pandemic and compare them with the same period in the previous year.

Material and methods A retrospective observational study of ME and AE notifications in the TPSC Cloud from March 2020 to February 2021 compared to notifications recorded from March 2019 to February 2020.

Five types of incidents were differentiated: situations with the capacity to cause ME, ME that do not reach the patient, ME that reach the patient without ADE, ME with ADE, and ADE without ME. The drugs involved in those incidents and the professional notifier also were identified.

Results 249 incidents were reported from March 2020 to February 2021, which was 31.02% less than in the previous period (n=361) from March 2019 to February 2020. The most common ME was prescription error in both periods (70.4% vs 67.3%). The incident profile by typology was similar in both periods. The most frequent was ME that did not reach the patient (40.24% vs 43.47%), followed by ME that reached the patient without ADE (23.42% vs 28.53%). Systemic anti-infectives drugs were the most involved in both periods (n=57; 22.89% vs n=73; 20.22%).

84 ADE without ME were reported from March 2020 to February 2021, representing an increase of 500% compared with March 2019 to February 2020 (n=14). Emphasising the notification of 35 ADE of lopinavir/ritonavir and 4 of hydroxychloroquine used in the initial treatment of COVID-19.

The main notifier in both periods was the pharmacist (80.48% vs 65.60%).

Conclusion and relevance During the first COVID-19 pandemic year, notifications of ME decreased, due to care load pressure, but incident profile was similar. Otherwise, ADE notifications increased notably, due to active pharmacovigilance carried out by pharmacists on off-label drugs used to treat COVID-19.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-106 IMPLEMENTATION OF ADVANCED THERAPY MEDICINAL PRODUCTS (ATMP) RECONSTITUTION IN A UNIVERSITY TEACHING HOSPITAL IN FRANCE: PROPOSAL OF A DECISION-MAKING ALGORITHM

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Background and importance ATMP (genetically modified organisms (GMO) ones or not) use is rising in oncology, and requires the establishment of a specific organisation to ensure a safety circuit.

Aim and objectives To implement ATMP reconstitution in our institution we built a decisional algorithm for risk and feasibility assessment for each ATMP.

Material and methods A team of seven oncology pharmacists was constituted to take into account the complexity of the organisations in our institution and associate several pharmaceutical competencies. They first identified a flow diagram based on critical steps. For each step, according to regulations, professional guidelines and expertise field of each pharmacist, three brainstorming sessions were organised to identify main subprocesses and key points which must be evaluated for each ATMPs. Critical points were retained and a decision-making algorithm for ATMP risks and feasibility assessment, based on a yes/no dichotomy progression, was built and validated with circuit of ATMP in clinical trials (CT) ever conducted in our institution.

Results The decision-making algorithm we built consists of six steps (ATMP nature, storage conditions, thawing conditions, preparation of a not-GMO ATMP, preparation of a GMO-ATMP, waste disposal). Each step consisted of several questions (34). If a step fails, ATMP can not be used. Critical points such as security storage back-up or qualification of waste inactivation process are yet to be implemented into the algorithm. Moreover, as some facilities might routinely be unavailable yet in hospital pharmacies (storage in vapor phase nitrogen), the algorithm takes into account availability of these facilities outside of the pharmacy through subcontracting with a warranty of ATMP quality. After retrospective scrutiny of our algorithm with ATMP circuits ever conducted in CTs (talimogene laherparepvec, axicabtagene ciloleucel), it appeared to meet all our needs.

Conclusion and relevance This tool was used prospectively to implement tisagenlecleucel, onasemnogene abeparvovec and soon betibeglogene autotemcel in our centre. Furthermore, the French Regional Health Agency identified it as a key point to make our ATMP circuit secure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-107 SECURISING OF TISAGENLECLEUCEL THAWING AND DELIVERING

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Background and importance Tisagenlecleucel is available in 50 mL and 250 mL frozen bags (containing 10–30 mL and 30–50 mL cell suspension, respectively). Tisagenlecleucel should be thawed at 37° C then infused within 30 min to maintain cell viability. Thawing time according to volumes is a critical point which is not known.

Aim and objectives We evaluated in this work the thawing times of tisagenlecleucel according to volumes.

Material and methods Ethylene vinyl acetate empty infusion bags were provided by Novartis. Freezing tisagenlecleucel matrix was reconstituted. Empty bags (50 mL and 250 mL) were respectively filled with 10 and 20 mL and 30, 40 and 50 mL of reconstituted matrix, then frozen at –150°C. To mimic real conditions, they were placed into a second sterile bag and thawed in a water bath at +37°C. To evaluate thawing duration, volume of remaining icicles was calculated by multiplying surface (GeoToolsoftware) by thickness (measured with a caliper). Furtheremore, the time to deliver the bags was measured by two different operators in triplicate.

