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
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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.

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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