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

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

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

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

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

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

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

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

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

REFERENCES AND/OR ACKNOWLEDGEMENTS

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

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

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

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

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

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

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Pembrolizumab summary of product characteristics, https://www.ema.europa.eu/en/documents/product-information/keytruda-epar-product-information_en.pdf

No conflict of interest.