



*National Patient
Safety Agency*

The fourth report from the Patient Safety Observatory

Safety in doses: medication safety incidents in the NHS

PSO/4

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	<h1>Acknowledgements</h1>

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Foreword

Patient safety is recognised as a priority for healthcare organisations and is the first domain in the NHS *Standards for better health*.¹ Managing medicines safely is a key component of this, as highlighted in the Department of Health’s seminal report on medication safety published in 2004.² This new report from the National Patient Safety Agency gives detailed analysis of the medication incidents reported by the NHS since 2005 and other relevant data from defence and litigation organisations. It provides detailed evidence that confirms many of the risks identified in the Department of Health’s 2004 report² and also highlights areas of medication practice, such as omitted medicines and insulin therapy, where patient safety could be improved.

The report describes the types of medication incident that can be prevented and includes examples of severe harm to patients, such as:

- “Patient on warfarin (oral anticoagulant) suffered gastro-intestinal bleeding and re-admitted to hospital, having been discharged without an appointment or follow-up arrangements with an anticoagulant clinic.”
- “Patient died following a 30 mg intravenous dose of the strong analgesic diamorphine, instead of the intended 5 mg dose.”
- “Patient had a cardiac arrest and died as a result of high and untreated potassium blood levels, when necessary infusions of glucose and insulin not given.”
- “Child needed stomach pumping after, having received over 12 times the intended dose of the anticonvulsant clonazepam due to prescribing and administration errors.”

Increasingly, healthcare organisations are becoming aware of the importance of safe medication practice. Medicines management issues have also been the subject of recent reports published by the Healthcare Commission^{3,4} and the Commission for Social Care Inspection (CSCI).⁵

The Department of Health has recommended reducing the risks of medication incidents through the use of dedicated procedures for organisation-wide management of medication safety. These procedures include the regular review of incident reports, actions by a multidisciplinary group and publication of summary reports of progress in reducing these risks.² Chief pharmacists and pharmaceutical advisers have key leadership roles, but making medication practice safer needs engagement by doctors, nurses and other staff, as well as the pharmacy team.

This report reveals underlying weaknesses in current medication practice. Although most medicines are prescribed and used safely, sometimes things go wrong. The importance of tackling medication safety incidents should not be underestimated, as their impact on the NHS could be similar to healthcare-associated infections, which are now a key concern for the health service.

This report recommends seven priorities for action by healthcare organisations and staff to help ensure the safe use of medicines.

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Executive summary

Every day, about two and a half million medicines are prescribed in the community and in hospitals across the UK.^{2,6} Most medicines are used safely and help people to get better or stay well. But sometimes errors occur and these can lead to harm.

This report presents learning about medicine safety, drawn from almost 60,000 medication incidents reported to the National Patient Safety Agency (NPSA) via the National Reporting and Learning System (NRLS) between January 2005 and June 2006. It brings together the key messages from reports to the NRLS and evidence from published research and data from other organisations, for example the NHS Litigation Authority (NHSLA).

There are some notes of caution in interpreting the data from the NRLS. As with any voluntary reporting system, the data is subject to bias. Data may be incomplete and may be reported immediately after an incident, before the patient outcome is known. The vast majority (over 80 per cent) of medication incidents reported to the NRLS are from hospitals, even though most patient contact happens in the community. However, each reported incident tells a story and, taken with other sources, provides a picture of current medicines practice in the NHS.

The majority of medication incidents (82.8 per cent) were reported as resulting in no harm to patients. This is a larger proportion than for all other incidents reported to the NRLS. However, even the incidents resulting in no harm are worth detailed review as they provide information about why errors occur. These include 'near misses', which are incidents that did not cause harm but had the potential to do so.

Recent studies have suggested that up to 6.5 per cent of all patients admitted to hospital⁷ and up to nine per cent of all patients staying in hospital⁸ experience medication-related harm. Many of these incidents are preventable. From this evidence, we estimate that preventable harm from medicines could cost more than £750 million each year in England.ⁱ

Between January 2005 and June 2006, four in every five medication incidents reported to the NRLS occurred in a general, acute, or community hospital, although most medication activity happens in the community.

