REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-018

IMPLEMENTATION OF QUALITY CONTROL OF PAEDIATRIC CYTOTOXIC DRUG PREPARATIONS: PILOT TRIAL WITH ETOPOSIDE

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Background The lack of quality control of cytotoxic preparations can reduce the security of the chemotherapy circuit. In fact, an overdose may result in serious side effects at the expense of treatment efficiency. On the other hand, a sub-dosage can compromise treatment efficiency and potential recovery, especially in children.

Purpose The aim of this pilot trial is to develop and to validate an analytical method to control the concentrations of etoposide preparations in hospital.

Material and methods It is a fast, simple qualitative and quantitative analysis, using UV spectroscopy.

Appropriate aliquot portions of etoposide solution (20 mg/ml) were diluted in NaCl 0.9% to obtain a calibration range covering all paediatric therapeutic concentrations. Solutions were scanned in UV-visible for identification.

Absorbances of solutions were measured at 283 nm and a calibration curve was constructed.

For samples, we prepared 10 etoposide preparations. One mL was withdrawn from each bag and diluted with NaCl 0.9%.

Absorbances of samples were measured in 283 nm and amounts of etoposide were determined by referring to the calibration curve. The validation of the method was carried out according to guideline ICH Q2.

Results Etoposide was identified qualitatively by comparing absorption spectra of the samples to reference spectra. The same spectra were observed with a wavelength of maximum absorption (283 nm).

For quantitative analysis, the proposed method has successfully estimated the amount of etoposide. Linear regression of absorbance gave equation $y = 0.0085x - 0.0022$ with $R^2 = 0.9992$. Relative standard deviation was 0.56, indicating that the method was precise. Results also showed good accuracy.

Our method is easier and more accurate than any other methods published in the literature, such as gravimetric and balance control.

Conclusion This trial is the first in our hospital centre and in our country. The method was validated and the concentrations of all samples were exact, and it can be used for routine quality control analysis of etoposide. This trial allows us, in the future, to implement analytical control for all cytotoxic measured by UV-visible.

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No conflict of interest.

3PC-019

RISK MANAGEMENT OF CROSS-CONTAMINATION OF PAEDIATRIC ANTI-CANCER PREPARATIONS USING FAILURE MODE AND EFFECTS CRITICALITY ANALYSIS

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Background Cross-contamination of hospital preparations is one of the most frequent problems in hospitals. It is responsible for quality defects of the drug and the consequences can be very serious. The failure mode and effects criticality analysis (FMECA) is a simple and effective tool for minimising the high risk related to the cross-contamination of preparations.

Purpose The aim is to realise a risk analysis using FMECA, focused on the preparation process of anti-cancer drugs in a paediatric hospital and to propose corrective and preventive actions in minimising the risks.

Material and methods The first step was to carry out a cause-effect diagram (Ishikawa diagram), that facilitates the identification of possible causes of cross-contamination during preparation. After that, we identified all failure modes and possible risks for each step of the preparation process and we listed each failure mode, and assigned a score for likelihood occurrence (1 to 4), severity (1 to 4) and detection (1 to 4). Finally, the risk priority number was calculated by multiplying the three scores and identifying the critical points associated with preparation. The rating of each criterion is based on predetermined rating tables.

Results We classified the identified risks according to their criticality, and defined priority areas of work. Thus, the criticality values suggest focusing on five major risks in priority: contamination of the hood; contaminated materials (syringes, serum pouch); bad identification of materials; errors in the use of raw materials; and poor cleaning.

Improvement measures have been defined and implemented to reduce major risks to an acceptable level, such as: training preparers in good manufacturing practices; cleaning; biodecontamination of materials before preparation; and development of a cleaning procedure.

Conclusion In general, FMECA gave satisfactory results, with no critical risk and 30% of the major risks decreased after the implementation of corrective and preventive actions.

The continuous training of staff, the traceability of each stage of the process and the good organisation of the circuit makes it possible to reduce the risk of cross-contamination and to guarantee good quality preparations that can be administered safely to the patient.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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3PC-020

NIVOLUMAB WEIGHT-BASED DOSING VS FLAT DOSE ECONOMIC ANALYSIS

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Background Nivolumab is a highly selective anti-programmed death1 (PD-1) human monoclonal antibody that potentiates

T-cell responses by blocking the binding of PD-1 to its ligands. Nivolumab, on June 2015 was authorised to treat melanoma, renal cell cancer (RCC) and non-small-cell lung cancer (NSCLC) administered in weight-based dosing (BW) schedules at 3 mg/kg every 2 weeks. In May 2018 the European Commission approved 240 mg flat dose (FD) every 2 weeks based on pharmacokinetics parameters.

