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Title Page: An Investigation in to Prescribing Errors Made by Pharmacist Independent Prescribers and Medical Prescribers at a Large Acute NHS Hospital Trust: A cross-sectional study

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ABSTRACT:

Introduction: Pharmacists in the UK can register as Independent Pharmacist Prescribers (IPPs) upon completion of appropriate Higher Education training. IPPs have had the same prescribing privileges as medical doctors since 2009. Despite the years since their introduction, there is little data available to demonstrate the frequency and type of errors made by IPPs. Furthermore, there is no literature available comparing IPPs to doctors with regards to prescribing safety. This study aimed to start to fill this gap in the literature. **Methods:** Pharmacists working in one NHS Trust, in areas with a large proportion of prescribing undertaken by IPPs, were purposefully recruited to collect data over a one week period in May 2018. They collected data on all prescription items validated that were prescribed by IPPs and doctors. Errors that were identified were recorded in detail. Data collection forms and error definitions were taken from the EQUIP study, a large study looking at prescribing errors by junior doctors in the hospital setting.

Results: 5840 prescriptions items were recorded; 1026 (17.6%) were prescribed by an IPP. 479 errors were recorded in total. Experienced IPPs, had a 1% error rate (7 errors); IPPs with less experience had a 0% error rate. Overall the error rate for pharmacists was 0.7% (95% CI 0.0-1.0). In comparison, doctors made an average of 9.8% errors (95% CI 9.0-11.0). Pharmacists made significantly less prescribing errors than doctors (p<0.01). 85.7% of IPP errors were recorded as minor in significance, compared to an average of 31.7% for all doctor's prescribing errors. Actual patient harm occurred from 0.04% of all prescriptions. **Conclusion:** In a single NHS Trust, pharmacists make significantly less prescribing errors than doctors. Embedding IPPs with more integrated roles in the multi-disciplinary team is recommended. Further large trials are required to validate the results of this study.

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Keywords: Clinical Pharmacy, Electronic Prescribing, Medical Errors, Risk Management,

Clinical Audit, Competency Evaluation

Key Messages:

What is already known on this subject:

- The error rate for Independent Pharmacist Prescribers (IPP) is documented to be between 0-1.2% from small observational studies.
- The error rates for doctors' prescribing is documented to be 8.9% from a large multicentre study.
- There is no literature that directly compares IPP and doctors' prescribing errors in terms of frequency or types of errors.

What this study adds:

- This study provides the first set of data demonstrating that IPPs have a significantly lower prescribing error rate than doctors.
- This study provides a starting point for future research to support the increased utilisation of pharmacist prescribers in the multi-disciplinary team in the hospital setting.

INTRODUCTION

Pharmacists, who have been on the professional register for more than two years and who have successfully completed an accredited course at a Higher Education Institute, have been able to act as supplementary prescribers (prescribing within a clinical management plan agreed with the patient's doctor) since 2003. ¹ Further legislative changes in 2006², 2009³ and 2012⁴ resulted in pharmacists prescribing independently with the same prescribing powers as doctors.

Rational prescribing is a complex process; the healthcare professional must generate or confirm a diagnosis and select a suitable therapy, being mindful of the relative appropriateness of the intervention for that patient⁵. Like any complex processes, there is potential for error at various points. Clearly defining a 'prescribing error' is difficult as the terms 'medication errors' and 'prescribing errors' are often used interchangeably. For the purposes of this study: "A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice".⁶

An observational study by Baqir et al examined the prevalence of prescribing error rates for IPPs within a UK hospital. Of the 1415 prescription items reviewed, they found a 0.3% error rate amongst IPP prescriptions.⁷ Three other studies report the IPP prescribing error rate to be from 0% to 1.2%^{8,9,10}, although these three studies did not focus exclusively on errors. The EQUIP study investigated doctors' prescribing errors across 19 hospitals and found an

average of 8.9% errors amongst doctors' prescription items. This study also recorded IPP prescriptions however only 179 items were prescribed by pharmacists with a 0% error rate. There is no literature that directly compares IPP and doctors prescribing errors in terms of frequency or types of errors.¹¹

The aim of this research was to determine if there is a statistically significant difference in error rates between IPP prescriptions and doctors' prescriptions. Secondary aims were to determine the types of errors made by IPPs and whether experience affects the frequency and types of errors.

