

Results For each solvent, cefotaxime solutions at 83.3 mg/mL and 125 mg/mL retained more than 90% of the initial concentration after 12 hours. During the study, pH values decreased slightly, the intensity of the yellow colour increased and absorbance values increased progressively for each wavelength and each condition. An additional peak with a relative retention at 3.01 was also observed after the forced degradation gradually increased up to 4.01% in 0.9% NaCl and 3.17% in G5% of the total surface area of the peaks present on the chromatogram after 12 hours.

Conclusion In view of the results and despite the fact that the solutions retained more than 90% of the initial concentration after HPLC analysis, we propose to limit the stability of cefotaxime in 0.9% NaCl and G5% at 83.3 and 125 mg/mL at 6 hours. These stability data of highly concentrated solutions provide additional knowledge to assist ICUs in daily practice. Highly concentrated cefotaxime solutions are unstable after a 6 hour storage and cannot be administered as a daily infusion.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-016 PHYSICOCHEMICAL STABILITY OF VANCOMYCIN HYDROCHLORIDE IN POLYPROPYLENE SYRINGES AT HIGH CONCENTRATIONS FOR INTENSIVE CARE UNITS

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10.1136/ejhp-2019-eahpconf.97

Background In severe infections such as in intensive care units (ICUs), the recommended dose of vancomycin may be 60 mg/kg/day. Studies demonstrated that continuous infusion of vancomycin allowed rapid target concentration. In ICUs, a minimum volume is used to avoid fluid overload for patients requiring fluid restriction, leading to high concentrations of vancomycin.

Purpose The first objective of this work was to study the impact of an electric syringe pump on physical stability. The second objective was to study the stability of vancomycin solutions at 62.5 mg/mL and 83.3 mg/mL, diluted in two solvents: 0.9% sodium chloride or 5% glucose, in polypropylene syringes after the preparation and after a 6 hour, 24 hour and 48 hour storage at room temperature.

Material and methods Chemical stability was analysed by high-performance liquid chromatography coupled to a photodiode array detector at each time of analysis. The method was validated according to the International Conference on Harmonisation Q2 (R1). Physical stability was evaluated by visual and subvisual inspection (turbidimetry by UV spectrophotometry at 350, 410 and 550 nm as recommended by the European Consensus Conference). Three syringes for each condition were prepared. At each time of analysis, three samples were analysed for each syringe. pH and osmolality values were evaluated at each moment of the analysis. Chemical stability was defined as not less than 90% of the initial concentration.

Results The action of an electric syringe pump did not cause visual modification. Vancomycin diluted in 0.9% sodium chloride at 62.5 mg/mL and at 83.3 mg/mL retained more than 90% of the initial concentration after 48 hours and 24 hours respectively. Diluted in 5% glucose and stored at 20°C–25°C, vancomycin solutions at 62.5 mg/mL and 83.3 mg/mL retained

more than 90% of the initial concentration after 48 hours. Some precipitates were visible after 48 hour storage for the vancomycin syringe at 83.3 mg/mL in 0.9% sodium chloride. In other conditions, no visual modification was observed.

Conclusion Vancomycin hydrochloride diluted in 5% glucose at 62.5 mg/mL and 83.3 mg/mL were physically and chemically stable over a period of 48 hours at room temperature. For high concentrations of vancomycin, 5% glucose as solvent is recommended.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-017 PHYSICAL COMPATIBILITY OF INTRAVENOUS ANTI-INFECTIVE DRUGS WITH MEDICATIONS COMMONLY USED IN INTENSIVE CARE UNITS

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10.1136/ejhp-2019-eahpconf.98

Background In intensive care units (ICUs), intravenous (I.V) accesses are usually limited, leading to concomitant administration of different drugs in the same infusion line.

Purpose The objectives were: to perform an observation of the administration of anti-infective drugs (antibiotics, antiviral and antifungal drugs) in the ICUs; to compare with compatibility data available in the literature; and in the absence of compatibility data, to test the physical compatibility in our laboratory.

Material and methods Between April and June 2018, an observational prospective study was realised over 2 weeks in each of the three ICUs selected. Patients receiving more than one I.V drug including an anti-infective drug in the same line simultaneously (Y-site injection or mixed in the same container) were included. All I.V. drugs were recorded as concentration, solvent, type of container and flow rate. Compatibilities were assessed pairwise by using three databases: The Handbook on Injectable Drugs 19th edition, King Guide to Parenteral Admixtures and Stabilis.

For missing data, three tests were realised for some pairwise: (drug A/drug B): 1 mL/9 mL; 9 mL/1 mL; and 5 mL/5 mL. Drugs were considered compatible if no precipitate, colour change or gas formation were observed after preparation and after a 1 hour and 4 hour storage at room temperature. For subvisual evaluation, turbidimetry by UV spectrophotometry was performed at 350, 410 and 550 nm as recommended by the European Consensus Conference.

Results A total of 123 associations between an anti-infective drug and another medication were observed. According to the literature, 33.3% (n=41/123) associations were compatible, 9.8% (n=12/123) were incompatible, 6.5% (n=8/123) had divergent data according to the databases and 50.4% (n=62/123) had no data available. Thirty-eight pairwise mixtures were studied. After laboratory tests, 71.0% (n=27/38) were evaluated as physically compatible, 7.9% (n=3/38) were found to be incompatible after visual evaluation and 21.1% (n=8/38) after only subvisual evaluation.

Conclusion This study demonstrated that some incompatible drugs were mixed before administration to the patient. After laboratory tests, new incompatibilities were found which gives additional information to the literature. However, many other mixtures should be still studied due to missing data.

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/ejhpharm-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/ejhpharm-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 (FEMECA) 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 FEMECA, 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, FEMECA 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/ejhpharm-2018-eahpconf.470

No conflict of interest.

3PC-020 NIVOLUMAB WEIGHT-BASED DOSING VS FLAT DOSE ECONOMIC ANALYSIS

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10.1136/ejhpharm-2019-eahpconf.101

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