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The Incidence of Prescribing Errors in Hospital Inpatients

An Overview of the Research Methods

Bryony Dean Franklin,[1] *Charles Vincent*,[2] *Mike Schachter*[3] and *Nick Barber*[4]

1 Academic Pharmacy Unit, Hammersmith Hospitals NHS Trust & School of Pharmacy, University of London, London, UK
2 Surgical Oncology and Technology, Imperial College School of Medicine, London, UK
3 Clinical Pharmacology, Imperial College School of Medicine, London, UK
4 School of Pharmacy, University of London, London, UK

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Abstract

Many different methods have been used to study the incidence of prescribing errors in hospital inpatients. The objectives of this review were to outline the methods used, highlight their strengths and limitations, and summarise the incidence of prescribing errors reported.

Methods used may be retrospective or prospective and based on process or on outcome. Reported prescribing error rates vary widely, ranging from 0.3% to 39.1% of medication orders written and from 1% to 100% of hospital admissions. Unfortunately, there is no standard denominator for use when expressing prescribing error rates. It could be argued that the most meaningful is the number of medication orders written; however, it is also helpful to consider the number of medication orders written per patient stay in order to understand the risk that a given prescribing error rate poses to an individual patient. Because of wide variation in the definitions and methods used, it is difficult to make comparisons between different studies.

Each method for identifying prescribing errors has advantages and disadvantages. Process-based studies potentially allow all errors to be identified, giving more scope for the identification of trends and learning opportunities, and it may be easier to collect sufficient data to show statistically significant changes in

prescribing error rates following interventions to reduce them. However, studies based on process may be criticised for focusing on many minor errors that are very unlikely to have resulted in patient harm. Focusing instead on harm, as in outcome-based studies, allows efforts to reduce errors to be targeted on those areas that are likely to result in the highest impact. Therefore, the most appropriate method depends on the study's aims. However, using a combination of methods is likely to be the most useful approach if comprehensive data are required.

Medication errors have been estimated to harm 1–2% of patients admitted to both UK and US hospitals,[1,2] with the majority of these probably attributable to prescribing errors.[3,4] These figures are alarming and should, on the face of it, lead to urgent action. However, estimates of the extent of patient harm are not always believed by either patients or professionals.[5] For medication errors in general and prescribing errors in particular, widely differing estimates of their incidence appear in the literature. Clearly it is difficult to attack the problem or assess the effectiveness of interventions without understanding the scale of the underlying problem.

Studies of prescribing errors use a range of definitions, denominators and methods, all of which make interpreting the literature a considerable challenge. In this paper we attempt to make sense of this diverse literature. Our objectives are to outline the main approaches used to assess the incidence of prescribing errors, to highlight the strengths and limitations of these methods and to summarise the incidence of prescribing errors in hospital inpatients reported in the literature.

1. Literature Search

A literature search was carried out in January 2005 in the MEDLINE and Pharm-line databases, using the search term 'prescribing error'. Only English language quantitative studies of prescribing errors in hospital inpatients were included; review articles, case reports and studies relating to specific drugs or classes of drug were excluded. The research team's database of references relating to medication errors was also searched. The studies identified were reviewed with respect to the definitions, denominators and methods used, and a summary produced of the error rates reported.

2. Definitions

Before reading any studies of iatrogenic harm, it is important to be clear about what is being studied. The following list provides an explanation for the common terminology.

- **Iatrogenic harm:** Any harm induced by medical treatment or diagnostic procedures. This includes unintended harm associated with surgery, hospital-acquired infections, diagnostic errors and medication.
- **Adverse drug event:** Any iatrogenic harm related to medication. This includes harm due to both adverse drug reactions and medication errors.
- **Adverse drug reaction:** Defined by the WHO as a response to a drug that is noxious, unintended and occurs at doses used in man for prophylaxis, diagnosis or therapy.[6] It is usually assumed that most adverse drug reactions are not preventable. Somewhat confusingly, some authors use the WHO definition of an adverse drug reaction to define an adverse drug event.[7,8]
- **Medication error:** Any error in prescribing, dispensing or administration of medication. A medication error may or may not result in patient harm, but is considered to be preventable.

