Results A total of 16,039 reports were analysed for validation, between March and December 2022. The reports that registered some incidence were 1930 (12%), remaining pending observations and not validated. The reasons for refusal were the following: unfunded indication (58.8%), completion errors – insufficient or incorrect prescription data – (23.6%), absence of computerised validation report (13.5%), absence of clinical report (2.9%) and other causes -unauthorised indication in the technical sheet, hospital diagnostic medication without a specialist report and shortages (1.2%).

Conclusion and Relevance Validation is positioned as a useful tool for the proper use of medicines since it guarantees that they are used according to the indications authorised in the technical sheet. It represents an improvement in the quality of the prescription, because, although most prescriptions conform to their financed indication, some incidents have been detected that were resolved by pharmacists, thus avoiding errors that affect patient safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-020 EVALUATION OF THE EFFICACY AND SAFETY OF EPCORITAMAB-BYSP IN PATIENTS WITH FOLLICULAR B LYMPHOMA: A CASE REPORT

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Background and Importance Follicular B-lymphoma (FL) is an indolent lymphoid neoplasm derived from germinal centre mutated B-cells with a nodular or follicular histological pattern. Approximately 2–3% of patients will transform their neoplasm to diffuse large B-cell lymphoma (DLBCL). Epcoritamab-bysp (EPKINLY®) is a bispecific IgG1 antibody designed to simultaneously bind to CD3 on T-cells and CD20 on B-cells, and induces T-cell-mediated killing of CD20+ cells.

Aim and Objectives The aim of this study is to evaluate the efficacy and safety of epcoritamab-bysp in a patient with LF refractory to previous lines.

Material and Methods Retrospective study of a clinical case in which we follow-up a patient with Relapse/Refractory FL under treatment with epcoritamab-bysp. Administration was done in the lower abdomen or thigh and at a different site each time it was administered. Data were obtained using the digitised clinical history (Diraya) and the electronic chemotherapy or immunotherapy prescription programme (Oncofarm).

Results We present the case of a 57-year-old woman, 48.8 kg and 153 cm. Diagnosed in August 2020 with stage IV FL without B symptoms. FL was refractory to the first two lines of treatment (1L:R-CHOP, 2L:R-ESHAP), as well as to a clinical trial based on CAR-T therapy. In May 2023, expanded use of epcoritamab-bysp in monotherapy with weekly subcutaneous administration in C1 with dose step-up (0.16, 0.8, 48 mg); every 2 weeks C4–9 (48 mg), every 4 weeks from C10 to progression (48 mg) was decided. In all immunotherapy sessions the patient was admitted for 24h due to risk of severe adverse reactions (CRS or ICANS). In the second administration (0.8mg) of epcoritamab-bysp the patient had a CRS:G1, so in the administration of the first target dose (48 mg) 3ªweek of C1, the dose was reduced to 50% (24 mg). Even so, the patient had to be treated with IV tocilizumab (8mg/kg) by CRS: G2 and was admitted for observation for 48h. From C2 onwards, there were no further incidents. Regarding the clinical evolution of the LF PET-CT scan, a partial metabolic response (Deauville:4) was observed with respect to the previous study.

Conclusion and Relevance Despite the need for extended study time to evaluate the clinical benefit and safety in real clinical practice of epcoritamab-bysp in patients with FL or DLBCL, this immunotherapy offers an innovative mechanism of action and an interesting alternative for patients with non-Hodgkin's lymphoma refractory to conventional therapies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-021 EVALUATION OF THE PREVALENCE OF MULTI-RESISTANT BACTERIA IN THE INTENSIVE CARE UNIT AFTER SELECTIVE DECONTAMINATION OF THE GASTROINTESTINAL TRACT

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Background and Importance One of the measures to reduce the rate of infections by multidrug-resistant bacteria in Intensive Care Unit (ICU) services promoted in the Pneumonia Zero (NZ) programme is oropharyngeal decontamination (DOF) and/or selective digestive decontamination (SDD). Of the different existing protocols, we implemented the administration of non-absorbable topical antimicrobials (colistin, gentamicin and nystatin) in the oropharynx (paste) and gastrointestinal tract (solution). Both were developed as magistral formulas. In the event of MRSA isolation or an increase in the MRSA rate in our hospital, vancomycin would be added.

Aim and Objectives The aim was to assess the effect of such a measure on studies of the prevalence of multidrug-resistant bacteria in critically ill patients, and to see if there is selection for resistance mechanisms.

Material and Methods Ambispective study comprising the pre-DDS (01/01/2022–30/04/2022) and DDS (01/01/2023–30/04/2023) periods conducted in the 22-bed ICU.

From July 2022, ICU patients with isolation of multidrug-resistant bacteria in both clinical or surveillance samples, as well as patients with estimated intubation >72 h or non-intubated patients with risk factors for developing pneumonia are administered DDS/DOF. In addition, nasal, pharyngo-tonsillar and perianal exudate samples are collected for microbiological surveillance cultures on admission and every Tuesday thereafter. Incubate at 37°C for 48h.

Results In the pre-DDS period in the ICU, 626 samples are received for colonisation studies from 132 patients. Excluding repeat isolates in each patient,2 3 multidrug-resistant bacteria were detected. In the DDS period, 537 samples are received from 124 patients, detecting nine multi-resistant bacteria. There is a significant difference (p=0.0138) between the proportion of multi-drug resistant bacteria detected in the surveillance studies after applying ICU decontamination measures.

