(VE) for the treatment of otomycosis and analyse its effectiveness and safety.

Material and methods Antifungal ear drops are not commercially available. The otolaryngology service requested a broad spectrum topical antifungal for recurrent otomycosis. After a literature review, a sterile aqueous formulation of voriconazole 10 mg/mL was considered, ensuring the absence of ototoxic effects, with an optimal pH of 6.3 that allowed contact with the external channel. We assigned a beyond use date of 14 days refrigerated, 45 days frozen and protected from light.

Baseline data were collected from the clinical history. Patients reported their outcomes in interviews with the pharmacists,: humidity, otorrhoea, earache, itching, loss of hearing before/after treatment and possible adverse events (AE) were recorded. Patients were informed and consent was requested for participation. Statistical analysis was made with SPSS and STATA. The results were analysed using the McNemar test of paired data.

Results Following the macroscopic finding of hyphae, microbiological culture was requested in 55.5% of cases, and *Candida* (33%) and *Aspergillus* (22%) isolates were found. All patients were treated previously with topical drugs (94.4% antibiotics, 55.5% antifungals) and 83.3% also with oral agents (83.3% antibiotics, 22.2% antifungals), without improvement. Eighteen patients (58.8% women, median age 67 years (range 44.5–75)), were treated with VE for an average of 4 weeks (SD 1.8), administering 1–2 drops 2–3 times a day.

Interviews were conducted in 14 patients: 93.3% reported a general improvement in symptoms and 86.7% associated it with VE. Patients experienced a significant improvement in humidity (pre 88.2%, post 13.3%, $p<0.05$), otorrhoea (pre 100%, post 6.7%, $p<0.05$), earache (pre 41.2%, post 0%, $p<0.05$) and itching (pre 41.2%, post 6.7%, $p<0.05$), and 36.4% perceived an improvement in hearing loss ($p>0.05$). Only one AE (mild tingling) was recorded.

Conclusion and relevance Our observations showed that voriconazole ear drops were an effective and safe option that significantly reduced symptoms in patients with recurrent otomycosis which failed to respond to other therapeutic alternatives. Further prospective studies are needed to confirm these findings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-010 EVALUATION OF THE PRODUCTION ACCURACY AND ERROR RATE IN THE AUTOMATED COMPOUNDING OF CYTOTOXIC PREPARATIONS BY A ROBOT

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Background and importance In chemotherapy compounding, the accuracy of the preparation is related to patient safety. A fully automatic production through a robotic system should ensure not only complete documentation and minimisation of the risk of pharmacy personnel being exposed to toxic drugs, but also greater accuracy of the compounding, consequently improving patient safety.

Aim and objectives The study aimed to verify the production accuracy of APOTECAchemo as well as the error rate of the robot during compounding.

Material and methods Using the statistical software 'APOTECAm@A', which allows regular checking of the performance of the robot, the pharmacy production of 20 anticancer active ingredients was monitored from January to October 2018, focusing on the dosage accuracy (%) of the preparations automatically compounded and the robot error rate.

The results of the analysis will define the performance of the automation in terms of preparation quality and safety, and production efficiency in the daily routine of the pharmacy.

Results During the study period, 8478 automated preparations were compounded with APOTECAchemo by the pharmacy. The error rate of the robot was ~1% of the total automated production. Regarding the accuracy of the successful preparations compounded by APOTECAchemo, 97.5% of the preparations had a dosage accuracy between 0 and ±3%. The remaining 2.5% of the preparations produced with the robotic system were within the ±5% tolerance limits defined by the pharmacy as acceptable.

Conclusion and relevance The analysis carried out by APOTECAm@A showed high dosage accuracy in combination with a low percentage of errors in the automated production. The data show high quality as well as high reproducibility of safe production using APOTECAchemo.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-011 CLOSED SYSTEM TRANSFER DEVICE BASED ON AIR FILTRATION: THE DRUG VAPOUR CHALLENGE

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Background and importance Chemotherapy drugs were shown to form hazardous vapours that pose a health risk to pharmacists and nurses. One of the aims of using a closed system transfer device (CSTD) is to prevent this harmful exposure. The vapour containment efficiency of air filtration CSTDs is perceived as less obvious compared with that of physical barrier based CSTDs, and therefore should be proven throughout the shelf life of these devices in order to support the claims of its instruction for use (IFU).

Aim and objectives The aim of the study was to test the drug vapour containment capacity of Chemfort, a new air filtration CSTD. The objective was to investigate if the air filter remained fully functional at the end of the shelf life (3 years). According to the IFU, the device can be used on a drug vial for a period of 7 days, and thus the study also tested the filter functionality after it was exposed to vapours of a hazardous drug for 7 days.

Material and methods The study was performed by Nextar Labs (Nes Ziona, Israel). Vial adaptors (VA) were applied on drug vials (cyclophosphamide, 5-fluouracil (5-FU)). Extreme conditions were used to generate vapours—heating to 50°C and having a nitrogen gas flow (250 mL/min) into the vial for 5 hours via the VA fluid pathway. A closed test chamber was employed for capturing drug vapours. Vapours released through the air filter were trapped, recovered and quantified using validated LC/MS/MS methods. As a positive control,

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parallel testing was performed using Chemfort VA from which the filter system had been removed.

