visually inspected for turbidity after 14 days of incubation. The number of colony forming units (CFU) per plate were counted and identified.

Results The results of the KI discus test were far below the acceptance limit, demonstrating the effectiveness of laminar airflow in preventing the escape of particles from the internal areas of the robot. None of 240 media fills showed turbidity after incubation, thereby indicating no contamination with microorganisms. The working area met the grade A limit (0 CFU/sample). In the warehouse, 1 CFU was found in two samples (mean 0.2 CFU/contact plate, 0.1 CFU/settle plate). Microbial contamination was slightly higher in the loading area (mean 0.3 CFU/contact plate, 0.8 CFU/settle plate). Most of the CFUs were identified as skin related microorganisms, such as *Staphylococcus epidermidis* and *Staphylococcus hominis*.

Conclusion and relevance Extensive media fill tests and environmental monitoring during automated preparation with the robot revealed well controlled aseptic procedures and adequate sterility levels, thereby complying with the quality standard set by the hospital pharmacy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-064 A MULTICENTRE STUDY COMPARING CHEMOTHERAPY PREPARATIONS USING DIGITAL VIDEO MONITORING

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10.1136/ejhp-pharm-2021-eahpconf.39

Background and importance Preparation of chemotherapy treatment is a risky step. Therefore, the production circuit in the chemotherapy reconstitution unit (CRU) must be secured. The Drugcam digital tool is a preparation control system that guides the hospital pharmacy preparer (HPP) in their manufacturing process.

Aim and objectives A remote, multicentre and retrospective digital audit analysed qualitatively and quantitatively the practices of different CRU to find ways to optimise the preparation step for chemotherapy treatment.

Material and methods Over 1 year, data from 10 public and private healthcare institutions on three types of chemotherapy treatment, lyophilisate (pemetrexed), ready-to-use standard dose (nivolumab 240 mg) and dispenser (5-fluorouracil (5-FU)) were collected. This study analysed quantitative data extracted in Excel by pharmacists using local Drugcam data. Qualitative data obtained from audits made by pharmacists analysing 10 video recordings per chemotherapy preparation were also analysed.

Results 14 218 preparations made by 119 HPP were analysed: 2217 pemetrexed by 99 HPP, 1819 nivolumab by 90 HPP and 12827 5-FU by 110 HPP. The median preparation times for pemetrexed, nivolumab and 5-FU from all centres were 6.2, 4.2 and 4.9 min, respectively. Regardless of the three molecules, the results showed no significant difference between the experience of the Drugcam preparer and its productivity.

Qualitatively, analysis of the films showed heterogeneous practices between establishments: no compress for all stages, reconstitution by shaking of the lyophilisate as well as its mirage was not protocolled and rapid injections into the solvent were observed. The equipment used (infusion line or extension for infusion tree), the Drugcam practice (labelling of the preparation filmed or not, automatic or not automatic detection by the data matrix of the solvent/vial bags) and the organisation of each centre had a strong impact on the quality and productivity of the centres.

Conclusion and relevance If this study showed no correlation between time production, annual number of preparations and number of HPP, the analysis will allow us to recommend the practices of Drugcam for the preparation of chemotherapy treatment. Moreover, organisational modifications (series preparation, change of material reference) and practice harmonisation (standardised reconstitution of lyophilisates) will improve productivity and safety.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

3PC-065 IMPACT OF LIGHT STRESS ON THE ISOFORM PROFILE OF NIVOLUMAB (OPDIVO) IN OPENED VIALS ESTIMATED BY (RP)UHPLC-UV-(HESI/ORBITRAP)-MS

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10.1136/ejhp-pharm-2021-eahpconf.40

Background and importance Nivolumab (Opdivo) is a human IgG4 monoclonal antibody from the group of immunomodulators which bind to the programmed death receptor 1 (PD-1). As a complex protein, physical aggregation and chemical degradation can occur throughout its life, and even modest environmental stresses can cause extensive damage.¹ As indicated in its technical report,² the unopened vials can be stored at a controlled room temperature up to 25°C with room light for up to 48 hours.

Aim and objectives To assess the impact on the isoform profile of nivolumab 10 mg/mL (Opdivo) promoted by exposure to light in its own opened vial at a controlled temperature of 25°C to evaluate likely risks from unintentional mishandling in real hospital conditions.

Material and methods Nivolumab (Opdivo, 10 mg/mL) was placed in an accelerated stress test chamber to simulate sunlight (Solarbox 3000e RH, Cofomegra, Milan, Italy) for 24 hours at 25°C. Irradiation was set at 250 W/m², between 320 and 800 nm.³ A validated reverse phase ultra high resolution liquid chromatography coupled to high resolution mass spectrometry and exact mass ((RP)UHPLC-UV-(HESI/Orbitrap)-MS) method was used to analyse intact nivolumab. UV-chromatograms and total ion chromatograms (TICs) were recorded and the deconvoluted mass spectra gave the nivolumab mass isoform profile.

Results UV chromatograms and TICs suggested no degradation products after light exposure. However, isoform profiles clearly showed changes in the light submitted nivolumab