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for each step, the IPR (Risk Priority Index) and hypothesising possible corrective actions. The frequency of the bioburden test has also been modified. The overall IPR calculated in the preparation of the F18-labelled galenic radiopharmaceutical has a value of 120, while in the cold kit labelling process it is 90. The first process involves a greater number of steps (radioisotope production, synthesis, etc.), raw materials, and operator activity, with possible product contamination. Human error is estimated in our FMEA analysis as the main element of process failure. The critical evaluation (FMECA) indicated possible corrective actions to be implemented to lower the risk: training of personnel in dressing, standardizing operating procedures to improve reproducibility and minimize human error, and greater attention to cleaning and disinfecting the premises. The bioburden test reported no microbial growth. The CCS performed through the integration of the two FMEA/FMECA analysis methods highlighted a higher risk of contamination in the preparation of the sterile 18F-labeled galenic product. However, it is possible to keep production processes under control by paying greater attention to dressing and cleaning procedures in order to obtain a quality product that complies with Annex 1.

Key words: Annex 1, CCS, nuclear medicine.

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P0600

APPLICATION OF FMECA ANALYSIS FOR THE PREVENTION OF THERAPY ERRORS IN A UFA

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The preparation of antineoplastic drugs is an activity that carries a risk of error for the patient. In addition to the strategies that are implemented on a daily basis to minimize errors (procedures, operating instructions, computerized prescription and preparation), FMECA (Failure Mode and Effects Criticality Analysis) can be used, a proactive methodology that assesses the probability of an event occurring and, if necessary, the actions to be taken to mitigate critical issues. The analysis was conducted in the UFA of a second-level hospital in Lazio, as part of the process carried out to maintain ISO 9001:2015 certification. The aim of the work was to identify the stages most at risk of error during preparation a n d to find risk mitigation strategies. Initially, the regulatory (Ministerial Recommendation 14) and organizational (Procedures and Operating Instructions) requirements governing the entire macro-process were considered; then proceeded to apply five steps: process selection, establishment of a multidisciplinary team of pharmacists and nurse preparers, data collection, analysis, and development of improvement actions. As per protocol, the preparation process was broken down into sub-processes, for each of which the RPI (Risk Priority Index) was calculated, taking into account the following parameters: G (severity of the consequences of an error), P (probability of the event), and R (detectability of the error). Using a rating scale, a score between 1 and 10 was assigned t o G, P, and R, and the RPI was then calculated by multiplying the three values. Of the eight sub-processes analyzed, those most susceptible to error were: the preparation/control phase concerning the use of medical devices, with an RPI of 64, due to forgetfulness, incorrect choice of device, or incorrect indication on the patient-specific work sheet; the dilution phase, which involves an error in the type of diluent used by the nurse, with an IPR of 40; the reconstitution/dilution phase, in terms of microbiological contamination from incorrectly performed handling techniques, with an IPR of 32. The IPR scores were compared with a qualitative and quantitative risk and severity assessment table, which showed that only one sub-process was at medium risk, while all the others were low risk. The use of FMECA analysis made it possible to identify areas of risk and plan specific, targeted corrective actions, such as the introduction of double checks for the medium-risk phase and updates for the low-risk phases.

Key words: FMECA analysis, oncological galenics, clinical risk.

P0601

PROSPECTIVE EVALUATION OF THE PERFORMANCE OF A ROBOTIC SYSTEM IN THE PREPARATION OF ANCILLARY DRUGS AT AN ANTIBLASTIC DRUG UNIT (UFA) IN FRIULI-VENEZIA GIULIA