Results No drug was found in any of the test samples with the intact air filter system in Chemfort VAs, either fresh, following aging for 3 years or after 7 days of exposure to drug vapours. Recovered vapour was consistently found in the positive control samples which had Chemfor VAs without a filter system. Mean±SD (n=5) levels were 69±34 and 35±20 ng for cyclophosphamide and 5-FU, respectively.

Conclusion and relevance The results confirm the efficacy of the Chemfort air filtration system, even after 7 days of exposure to drug vapour or a shelf life of 3 years.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest Corporate sponsored research or other substantive relationships:

The author is an employee of Simplivia Healthcare.

3PC-012 MANAGEMENT OF NON-ADMINISTERED CHEMOTHERAPY PREPARATION: AN OPPORTUNITY TO MINIMISE DRUG WASTE IN ONCOLOGY PHARMACY

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Background and importance The non-administration of cytotoxic preparations contributes significantly to drug waste and costs in the centralised cytotoxic preparation units (CCPU). Monitoring and proper management of returns of preparations could reduce drug wastage.

Aim and objectives The aim of the study was to analyse the reasons for returns and quantify reused cytotoxic preparations before and after implementation of corrective measures.

Material and methods A prospective study was conducted at our hospital pharmacy at the National Institute of Oncology over two 8 month periods (January to August 2018, January to August 2019). Data on the reasons, content and fate of returns were collected and analysed.

Results At the end of the first period, 125 preparations corresponding to 90 prescriptions were returned. Absence of the patient was the most common reason (56%), followed by crystallisation of product (19%), mainly taxanes. Docetaxel was the most returned preparation (17.6%). The corrective measures taken were: optimisation of communication between the CCPU and clinical services, strict dilution of taxanes and etoposide in glass vials and updating of physicochemical and microbiological stability sheets for cytotoxics. During the two study periods, we found a similar number of returns (0.6%) corresponding to 15 851€ and 16 874 €. The absence of the patient, the most frequent reason in the two periods, decreased from 56% to 40%. Product crystallisation decreased considerably (19% vs 2%). The number of reassigned preparations increased from 2.4% to 7%. Reusing corresponded to 64€ and 2760€ for period 1 and period 2, respectively.

Conclusion and relevance This study found a high number of preparations returned due to crystallisation by taxanes via interactions containing content. Updating the stability data of the anticancer drugs used in our hospital based on recent international guidelines and follow-up of chemotherapy preparations had a significant impact on the reasons and cost of returns. Vigilance by pharmacists is required when validating prescriptions in order to minimise the avoidable causes of chemotherapy wastage and to make savings.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-013 COMPARATIVE BIOPHYSICAL STABILITY STUDY OF ZIV-AFLIBERCEPT (ZALTRAP, OPENED VIALS) STORED AT 4°C AND ROOM TEMPERATURE FOR 2 WEEKS

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Background and importance Ziv-aflibercept (Zaltrap) is an Fc-fusion protein used in the treatment of colorectal cancer. Changes in the structure or aggregation, which may arise from handling and storage, may affect the efficacy of the treatment and it could cause severe immune reactions in patients. The shelf life indicated by the manufacturer for the unopened vial is 3 years; there is no information on the surplus of opened vials.

Aim and objectives To compare the biophysical stability of ziv-aflibercept (Zaltrap) stored refrigerated at 4°C and at room temperature protected from light for 2 weeks.

Material and methods Three independent samples of fresh ziv-aflibercept were collected from hospital and stored in amber glass vials protected from light at 4°C and at room temperature.

Particulate: dynamic light scattering (DLS) readings were carried out in a protein solution DynaPro-99 system dynamic light scattering module equipped with a temperature control micro sampler (Wyatt, Santa Bárbara, California, USA) for obtaining the hydrodynamic radius and polydispersity.

Tertiary structure: intrinsic tryptophan fluorescence measurements were carried out on a Cary eclipse spectrofluorometer (Agilent, Santa Clara, California, USA). Each spectrum was reduced to a single a dimensional number (centroid):

$$C = \frac{\sum_{i=1}^{n}(f_i \lambda_i)}{\sum_{i=1}^{n} f_i}$$

LMW aggregates: size exclusion chromatography (SEC) was used. The analysis was performed by liquid chromatography using an Agilent 1100 chromatograph equipped with a quaternary pump, degasser, autosampler, column oven and photodiode array detector (Agilent).

Results No significant changes were detected in the samples stored refrigerated by any of the techniques used: aggregation did not occur, supported by the results from DLS and SEC. No changes in conformation were detected: fluorescence centroid was maintained.

Significant changes were detected in the samples stored at room temperature: the start of aggregation was detected by SEC but larger aggregates were not detected by DLS. Centroid value increased significantly, indicating conformational modifications.

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