th Search: a statistical estimation of the viability, efficacy, accuracy, and reliability was requested.

Results All OpenAI models reached a common conclusion about the areas where new drugs are most likely to emerge in the near future: chronic diseases, weight control, and rare and genetic-based diseases. They identified up to 143 drugs with potential likelihood of approval. However, significant limitations were observed in the models' ability to provide accurate and reliable information on statistical comparisons and probabilistic estimates. The models had difficulties providing data on the relative efficacy and safety. Furthermore, when narrowing or specifying search parameters, the models became blocked and began to provide incorrect/fabricated data.

Conclusion and Relevance OpenAI could be a valuable Horizon Scanning tool in hospital pharmacy practice, offering the potential to improve the identification of emerging trends and technologies relevant to patient care. However, today they present significant limitations that require further development to ensure their reliability and accuracy in complex tasks.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-016 THE TECHNICIAN: A KEY PILLAR IN STAFF TRAINING FOR COMPOUNDING

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Background and Importance Compounding technicians (CTs) are responsible for the preparation of compounded formulas (CFs), while the pharmacist oversees the final validation. It is

essential to involve CTs in training new CTs so they can acquire the necessary skills for compounding, ensuring comprehensive technical training.

Aim and Objectives The main objective is to design a training procedure to get CTs involved in new CTs training which is essential to ensure acquisition of compounding skills by CTs. The secondary objective is to create a record of trained CTs, prior to definitive pharmaceutical validation.

Material and Methods

1. Training procedure was designed and implemented in our hospital Pharmacy Service between June and September 2024. Steps involved were:.
2. Define several working areas (WA) based on the activity carried out in each of them.
3. Assign training CTs for each area, based on their experience and work capacity.
4. Create checklists for each WA with mandatory items for validation of new CTs, based on standardised work protocols and differentiating between pharmaceutical forms.
5. Review and discuss the previous checklists by training CTs.
6. Implement changes in checklists according to training CTs view.
7. Record videos to demonstrate compounding techniques more precisely to increase training quality.
8. Use the videos and checklist to train new CTs over the first four weeks of work in Pharmacy Service.

To verify efficiency of the procedure, final pharmaceutical validation through the CTs training was done. Registration of trained CTs in an Excel after completing the training procedure was performed.

Results Three work areas were identified: non-sterile compounding, sterile compounding, and hazardous medication compounding. Two CTs were appointed as training CTs. Three checklists were created according to the preparation areas in agreement with the training CTs. Eleven videos were recorded, including CFs preparation and general working in the previously defined areas videos. New CTs were trained, and their training was documented. Final pharmaceutical validation of CTs training was conducted successfully.

Conclusion and Relevance The procedure implementation has facilitated the active involvement of CTs, which is indispensable for new CTs training and enhance the quality and safety of care. The registration of trained CTs assist the pharmacist to follow new CTs training and to perform the final validation.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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6ER-017 ABSTRACT WITHDRAWN

6ER-018 ATTITUDES TOWARDS DEPRESCRIBING AMONG OLDER PATIENTS WITH RHEUMATIC DISEASES

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Background and Importance There is a high prevalence of polypharmacy among the elderly population, which increases the likelihood of having potentially inappropriate medication. Deprescribing has been introduced as an approach to improve appropriate medication use. Patient's involvement is important for the success of deprescribing.

Aim and Objectives To assess the attitudes, beliefs, and experiences of older patients with rheumatic diseases regarding the number of medications they are taking and their feelings towards deprescribing.

Material and Methods Cross-sectional study conducted in a third-level hospital in June-2024. Patients ≥65 years with rheumatic diseases, who attended the hospital pharmacy department, were given the validated Spanish version of the Patients Attitudes Towards Deprescribing' (rPATD) questionnaire[1]. rPATD questionnaire has 22 items on a 5-point Likert scale: from 1 (strongly agree) to 5 (strongly disagree). We excluded patients who didn't sign the informed consent and those in clinical trial.

Results Thirty-three patients were included, median age: 72 years (IQR:68.8–76.8), 68.8% women; median drug/patient: 9.5 (IQR:6–12). rPATD results are shown in table 1.

Majority of participants (90.9%) stated that they were dissatisfied with their medications and 97% would be willing to deprescribe one or more medications if their doctor thought it appropriate.

Conclusion and Relevance Patients with rheumatic diseases are not willing to have their medicines deprescribed. General satisfaction with their pharmacotherapy is high. Pharmacists should recognise such patients and lead them towards a shared

Abstract 6ER-018 Table 1

	Mean(±SD)
Involvement factor	**1.7(0.8)**
good understanding	3.1(1.5)
know current medicines	1.9(0.8)
know as much as possible	1.2(0.4)
involved in decisions	1.1(0.3)
always ask if I don't understand	1.2(0.4)
Burden factor	**1.9(0.7)**
money/expensive medicines	3.3(1.1)
inconvenient	1.7(0.8)
large number of medicines	1.7(0.8)
burden	1.5(0.6)
too many medicines	1.5(0.7)
Appropriateness factor	**2.1(0.5)**
one or more medicines that I no longer need	2.1(0.7)
would like to try stopping	1.4(1)
reduce the dose	1.8(1)
not working	2.6(0.9)
Side effects	2.6(1.1)
Concerns about stopping factor	**3.5(0.7)**
reluctant to stop a long-term medicine	4.3(0.8)
missing out on future benefits	3.3(1.5)
stressed	2.3(1)
giving up	4.1(0.9)
previous bad experience	3.7(0.9)
Global questions	**2.8(1.4)**
willing to stop	1.4(0.8)
satisfaction	4.1(0.5)

decision making attitude. Therefore, it is imperative to carry out strategies to implement patient-centred care based on their attitudes and expectations.

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Conflict of Interest No conflict of interest

6ER-019 COLCHICINE: HOSPITAL-WIDE EVALUATION AND BENEFITS OF A VIDEO COURSE

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Background and Importance The 2024 update of 'Never Events' by the ANSM put Colchicine on the front stage. Colchicine is widely used and its good prescription is a necessity, especially for the elderly.
Aim and Objectives Through an educational video and a survey, we aimed to inform HP about colchicine to prevent mistakes in prescription.
Material and Methods Three pharmacists created a survey on colchicine about: indications, adverse events and toxicity, usual dosing, medical interactions, pharmacokinetic, patient advice, and improvement ideas. The form was shared via paper, a QR code, or by email to the HP in our hospital.
Results We made an educational video highlighting the critical points in the knowledge of colchicine.

54 forms were collected. 50% were from medical doctors (mostly geriatrics, nephrology and emergency department), 25.9% nurses, 18.5% pharmacists and 5.6% pharmacy technicians.

Critical points: the rate of correct answers for the true item '0.5mg per day initially for elderly patients' were of 74%. It was of 83% for the item about the adequate dosing in patients with renal failure, of 88% for the inappropriate drug associating colchicine and opium which hides the first signs of overdosing, and of 85% for the true risk of medical interactions with some antibiotics (macrolids).

Most errors concerned: the lack of knowledge on colchicine's cardiac toxicity (70%), the ignorance of medical interactions with cholesterol regulating drugs (statins) and anti-infectious drugs of imidazoles type (63%). Lastly, the inadequate use of colchicine chronically in the prevention of gout attacks was deemed true by 31%.The most frequent cause of overdosing was renal failure (57%), intentional overdosing or hepatic failure (experienced by 28% HP).

As for the most rated idea for risk management: 63% thought that the production of 0.5mg pills, fit for the elderly and patients with renal failure, would be an improvement.

The video assessing the issues of the survey is shared through the hospital's document management system.
Conclusion and Relevance The survey showed an overall good knowledge about colchicine. We aim for an improvement, especially for nurses and pharmacy technicians who can give alert in case of a prescription mistake. We will conduct an analysis of the prescriptions before and after the video to evaluate the impact.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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6ER-020 LARGE LANGUAGE MODEL: METHODOLOGY PROPOSAL FOR AN ASSISTED META-ANALYSIS TO CATALOGUE MEDICAL DEVICES USED IN PREOPERATIVE PROGRESSIVE PNEUMOPERITONEUM FOR THE MANAGEMENT OF COMPLEX VENTRAL HERNIAS

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Background and Importance With the rise of artificial intelligence (AI) tools, especially Deep-Learning models, meta-analyses are likely to evolve. However, it is necessary to provide a framework for this purpose. This study focused on the Goñi-Moreno technique, which increases abdominal cavity volume prior to complex ventral hernia surgery in order to reduce postoperative respiratory issues. Subcutaneous emphysema, caused by multi-perforated catheters, is a common complication. Medical devices used depend on practitioners. Here we conducted a meta-analysis to explore medical devices mentioned in literature related to this technique using AI.
Aim and Objectives The objective of this study was to propose a state-of-the-art meta-analysis technique, assisted by a large language model (LLM), to identify an exhaustive list of the medical devices and gases employed in the Goñi-Moreno technique worldwide. And compared these findings with our practices.
Material and Methods Articles with the keywords 'goñi-Moreno' and 'preoperative progressive pneumoperitoneum' from PubMed (1948–2024) where selected. Full-text articles from the PMC repository were retrieved using a web crawler, while others were manually downloaded. We then used the GPT-4 LLM API to extract sentences referring to medical device and gases. Prior to this, a pre-processing step was carried out to extract text from the PDFs using Python's PyPDF2 library. The extracted output was subsequently integrated, along with the corresponding PDFs, into an SQLite3 database. Each extracted sentence was meticulously reviewed to accurately identify the mentioned medical devices and gas injected.
Results Out of 200 PubMed articles (1948–2024), 63 were analysed after excluding 105 inaccessible paper articles and 32 irrelevant articles. Most cited devices were intra-abdominal implantable chamber and central venous catheter, followed by multi-perforated drainage catheter (MPDC) and lumbar needle. Air was the most used gas, with some mentions of NO and CO2. At our hospital centre, filtered air is used with MPDCs.
Conclusion and Relevance Some studies, like Takehiko et al. (2024), show promising results using LLMs in meta-analysis. Here we propose a methodology to help practitioners quickly answer surgical questions, complementing rigorous methods that require re-evaluation. Fine-tuning small language models for medical device research is the next step.