In the first period, the following bacteria were detected: one MRSA, one Acinetobacter baumannii, eight extended-

spectrum beta-lactamase (ESBL)-producing enterobacteria and 13 carbapenemase-producing gram-negative bacilli.

Pathogens isolated in the post-decontamination period were: one MRSA, one A.baumannii and 8 BLEE-producing enterobacteria. None of the isolates are carbapenemase-producing.

Conclusion and Relevance The DDS/DOF protocols applied in the ICU of our hospital have shown a significant decrease in colonisation by multidrug-resistant bacteria in critically ill patients. As for MRSA, no differences could be seen in this period, so it would be advisable to extend the study period. However, the role of this measure in the disappearance of carbapenemase-producing bacteria should be highlighted.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-022 DRUG-INDUCED APLASTIC ANAEMIA: AN ANALYSIS OF THE FDA ADVERSE EVENT REPORTING SYSTEM (FAERS)

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Background and Importance Aplastic anaemia (AA) is a rare condition resulting from a deficit in hematopoietic stem and progenitor cells, characterised by a huge social and economic burden. AA is included in the Designated Medical Event (DME) list developed by the European Medicines Agency (EMA), which contains medical conditions that are inherently serious and often medicine-related.

Aim and Objectives In this analysis, we aimed to shed light on the most frequent aplastic anaemia associated drugs in real-life by mining the FDA Adverse Event Reporting System (FAERS). FAERS is one of the largest spontaneous reporting databases in the world, used to perform signal detection in pharmacovigilance.

Material and Methods A disproportionality analysis of the FAERS was conducted by analysing the Individual Case Safety Reports (ICSRs) from the first quarter of 2004 (2004 Q1) to the third quarter of 2021 (2021 Q3). The reporting odds ratio (ROR) with a relevant 95% confidence interval (95% CI) as a disproportional measure was calculated. The ROR was considered statistically significant when the lower limit of the 95% CI of the ROR exceeded 1, with at least three cases reported (N≥3).

Results Overall, during the examined period (2004 Q1–2021 Q3), on a total of N=11.631.635 reports, N=3.413 ICSRs containing the preferred term 'aplastic anaemia' were retrieved. AA affected people with a median age of 49.62 (±25.08) years, mostly female (N=1.645, 54.9%). According to the ROR value, ferrous phosphate 594.82 (95% CI 184.68–1.915,80), sucrose 98.86 (95% CI 36.89–264.90), aminopyrine 82.04 (95% CI 26.32–255.76), levosimendan 81.41 (95% CI 54.90–120.73) and methenolone 81.41 (95% CI 54.90–120.73) were associated with disproportionate reporting, resulting in a potential signal. Regarding the number of ICSRs, the most frequent AA-associated drugs on FAERS were eculizumab N=431, lymphocyte immune globulin, anti-thymocyte globulin N=228, eltrombopag N=204, pentamidine N=77 and ethosuximide N=28.

Conclusion and Relevance Knowing the drugs associated with aplastic anaemia is essential for promoting appropriate use of them and improving patient safety during therapy. Furthermore, healthcare professionals should be aware of the necessity of strictly monitoring patients treated with these drugs and promptly recognising signs and symptoms of drug-associated AA. Further investigations are required to confirm if these drugs play a role in the development of AA.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-023 SAFETY AND TOLERABILITY OF VORICONAZOLE TREATMENT: A RETROSPECTIVE OBSERVATIONAL STUDY

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Background and Importance Voriconazole is an antifungal agent with concentration-dependent activity and high individual variability. It is generally well tolerated. However, adverse effects (AEs) may occur, requiring dose reduction (DR) or discontinuation of treatment.

Aim and Objectives To describe the safety and tolerability of voriconazole treatment in a cohort of patients admitted to a tertiary hospital.

Material and Methods Retrospective observational cohort study that included patients treated with voriconazole during 2022.

Variables collected were age, sex, diagnosis, route of administration, treatment start date, date and type of AEs, post-AE measures, and therapeutic drug monitoring (TDM).

Voriconazole AEs were classified as concentration-dependent or non-concentration-dependent.

Results A total of 135 patients were treated with voriconazole. The median age was 64 years (4–91). Men represented 61%. Most patients were immunocompromised (42%).

Treatment was empiric in 21%, prophylaxis in 10% and targeted therapy in 69%. The main diagnosis was Aspergillus (81%), 11% Candida and 8% other infections. It was administered intravenously in 45%, orally in 30%, and 25% were switched from intravenous to oral. The median duration of treatment was nine days.

Voriconazole-related AEs occurred in 38 patients (28%). The median time to AE onset was five days.

Concentration-related AEs were hepatotoxicity in seven patients (18%), visual disturbances in 11 patients (29%), psychiatric disorders in 12 patients (31%) such as hallucinations (10) or confusional syndrome (2) and neurologic disturbances in 12 patients (31%) who experienced somnolence (4), vivid dreams (4), tremor (3) or disorientation (3). Four patients required DR and 10 discontinued treatment.

Non-concentration-related AEs were dermatologic reactions in eight patients (21%), including photosensitivity (3), alopecia (2), erythema (4), or warm sensation (4), and digestive disorders (diarrhoea) in one patient. Two patients discontinued treatment.

Of 38 patients with AEs, 22 (58%) had voriconazole TDM: 17 had therapeutic concentrations, two infratherapeutic and three supratherapeutic, of whom two tolerated treatment with DR and one discontinued voriconazole for other reasons.