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Edited by Molly Courtenay and Matt Griffiths

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## Chapter

## 1

# Introduction to medication errors and medication safety

Molly Courtenay and Matt Griffiths

A medication safety incident is defined by the National Patient Safety Agency (NPSA) as: 'any unintended or unexpected incident which could have or did lead to harm for one or more patients' (NPSA, 2007:9).

These incidents can occur at each stage of the process involved in the delivery of medicines to patients, i.e. prescribing (including transcribing or physician ordering), dispensing, preparation, administering and monitoring (NPSA, 2007). Medication incidents have been reported as accounting for 10%–20% of all Adverse Events (AE) (Department of Health (DoH), 2004), i.e. an event that causes an unintended injury to a patient that either prolongs hospitalization or produces disability (Karson & Bates, 1999).

The impact of medication safety incidents on patient outcomes includes increased length of stay, disability and mortality (Vincent *et al.*, 2001). Across the UK, about two and a half million medicines are prescribed across hospitals and the community every day (DoH, 2004) and an indicator of quality, adopted to demonstrate medication safety, is the incidence of medication errors (DoH, 2004). The Government has committed to reducing the incidents of medication errors in prescribed drugs by 40% (DoH, 2004).

Between January 2005 and June 2006, 60 000 medication incidents were reported to the NPSA via the National Reporting and Learning System (NRLS) (NPSA, 2007). Although most medicine-related activity is carried out in the community, over 80% of the incidents reported to the NPSA were from the hospital setting. The majority of these incidents (over 80%) did not result in harm. Wrong dose, strength or frequency of medicine, omitted medicine and wrong medicine were errors that occurred most frequently and accounted for nearly 60% of all incidents reported.

Ninety-two out of the 60 000 medication incidents reported to the NPSA resulted in severe harm or death and arose from errors involving the administration and prescribing of medicines. Medicines most frequently associated with these incidents included opioids, anticoagulants, anaesthetics, insulin, antibiotics, chemotherapy, anti-psychotics and infusion fluids. The two groups of patients associated with medication errors, and highlighted in the NPSA report, included patients with known allergies being given medicines to which they were allergic (notably antibiotics), and errors involving specific medicines and dose calculations in children up to 4 years old.

Other important areas highlighted by the report included the high number of injectable medicines resulting in death and severe harm; risks associated with care transfer and the importance of accurate documentation; the availability and supply of certain medicines at the point they are required; medicines given outside a medicines ward round, or to those patients with specific needs.

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Legislative changes over the last decade mean that there are now a number of groups of healthcare professionals, in addition to doctors, able to prescribe medicines for patients. As of 1994, community nurse practitioners have been able independently to prescribe from a limited list of medicines. Independent prescribing rights were later extended in 2001 to include any appropriately qualified first level registered nurse and, as of 2006, Nurse Independent Prescribers (NIPs) have been able independently to prescribe any licensed medicine for any condition and some controlled drugs (CDs) provided that it is within their area of competence (DoH, 2005). These nurses are also able to prescribe any medicine as a supplementary prescriber (DoH, 2002), i.e. prescribe any medicine for any condition in partnership with a doctor and provided that the medicine is within their area of competence and listed on the patient's Clinical Management Plan (CMP).

As of 2003 (DoH, 2002), appropriately qualified pharmacists have been able to prescribe any medicine as a supplementary prescriber. In 2006 legislative changes (DoH, 2005) enabled these healthcare professionals independently to prescribe any licensed medicine (apart from controlled drugs).

In 2005, legislative changes enabled the prescription of medicine by optometrists and allied health professionals (i.e. physiotherapists, radiographers, and chiropodists/podiatrists) under supplementary prescribing. Further changes to legislation in 2007 (DoH, 2007) enabled appropriately qualified optometrists to independently prescribe any licensed medicine for ocular conditions affecting the eye, and the tissues surrounding the eye, within the recognized area of expertise and competence of the optometrist.

There are now approximately 14 000 nurses, 1500 pharmacists, and several hundred optometrists and AHPs able to prescribe medicines and these numbers are set to rise. The latest figures from the NHS Information Centre (<http://www.ic.nhs.uk/>) show that in the year ending March 2008, nurses in primary care prescribed items worth £29.2 m. In the year ending March 2009, this figure was £33.0 m i.e. a percentage increase of 13.1%. Pharmacists prescribed items worth £205 000 up to year end March 2008 and £381 000 up to March 2009 i.e. a percentage increase of 86.0%. The figure for GP prescribing for 2008 (January-December) was £7.9 billion.

