

On day 0, 56 infusion bags were produced in a positive air pressure isolator (Isocyt Freja; Getinge). Half of them were stored at room temperature and the other half at 4°C.

Twenty mL samples were taken and inoculated on day 0, 2, 7, 14, 21, 28 and 42 under laminar flow at the pharmacy. This volume represents 10% of the final volume of the bag according to the 2.6.1 chapter of sterility test of the European Pharmacopoeia 9.7.

Liquid medias used at the hygiene laboratory were thioglycolate and trypticase. Fertility and sterility of these medias were checked. American Type Culture Collection strains were used to test the fertility of these medias.

Liquid medias were incubated at the hygiene laboratory for 14 days at 22°C and 34°C. The positivity of the liquid medias was observed by the appearance of a turbidity, visible to the naked eye.

**Results** Fertility and sterility controls were validated. After 14 days of incubation, no microbiological growths were observed. The main limit of this study was the decision to use one media per bag, to avoid accidental contamination at sampling time.

According to a previous study<sup>1</sup> carried out in our medical centre, the majority of the centres that use dose-banding, have only achieved a chemico-physical stability study. Since sterility control cannot be performed systematically, it seemed important to us to prove the microbiological stability of these preparations.

**Conclusion** This preliminary study proves the sterility of chemotherapy bags after 28 days of storage. It allows dose-banding in order to shorten waiting periods for dispensation.

#### REFERENCE AND/OR ACKNOWLEDGEMENTS

<http://www.gerpac.eu/etat-des-lieux-des-pratiques-du-dose-banding-en-france>

No conflict of interest.

3PC-023

#### A RISK ANALYSIS METHOD TO EVALUATE THE IMPACT OF A CHEMOTHERAPY COMPOUNDING WORKFLOW MANAGEMENT SYSTEM ON CANCER PATIENTS' SAFETY

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**Background** The implementation of technology for chemotherapy compounding is recommended by several organisations to improve patient safety. However, a careful evaluation of their benefits and risks is needed.

**Purpose** To evaluate the safety before and after the implementation of an imaged-based volumetric compounding workflow software system (PhocusRx), and stratification of residual risks to drive future developments.

**Material and methods** Setting: chemotherapy compounding pharmacy unit of a 1300-bed tertiary teaching hospital provided with a Computerised Prescription Order Entry program, online pharmacy validation and online printing of compounding order sheets. In the before phase, quality control was made by a pharmacy technician who verified starting products, number of vials used, aspects of the final product and label accuracy.

**Design:** comparative risk analysis of the chemotherapy compounding process before and after the implementation of PhocusRx, according to the Failure Modes, Effects and Criticality Analysis (FMECA) method.

**Measurements:** the failure modes were defined and their criticality index (CI) calculated on the basis of the likelihood of occurrence, potential severity for patients and detection probability. CI of the before and after phases were compared, and new measures were proposed.

**Results** In the pre-implementation phase, the sum of CI of 16 identified failure modes was 1999. After PhocusRx implementation, 21 failure modes were identified and the CI was reduced to 668 (a 67% reduction). According to the compounding subprocess, the material preparation CI was reduced by 46% (318 vs 171), the drug production by 76% (1411 vs 341) and the quality control by 48% (126 vs 240). The five failures modes exclusively detected after the implementation of the robot were associated with very low CI (CI <30).

After PhocusRx implementation, the failure modes with the highest CI reduction were: wrong vehicle type (-96.7%); incorrect label (-96%); forgotten bag preparation (-83.3%); incorrect drug packaging (-80%); incorrect drug measure (-77.8%); and incorrect drug (-75%).

High-priority recommendations defined were: improving barcode identification of the starting products vials and process improvements in the image-based quality control.

**Conclusion** PhocusRx implementation has increased the safety of the compounding process in the pharmacy department. FMECA is a useful method for evaluating the impact of compounding technology implementation and identifying further improvement strategies.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-024

#### THE VALIDATION OF CONTROL METHOD: THE GRAVIMETRIC ANALYSIS IN CYTOTOXIC DRUG PREPARATION

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**Background** Our production unit realises more than 35 000 cytotoxic drug preparations per year in an isolator chamber (IC). The control method is done by in-process gravimetric analysis coupled with scan identification, led by software with interactive instructions. The balances are certified once a year, yet outside the IC. Indeed, turbulent airflow could impact the scales' measurements. The accepted errors percentages are a function of the volumes weighted.

**Purpose** After software development and setup, we need to validate this control method with the two components: the weighing scales and the software.

**Material and methods** For the weighting scales, a qualification was made inside and outside the IC with standard weights. For the validation the tests performed were fidelity, accuracy and eccentricity. Then, a comparison to visual control was performed to evaluate the bias of the balance. Six syringes with different volumes were made and then verified by a third person. Next, they were weighed 15 times to obtain the total error. For the software, a method is being developed to analyse the specificity and the sensitivity. For the specificity,

an extraction of the software was done to study the forced steps (the steps refused by the software but accepted by the pharmacist because of the correct volume read) over a period of 6 months.

