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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10.1136/ejhp-2019-eahpconf.99

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 One mL was withdrawn from each bag and diluted with NaCl 0.9%.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.

REFERENCE AND/OR ACKNOWLEDGEMENTS

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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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10.1136/ejhp-2019-eahpconf.100

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

10.1136/ejhp-2018-eahpconf.470

No conflict of interest.

3PC-020

NIVOLUMAB WEIGHT-BASED DOSING VS FLAT DOSE ECONOMIC ANALYSIS

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10.1136/ejhp-2019-eahpconf.101

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