P146 USE OF FAILURE MODES, EFFECTS AND CRITICALITY ANALYSIS (FMECA) TO IMPROVE SAFETY IN THE INJECTABLE CHEMOTHERAPY PRODUCTION PROCESS

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Abstract - Introduction
In concern for continuous quality improvement, we have undertaken to analyse the risks linked to in injectable chemotherapy production process in our hospital.
The aim of our work was to identify the likelihood and the causes for the process to fail at various steps and prioritise them to propose areas improvement.

Abstract - Material and method
We realised an analysis of risks according to the FMECA method applied in each step of the chemotherapy process (prescription, validation, manufacturing, and administration). All actors involved in chemotherapy process, pharmacist, technician, nurse and doctor review Ishikawa diagram to determine most important steps. For each step of the process, the causes and effects of failures were detailed, as well as improvement areas. The criticality index (CI) was calculated for each risk in terms of gravity (G) and frequency (F) according to the equation CI = F * G.

Abstract - Results and discussion
We identified 47 failure modes, of which 10 were unacceptable criticality requiring corrective actions. 28 failure modes had tolerable criticality under control and 9 of acceptable criticality with no action to be taken. The priority actions concern patient identity errors as well as the prescriptions errors and administration errors. The checklist of process of administering cancer medications was introduced. To reduce prescribing risks, a strengthening of communication between the oncology unit and the centralized chemotherapy unit was also proposed. For support processes, identified risk was related to the out of stock. Manufacturing was the best mastered processes in the circuit. However, improvements are to be considered in particular, the analytical control of preparations, the automation manufacturing to avoid musculoskeletal disorders and also the use of systems without needles.

Abstract - Conclusion
This work has identified areas for improvement in injectable chemotherapy process in our hospital. It highlighted the risks generated by supply disruptions (cessation of treatment, patient recusal, and change in the concentration of the specialty). Risk analysis should be seen as a dynamic and continuous tool for improving quality.

P147 ESOP's yellow hand: are the pharmaceutical laboratories really are devoting all the necessary?

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Abstract - Introduction
Anticancer drugs are carcinogenic, mutagenic and/ or reproductive toxicity so must be handled with caution. ESOP (European Society of Oncology Pharmacy) has issued recommendations for the transport of cytotoxic drugs: a "yellow hand" logo indicating the danger of cytotoxic products and the precautions to be taken.
The aim of our work was to assess the use by pharmaceutical companies of the "yellow hand" logo during the transport of anticancer drugs.

Abstract - Material and method
Data collection occurred between August 2020 and November 2020.
Upon the delivery of anti-cancer drugs, we check on packing for the ESOP "yellow hand" logo or other "anti-cancer" notification. For each intake, the logistician writes on the receipt book: the date, the name of the pharmaceutical laboratory and the anti-cancer drugs, the presence of the ESOP "yellow hand" logo or other "anti-cancer" notification. The data was then processed into an Excel file for analysis.

Abstract - Results and discussion
Over the study period 138 orders for anti-cancer products were received. These receptions concerned 17 pharmaceutical companies.
Anticancer drugs are classified into 2 groups: cytotoxic anticancer drugs requiring an "anticancer" logo and monoclonal antibodies that do not require a logo.
Two pharmaceutical companies (CELGENE, SANOFI) delivered anti-cancer drugs with the logo recommended by ESOP "Yellow hand". Eight pharmaceutical companies (ACCORD, FRESENIUS KABI, JANSSEN, LILLY, PFZIER, PIERRE FABRE, SANDOZ, TEVA) use other "anti-cancer" notification logo. However, this logo does not mention the precautions to be taken with anticancer drugs.
Monoclonal antibodies anti-cancer from BMS, MERCK SERONO, MSD, ROCHE, SANDOZ laboratories were delivered without "anti-cancer" notification logo. SANOFI laboratory delivers its monoclonal antibodies with the ESOP "yellow hand" logo. Four laboratories do not use "anti-cancer drugs" notification logo (BAXTER, MEDAC, MYLAN and PHARMA MAR).

Abstract - Conclusion
To complete our work, we called the pharmaceutical laboratories that do not use ESOP's yellow hand. One pharmaceutical companies did not respond. Others do not know or prefer to use their own logo.
ESOP's Yellow hand is not very much used by pharmaceutical companies.
This work allowed taking a picture on the use by pharmaceutical laboratories of the yellow hand "ESOP recommendation".