Training for non-medical prescribers involves 27 days in the classroom (although some programmes have a distance learning element) and 12 days in practice with a Designated Medical Practitioner (DMP) responsible for the education and assessment of the prescribing student. A range of techniques are used to assess students' prescribing knowledge (which includes assessment of numeracy and drug calculation skills). In response to increasing numbers of nurses being involved in the prescription of medicines for children, it is now a requirement that nurse prescribers are competent to prescribe for children, or know when to refer to another prescriber when working outside their area of clinical competence (Nursing and Midwifery Council (NMC), 2008).

In addition to the expansion of prescribing rights to these groups of healthcare professionals, exemptions in the Medicines Act enable paramedics and midwives to supply or administer medicines, and a number of different groups of healthcare professionals (including midwives, nurses, pharmacists, optometrists, podiatrists/chiropodists, radiographers, orthoptists, physiotherapists, and ambulance paramedics) are also able

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to supply or administer medicines to patients under Patient Group Directions (PGDs). A PGD, signed by a doctor and agreed by a pharmacist, acts as a direction to supply and/or administer a Prescription Only Medicine (POM) to a patient (using their own assessment of patient need) without necessarily referring back to a doctor for an individual prescription. PGDs 'fit' best in services where the use of medicines follows a predictable pattern and are less individualized (National Prescribing Centre (NPC), 2004). The use of PGDs are popular, for example, in first contact services where one-off treatments are required as opposed to a number of treatments over a long period of time.

It is evident that around 90% of the 14 000 Nurse Independent/Nurse Supplementary Prescribers are prescribing medicines (Courtenay & Carey, 2008a). Although the majority of these nurses are in primary care, increasing numbers of nurses from secondary care are accessing the prescribing programme. Nearly a third of these nurses prescribe medicines for diabetic patients and nearly 50% of these nurses prescribe insulins (Courtenay & Carey, 2008b, c). Although there are currently restrictions surrounding the prescription of CDs, there is some evidence that lifting these restrictions in the area of acute and chronic pain in the hospital setting will increase the prescription of these medicines (Stenner & Courtenay, 2007). Proposals to lift these restrictions are currently awaited (Home Office (HO), 2007). Several researchers have identified factors that may lead to errors with regards to the prescription of medicines by non-medical prescribers. These factors include a lack of questioning by nurses about allergies to medicines (Latter *et al.*, 2005), a lack of access to patient records (Candlish *et al.*, 2006; Hall *et al.*, 2006), duplication of records and transcription errors (Bradley & Nolan, 2007; Weiss *et al.*, 2006). Insulin and opioids were medicines associated most frequently with incidences reported to the NPSA that resulted in severe harm or death. Patients with known allergies being given medicines to which they were allergic, risks associated with care transfer and the importance of accurate documentation were all areas highlighted by the report.

The NPSA have identified seven key actions to improve medication safety. These actions include:

- Increased reporting and learning from medication incidents.
- Implementation by NPSA of safer medication practice recommendations.
- Improved staff skills and competence.
- Minimization of dosing errors.
- Ensurance that medicines are not omitted.
- Ensurance that correct medicines are given to the correct patient.
- Documentation of patients' allergy status.

These actions apply to all healthcare professionals involved in delivering medicines to patients, including those on undergraduate programmes. Additionally, given the recent legislative changes expanding prescribing powers to include other groups of healthcare professionals (in addition to doctors) and the research evidence described above, it would seem particularly important that those responsible for the education and training of non-medical prescribers are aware of these actions.

The lack of incidents reported in the community to the NPSA perhaps highlights the need to monitor patients in these settings more closely – particularly as the majority of nurse prescribers work in primary care settings. One way to encourage such

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reporting would be to make the reporting of errors a statutory requirement as opposed to a professional one.

Other schemes and initiatives that would help to ensure medicine safety, some of which are simple and others that would require a substantial investment, include:

The red tabard scheme, ensuring nurses undertaking medication rounds are not disturbed.

Specifically designed intravenous (IV) connectors, that only allow attachment of IV syringes.

Specifically designed naso-gastric tubes that do not enable the attachment of IV syringes.

Specific medicine labels that can be transferred to IV syringes.

Allergy bands for patients with known allergies.

Medication administration charts that clearly identify those patients with allergies on each page of the chart.

Bar coding of both medicines and patients' identity bracelets to ensure medicines are given to the correct patient.

Electronic prescribing.

Safe storage of medicines.

