**Purpose** To develop and implement a tool for regulatory audits and identify case studies from these audits to recommend improvements in patient safety.
**Material and methods** The method is based on retrospective analysis of 512 audit reports and interviews with 12 pharmacists to develop an audit tool for regulatory audits. The audit consisted of a documentation phase that entailed the identification of deficiencies related to regulatory requirements and an observation phase for the provision of pharmaceutical care provided by the pharmacist. Interactive educational discussions with the practising pharmacists identified desirable patient-related improvements. Seven case studies on the identified deficiencies related to patient safety were addressed.
**Results** The tool was applied in 85 audits (January–November 2017). Opportunities for improvement related to patient safety were identified and addressed in seven case studies namely: four dispensing problems (errors, near misses, lack of proper prescription, unsupervised pharmacy staff); two inventory deficiencies (expired items, inappropriate storage temperature); and one equity of treatment between private and government-sponsored patients. Concordance with the pharmacist was reached and 46 corrective and preventive actions were taken to address the deficiencies. Examples of actions identified included: development of standard operating procedures, such as for temperature monitoring; implementing precautions to avoid dispensing errors especially for cytotoxic and high-alert medicines, such as labelling of shelves and implementing methods of alert for 'sound-alike', 'look-alike' and 'written-alike' medicines; ensuring double-checking before dispensing; and performing routine stock rotation to prevent dispensing of expired medicines.
**Conclusion** A tool was developed, validated and implemented for regulatory audits. Follow-up audits confirmed that an approach that emphasises on reaching concordance with the pharmacist through identifying opportunities for improvement, rather than non-compliance, improves pharmacist motivation, patient safety and care outcomes. Future studies may include the harmonisation of actions across all pharmacy services.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**
Nil.
No conflict of interest.

## 5PSQ-107 ASPIRIN AND NOVEL ORAL ANTICOAGULANTS: REPORTING OF ADVERSE DRUG REACTIONS

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**Background** The novel oral anticoagulants (NOACs) provide alternative options for thromboprophylaxis. The efficacy of antithrombotic medications such as aspirin may vary between patients and alternative medications need to be identified.
**Purpose** To carry out comparative analysis of adverse drug reactions (ADRs) reported for aspirin and NOACs.
**Material and methods** Pharmacovigilance (PV) reports from Eudravigilance were used to compare 15 ADRs listed as commonly occurring in the Summaries of Product Characteristics, for aspirin and the three NOACs: apixaban, dabigatran and rivaroxaban. ADRs reported between 2013 and 2017 were used for the study. A questionnaire was developed to collect information related to ADRs encountered by patients while taking aspirin or NOACs. Fifty patients were recruited (25 taking aspirin, 25 taking rivaroxaban). Documented ADRs from PV reports were compared to patient-reported ADRs. The consumption trends for NOACs were analysed from published articles.
**Results** For the 15 ADRs, 51,391 PV reports were reported to Eudravigilance, with bleeding-related ADRs (38,826/51,391) being the commonest reported ADRs. Gastrointestinal bleeding (n=25,892) was the commonest reported ADR for rivaroxaban (n=12,974), aspirin (n=5,855), dabigatran (n=5,321) and apixaban (n=1,742). Reported ADRs were highest for rivaroxaban (n=24,832). The four medications differed as regards the safety profile. For all 15 ADRs investigated, statistically significant differences were observed between reported cases of ADRs for the four medications. Thirty-six patients who completed the questionnaire reported at least one ADR (aspirin=18, rivaroxaban=18). Bleeding-related ADRs were least reported by patients (aspirin=11, rivaroxaban=4).
**Conclusion** Bleeding-related ADRs were highest in PV reports and the lowest reported in questionnaires, suggestive of under-reporting of ADRs considered as minor or less serious by patients. High numbers of reported ADRs for rivaroxaban compared to dabigatran and apixaban possibly reflect consumption trends. Consumption trends show that rivaroxaban is the most used NOAC. Differences in reported ADRs could be due to differences in consumption trends, differences in safety profiles of medication or reporting bias. ADRs are more likely to be reported for novel medications such as NOACs, for which clinical experience may be limited when compared to conventional drugs such as aspirin. More data on the safety and efficacy of NOACs is necessary to help determine the risk-benefit ratio of therapy.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**
No conflict of interest.

