Two phases: pre-implementation (1 month) and post-implementation (1 month) of the RM.

All preparations of parenteral antineoplastic drugs in the HPD were included in the analysis.

Standard local protocols for preparation and storing of remaining starting material (vials) were followed in both phases.

All remaining vials that exceeded the expiry date were stored separately and the amount of product within was measured. Finally, the cost for all discarded products was calculated in each phase and compared.

Results Expiry dates were reduced in only six drugs (9%) after modifying stability according to the RM.

The number of preparations in the anti-neoplastic preparation unit was 1479 in the pre-implementation phase and 1434 in the post-implementation phase.

Previous to the implementation of the RM, 1.01% of the cost of drugs prepared in the HPD was due to discarded product after storing dates were exceeded. After the implementation of the RM, this was 0.97%.

Conclusion The implementation of a risk matrix in the preparation of parenteral anti-neoplastics has no significant economic impact in terms of discarded product.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

3PC-058 ROBOTIC COMPOUNDING: SAFETY AND PRODUCTIVITY ACHIEVEMENTS IN THE PREPARATION OF HAZARDOUS DRUGS

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Background Robots arrived a few years ago to compounding units and, as a new health technology, it is necessary to assess their implications on safety and efficiency

Purpose Evaluate the impact on safety and productivity issues after the implementation of Kiro® Oncology.

Material and methods Failure mode, effect and criticality analysis were used to identify all risks related to the manual and robotic compounding processes. Criticality index (CI) was calculated for all of them, using a 1–4 scale.

The percentage of preparations within the ±5% accuracy range was evaluated by gravimetric control for nine common drugs prepared manually and using the robotic system.

To evaluate the role of the robot avoiding high-volume syringe handling, the number of preparations suitable to use 50 mL syringes (dose volume >20 mL) was estimated in a 6 month period (March–August 2018).

Robot productivity (mean and maximum number of preparations) was evaluated during 6 months.

Results Twenty-three failure modes were identified in the manual system, ahead of 14 for the robotic process, with a global decrease in CI of 32%. Risks with the highest scores were related to labelling errors.

Dosing accuracy was compared for 1031 manual preparations and 756 robotic preparations of carboplatin, cyclophosphamide, doxorubicin, epirrubicin, 5-fluorouracil, gemcitabine, irinotecan, oxaliplatin and paclitaxel. No statistically significant difference was observed between manual and robotic preparations (percentage within ±5%: 99.8% manual vs 96.9% robot; $\chi^2=1.11$, p=0.29).

Doses above 20 mL prepared during the evaluation period were 730±56 (mean ±SD) per month.

The mean number of daily preparations by the robot during the period studied was 50 (40% of total daily production), with a maximum of 90. Technical incidences and workflow interruptions were major obstacles in improving productivity.

Conclusion Robotic compounding might decrease the global risk of the process by the suppression of human intervention in some tasks. It showed similar accuracy rates to manual compounding in our setting. It has a major potential role avoiding stress injuries due to the repeated handling of high-volume syringes. Regarding productivity, the percentage of preparations assumed by the robot is still under expected; so, different strategies based on technical improvements and optimisation of cycle management should be implemented in the near future.

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No conflict of interest.

3PC-059 USE OF EXTEMPORANEOUS ORAL SUSPENSIONS OF OXYBUTININ AND PRAZOSINE IN NEONATES

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Background Primary bladder neck obstruction (PBNO) is a failure in which the bladder neck does not open appropriately or completely during voiding. α-Blocker together with anticholinergics are the pharmacological therapy that has shown some benefit in children. Off-label therapy with prazosin and oxybutynin was proposed in two neonates with PBNO.

Purpose To compound oxybutynin and prazosin correctly for dosing and administration in these patients and monitoring them.

Material and methods A bibliographic search of indication, dosage and formulation was made in Pubmed, Micromedex and other compounding pharmaceutical sources. Keywords: prazosin, oxybutynin, neonate, PBNO.

Clinical monitoring and interviews were carried out with the parents of two neonates (5 and 12 months' old) in treatment from the first month of life to the present.

Results We did not find any bibliographic reference describing its use in neonates.

Initially, we formulated sachets with their specific dose. Later, we formulated in suspension, 100 mcg/ml prazosin and 1 mg/ml (minurin) and oxybutynin (raw material), using simple syrup without preservatives as a vehicle.

The initial doses collected were the minimum referenced in children: 10 mcg/kg/12 hour for prazosin and 0.1 mg/kg/12 hour for oxybutynin. The dose of prazosin was increased weekly, in both neonates, because of the improvement in urodynamics tests and no significant adverse effects detected. It was increased until 25 mcg/kg/8 hour (maximum collected in paediatrics 25 mcg/Kg/6 hour).

The dose of oxybutynin was maintained in one patient with the initial dose and, in another, rose to 0.1 mg/kg/8 hour (the maximum 0.2 mg/kg/8 hour).