METHODS

Data were collected from prescription items for adult inpatients across medical and surgical wards at one large acute hospital Trust in England throughout May 2018; the time restriction determined the sample size. Pharmacists (IPPs and non-prescribing pharmacists) working across a range of specialties and wards volunteered and were trained to collect data. This convenience sampling approach to data collection allowed us access to a much larger data set than using random sampling with potentially lower numbers of data collectors. Haematology, oncology and paediatric wards were excluded from data collection.

Pharmacist and doctors were grouped according to the grading of their job roles. In England, IPP Foundation Pharmacists (FP) have two years post-qualification experience, band 7 pharmacists have > two years' experience and band 8a and above the most experience or level of seniority. Foundation Year 1 (FY1) doctors are newly qualified and for doctors have the least prescribing experience followed by FY2, core trainees, registrars and consultants being the most experienced. Data collection included details regarding the grading of the prescriber to allow us to determine if experience level affects the frequency of prescribing errors.

Classification of prescribing errors is usually undertaken by defining the type of error and/ or the severity of the error. This study recorded both the type and the severity of all errors documented. The classification of errors was reviewed by the lead author and one other experienced pharmacist to ensure correct classification and identification of errors.

The 'error type' definitions used in this study (*table 1*) were used in the EQUIP study.¹¹ Following a pilot of the data collection form, it was identified that two types of errors were not well described by the classification; incorrect choice of antibiotic and incorrect dosage due to renal function. Therefore these types of errors were added to the classification in the EQUIP study.¹⁰

Table 1: Error Types

Omission on admission	Drug not prescribed but indicated		
Underdose	Continuation for longer than needed		
Overdose	Route missing		
Strength/dose missing	Start date incorrect/missing		
Omission on discharge prescription	Controlled Drug requirements		
	incorrect/missing		
Administration times incorrect/missing	Drug interaction		
Duplication	Daily dose divided incorrectly		
Product/formulation not specified	Significant allergy		
Incorrect formulation	Continuation after adverse drug		
	reaction		
No maximum dose	Premature discontinuation		
Unintentional prescription of drug	Drug interaction not taken into account		

No signature	No dosage alteration after levels out of		
	range		
Clinical contra-indication	Dose/rate mismatch		
Incorrect drug or dosage for renal function	Incorrect choice of antibiotic		
Incorrect route	Drug not prescribed but indicated		
No indication	Continuation for longer than needed		
Intravenous administration instructions	Route missing		
incorrect/missing			

The severity classification of errors was also taken from the EQUIP study¹¹ which categorises

errors as 'minor', 'significant', 'serious' and 'potentially lethal' (table 2).

All data were reviewed by the authors to ensure it was accurately classified and unbiased.

Data were analysed by descriptive statistical analysis using SPSS.

