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 Chemfort VAs without a filter system. Mean $\pm$ SD (n=5) levels were 69 $\pm$ 34 and 35 $\pm$ 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

¹A El Assil*, ¹C Adade, ¹R Issa, ²H Bechar, ²A Zedou, ²A Fassi Fihri, ^{1,2}Y Rahali. ¹Mohamed V University-Faculty of Medicine and Pharmacy, Department of Pharmacy, Rabat, Morocco; ²National Institute of Oncology-Ibn Sina University Hospital, Department of Pharmacy, Rabat, Morocco

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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 reasigned 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

¹J Hermosilla Fernández*, ²A Salmeron García, ²J Cabeza, ¹N Navas. ¹Biomedical Research Institute Ibs Granada, Analytical Chemistry-Science Faculty-University of Granada, Granada, Spain; ²Biomedical Research Institute Ibs Granada, Clinical Pharmacy-San Cecilio University Hospital, Granada, Spain

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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.

Conclusion and relevance Ziv-Aflibercept (Zaltrap) remained stable for 14 days regarding visual appearance, LMW aggregates, particulate and conformation when stored at 4°C. However, storage at room temperature promoted ziv-aflibercept modifications. This result encourages more studies with samples stored at 4°C to establish the stability of opened vials of Zaltrap.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

3PC-014 USE OF CABAZITAXEL AND REDUCTION OF WASTE: THE POTENTIAL OF DRUG DAY

L Gasperoni*, M Nardelli, A Caraffa, A Colicchio, M Mancini. Azienda Ospedaliera Ospedali Riuniti Marche Nord, Uoc Farmacia, Pesaro, Italy

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Background and importance Cabazitaxel is an antineoplastic agent indicated for the treatment of adult patients with metastatic castration resistant prostate cancer, previously treated with a docetaxel containing regimen. The formulation available on the market consists of a vial of concentrate which, after dilution, makes 60 mg of drug available. The recommended dose of cabazitaxel is 25 mg/m² administered every 3 weeks and generally doses range from 20 to 50 mg. This results in waste with a strong economic impact considering the cost of the drug. From January to September 2019, 12 patients were treated with cabazitaxel in hospital for a total of 64 administrations (average dose of 37 mg) on 49 different days. Consumption was increased compared with the previous year (in 2018 from January to September 7 patients were treated and 42 administrations). It is appropriate to check the advantages of introducing drug day (administration of the drug on the same day of the week for all patients requiring therapy).

Aim and objectives The objective of the study was to verify the current wastage of cabazitaxel, and the potential waste with the introduction of drug day.

Material and methods Leftover drug was calculated for each day of administration (49 days). In the case of multiple administrations on the same day, leftover drug was calculated based on vial sharing. The same method was used to calculate leftover drug for every week of therapy, as if the therapies had been administered on the same day (drug day).

Results In 9 months, 2370 mg of cabazitaxel were administered and the waste calculated from leftover of single therapy days was 1350 mg (+57% compared with ideal consumption). Projecting consumption and waste at 12 months gives an annual consumption of 4960 mg of cabazitaxel (83 vials, of which 30 are considered waste).

With the introduction of drug day, waste would decrease to 810 mg (+34% compared with ideal consumption) and the projection would lead to an annual consumption of 4240 mg (71 vials, of which 18 would be considered as waste).

Conclusion and relevance The introduction of drug day for cabazitaxel is fundamental to reduce waste, optimise resources and safeguard costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-015 SHORT TERM STABILITY OF DILUTED SOLUTIONS OF THE MONOCLONAL ANTIBODY DARATUMUMAB

¹G Mangoni*, ²F Selmin, ¹L Camuffo, ¹L Cancanelli, ¹M Piccoli, ¹M Rivano, ³L Cervi, ²F Cilirzo, ²P Minghetti. ¹Università Degli Studi Di Milano, School of Specialisation in Hospital Pharmacy, Milano, Italy; ²Università Degli Studi Di Milano, Department of Pharmaceutical Sciences, Milano, Italy; ³Asst Grande Ospedale Metropolitano Niguarda, SC Farmacia, Milano, Italy

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Background and importance Monoclonal antibodies (mAb) are biotechnological products used as therapeutic agents. Because of their nature, mAb may go through a variety of chemical and physical degradation processes on handling. For this reason, extended in use conditions are not included in stability assessments prior to regulatory approval. Daratumumab, a CD38 targeting human IgG1κ mAb, is used in the treatment of multiple myeloma. After dilution in saline (0.9% sodium chloride) solution using the appropriate aseptic technique, it is reported to be physically and chemically stable for 24 hours under refrigerated conditions (2–8 °C) protected from light.¹

Aim and objectives We conduct a study to evaluate the physicochemical stability of daratumumab diluted at clinically relevant concentrations over a 14 day period.

Material and methods Daratumumab was diluted to concentrations of 1.2 and 2.0 mg/mL in a low density polyethylene (LDPE) infusion bag in saline solution for intravenous injection. To determine changes in physicochemical properties over a 14 day period, various methods were used—that is, size exclusion chromatography-high performance liquid chromatography (SEC-HPLC), dynamic light scattering (DLS), nanoparticle tracking analysis (NTA), turbidimetry, pH and osmolality. They were selected based on the preliminary results of a forced degradation study.²

Results All samples remained clear with no precipitates or particulate matter detected with the naked eye. No change in colour or turbidity was observed. The pH of both dilutions shifted from 5.5 to 5.8, while the osmolality value ranged from 296 to 313 mOsm/kg. SEC-HPLC did not show the formation of aggregates or fragmentations. The ratio between the major peak (retention time=13 min) and a minor signal (retention time=11 min) remained constant over time. No clear trend in the presence of sub-visible particles was observed by DLS. Indeed, the main peak of daratumumab was detected at about 13 nm which accounted for up to 98% and 95% for the 1.2 mg/mL and 2.4 mg/mL solutions, respectively. These results were in agreement with the NTA data.

Conclusion and relevance No physicochemical variations were evident in daratumumab solution at 1.2 mg/mL and 2 mg/mL stored in an LDPE infusion bag at 2–8°C. Evaluation of the biological activity is required to confirm the extended in use stability.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Darzalex summary of product characteristics. https://ec.europa.eu/health/documents/community-regis- ter/2017/20170428137394/anx_137394_en.pdf
2. Joubert MK, et al. *J Biol Chem* **267**(30): 25266–25279.

No conflict of interest.