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Conflict of Interest No conflict of interest

6ER-021 PROGNOSTIC FACTORS OF CLINICAL OUTCOME IN REAL-WORLD ADVANCED CERVICAL CANCER PATIENTS RECEIVING PEMBROLIZUMAB TREATMENT: A RETROSPECTIVE STUDY

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Background and Importance Cervical cancer ranks as the fourth most prevalent cancer among women globally, particularly in Asia. Since 2015, pembrolizumab has constantly demonstrated its effectiveness of significantly improving progression-free survival and overall survival through KEYNOTE 158, KEYNOTE 826, and KEYNOTE A18 trials. However, those trials included patients with various stages (based on the International Federation of Gynecology and Obstetrics (FIGO) 2014 staging system), resulting in high heterogeneity. Moreover, real-world data specified on prognostic factors in advanced cervical cancer patients after receiving pembrolizumab also remains limited and requires further investigation.

Aim and Objectives This retrospective study aimed to analyse the prognostic factors in advanced cervical cancer patients receiving pembrolizumab treatment.

Material and Methods This retrospective study extracted data from the electronic medical records database of the largest multi-institutional hospital system in Asia between January 2016 and December 2023. Patients diagnosed with advanced cervical cancer, defined as stage IV based on the FIGO 2014 staging system, and newly receiving pembrolizumab were included. We analysed clinical characteristics and prognostic factors including ages, pembrolizumab doses (fix 100 mg and fix 200 mg), previous systemic treatment, metastasis sites, de novo or recurrence metastasis, and PD-L1 positive score. The primary outcome was median overall survival (OS) by using Kaplan-Meier method. We employed univariable Cox regression to estimate the association of above prognostic factors and overall survival.

Results We involved 63 pembrolizumab naive users, all Asian females, with a median age of 56.3 (IQR: 45.6 – 62.0) years and treatment duration of 6.0 (3.0 – 11.0) cycles. With an average follow-up time of 20.9 months, the median OS was 17.0 months (95% CI: 9.8 – 24.3). Analyses revealed that the metastasis site, specifically brain metastasis (HR: 7.9, 95% CI: 1.7 – 36.1) and liver metastasis (HR: 2.2, 95% CI: 1.1 – 4.5), significantly worsened OS. But, a fixed dose of 200 mg pembrolizumab (HR: 1.4, 95% CI: 0.7 – 2.6) had an insignificant worsening clinical outcome.

Conclusion and Relevance This study indicates that brain and liver metastases significantly decreased overall survival. However, the impact of different dosages could not be determined by current outcomes. Further research is still required to investigate the prognostic factors in advanced cervical cancer patients receiving pembrolizumab treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-022 ANALYSIS OF THE PERFORMANCE OF GENERATIVE ARTIFICIAL INTELLIGENCE IN THE CRITICAL EVALUATION OF ARTICLES

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Background and Importance Critical reading of scientific articles ensures the quality and internal validity of pharmaceutical research. Generative artificial intelligence (AI) can optimise this process by enhancing evaluation and bias detection. However, rigorous assessment is crucial to ensure its effectiveness and accuracy in this field.

Aim and Objectives Evaluate if generative AI matches human critical analysis in assessing the internal validity of clinical trial-based scientific articles

Material and Methods Eight articles were analysed according to the recommendations of the CASPe methodology. The answers to the questions on internal validity were compared with those provided by ChatGPT-4.0 (Turbo).

Results When analysing the internal assessment questions, those with objective answers, such as whether it was a controlled clinical trial, if there was a defined question, or if the patient assignment was random, were correctly answered by the AI achieving 100% accuracy. However, in more complex and subjective questions, which required deeper analysis, such as the influence of an open-label design on the primary outcome, potential changes in sample size, or whether the populations were balanced, the AI showed limitations. In these cases, it failed in at least one trial, and regarding changes in sample size or the primary outcome, it only succeeded in two trials, demonstrating lower accuracy in areas that require interpretation.

Conclusion and Relevance Critical reading of clinical trials is essential for advancing knowledge. While AI can analyse textual information, it currently lacks the expertise of human specialists. However, with further training, its analytical abilities could improve, offering a promising line of future research.

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Conflict of Interest No conflict of interest

6ER-023 ANALYSIS OF THE INCIDENCE OF SEXUALLY TRANSMITTED DISEASES IN USERS OF HIV-1 PRE-EXPOSURE PROPHYLAXIS

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Background and Importance HIV pre-exposure prophylaxis (PrEP) is a biomedical intervention for the prevention of HIV infection that is recommended by the World Health Organization. It includes a combination of tenofovir disoproxil fumarate and emtricitabine.

Aim and Objectives To analyse and describe the incidence of sexually transmitted diseases in candidates for HIV-1 pre-exposure prophylaxis.

Material and Methods Retrospective observational study from January 2021 to September 2024. All patients who initiated PrEP during the study period were included.

Variables: age, sexual partners per year (>10 or <10); prophylactic use, drug use during sex, administration of post-exposure prophylaxis (PEP) prior to PrEP, number of PEP, infection of sexually transmitted diseases prior to PrEP (previous_STDs), number of previous_STDs, time since initiation of PrEP; number of consultations with the doctor, number of STDs after starting PrEP, type of microorganism causing STDs, treatment for STDs, adherence, treatment interruption and need for PEP after interruption.

Results were analysed by descriptive statistics using STATA-MP17.0.

Results 86 PrEP users were included, mean age=34 years (standard deviation (SD=9.64). All users were men who have sex with men, except for one woman in prostitution. 94% of users had >10 sexual partners; 91% do not regularly use prophylactic, 32% use drugs in sex. Prior to starting PrEP 28% needed PEP with a mean frequency of 1.34 (SD=0.77) times. 60% were infected with an STD before PrEP, getting infected a mean of 1.7 (SD=1.03).

The mean time on PrEP was 13 months (SD=10) and the mean number of consultations by a doctor was 4.4 (SD=2.7). The incidence of STD infection was 53.5%, the mean number of STDs was 1.06 STDs(SD=1.34), the difference in STDs compared to STDs before PrEP was not statistically significant, p=0.064. The causative agents of STDs were: 28%-Neisseria-gonorrhoeae, 23%-Treponema-pallidum, 16%-Chlamydia-trachomatis, 16%-Mycoplasma-genitalium, 10%-Human-Papilloma-Virus, 4%-Herpex-simplex, 3%-Monkeypox.

The mean adherence rate was 91% (SD =16.5), 27% treatment discontinuations and 2% had to use PEP after the end of the PrEP.

Conclusion and Relevance PrEP users have a high incidence of STDs, with Neisseria gonorrhoeae being the most common causative agent. However, comparison of STD incidences before and after starting PrEP shows no significant differences. **Treatment adherence was high**

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-024 ADHERENCE TO INHALED TREATMENT IN PATIENTS WITH SEVERE UNCONTROLLED ASTHMA ON TREATMENT WITH BIOLOGICAL THERAPY

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Background and Importance Medication adherence is essential in the treatment of patients with severe uncontrolled asthma. The improvement in symptoms may vary depending on the type of biological therapy used, which in turn may influence the administration and adherence to inhaled therapy in these patients.

Aim and Objectives The objective of this study was to describe and evaluate treatment adherence to bronchodilators and inhaled corticosteroids in patients with any biological therapy for severe uncontrolled asthma.

Material and Methods A retrospective and descriptive study of adherence to inhaled treatment was carried out in patients diagnosed with severe uncontrolled asthma who were being treated with biological therapy. Data collection was carried out from May 2023 to May 2024. Optimal adherence was considered above 80% according to the dispensation record.

Results The study included 150 patients with a diagnosis of severe uncontrolled asthma who were receiving inhaled treatment and biological therapy. Characteristics of the patients at baseline are shown in table1. 76% of patients had optimal adherence to treatment with bronchodilators and inhaled corticosteroids. Regarding adherence to inhaled treatment and biological therapy: patients treated with Dupilumab had an adherence to inhaled treatment of 81,8%, with benralizumab and omalizumab of 78,3%, with reslizumab of 75,3% and with mepolizumab of 74,5%. No statistically significant differences were found between the choice of biological therapy and adherence to inhaled treatment.

Conclusion and Relevance Three out of four patients treated with biological therapy had optimal adherence to inhaled treatment despite clinical improvement and a decrease in exacerbations throughout the follow-up with biological therapy.

