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 required. Constant 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), asthenia (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.