based on quality criteria from different societies when it is carried out in a generalised, standardised and regulated way.

Aim and objectives To describe the implementation of a computerised checklist for the validation of prescriptions of oncological chemotherapy (ChemO) according to recommendations and clinical practice guidelines; and to evaluate the results of its implementation in terms of safety interventions.

Material and methods The checklist was designed in database format. This included the BOPA and GEDEFO recommendations for validation by having a series of different coloured alerts when laboratory values were not within normal limits for administration of ChemO. From this database the variables number of validations, interventions, type, and acceptance or not by the oncologist were collected from 1 January to 30 June 2019. Demographic data of the patients (age and sex) were also collected. Frequencies and means were analysed for the variables studied.

Results The data of 3050 validated prescriptions were included, with the checklist corresponding to 1162 patients of whom 593 (51%) were women. Mean age of the patients was 59.3 years ($\sigma=15.0$). A total of 293 interventions were performed (9.6% of prescriptions). The most common reasons for intervention were related to the diagnosis not reflected in the prescription (165 interventions (5.4%)), the periodicity of the chemotherapy scheme (46 (1.5%)) and the location of the patient within the hospital (63 (2.1%)). Seventeen (0.6%) interventions were related to the scheme, cytostatic, volume and prescribed serum. Regarding the severity of the intervention, 31 (1.0%) required consultation with the oncologist, 22 (70.1%) of which were accepted. Among the latter, the main reason for the consultation was related to laboratory parameters outside normal limits.

Conclusion and relevance The application of a checklist to the validation of the prescription served to improve patient safety as it standardised the process and marked the order for all the items reviewed. It was also useful for unifying the criteria among pharmacists and was helpful in the training of resident pharmacists.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-043 IMPLEMENTATION OF A PREPARATION PROTOCOL FOR CHEMOTHERAPY ADMIXTURES OF HIGH ECONOMIC IMPACT

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Background and importance The administration of intravenous admixtures (IVMs) in the haemato-oncology day hospital is determined by the patient's health status. Poor health is a cause of non-administration of IVMs, causing medication and economic losses due to their low stability.

Aim and objectives To implement a protocol for the preparation of IVMs of antineoplastic drugs with high economic impact, low physical-chemical stability and/or high frequency of adverse effects; and to analyse the results obtained and to propose lines of improvement.

Material and methods The protocol consisted of review of the analytical data available early in the morning by the pharmacist and assessment of the physical condition of the patient by

the nursing staff before preparation. All data on IVMs of the drugs included in this protocol and their cost were collected as well as the total number of IVMs prepared over a period of 3 months. We calculated the percentage of unprepared IVMs overall and per drug, including the amount of IVMs unprepared and the savings that they represented with respect to the total number of controlled IVMs.

Results The number of drugs included in the protocol was 17. In the period evaluated, a total of 5426 IVMs of antineoplastics were programmed: 399 IVMs were included in the protocol. Of these, 58 (14.5%) IVMs were not prepared. Seven of the 17 drugs included in the protocol presented causes for not being administered and, therefore, were not prepared. Drugs not prepared: panitumumab and nab-paclitaxel (10.4%), eribulin (8.6%), nivolumab and aflibercept (5.2%), pemetrexed and liposomal doxorubicin (1.7%). Fluorouracil (13.7%), gemcitabine (6.9%), oxaliplatin and irinotecan (5.2%), carboplatin and denosumab (3.4%) were not prepared in association with these drugs. The most frequent reasons for non-preparation were haematological adverse effects (36 (62.0%)), digestive adverse effects (10 (17.2%)), surgical intervention (4 (6.8%)) and other (4 (6.8%)). The economic savings in unprepared mixtures was € 24 703.24 (7.1% of the total controlled mixtures included).

Conclusion and relevance The protocol was an important tool for cost savings in the preparation of antineoplastic IVMs. Of the drugs involved, only a limited number had reasons not to be prepared, so that the protocol could be updated with a smaller number of drugs while maintaining its objectives.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-044 IMPACT OF DRUG INTERACTIONS IN HIGH DOSE METHOTREXATE ELIMINATION

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Background and importance High dose methotrexate (HDMTX) chemotherapy, defined as a dose $>500 \text{ mg/m}^2$, is used to treat several oncological and haematological malignancies. Despite appropriate hydration, urine alkalisation and leucovorin rescue, nephrotoxicity remains a risk which can lead to significant morbidity and mortality. Different drugs have been associated with altered elimination (AE) of HDMTX due to delayed elimination or nephrotoxicity.

Aim and objectives To describe the incidence of AE and assess the impact of drug interactions in HDMTX induced AE.

Material and methods A bibliographic research in the Lexi-comp database was conducted to identify drug interactions with HDMTX. A retrospective study was carried out including all patients who received HDMTX between 2010 and 2019. Data collected were age, sex, methotrexate dosage, number of HDMTX cycles, creatinine level before and after HDMTX, serum levels of methotrexate and potentially interacting medications (PIM) prescribed 24 hours before HDMTX infusion and during methotrexate elimination. AE was defined as plasma concentration $>1 \mu\text{mol/L}$ at 48 hours and/or $0.1 \mu\text{mol/L}$ at 72 hours, or nephrotoxicity according to the Common Terminology Criteria for Adverse Events criteria V4.0.