P148 Quality and economic value of returned unused oral targeted anticancer medication from patients and measures to reduce medication waste.

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Abstract - Introduction
The use of oral targeted anticancer medication has been increasing in the last years and decades. Medication waste is an escalating problem worldwide with harm to the environment and nature, and waste of resources.

Abstract - Material and method
This retro- and prospective research study was conducted at Landspitali Hospital. A retrospective data collection for one year in 2020, for the use and economic value of TKIs for cancer patients. A prospective data collection from January to March 2021, for the quantity and quality of returned TKIs, reasons for return and ecomomic value. A questionnaire was sent to cancer patients and healthcare professionals to examine their attitutes to medication waste, return of medication, redispensing, willingness to use returned medication and activities to reduce medication waste.

Abstract - Results and discussion
A total of 453 treatments with TKIs were issued in 2020 for 283 individual cancer patients. The total economic value of the medication dispensed in 2020 was 608 million ISK (4.2 million EUR).
A total of 2,193 prescription units of returned medication was collected and the total economic value of 24 million ISK (168.000 EUR) calculated. Around 71% of the returned medication was reusable according to specific quality criteria, which could have saved up to 75% of the economic resources.
The most common reasons for return of medication was discontinuation of treatment due to adverse effects and progress of cancer.
The attitudes of patients and healthcare professionals and willingness to redispense and use returned unused medication was very positive. The vast majority of healthcare professionals suggested that improvements were needed in procedures in order to be able to reduce medicinal waste.

Abstract - Conclusion
The economic value of TKI treatments for cancer patients is very high. The quality of returned medication, is very good and suitable for redispensing. The results of this study suggest that the perspectives of patients and healthcare professionals are very positive and supportive, for the implementation of procedures to minimise medication waste, through redispensing of unused returned medication.

P149 National Cancer Information System, Ireland – configuring a national drug file and regimen library

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Abstract - Introduction
The National Cancer Information System (NCIS) is a clinical information system that supports the care of oncology and haemato-oncology patients across Ireland. NCIS will be rolled out to all 26 publicly funded hospitals providing systemic anti-cancer therapy (SACT) services; to date, NCIS has been implemented in 6 of these.

Key functionalities of NCIS include prescribing, electronic medication administration records, support for aseptic compounding, MDM, documentation and reporting. Configuration of NCIS is completed nationally and includes a drug file and regimen library.

Abstract - Material and method
The National Cancer Control Programme develops national chemotherapy regimens. These regimens are paper-based and required a manual process for transcription into NCIS. The drug file underpins the regimen build and in the absence of a national drug file, a bespoke drug file needed to be built.

Keeping quality and clinical safety to the fore, a broadly similar approach was adopted for both the drug file and regimen library build in NCIS:
1. Define the governance
2. Define the scope
3. Develop a build and validation process
4. Testing
5. Review and apply learning for continuous improvement

Abstract - Results and discussion
1. The governance of the build and maintenance phases was defined and approved by the project Implementation Group. This included: build, change management, data standardisation and definition.
2. The scope was expanded to include supportive medications to ensure a complete longitudinal record of cancer treatment was attained.
3. A multi-step build and validation process, using the four-eye principle was designed to ensure data quality and accuracy.
4. The test process included applying each regimen to a test patient as part of a standardised testing template, scenario testing for elements such as drug stability and unit testing for updates and changes.
5. Learning from these phases is fed back into the development process as a component of the NCIS quality improvement cycle.

The NCIS drug file currently contains >1500 lines of data, including 172 parenteral SACT medications, 75 oral SACT medications and 82 supportive medications. The regimen library has >300 regimens available.

Abstract - Conclusion
A constant process of learning and development is required to ensure the NCIS drug file and regimen build continues to meet the needs of the end user and the project objectives. Learning from the build and testing phases and feedback from users is fed back into the development process. This is an integral part of the NCIS quality improvement cycle, which iteratively informs the build.

P150 Improving the safety on the pathway of patients receiving CAR-T cells: risk analysis at the Pitié-Salpêtrière hospital

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Abstract - Introduction
CAR-T cells are advanced therapy medicinal products commercialized since 2019 and considered as a medical revolution in the haematology field. This high-risk treatment couldn't be used without scaling up or establishing a specific hospital organization. In fact, medication and patient pathways are interdependent. Moreover, these pathways require a multidisciplinary expert team throughout the CAR-T patient's treatment pathway. This work aimed to improve patient safety by highlighting risks and proposing corrective and preventive actions (CAPA) before first CAR-T cells administration on site.

