Conclusion and Relevance Regarding the safety guidelines, the recommended screening and vaccination schedules are completed and recorded in the majority of patients (>85% patients). Nevertheless, it would be necessary to reconcile the way of registering data in order to simplify the recording of tests performed and the monitoring of administered vaccines.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

3PC-021 FORMULATION OF VORICONAZOLE OVULES AND EFFICACY IN VULVOVAGINAL CCANDIDIASIS BY CANDIDA GLABRATA: A CASE REPORT

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Background and Importance *Candida glabrata* is a vaginal coloniser causing vulvovaginal candidiasis (VVC), usually asymptomatic. Typical first-line therapies, boric acid or nystatin ovules, are not effective due to their inherent resistance. Flucytosine, amphotericin B or voriconazole would be the treatment of choice.
Aim and Objectives To formulate voriconazole ovules (VO) and describe our clinical experience in the treatment of VVC by *C.glabrata*.
Material and Methods The patient was a 52-year-old woman with VVC by *C.glabrata* who presented vulvar pain, irritation, and burning. She was treated with oral fluconazole, oral voriconazole, topical amphotericin B, boric acid ovules and combined therapy by fluconazole-amphotericin B, but her symptoms did not resolve and the culture remained positive.

A bibliographic search was carried out (Pharmacopoeia, UpToDate and PubMed) about VO formulation and its solubility in polyethylene glycol (PEG) was confirmed. Other magistral formulations of ovules containing PEG as an excipient were used as a reference for formulation design. Galenic validation included organoleptic controls and physical tests, mass uniformity and dissolution time.

Finally, treatment efficacy was assessed by symptom resolution and negativisation of the vaginal exudate culture.
Results Modus operandi for 30 units VO 15 mg with an excess of 20%:

1. Melt: 81.36 g PEG 400 and 54.72 g PEG 4.000.
2. Crush 11 tablets of voriconazole 50 mg in a mortar and pestle. Work in biological safety cabinet type I if there is reproductive risk, otherwise Personal Protective Equipment (PPE).
3. Add powder to the melted mass and homogenise.
4. Pour mixture into 3 g ovule moulds and allow to cool.
5. Unmould, package and label.

Regarding galenic validation, the surface of VO was shiny, smooth and without cracks. All were within the weight range (±5) and took 34 minutes to dissolve. The given expiry date was 6 months.

The patient started treatment with daily VO and after 3 months of treatment, complete resolution of symptoms and negative cultures were achieved. The frequency of administration increased to every 48 hours and then every 72 hours until 6 months of treatment, without reactivation of the infection.
Conclusion and Relevance The magistral formulation was validated and proved to be effective in the treatment of VVC by *C.glabrata*.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of Interest No conflict of interest.

3PC-022 DESIGN AND STABILITY STUDY OF AN ISONIAZID AND PYRIDOXINE ORAL LIQUID FORMULATION

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Background and Importance Infant tuberculosis treatment is a combined therapy, which entails two main issues: commercialised paediatric presentations scarcity and inadequate adherence. Isoniazid is indicated as a front-line treatment. In order to prevent isoniazid's induced peripheral neuropathy, pyridoxine should be supplemented.
Aim and Objectives The aim of this study was to develop and study the physicochemical and microbiological stability of a combined isoniazid+pyridoxine oral liquid formulation.
Material and Methods Literature search was performed to study isoniazid + pyridoxine formulation stability. As there were no published data in this field, the active pharmaceutical ingredients physicochemical proprieties and quality conditions were checked in Pharmacopeia and scientific literature. Stability-indicating methods were conducted and validated according to the Methodological Guidelines for non-sterile products.

- Physical study: organoleptic characters (colour, odour, flavour); clarity and degree of opalescence; and pH. The pH-goal of combined doses to avoid any possible active ingredient degradation was settled at 5.
- Microbiological study: total aerobic microbial count <103 UFC/ml; total combined yeasts/moulds count <102 UFC/ml; and absence of Escherichia coli/ml.
- Chemical study: high-performance liquid chromatography (HPLC) analysis and method validation to quantify isoniazid +pyridoxine recommended acceptable purity limit (90–110%).

Results Isoniazid 50 mg/ml + pyridoxine 8,3 mg/ml oral liquid formulation was compounded using aqua conservans and 70% liquid sorbitol. Samples were stored at aliquots, light and non-light-exposed, at room and refrigerated temperature, for 28 days. Each sample was analysed at 0, 7, 14, 21 and 28 days.