The NPSA estimates that preventable harm from medicines could cost England as much as £750 million each year. Statistically, we as individuals or our loved ones will almost certainly be victims of a medication error. The reduction of prescribing errors is now a major Government initiative (National Patient Safety Agency (NPSA), 2007). Given this initiative, combined with the recent introduction of non-medical prescribing, this is a timely and much needed text.

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Chapter

## 2

## Safety in prescribing

Anne Twidell and Simon de Lusignan

### Introduction

This chapter sets out the rationale for improving prescribing safety, namely the high rate of deaths, unnecessary hospital admissions and illness caused by unsafe prescribing; and what practical steps prescribers should take to reduce the risk of issuing an unsafe prescription. The tragedy in Northwick Park in 2006 when healthy volunteers suffered catastrophic consequences, albeit in the first test of a new drug, highlighted how pharmaceuticals need to be treated with caution and respect (Sunthralingham, 2006). However, it is not just new drugs which can be unsafe; drugs which have become established after many years of clinical use can also cause problems (Lasser *et al.*, 2002). For example, after several years of use, a widely used non-steroidal anti-inflammatory drug was found to be associated with an increased risk of myocardial infarction (Solomon *et al.*, 2004).

The first part of this chapter describes why prescribing safety is so important and this is addressed under the following four themes:

- (1) **Key issues for safe prescribing at the point of care.** Theme one explores the safety issues that should be considered by an individual prescriber before issuing a prescription. A key message for prescribers is that they need to have the necessary information to hand at the point of prescribing: an understanding of the patient's wishes; access to a comprehensive medical record; and access to information about the drug they are about to prescribe.
- (2) **Clinical governance and systems to ensure safe prescribing.** The second theme looks at the systems that should be in place to monitor and quality assure safe prescribing. Our key message here is that good prescribing must be in the context of ongoing audit and evaluation of its safety and effectiveness. Had systems been in place, including improved data quality on death certificates or indeed diamorphine use, the notorious Dr Harold Shipman may have been flagged as an outlier for his high death rate (Aylin *et al.*, 2004). The same principles may help identify unsafe practice of medicines.
- (3) **Communication and team work.** Healthcare professionals increasingly work as part of multidisciplinary teams where effective communication is essential. Good communication with patients, including how to recognize and act on adverse events, and keeping good-quality records are essential.
- (4) **Computer decision support systems and using technology to support safer prescribing.** Information technology (IT) has the potential to reduce prescribing errors. However, implementing IT systems in healthcare is challenging. IT is changing the nature of the clinical task from the clinician as the holder of information to having the skills to critically appraise the evidence. Patients and the



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public now have access to the same information as their prescriber (de Lusignan, 2003). This final theme explores these issues.

The chapter is written from the perspective of prescribers in the developed world, where the supply chains for pharmaceuticals and pharmacies are generally well regulated, safe and efficient. Issues relating to drug availability, cost, and risks associated with counterfeit medicines are beyond the scope of this chapter. Readers interested in these issues should explore the World Health Organization's (WHO) *Essential Drugs Programme* (WHO) and issues around the pharmacy supply chain and good pharmacy practice (International Pharmacy Federation). However, although the pharmacy supply chain is rarely an issue in developed countries, we do have some supply chain issues. These include:

**Parallel imports.** Parallel importing of medicines is the process of importing medications, due to be supplied to another country, at a lower cost. In the UK in the 1980s there were concerns surrounding the supply of these medications as their instructions for use were written in another language – potentially denying patients access to information which could impact on safety (Fullerton, 1984).

**Generic substitution.** Over the last two decades there has been a shift towards generic prescribing (i.e. prescribing by drug rather than brand name). However, generic equivalents may vary with regards to frequency of dose or application, and occasionally, this can affect bioavailability. Generic prescribing has rightly been driven as a cost-saving exercise in hard-pressed health services. Whilst a lot of data have been collected about bio-equivalence, few studies have explored the safety issues. An exception is the American Food and Drug Administration (FDA) which provides a searchable online database, which describes where generic substitution is or is not safe (Food and Drugs Administration). The authors' own experience is that some patients on long-term treatments may never be reassured that a generic medicine is equivalent to their branded alternative. Patients may prefer a particular brand (Mott & Cline, 2002). Prescribing the generic equivalent may actually put patients at risk because they are confused about a different physical appearance of one or more of their medications. In these situations it is more important that a patient takes their medicine, and so prescribing some by brand name is justified. Additionally, in some instances, the difference in bioavailability is sometimes clinically significant (Borgheini, 2003).