Abstract 6ER-024 Table 1 Characteristics of the patients at baseline (n=150)

Female sex – no. (%)	91 (60,7%)
Mean age (range) – yr	59 (25–85)
Former smoker – (%)	0.7%
Never smoker – (%)	56%
Allergic rinitis – no. (%)	37 (24,7%)
Chronic Rhinosinusitis with Nasal Polyps – no. (%)	58 (38.7%)
Mepolizumab – no. (%)	48 (32%)
Benralizumab – no. (%)	30 (25,3%)
Reslizumab – no. (%)	14 (9,3%)
Omalizumab – no. (%)	38 (20%)
Dupilumab – no. (%)	20 (13,3%)

The choice of biological therapy did not affect adherence to inhaled therapy.

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

6ER-025 WOMEN IN FOCUS: FEMALE REPRESENTATION IN HOSPITAL PHARMACY CONFERENCES

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Background and Importance Although 74% of the Spanish Society of Hospital Pharmacy (SEFH) members and 75.6% of practicing hospital pharmacists are women, female representation in leadership positions is in decline: 66% of department heads, 63% of working group coordinators, and 55% of SEFH board members.
Aim and Objectives This study aims to evaluate the representation of women in SEFH congresses to understand their visibility in hospital pharmacy and explore trends over time.
Material and Methods A multidisciplinary, retrospective, observational study analysed SEFH congress committees and presentations from 2015 to 2023. Industry-sponsored symposia and pharmacy technician workshops were excluded.

Data were extracted from official congress websites and programs using REDCap. Variables recorded included gender, role (speaker or moderator), session type (working groups, plenaries, symposia, expert meetings), and whether participants were hospital pharmacy specialists or external speakers (e.g., medical staff, patients, consultants, academics). Pearson's Chi-squared test was applied (SPSS Statistics v26.0). A sub-analysis compared two periods: before (2015–2019) and after (2020–2023) a woman held the SEFH presidency.
Results Female representation on committees was 63.8%, and 57.2% of the 935 recorded presentations were given by women. The proportion of female participation by year ranged from 38.3% in 2017 to 72.7% in 2020.

A significant association was found between gender and session type, with more women in working group sessions (45.5% vs. 33.9% for men, $p<0.001$), and between gender and speaker origin (13.3% vs. 21.6% for men as external speakers, $p=0.001$). No significant differences were found for gender and role (speaker or moderator). In 2015–2019, women made up 54.7% of presenters and 57.7% of committee members. A significant relationship was found between gender and session type (33.8% of women vs. 24.1% of men in working groups, $p=0.007$) and speaker origin (12.5% of women vs. 23.1% of men as external speakers, $p<0.001$). In 2020–2023, these proportions increased to 62.8% and 74.2%, respectively, with no significant differences across variables.
Conclusion and Relevance Although female participation in SEFH congresses is increasing, it remains below their overall membership proportion. Greater visibility of women in academic and scientific events, especially in a female-dominated field like hospital pharmacy, is essential to promote their recognition as experts and encourage future generations to pursue leadership roles.

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

6ER-026 A NETWORK META-ANALYSIS OF BIOLOGICAL AND TARGETED SYNTHETIC DRUGS IN REFRACTORY PSORIATIC ARTHRITIS

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Background and Importance At present, a considerable number of drugs are available for the treatment of refractory psoriatic arthritis (PsA). However, the lack of direct comparative studies of the available alternatives results in considerable uncertainty regarding their respective therapeutic positions.
Aim and Objectives To develop a network meta-analysis (NMA) to provide a comparison of the efficacy of treatments in PsA.
Material and Methods A systematic review was conducted on 1 March 2024 in PubMed and Embase. Inclusion criteria: phase II/III randomised controlled trials (RCTs) that included biological disease-modifying antirheumatic drugs (bDMARDs) (etanercept, infliximab, adalimumab, certolizumab pegol, golimumab, secukinumab, ixekizumab, brodalumab, remtolumab, bimekizumab, guselkumab, risankizumab, and tildrakizumab) and targeted synthetic (tsDMARD) (tofacitinib, upadacitinib, and deucravacitinib) as treatments for patients with PsA, reporting outcomes for the American College of Rheumatology 50% improvement criteria (ACR50). Exclusion criteria: patients under 18 years-old. Efficacy outcome: ACR50 at week 12 or the forthcoming time point. The NMA combined direct and indirect evidence in order to calculate pooled odds ratios (ORs) using Bayesian methodology. The GEMTC and BUGSNET packages for R-Statistics and the MetaInsight application were utilised for this analysis.
Results A total of 53 RCTs with 22,365 patients and 51 different intervention arms were included. An NMA using Bayesian random effects models was performed for the ACR50 outcome against placebo. Ixekizumab 80mg every 2 weeks (IXE80 Q2W) demonstrated the most favourable outcome in comparison to the comparator and was therefore used as the reference treatment. The NMA comparing all treatments to IXE80 Q2W demonstrated no treatment superiority, and the majority of comparisons did not reveal statistically significant differences. Nevertheless, IXE80 exhibited statistically significant superiority ($p<0.05$) in comparison to the following treatments: abatacept, apremilast 20 mg and 30 mg, etanercept 50 mg, guselkumab, risankizumab, secukinumab 75 mg, tildrakizumab 20 mg and 100 mg, tofacitinib 5 mg, and ustekinumab 45 mg Q12W. A sensitivity analysis employing frequentist methods corroborated the consistency of these results.
Conclusion and Relevance Ixekizumab 80 mg Q2W has been demonstrated to be an efficacious standard treatment, with no other treatment demonstrating superior efficacy. Furthermore, the safety criteria must be considered into account when determining the optimal therapeutic positioning of drugs in this clinical context.

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

6ER-027 MANAGEMENT OF HEART FAILURE IN 16 SUB-SAHARAN AFRICAN COUNTRIES: DRUG STRATEGIES AND 8-YEAR TRENDS (THE FEBRUARY STUDY 2016–2023)

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Background and Importance Heart failure (HF) is a growing cause of hospitalisation in Sub-Saharan Africa (SSA). However, scarce data are available about drug management of HF in SSA.

Aim and Objectives To describe in hospital drugs management of HF and 8-year trends in Africa.

Material and Methods We conducted a transversal and longitudinal study in cardiology departments of 37 hospitals (public and private) in 16 SSA countries. The February study is an ongoing observatory included all inpatients in February from each year since 2016. Collected data included socio-demographic and clinical characteristics, clinical, biological, complementary examinations, medicines, length of stay were collected by the investigating physicians. HF severity was defined according to proportion of left ventricular ejection fraction (LVEF): reduced (LVEF£40%), mildly reduced (LVEF(41–49%) or preserved (LVEF^{3}50%). All analyses were performed with random effect on countries through scripts developed in the R software (4.0.3(2020–10–10)).

Results Overall, 2351 patients (57±17.5 years; 54% men) were admitted for HF in the February study. At admission, 56% of patients had reduced LVEF; 12.5% had mildly reduced and 31.5% had preserved LVEF. Proportions of drug classes varied significantly according to LVEF: diuretics were significantly less prescribed in patients with preserved LVEF (65%) compared to patients with mildly reduced (77%) or reduced (73%) LVEF ($p>0.01$). The same result was observed for beta blockers (BB) (30% vs 46% and 46%) and angiotensin-converting enzyme inhibitors (50% vs 77% and 71%) ($p<0.01$). Mineralocorticoid receptor antagonists were significantly more prescribed in patients with preserved LVEF ($p<0.01$). The proportion of treated with BB increased significantly over the years ($p<0.05$) from 17% in 2016 to 62% in 2023. Drug strategies differed significantly according to LVEF ($p<0.01$). The more reduced the LVEF, the more the drugs strategy increased. In patients with preserved LVEF, the proportion of monotherapy was 20%; this decreased to 9% in patients with reduced LVEF. Combinations of three drugs increased from 35% in patients with preserved LVEF to 46% in patients with reduced LVEF. Overall, drug strategies differed across years ($p<0.05$): three-drug strategies increased from 35% in 2016 to 51% in 2023 and two-drug strategies decreased from 38% in 2016 to 23% in 2023.

Conclusion and Relevance Up-titrated strategies were prescribed according to severity of HF and access to BB increased across years according to international guidelines. However, novel drugs classes remain unavailable in SSA.

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

6ER-028 A COMPARATIVE ANALYSIS OF THE EFFICACY OF ADJUVANT TREATMENT WITH PEMBROLIZUMAB OR NIVOLUMAB IN PATIENTS WITH STAGE IIB/IIC MELANOMA

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Background and Importance Patients with stage IIB/IIC melanoma have a comparable or elevated risk of recurrence and metastatic disease in comparison to those with stage III melanoma. Two drugs have recently been approved for adjuvant treatment. At present, there are no direct or indirect comparisons between existing treatments.

Aim and Objectives The objective is to ascertain whether pembrolizumab and nivolumab can be designated as equivalent therapeutic alternatives (ETA) for patients with stage IIB/IIC melanoma through an indirect treatment comparison (ITC) adjusted using a common comparator.

