

**Material and Methods** We performed medication reviews on 1000 patients from 0 – 18 years on paediatric general wards before and after the implementation of a CPOE. The CPOE included limited clinical decision support (CDS) such as a drug-drug interaction check and checks for duplicates. Prescribing errors, their type according to the PCNE classification, their severity (adapted NCC MERP index) as well as the interrater reliability (Cohen's Kappa) were analysed.

**Results** CPOE significantly reduced the rate of errors from 25 errors/100 prescriptions (95% CI: 23 – 27) to 16 errors/100 prescriptions (95% CI 14 – 18). Particularly the prescribing quality was improved by reducing PCNE error 5.2 (e.g. lacking drug form or maximum possible number of doses for reserve medication). Medication reconciliation problems (PCNE error 8), such as drugs prescribed on paper as well as electronically, were significantly increased after introduction of the CPOE. The most common paediatric prescribing errors, the dosing errors (PCNE errors 3), were not statistically significantly altered after introduction of the CPOE. Overall severity of errors was reduced. Interrater reliability showed moderate agreement ( $K = 0.48$ ).

**Conclusion and Relevance** The CPOE increases patient safety by reducing the rate and severity of prescribing errors. The reason for the observed increase in medication reconciliation problems might be the hybrid-system with remaining paper-prescriptions for special medication. The lacking effect on dosing errors might be explained by the fact that a web application CDS covering dosing recommendations (PEDeDose) was already in use before implementation of the CPOE. Further investigations should focus on eliminating hybrid systems, interventions on how to increase the usability of the CPOE, and full integration of CDS tools into the CPOE.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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**Conflict of Interest** Corporate sponsored research or other substantive relationships:

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#### 5PSQ-031 ANALYSIS OF THE USE OF ISAVUCONAZOLE IN CRITICALLY ILL PATIENTS WHEN THE USE OF VORICONAZOLE IS INDICATED

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**Background and Importance** Isavuconazole and voriconazole are antifungals that have shown similar clinical efficacy in the treatment of invasive aspergillosis. Isavuconazole has certain advantages such as a lower interaction profile and can be used in patients with renal insufficiency; however, its similar efficacy limits its use in situations where voriconazole is contraindicated.

**Aim and Objectives** The aim of this study is to describe the proportion of isavuconazole prescriptions in which the use of voriconazole would not be contraindicated.

**Material and Methods** Descriptive, observational and retrospective study in which all patients over 18 years of age who

received isavuconazole in 2021 in a hospital were included. Exclusion criteria were: age less than 18 years, pregnancy or duration of treatment less than 24 hours.

The use of intravenous voriconazole is contraindicated in patients with moderate to severe renal insufficiency (ClCr <50mL/min), in severe hepatic insufficiency (Child-Pugh C) and in combination with CYP450 substrates.

The main variable under study was the proportion of isavuconazole prescriptions in which the use of voriconazole would not be contraindicated.

The following variables were also collected: sex, age, number of days of treatment and mycological culture results.

Patients treated with isavuconazole were obtained from a database of the pharmacy service, sociodemographic and clinical variables from the OrionClinic computer program.

A descriptive statistical analysis was performed using measures of central tendency such as mean and median, through the SPSS v.23<sup>®</sup> program.

**Results** 37 patients treated with isavuconazole were included. Four patients were excluded. The median age was 63 years (24–82) and 68% were male.

Voriconazole was not contraindicated in 65% of the isavuconazole prescriptions. Thirty-five percent of the patients had renal insufficiency. The mean number of days of treatment was  $6 \pm 4.9$  days.

A mycological culture was performed in 89% of the patients, with 78% of the results being negative.

**Conclusion and Relevance** A high percentage of patients treated with isavuconazole in our critical care unit did not meet the conditions for which it was included in the pharmacotherapeutic guide of the hospital. These results suggest the need for a specific PROA in critical patients or the multidisciplinary elaboration of a protocol for the use of antifungals.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

**Conflict of Interest** No conflict of interest.

#### 5PSQ-035 MASS UNIFORMITY OF HARD CAPSULES: ROYAL SPANISH PHARMACOPOEIA VS UNITED STATES PHARMACOPOEIA

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**Background and Importance** Quality control (QC) is an important part of the quality assurance of the elaborating process in a Hospital-Pharmacy-Department (HPD). The mass uniformity is the most commonly procedure used for QC of hard-capsules.

**Aim and Objectives** Analyse comparatively the Royal-Spanish-Pharmacopoeia (RSP) hard-capsule mass uniformity method versus the United-States-Pharmacopoeia (USP).

**Material and Methods** The following parameters of each method were analysed: sample, average reference weight, percentage and acceptance requirements. Also, the elaborating process necessary to apply each method.

Finally, the elaboration of a batch of 100 hard-capsules of dexamethasone 40mg according to the HPD Standard-Operating-Procedure was taken as a reference. Then the elaborations

were retrospectively reviewed from February-2020 to February-2021.