ⁱ See appendix 5: Calculation of costs to the NHS

A quarter of NHS organisations, largely primary care organisations, reported no medication incidents at all over six months. It is recognised that there is a gap between the actual number of safety incidents that occur and those that are reported.⁹ However, rich learning was gained from the data received.

In a few cases, the reported medication error led to severe harm or death. This report reviews the 92 reported medication incidents of severe harm or death in detail (of these incidents, 38 resulted in death). These 92 incidents included errors in the administration and prescribing of medicines. The medicines most frequently associated with severe harm were opioids, anticoagulants, anaesthetics, insulin, antibiotics (allergy related), chemotherapy, antipsychotics and infusion fluids.

The three most frequently occurring types of medication error (wrong dose, strength or frequency of medicine, omitted medicine and wrong medicine) accounted for over half of all reported medication incidents (57.3 per cent). Of these, the most common type of error was wrong dose, strength or frequency of medication (28.7 per cent). Systems for checking doses are essential for those prescribing, dispensing and administering medication.

Omitted medicines were also commonly reported. Omission is not always considered as a serious error but the NRLS data included reports of permanent harm or death where vital medicines (for instance, medicines used to treat epilepsy or prevent strokes) had been omitted.

Selection of the wrong medicine was often reported, but progress has been made in working with industry to tackle problems of 'look-alike' and 'sound-alike' medication.

The NRLS data reviewed highlighted two groups of patients associated with medication errors. One is patients with known allergies to certain medicines, particularly antibiotics, being given those or similar medicines. Although these errors constituted only 3.2 per cent of the total reported medication incidents occurring in hospitals, a third (30.9 per cent) of these reports resulted in harm (including death).

Children aged up to four years were involved in 10.1 per cent (2,081) of medication incident reports where age was stated.

ⁱⁱ Further review of these reports highlighted issues with dose calculation (including 10-fold errors) and particular medicines (for example, gentamicin).

ⁱⁱ Only 38.8 per cent of medication incidents reported between January 2005 and June 2006 indicated the age of the patient.

Four other important issues emerged from the data:

- injectable medicines (accounting for over half of reported deaths and severe harm medication incidents) – these have been addressed in recent NPSA guidance;
- medication risks associated with transfers of care and the importance of accurate documentation (including medicine charts);
- problems with the availability and supply of medicines at the point where they are needed (including intubation and other essential medicines);
- medicines given outside normal ward round times or to patients with special medicine needs, such as children treated in general (non-paediatric) areas.

This report shows the power of learning from reported incidents. Some NHS organisations have used this learning and audits of practice to target areas for action. Examples of local initiatives can be found in this report. All trusts could improve medication practice by adopting at least one of these service developments.

This report identifies seven priority actions for healthcare staff, NHS organisations and healthcare commissioners. There are three general recommendations and four relating to particular risks that, together, accounted for 65 per cent of all medication incidents reported to the NRLS.

Safer medication is everybody's business and small changes can make a real difference in reducing harm to patients.

Seven key actions to improve medication safety

1. Increase reporting and learning from medication incidents

Increase reporting and learning from medication incidents and identify actions against local risks in an annual medication report.

2. Implement NPSA safer medication practice recommendations

Implement and audit the NPSA safer medication practice recommendations, including the alerts on anticoagulants, injectable medicines and wrong route errors published in March 2007.

3. Improve staff skills and competences

Healthcare workers should ensure they have the required work competences and support to use medicines safely. Work competences for anticoagulant therapy, use of injectable medicines and paediatric infusions are set out in the NPSA safe medication practice work programme for 2007-08.

4. Minimise dosing errors

Provide information, training and tools for staff to make calculations of doses easier, and target efforts towards high-risk areas (such as children) and high-risk drugs (such as insulin).

