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No conflict of interest.

3PC-041 SURFACE CONTAMINATION WITH CYTOTOXIC DRUGS IN EUROPEAN HOSPITAL WARDS

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Background and importance Several studies have shown that antineoplastic drug contamination is found on various work surfaces in hospitals and varies widely on wards. The MASHA project (research about environmental contamination by cytotoxics and management of safe handling procedures) was to set up to conduct new research, in cooperation with the European Society for Medical Oncology, into contamination levels in hospital wards.

Aim and objectives To obtain an overview of the current levels of cytotoxic contamination in European hospital wards and increase awareness among healthcare workers and their employers about the risks associated with working with hazardous drugs, and to provide them with additional measures to improve safety.

Material and methods The assessment of surface contamination with cytotoxic drugs was done by evaluating wipe samples collected from four comparable surfaces on the wards (work benches, floors, armrest of patient's chair and lids of waste containers). Each sample was analysed for the presence of five commonly used cytotoxic drugs (cyclophosphamide, 5-fluorouracil, paclitaxel, gemcitabine and total platinum for platinum drugs), using ICP-MS for total platinum and LC-MS/MS for other substances.

Results The database includes results collected from 28 hospital units from 16 European countries. Of the 560 samples collected, 268 were positive (48%). Measurable amounts of at least one substance were detected on investigated surfaces in every hospital: 21/28 (75%) hospitals had over 30% positive samples. Contamination was detected mostly on the floors (58%), armrests (50%), lids (42%) and work benches (40%). The highest values were found for cyclophosphamide (380 ng/cm²) and 5-fluorouracil (130 ng/cm²) on the lids. The highest number of positive results were recorded with platinum drugs (33%), 5-fluorouracil (25%), gemcitabine (19%) and cyclophosphamide (18%). Substances were detected on 45/112 of surfaces (40%) which had not been used for cytotoxic drug preparation on the day of the wipe sampling.

Conclusion and relevance Contamination is detectable on the ward but at different levels in different hospitals. Cleaning procedures are still not effective. Therefore, evaluation of exposure of healthcare workers is crucial. Greater collaboration with medical and nurse societies, to improve safe handling procedures in hospitals and thus improve the safety of all healthcare workers, is required.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-042 THE SIGNIFICANCE OF PHARMACY PREPARATION IN PAEDIATRICS: MAKING INDIVIDUAL THERAPIES FOR CRITICALLY ILL CHILDREN POSSIBLE

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Background and importance The 1000 bed Donauspital, Vienna, provides all types of care for children, including a paediatric intensive care unit (PICU) and a neonatal intensive care unit (NICU). Pharmacotherapy in paediatrics is often limited because no licensed medication is available for the condition of the child or, if available, the dosage is not correct for age and/or developmental stage. Therefore, individually manufactured medicines play an important role in the therapy of children.

As we had to assess the appropriateness of our allocation of human resources, we conducted this study to find out what amount of manufactured medicines are needed to treat our paediatric patients.

Aim and objectives We investigated the extent of individually manufactured medications for children in our hospital (figure 1). These medications included all types of dosage forms (eg, capsules, suppositories, intravenous preparations and compounded solutions for parenteral nutrition (TPN)) to see if drug therapy in critically ill children can be successful without manufacturing in the pharmacy and to evaluate the significance of pharmacy production.

Material and methods For three months (May to July 2019) all prescriptions for patients in the PICU and NICU were recorded from the critical care information system of the hospital. We compared the number of individually manufactured medications with the number of drugs used that were commercially available. All drugs were counted once per used dosage, even when prescribed several times for the same patient. We also counted TPN only once per patient (one solution containing amino acids, electrolytes and trace elements and one lipid emulsion containing vitamins), although the amount of the components prescribed changed almost daily.

Results During our study period in both the PICU and NICU, 99 children were hospitalised and treated with 1286

Abstract 3PC-042 Figure 1 Comparison of individually manufactured and commercially available medications used in the NICU and PICU

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

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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 antineoplastic 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.

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No conflict of interest.