Figure 1 summarises the relationships between medication errors, adverse drug events and adverse drug reactions. Medication errors can be further subdivided into prescribing errors, dispensing errors, monitoring errors and administration errors. In some countries and inpatient medication systems there is also a transcribing stage, for example if handwritten medication orders have to be entered into a computer system by pharmacy staff prior to administration, which can give rise to transcribing errors. This paper focuses on prescribing errors.

Prescribing errors have been defined in many different ways. A common approach has been to

consider that a prescribing error has occurred if a pharmacist's intervention was required[9-11] or if a doctor changes a medication order as a result.[12,13] Although pragmatic, this approach is limited by potential differences in the knowledge and skills of individual pharmacists. There are also many situations where prescribing errors may be identified but do not result in a pharmacist's intervention (for example, because the drug had already been given or the patient has been discharged) and where interventions occur for reasons other than prescribing errors (for example, to enforce drug formularies or help patient compliance). Other studies have used outcome-based definitions,[3] including only those errors that result in patient harm. However, in many cases, pharmacists or other healthcare professionals intervene to prevent errors from reaching the patient.[9,12] In these cases the true outcome remains unknown and the reported outcome reflects the whole system rather than just the prescribing act.

Even where prescribing errors are defined more explicitly, there is wide variation in the types of event included. For example, Betz and Levy[14] include "prescribing a medication without sufficient education of the patient on its proper uses and effects", Tesh et al.[15] include the prescription of medication by brand (rather than generic) name and Potts et al.[16] include prescribing for a child whose body weight is not documented. Others do not consider these to be prescribing errors. In many published studies, prescribing errors are not defined explicitly, are defined in very general terms or by giving a list of categories of error without defining them clearly. Finally, some studies define prescribing errors only as deviations from prescription writing standards and do not include errors in the prescribing decision.

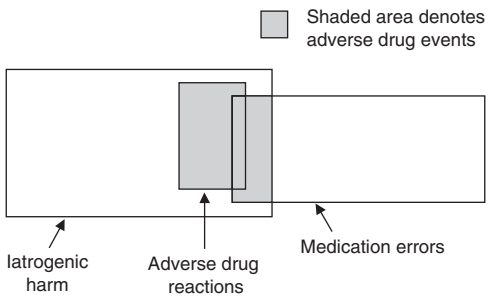

Fig. 1. Relationship between medication errors and different types of iatrogenic injury. The issue of whether or not there is any overlap between medication errors and adverse drug reactions (because some medication errors may lead to an adverse drug reaction) is controversial; we represent an overlap here.

As a result of these problems, we used the Delphi technique[17] to develop a practitioner-based definition of a prescribing error and guidance as to the types of event that should be included and excluded. A clinically meaningful prescribing error was defined as a prescribing decision or prescription-writing process that results in an unintentional, significant reduction in the probability of treatment being timely and effective *or* increase in the risk of harm, when compared with generally accepted practice.[18] This definition is accompanied by lists of events that should and should not be included. For example, prescribing 'one tablet' of a drug that is available in more than one strength, omission of the prescriber's signature and doctors' transcribing errors (from one chart to another) were all considered prescribing errors. However, failure to adhere to standards such as prescribing guidelines or the drug's product licence were not considered errors if this reflected accepted practice.[18] This definition has subsequently been used in several empirical studies[19-24] and by the UK Department of Health.[25]

3. Denominators

Studies also differ in the denominators used. Some are based on hospital admissions,[2] some on patient days,[26] some on prescriptions or medication orders written[20] and others on the number of medication orders checked by pharmacists.[22] It has been shown that for studies of medication administration errors, the denominator used can have a dramatic influence on the conclusions drawn[27] and there is no reason to suspect that the situation is any different for prescribing errors. If the denominator used is the number of medication orders written, the results will also be affected by whether or not each medication order can be considered to have more than one prescribing error. Often this is not stated explicitly. Ideally, it should be possible for each medication order to have more than one prescribing error, but the results should also indicate how many medication orders were affected. Unfortunately, there is no standard denominator for use when expressing pre-

scribing error rates. It could be argued that the most meaningful is the number of medication orders written; however, it is also helpful to consider the number of medication orders written per patient stay in order to understand the risk that a given prescribing error rate poses to an individual patient.