5. Ensure medicines are not omitted

Identify current levels of omitted medicines and target areas for action (for instance, anticoagulation or other high-risk medication). Review medicine storage and medication supply chains.

6. Ensure the correct medicines are given to the correct patients

Improve packaging and labelling of medicines and support local systems that make it harder for staff to select wrong medicines or give medicines to wrong patients.

7. Document patients' medicine allergy status

Improve recording of patient allergies, and raise awareness amongst staff of high-risk products and the importance of knowing the patient's allergy status.

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Introduction

This is a report from the National Patient Safety Agency (NPSA), which was set up in 2001 to improve patient safety in the NHS.¹⁰ A core function of the NPSA has been the development of the National Reporting and Learning System (NRLS). The NRLS is the first national reporting system of its kind in the world and the NPSA's primary mechanism for collecting information on patient safety incidents. It draws on the incident reporting systems that all NHS organisations should have in place¹ to collect reports made by NHS staff across England and Wales. These reports provide a valuable resource for identifying areas of risk and taking action. NHS organisations started to use the NRLS in 2004, and reporting is continuing to increase every month.¹¹

The NRLS is a confidential and voluntary system, so it may not capture all patient safety incidents. International research suggests that there is significant under-reporting of incidents and bias in the types of incident that are reported. For this reason, the NPSA set up the Patient Safety Observatory to review reports collected through the NRLS alongside other data and research literature in order to get a more rounded picture of patient safety.ⁱ

This is the fourth report from the Patient Safety Observatory. It reviews new evidence relating to medication safety and builds on previous reports and research. It aims to highlight the importance of medication safety in delivering quality patient care; and help managers, policymakers, healthcare professionals and patients to focus on priority areas highlighted by this evidence.

Scope of this report

The findings in this report are based primarily on incidents reported to the NRLS by NHS staff in England and Wales. The examples used are taken from these reports (unless otherwise stated). It is outside of the scope of this report to provide in-depth analyses of individual incidents.

The report does not include information on *non-preventable* adverse drug reactions (ADRs) collected via the 'Yellow Card' scheme by the Medicines and Healthcare products Regulatory Agency (MHRA) (see page 10). The MHRA has consistently received approximately 20,000 reports a year for the past 15 years,¹² mainly from general practitioners (GPs). These provide useful information about medicines for the health regulator and the pharmaceutical industry. However, such information is not the focus for this report, which is concerned with medicines practice. This report does not examine incidents relating to over-the-counter medicines or illicit use of prescription medicines, although clearly there are implications for patient safety.

Empowering patients to understand their medicines and take them safely has the potential to enhance patient care. However, issues of medicine concordance and compliance are outside the remit of this report (see page 39).

The data on medication incidents presented in section 2 include those incidents reported in mental healthcare settings. However, these incidents are not reviewed in depth as an earlier report from the Patient Safety Observatory examined incidents reported from mental healthcare settings, including over 1,600 medication-related incidents.¹³ Those findings, including particular issues such as antipsychotic medicines, should be viewed alongside the medication safety themes in this report.

What this report adds

The framework for patient safety in the NHS was set by the publication of the report *Organisation with a memory* in 2000.¹⁴ In 2004, *Improving medication safety* set an agenda for improving medicines safety.² It outlined the scope of the issue and ways of learning from and preventing errors, and highlighted high-risk areas where changes could be made. Other policy initiatives^{6,15} have also highlighted medicines management issues and there is increased scrutiny of the way medicines are handled in the NHS, including by the Audit Commission,¹⁶ the Healthcare Commission^{3,4} and the Commission for Social Care Inspection.⁵ This report builds on preceding reports and brings together a detailed analysis of medicines safety incidents reported by NHS trusts with data from other organisations and research literature.

ⁱ Further information about the NRLS is in appendix 1 and information on the Patient Safety Observatory is in appendix 3

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Section 1 Defining medication incidents

Summary

Most medications are used safely and effectively, but errors can occur at all stages of the medication process.

