Organisation and management

P114 Observational study of cytotoxic drugs administration practice in oncology day hospital

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Abstract - Introduction
Anticancer intravenous drugs have more often as narrow therapeutic index and are defined as risky drugs to patients. In order to avoid the occurrence of serious adverse events, it is recommended to control and follow the steps of cytotoxic drugs administration. The aim of this study was to analyze the discrepancies between nursing practices and the chemotherapy protocol prescribed by oncologist (cytotoxic drugs and premedication including rinsing).

Abstract - Material and method
A prospective observational study of drugs administration practice in oncology day hospital was conducted. Three observers from the pharmacy specifically trained in the direct observation technique followed nurses during their administration rounds. They recorded the drugs administered to patients using a standardized collection data sheet including the patient identity, molecule, dose, duration and rate of infusion. The primary outcome was the rate of molecules administered with at least one discrepancies in practice using the prescribed protocol as reference.

Abstract - Results and discussion
In total, 29.4% of the administered molecules (n=126) showed at least one discrepancies between protocole and practice, with a significant difference ($p < 0,05$) depending on the type of molecule: 3.1% of mismatch for the anticancer drugs (n=64) versus 56.4% for the premedication drugs (n=62). For anticancer drugs, no difference was observed concerning the molecule and the dose, two discrepancies in infusion rate were observed. For premedication drugs, 68.6% of the observed differences were related to the infusion duration, 11.4% to the dose, 8.6% to the order of anticancer or premedication drugs administration, 8.6% to premedication drugs not administered (due to anticancer drug cancellation) and 2.8% to premedications administered with a different diluent. Some differences can be explained by an oral modification of the medical prescription (i.e. perfusion duration for cytotoxic drugs)

Abstract - Conclusion
The study highlighted discrepancies from the prescription for more than half of the patients and the lack of traceability of these decisions. However, no adverse event occurred. In order to reduce discrepancies in administration, smart administration pumps connected to the prescription software have set up to secure administration.

P115 Outpatient administration of blinatumomab for acute lymphocytyc leukemia

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Abstract - Introduction
Blinatumumab is drug approved for relapsed ALL which is administered continuously during a 28 days infusion. Due to the risk of toxicity, it is initially administered in the inpatient setting and then transitioned to the outpatient, requiring an important interdisciplinary coordination.
The aim of this study was to describe our experience transitioning this high economic impact drug from inpatient to outpatient setting.

Abstract - Material and method
Pharmacy and haematology services designed a workflow for the outpatient administration of blinatumomab.
Firstly, we reviewed blinatumomab stability, material compatibility and transfer set for both hospital and domiciliary administration (DA).
Then, we coordinated with the haematology service the patient´s scheduled visits to the hospital to replace the infusion bag.
Finally, we reviewed all patients who received blinatumomab from May 2020-December 2021 in outpatient administration and evaluated the potential problems which could be associated with it.

Abstract - Results and discussion
Reconstituted blinatumomab may be stored at refrigerated for up to 24 hours. Prepared infusion bag (with preservative) may be stored at room temperature (up to 27°C) for up to 96 h and for up to 10 days refrigerated.
Patients began treatment on Monday, Thursday or Friday, in order to avoid visits during weekends. Once they discharged, the just came to the hospital to change the infusion bag every three or four days.
In order to take advantage of the rest of the vial, we diluted it in a new bag with stabilizer solution. We noted the date of elaboration and the amount of medication remaining.
We used this previously prepared preparation in each new patient visit and added the necessary dose to complete it, including an in-line filter. We primed the filter with the prepared solution.
Three out of four patients who received blinatumomab have benefited of this circuit.18 infusion bags were administered at home, avoiding 68 days of hospital admission. No patient had problems due to the DA.

Abstract - Conclusion
Blinatumumab outpatient administration was a safe alternative in our center. This administration offers several potential benefits: reduced exposure to hospital infections, less disruption of routine life, lower health care cost, … Since blinatumumab is an expensive therapy and their use is not very common, there is not much evidence and our experience could help other Pharmacy Services.