Material and Methods A literature search was conducted to identify phase III clinical trials (CTs) involving the use of pembrolizumab or nivolumab in similar patient populations, with comparable treatment durations and endpoints. The primary endpoint was recurrence-free survival (RFS) at 12 months. An ITC of pembrolizumab versus nivolumab was conducted using the Canadian Health Technology Agency's Indirect Treatment Comparisons calculator, in accordance with the methodology proposed by Bucher. In accordance with the ESMO criteria, a hazard ratio (HR) <0.65 (and its inverse, 1.54) was identified as a relevant indicator in the context of comparing treatments for the clinical scenario under consideration (delta value). Subsequently, the results were subjected to graphical analysis, with particular attention paid to the relative positioning of the 95% confidence interval (95% CI) and the equivalence margin. This was conducted in accordance with the ETA Guidelines.

Results Two CTs were included in the ITC between pembrolizumab (KEYNOTE-716) and nivolumab (CheckMate-76K). The included CTs were: phase III, multicentre, randomised, double-blind, placebo-controlled and and the patients were older than 12 years with stage IIB/IIC melanoma. The results of each trial, as well as the ITC performed, are presented in table 1.

The 95% CI exceeds the equivalence margin by more than 50%.

Abstract 6ER-028 Table 1

Reference (CT)	SLR (HR (95% CI))	ITC (HR (95% CI))
Pembrolizumab (Keynote-716)	0.65 (0.46 – 0.92)	1.548 (0.954 – 2.512)
Nivolumab (CheckMate-76K)	0.42 (0.30–0.59)	

Conclusion and Relevance In accordance with the ETA guideline, pembrolizumab and nivolumab cannot be considered ETA for adjuvant treatment of patients with stage IIB/IIC melanoma, as there could be a probably relevant difference. The 95% CI obtained is wide, reflecting the imprecise result for pembrolizumab, which would be a limitation of our study.

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

6ER-029 LONG-TERM EXPERIENCE WITH ERENUMAB, GALCANEZUMAB AND FREMANEZUMAB IN THE TREATMENT OF CHRONIC MIGRAINE

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Background and Importance Monoclonal antibodies targeting the calcitonin gene-related peptide (anti-CGRP): erenumab (ERE), galcanezumab (GAL), and fremanezumab (FRE), have shown clinical effectiveness in the treatment of chronic migraine (CM). However, long-term evidence remains limited.
Aim and Objectives This study aimed to evaluate the 2 year effectiveness of anti-CGRP antibodies in patients with chronic migraine.
Material and Methods A retrospective study (2020–2023) was conducted, including all patients diagnosed with CM who had initiated treatment at least two years prior. Demographic and clinical variables such as age, sex, type of anti-CGRP treatment, and the number of previous preventive treatments were analysed.

Effectiveness was assessed by changes in Migraine Headache Days (MHD) and the number of days requiring specific symptomatic medication (ME). Data were recorded at baseline (week 0) and after 96 weeks of treatment. Responders were defined as those achieving a $\geq$50% reduction in MHD by week 96. A Wilcoxon signed-rank test was used to compare pre- and post-treatment data, with significance set at $p \leq 0.05$.
Results The study included 110 patients (mean age 47.4 years (27–66); 88.2% female). Treatment distribution was as follows: ERE (43.6%, n=48), FRE (18.2%, n=20), and GAL (38.2%, n=42). The mean number of failed preventive treatments was 7.3.

At week 96, 54.5% (n=60) of patients were still receiving treatment: ERE (38.3%, n=23), FRE (21.7%, n=13), and GAL (38.3%, n=23).

Significant reductions in MHD and ME from baseline were observed for ERE (MHD: 11.7 vs 21.8 days, p=0.002; ME: 5.6 vs 17.5 days, p=0.004), GAL (MHD: 8.9 vs 20.6 days, p<0.001; ME: 6.8 vs 15.3 days, p=0.006), and FRE (MHD: 8 vs 16,1 days, p=0.023; ME: 4.1 vs 9.1 days, p=0.025). A $\geq$50% reduction in MHD was achieved by 52.9%, 75%, and 41.7% of patients on ERE, GAL, and FRE, respectively.
Conclusion and Relevance Our findings demonstrate the long-term effectiveness of anti-CGRP antibodies in chronic migraine treatment. Further prospective studies with larger sample sizes are needed to confirm these results.

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

6ER-030 EXPERIENCE WITH NATALIZUMAB IN THE TREATMENT OF MULTIPLE SCLEROSIS

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Background and Importance One of the main limitations of treating multiple sclerosis (MS) with natalizumab is the risk of developing progressive multifocal leukoencephalopathy (PML).
Aim and Objectives This study aims to assess the effectiveness and safety of natalizumab in the treatment of relapsing-remitting MS.
Material and Methods Single-centre, observational-retrospective study (October 2007 to March 2024), including all MS patients treated with natalizumab. The patients' characteristics and necessary clinical data were obtained from the patients' medical records.

Disease progression was evaluated using the Expanded Disability Status Scale (EDSS) and radiological activity through MRI, identifying new T2 lesions or gadolinium-enhancing (Gd +) lesions.
Results A total of 43 patients were included (mean age 41.9 years (24–62); 74.4% female). The mean baseline EDSS was 2.3, remaining stable after the first year of treatment (n=37), increasing to 2.6 in the second year (n=33), and reaching 3.4 after 10 years (n=9).

In the first 2 years, 32.5% (n=14) of patients developed at least one new T2 lesion, and 16.3% (n=7) developed at least one new Gd+ lesion. After 10 years, these rates rose to 48.9% (n=21) and 25.6% (n=11), respectively.

The mean treatment duration was 65.6 months (2–173). The main reasons for treatment discontinuation (n=22) were high-risk of PML (68,2%, n=15) and radiological progression (22,7%, n=5).

Regarding safety, 44.2% of patients (n=19) experienced treatment-related adverse events, mainly infections (36.8%, n=7). No cases of PML were reported.
Conclusion and Relevance Natalizumab remains a viable option for the treatment of relapsing-remitting MS, demonstrating both short and long-term effectiveness, high persistence, and a favourable safety profile.

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

6ER-031 EFFECTIVENESS OF ABEMACICLIB, PALBOCICLIB AND RIBOCICLIB IN METASTATIC BREAST CANCER

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Background and Importance Cyclin-dependent kinase 4/6 inhibitors (CDK4/6 inhibitors): abemaciclib-(ABE), palbociclib-(PAL), and ribociclib-(RIB), have shown efficacy in treating metastatic hormone receptor-positive (HR+) breast cancer (MBC), as demonstrated in the MONARCH-3, PALOMA-2, and MONALEESA-2 trials, respectively.

Aim and Objectives To evaluate and compare the effectiveness of CDK4/6 inhibitors in routine clinical practice.

Material and Methods This was a 7-year retrospective observational study (September 2017 to May 2024) including all patients treated with CDK4/6 inhibitors for HR+/HER2- MBC.

Effectiveness was assessed by analysing median progression-free survival (PFS) and overall survival (OS) for each treatment. Comparisons of these medians were performed using a log-rank test, with Kaplan-Meier analysis conducted via SPSS v26.

Results A total of 164 patients were included, with a mean age of 64.7 years (31–90), ECOG 0–2. Bone metastases were present in 72% of patients, visceral metastases in 43.9%, and central nervous system involvement in 4.9%.

Abemaciclib was given to 29.9% (n=49) of patients (75.5% in 1st-line), ribociclib to 31.7% (n=52) (88.5% in 1st-line), and palbociclib to 38.4% (n=63) (74.6% in 1st-line). In 8.5% of 1st-line cases, prior CDK4/6 inhibitors therapy had been discontinued due to toxicity.

Median PFS for 1st-line therapy was 10.4 months with ABE (95% CI: 4.9–15.9), 18.1 months with RIB (95% CI: 2.9–33.3), and 15.4 months with PAL (95% CI: 11.9–18.9). Significant differences were observed between ABE-RIB (p=0.014) and between ABE-PAL (p=0.035), but not between RIB-PAL (p=0.193).

Median OS was 12.2 months with ABE (95% CI: 0–28.4), 9.2 months with RIB (95% CI: 0–36.2), and 20.2 months with PAL (95% CI: 14.5–25.9), with no statistically significant differences between ABE-RIB (p=0.204), ABE-PAL (p=0.312), or RIB-PAL (p=0.464).

Conclusion and Relevance The median PFS and OS observed were lower than those reported in pivotal trials, likely due to the observational study design, smaller sample size, and patient characteristics in routine clinical practice. Larger prospective studies are needed to confirm the observed PFS differences between ABE and other CDK4/6 inhibitors.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-032 ABSTRACT WITHDRAWN

6ER-033 EVALUATING ADHERENCE IN HIV PRE-EXPOSURE PROPHYLAXIS (PREP): A RETROSPECTIVE ANALYSIS

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Background and Importance HIV Pre-Exposure Prophylaxis (PrEP) is an established preventive therapy, made reimbursable in Italy since August 2023.[1] In this context, the prescription form was digitised with the goal of improving its clinical management and monitoring therapeutic adherence. This tool assists clinicians by streamlining the prescription process and enabling quick therapies' monitoring for individuals at risk of HIV. However, understanding gaps between prescribed therapy and patient adherence is crucial for improving outcomes.

Aim and Objectives This analysis aimed to evaluate patient adherence to PrEP, assess how well patients followed the prescribed regimen and to identify factors related to suboptimal adherence.