Literature suggests that up to one in 10 medicines prescribed, dispensed and administered may result in error, and in some cases (such as injectable medicines) this rate is much higher.

Published research estimates that approximately 247,000 (6.5 per cent) hospital admissions in England each year are due to harm from medicines, of which nine per cent were preventable and 63 per cent were possibly preventable.⁷ In addition, 3.5 per cent to nine per cent of inpatients may experience severe harm from their medicines each year.

Using findings from published research, we estimate that medication error could cost the NHS more than £750 million each year in England (see appendix 5).

What is known about medicines use?

Every day in the UK, around two million prescriptions are written by GPs and approximately half a million by doctors (and others) in hospital.^{2,6} Each hospital in England and Wales administers around 7,000 medicine doses a day and this activity can take up a substantial amount of time.¹⁶

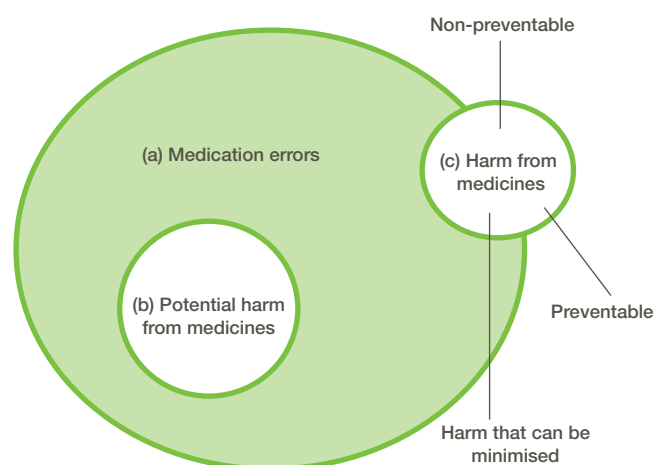
The volume of medicines prescribed in England has increased year on year.¹⁷ During the year up to September 2006, 736 million items were prescribed in England, at a cost of around £8 billion.¹⁸ This increase (which was particularly marked for medicines relating to cardiovascular and diabetes care) is partly due the growing number of people with chronic conditions. It also reflects higher treatment standards (as required by national service frameworks),^{15,19,20} availability of new medicines (as guided by the National Institute for Health and Clinical Excellence, NICE) and general advances in what can be done for patients.

However, these advances have resulted in more complex treatments and a greater potential for mistakes to happen. For example, some older people may take up to 10 medicines a day at different times, and may receive care from different health professionals in different settings. In hospitals, staff may be caring for sicker patients with shorter lengths of stay and more complex needs.

What is a medication safety incident?

The NPSA defines a patient safety incident as 'any unintended or unexpected incident which could have or did lead to harm for one or more patients'. However, many terms have been used to describe medication incidents^{21,22} and the model in figure 1 shows the relationship between these terms.

Figure 1: A model of the types of medication incident (adapted from Bates DW et al. 1995)²³



(a) Medication errors

Medication errors are incidents in which there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring, or providing medicine advice, regardless of whether any harm occurred. This is a broad definition and most errors do not result in harm.

(b) Potential harms from medicines (near misses)

Another type of medication incident is often called a near miss. These are incidents that did not cause harm but which are judged to have had the potential to cause harm. These incidents provide valuable insight into areas of risk and where systems can be improved to prevent death or harm.

(c) Harms from medicines

A smaller proportion of medication incidents will result in actual harm to patients. These are sometimes called adverse drug events (ADEs). These types of incident can be divided into two groups depending on whether the ADE was caused by an error (preventable) or not (non-preventable).

Where medicine has caused harm to a patient but no error took place, the incident is judged to be 'non-preventable' and is usually called an adverse drug reaction (ADR). For example, a patient experiencing a side effect to a medicine for the first time, which could not have been predicted. Data on ADRs are not collected by the NPSA, but these should be reported to the MHRA Pharmacovigilance 'Yellow Card' System.²⁴

Where a medication error results in harm, the incident can be categorised as either 'preventable' or an incident where the 'harm can be minimised'. Examples of preventable incidents include: where a medicine is prescribed for a patient who had a known allergy to the medicine; and where a dose 10 times the actual dose is prescribed, dispensed or administered. Medication incidents where the harm from medicine could be minimised often involve an error in the medicine monitoring process, for example, the failure to monitor and adjust the dose of warfarin. These incidents are also known as 'ameliorable incidents' and are not always included in medicines safety research.