P116 Environmental contamination of a dematerialized chemotherapy production unit: current situation and future prospects

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Abstract - Introduction
The number of cancer in the world is constantly increasing. This leads to an increase in the production of antineoplastic drugs (AD) and therefore an increase of the exposition for manipulators.
The study was carried out in collaboration with the occupational medicine service in a dematerialized unit production composed with hoods. Its objectives were to identify areas contaminated by AD to improve practices, and to estimate the impact of this contamination on the health professionals (HP) as AD have carcinogenic, mutagenic and reproductive toxicity properties even at low doses.

Abstract - Material and method
Environmental samples were taken at the pharmacy and the cytotoxic reconstitution unit (CRU). Each sampling point (SP) corresponded to a single sampling made with an adapted sampling kit. Dosage were performed by an ultra high performance liquid chromatography coupled to a tandem mass spectrometer (UHPLC-MS/MS) which allowed detection of 15 AD, with low quantification limits: from 0.25 to 50 pg/cm2 of surface. In parallel, an assay in the urine of HP was performed. The residues of 5 AD were analyzed with a UHPLC-MS/MS method with limits of quantification of 2.5 ng/L to 20 ng/L.

Abstract - Results and discussion
A total of 27 SP were tested in the CRU and the pharmacy. Only one SP was under the limit of detection. In the CRU a majority of results were between 1000 and 10000 pg/compress (n=10 SP). The maximum concentration found (CMR) was 24509,6 pg/compress in the production area (PA). However, the contamination was not limited to the PA and extends beyond, into the storage area (SA) and even to the pharmacy where the CMR was of 5556.9 pg/compress even though vials are slightly handled there. Contaminations were for the most part hand-carried. Therefore, a reminder on the importance of changing gloves between each step of the circuit was made and a reinforcement of the surfaces cleaning protocols was studied. A protocol for decarting or cleaning AD vials should also be studied to mitigate external contamination, as well as the creation of a specific reception and SA. Urine samples (n=22) all came back negative to AD.

Abstract - Conclusion
Environmental contamination by AD spread the entire pharmacy. Thus, measures have been taken on the whole production circuit to limit them and more regular sampling and biomonitoring campaigns are planned to strengthen their monitoring, especially with the future classification of AD in the CMR substance list.

P117 Evolution of clinical trials in onco-hematology in a reference center: does it worth a dedicated structure?

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Abstract - Introduction
As part of the reorganization of our outpatient activity in onco-hematology (OH), questions were raised about the relevance of dedicating a specific structure to clinical research in this field. These questions arise all the more so as the proportion of OH clinical trials (CT) in our center has increased from 10% to 45% of all CT between 2000 and 2020. The aim of this study is to assess the evolution of this activity and thus to consider the interest of such a structure.

Abstract - Material and method
A retrospective data review of new CT related to OH in our center from 2016 to 2021 was performed. The evolution of 3 key indicators was assessed: distribution of OH CT among all CT, main OH indications and preferred routes of administration.

Abstract - Results and discussion
Over the period 2016-2021, OH CT represented an average of 32% of newly activated CT corresponding to 34% in 2016 and 48% in 2021 (approximately 90 CT start each year for a total of 420 CT in our center). A short decrease was observed in 2019 and 2020, 25% and 24% respectively, probably related to Covid-19. In terms of sterile preparations, OH represented steadily more than 60% of our activity over the period. The main indications were lymphomas (30%), acute myeloid leukemias (AML - 19%), myelodysplastic syndromes (12%) and CT related to transplant center (12%) in steady distribution overtime. Only new CT in myeloma increased from 7% to 18% in relation with increased subcutaneous (SC) use of daratumumab. Regarding preferred routes of administration, an increased trend in oral and SC routes is observed (respectively 53% and 7% in 2016 *vs.* 69% and 28% in 2021). The increasing use of SC intensified in 2017 as part of the arrival of AML treatments combining azacitidine (SC) with venetoclax (oral). New CT using the intravenous route decreased from 70% in 2016 to 51% in 2021 even if bispecific antibodies araised in 2021. Focusing in 2021, 1359 visits (772 in day hospital for protocol chemotherapy and 597 for oral treatment) were observed, *i.e.* 6 patients per day.