Pharmaceutical care was performed by the explanation of the doses in milliliters adjusted to the weight and monitoring of possible adverse effects. Strawberry essence was incorporated into the suspension to improve flavour.

Since birth, the number of catheters has decreased, with an improvement in the patient's symptoms. Regarding safety, no adverse reactions attributable to the drugs have been observed.

Conclusion Both oral suspensions were appropriated for the pathology of our patients, which continue in treatment. They are well tolerated, for an age range not included in the bibliography, with good response. Pharmaceutical care was given from the beginning to the family and the paediatric service.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

3PC-060 HOT-MELT RAM EXTRUSION 3D PRINTING: A SMART METHOD FOR COMPOUNDING ORODISPERSIBLE FILMS IN HOSPITAL PHARMACIES

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Background Orodispersible films (ODF) have been proposed as a valid alternative to conventional oral dosage forms to personalise the therapies and to improve patient adherence, especially in special populations (e.g., dysphagics, paediatrics, geriatrics). Since manufacturing technologies used by the industries (e.g., the solvent-casting technique) cannot be easily applied in a pharmacy setting, alternative methods have been proposed for compounding. 3D-printing permits the preparation of ODF of different strengths and geometries that fulfil the Ph.Eur. specifications concerning the uniformity of dosage units.

Purpose To demonstrate the feasibility of the preparation of ODF by hot-melt ram extrusion 3D printing.[1]

Material and methods This novel technology consists of three simple operations. First, maltodextrins, drug and other excipients (e.g., colourants, flavours, sweeteners) are mixed in a mortar and wetted with the plasticiser (i.e., glycerine). Then, the mixture is fed into the chamber of the ram-extruder and heated. ODF are individually printed using an 18G needle on the packaging material foil and sealed without further manipulation. The critical formulation attributes and process variables were investigated to define the processability space and their impact on the disintegration time and tensile properties of the ODF. The paracetamol (PAR) was used as a model drug to assess the drug-loading capacity of the ODF and the dissolution profile.

Results Preliminary results allowed to the optimization of the process parameters (heating temperature, 85°C; maximum print rate, 50 mm/s; filling angle, 120°) and composition (maltodextrins/glycerine: 80/20 w/w) to obtain homogeneous ODF. The compounded ODF (6 cm^2; thickness 150–250 μm) disintegrated in less than 1 min and showed acceptable tensile properties for product handling. Different doses of PAR (12.5, 25, 37.5% w/w) were loaded to such basic composition without altering the ODF performances. The CV% of PAR assay remains lower than 5%. The PAR dissolution profile of printed ODF (t_{80} <6 min) overlapped that obtained by ODF prepared by the solvent-casting technique.[1]

Conclusion The overall results suggested that hot-melt ram extrusion 3D printing can be used in a pharmacy setting to prepare well-accepted orodispersible dosage forms and to personalise the drug dose according to the needs of the patient.

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No conflict of interest.

3PC-061 OPTIMISATION OF INTRACAMERAL CEFUROXIME CONSUMPTION IN THE PREVENTION OF POSTOPERATIVE ENDOPHTHALMITIS

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Background The ESCRS study (a study of prophylaxis of endophthalmitis after cataract surgery) demonstrated the effectiveness of cefuroxime (1 mg/0.1 mL) administered in the anterior chamber at the end of cataract surgery for the prevention of the appearance of endophthalmitis. The marketed presentation (Prokram) contains 50 mg per vial in a final volume of 10 ml. The manufacturer recommends the use of one vial per patient (even if it involves discarding 98% of the contents of the vial).

Purpose To describe the optimisation in the use of Prokram (cefuroxime) vials through its redosification in order to obtain prefilled syringes with a concentration of 1 mg/0.1 mL.

Material and methods A bibliographic search was carried out, both for the indications for which the preparation was requested, as well as of its galenic properties, collecting the stability, the conservation and the necessary microbiological controls.

After agreement with the ophthalmology service, it was agreed to prepare pre-filled syringes containing cefuroxime 2 mg/0.2 ml in order to administer 1 mg of cefuroxime. The syringes are made in batches of 20 units and are frozen at −18°C. The units that are ordered according to the daily surgical part are sent to the operating room.

For the elaboration of the cost analysis, the cost of the vial of cefuroxime 50 mg, the insulin syringe of 0.3 ml, the sterile cap, the double bag for the packaging and the cost of the personnel elaborating them, has been quantified.

Results In 2017, 1239 syringes (associated cost of € 847) were prepared. The cost for the hospital of each vial of Prokam is € 7.80, so if they had not been redosed in the pharmacy service the cost would have amounted to € 9664.

No postoperative endophthalmitis has been described.

Conclusion The preparation of pre-filled syringes of cefuroxime 0.2 mg/0.2 ml has produced a cost optimisation of 91%.

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