4. Methodological Approaches

Many different methodologies are available for studying errors and adverse events, and each has its strengths and limitations.[28] Studies may be classified according to whether they focus on outcome or process and whether study designs are retrospective or prospective (table I). We now consider each of these in turn.

4.1 Outcome-Based Studies

Outcome-based studies are based on identifying actual patient harm. Most studies that fall into this category were designed to study all types of iatrogenic injury or all types of adverse drug events, rather than prescribing errors in particular. However, depending on how the data are analysed and presented, the incidence of prescribing error-related events can sometimes be determined. Data collection can be either retrospective or prospective.

4.1.1 Retrospective Studies of Outcome

The Harvard Medical Practice Study[30] is probably the most well known retrospective study of iatrogenic harm; a two-stage review of medical notes was used to identify patients that had experienced harm. This US-based medical notes review suggested that adverse drug events occurred in 0.7% of inpatients. A more recent US study[31] suggested a similar figure of 0.6%. However, these figures include both non-preventable and preventable adverse drug events. Among the preventable adverse drug events, prescribing errors were included with other types of error. From Australian and UK studies using similar methodology,[2,32] it can be estimated that preventable medication-related harm (harm due to medication errors) occurred in 0.8% of admissions, but again it is not clear how these were distributed between prescribing errors and other types of error. In theory, it should be possible to study the incidence of prescribing errors using this type of approach or elucidate the results relating to prescribing errors from studies of all types of iatrogenic harm. However, some doubts have been cast over the validity and reliability of the assessment of preventability in such studies[33] and because the medical notes used as a data source were originally created for a different purpose, inadequacies in documentation could result in both false negative and false positive results.

Another approach to retrospective data collection is to use 'triggers' such as the results of laboratory tests or medication prescribed that may indicate that an error or other adverse event has occurred.[7,34] The medical notes of the patients identified are then examined in more detail. However, the studies carried out to date focus on adverse drug events in general and it is not possible to separate prescribing errors from other types of adverse event. Furthermore, this methodology has not been fully validated and the percentage of all events that can be identified using this method is not yet known. When the real incidence of errors is low, it is easy for tests with low sensitivity and specificity to generate more false than true alerts.

Table I. Different types of prescribing error studies, with an example of a study of each type

Study focus	Prospective	Retrospective
Outcome based	Daily review of medical notes and asking staff for potential reports of harm[3]	Retrospective review of medical notes[2]
Process based	Pharmacist review of medication orders during prescription monitoring.[9] Self reporting[29]	Retrospective review of medication orders[15]

4.1.2 Prospective Studies of Outcome

Prospective approaches potentially offer a more rigorous and robust approach without some of the biases associated with retrospective review. Prospective studies allow additional checking and investigation that is not possible in retrospective reviews that may be carried out months or years later.

The US-based Adverse Drug Event Prevention Study Group carried out a prospective study to examine medication-related harm in detail.[3] Adverse drug events included all types of medication errors that resulted in harm, as well as adverse drug reactions; adverse drug events were identified using self

reporting by practitioners and daily medical record review by researchers. It was concluded that medication errors caused harm in 1.8% of inpatients, of which prescribing accounted for the majority (1.0% of all inpatients). This approach is likely to be more comprehensive than retrospective methods; however, there are no studies that directly compare the two. Definitions of harm also vary. For example, in the retrospective Harvard Medical Practice Study,[30] harm was defined as "measurable disability at discharge or increased length of stay due to the event". This study, therefore, included only events that resulted in more serious levels of harm. The Adverse Drug Event Prevention Study Group suggests that only 8% of the adverse drug events they identified met the definition used in the Harvard Medical Practice Study.[3]

Computer-based[35-37] systems have also been developed to prospectively screen for adverse drug events, including preventable adverse drug events (medication errors), using similar triggers[38] to those used in the retrospective methods previously described. Prospective screening means that preventative action can be taken. One study has explored the validity of this method and compared the data collected with daily chart review and stimulated self reporting.[35] It was found that the computer-based system identified 70 of 166 (42%) preventable adverse drug events but was less time consuming than routine chart review. Again, most studies do not report rates of prescribing errors, as they were intended to assess adverse drug events in general.