Table 2: Assessing severity of prescribing errors

Error description
An error is defined as potentially lethal if it could have one or more of the following consequences:
The serum level resulting from such a dose is likely to be in the severe toxicity range based on common dosage guidelines, e.g. serum theophylline concentrations greater than 30 micrograms per ml.
More than 10 times the dose of chemotherapy agent
The drug being administered has a high potential to cause cardiopulmonary arrest in the dose ordered.
The drug being administered has a high potential to cause a life threatening adverse reaction, such as anaphylaxis, in light of the patient's medical history.
The dose of a potentially lifesaving drug is too low for a patient having the disease being treated
The dose of a drug with a very low therapeutic index is too high (ten times the normal dose)
An error is defined as serious if it could have one or more of the following results:
The route of drug administration ordered is inappropriate, with the potential of causing the patient to suffer a severe toxic reaction.
The dose of the drug prescribed is too low for a patient with serious disease who is in acute distress
The dose of a drug with a low therapeutic index is too high (four to ten times the normal dose)
The dose of the drug would result in serum drug levels in the toxic range, e.g. theophylline levels 20-30 micrograms per mL.
The drug orders could exacerbate the patient's condition, e.g. drug-drug interaction or drug-disease interaction and a clear clinical consideration has not been documented.
The name of the drug is misspelled or illegible creating a risk that the wrong drug might be dispensed including errors in decimal points or units if the error could lead to the dose being given
High dosage (ten times) normal of a drug without a low therapeutic index
An error is defined as significant if it could have one or more of the following results:

	The dose of the drug with low therapeutic index is too high (half – four times the normal dose)
	The dose of the drug is too low for a patient with the condition being treated
Significant error	The wrong laboratory studies to monitor a specific side effect of a drug are ordered e.g. CBC and reticulocyte counts are ordered to monitor gentamicin toxicity
	The wrong route of administration for the condition being treated is ordered e.g. the inadvertent change from IV to oral therapy for the treatment of bacterial meningitis
	Errors ordering fluids are made e.g. specific additives needed for complete therapy are omitted or incompatible fluids are ordered
	Errors of omission whereby patient's regular medication is not prescribed either on admission, during a rewrite and on discharge
Minor error	An error is defined as minor if it could have one or more of the following results:
	Duplicate therapy was prescribed without potential for increased adverse effects
	The wrong route was ordered without potential for toxic reactions or therapeutic failure
	The order lacked specific drug, dose, dosage strength, frequency, route or frequency information
	Illegible, ambiguous or non-standard abbreviations
	An errant order was written that was unlikely to be carried out given the nature of the drug, dosage forms, route ordered, missing information etc
	Examples include, simvastatin prescribed in the morning rather than at night. Bisoprolol – two puffs four times a day

ETHICS

NHS ethical approval from the NHS Health Research Authority was not required. Ethical approval was gained from the University of Leeds, School of Healthcare Ethics Review Committee.

No funding was received for this project.

RESULTS

The primary outcome of this study was the frequency of prescribing errors made by IPPs compared to doctors. *Table 3* demonstrates the number of prescriptions written in total and by each professional group and the % error rate for each group. The prescribing error rate for IPPs was 0.7% (95% CI 0.0-1.0) compared with a prescribing error rate of 9.8% (95% CI 9.0-11.0) for all doctors' prescriptions (p<0.01). *Figure 1* shows the severity of errors made by each professional group.

Table 3: Number of prescribed items written and prescription errors made by professional group

	Type of prescriber						
	Pharmacist 8a or above	Pharmacist band 7 or 3rd year FP	Doctor FY1, FY2,CT or equivalent	Registrar	Consultant	Doctor unknown	
Total prescriptions written	699	327	4041	464	171	138	5840
Number of errors	7	0	388	66	10	8	479
% prescribing errors	1.0%	0.0%	9.6%	14.2%	5.8%	5.8%	8.4%

Registrars were the professional group contributing the largest error rate at 14.2% (95% CI 11.0-17.0). Band 7 or 3rd year FP pharmacists contributed the smallest error rate at 0%,

closely followed by band 8a and above pharmacists with a 1% (95% CI 0.0-2.0) error rate.

Box 1 describes the errors made by pharmacists.

Seventy seven errors, all made by doctors, were removed from the full analysis due to lack

of detail provided; these errors are included in the overall error frequencies.