Material and Methods Data extracted from digital form and pharmaceutical flows were crossed to create a dataset of individuals with at least one PrEP refill between July 2023 and September 2024. Only patients receiving Continuous Dosing Therapy (CDT) were included in the analysis, and those who chose On-Demand therapeutic regimen (ODT), interrupted or switched it, were excluded. Adherence was assessed by calculating the proportion of days covered (PDC),[2] with a threshold of ≥80% considered adherent. PDC data were compared with self-reported adherence from patients during therapeutic planning.

Results A total of 515 individuals were collected, consisting of 509 males (98.8%), three females, and three with unspecified gender, with a median age of 38 years (IQR 32–46). Of these, 213 (41.4%) opted for CDT regimen, while 302 (58.6%) chose ODT regimen. The final analysed sample comprised 179 users (34.7%) who maintained the CDT, with 100% self-reported adherence. However, our analysis revealed that 21 users had a PDC ≤80%, indicating suboptimal adherence, 131 users had a PDC ≥80%, reflecting adequate adherence. Additionally, 27 users had a PDC ≥120%, suggesting potential overuse, which warrants further investigation.

Conclusion and Relevance The digital prescription tool proves to be an effective system for monitoring and evaluating adherence. Despite high self-reported adherence, discrepancies between reported and actual adherence were observed, underscoring the need for continuous and objective monitoring. These findings highlight the importance of collaboration between infectious disease specialists and pharmacists to enhance clinical support. Future efforts should prioritise identifying and addressing adherence barriers while strengthening patient support to ensure sustained efficacy in HIV prevention

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Conflict of Interest No conflict of interest

6ER-034 ABSTRACT WITHDRAWN

6ER-035 A COMPARATIVE ANALYSIS OF THE EFFICACY OF BIOLOGICAL DRUGS AND ORAL SMALL MOLECULES IN THE TREATMENT OF ATOPIC DERMATITIS

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Background and Importance Atopic dermatitis (AD) is a chronic inflammatory dermatological condition that often

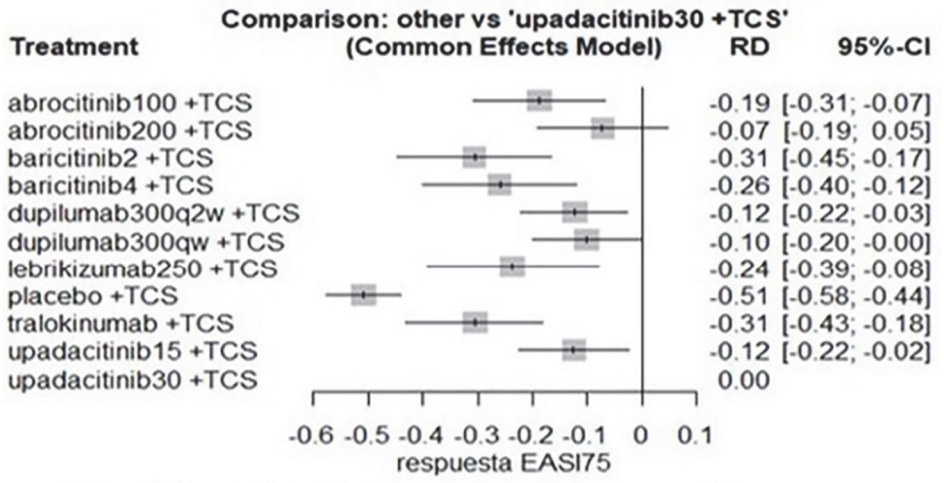

Figure 1. Forest-plot of the decrease in EASI75 response. Comparator: Upadacitinib 30mg+TCS. RD: risk difference. 95% CI: 95% confidence interval

Abstract 6ER-035 Figure 1

requires systemic treatments when topical therapies are insufficient. Previously, the only available systemic treatments were immunosuppressants. However, recently, monoclonal antibodies and oral small molecule therapies have been approved, offering more targeted and effective treatment options with fewer side effects

Aim and Objectives To analyse whether the different therapeutic options could be considered as equivalent therapeutic alternatives (ETA) in AD.

Material and Methods A systematic search was conducted in PubMed, including randomised, double-blind, phase 2–3 controlled trials that assessed systemic therapies combined with topical corticosteroids (TCS). Efficacy was measured as a 75% reduction in the Eczema Area and Severity Index (EASI75) at week 16. The analysis was performed using R and RStudio software (v4.04) to estimate Bayesian statistics, with placebo as the reference. ETA[1] guidelines were applied to determine therapeutic positioning, using a delta value of 12% as the maximum acceptable non-inferiority margin, based on Blauvelt et al., 2021.[2]

Results Six studies were included. All therapies showed favourable reductions in EASI75 compared to placebo, with statistically significant differences. As upadacitinib 30 mg demonstrated the most favourable outcomes (0.51 (0.44;0.58)), a subsequent analysis was performed to compare its efficacy against the other therapeutic alternatives. As shown in figure 1, abrocitinib 200 mg (−0.07 (−0.19; 0.05)) and dupilumab 300 mg weekly (−0.10 (−0.20; 0.00)) showed the most similar efficacy result; in fact, statistically difference was not shown.

Conclusion and Relevance This study identifies upadacitinib, abrocitinib and weekly-dupilumab as highly effective options. However, according to the Pharmacovigilance Risk Assessment Committee (PRAC) recommendations about JAK inhibitors (JAKi) safety and the unapproved weekly-dupilumab dose, only biweekly dupilumab, lebrikizumab and tralokinumab are considered viable ETAs.

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Conflict of Interest No conflict of interest

6ER-036 SUBSTANCE ABUSE IN PATIENTS WITH SCHIZOPHRENIC OR BIPOLAR DISORDER

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Background and Importance Substance abuse is a common comorbidity in patients with severe psychiatric disorders such as schizophrenia and bipolar disorder. The interaction between these conditions and substance use complicates diagnosis and treatment, as it can worsen symptoms and affect management.

Aim and Objectives This study explores the prevalence of substance abuse in patients diagnosed with schizophrenia or bipolar disorder in a psychiatric unit. It examines differences in substance use by sex, diagnosis, and type of substance consumed, alongside the presence of psychotic episodes before diagnosis. These findings offer insights into comorbidity patterns and their clinical implications.

Material and Methods This 1 year retrospective observational study (January to December 2023) was conducted at a 450-bed university hospital. It included patients admitted to the psychiatric unit (acute and subacute) diagnosed with schizophrenia or bipolar disorder, and/or documented substance abuse. Data from medical records included sex, birthdate, diagnosis type, diagnosis date, substance use (alcohol, opioids, cannabis, cocaine, amphetamines, hallucinogens, others), age of substance use onset, and history of psychotic episodes before diagnosis. Patients missing any information were excluded. Descriptive statistical analysis was conducted using frequencies for categorical variables and measures of central tendency and dispersion for quantitative variables.

Results A total of 246 patients were included: 157 (63.8%) men and 89 (36.2%) women, with a mean age of 47 ± 14 years. Of these, 149 (60.6%) had a psychiatric diagnosis: 94 (63.1%) with schizophrenia and 55 (36.9%) with bipolar disorder. Among schizophrenia patients, 60.6% were men, while among bipolar patients, 58.2% were women.

Substance abuse was reported by 103 (69.1%) patients, with a mean onset age of 17 ± 4 years. Alcohol (79.6%), cannabis (78.6%), and cocaine (53.4%) were most frequently used. Polysubstance use was common, especially in schizophrenia patients (72.7%). Prior psychotic episodes were found in 61.9% of schizophrenia patients and 50.0% of bipolar patients.

Conclusion and Relevance There is a high prevalence of substance abuse in patients with schizophrenia and bipolar disorder, particularly among men and schizophrenia patients. Polysubstance use and prior psychotic episodes were more common in schizophrenia patients. It is important to understand the dynamics of substance abuse in schizophrenic and bipolar patients for a comprehensive approach to managing their conditions.

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

6ER-037 PERFORMANCE AND CONCORDANCE OF ARTIFICIAL INTELLIGENCE IN THE BOARD OF PHARMACY SPECIALTIES

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Background and Importance Artificial Intelligence (AI) is increasingly assuming a pivotal role in modern society. Its diverse applications are transforming numerous tasks, including those within hospital pharmacy. However, the development of robust AI evaluation tools is essential to ensure their effective integration into professional workflows.

Aim and Objectives To assess the performance and concordance of three AI systems (ChatGPT 3.5, ChatGPT 4.0, and Gemini) in addressing Board of Pharmacy Specialties (BPS) examination questions.

Material and Methods Observational and cross-sectional study conducted in August 2024. All sample questions and answers provided on the BPS website, designed to familiarise candidates with the structure and format of BPS certification exams, were extracted. A protocol was developed to guide the AIs in responding to the questions, instructing them to rely on high-quality references and to refrain from generating answers not based on data. A total of three tests were conducted for each AI, with each test being administered by a different researcher. In cases of insufficient information or uncertainty, they were encouraged to opt for 'DK/NR' (*Doesn't Know/No Response*). Six researchers independently administered the test to each AI. The Chi-Squared test was used to compare the total proportions of correct answers across the different AIs. The Kappa index, along with Altman's criteria, was applied to assess the concordance of responses from each AI in comparison to the various researchers.