Abstract - Material and method
We assessed risks taking into account all the key steps of both pathways (patient, treatment), from patient selection to toxicities management. We have opted for Failure Mode and Effect Critical Analysis (FMECA) method. The risks associated to each step were scored based on their severity, occurrence and detectability to set up a criticality index (CI). Based on this CI, all identified risks were ranked as acceptable, moderate or unacceptable (major risks that must be addressed through actions plans). CAPAs were set up for most of failure scenarios, first and foremost for unacceptable risks.

Abstract - Results and discussion
For 111 failure modes identified, 9 % were evaluated as unacceptable (n = 10), 34 % moderate (n = 38) and 57 % acceptable with no action required (n = 63).
Most of unacceptable risks were related to infectious risks and specific CAR-T cells toxicity management. Frequency and detectability of these risks were improved thanks to specific guidelines and multidisciplinary expert team communication. As multidisciplinary expert team communication was identified as the key requirement for the successful risk management of the CAR-T cells hospital pathway, we set up specific checklists and communication channels. In addition, several particular risks related to CAR-T product handling were highlighted such as risks related to genetic modified organism or nitrogen manipulation. Those risks were scaled down by using specific operational procedures and by setting up specific staff trainings.
This study limits included a lack of analysis of cell therapy unit processes.

Abstract - Conclusion
Risk analysis and CAPAs set up permitted to anticipate and mitigate failure modes related to the CAR-T cells hospital pathway. This study highlights the need of a specific organization and the implementation of a standardized communication in the multidisciplinary team to ensure the risk management, secured practices and optimal outcomes for patient care.

P151 Destruction of chemotherapy preparations after non-compliant analytical control: what types of errors and for which molecules?

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Abstract - Introduction
The chemotherapy preparations in our unit are subject to a pre-release control. 56% of the production has an analytical control (AC) with HPLC or UV/Raman spectrophotometry.
If the result of the AC deviates from +/-15% of the target concentration, a second sample (SS) is collected. If this one is still outside the accepted values, the bag is destroyed and then remanufactured.
This study aims to characterize the types of preparations destroyed after SS and their causes.

Abstract - Material and method
A 3-year retrospective study (2019-2021) was conducted. Data were extracted from an Excel® file filled with the traceability of SS controls. The reasons for non-conformity (NC) and the SS rejection frequency by molecule (number of bags destroyed out of the number of preparations made for each molecule) were analyzed.

Abstract - Results and discussion
1,419 bags were subjected to SS, which represents 1.28% of the analytically controlled production. Of these, 848 (60%) were released. The main NC related to production were: insufficient homogenization of the bag (679; 80%), and a pharmaceutically validated volume- or solvent-error (55; 6%). 105 NC (12%) were related to laboratory operations, such as equipment failure or insufficient volume.
571 SS analyses led to the destruction of the bags: 471 drug's volume NC ($|\text{mean}| = 23\%$ [-99%; 134%]), 55 solvent volume NC, 36 qualitative NC (including 22 wrong molecules), and 8 NC related to laboratory operations. The cost of destruction is €158,510 (€52,8327 per year).
5 molecules had a destruction frequency higher than 1%: carmustine (3.04%), ganciclovir (2.00%), fludarabine (1.30%), docetaxel (1.19%) and carfilzomib (1.15%). Of these preparations, 78 (62%) were powder-based and 83 (66%) had a product volume ≤10 ml.

Abstract - Conclusion
AC, unlike other techniques (e.g. video), highlights homogeneity defects (46% of SS). The low rate of NC due to the laboratory running (8% of SS) shows its robustness. Qualitative NC are a small proportion of SS (2.5%). The recent acquisition of 5 Drugcam® will allow us to control the preparations highlighted as difficult by this study and detect the NC before manufacturing the bags.

P152 A simulation tool to evaluate experimental drugs preparation practices

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Abstract - Introduction
Injectable experimental drugs are prepared by the pharmaceutical team at Lyon Sud Hospital (Hospices Civils de Lyon), involving pharmacists to analyse prescriptions according to clinical trials protocol and technicians to prepare experimental drugs. This work aims to evaluate the experimental drug preparation practices of the pharmaceutical team, through error simulation.