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The use of automation in the preparation of chemotherapy drugs has been documented in several scientific studies, while the use of robots for the preparation of ancillary drugs is less common. Primary objective: to evaluate the effectiveness of a robot for the preparation of chemotherapy drugs applied to the alternative field of ancillary drug preparation, in order to automate manual operations prone to error, freeing up man-hours and generating useful evidence for the national healthcare technology asset. Secondary objective: validation of the reliability and accuracy of dosing for volumes <2 ml. The robot used operates under a laminar flow hood and has an integrated gravimetric cell. Inserted in a class A hood, it allows the sterile production of ancillary bags in the UFA room (class B), with an output of 12 preparations per work list. The four drugs being tested are among the most commonly used in treatment regimens: metoclopramide MCP 10 mg/2 ml, dexamethasone DES 8 mg/2 ml, ondansetron OND 8 mg/4 ml, and chlorphenamine CLO 10 mg/1 ml. Master bottles of each drug are pre-prepared in accordance with the stability data in the literature, from which batches of final bags for administration are produced. A dosage and diluent constraint is set for each one. Data collection takes place in two parts: 180 preparations with the original system and 168 with software optimized for volumes <2 ml. In addition, 192 sample preparations are weighed with a certified external scale to verify the accuracy of the robot's gravimetric control. The first preparations with the original software show 12 bags (7%) that are non-compliant (NC). The average dosage errors (ED) reported by the robot for each drug are OND 1.84%, CLO 3.83%, MCP 1.42%, and DES 7.61%. Preparations with optimized software show only 1 NC bag (0.6%), with ED for OND 0.69%, CLO 1.67%, MCP 1%, and DES 1.78%. The average deviation between the weight measured by the device and the weight measured by the scale is: OND 0.03 g (0.85%), CLO 0.03 g (2.92%), MCP 0.02 g (1.2%), DES 0.07
g (3.49%). The average time taken for dosing is 1.12 minutes. Optimisation of the robot has improved accuracy for volumes below 2 ml. Gravimetric analyses confirm the reliability of the system in this area of application too, with deviations of less than 0.07 g (3.5%). In conclusion, the complete automation of the dosing process, the reduced setup time, and the versatility of the software settings confirm that this system is reliable and accurate, allowing for the repeatability and traceability of repetitive operations that would otherwise be prone to error.

Key words: setup, ancillaries, automation.

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P0602

THE VALUE OF GALENICS IN CLINICAL PRACTICE: SYNERGY BETWEEN HOSPITAL PHARMACY AND INTERVENTIONAL RADIOLOGY IN TRANSARTERIAL CHEMIOEMBOLIZATION AT A HOSPITAL IN LAZIO

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and implementation. The contribution of patients, who are experts not only in their own illness but also in public healthcare procurement, will bring added value to centralized purchasing procedures. With the involvement of expert patients in public health decisions, we expect to see improvements in the healthcare system and patient-centered care.

Key words: training, patient involvement, procurement.

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P0790

DEFINITION OF A PROTOCOL FOR PLANNING CONTROLS BASED ON RISK ASSESSMENT. MANAGERIAL MANAGEMENT OF A MULTIDISCIPLINARY TEAM BY A SPECIALIST PHARMACIST

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The activity of the Outpatient Control Operational Unit (NOC) consists of random checks on the correct provision of outpatient LEA services by contracted facilities, through the evaluation of medical records. Since 2023, the NOCs have been made up of a multidisciplinary group: 3 doctors, 1 healthcare assistant, 1 administrator, 1 IT specialist, and a specialist pharmacist as manager. Initial analysis highlighted the need to review the process in order to ensure transparency, consistency, and efficiency of assessments and to guarantee checks on all facilities within a reasonable time frame. A protocol was developed for weighing facilities based on risk grading, with the definition of appropriate multi-year planning, frequency, and types of checks. According to data from 2019-2022, 28 out of a total of 64 facilities were inspected, with inconsistencies in the assessments. The factors that define the complexity of the facilities were identified, including four facility indicators (number of branches, degree of complexity of services, economic output/year, average value of services provided); three outcome indicators (percentage of incorrect records based on a sample for the 2019-2022 reports, penalties applied, failure to send counter-arguments or delayed submission). The seven indicators have a score, defined by scales, and the sum of the scores expresses the 'basic risk' and 'outcome risk' of the structures. Overall, this gives the 'structure risk': the higher the score, the greater the degree of risk. The scores define: the frequency of checks (annual, biennial, triennial, or quadrennial), the need to repeat a check, and recurring anomalies (poor document quality, poor administrative-accounting quality). The Protocol has been automated to facilitate and standardize updates over time. The Protocol was applied, in the Pilot Phase, to the 2024 Regional Control Plan, and the objective was achieved by 102% of the target (180,932 out of 177,460). Eighteen facilities were inspected for clinical controls.

No. 34 Structures for administrative and accounting controls. The Protocol is applicable, effective, flexible, transparent, and standardized. It defines an objective method for multi-year planning of controls, through the risk grading of structures, and produces benefits: planning and guarantee of total verification of structures in four years, reasoned and documentable choices, favoring the improvement of the representation of services in the 28/SAN flow and the documentary quality of services to citizens. Pharmacists are able to guide change through management tools.

Key words: risk grading, indicators, planning.