Results A total of 137 questions were asked. The proportion of correct answers for each test administered by the researchers were as follows:

- ChatGPT 3.5: 83.2%, 76.6%, and 83.9%. Mean: 81.3%.
- ChatGPT 4.0: 86.1%, 83.9%, and 73.7%. Mean: 81.3%.
- Gemini: 65.0%, 59.1%, and 65.0%. Mean: 63.0%.

Statistically significant differences were found by ChatGPT 4.0 and ChatGPT 3.5 (81.3%) compared to Gemini (63.0%) ($p < 0.01$). No statistically differences were found between ChatGPT 3.5 and 4.0.

The Kappa indices and their mean for each AI were:

- ChatGPT 3.5: 0.773, 0.862, and 0.792 (mean 0.809; excellent agreement).
- ChatGPT 4.0: 0.686, 0.941, and 0.676 (mean 0.809; excellent agreement).
- Gemini: 0.548, 0.621, and 0.584 (mean 0.572; moderate agreement).

Conclusion and Relevance ChatGPT 3.5 and 4.0 show comparable performance with excellent agreement, while Gemini has significantly lower accuracy and consistency.

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

6ER-038 INVESTIGATING CO-MEDICATION-RELATED TOXICITY IN CANCER PATIENTS TREATED WITH IMMUNOTHERAPY: AN OBSERVATIONAL STUDY

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Background and Importance Immunotherapy has revolutionised cancer treatment over the past decade. Nevertheless, significant side effects and toxicities remain critical concerns. These adverse reactions are often referred to as immune-related adverse events (irAEs),[1] and they continue to pose challenges in the clinical application of this innovative treatment approach.

As part of a programme focusing on patients who have received immunotherapy alone or in combination and have experienced toxicity, we have established a multidisciplinary consultation team, including a clinical pharmacist (CP), to identify the root causes of toxicity.

Aim and Objectives Our aim was to identify and analyse the possible co-medications that may cause or enhance the toxicity of immunotherapy and their potential clinical impacts.

Material and Methods The co-medications of patients receiving immunotherapy were collected during individual consultations with the clinical pharmacist (CP). Each co-medication was recorded according to the Anatomical Therapeutic Chemical Classification, as well as all complementary and alternative medicine (CAM) practices. Causality was assessed between the introduction of the product (drug or CAM) and the occurrence of toxicity. A two-week clinical follow-up was

performed after discontinuing the co-medication responsible for the toxicity to confirm or reject the hypothesis of drug related causality.

Results Out of 219 patients, 216 used additional medications. For 32 of them (14.8%), we could identify a causality between co-medication and toxicity.

The collected data indicate that the majority of auto and co-medications are associated with hepatic toxicity (n=11), potentially worsening oncological treatment-related toxicity to grade 3 or 4, followed by haematological disorders (n=8) and neurological disorders (n=2).

The co-medications involved included drugs acting on the gastrointestinal system (n=9), treatments for cardiovascular comorbidities (n=7), serotonin antagonists (n=5), as well as complementary and alternative medicine (CAM) such as curcumin (n=2) and red yeast rice (n=2).

Conclusion and Relevance We found that most co-medications analysed played an important role in enhancing irAEs, suggesting the promotion of immunotherapy toxicity. The detection of these cases could enable clinicians to monitor the treatment instead of discontinuing treatment altogether, likely to jeopardise the patient vital prognosis.

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6ER-039 CONCOMITANT USE OF PROTON PUMP INHIBITORS AND ABEMACICLIB, PALBOCICLIB AND RIBOCICLIB IN BREAST CANCER

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Background and Importance The impact of concomitant use of proton pump inhibitors (PPIs) and cyclin-dependent kinase 4/6 inhibitors (CDK4/6 inhibitors) has shown contradictory results in the literature.

Aim and Objectives To evaluate the effect of concomitant PPI use (with PPI (cPPI) and without PPI (sPPI)) on the effectiveness of CDK4/6 inhibitors (abemaciclib (ABE), ribociclib (RIB), and palbociclib (PAL)) in patients with metastatic breast cancer (MBC), hormone receptor-positive (HR+) and HER-2 negative.

Material and Methods This was a 7-year retrospective observational study (September 2017 to May 2024) including all patients treated with CDK4/6 inhibitors for MBC.

Effectiveness was assessed by analysing median progression-free survival (PFS) and overall survival (OS) using Kaplan-Meier analysis. Survival curves were compared with the log-rank test, and qualitative variables were analysed with Pearson's Chi-squared test using SPSS version 26.

Results A total of 164 patients were included during the study period (mean age 64.7 years (31–90); ECOG 0–2). Among the patients, 29.9% (n=49) received treatment with ABE (67.3% cPPI; 75.5% (n=37) first-line: 67.6% cPPI), 31.7% (n=52) were treated with RIB (46.2% cPPI; 88.5% (n=46) first-line: 47.8% cPPI), and 38.4% (n=63) underwent treatment with PAL (63.5% cPPI; 74.6% (n=47) first-line: 59.6% cPPI).

Dose reductions in cPPI vs. sPPI patients were: ABE 45.5% vs. 50% (p=0.765), RIB 33.3% vs. 46.4% (p=0.337), and PAL 35% vs. 69.6% (p=0.008).

Median PFS for first-line cPPI vs. sPPI patients was: ABE 10.8 vs. 7.1 months (p=0.581), RIB 10.9 vs. 20.6 months (p=0.337), and PAL 15.2 vs. 15.7 months (p=0.326).

Median OS for first-line cPPI vs. sPPI patients was: ABE 12.2 vs. 5.1 months (p=0.357), RIB 8.9 vs. 9.2 months (p=0.270), and PAL 20.2 vs. 16.8 months (p=0.850).

Conclusion and Relevance The results suggest that concomitant PPI and CDK4/6 inhibitors use does not significantly impact PFS or OS. However, cPPI patients on PAL required fewer dose reductions, possibly indicating lower drug concentrations. Further prospective studies with larger patient cohorts are needed to confirm these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-040 EFFICACY AND SAFETY OF ANTIBODY-DRUG CONJUGATES FOR LUNG CANCER THERAPY: A SYSTEMATIC REVIEW OF RANDOMISED AND NON-RANDOMISED CLINICAL TRIALS

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Background and Importance Lung cancer is the leading cause of cancer-related deaths worldwide. Non-small-cell lung cancer (NSCLC) accounts for 80–90% of all lung cancers. Antibody-drug conjugates (ADCs) represent an expanding targeted therapy option for the treatment of NSCLC.

Aim and Objectives To perform a systematic review of the literature aiming to investigate the efficacy and safety of ADCs in clinical trials for NSCLC treatment.

Material and Methods The study adhered to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement. Literature searches were conducted in PubMed, ClinicalTrial.gov and Web of Science databases, covering the period from 2014 to 2024. Only randomised and non-randomised phase II-IV clinical trials focusing on ADC-based therapies for adult patients affected by NSCLC were selected. Efficacy endpoints included Objective Response Rate (ORR) and Duration of Response (DOR). Safety was assessed through the frequency and severity of Treatment-Emergent Adverse Events (TEAEs).

Results Six studies (two randomised, three non-randomised, one without specific allocation) investigating four ADCs (Trastuzumab Deruxtecan (T-Dxd), Trastuzumab Emtansine (T-Dm1), Telisotuzumab Vedotin, Patritumab Deruxtecan) with a total of 697 patients (average age 63 years-old) were deemed suitable for the study. T-Dxd achieved higher efficacy in terms of ORR in HER2-overexpressing than HER2-mutant NSCLC patients (52.9% (95% CI:27.8–77.0) and 49.0% (95% CI:39.0–59.1), respectively); while higher DOR was seen in HER2-mutant than HER2-overexpressing NSCLC patients (16.8 (95% CI:6.4-Not Estimable) and 6.2 months (95% CI:4.0–11.7), respectively). Grade ≥3 TEAEs

occurred in 22% of HER2-overexpressing and 38.6% of HER2-mutant NSCLC patients. T-Dm1 showed a better efficacy and safety profile in HER2-overexpressing than HER2-positive relapsed NSCLC patients (ORR 20% (95% CI:5.7–43.7) and 6.7% (90% CI: 0.2–32.0)). Grade ≥3 TEAEs occurred in 24% and 60% of patients, respectively. Telisotuzumab vedotin has been evaluated in c-MET-positive recurrent NSCLC patients (ORR 9% (95% CI: 0–20); DOR 7.5 months (2.3–12.7)); 3 (13%) grade 5 TEAEs occurred. Patritumab deruxtecan has been evaluated in EGFR-mutated NSCLC patients (ORR 39% (95% CI:26–52); DOR 7.0 months (95% CI:3.1-NE)). Grade ≥3 TEAEs occurred in 40% of patients.

Conclusion and Relevance Tumour-agnostic approaches are revolutionising cancer treatment by focusing on the specific mutations driving the disease. Trastuzumab deruxtecan has shown significant efficacy and manageable safety profile in treating NSCLC, especially in patients with HER2 mutations, promising better response rates and patient outcomes.

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

6ER-041 SWITCHING CALCITONINE GENE-RELATED PEPTIDE MONOCLONAL ANTIBODIES (CGRP MAB) IN PATIENTS WITH REFRACTORY MIGRAINE: REAL-WORLD DATA

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Background and Importance There is growing evidence about the benefit of using a second CGRP mAb in patients with loss of response to one of them. We have clinical experience with patients who have used two or more CGRP mAbs.

