

staff is divided into an investigator team and a pharmacy team.

**Aim and Objectives** Quality assessment at the initiation visits of a clinical trial.

**Material and Methods** Observational, prospective, single-centre, prospective study to evaluate the quality at the start of a CE in a tertiary level hospital. The study period was from June to August 2022. A 16-item survey was carried out, which includes the aspects to be taken into account in the performance of a CE. The questions collected were: investigator service, phase of the trial, knowledge of the presentation and stability of the drug, mode of preparation, administration and destruction of the experimental product. When the trial monitor (CRA) knew the question, a score=1 was assigned if he/she did not know=0. The tools used were: Excel® for data collection, Fundanet® for EEC registration and Google Teams® for meetings. The maximum score obtained was 20 and a poor start was considered with scores below 13.

**Results** Thirty CT onsets were analysed during the study period. The main clinical services under investigation were: oncology > dermatology > haematology. The phases of the trials to be initiated were: III (14), II (10), I/IB (6) and IV (0). The mean quality score obtained was 16.62. There were 4 clinical trials with a score between 10-13 and 2 trials with a score of less than 10. This led to a second review of the CE by the sponsor, which meant a delay in the start of the investigation.

**Conclusion and Relevance** Although most of the clinical trials met the quality criteria for initiation, there is a non-significant proportion with poor results. In those clinical trials that do not meet the minimums, a delay in initiation is necessary for the resolution of doubts on the part of the sponsor.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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

#### 4CPS-082 MOST FREQUENT ERRORS IN THE INHALATION TECHNIQUE OF ASTHMATIC CHILDREN

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**Background and Importance** Asthma is a real public health problem. Inhalation therapy is the mainstay of the management of this chronic disease. one of the most important reasons for failed therapy is improper inhaler technique.

**Aim and Objectives** Demonstrate the most frequent errors in the technique of inhalation in asthmatic children treated in our establishment

**Material and Methods** A prospective observational study was conducted with asthmatic children admitted to our establishment over a period of 2 months. We have developed an evaluation grid for the inhalation technique. it was considered correct when all steps were performed correctly.

**Results** A total of 50 patients were included. The average age was 3.7 years. Inhalers observed were metered-dose inhalers. All patients declared having had a demonstration of the

inhalation technique mainly by their doctor. Among 50 participants, 30 (60%) performed the inhalation technique incorrectly. Errors were most common at the stage of slow, full, deep breathing as recommended by the guidelines (70%), followed by no spray agitation (15%).

**Conclusion and Relevance** Our results support poor inhaler technique in children that may have adverse consequences on therapeutic efficacy. The educational role of the clinical pharmacist is very important to improve the proper use of the inhalation technique and the management of patients.

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#### 4CPS-083 CREATININE AND CYSTATIN-BASED ESTIMATED RENAL FUNCTION IN VANCOMYCIN MONITORING

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**Background and Importance** Glomerular filtration rate (GFR) is usually estimated by using renal markers like creatinine (cr) or cystatin C (cysC), but results are not always overlapping.

**Aim and Objectives** Evaluate the effect of using Cockcroft-Gault (CGcr) and Chronic Kidney Disease-Epidemiology Collaboration (EPIcr, EPIcysC and EPIcr/cysC) equations in vancomycin monitoring.

**Material and Methods** Data from the last 5 years were collected retrospectively. All patients (n=34) who had simultaneously cr, cysC and observed vancomycin concentrations (Cobs) obtained within a range of 48h (n=47), were included. Pharmacokinetic Bayesian estimation was performed with PKS – Abbott®. For each pair GFRs/Cobs, the predicted concentration (Cp) and the daily dose required to obtain a maximum and minimum concentration of 25 and 15 µg/ml, respectively, were determined. The absolute error (E), E=Cobs-Cp=0, was used as an indicator of the adequacy of the equations used.

**Results** Estimated GFR showed statistically significant differences (mean ± standard deviation): CGcr=110.6 ± 76.5, EPIcr=97.5 ± 36.3, EPIcysC=42.8 ± 18.6 and EPIcr/cysC=64.3 ± 25.2 ml/min/1.73 m<sup>2</sup> (p<<0.05).

CGcr, EPIcr and EPIcr/cysC equations overestimated (E>0) renal function: E=1.50 ± 1.53 (95% confidence interval [CI]: 1.05 to 1.95), E=1.62 ± 1.35 (95% CI: 1.22 to 2.02) and E=0.47 ± 1.14 (95% CI: 0.14 to 0.81) µg/ml, respectively. Renal function was underestimated (E<0) with EPIcysC, E=-1.06 ± 1.54 (95% CI: -1.51 to -0.60) µg/ml.

The estimated differences in daily doses ranged from 100 to 1600 mg/70Kg/day, considering CGcr equation as reference.

**Conclusion and Relevance** The overestimation of GFR with equations dependent on cr, CGcr, EPIcr and, to a lesser extent, EPIcr/cysC, was marked in patients with abnormally low cr. Conversely, with EPIcysC equation, which depends on cysC, a biomarker independent of muscle mass, GFR was underestimated. This may be due to factors that increase cysC, without renal function impairment, such as hypertension, corticosteroid therapy and malignancy, all common in hospitalised patients, but poor data did not allow to explore this association.