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P0791

ASSESSMENT OF THE ORGANIZATIONAL AND OPERATIONAL IMPACT OF AUTOMATION IN THE PREPARATION OF INJECTABLE ONCOLOGICAL DRUGS: REAL DATA FROM A HOSPITAL EXPERIENCE

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The adoption of robotic systems for the preparation of injectable oncology drugs responds to the growing need to improve operator safety, ensure traceability, and optimize the use of human resources in hospital pharmacies. The study aims to assess the impact of the introduction of automation in terms of production efficiency, error rate, technical hours freed up, potential economic savings, and level of use. A retrospective analysis of preparations from January 1, 2025, to May 31, 2025, was conducted. The following were analyzed: number and type of work orders (WOs), average time per order and preparation, number of errors, rework rate, daily use, and staff utilization. The technical hours freed up and the productivity of the device were calculated. The robot was used on 87 out of 103 days (84%) to prepare 1,700 preparations, of which 1,626 were successfully released without errors (95.6%) and 74 (4.4%) with error notifications. The errors affected 62 ODLs out of 460 (13.5%) and required corrective action by staff: in 27 cases, the error was considered tolerable, while in 47 cases (2.7%), reworking was necessary. Currently, the robot handles 12 molecules, including 3 in multidose bags. Each ODL can contain up to 12 requests, using a maximum of 16 vials of medication. The average time per ODL was 14 minutes, with an average preparation time of 3 minutes and an average of 3.7 preparations per order. The total activity time was 109 hours, with an average productivity of 15 preparations/hour. The time saved was used for other laboratory-related activities such as material restoration or inventory. Utilization was lower on Thursdays and Fridays, due to the lower complexity of therapies and the closure of the external facility on Thursdays. Automation was limited for fixed-dose preparations, where the cost/benefit ratio was not favorable, and favored for highly complex preparations, where precision and safety represent added value. The robot handled an average of 20% (CI 6-41%) of daily requests, with an average dosing error of 0.41%. Automation ensured high precision and traceability, reducing staff exposure to cytotoxic drugs and freeing up technical hours for other activities. Stable productivity and a high success rate confirm the value of the system, especially on busy days, with significant potential in terms of efficiency and economic sustainability.

Key words: automation, logistics, oncology.

P0792

MANAGEMENT OF SHORTAGES AND REDUCTION OF WASTE OF INJECTABLE ONCOLOGY DRUGS: IMPLEMENTATION OF A TRACEABILITY AND DEPARTMENT-PHARMACY COLLABORATION MODEL

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In recent years, there has been an increase in shortages of injectable oncology drugs, with an impact on adequate supply and treatment planning. To address this critical issue, a project was launched to raise awareness in the oncology department about the waste of unused drugs and to strengthen logistical collaboration with the pharmacy. In the initial period between March and October 2024, the hospital pharmacist and laboratory technical staff tracked oncology preparations returned for disposal or potential reuse, recording their quantity and type.

logic involved. Analysis of data for January 2024 and January 2025 showed a marked improvement in waiting times: the average decreased from 23 to 12 minutes, and the most frequently recorded time fell from 16 to 4 minutes. The percentage of outpatients served within 15 minutes increased by 146%, while those with waits of more than 30 minutes decreased by 62%. The positive outcome of the IT systems integration tests made it possible to update the warehouse accounting records at the same time as the medication was delivered. The logistical reorganization and reduction in the use of internal transport systems made the delivery process faster and more reliable, which was unanimously appreciated by users. The volume of drugs dispensed remained stable, confirming that operational efficiency was maintained despite the change in processes. The application of the Lean model to the Direct Distribution process led to a measurable improvement in efficiency and service quality. The intervention demonstrated how the success of organizational transformation depends heavily on the integration of corporate strategies. The synergy between pharmacists, the Healthcare and Social Professions Management Department, administrative staff, and ICT staff proved to be a key element in the effective and sustainable implementation of a model that can be replicated in other complex healthcare contexts.

Key words: direct distribution, lean thinking, continuous improvement.

P0812

FEASIBILITY STUDY FOR THE ROBOTIZED PREPARATION OF READY-TO-USE SYRINGES FOR PEDIATRIC INFUSION THERAPIES: A PILOT PROJECT IN THE PEDIATRIC ANESTHESIA AND RESUSCITATION DEPARTMENT

