clinical trials before and after the implementation of the software module APOTECAtrial.

Material and methods The conventional manual process and the improvements introduced after the implementation of APOTECAtrial were assessed through a comparative risk analysis. First, the process was divided into seven phases (delivery to the pharmacy, preparation/dispensing, returns management, disposal, storage, data management, monitoring). The activities related to each phase and the corresponding potential failures were identified. The risk was assessed by rating the severity (S), frequency (F) and detectability (D) of the potential effect of the failures. The risk index (S×F×D) was calculated for each activity (RI) and for the entire process (RI_{total}). The index of improvement (IR before implementation divided by IR after implementation) was calculated for each area (IM) and for the entire process (IM_{total}).

Results Overall, 37 activities were assessed. The RI_{total} decreased by 53%, from 449 (before implementation) to 207 (after implementation). The IM_{total} amounted to 2.2. The highest IR reduction was found in the preparation/dispensing phase (from 152 to 42) with an IM equal to 3.6. IM values ranged between 1.7 and 4.5. Most of the improvements introduced (79%) referred to traceability and data integrity, while 21% impacted on the quality of the drug dispensed.

Conclusion and relevance The risk analysis revealed that fully-automated management of clinical trials represents an important improvement of the clinical pharmacy practice in terms of safety. Since the potential risks are significantly reduced, the automated process guarantees high-quality standards and GCP-compliance. Several manual and repetitive activities were simplified, thereby allowing pharmacists to spend more time on clinical and patient-oriented tasks.

.References and/or acknowledgements

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Conflict of interest No conflict of interest

4CPS-214 EXPERIENCE OF USE OF CANNABIDIOL IN PAEDIATRIC PATIENTS

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Background and importance Cannabidiol (CBD) is an orphan medicine recently approved in Europe for the treatment of Dravet (DS) and Lennox–Gastaut syndromes (LGS) in combination with clobazam, and for tuberous sclerosis. However, there is growing evidence that other types of refractory epilepsy could be treated with this drug.

Aim and objectives To evaluate the use of CBD in a paediatric hospital, as well as its effectiveness and safety.

Material and methods Observational, retrospective study carried out between January 2017 and September 2021, including all patients treated with CBD in our hospital.

Variables included Age, sex, weight, concomitant antiepileptic drugs (AEDs), length of treatment, initial and maintenance dose, reasons for discontinuation and adverse events (AEs) related to CBD. Efficacy was assessed following two criteria: reduction in number of seizures and opinion of caregivers.

Data were collected from electronic medical records and the pharmacy dispensing program.

Results Thirty-one patients were included: male 61.3% (n=19); median age 10 (2–16) years. Median weight 28 (14–80) kg median initial dose: 3 mg/kg/day (1–12). CBD was prescribed for LGS 61.3% (n=19), refractory epilepsy 13% (n=4), DS 6.5% (n=2), epileptic encephalopathy 6.5% (n=2), West syndrome 6.5% (n=2), Rett syndrome 3.1% (n=1) and tuberous sclerosis 3.1% (n=1). Median of concomitant AEDs was 3 (0–4). Twenty (64.5%) patients received CBD in combination with clobazam.

Two patients (6.5%) discontinued CBD in the first 2 weeks of treatment. Both presented a significant increase in number of seizures. Twenty-nine (93.5%) patients reached a maintenance dose of 15 mg/kg/day (5–44); the median length of treatment was 7 (3–69) months. Treatment was discontinued in 8 cases (25.8%) because the number of seizures was not reduced, and one also presented rash (3.4%). To date, 21 (67.7%) patients continue on CBD: in 14 (45.2%) cases, number of seizures was significantly reduced and caregiver's appreciation of effectiveness was good; and 7 (22.5%) responded partially.

Most frequent AEs were: irritability 24.4% (n=7), diarrhoea 13.79% (n=4) and anorexia 10.34% (n=3). Other AEs described were: drooling 6.9% (n=2), somnolence (n=2); rash 3.4% (n=1), hepatobiliary disorders (n=1) and asthenia (n=1).

Conclusion and relevance CBD was prescribed in numerous indications due to the lack of therapeutic alternatives in some seizures-refractory patients. It has been an effective option in most of our patients and its security profile is consistent with clinical trials.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-218 EVALUATION OF THE IMPACT OF INCORPORATING A PHARMACIST INTO A HOSPITAL EMERGENCY DEPARTMENT

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Background and importance Attending a hospital emergency department (HED) is considered a high-risk situation regarding medicines appropriate reconciliation and medication errors. Thus, patients may well benefit from incorporating a pharmacist into the healthcare team who helps with medication management review.

Aim and objectives This study aimed to analyse the interventions proposed by the pharmacy team to the medical team in our HED setting and to evaluate the positive impact this may have on patients' management.

Material and methods Patients' prescriptions were assessed and pharmacotherapy changes, if needed, were registered in their clinical history. At the end of the work day, we reviewed if proposals had been accepted or rejected. This prospective study was conducted in a tertiary hospital over 1 month.