Results 124±5 s and 191±30 s were necessary to achieve complete thawing of 50 mL bags filled at 10 and 20 mL,

respectively. 155±16 s, 221±12 s and 240±6 s were needed to achieve complete thawing of 250 mL bags filled at 30, 40 and 50 mL, respectively. For a type of bag, decreasing volumes thawed faster, but 50 mL bags filled at 20 mL took longer to thaw than 250 mL bags filled at 30 mL (different spatial conformation and specific surfaces). Delivery of thawed bags from the pharmacy to the transplant unit was done in 4.5±0.21 min.

Conclusion and relevance Thawing duration may vary by twice a function of volume. Mean lengths provide an optimal organisation in a circuit where every minute must be taken into account. A total thawing-addressing time rate of between 6.5 and 8.5 min means that the nursing team has almost 20 min to administer tisagenlecleucel.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-108 SECURISING OF TISAGENLECLEUCEL (KYMRIAH) STORAGE

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Background and importance Tisagenlecleucel is available in frozen bags stored and shipped under –120°C. The Summary of Product Characteristics (SPC) allowed storage in a cryogenic freezer (vapour phase of nitrogen (LN2) is cited only as an example). As the pharmacy does not have LN2 storage facilities, tisagenlecleucel bags are stored in a freezer set at –150°C. With only one freezer available, another freezer located in the biological haematology laboratory was chosen as a back-up freezer in case of failure.

Aim and objectives The aim of this work was to validate the thermal performance of the container transfer system between our facility and our back-up ones.

Material and methods Freezer and rooms were equipped with Cobalt2 sensor, with Thermoserver software allowing monitoring, temperature recording, and triggering of the alarm in case of temperature excursion. A Cryoexpress polystyrene transport container was preloaded with 10 × 100 mL sodium chloride bags and one aluminium cassette used for tisagenlecleucel bag storage in order to mimic real-life conditions. The transport container was equipped with an Emerald sensor, with Oceaview software allowing real-time monitoring of the temperature inside the container. The transport container was placed inside the freezer, the cover was opened, and the temperature was set on –140°C in order to mimic a temperature excursion. After temperature stabilisation, the freezer was opened, the container was hermetically closed and the temperature inside it was measured every 30 s until an overrun of –120°C. Two situations were tested: the container left at room temperature (+20°C), and, in order to mimic the worst case scenatio, left in a room maintained at +30°C. Each measurement was done in duplicate. Measurement of transfer time from the pharmacy to the back-up freezer was done by two different operators in triplicate.

Results Whatever the external temperature, conditions needed by the SPC is maintained for more than 25 min (28 min and 33.5 min for an external temperature of +20°C and +30°C, respectively). The transfer time from the pharmacy to the biological haematology laboratory was 3.25±0.25 min.

Conclusion and relevance Transfer duration to the back-up installation is far lower than the time for which an optimum storage temperature for tisagenlecleucel is maintained with our transport system.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

5PSQ-110 OMEPRAZOLE DEPRESCRIPTION PROJECT IN A SOCIAL HEALTH CENTRE WITH A DEPOSIT OF MEDICINES ASSOCIATED WITH A HOSPITAL PHARMACY SERVICE

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Background and importance The use of omeprazole has become very frequent in recent years, not being indicated on many occasions, so deprescription is necessary to reduce the possible associated adverse effects.

Aim and objectives Analyse the adequacy of omeprazole treatment in institutionalised elderly patients in a social health centre.

Recommend deprescription or dose reduction in susceptible patients.

Material and methods Review of all patients treated with omeprazole in the social health centre. The data were obtained from the electronic prescription and the medical history. Data collected: age, sex, dose, duration of treatment, indication, concomitant medication and interactions. Risk factors for bleeding were also analysed in patients older than 65 years: potentially gastrolesive drugs: anticoagulants, anti-aggregants, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids and selective serotonin reuptake inhibitors (SSRIs) and a history of peptic ulcer.

The deprescription criteria were: no indication for use, duration of treatment exceeds the technical data sheet, and absence of gastrolesive drugs that justify the association of omeprazole.

The pharmacist's recommendations were carried out in the electronic prescription program and the analysis of acceptance/rejection of the interventions took place 1 month afterwards.

Results 38 patients were being treated with omeprazole. Mean age was 84 years and 74.4% were women.

45% (17 patients) did not meet the criteria for the use of omeprazole; 16 patients were proposed for deprescription and 1 for minimum dose.

Of the 17 patients, 5 (29.4%) took omeprazole for an indicated use but all exceeded the duration recommended.

Regarding the use of potentially gastrolesive medication: 7 patients (41.2%) were being treated with NSAIDs, 5 (29.4%) with SSRIs and 2 (11.7%) with acenocoumarol, but none of them were being treated with acetylsalicylic acid or with associations of high risk of bleeding, so the use of omeprazole was not justified.

One month later, 35.3% (6/17) of the interventions have been accepted, suppressing omeprazole from treatment in 5 cases and reducing to a minimum dose in 1 case.