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Errors during pediatric drug therapy represent a significant cause of risk. Thanks to its collaboration with a leading private robotics company, a tertiary hospital has launched a program to centralize and robotize the preparation of hazardous and, subsequently, non-hazardous sterile injectables: the Centralized Intravenous Additive Service (CIVAS). In 2016, a new robot was introduced for the preparation of customized/standard pediatric infusion therapies in syringes/bags. A feasibility study was conducted for the preparation of two ready-to-use, standard-dose, non-hazardous injectable drugs in collaboration with the Pediatric Anesthesia and Resuscitation Department. A workflow was designed for the management, preparation, and transport of drugs from CIVAS to the Department. The feasibility study consisted of three phases: analysis of the Department, evaluation of the 20 most requested active ingredients between September and December 2023 (source: company IT management system), analysis of chemical/physical/microbiological stability after reconstitution/dilution in polypropylene syringes or ethyl vinyl acetate bags (sources: RCP, Stabilis.org). Drugs in non-perforable vials, narcotics, solvents/electrolyte solutions were not evaluated. The study then focused on drugs with stability >24 hours between 2-8 °C. After consultation with the ward's medical and nursing staff, it was decided to prepare ready-to-use syringes of pantoprazole 4 mg/ml and cefotaxime 50 mg/ml. In order to evaluate the standard volume, infusion therapies prescribed between September and December 2023 were analyzed. A production batch of 10 syringes for each drug was prepared in order to assess their feasibility in the machine, sterility (aerobic, anaerobic, and fungal testing), and apyrogenicity (LAL test method). Pantoprazole was prescribed to 68 patients (353 doses) at a dosage of 4 mg/kg (maximum 40 mg/dose); 10 ml syringes were prepared to cover the needs of patients with a pro-dose >= 4 mg. (98% of patients). Cefotaxime was prescribed to 14 patients (128 doses), 11 of whom received a dose ≤ 1 g; 20 ml syringes were prepared for patients with a pro-dose ≤ 1 g (79% of patients). Pantoprazole was given a shelf life of 96 hours and cefotaxime a shelf life of 7 days at 2-8 °C, protected from light. The prepared syringes were found to be sterile and apyrogenic. After computerized prescription by the Department and validation by the Pharmacist, the drugs are prepared and sent to the Department with three daily deliveries (8, 11, 17), ensuring customization when necessary. The centralization and robotization of the preparation of standardized pediatric infusion therapies is emblematic in that it reduces individual variability in preparation and, therefore, related errors, ensuring high production performance in a single facility.

Key words: clinical risk, robotization, infusion therapy.

P0813

AUTOMATION OF ONCOLOGICAL DRUG PREPARATION: EXPERIENCE WITH CHEMOMAKER+®IN A UFA LABORATORY

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The introduction of automation in the preparation of chemotherapy drugs represents a significant advance in the field of hospital pharmacy. The model in question is an innovative automated system equipped with a double rotor, capable of handling up to 12 final containers and 16 vials of medication. The active ingredient is measured using a high-precision gravimetric scale. Since April 2025, this device has been successfully integrated into the activities of a UFA laboratory within a hospital in Sicily, connecting directly to the prescription software already in use. The installation took place inside a vertical laminar flow hood. The system was used simultaneously to create stocks of biological drugs, using the stability data reported in the respective SPCs (summary of product characteristics). This allowed for the advance preparation of therapies, stored in dedicated refrigerators, which are ready for administration. The purpose of this analysis is to evaluate the workload assigned to the system and the quality of this workload calculated as a percentage deviation from the prescribed dosage. Data relating to the preparation of anticancer drugs from March 31, 2025, to June 12, 2025, were analyzed, focusing on the active ingredients processed by the system: pembrolizumab, nivolumab, avelumab, cemiplimab, durvalumab, rituximab, docetaxel, and atezolizumab. The study examined the total daily production and distribution per drug, while also assessing the accuracy of the preparations in terms of percentage deviation from the prescribed dose. During the period considered, 301 preparations were made, the average number of patients treated per day at the facility was 60, and the robotic system was used in 23% of cases. According to the technical specifications, the robotic system in question is capable of dispensing doses with a maximum margin of error of ±1%. The data collected show an average deviation of 0.58%, with a peak for docetaxel, probably due to the extreme viscosity of the molecule. The most commonly prepared drug was atezolizumab, with 66 preparations, followed by avelumab (58), nivolumab (55), cemiplimab (44), and pembrolizumab.
(15), docetaxel (7), durvalumab (5), and rituximab (5). Staff involvement is only required for loading and unloading, allowing for significant savings in operator time, which can be reallocated to other activities. This experience demonstrates how automation represents a strategic step towards a future in which hospital pharmacies will be increasingly efficient, safe, and focused on quality of care. The robotic system helps to optimize resources, preparation times, operator safety, and the quality of therapeutic services offered to patients.

Key words: automation, safety, UFA.