Box 1: Description of errors made by pharmacists

Significant errors:

- 1. Valganciclovir PO twice weekly
 - a. Prescribed to have twice weekly Saturday and Wednesday evening. However not prescribed to start until Saturday when initially prescribed Wednesday morning. Patient would have missed a dose if not corrected
 - *i.* Error type: Start date incorrect/missing
- 2. Darbopoetin
 - a. 30mg prescribed instead of 130mg on admission (patient already prescribed prior to admission).
 - i. Error type: Underdose

Minor errors:

- 3. Teicoplanin IV
 - a. correctly prescribed but without an indication on the chart
 - i. Error type: No indication
- 4. Lansoprazole
 - a. Re-prescribed formulation as per admission but didn't cease incorrect prescription
 - i. Error type: Duplication
- 5. Fostair inhaler
 - a. Re-prescribed formulation as per admission but didn't cease incorrect prescription
 i. Error type: Duplication
- 6. Laxido sachets
 - a. Re-prescribed dose as per admission but didn't cease incorrect prescription
 - i. Error type: Duplication
- 7. Salbutamol
 - a. Re-prescribed formulation as per admission but didn't cease incorrect prescription
 - i. Error type: Duplication

DISCUSSION

To our knowledge, this is the first study that focuses on prescribing errors and directly compares IPP prescribing with doctors' prescribing in any sector of care. It is only the second study that provides coverage of errors by a large group of IPPs, across a number of specialities. It is also only the second study with a specific focus on IPP prescribing errors. With an overall error rate of 0.7% for IPPs, compared to 9.8% for doctors, this study demonstrates that pharmacists make significantly less prescribing errors, and are therefore significantly safer prescribers than doctors based on this cross sectional observation.

A mean prescribing error rate of 0.7% by IPPs compares favourably to other studies who reported a 0.18% to 1.2% error rate.^{7,8,9,10}

Band 8a IPPs with (generally) more experience than band 7 IPPs made more prescribing errors; band 7 IPPs made no errors from the data collected. The sample size of band 7 IPP errors was smaller, limiting the power to detect a true error rate. One theory for the difference may be a difference in confidence level between the two groups.

Complexity of medicines regimens prescribed by IPPs may be associated with their level of experience. From the errors made by experienced pharmacists, three were complex medicines (only prescribed in specialist areas or with a complex dosing or administration regime) whereas four were on commonly prescribed medicines. None of these were knowledge-based mistakes, all were slips of action or memory lapses.¹² Another theory, better supported by the data, may be that increasing experience means completing tasks that the individuals are strongly familiar with and do not require full attention; they may

also be more likely to become distracted as they are more familiar with the task.¹² System 1 'automatic' thinking occurs when one is familiar with a task; system 1 thinking leads to an increased error rate but decreased significance of errors.¹³ More senior staff usually have increased responsibilities, including supervising and supporting junior staff; the increase in workload outside prescribing activities may also contribute to error rates.

With 85.7% of IPP errors being classed as 'minor', the severity of pharmacist errors was also lower than those made by doctors which impacts positively on patient safety. None of the pharmacist prescriptions led to harm, this was comparable to other groups of prescribers with the exception of FY1/FY2/CT or equivalent with a harm rate of 0.05% from all prescriptions written by this group. Overall, the severity of errors reported for doctors was comparable to those described in the EQUIP study.¹¹ Overall, the incidence of actual harm to patients from prescribing errors was low. This demonstrates that although the overall error rate was high, either these errors did not cause harm or were corrected prior to the drug being administered. A UK study looking at prescribing errors in hospital inpatients found that 57.7% of errors were rectified by a pharmacist prior to a dose being administered to the patient.¹⁴ The EQUIP study also found that doctors rely heavily on pharmacists and nurses to identify and correct prescribing errors.¹¹