The association of PIM with AE was determined by OR and the χ^2 test or Fisher's exact probability test.

Results Sixty-four patients were treated with HDMTX for 160 cycles with a median HDMTX dose of 11760 mg (IQR 3370–14 207.5 mg). Median age was 66.4 years (IQR 55.6–75.3) and 42.2% were women. Eleven patients were treated for leukaemia and 53 for lymphoma.

Median baseline creatinine was 0.66 (IQR 0.57–0.78) mg/dL. AE was present in 80 cycles (50%). In 91.3% of these, patients were receiving concomitant PIM with methotrexate elimination. In 52 cycles methotrexate elimination was altered only after 72 hours.

PIM associated with AE were: levetiracetam (OR=6.9, 95% CI 1.5–32.4; $p<0.05$), non-steroidal anti-inflammatory drugs (OR=10.9, 95% CI 2.4–49.4; $p<0.05$) and doxycycline (OR=0.5, 95% CI 0.4–0.6; $p<0.05$). There were no significant differences between use of proton pump inhibitors, loop diuretics, amphotericin B, penicillin and derivate, aminoglycosides, ciprofloxacin or p-glycoprotein/ABCB1 inhibitors.

Conclusion and relevance There was a high prevalence of patients with AE of HDMTX. Potentially interacting medications with HDMTX are frequently used during treatment. Only levetiracetam and non-steroidal anti-inflammatory drugs were associated with methotrexate AE in our patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5SPSQ-045 OLARATUMAB: WHAT IS THE ECONOMIC IMPACT ON THE NATIONAL HEALTH SYSTEM?

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Background and importance The US Food and Drug Administration (FDA) granted olaratumab (human anti-PDGF α monoclonal antibody) fast track authorisation in November 2016 to treat advanced soft tissue sarcoma (STM). Also, the European Medicines Agency (EMA) allowed conditional marketing authorisation for this drug after the phase 1b/2 trial. In the post-authorisation phase III trial ANNOUNCE, data were limited because of the small number of patients included and the lack of confirmation of efficacy and clinical benefit. Consequently, the EMA banned the treatment of new patients with olaratumab.

Aim and objectives We studied the economic impact of olaratumab on the National Health Service (NHS) for our hospital patients, from its introduction in our country (November 2017) to the EMA ban (January 2019).

Material and methods A retrospective analysis was conducted. In our hospital 17 patients, 11 of which were women (64.7%), with a mean age of 54.7 ± 24.5 years, were treated with olaratumab. Data (weight and doses prescribed) were extracted from our chemotherapy prescriptions and preparations database software. We selected patients treated with olaratumab.

Results An olaratumab vial cost € 1375 (€ 2.75/mg). The recommended dose was 15 mg/kg on days 1+8 of each 21 day cycle. Between November 2017 and January 2019, in our

hospital, 17 patients completed 79 total cycles for a total cost of € 457 035.

The primary outcome of the authorisation study showed a better progression free survival (6.6 months). Only five of our patients exceeded this period and had to discontinued treatment because of progression of disease. The total cost of their therapy was € 294 596 (48 total cycles for 5 patients). For the other 12 patients, the cost was € 162 439 (31 total cycles). The average cost of administration to the NHS was € 2815/patient.

Conclusion and relevance After conditional marketing authorisation, further research costs of the approved drug are necessarily at the expense of the NHS. This was the case for olaratumab, that resulted in it not being effective. For this reason, for fast track authorisation, the reimbursement price of the drugs should be taken into account in the post-authorisation costs. Furthermore, it is important to provide hospital monitoring of the clinical effects of the drug and consequent cost.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5SPSQ-046 PREVALENCE OF NIVOLUMAB ADVERSE EVENTS IN ROUTINE CLINICAL PRACTICE

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Background and importance Nivolumab was authorised in Spain in 2015. It is a human immunoglobulin monoclonal antibody that binds to PD-1 receptor and blocks its interaction with PD-L1 and PD-L2. It is indicated in adjuvant or metastatic melanoma (MC), metastatic non-small cell lung cancer (NSCLC), renal cell carcinoma (RC) and squamous cell carcinoma of the head and neck (HNC), among others. Its recent commercialisation means there are no data on adverse events (AE) following long term treatment in routine clinical practice.

Aim and objectives To assess the tolerability of nivolumab, to identify and calculate the prevalence of AE related to nivolumab and to compare its frequency with the that described on the data sheet (DS).

Material and methods A descriptive, retrospective, observational study was carried out from March 2016 to September 2019 in a tertiary hospital. It included all patients treated with nivolumab since it was commercialised. Medical records and blood tests of all treated patients were reviewed from the start of nivolumab treatment. Information was collected from the applications Abucasis, Mizar, Farmis-Oncofarm and Gestlab. Variables collected were sex, age, diagnosis, number of nivolumab doses, AE, if the patient died, nivolumab start/end date and reason for stopping treatment. AE were classified according the prevalence described on the DS: very common ($>10\%$), common (1–10%), not common (0.1–1%), rare (0.01–0.1%) and very rare ($<0.01\%$).

Results A total of 48 patients were included, 77% were men and median age was 63 years. The main diagnoses were NSCLC (40%), followed by RC (29%), MC (21%) and HNC