Refrigerated samples stayed physically stable and pH measure was 4,8±0,15. Room temperature samples got darker, bitter and slightly acidified. The concentration of isoniazid and pyridoxine was found to be at day-28 50,6±0,6 + 8,2±0,2 at room temperature and 51,3±0,6 + 8,3±0,1 at refrigerated temperature, respectively. Moreover, all samples maintained microbiological stability.

The validated method proved to be selective and linear. It exhibited an adequate repeatability and intermediate precision with variation coefficient lower than 2%, and a recovery higher than 98%.

Conclusion and Relevance

- Isoniazid+pyridoxine oral liquid formulation was physicochemical and microbiologically stable stored at refrigerated conditions for 28 days.
- The proposed analytical method was viable to simultaneously determine two different active ingredients.
- It provides a reliable solution to enhance therapeutic adherence of children.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

3PC-023 NEW ACTIVITIES WITHIN A CLINICAL TRIAL MANAGEMENT UNIT: WHAT NEW RISKS FOR THE STAFF?

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Background and Importance Pharmaceutical personnel continually face occupational risks (OR) during clinical research, necessitating regular updates to address evolving activities like Advanced Therapy Medicinal Products (ATMPs) and direct patient dispensation.

Aim and Objectives Our goal was to comprehensively assess these risks, utilising a risk mapping approach and implementing tailored preventive measures (PM) for effective mitigation.

Material and Methods In collaboration with pharmacists, managers, and risk assessors, we conducted a thorough risk mapping, evaluating ORs based on severity, frequency, and control mechanisms. Criticality levels were established, leading to categories of very significant, significant, to be monitored, or tolerable risks. Subsequently, PMs were developed, and an action plan was created. Reassessment using the same parameters resulted in residual risk identification, culminating in a comprehensive risk assessment document.

Results Our assessment revealed nine novel ORs in three categories: travel associated with experimental treatment delivery, biological risks linked to ATMPs, and workplace hazards like burns from nitrogen handling. Five were deemed significant, three required monitoring, and one was tolerable. Post-risk mapping, seven PMs were identified, including individual oximeters and respiratory isolation equipment to address hypoxia risk during ATMP handling. Residual risk evaluation indicated three significant risks, five requiring monitoring, and one tolerable, with no risks considered very significant after PM implementation.

Conclusion and Relevance In conclusion, the assessment and targeted implementation of PMs significantly reduced risk criticality within our unit. This approach enhances staff protection during new assignments and activities. Further evaluations will gauge PM effectiveness in maintaining a safe environment for pharmaceutical personnel involved in cutting-edge clinical research and ATMP management.

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3PC-024 IMPLEMENTATION OF A STRATEGY TO OVERCOME THE POTENTIAL TOXIC EFFECTS OF PROPYLENE GLYCOL IN NEONATES

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Background and Importance Available evidence on the safety of excipients in compounded formulations is somewhat limited. Contributing to a higher level of evidence seems relevant, particularly regarding compounded formulations for use in neonatology. In a previous study on the presence of problematic excipients in oral compounded formulations, intake above the recommended limits was reported, mainly of propylene glycol (PG), in neonates under 28 days of age.[1]

Aim and Objectives To implement a strategy aimed at overcoming the potential toxic effects due to the exposure of neonates to PG present in oral compounded formulations.

Material and Methods Evaluation of the composition of compounded formulations regularly used in a neonatal intensive care unit to identify the source of PG.

Assessment of alternatives, considering their preservative power, by calculating the concentration of parabens, and analysing the solubility of the chemical forms of parabens used.

Results The source of the PG in the formulations was the preservative solution used – Paraben Concentrate (B.8).[2] As an alternative to B.8, we evaluated three paraben solutions described in the literature, taking into account the respective parabens concentrations, the nature of the solvent and the reported stability. Since the parabens concentrations were at least 100 times lower than that of the B.8, we decided not to adopt any of the solutions described, since this could compromise the preservation of the formulations and, at the time, we were unable to test it.

In an alternative approach, the preparation of a 10% paraben concentrate in water, instead of PG, was implemented. To promote the dissolution of methylparaben and propylparaben (7:3) in water, the respective sodium salts were used. The solution was prepared after calculating the respective equivalent concentrations and ensuring compliance with the solubility data.[3]

Conclusion and Relevance A water-based, PG-free paraben solution has been developed, suitable for preserving oral compounded formulations. This strategy makes it possible to overcome the potential toxic effects of PG in neonates, thereby increasing the safety of the formulations.

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Conflict of Interest No conflict of interest.