Abstract - Material and method
Simulations of experimental drug preparations were set up using tray photos showing experimental drugs vials, associated medical devices and corresponding manufacturing sheets. Errors were deliberately made in the manufacturing sheet or in the tray. For some preparations, there were no errors. Each participant was allocated a set of 6 trays, 4 with an error (medical devices error, a product error, a billing error and a manufacturing sheet error) and 2 trays without error. Participants had 3 minutes per tray to find the error or the absence of error. A pharmacy resident and a pharmacy technicia

Abstract - Results and discussion
We created 133 trays corresponding to 34 clinical trials and 45 different experimental drugs. 79 trays (59%) had an error: 32 medical devices errors, 32 manufacturing sheet errors, 11 experimental drugs errors and 4 billing errors. 15 pharmacy technicians (12 for chemotherapy and 3 for clinical trials) and 11 pharmacists (9 for chemotherapy and 2 for clinical trials) carried out the simulation. The overall success rate was 86.5%. The majority of undetected errors involved trays with a manufacturing sheet error (46.2%). Other common errors were medical devices errors (11.5%), experimental drugs errors (11.5%) and billing errors (7.7%). The success rate for technicians and pharmacists was respectively 82.2% and 92.4%.

Abstract - Conclusion
This evaluation of professional practices highlighted the errors not detected by the pharmaceutical team during experimental drugs preparation. Missed errors are mainly related to the interpretation of the manufacturing sheet (expiry date, treatment number, etc.). The presentation of corrected trays allowed the participants to identify their mistakes and retrain themselves on critical points of ex

P153 Implementation of an Advanced Therapy Medical Product (ATMP, Tabelecleucel) in a University Teaching Hospital in France. Application of the Preliminary Risk Analysis Method

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Abstract - Introduction
Tabelecleucel is an Advanced Therapy Medicinal Product (ATMP). It consists in allogenic cytotoxic T lymphocytes specific for Epstein - Barr virus antigens. It is available in Europe under compassionate use to treat post transplantation lymphoma. ATMP are currently managed by the anticancer drugs reconstitution unit in our institution. In order to secure tabelecleucel pharmaceutical circuit, we implement preliminary risk analysis (PRA).

Abstract - Material and method
We examined this risk through a PRA in order to identify, evaluate, and reduce the risk of this tabelecleucel circuit. According to PRA guidelines, a multidisciplinary team developed a flow diagram of the process and identified the main subprocesses and main hazards. Brainstorming sessions were organized to create and rate scenarios, and the PRA team developed a risk management plan to reduce the more critical risks.

Abstract - Results and discussion
The global risk mapping identified 56 very vulnerable hazardous situations, which led to the description of 73 scenarios and revealed 12 hazards: Professional know-how, Human Factors, Equipment/ materials, Financial, Legal, Information technology, Environment, Organizational, Programmatic, Patient's condition, Treatments, Professional risks professional. Before the intervention, we found 41% unacceptable scenarios and 59% tolerable, under control scenarios. The risk reduction actions taken by the group concerned the entire process. After implementation of risk-reducing actions, all the average risks, by step, became tolerable. Some risk reduction actions consisted in specific subprocess validation (for instance validation of the delivery process, cartography of facilities,…). Residual risk would be controlled with the implementation of a dedicated ATMP team and reconstitution unit.

Abstract - Conclusion
Finally, PRA, which allows “risk zooming” on a specific drug circuit, constitutes a useful method to detect failure and avoid accidents in clinical practice. Former ATMP specific organization in our institution will improve risks control

P154 Implementation of the Advanced Therapy Medical Product (ATMP) Tisagenlecleucel in a University Teaching Hospital in France. Application of the Preliminary Risk Analysis Method

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Abstract - Introduction
Tisagenlecleucel is an Advanced Therapy Medicinal Product (ATMP). It consists in Chimeric Antigen receptor T lymphocytes to treat paediatric patients with B-cell acute lymphoblastic leukaemia and adults with lymphoma. Delivered in cryo-shipper under liquid nitrogen vapor, it is stored in an ultralow temperature freezer (-150°C) and then must be thawed before infusion. ATMP are currently managed by the anticancer drugs reconstitution unit in our institution. In order to secure Tisagenlecleucel pharmaceutical circuit, we implement preliminary risk analysis (PRA).

Abstract - Material and method
We examined this risk through a PRA in order to identify, evaluate, and reduce the risk of this Tisagenlecleucel's circuit. According to PRA guidelines, a multidisciplinary team developed a flow diagram of the process and identified the main subprocesses and main hazards. Brainstorming sessions were organized to create and rate scenarios, and the PRA team developed a risk management plan to reduce the more critical risks.