Abstract - Conclusion
This review showed OH's activity growth in our center. The increasingly frequent use of SC and oral routes requires that patients be fully informed and trained about their own management. In this context, a pharmacist has its place and could best inform patients about the adverse effects of new complex therapies (antibodies, targeted therapy). A unique place, organized and dedicated to clinical research in OH, would allow patients benefiting from a structured and exhaustive support as well as meeting all the healthcare professionals involved and finally ensuring the conditions for optimal care.

P118 Improving healthcare organization of patients treated by anticancer oral therapy: what expectations?

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Abstract - Introduction
To date, more than half of cancer patients received oral therapy(OT) during their treatment course. OT have highly modified cancer patients' management and changes practices. At home-treatment improves patient quality of life and autonomy, and involves patients in their own care. Nevertheless, close watchfulness of adverse events and non-adherence to treatment is important. For nearly 10 years, pharmaceutical consultations for home-based anticancer OT patients are proposed on medical request. Organizational changes led us to integrate dedicated nurses to create an Oral Therapy Unit (OTU).

Abstract - Material and method
This was a prospective monocentric study of the healthcare professionals and patients' needs and expectations for the implementation of a new home-based anticancer oral therapy course of care. The first questionnaires helped to set up this new care pathway, and, few months later, the second was used to assess the impact of this new support for patient care and health professionals' organization.

Abstract - Results and discussion
With the new OTU pathway, professionals expect a patient course improvement (94%), a better compliance (88%), a therapeutic accidents reduction (81%) and an improvement in the patient-caregiver relationship (69%). Regarding the organization, 56% of them are expecting to save medical and pharmaceutical time. Two key ideas emerged from this study: the first point is the patients support with multi-professional teams to promote efficient and high-quality care, the second concerns the health care organization with supporting coordination and task shifting. The OTU deployment has improved both: patient information and healthcare professionals' organization. The OTU surveys have highlighted organizational aspects to be improved and challenges to be experienced for multidisciplinary unit creation specific to home-based anticancer oral therapies.

Abstract - Conclusion
The OTU creation in our center and these new multi-professionals' teams' management of patients has obtained a favourable opinion from healthcare professionals and patient satisfaction. This organization based on multidisciplinary health professionals benefits from a financial valuation which has led to health staff recruitment in our center, supporting the OTU deployment.

P119 Application of a Lean Six Sigma methodology for the organization and production of chemotherapy

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Abstract - Introduction
Improving the efficiency of organizations is today a challenge for healthcare establishments,which must provide high quality care to patients while reducing costs and maintaining a pleasant working atmosphere. In recent years Lean Six Sigma has been very popular in all health sectors .The hospital pharmacy in turn is beginning to use this type of process derived from industrial engineering in a context of economic constraints and quality, safety and efficiency requirements.The aim of work is to present the DMAIC approach and the Lean tools that can be adapted in a cytotoxic reconstitution unit

Abstract - Material and method
The application of the DMAIC method and Lean tools and methods such as the search for waste, value stream mapping, just-in-time, standardization and simplification. This work leads to a reflection of a production team, under the supervision of pharmacists and lean expert professor of pharmacy is carried out according to a classic 5-step approach: Define: objectives, mapping, families of processes...
Measure: steps, duration of the process, trace of movements...
Analyze: added values of steps, waste, waiting times ; Implement: implement solutions;
Control: efficiency, performance, satisfaction

Abstract - Results and discussion
Several points for improvement have been proposed impacting the efficiency of the process classified into several themes, the main ones being: for space: reorganization of local (reduction in movements); with regard to stock and ordering: rationalization of stock and orders. In relation to the flow: smoothing the activity and the peak of morning production, by reviewing the double-blinding stages and using correctors. For the management component: creation of a "coordinator of the day" position and daily meetings to reallocate tasks...
The application of lean will optimize the process of preparing chemotherapy and save human time. The main actions were to eliminate production peaks and smooth daily activity, to reorganize roles, local and stock.

