pharmacy department by both qualified and non-qualified staff.

Purpose

- To determine the present ERR and identify the difference in ERRs between this and the previous study.
- To identify the reasons for under–reporting errors.
- To produce a protocol for error reporting and to measure the effect.

Material and methods Staff received a pre-study questionnaire as a tool to document their reasons for not reporting, and received an explanatory tool showing the importance of error reporting.

The study covered two 3 month periods.

- Staff received a personal monthly report showing their ERRs.
- A protocol for error reporting was introduced at the end of the first period.

Results

- The first period of monthly reports initially increased, then decreased (17 > 29 > 18).
- The second period started lower and remained static (11 > 10 > 11).
- The previous study produced 12 reports during the first period and 46 during the second. (380% increase),
- This study produced 64 and 32 respectively *(50% decrease).
- 2.The two commonest reasons for not reporting were:
  a. No need to report an error if immediately corrected (33%).
  b. Not wanting a colleague reprimanded (19%).
- * Introducing the protocol did not increase ERRs.

Conclusion The initial rise of ERRs in the first period was probably due to the study having a positive behavioural influence. The second period decrease was probably due to a holiday effect. Those deputising had an increased workload, and less time or inclination to report. Advanced planning is requiredConstant reminders of the importance of reporting are required to improve and maintain ERRs. Reasons for not reporting need to be further addressed.

The protocol had no positive effect. The method of introducing the protocol needs reviewing.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-105 EFFECTIVENESS AND TOXICITY PROFILE ANALYSIS OF ANTIFIBROTIC AGENTS IN IDIOPATHIC PULMONARY FIBROSIS

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Background Nintedanib and pirfenidone are the only antifibrotic agents commercialised for the treatment of idiopathic pulmonary fibrosis (IPF). Both were approved after being compared to placebo, so comparative studies are needed.

Purpose To evaluate the effectiveness and safety of nintedanib and pirfenidone in patients with IPF in real clinical practice.

Material and methods A retrospective observational study including all patients with IPF who started treatment with nintedanib or pirfenidone (March 2015–June 2018) was carried out.

Demographics (age, sex), clinical (forced vital capacity (FVC)) and safety (dose reductions, adverse effects (AEs)) variables were collected. Differences in FVC at the end of the study were evaluated with the *t*-student test.

Statistical analysis was carried out using Stata®14.

Results Throughout the study 67 patients (70% males, median age 71.4±8 years, median FVC 70%±19%) started treatment with nintedanib (n=25) or pirfenidone (n=42). Six patients with nintedanib and five with pirfenidone were excluded for lack of monitoring.

The median FVC percentage change at the end of the study was −4.1±9.9% in the nintedanib group and −2.1 ±10.2% in the pirfenidone group (p=0.48).

Nine patients (47%) showed an improvement in FVC during treatment with nintedanib and 17 (46%) with pirfenidone, with a median change of 4.9%±4.6% and 6.6%±6%, respectively. In the other patients, FVC value decreased with a median change of −11.7±6.4% (nintedanib) and −9.5±6.5% (pirfenidone).

Five patients treated with nintedanib and nine with pirfenidone would be candidates to discontinue treatment due to a lack of effectiveness, according to discontinuation criteria established at the hospital (absolute decrease of ≥10% in FVC during the first year of treatment).

The most frequent AEs related to nintedanib were diarrhoea (60%, n=15), weight loss (32%, n=8) and hepatotoxicity (32%, n=8), whereas with pirfenidone, hepatotoxicity (38%, n=16), gastrointestinal intolerance (33%, n=14) and cutaneous toxicity (26%, n=11).

Dose reductions were necessary to manage AEs in 16% of the patients treated with nintedanib and in 26% with pirfenidone.

Twelve per cent of the patients discontinued nintedanib due to diarrhoea (n=1), gastrointestinal intolerance (n=1) and cutaneous toxicity (n=1), and 26% pirfenidone due to cutaneous toxicity (n=5), hepatotoxicity (n=3), asthaenia (n=2) and gastrointestinal intolerance (n=1).

Conclusion In our study, nintedanib and pirfenidone have similar effectiveness. Differences in toxicity may be decisive in the choice of either treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-106 FOCUSING AUDITS ON PATIENT SAFETY

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Background Pharmacy practice is evolving to incorporate a patient-centred approach to the scientific background. Regulatory audits often take the form of a policing exercise. This method may not always produce optimal outcomes. In parallel with the pharmaceutical patient advice process, advancing from compliance, adherence to concordance, an exercise is carried out to examine the application of this concept in regulatory policies to enhance patient safety.

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