The remainder of the chapter examines prescribing errors, and the rate at which these errors occur. This is something that everyone involved in prescribing or health service management should be aware of, and actively take steps to reduce. No prescription is 100% safe, and decisions about prescribing should always take into account risk; modulated by patients' wishes. A key theme across this chapter is encouraging recognition of the complexity of prescribing decisions. We encourage prescribers to see their task as a complex, safety-critical decision.

### Why is prescribing safety important?

Two landmark reports, both from the USA, identified high levels of medical error, of which prescribing errors comprised a major component. These two reports produced by the Institute of Medicine were called: *To Err is Human* (Committee on Quality of

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Healthcare in America, 2000) and *Crossing the Quality Chasm* (Committee on Quality of Healthcare in America, 2001).

*To Err is Human* identified that 50–100 000 preventable errors result in death in the USA; that they are costly, and that systems can be improved and errors reduced. Probably the best known quote from *Crossing the Quality Chasm* is:

‘...between the health care that we now have, and the health care we could have, lies not just a gap, but a chasm.’

Although these reports addressed a wide range of issues about the importance of evidence-based patient-centred care, delivered in a timely, efficient and equitable way; they placed delivering safe healthcare at the top of its list. It is evident from these studies that as many as 10% of people admitted to hospital have had an adverse medical event, and that most of these events are prescribing errors (Committee on Quality of Healthcare in America, 2000). Prescribers in the UK have traditionally been medical practitioners; however, in recent years non-medical prescribers (nurses, pharmacists, radiographers, podiatrists, physiotherapists and optometrists) have become more prevalent. Although the majority of prescribing episodes are undertaken by medical prescribers, the number of non-medical prescribing episodes is increasing. To date, there have been no identified prescribing errors by non-medical prescribers in England. Unfortunately the profession of the prescriber in the National Reporting and Learning System (NRLS) dataset is not available (National Patients Safety Agency (NPSA), 2007). However, no prescriber can afford to be complacent; all need to be mindful of the potential hazards that can arise, and could apply to any prescribing professional.

Prescribing errors are embedded in current clinical practice. The rates of error remain high and there is a suggestion that not having sufficient time to think through all the relevant factors may be significant. Koppel *et al.* (2008) found that, where physicians cancel computer requested prescriptions, soon after placing an order, it is associated with prescribing errors. Where prescriptions are cancelled within 45 minutes, two-thirds of them are inappropriate – incorrect dose, etc. Where they are cancelled within 2 hours, 55% are inappropriate. One possible interpretation of these data is that information that led to the cancellation was not considered properly at the time of the prescription (Koppel *et al.*, 2008). It is known that neonatal prescribing errors can be dangerous and have severe consequences. Recent findings from a neonatal intensive care unit suggested that a lack of awareness amongst staff of drug safety issues was common, and identified prescribing and drug administration errors as the commonest causes of error (Kunac & Reith, 2005). The rate of non-compliance with good prescribing practice in neonatal paediatrics has been reported as being evident in 40% of prescriptions; though training and provision of better information systems has substantially reduced this figure (Pallas *et al.*, 2008).

In primary care adverse drug reactions are also common, many are preventable and can cause harm including unnecessary hospital admission. A systematic review by Thomsen *et al.* (2007) suggested that 85% of the preventable adverse reactions were caused by a small number of types of therapy: cardiovascular drugs, analgesia and hypoglycaemic agents. Interestingly, of the people who had unnecessary admissions, nearly half (45%) were inadequately monitored (Thomsen *et al.*, 2007). In an international study undertaken in primary care (in Canada, Australia, England, the Netherlands, New Zealand and the



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United States) over a 7-month data collection period, the error rates per month of practice were similar; GPs saw around one error per month. Thirty to 40% of these errors were serious, i.e. resulting in harm to patients. Six to 7% of errors were very serious and resulted in hospital admission or death (Rosser *et al.*, 2005).

Errors by individuals, systems which perpetuate unsafe practice, poor teamwork and under-developed information systems all contribute to a situation where there are unnecessary medication errors.

**Key issues for safe prescribing at the point of care****Is prescribing the right decision?**

The first question which any prescribers should ask themselves is whether a prescription is really indicated. This is, in one sense, an easy question and, in another, extremely challenging. In many scenarios there is a non-drug option, which does not risk side effects or patient safety. For example, the natural history of viral warts and verrucae is that they get better – albeit over a considerable time period; the same is true for many cases of tennis and golfer's elbow. Many patients are very happy to await natural cure rather than risk the side effects of treatment. Cryotherapy for warts can leave a hypopigmented halo which is much more noticeable when the skin is tanned. Steroid injections for tennis elbow can risk skin thinning and infection.