Abstract - Conclusion
The positive impact on the duration of the process, the production performance and the satisfaction of the production team demonstrate that lean is a tool to be promoted in cytotoxic reconstitution units.

P120 Personalized pharmacy center of Ukraine. Exceptional opportunities for patients

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Abstract - Introduction
Best practice in Ukraine of extemporaneous drug manufacturing in personalized pharmacy center.

Abstract - Material and method
New model of modern pharmacy for patient care and business development.
First compounding center in Ukraine according international standards of extemporaneous drug manufacturing.
First Ukrainian project which got license of Ukrainian government for manufacturing extemporaneous drugs and cytostatiques

Abstract - Results and discussion
First onco pharmaceutical web portal which gives opportunity of creating scheme of treatment online or choose it from the list of approved protocols .
Ready to use drugs option which gives to avoid dangerous carcinogenic and mutagenic effects of cytostatics on the body of medical personnel while diluting the solution in a hospital

Abstract - Conclusion
benefits for patients, high manufacturing standards, a new management model in the pharmacy, affordability for patients in low-income countries and social guarantees for free provision of medicines

P121 Risk mapping in a chemotherapy preparation unit (CPU) using a tool developed by a French regional health agency

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Abstract - Introduction
The chemotherapy circuit is a high-risk process for the patient, the professional and the environment. Self-evaluation must be done on a regular basis, in order to remain in a continuous improvement process.

Objective: Carry out a risk mapping at the chemotherapy preparation unit (CPU) level, in order to determine an action plan to improve the safety of the chemotherapy preparation activity.

Abstract - Material and method
The self-diagnosis is based on the ChimioPrep®[1] tool, developed by the Île-de-France regional health agency. This questionnaire allows to review the whole chemotherapy circuit, divided into three tabs: "Steering and management" (hygiene, quality, training, facilities...), "Process" (preparation from prescription to administration) and "cooperation - subcontracting".

[1] : http://www.omedit-idf.fr/medicaments-anticancereux-mise-a-disposition-par-lars-de-loutil-chimioprep/

Abstract - Results and discussion
Risk mapping showed that the majority of the chemotherapy process is controlled. However, a corrective action plan has been established to optimize the entire circuit.

The score for the "Process" tab is 70%: preparation is the point with the lowest score with only 47%. Continuous education and weekly training on protocols for preparers were thus introduced. Chemotherapy return circuit was also reviewed to ensure traceability to facilitate their reallocation. Traceability of non-conformities is now carried out daily and their management weekly.

The score for the "Steering and management" tab is 70%: quality and risk management part have a score of 38% while hygiene and communication get 100%. To improve risk management in the event of a cyber-attack or breakdown, various quality procedures are being improved.

The score of the "Cooperation - subcontracting" tab is 58%. A documentary update on risk management is planned, in cooperation with the contractor to improve this part.

Abstract - Conclusion
Following this analysis, critical points have been identified, especially on preparation part.
Some improvements have been made and must be continued in order to secure the whole process.

Moreover, this mapping will be a valuable decision support tool during the study phase of the new CPU planned for 2023.

P122 Human Intratumoral Immunotherapy (HIT-IT) or Interventional immunotherapy: an experience from a French Cancer Center

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Abstract - Introduction
HIT-IT consists of injecting directly into the tumor immunostimulatory molecules. This affects the tumor microenvironment by creating an inflammatory with neoantigens releasing, activating antigens presenting cells and recruiting cytotoxic lymphocytes. Our project aims to describe our hospital experience and management of intratumoral administrations.

Abstract - Material and method
We conducted a retrospective study from 2015 to march 2022, in a university hospital including HIT-IT clinical trials. The data were collected from our traceability software PharmEssai® (JK concept™) and trials documentations.