## 5PSQ-108 PROCEDURE FOR PAEDIATRIC EMERGENCY AND RESULTS OF A SURVEY ON USE

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**Background** In 2018 Campania reorganised the regional hospital network, therefore our hospital was identified as the Zone Trauma-Centre and the Emergency Medicine Unit has been established with general first aid. The pharmacy has developed diagnostic therapeutic routes including that for paediatric emergency, with the aim of optimising assistance, especially for those cases with infrequent access.
**Purpose** To describe the process developed and the improvements made in clinical practice verified through a survey.
**Material and methods** The Broselow method[1] was used for a rapid selection of devices and drug dosages. It uses a colorimetric visualisation tape based on weight and height, and provides indications for shock, cardio-respiratory arrest and respiratory failure. The weight and height identified on the tape provide, translated into colour code, measures of endotracheal tubes, catheters, drainage, needles, tubes, dosage of drugs, indications for ventilation, and tables with vital signs divided by age and severity scores. We organised a first aid area by dividing the devices into boxes whose colour matched the one identified by the tape, with the aim of quickly identifying what was required to help the children during the

emergency. We have instructed the doctors and nurses on how to use the tape. Six months after the start of use, we gave a questionnaire to 11 doctors and 42 nurses to see if they found the system easy to manage and safe.

**Results** Of 53 participants interviewed, 38 (72%) found the Broselow easy or very easy, 43 (82%) reported that the material for intubation and nsertion of the naso-gastric tube was quickly found. Forty-seven (89%) stated that the detection of dosages was very easy and 52 (99%) reported that the method involved greater safety.

**Conclusion** The results indicate that despite progressive aging, focusing on the paediatric population is a deeply felt need. It is essential to be sensitive to the recording of near misses and errors through incident reporting and implement procedures that make it possible to standardise behaviours and the use of appropriate resources. The clinical pharmacist is an integral part of this path as it helps to make the patient's hospitalisation safer and directs the staff towards more effective and appropriate choices.


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## 5PSQ-109 ABSTRACT WITHDRAWN

## 5PSQ-110 COMPUTERISED PHYSICIAN ORDER ENTRY SYSTEMS AND RELATED CLINICAL DECISION SUPPORT TOOLS IN INPATIENT CARE – BARRIERS OF COST-EFFECTIVENESS


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**Background** Medication errors (ME) and the consequent preventable adverse drug events (pADE) are a major burden on inpatient care. They are not only a possible source of patient harm but may lead to increased healthcare cost due to prolonged length of stay (LOS) as a consequence of pADEs. Computerised Physician Order Entry (CPOE) occasionally with a clinical decision support tool (CDS), has been shown to increase patient safety, and it is essential for patient-level medication ordering. Due to the scarce financial resources of clinics and inpatient care, exploration of new ways for being more cost-effective is essential.

**Purpose** Studies examining CPOE systems in inpatient care were collected with cost or other resource utilisation-related outcomes. Development of these services might be a good opportunity to expand clinical pharmacist competencies.

**Material and methods** We conducted a systematic search of Scopus, PubMed and Web of Science databases. Search terms were determined according to PICO. Non-English papers and studies providing no original data were excluded.

**Results** One-thousand six-hundred and ninety-three abstracts were screened, thereafter 67 full text articles were analysed, of which 27 met the inclusion criteria. We have identified 18 partial and nine full economic evaluations. Apart from one cost-benefit and one cost-utility analysis, all the publications included were cost-effectiveness studies. The clinical outcomes were dominated by pADE, although LOS (one case) and