**Results** The metrological tests enable to qualify the balances. The bias of the weighing scales fluctuates between 0.94% and 4.40%. Over 6 months, 15 227 preparations were realised with a total of 1 89 334 steps including 49 180 weighing steps. Among those, there were 2023 forced steps (4.1%). The most forced cytotoxic molecules were identified. The two most forced stages were the weighing of the syringe with cytotoxic (41%) and of the final pouch (23%). The 50 ml syringe is responsible for 41% of this forced stage and, in 85% of the cases, it is because the volume to collect has a decimal value.

**Conclusion** Concerning the sensitivity, a method is elaborated to determine the rate of the false negatives with a fake cytotoxic preparations plan and calculated weighing errors. Our method validation plan is complete with the validation of the two components: precision scale and software.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

#### 3PC-025 OPTIMISATION OF COMPOUNDING ORGANISATION AFTER IMPLEMENTING A ROBOTIC SYSTEM FOR AUTOMATED PREPARATION OF ONCOLOGIC DRUGS

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**Background** The aseptic preparation of oncologic drugs is performed in the centralised, pharmacy-based cytotoxic drugs preparation unit equipped with a biological safety cabinet and the robotic system APOTECaChemo (Loccioni, Italy), installed in 2012. Manual and fully automated preparations run in parallel are operated by two and one pharmacy technicians (PT), respectively. On average, the annual workload amounts to 35 000 preparations, two-thirds of which are prepared with the robotic system.

**Purpose** The aim of this study was to evaluate the working efficiency of PT after implementing the robotic system and calculate the amount of preparations to be transferred from the manual to the automated process to optimize human resources' utilisation.

**Material and methods** Manual and automated preparation were analysed over three years (2014–2016). Full-time equivalents (FTE) required by both processes were calculated for each year. A FTE of 1.0 was equivalent to a PT working full-time 40 hours per week, 1,700 hours per year. The throughput in terms of annual preparations per FTE was calculated including direct activities (compounding) and indirect activities related to production (quality controls and standard operating procedures, e.g. cleaning and gowning). The calculation was performed for both manual and automated preparation processes.

**Results** On average, the overall working time spent by PT on direct and indirect activities amounted to 4,670 hours/year for the manual process and to 2,441 hours/year for the automated process, resulting in 14 151 and 21 534 preparations, respectively. The annual amount of preparations per 1.0 FTE in the automated process (mean: 15,066) was three times higher than in the manual process (mean: 5,036). The production

times were comparable, but the working time spent by PT on indirect activities was reduced by 85% by using the robotic system. Each 7600 preparation transferred from the manual process to the robotic system results in 1.0 FTE made available for different working activities.

**Conclusion** Results of this study revealed that the automated process with the robotic system improves the working efficiency of PT, thereby allowing the reallocation of human resources and the optimisation of workload distribution in the daily pharmacy practice. Other indirect advantages related to cost and production quality are achieved.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

#### 3PC-026 WHAT IS THE BEST CHEMICAL DECONTAMINATION SOLUTION FOR CONVENTIONAL ANTI-NEOPLASTIC DRUGS IN A HOSPITAL COMPOUNDING UNIT?

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**Background** Several decontamination methods are currently available to reduce the occupational exposure of hospital facilities to conventional anti-neoplastic drugs. Alcohol-based microbicides are not sufficiently efficient in removing chemical contamination and data are lacking on many marketed biocides. Recent data confirm that using a specific chemical decontamination solution is helpful in removing traces of contaminants.

**Purpose** To perform a literature review in order to help pharmacists in choosing a chemical decontamination solution to implement in their compounding unit.

**Material and methods** Articles were searched on Pubmed using the following requests: 'antineoplastic agents AND cleaning' or 'antineoplastic agents AND chemical degradation' or 'antineoplastic agents AND chemical decontamination'.

Criteria used to classify the performance and usability of decontamination solutions were: decontamination efficiency, number and nature of tested contaminants, hazardousness of the decontamination solution, implementation difficulties and respect of the aseptic environment.

**Results** Two-hundred and seventy-four articles were retrieved following the request application. Two-hundred and fifty-seven articles were discarded for different reasons leading to the analysis of 17 articles. Fifty-nine methods were tested as degradation (n=19) or desorption methods (n=40) with various decontamination efficiencies ranging from ≤10% to 100%.

Applying the selection criteria, three decontamination solutions were chosen: sodium hypochlorite, admixture of 10<sup>-2</sup> M sodium dodecyl sulfate (SDS) and 70% isopropanol (80/20), marketed two steps towelettes kit (1. Quaternary ammonium solution, 2. Isopropanol). Their inertness to facilities' surfaces is different and sodium hypochlorite solutions oxidise metals. Solutions involving tension-active agents such as SDS may form a film on the facilities surface, which may alter the sterility environment.

**Conclusion** The applied selection criteria led to select only three decontamination solutions. Their application modalities are also to be discussed regarding the biological and chemical facilities' monitoring. As the solutions were assessed with