In outcome-based studies, only those errors that reach the patient and result in injury are included. The advantage of this approach is that only the errors that actually cause harm are included, removing the need to estimate the potential clinical significance of an event. However, the disadvantage is that errors that do not result in harm, either due to the intervention of another healthcare professional or because of sheer good fortune, are not included. This means that these errors cannot be learnt from. This is in contrast to the next type of study, which is based on the prescribing process.

4.2 Process-Based Studies

Process-orientated studies are based on healthcare professionals, usually pharmacists, reviewing prescriptions to identify prescribing errors. Although such studies may be retrospective or prospective in design, the majority are prospective. Since pharmacists prospectively identifying prescribing errors will generally draw these to the prescriber's attention, the prescriber will often correct the medication order before the patient receives any medication or before many doses have been received. There are, therefore, few actual adverse outcomes.

4.2.1 Retrospective Studies of Process

Thirty years ago, Tesh et al.[15] carried out a retrospective review of drug charts and medical notes in three wards in a UK hospital. It was concluded that 3.6% of all medication orders were associated with an error in drug use; these included errors in dose and frequency, route of administration and potential drug interactions. In addition, there were errors in prescription writing (such as the use of brand names and spelling errors) in 7.9% of the medication orders studied. However, the definitions used were very broad, including prescribing by brand name, and the results cannot easily be compared with other studies. No more recent studies of this type have been published, although it should be possible to identify prescribing errors by retrospective review of patients' medical notes and medication administration records. The reliability and validity of this approach has not yet been explored.

4.2.2 Prospective Studies of Process

Process-based prospective studies may be based on either pharmacists recording prescribing errors identified as part of their routine clinical practice or a thorough review carried out with the primary aim of collecting research data. There are potential advantages and disadvantages of each of these approaches. Data collected by researchers is likely to be more comprehensive, but pharmacists directly involved with patient care may be aware of additional contextual information about the patient that may facilitate error identification.

Studies show that US pharmacists prospectively reviewing medication orders in the course of their prescription monitoring duties identify (and prevent) prescribing errors in 0.3–6.2% of all orders written.[9,11-13,39] However, careful examination of these studies reveals some variation in the defini-

tions used and comparisons between them should be made with caution. As one of the most prolific authors in this area points out, some of the error rates quoted are also likely to be an underestimate of the true error rate, as many errors will go undetected by the dispensary-based pharmacists who collected the majority of these data.[40] This will depend on the type of pharmacy service in operation, but dispensary-based pharmacists will not have physically seen the patient and will not necessarily have access to data on indications and concurrent medical conditions. Ward-based pharmacists will have access to a wider information set. Little is also known about the number of errors identified and rectified by pharmacists but not recorded. A study in paediatric inpatients used similar data collection methods to those used by the Adverse Drug Event Prevention Study Group,[3] but included all medication errors instead of only those that resulted in harm.[41] In this study, a prescribing error was identified in 40.5% of admissions or 4.2% of medication orders written.

There have been fewer studies outside of the US. Several prospective UK studies have studied pharmacists' clinical interventions.[26,42] However, such studies do not allow firm conclusions to be drawn regarding the frequency of prescribing errors, as pharmacists' interventions may be for many other reasons such as advice giving, formulary issues and patient counselling. In a recent study on one surgical ward, we found that only about one-half (38 of 73; 52%) of pharmacists' interventions related to prescribing errors. Another 56 prescribing errors were identified but did not result in an intervention (unpublished data). In a more recent study, pharmacists prospectively identified prescribing errors in UK hospital inpatients[20] using a standard definition of a prescribing error.[18] This study identified a prescribing error in 1.5% of all medication orders written and a potentially serious prescribing error in 0.4%.[20] All of these were identified by pharmacists during routine monitoring and were rectified. Again, nothing is known about the numbers of errors that the pharmacists missed and the number that they identified but failed to record.