Abstract - Results and discussion
28 HIT-IT clinical trials had been set up on our site: 18 ongoing. 200 patients [62 years ± 6.4 y] were treated, sex ratio M/F 1.4 and ECOG 0-1. All had unresectable advanced or metastatic tumors, relapsing after conventional therapies. Most of the studies (36%) aim to treat all kind of solid tumors.78% of our HIT-IT trials combine two immunostimulatory agents. The IT agents in our trials are: oncolytic virus GMO 1 (40%), Immune checkpoint inhibitors (24%), PRR agonists (12%), cytokines (12%) and nanoparticles (12%).The products are prepared by the hospital pharmacy in IIB class BSC. 606 syringes were prepared. The IT administration can be superficial or deep, considering the tumors' localization. An interventional radiologist and an operating room are mandatory. 60% IT products expire within 8 hours, including six (24%, and 100% oncolytic virus) expire with 5 hours. Patients are isolated if the IT product is a GMO. Most of the time, the product is injected on an outpatient basis.

Abstract - Conclusion
The number of HIT-IT trials ongoing in our center increase and most of the products are advanced therapy (ATPM). A multidisciplinary HIT-IT meeting is organized to screen eligible patients and a multidisciplinary approach with a good coordination between the pharmacy and the clinical department are required to manage HIT-IT trials.

P123 Axitinib's distribution: between environmental impact and indirect costs

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Abstract - Introduction
In Italy, the 1st line treatment of advanced renal cell carcinoma (RCC) involves 4791 patients incidence/year eligible. The most innovative therapie implies the association of intravenous therapy (IV): Pembrolizumab 200mg IV/21 days and oral chemotherapy: Axitinib (56 cpr/pack) P.O./BIS. The Hospital Pharmacist (HP) can assist compliance and help to minimise costs such as: indirect costs (IC), often underestimated, by reducing the patient (pt) and/or caregiver's (CG) transfers, decreasing the environmental impact of CO2 emissions that, in 70% of the cases, are generated by road transportations

Abstract - Material and method
Considering the Axitinib's pack, to allign the therapies, both are given in the same day, unpacking the Axitinib and giving 42 cpr instead of 56, with the required documents.
For the IC we considered the average hourly earning (13,6€/h) and the time commitment that, in the worst case, is a 2h return journey (150km) to the dispensation point, and 0,5h to park, arrival, waiting time, drug pick-up and back in the car.
It has been considered an average diesel-engined utility car with 95g of CO2 emissions/km.

Abstract - Results and discussion
Each avoided trip to the pt/CG is 2h x 13,6€ = 34€ for missing productivity, and 68€ if both are involved.
The total IC avoided/year/pt is the number of avoided added journeys/year x 34€ = 306€ (612€ if both are involved).
The CO2 emissions is equal to 95g x 150km =14,25kg/dispensation/ pt or 128,25 kg/year/pt, equal almost to 2,3% of CO2 emission perceived in Italy, that, in worst case, times the incident pts/year that will become 614.000.
Considering also the financial factor, unpacking the Axitinib therapy, have produced 14.615,37€ saving/year treating n°5 pts as shown in the table below.

PT	€/UNPACKED DRUG/YEAR	€/PACK/YEAR	Savings/Year
1	25.280,64 €	33.707,52 €	8.426,88 €
2	3.950,10 €	5.266,80 €	1.316,70 €
3	1.580,04 €	2.106,72 €	526,68 €
4	3.950,10 €	5.266,80 €	1.316,70 €
5	9.085,23 €	12.113,64 €	3.028,41 €

Tot savings/year 14.615,37 €

Abstract - Conclusion
The HP is the only health professional to be trained to rightly unpack drugs to avoid that the delivery of the two drugs would coincide just 4 times in a year, affecting negatively the compliance, the IC, the PT's follow-up and environmental impact. This project shows that the HP is able to affect on more layers, clinic, economic, and environmental to benefit the PT, our NHS and the earth planet.