The NPSA is interested in all medication errors. However, distinguishing between these errors in practice can be difficult, and there may be some overlap between preventable errors (reported to the NRLS) and non-preventable ADRs (reported to the MHRA's Yellow Card System). For this reason, the NPSA is working closely with the MHRA to ensure that reports and subsequent learning are shared as appropriate.

Stages of the medication process and medication errors

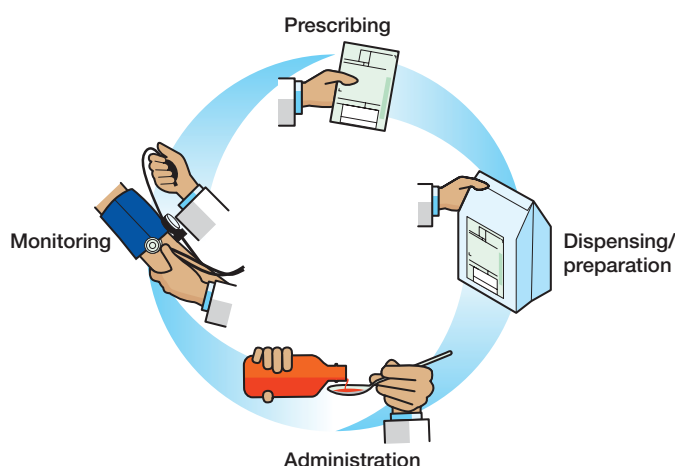
The medication process consists of a series of stages (see figure 2):

- prescribing (ordering a given medicine and dose);
- dispensing (supplying medicines to individuals or to hospital wards)
- preparation (preparing a dose of medicine for administration);
- administration (administering the dose of medicine by the appropriate route and method);
- monitoring (checking the administration and effect of a medicine).

In the traditional model, doctors prescribed, pharmacists dispensed and nurses administered medication. Now the picture is more complex. Many professionals are involved at every stage of the medication process, and medication safety has become a multi-professional concern.

This report reviews the safety aspects of all stages of the medication process.

Figure 2: The medication process



Errors can occur in all stages of the medication process. Research has shown that the types and rates of errors vary at different stages of this process. A brief account of research conducted in the UK is presented here (see appendix 6 for a summary of the literature reviewed). Other research was not considered because medication systems used outside the UK (particularly in the USA) are significantly different from those used in the UK.ⁱ

(1) Prescribing errors

Prescription is the first stage of the medication process and errors here can lead to problems further down the line. Historically, only doctors prescribed medication, but a range of healthcare workers are now able to do this. Thirty-thousand community nurses can now prescribe from a limited restricted list. Since May 2006, more than 9,000 nurses in different settings have been able to independently prescribe any licensed medicine for any medical condition within their competence, including some controlled drugs.²⁵ In addition, independent prescribers can prescribe most medicines in the British National Formulary (BNF).

ⁱ For example, the medication system in hospitals in the USA involves written transcription of the original prescription, hospital pharmacy services that prepare all injectable medicines and supply unit dose supplies of oral medicines, use of computerised dispensing cabinets in clinical areas and no supply of medicines on discharge from hospital. In other European countries, there is very limited visiting of pharmacists to hospital clinical areas to review prescriptions and provide advice, and patients are dispensed commercial packs of medicines without a dispensing label giving details of the prescribed dose and frequency of administration, or the patient's name and the date of dispensing. Cousins DH. *International perspectives on patient safety*. In: Manasse H, Thompson K Eds. *Improving Medication Safety*. American Society of Health-System Pharmacists, Bethesda, USA. (2005).