Sagripanti et al.[21] studied prescribing errors in a cohort of 76 elective surgery patients in a UK hospital who were followed from pre-operative assessment clinic to discharge by a researcher. Prescribing errors were identified in 67 (36%) medication orders written on admission, 24 (3%) written during the inpatient stay and 86 (27%) written at discharge. The latter were generally the omission from the electronic discharge prescription of medication that patients reported having supplies of at home. Other studies focus specifically on the admission[43] or discharge[44] processes.

Studies based on self reporting of errors[45,46] can also be classified as prospective and process based, although data on patient outcome may also be included. The extent and nature of what is reported is likely to vary widely depending on the nature of the reporting system, the organisational culture, how easy it is to report and other factors. Reporting systems can be used to highlight commonly reported problems and serve an important function in raising awareness and enhancing safety. It is important to be aware that the data cannot be used to obtain quantitative estimates of error rates due to the gross underreporting that is known to occur.[35,47-50]

Table II summarises the prescribing error rates reported for hospital inpatients. Although some are retrospective and some prospective, the majority of studies are process based.

5. Discussion

Prescribing error rates reported in the literature vary widely. Studies suggest that prescribing errors occur in 0.3–9.1% of medication orders written for hospital inpatients and in 1–100% of hospital admissions. However, the wide variations in methods and definitions used mean that comparisons between studies should be made with caution. Harm due to prescribing errors has been reported in approximately 1% of inpatients. Less is known about prescribing error rates in primary care[57] and in hospital outpatients, although several studies of community pharmacists' interventions have been carried out.[58-61]

There are many different methods that have been, or could be, used to measure the incidence of prescribing errors. Currently, there have been few published studies comparing different methods using the same definitions in the same cohort of patients and so any differences in the errors identified by each method are not clear. One study of adverse drug events conducted using several different meth-

Table II. Summary of prescribing error rates reported in hospital inpatients[a]

Setting	Study design	Prescribing error rate	Methods	Reference
11 medical and surgical units in 2 US hospitals	Prospective	1.0% of 4031 admissions	Daily medical record review and stimulated self reporting	3
3 wards in a UK hospital	Retrospective	3.6% of 7526 medication orders	Review of medication charts and medical notes	15
2 US children's hospitals	Prospective	0.5% of 101 022 medication orders	Pharmacists recording errors identified during routine review	12
2 US hospitals	Prospective	1.9% of 123 367 medication orders	Pharmacists recording errors identified during routine review	13
US hospital	Prospective	0.3% of 289 411 medication orders	Pharmacists recording errors identified during routine review	9
Paediatric hospital in Australia	Prospective	68% of 212 admissions, 44% of 325 admissions 1 year later following various interventions	Review by clinical pharmacist twice daily, 7 days a week for 1 month	51
US hospital	Prospective	0.4% of approximately 525 750 medication orders	Pharmacists recording errors identified during routine review	39
Paediatric cardiac ward and ICU in a UK hospital	Prospective	44.3% of 682 admissions	Self reporting	46
Paediatric patients in 2 US hospitals	Prospective	4.2% of 10 778 medication orders, 40.5% of admissions	Daily medical record review and stimulated self reporting	41
Elective surgery patients in a UK hospital	Prospective	100% of 76 patients (177 errors in 76 patients)	Researcher reviewing medical notes and drug charts	21
Two Dutch hospitals	Prospective	9.9% of 3540 medication orders	Pharmacists recording errors identified during routine review	52
1 medical team in a US hospital	Retrospective	1.33 per patient (n = 35), 0.85 per patient (n = 35) with pharmacist on round	Review of medication charts and medical notes	53
UK hospital	Prospective	1.5% of 36 168 medication orders	Pharmacists recording errors identified during routine review	20
2 teaching hospitals in The Netherlands	Prospective	14% of 5302 prescriptions	All new prescriptions screened by pharmacist and clinical pharmacologist	54
UK psychiatric hospital	Prospective	2.2% of estimated 2274 prescription items checked	Pharmacists recording errors identified during routine review	22