Comparison of the prescribing activity of pharmacists and doctors, particularly workload pressures, the complexity and autonomy of the process, was not investigated as part of this study. It is likely to be very difficult, even with a controlled study, to investigate the effect of workload pressures however this could lend weight to the argument for increasing pharmacist prescribing to reduce workload pressures on doctors and improve safety for

patients. The literature, demonstrates that pharmacists are prescribing across broad areas including complex medicines and conditions.^{7,8,9,10} Experience from practice indicates that IPP activity is very comparable to that of junior doctors; a considerable amount of prescribing is undertaken with support from the multidisciplinary team (MDT). Some pharmacists prescribe completely autonomously; making decisions without the support of others, similar to consultants and senior registrars. Fully autonomous IPP prescribing may occur in a number of settings however those IPPs who do a majority of their prescribing completely autonomously work in pharmacist led outpatient clinics where they are not fully supported by the presence of a doctor; this data was not captured as part of this study. Further study would be required to investigate the safety of pharmacist prescribing while working out of hours to support increased utilisation of pharmacist prescribers to improve safety 24/7.

There is a body of literature available evaluating the clinical effectiveness of IPPs in practice. This demonstrates that IPPs are as effective as doctors, or more so, at gaining positive clinical outcomes for patients when prescribing^{15,16,17,18} and views of patients on IPP prescribing in the literature are encouraging.^{19, 20} It has also been shown that IPPs involve the patient more in decisions about their medicines.²¹

In addition to the study by Baqir et al, who demonstrated that IPPs make very low numbers of errors,⁷ we can provide evidence that pharmacists are not only safe, but due to the significantly reduced error rate are perhaps safer than doctors. Recommendations from the evidence produced by this study include the wider role out of IPPs in hospital practice and deeper involvement in the MDT. It is suggested that the results of this study can be used to

support shaping the future IPP workforce; IPPs should be deployed to undertake a much higher proportion of prescribing in order to improve patient safety.

Limitations of this study include the use of pharmacists to collect data about errors made by other pharmacists. Pharmacists and doctors knew that the study was being undertaken; this may have improved focus on prescribing accuracy via the Hawthorne effect.²² The option provided to data collectors of selecting the days of data collection may have led to all data being collected by an individual on a certain week day as it was quieter which could have impacted on the results. Furthermore, data were only collected on week days; data from weekends could show a different result. Pharmacists were prescribing in a ward-based setting only; data from outpatient clinics may show a different result.

It should be noted that this study is observational and not controlled to directly compare like for like. Results are correlational and can only provide a basis for speculation as to the difference in error rate between professional groups which could be explored further. There was no consideration of the variances between the type of work undertaken by pharmacists and doctors, workload pressures or the influence of shift working on medical prescribing.

Analysis comparing like for like in experience level was not undertaken. Prescribing pharmacists already have at least 2 years post-qualification experience and may be working permanently in a single speciality. Newly qualified doctors were included in this study; they move clinical areas regularly and must quickly become familiar with specialisms. The authors tried to mitigate for this by collecting data only in 'non-specialist' areas however variances between generalist areas will still be present; more detailed future studies may allow for

this. The generalisability of the findings of this study outside adult medicine and surgery, or outside the individual hospital Trust is also perhaps limited.

CONCLUSION

This study demonstrates that in a single NHS Trust, IPPs working in adult medicine and surgery are safer prescribers than doctors. Errors made by IPPs are low in significance and do not lead to patient harm. This suggests that increasing prescribing activity of IPPs and embedding this activity into the MDT would improve patient safety around prescribing. Further large controlled studies are required to validate the results of this study outside the individual Trust and across wider areas of practice, taking in to consideration the limitations of this study to support future workforce development from a safety perspective.

FIGURE LEGEND

Figure 1: The severity of errors made by prescribers by professional group. Pharmacists made no serious errors and a majority of pharmacist errors were minor. Overall, pharmacist errors were less serious than medical prescriber errors. Only FY1/FY2/ SHO and registrars made any serious errors. No potentially lethal errors were made.

Box 1: A description of the errors made by pharmacists broken down in to severity and error type. The most common pharmacist error type was duplication.

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