Lifestyle change can sometimes be a much safer and effective option. For example, some people can make a significant reduction in their cholesterol by changing their diet, and so avoid the risks of statins. Some obese people can control their diabetes effectively by change in diet, exercising more and losing weight.

All prescribing has risks and the prescriber has to weigh up the risk–benefit ratio for the patient; and be strongly influenced by the wishes of the patient. The risk–benefit ratio should be considered in the context of the long-term relationship with the patient as well as the pros and cons of the particular decision.

For example, a patient who had previously had pneumonia may be very frightened by their next respiratory infection. Whilst the clinician might not normally prescribe for them based on the symptoms alone – the circumstances might dictate that the small risk to patient safety in prescribing is justified by the potential damage to the clinician–patient relationship if they do not.

The 'delayed prescription' is a halfway house between not prescribing and prescribing and where there is a possibility that a prescription is not required. This is a useful approach where a patient does not currently have symptoms but might deteriorate. It reduces both the number of prescriptions dispensed and risks associated with prescribing. For example, a patient may have a minor deterioration in their asthma symptoms. There are many patients in these circumstances who can be advised to increase their current inhalers, and given a 'delayed prescription' for an oral steroid and antibiotic should their condition deteriorate. This is recommended by the National Institute for Health & Clinical Excellence (NICE, 2008). The practice of delayed prescriptions also has the potential to be beneficial in reducing actual antibiotic use, which could be a major benefit in the current climate of overuse of antibiotics and the associated risks to public health.

It is essential when the decision is made to issue a prescription to explore treatment options and patient choice and that the final choice is as a result of a shared

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decision-making process. Most patients are happy with 'usual practice' but the internet has made information as widely available to patients as to clinicians. Open honest discussion of benefits and risks are an essential part of safe practice. Treatment options should always include the choice of no treatment and an explanation of the natural history of the condition. Shared decision-making can be checked by asking the patient if they would mind summarizing back the key points about the next steps.

The patient should be able to give informed consent. Usually, consent is implied rather than explicit, in that the patient usually accepts the prescription from the clinician, then takes it to the pharmacist for it to be dispensed. However, there are special circumstances where others speak on behalf of the patient. Commonly, this happens at the beginning and end of life. Children and young people usually have a parent as their prime carer; the elderly, their spouse or other relative. Problems with patient safety can arise where the carer either refuses what the clinician feels is the best treatment or wants something outside of best practice. For example, there is no clear-cut diagnostic test for asthma in very young children. This may be the clinician's diagnosis and yet the child's parent may not want them to have asthma and is not keen to try an inhaler or other therapy. The clinician needs to discuss carefully the level of risk with the carer; and if there is any significant risk with other team members.

Ultimately, the prescriber is the patient's advocate and is there to give best advice and recommend appropriate therapy, in each given circumstance. Prescribing is only one of many options. Before going on to issue a prescription, the prescriber needs to ensure that the patient has the right diagnosis and that the prescription they issue is safe. These issues are explored in the next two sections.

## Right diagnosis/rational basis for prescribing

Traditional approaches to diagnosis use deductive reasoning and, like most processes, are not completely reliable. Medical students and junior doctors arrive at a diagnosis through carefully taking a detailed and systematic history, followed by examination and investigations (blood tests, X-rays, etc.) – so-called 'clerking' a patient. The diagnosis is largely based on the history combined with examination and investigation findings. A combined process of looking for recognizable patterns of disease and elimination contribute to the final diagnosis. Some diagnoses are reliable and others much less so. For example, heart failure and chronic obstructive pulmonary disease are both diseases usually secondary to cigarette smoking (in the former case by causing ischaemic heart disease, and in the latter by damaging the airways). Both occur in older people and often present with shortness of breath. Unfortunately, there is often clinical overlap between the two, and consequent inappropriate and potentially unsafe therapy. Prescribers should always be prepared to reconsider a diagnosis and be able critically to appraise the information on which any diagnosis is made.

Therapeutic decisions in primary care are frequently made on a heuristic basis (intelligent rules of thumb) (Essex, 1994). The 'rules' reflect the health beliefs and experience of that practitioner and the nature of a problem may be elucidated over several consultations. The contrast between the nature of the family practitioner and hospital decision-making is illustrated in Table 2.1. Although an over-simplification, it serves to illustrate the fundamentally different environment within which the primary care practitioner is required to operate. Inevitably, there will be many circumstances in