Continued next page

Table II. Contd

Setting	Study design	Prescribing error rate	Methods	Reference
2 wards in a UK hospital	Prospective	3.15 per patient (n = 235)	Pharmacists recording errors	55
US hospital	Prospective	1.1% of 45 366 orders	Research pharmacist evaluating medication orders	10
Paediatric intensive care units in 9 US hospitals	Prospective	11.1% of 12 026 medication orders, reduced to 7.6% of 9187 orders following interventions at each site	Pharmacists and nurses identifying errors during routine practice, verification by researchers	56
US hospital	Prospective	6.2% of 17 808 orders	Pharmacists recording errors identified during routine review	11
US paediatric ICU	Prospective	39.1% of 6803 orders pre-CPOE, 1.6% of 7025 orders with CPOE	Review by designated clinical pharmacist	16

a Studies are only included where the incidence of prescribing errors can be determined from the published results. Studies reporting pharmacists' interventions without specifying the number resulting from prescribing errors are excluded, as are studies focusing only on adherence to prescribing standards or only on admission or discharge. Within each category, studies are arranged in order of publication date.

CPOE = computerised physician order entry; **ICU** = intensive care unit.

ods found that the underlying rate appeared to be much higher than that suggested by any individual method;[35] this was also the case in a study of all types of iatrogenic injury.[62]

However, as well as potential differences in the numbers and types of error identified using different methods, there are other issues relating to the choice between them. Process-based studies potentially allow all errors to be identified, giving more scope for the identification of trends and learning opportunities, and it may be easier to collect sufficient data to show statistically significant changes in prescribing error rates following interventions to reduce them. Prospective process-based studies also allow opportunities for healthcare professionals to intervene to prevent errors from harming the patient and to feed back details of the error to those involved.[63] However, since errors may be rectified in prospective studies, it is important to be clear about whether prescribing error rates have been assessed before intervention (focusing on the prescribing process in isolation) or after any interventions have taken place (focusing on the whole system).

Studies based on process may be criticised for focusing on many minor errors that are very unlikely to have resulted in patient harm. Focusing instead on harm, as in outcome-based studies, allows efforts to reduce errors to be targeted on those areas that are likely to result in the highest impact. Not all errors have equal propensity for harm; one study of medication errors, the majority of which were prescribing errors, estimated that only 0.9% of errors resulted in harm.[64] Alternative approaches are to use process-based methods and then evaluate the potential clinical significance of the errors identified using validated methods[65] or to use a combination of more than one method. Both prescribing-related harm and prescribing errors are important and the best methods used to study each type are likely to be different.

Prospective studies are generally considered to be more time consuming and expensive than retrospective studies but provide more comprehensive data. Many errors are difficult to identify retrospectively because of lack of documentation and lack of real-time information about the clinical status of the patient. In hospitals, asking pharmacists to document details of the errors they identify during rou-

tine prescription and patient monitoring is a practical approach, although more work is needed to explore the reliability and validity of this approach. Little is known about the numbers of errors missed.

Discussions of appropriate methodology are frequently marred by a simplistic attempt to identify the 'best' method, as if only one type of study was needed. Instead, the most appropriate method will depend on the research questions being addressed, resources available, context of the study and whether its purpose is operations or research.[66,67]

6. Conclusion

It is clear that prescribing errors are a regular occurrence. However, the interpretation of published studies is made difficult by wide variations in the definitions and methods used. Researchers and systematic reviewers need to be aware of these issues in order to correctly represent the literature. Robust methods are needed to evaluate the impact of interventions designed to reduce prescribing errors and the resulting harm; more evaluations of the validity and reliability of the methods described would be useful. Using a combination of methods is likely to be the most useful approach if comprehensive data are required.

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Correspondence and offprints: Dr *Bryony Dean Franklin*, Academic Pharmacy Unit, Pharmacy Department, Hammersmith Hospital, London, W12 0HS, UK.
E-mail: bdean@hhnt.nhs.uk