Abstract - Results and discussion
The global risk mapping identified 37 very vulnerable hazardous situations, which led to the description of 55 scenarios and revealed 11 hazards: Professional know-how, Human Factors, Equipment/materials, Financial, Legal, Environment, Organizational, Programmatic, Patient's condition, Treatments, Professional risks professional. Before the intervention, we found 29% unacceptable scenarios and 71% tolerable, under control scenarios. The risk reduction actions taken by the group concerned the entire process. After implementation of risk-reducing actions, all the average risks, by step, became tolerable. Some risk reduction actions consisted in specific subprocess validation (for instance validation of transfer of the drug to freezer backup in worst cases situations, cartography of ultra-low temperature freezer as well as water bath, duration of thawing measurement). Residual risk (18% tolerable scenarios) would be controlled with the implementation of a dedicated ATMP unit.

Abstract - Conclusion
Finally, PRA, which allows "risk zooming" on a specific drug circuit, constitutes a useful method to detect failure and avoid accidents in clinical practice. Former ATMP specific organization in our institution will improve risks control

P155 Securizing advanced therapy medicinal product (ATMP) tabelecleucel delivery

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Abstract - Introduction
Tabelecleucel is an Advanced Therapy Medicinal Product (ATMP). It consists in allogenic cytotoxic T lymphocytes specific for Epstein - Barr virus antigens. It is available in Europe under compassionate use to treat post transplantation lymphoma. After reconstitution, it must be delivered maintained between 15°C and 25°C before administration. We validate our delivery process (temperature and time to deliver to clinical service).

Abstract - Material and method
Temperatures of transport containers and rooms were recorded with temperature sensors Rooms, in which containers were put, were thermostatically controlled in order to reproduce outdoor worst cases (winter/summer temperatures, 7.6±0.5°C/31.3±0.4°C, respectively). Two eutectics plates were conditioned, according to worst cases (25°C ±0.7°C for winter / 16,5±0.3 °C for summer) and then put inside containers. Temperature inside containers were measured, until 15°C or 25°C were reached, in both worst cases. Time to deliver to clinical service were measured. Experiments were done in triplicate.

Abstract - Results and discussion
For winter conditions (eutectic at 25°C and external temperature at 7,6°C), temperature remained between 15 and 25°C for at least 30 minutes. For summer conditions (eutectic at 16.5°C and external temperature at 31.3°C), temperature remained between 15 and 25°C for at least 50 minutes. Ten minutes and 24 seconds ± 28 seconds were needed to deliver treatment.

Abstract - Conclusion
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P156 Securing the administration of chemotherapy prepared in syringes for administration by electric syringe pump

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Abstract - Introduction
Some cytotoxic drugs (cytarabine, idarubicin...) can be administered by electric syringe pump (ESP) over 24 hours. In our hospital, it represents 400 preparations per year. Currently there is a risk of chemical contamination for nurses and hospital environment during the connection and disconnection of the material in contact with chemotherapy. To limit these risks, we assessed 5 models (M1 to M5) of assemblies with sterile medical devices (SMD) allowing to work in a closed system: a secure cap (Spiros®) and a tubing for ESP, both equipped with a bidirectional valve.

Abstract - Material and method
Model differences related to the type of cap (luer lock for M1 and M2; secure cap for M3 to M5) and the type of tubing process (with flushing at the end of administration for M2 to M5). M4 and M5 included a tubing for ESP with valve and M5 associated the purge with solvent before administration. Administration of 5 chemotherapy preparations was simulated for each model with fluorescein. Contamination was assessed by visual inspection using a UV lamp. For each model, the number of actions of the nurse was collected to assess feasibility; the additional cost in SMD was estimated.

Abstract - Results and discussion
M1 was the most contaminating. M5 (syringe – secure cap – tubing ESP with valve, purged with solvent before administration and flushing at the end of administration – three-way valve) appeared to be the lest contaminating (2 points of contamination), while bubbles were observed in the solvent-purged ESP tubing when connecting the syringe. At-risk steps of contamination were identified, both at connection and disconnection of the tubing ESP to the 3-way stopcock. The number of nurse actions for assemblies varied between 7 (M1) and 15 (M5). M4 and M5 represented an annual additional cost of 863€.

Abstract - Conclusion
The current practice to administer cytotoxic drugs by electric syringe pump is the most contaminating. Using closed system devices seems to be interesting but assemblies are more complex for nurses and represent an additional cost. Further studies have to be planned.