Purpose Compare the financial impact of FD methodology versus BW in our population.

Material and methods Patients treated with nivolumab for melanoma, RCC and NSCLC in 2017 in our hospital were included in the analysis. Patients with the treatment started before the drug was commercialised were excluded. We analysed prescriptions on our informatic application to obtain the personal data of patients (age, sex, weight). We calculated the number of drug vials needed to fill a single prescription and the hypothetical drug waste. We used tender price (€11.8/mg) to calculate the hypothetical cost of BW and FD.

Results Ninety-one patients were treated in 2017 (636 doses), median age 68 years (SD ± 8.7) and weight of 71 kg (SD ± 15.8). The percentage of men was 63%. Seventy-two (79%) patients weighed less than 80 kg (75% doses). The diagnoses were: melanoma 19 (21%), RCC 12 (13%) and NSCLC 60 (66%). In our centralised unit we used a processing residue drug during compounding to minimise waste. The hypothetical cost of BW would be €1,748,932 with a hypothetical waste of 7.970 mg (€94,620) which is 5% of the total drug cost. The real cost of nivolumab was €1,661,154. This policy allowed us to save €87,778 (5%). If the same patients received the FD, no waste would have been produced but the cost would be greater €1,777,950 (+7%).

Conclusion FD simplifies prescribing, preparation, inventory and billing but the costs would be greater. In our cohort the median patient's weight was less than 80 kg so we would have used fewer vials using BW versus FD protocol.

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No conflict of interest.

3PC-021

IMPACT OF A CENTRALISED INTRAVENOUS ADDITIVE SERVICE IN PATIENTS AND HEALTHCARE WORKERS RISK REDUCTION

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Background Parenteral drug compounding and its administration carries potential risks for patients. Safe handling procedures avoid healthcare workers' exposure to hazardous drugs. Compounding preparations in a Centralised IntraVenous Additive Service (CIVAS) could minimise both risks.¹

Purpose We conducted this study to assess patients and healthcare workers risk reduction by centralising parenteral preparations in a CIVAS compared to clinical areas (CA).

Material and methods Observational retrospective study in a 460-bed hospital. Inpatient parenteral preparations for CA (except Critical Care, Emergency Room and Neonatal Unit)

and outpatient preparations were included from January 2017 to December 2017.

For each preparation was recorded: compounding area (CIVAS/CA); number and type of preparation (fluid (F), parenteral nutrition (PN) or parenteral drug (PD)); type of admixture (standardised/individualised); risk level for patients (high/medium/low);² and hazardous level for healthcare workers (hazardous/non-hazardous).³

Results Overall, 3 22 693 preparations (F (19.8%), PN (1.6%) and PD (78.6%)) were compounded: 64.2% standardised, 26.9% medium-high risk preparations and 5.1% hazardous preparations. CIVAS coverage was 77.0% (248,254) (F (97.3%), PN (100.0%) and PD (71.3%)). CIVAS prepared 69.1% of total standardised preparations and 91.0% of individualised admixtures.

According to risk for patients, 89.6% (78,051) of medium-high risk preparations were centralised. Preparations that were not prepared in CIVAS corresponded to antibiotics, anti-epileptics, analgesics, proton-pump inhibitors and corticosteroids.

According to risk for operators, 75.7% (231,829) of non-hazardous drugs and 99.9% (16,425) of hazardous drugs were prepared in CIVAS, avoiding exposure risk for healthcare workers. Valproic acid was the only hazardous drug prepared in CA.

Conclusion Compounding in a CIVAS provides coverage of 77% parenteral preparations. Higher patient risk reduction and staff protection standards are provided by avoiding elaboration of 89.6% of medium-high risk preparations and 99.9% of parenteral hazardous drugs in clinical areas.

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No conflict of interest.

3PC-022

PRELIMINARY MICROBIOLOGICAL STUDY OF INJECTABLE CHEMOTHERAPY DOSE-BANDING

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Background In our medical centre, the production of injectable antineoplastic rose 20% between 2015 and 2017. As a consequence, the dispensing delay increased. It has therefore been decided to implement dose-banding. In order to guarantee the sterility of preparations after storage, we did a preliminary study of microbiological stability 28 days after making the preparation.

Purpose The study of microbiological stability of injectable chemotherapy produced at an oncological pharmacy after 28 days of storage.

Material and methods We simulated the production of antineoplastic preparation with dextrose 5% to avoid chemotherapy contamination at the hygiene laboratory.