Similarly, 750 pharmacists can also prescribe as a supplementary prescriber working in partnership with a doctor. In 2006, nurses prescribed almost 5.5 million items, pharmacists prescribed just over 23,000 items and a very small number of prescriptions were made by other healthcare workers (e.g. physiotherapists, podiatrists).¹⁸ The proportion of non-medical prescribing is still very small compared to medical prescribing and the profession of the prescriber is not discernible in the NRLS dataset.

A prescribing error has been defined as: the result of a prescribing decision or prescription writing process that results in an unintentional but significant reduction in the probability of the treatment given being timely and effective or an increased risk of harm compared with generally accepted practice.²⁶

Prescribing without taking into account the patient's clinical status, failure to communicate essential information and transcription errors are all considered 'prescribing errors'. However, the failure to adhere to standards such as national guidelines or a medicine's product licence is not considered as an error if the action reflects accepted practice.

Several studies have estimated the rates of error of prescriptions. The estimates range between less than one per cent and 11 per cent of all prescriptions²⁷ depending on the definitions used.

(2) Dispensing errors

There are more than 10,500 community pharmacies in England and Wales²⁸ whose dispensing activities account for over 75 per cent of the total estimated national drug cost.^{17,28,29} Over half of pharmacies form part of a chain (of six or more pharmacies).^{17,29} Changes to the community pharmacy contract in 2005 extended the range of activities which can be undertaken by pharmacies, including screening and repeat dispensing.³⁰ In some areas (particularly rural), GPs may also dispense medicines, but this represents a very small proportion of all dispensing.

Error rates seem to be lower for dispensing than for prescribing, administering or monitoring medication. One study found that on average 26 (0.1 per cent) dispensing incidents occur for every 10,000 items dispensed in community pharmacies.³¹ Of these incidents, 22 were classified as near misses (where the error was discovered before the medicine was supplied to the patient) and four incidents were classified as dispensing errors (when the incorrect medicine was supplied to the patient).

One or more dispensing incidents were identified at the final check stage of 2.1 per cent of items (4,849 of 194,584) dispensed in a UK hospital pharmacy.³² In this study, less than one per cent of items (39) left the hospital pharmacy with a dispensing error.

These studies give an indication of the types of incident that occur. In a study of errors in a UK hospital, it was found that the majority of errors identified before the medicines left the pharmacy involved picking errors.³² In community pharmacies, the most common type of error was incorrect strength of medicine and incorrect medicine.^{33,34} A study of over 7,000

reports of dispensing errors from 89 hospital pharmacies in the UK found that over six per cent resulted in harm (including one death).³⁵ In the same study, 10 medicines accounted for one in five errors and almost a third of the severe harm incidents.³⁵ These medicines were: prednisolone, morphine sulphate, isosorbide mononitrate, warfarin, aspirin, lisinopril, carbamazepine, diclofenac, co-codamol and flucloxacillin. Within this group of medicines the most common error was dispensing the wrong strength of prescribed medicine.

(3) Preparation and administration errors

Most medicine is dispensed in the community^{17,28} and it is likely that this is where most medicine is administered. However, there is little information on errors associated with self-administration in people's own homes.

In inpatient settings such as hospitals, nurses typically administer medicines.¹ There is a wide variation in the rates of error reported in studies of medicine preparation and administration in hospital, ranging between 3.5 per cent³⁶ and 49 per cent.³⁷ This wide range reflects the differences in definitions used for medication error, methods of data collection, and whether wrong-time errors (where the prescribed medicine is administered correctly but not within the time period prescribed) were included. Observational methods, where trained researchers observe practice on wards in real time, have been found to be a valid and reliable way of detecting errors in preparation and administration.³⁸

Studies on administration of intravenous medicines^{39,40} have shown that error rates for these medicines are much higher than for oral medicines (at least 25 per cent), and most happen within two days of prescription or admission.⁴¹

(4) Monitoring errors

Monitoring medicines is becoming increasingly important, given the rising numbers of people with chronic and often multiple conditions that require careful management. Repeat prescribing and dispensing is a useful index of potential monitoring activity. Over 80 per cent of medicines prescribed by GPs in the UK are repeat prescriptions.⁴² These prescriptions are made without the doctor seeing the patient. However, monitoring can be complex and requires input from many healthcare professionals. For example, blood tests and other laboratory investigations may be needed to assess the dose of medicine to be prescribed.