The QC had been carried out with the RSP-method and the USP-method was then applied. For this, the theoretical weight of a capsule was calculated taking the average weight of 5 empty capsules (0.0493g) as reference and the weight of the batch content (13.8g=dexamethasone (4g) + excipient (9.8g)) calculated in the compounding design being the acceptance interval 0.169–0.206g.

**Results** The RSP-method requires a sample of 20 capsules and uses their average weight as a reference, while the USP-method requires a sample of 5% or 10 capsules (whichever is less) and uses the theoretical weight of a capsule as a reference. The RSP-method admits a deviation of  $\pm 10\%$  or  $\pm 7.5\%$  depending on the average weight; and no  $>2$  capsules can deviate from the limits and none more than double. The USP-method accepts a limit of  $\pm 10\%$  respect to the theoretical weight, and no capsule must deviate.

Regarding the compounding method, the RSP allows elaboration by volumetric filling according to the Spanish-National-Formulary (excipients weight is not required). However, the USP-method requires knowing the theoretical capsule weight, which implies weighing the excipients.

Since February-2020 to February-2021, 8 batches of dexamethasone 40mg were elaborated. They were accepted with the RFE-method. After applying the USP-method, none were rejected.

**Conclusion and Relevance** The USP-method is safer than the RSP-method because for the same acceptance interval ( $\pm 10\%$ ) it does not admit any deviation. It also requires knowing the weight of all the excipients. Therefore, it is capable of detecting errors in the elaboration that the RFE-method would not detect (as long as the error is  $>10\%$  and the capsules are homogeneous).

Currently, the USP-method has been incorporated in the HPD as a reference of hard capsules QC, since it provides greater safety in their preparation.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

**Conflict of Interest** No conflict of interest.

#### 5PSQ-039 RAF-KINASI PATHWAY INHIBITORS IN TREATMENT OF METASTATIC MELANOMA: WHEN COMPLIANCE DOES NOT MATCH WITH TOLERANCE

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**Background and Importance** Background and importance: Melanoma is a malignant tumour that originates from melanocytes of the skin and mucous membranes or rarely from melanocytes located in extracutaneous sites. In 2020 in Europe, approximately 50.972 females and 55.397 males are diagnosed with melanoma, and 9.457 males and 7.031 females died because of it. 45–50% of melanomas have a mutation in the BRAF gene and the most frequent is V600E. Oncogenic mutations of BRAF lead to constitutive activation of the RAS/RAF/MEK/ERK pathway. Target therapies are the most appropriate to obtain an effective therapeutic action.

**Aim and Objectives** We analysed the 2 most prescribed oral associated therapies in our centre for the treatment of

mutated BRAF metastatic melanoma with the aim of identifying which is the most tolerated and highlighting the types of toxicity that emerged from real life data bases.

**Material and Methods** The data were extrapolated from our prescription software and from the electronic medical records of the investigated patients.

**Results** In the period 2019–2022 we considered 36 patients treated with Dabrafenib 75 mg + Trametinib 2 mg or Encorafenib 75 mg + Binimetinib 15 mg, 50% treated with both therapies. 33 patients started the combination therapy of Dabrafenib + Trametinib and of these only 7 (20%) did not show any severe toxicity leading to discontinuation of treatment. The most frequent toxicity was pyrexia (40%), followed by skin toxicity (25%), gastrointestinal toxicity (12.5%), asthenia (8%). Patients who discontinued treatment for progression disease were 9 (28%). Owing to unacceptable toxicity, 14 patients (43%) switched to Encorafenib + Binimetinib: only 2 of these patients showed toxicity (G1-G3 asthenia, G2 nausea) upon discontinuing treatment. 3 patients of analysed population started therapy with Encorafenib + Binimetinib as first-line treatment, without toxicity to discontinue therapy.

**Conclusion and Relevance** These data point out that the first choice is a combination therapy Dabrafenib + Trametinib associated with better patient compliance, thanks to more easily manageable number of tablets to take daily. However, the toxicity appears to be higher. For this reason, the therapy with a lower compliance is actually the best tolerated and prolonged therapy with fewer suspensions, ensuring better continuity of care and therapeutic efficacy.

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**Conflict of Interest** No conflict of interest.

#### 5PSQ-050 ANALYSIS OF THE USE OF USTEKINUMAB FOR CROHN DISEASE IN THE REAL CLINICAL PRACTICE

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**Background and Importance** Ustekinumab (UST) is an anti-IL-12/23 antibody which is used in Crohn disease. Although the dosage form is defined in its data sheet, in the clinical practice, intensifications and intravenous reinductions are performed when there is a loss or inadequate of response.

**Aim and Objectives** To describe and evaluate the different dosage regimens of UST performed in patients with Crohn disease by relating them to biomarkers of inflammation and clinical data.

**Material and Methods** Observational, retrospective and descriptive study included patients with Crohn disease who started with UST (January 2017-April 2022).

Data obtained from electronic medical records was: previous treatments, faecal calprotectin (Fcal) and C-reactive protein (CRP) levels, stools daily (SD) and abdominal pain (AP), and dosage regimen.

**Results** 45 patients were included, 68.8% women with a mean age of 49.2. Previous treatments: adalimumab (75.5%),