Aim and Objectives To assess the effectiveness of using other CGRP mAbs for the treatment of chronic migraine in patients who have already been treated with one of them.

Material and Methods A retrospective, observational study in a third-level hospital. All patients who had received two or more CGRP mAbs from January 2020 to September 2024 were included. The data collected from the electronic health record and the prescribing software were: age, gender, baseline monthly migraine days and every 3 months, number of CGRP mAbs used for each patient and each treatment duration. Response to treatment was defined as a reduction of at least 50% of the baseline monthly migraine days. Treatment was interrupted when loss of response was detected in the quarterly visits.

Results Forty patients: 75% female, median age 45 years (IQR 37–54), median baseline monthly migraine days 23 (IQR 16–30). 16 (40%) did not have response after 2 (n=5), 3 (n=8) or 4 (n=3) CGRP mAbs. 13 (32%) had treatment switches with good response: 2 patients were in treatment with 4 consecutive CGRP mAbs during 18 and 37 months respectively, achieving a reduction of 87% and 85% in baseline monthly migraine days; 2 patients with 3 consecutive CGRP mAbs during 50 and 27 months had a reduction of 78% and 73%; 9 patients were a median of 19 months (IQR 12–24) with one CGRP mAb and 11 months (IQR 7–12) with a second one, with a median reduction of 67% (IQR 63%-87%) in baseline monthly migraine days.11 (28%) had a reduction of 75% (IQR 65%-83%) in baseline migraine days during 15 months (IQR 9–21) (median values). They failed to 1 (n=7) or 2 (n=4) other CGRP mAbs.

Conclusion and Relevance Our data suggest that switching CGRP mAbs might be an option for patients with many monthly migraine days when loss of optimal response is detected. On the other hand, patients with no response to one CGRP mAb may not respond to other ones.

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

6ER-042 REPORTED DRUG INDUCED ACUTE KIDNEY INJURY: A PHARMACOVIGILANCE ANALYSIS

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Background and Importance Acute Kidney Injury (AKI) is a condition that may result from various factors, including the exposure to nephrotoxic drugs, which can lead to hospital admission but can also occur during hospitalisation, extending its duration. The incidence of AKI among hospitalised patients varies, with underdiagnosis rates estimated to exceed 20% in developed countries and approximately 7% in developing countries.

Aim and Objectives To identify the drugs most frequently reported to the Portuguese Nacional Pharmacovigilance Database associated with AKI in Portugal.

Material and Methods A case/non-case study was conducted, analysing data pertaining to the period between 2009 and 2020. 'Acute Renal Failure' standardised MedDRA query was used to define cases, and a random sample of four matched non-cases was used to estimate the reporting odds ratio (ROR) at the ATC level 2.

Results Our analysis focused on 53,505 reports, among which less than 1% were AKI cases (n=352). Nonetheless, nearly 10% of these led to death. Most frequently, AKI cases involved ≥2 'suspected' medicines, among 559 medicines classified as 'suspected' and 11 considered to be potentially associated with the occurrence of AKI. The therapeutic subgroups with the highest ROR was that of antithrombotic agents (ROR, 6.72; 95% CI: 2.23–20.22), followed by systemic antivirals (ROR, 4.02; 95% CI: 2.76–5.87), and also significant was that of antineoplastic agents (ROR, 2.14; 95% CI: 1.48–3.11).

Conclusion and Relevance This study underscores the importance of clinical pharmacy activities in closely monitoring the renal function of patients with known risk factors or those prescribed medications known to increase the risk of AKI.

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Conflict of Interest No conflict of interest

6ER-043 CASE REPORT: SPINAL CORD INFARCT SECONDARY TO VAPING?

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Background and Importance Smoking cigarettes is a well-recognised risk associated with stroke.[1] Worldwide, the healthcare systems have implemented measures to reduce the prevalence of smoking cigarettes, while the market of electronic cigarettes (vaping) has been expanding. Although vaping is a possible strategy to help smokers quit, it is also heavily marketed towards children and non-smokers.

The risk associated with vaping and stroke has been described. Spinal cord injury due to illicit drug misuse has been reported.

Aim and Objectives We report the case of a young male, non-smoker, heavy vaper, who sustained injury to the spinal cord as a result of infarct.

Material and Methods Retrospective review of patient's clinical case notes.

Results A 21-year-old male, with no known comorbidities. Patient says never having had smoked cigarettes; smokes e-cigarettes 'all the time' estimating and equivalent of 100 cigarettes per day.

While at work patient felt a sharp pain to the neck. Shortly after felt weak to his arms and legs, felt clammy and short of breath. Was taken to the Emergency Department where he required supported ventilation and tracheostomy. MRI of the whole spine diagnoses spinal cord infarct at C2-C5 level with hyper acute inset was made. No other injuries were noted. Investigations including viral serology, lumbar puncture with CSF analysis and coagulopathies studies were all unremarkable.

The patient was referred to a rehabilitation centre for a comprehensive rehabilitation programme. At admission peripheral neurological examination revealed incomplete tetraplegia AIS D at C3 level, as per the International Standards for Neurological Classification of Spinal Cord Injury, in central cord syndrome type of injury, with no hand function.

Conclusion and Relevance Spinal cord infarct remains an uncommon cause of spinal cord injury, compared to traumatic injury and other non-traumatic causes (e.g. infection, spinal tumours).

The more recent use of e-cigarettes and its possible impacts in public health, including morbidity and mortality, has not been yet fully described. Acute spinal cord ischaemia is life changing for the individual and expected clinical outcomes are still unclear.

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Conflict of Interest No conflict of interest

6ER-044 DOCTORS', NURSES', AND MIDWIVES' VIEWS OF HOSPITAL PHARMACIST PRESCRIBING: A CROSS-SECTIONAL SURVEY STUDY

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Background and Importance Hospital pharmacist prescribing (HPP) is established to varying extents in numerous countries, with evidence that stakeholders positively view the impact of HPP on hospital workflows and patient safety.

While there is currently no legislative basis for pharmacist prescribing in Ireland, a national report recommended HPP to be initiated in 2027. It is vital that the views of Irish prescribers (doctors, nurses, and midwives) on HPP are investigated prior to implementation.

Aim and Objectives To gather the views of doctors, nurses, and midwives working in Irish hospitals regarding HPP, and establish their perceived impacts on healthcare provision.

Material and Methods An anonymous online survey was distributed to doctors, nurses, and midwives working in Ireland via email and social media platforms. The survey was active for 12 weeks from 4 July 2024.

The survey comprised a combination of multiple choice and Likert scale questions, along with open comment sections. Data analysis combined descriptive and thematic analysis.

Results Complete responses were gathered from 238 participants. Doctors, nurses, and midwives accounted for 43.6%, 44.9%, and 11.4% of respondents, respectively.

A majority of the three professions surveyed, doctors (81.6%), nurses (89.6%), and midwives (96.3%) indicated support or strong support for HPP.

Consultant doctors comprised 56.2% of all doctor respondents. Support (support or strong support) for HPP was indicated by 86% of consultant respondents, of which 76% had over 20 years of experience in their profession.

Clinical Nurse Managers and Clinical Midwife Managers indicated support of 92.5% and 100% respectively for HPP.

Respondents overall agreed that HPP would result in reduced instances (84.7%) and faster correction (88.6%) of prescribing errors, reduced patient adverse drug reactions (80.5%), and improved workflows (80.1%).

When asked about HPP scope of practice independently or with supervision (direct/indirect), 61.4% indicated that pharmacists should independently prescribe pre-admission medicines, 59.3% indicated that pharmacists should independently prepare discharge prescriptions, while only 14.4% said that pharmacists should independently initiate a new medicine.

Conclusion and Relevance Doctors, nurses, and midwives are supportive overall of HPP in Ireland, with less support for pharmacists prescribing independently in some areas. Doctors, nurses, and midwives perceive that HPP will have several positive impacts on healthcare provision, and ultimately contribute to reduced prescribing errors and patient harm.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

6ER-045 EFFECTIVENESS AND SAFETY OF FIRST-LINE CHEMOIMMUNOTHERAPY WITH PEMBROLIZUMAB FOR METASTATIC NON-SQUAMOUS NON-SMALL-CELL LUNG CANCER

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Background and Importance Lung carcinoma is the leading cause of cancer-related death in the world. Pembrolizumab is a human IgG4 monoclonal antibody that binds to the PD-1, enhancing the immune response of T-cells.
Aim and Objectives To evaluate effectiveness and safety of chemoimmunotherapy with pembrolizumab for metastatic non-squamous non-small-cell lung cancer (NSQ-NSCLC), without driver mutations EGFR/ALK. Secondary endpoint was to evaluate the impact of different variables on overall survival (OS).
Material and Methods Retrospective observational study including all patients with metastatic NSQ-NSCLC who received platinum-based chemotherapy and pembrolizumab from January 2018 to July 2024. Data collected: histology, smoking, ECOG, metastasis, PD-L1 expression, chemotherapy, frequency and severity of adverse events (AEs), and treatment discontinuation due to AEs. Effectiveness was evaluated by median OS, progression-free survival (PFS), objective response rate (ORR) and disease control rate (DCR), calculated with Kaplan-Meier estimator, STATA v.16.0. Multivariate analysis was performed by Cox regression, expressed as hazard ratio (HR).
Results Eighty-eight patients (69% men) with a median age of 65 years (RIC:56–70) were included. Histology: adenocarcinoma (89%), undifferentiated (8%), large cell carcinoma (2%) and mixed (1%). The 91% were ex-/smokers, with a median Pack-Year-Index of 40 (RIC:25–50); and 65% had ECOG 0–1. The 53% presented bone, 29% brain and 18% liver metastasis. The 50% had PD-L1<1%, negative or not-performed, 33% 1–49% and 17% PD-L1≥50%. The 91% received carboplatin vs 9% cisplatin.