Studies have confirmed that failure to monitor medication can lead to severe harm to patients.⁴³ For example, patients with high blood pressure and heart failure may be taking diuretics. Such patients require careful monitoring because they can develop low levels of sodium and potassium (electrolytes) in their blood as a side effect. However, one study of patients who were taking diuretics in six general practices showed that fewer than a third had had their blood electrolyte levels checked.⁴⁴ Another study found that fewer than half of over 1,200 patients taking anti-epileptic medicines were being adequately monitored.⁴⁵ The NPSA guidance on anticoagulant therapy includes recommendations for improving the monitoring of patients.⁴⁶

¹The Nursing and Midwifery Council (NMC) have produced standards for education, training and practice of independent nurse prescribers. NMC. *Standards of proficiency for nurse and midwife prescribers: protecting the public through professional standards.* (2006).

Evidence of harm to patients

Estimates of preventable harm to patients have been derived either from studies of patients admitted to hospital because of medication-related problems or from studies of adverse events which occurred during a hospital stay. There is little evidence on rates of harms from medicines in the community, except for those which result in hospital admission.^{47,48}

A study of more than 18,000 patients admitted to two large hospitals over six months found that 6.5 per cent of admissions related to harms from medicines.⁷ The researchers judged nine per cent of these events to have been definitely preventable, 63 per cent were possibly preventable and 28 per cent were unavoidable ADRs. In total, the researchers concluded that 4.7 per cent of all admissions were as a result of avoidable (definitely preventable and possibly preventable) harms from medicines. The medicines most commonly implicated in all harms included low-dose aspirin, diuretics, warfarin and non-steroidal anti-inflammatory drugs other than aspirin. The most common reaction was gastrointestinal bleeding.ⁱ Patients on average stayed in hospital for eight days, accounting for four per cent of total hospital capacity.⁷

There were 28 deaths (0.2 per cent of all admissions) and from this, the researchers extrapolated that ADRs are responsible for 5,700 deaths each year. However, this estimate is based on a small number of deaths and also assumes that all possibly preventable deaths could have been prevented. If only the definitely preventable events are included in the estimate (0.5 per cent of all admissions), the expected number of deaths each year would be about 700.⁷

With regard to harms to patients during their hospital stay, a systematic review in 2002 concluded that between 3.5 per cent and 7.3 per cent of inpatients experience harm from medication.⁴⁹ More recently, the results of a pilot (125 patients) for a large, prospective study have shown that nine per cent of hospital inpatients may suffer severe harm from medication error.⁸

ⁱ A recent systematic review of international literature (including studies from the UK) found that the majority of preventable medicine-related admissions to hospitals involved either antiplatelets, diuretics, non-steroidal anti-inflammatory drugs or anticoagulants. Howard et al (2007) Which drugs cause preventable admissions to hospital? A systematic review. *British Journal of Clinical Pharmacology* 63(2): 136-147.

Costs to the NHS

Medication errors can cause unnecessary pain and harm to patients and can even lead to death. In addition, medication errors account for a substantial amount of NHS resources.

In 2004, the Department of Health estimated the costs of medication-related admissions to hospitals to be in the order of £200–400 million a year.¹ As described above, figures from the largest UK-based study of hospital admissions data suggest that 4.7 per cent of all admissions were as a result of avoidable (definitely preventable and possibly preventable) harms from medicines.⁷ The annual cost of these avoidable admissions translates to about £359 million across the NHS in England. Best available evidence suggests that around seven per cent of all inpatients experience preventable ADRs.⁴⁹ If a similar proportion of inpatient medication incidents was avoidable, it would translate into an annual cost of around £410 million to the NHS in England.