ORR was 56% (9% complete response) and DCR was 69%. Median OS and PFS were 10.6 months 95% CI (7.7–13.8) and 5 months 95% CI (4.3–7.7), respectively. One-year and 5 year OS rate were 46% and 13%, and 1 year and 5 year PFS were 21% and 12%, respectively.

Ninety-nine percent experienced AEs: asthenia (57%), anaemia (28%), neutropenia (26%) and infection (24%). 47% suffered grade 3–4 AEs, mainly asthenia (22%). 17% discontinued treatment due to AEs.

Regarding multivariate analysis, statistically significant variables were: ex-/smoker 5.0 (95% CI: 1.5–17); p=0.01; bone metastasis 2.6 (95% CI: 1.4–4.9); p=0.004; brain metastasis 1.9 (95% CI: 1.06–3.6); p=0.033 and ECOG 0–1 0.39 (95% CI: 0.21–0.72); p=0.003.
Conclusion and Relevance

- More than half of the patients responded to treatment, however only a small part were alive or free from disease 5 years later.
- Smoking, bone and brain metastasis were associated with less survival.
- Most patients experienced AEs that caused discontinuation of therapy, which emphasises the need to adequately select patients.

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

6ER-046 DURVALUMAB AS CONSOLIDATION THERAPY FOLLOWING CHEMORADIOTHERAPY IN UNRESECTABLE STAGE III NON-SMALL-CELL LUNG CANCER: REAL-WORLD SURVIVAL OUTCOMES

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Background and Importance Consolidation durvalumab following platinum-based chemoradiotherapy (CRT) is the global standard of care for patients with unresectable, stage III non-small-cell lung cancer (NSCLC), based on the results of the PACIFIC trial, that demonstrated a significant benefit in survival. Observational studies providing real-world evidence are essential to confirm these benefits.
Aim and Objectives This study aims to evaluate the effectiveness and safety of durvalumab as consolidation therapy after concurrent CRT in the treatment of unresectable stage III non-small-cell lung cancer (NSCLC) at a tertiary care hospital.
Material and Methods Observational, retrospective, single-centre study. All patients with NSCLC who received durvalumab after concurrent CRT from January 2018 to December 2023 were included. Socio-demographic, clinical and treatment-related data were collected using the hospital's electronic medical record program and the Farmis-Oncofarm oncohaematological patient management software. To evaluate the treatment's efficacy, we estimated progression-free survival (PFS) and overall survival (OS).
Results A total of 52 patients were included. The most prevalent histologies were adenocarcinoma (62%) and squamous cell carcinoma (35%). All patients had PD-L1 expression ≥1%; half of them classified as high PD-L1 expressors (≥25%). The majority (71%) achieved a partial response following concurrent CRT; the remaining (29%) had stable disease. The overall median follow-up was 2 years. More than half of the patients (N=28, 54%) did not complete the full year of consolidation therapy; 15 due to disease progression and 13 due to toxicity. Median PFS was 24.3 months (95% confidence interval (CI), 14 to NA); the 12-month PFS rate was 67%, and the 18-month PFS rate was 58%. Improved PFS rates were observed in the high PD-L1 expressor subgroup, with a median PFS of 33.8 months compared to 23.5 months in patients with PD-L1<25% (HR 0.67 (95% CI: 0.31–1.42)). Regarding OS, survival rates at 12, 18, and 24 months were 86.5%, 78.8%, and 71%, respectively.
Conclusion and Relevance Our results demonstrate favourable outcomes with durvalumab consolidation therapy in real-world clinical practice, achieving higher PFS and OS rates compared

to the PACIFIC trial. These superior outcomes may be attributed to the fact that our study exclusively included patients with PD-L1 expression ≥1%, whereas the PACIFIC trial included 20% of patients with no PD-L1 expression.

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

6ER-047 IMPACT OF BIOLOGIC THERAPY ON CARDIO-METABOLIC PARAMETERS IN PATIENTS WITH MODERATE TO SEVERE PSORIASIS: A SYSTEMATIC REVIEW

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Background and Importance Psoriasis is a chronic immune-mediated skin disease in which there is a high prevalence of cardiovascular comorbidities due to common pathophysiological mechanisms, most notably chronic inflammation. The biological therapy used for its treatment could have a favourable impact on cardiovascular risk factors by inhibiting the inflammatory cascade.
Aim and Objectives To analyse the impact of biologic therapies on cardio-metabolic parameters in adult patients with moderate to severe plaque psoriasis and to evaluate their effect in patients with cardiovascular comorbidities.
Material and Methods This systematic review was performed following the criteria established by the Preferred Reporting Items for Systematic reviews and Meta-Analysis statement. In January 2024 we searched MEDLINE, Scopus, Web of Science, and the Cochrane Central Register of Controlled Trials for phase III or IV randomised controlled clinical trials (RCTs) studying the effect of biologic drugs compared with placebo on cardio-metabolic parameters in adult patients with moderate-severe psoriasis with or without cardiovascular comorbidities. Lipid (total cholesterol, HDL, LDL, triglycerides, VLDL), glycaemic, adiponectin levels and inflammation-related parameters were analysed. For the assessment of the risk of bias of the clinical trials included in this systematic review, the risk of bias assessment tool of the Cochrane Handbook 5.1.0 was used.
Results Of the 230 records identified, 10 RCTs were selected. Statistically significant changes on lipid profile were: increase in total cholesterol with ixekizumab, etanercept, and secukinumab and in LDL-cholesterol with ixekizumab, secukinumab, and ustekinumab; increase in total VLDL-cholesterol with ixekizumab and decrease with ustekinumab; triglycerides were elevated with ixekizumab and etanercept, but decreased with secukinumab. Adiponectin decreased significantly with secukinumab. No statistically significant differences were found in glycemic parameters. CRP was reduced with adalimumab, etanercept, ixekizumab and ustekinumab, with ustekinumab being the most effective in reducing vascular inflammation. In the analysis by subgroups, there were significant changes only with etanercept, increasing CRP in obese patients. The results of the risk of bias assessment showed an overall trend toward a low-risk of bias.
Conclusion and Relevance The results of this systematic review show heterogeneity in the cardiovascular effects of the different biologic treatments for psoriasis. Further evidence is needed to justify the prioritisation of these drugs in different cardiovascular comorbidities.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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6ER-048 COMPARISON OF PEMBROLIZUMAB + CHEMOTHERAPY AND NIVOLUMAB + IPILIMUMAB + CHEMOTHERAPY IN METASTATIC SQUAMOUS NON-SMALL-CELL LUNG CANCER WITH PD-L1 < 1%

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Background and Importance First-line treatment for metastatic non-small-cell lung cancer (NSCLC) includes combinations based on immunotherapy and chemotherapy. Strategies involving nivolumab + ipilimumab (NIVO + IPI) and pembrolizumab (PEMBRO) can be considered alternatives with similar clinical benefit. However, they differ in management and toxicity, and have not been directly or indirectly compared.
Aim and Objectives To evaluate the efficacy of PEMBRO and NIVO + IPI in patients with metastatic squamous NSCLC and PD-L1 < 1%, based on subgroup analyses of pivotal clinical trials (CTs), and to assess the economic impact in our centre.
Material and Methods Data from the KEYNOTE-407 (PEMBRO) and CHECKMATE-9LA (NIVO + IPI) clinical trials were analysed to identify differences in overall survival (OS) among subgroups of patients with squamous NSCLC and PD-L1 < 1%. Interaction and indirect treatment comparison (ITC) adjusted analyses using Bucher's method, were performed to determine whether the differences between treatments were statistically significant and clinically relevant. Additionally, the budgetary impact of both therapies was evaluated in our centre.
Results No statistically significant interaction was observed among the three patient subgroups based on PD-L1 for PEMBRO ($p = 0.37$), nor for NIVO + IPI between squamous and non-squamous histologies ($p = 0.19$). Therefore, conducting an ICT exclusively with the PD-L1 < 1% subgroup would not be methodologically appropriate. An ICT between NIVO + IPI and PEMBRO in squamous NSCLC, regardless of PD-L1 expression, showed no significant differences in OS (HR 0.90; 95% CI 0.65–1.26; $p = 0.54$). Similarly, although methodologically incorrect, an ICT for the PD-L1 < 1% subgroup showed no significant differences (HR 0.80; 95% CI 0.53–1.20; $p = 0.27$). PEMBRO was more cost-effective, offering a 67% savings per patient compared to NIVO + IPI, according to current hospital pricing, translating to an annual savings of € 62,407 in hospital expenses.
Conclusion and Relevance Subgroup analyses do not demonstrate a superior clinical benefit of NIVO + IPI over PEMBRO in patients with squamous NSCLC and PD-L1 < 1%. The apparent differences lack methodological validity and are attributable to chance. PEMBRO is the more cost-efficient option in our centre.

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

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