Taken together with what is known of litigation costs, it is estimated that preventable harm from medicines could cost more than £750 million each year in England (see appendix 5). This figure is likely to be conservative. For instance, the best estimates of rates of harms from medicines among hospitalised patients are based on available evidence, which does not include administration errors and other key safety categories. In addition, there is very little literature on harms occurring in the community where the majority of drugs are prescribed, dispensed and administered, apart from those resulting in hospital admissions. Service costs associated with these harms include the costs of increased GP consultations, further prescriptions and community nursing visits.

The fourth report from the Patient Safety Observatory

Section 2 Overview of medication safety data

Summary

Between January 2005 and June 2006, 59,802 medication incidents were reported to the NRLS.

Just over 80 per cent of the medication incidents reported to the NRLS occurred in a hospital, although most prescribing and dispensing happens in the community.

Reporting among trusts is variable and just under one-third of trusts (mainly primary care organisations) reported no medication incidents at all over six months. All trusts could report more incidents.

The very young (children aged 0–4 years) were more likely to be involved in reported medication incidents (in which age is reported) compared with their hospital activity.

More medication incidents were reported as resulting in no harm than all other incidents reports to the NRLS.

Learning could be improved by reporting better-quality data. Only one in four reports included a medicine name, although some trusts have worked hard to improve data quality.

As with other kinds of safety incidents reported to the NRLS, the vast majority of medication-related reports come from acute trusts, even though most prescribing and dispensing activity happens in the community. A programme is currently underway that is connecting national community pharmacy chains so that they can also report to the NRLS. The first chain was connected in September 2005. Reports have been received from two of the large pharmacy chains (these are included in the data analysed for this report). The pharmacy contract³⁰ strongly encourages pharmacists to report all medication incidents for local and national learning.

Other data sources used

Table 1 summarises the other data analysed for this report and the key ways in which these data supplement information from the NRLS. Further information about the data analysis is given in appendix 3.

In addition to these supplementary data, the NPSA sought input from a range of health professionals working in the NHS, including a hospital pharmacists' reference group and community pharmacy group to inform this report. Members of these groups helped analyse data, suggested areas for investigation and provided feedback on findings.ⁱⁱ

ⁱⁱ A list of members of these groups and other experts consulted for this report can be found in appendix 4. Based on 607 NHS organisations that were in existence on 1 January 2005.

Sources of data used in this report

Reports to the NRLS

This report is based on reports to the NRLS from 1 January 2005 (when all NHS organisations in England and Wales were fully connected) to 30 June 2006. Most of the reports come from the local risk management systems (LRMS) of NHS organisations in England and Wales.ⁱ The reports are often made soon after the incident occurs but before the incident is investigated (the NPSA does not investigate incidents; this is done locally). Hence the reports to the NRLS may not contain complete information about the reported incident, especially findings of more detailed investigations such as root cause analysis. Nevertheless, the reports contain free text that explains what happened in varying degrees of detail. This text has been used in this report to illustrate the findings from the data. Unlike some reporting systems, reports to the NRLS include 'near-miss' incidents. These are incidents that may have involved serious error but did not in fact lead to harm. They provide a valuable resource for learning.

ⁱ In addition to reporting via LRMS, individuals can report independently direct to the NPSA. At present, this is a very small minority of reports (1.7 per cent of medication incidents). These data are included in the analysis for this report.

Table 1: Sources of litigation and defence data used in this report

Source	Time period of data analysed	Number of claims reviewed	Description	What these data add
NHS Litigation Authority (NHSLA)	April 1995 to June 2006	694	All claims notified to NHS trusts in England made via the Clinical Negligence Scheme for Trusts (CNST).	Small number of incidents, but provides rich information on longer-term outcomes for patients. Claimants tend to be patients or their relatives.
Medical Defence Union (MDU)	January 1996 to June 2006	194	Settled claims from the largest medical defence organisation in the UK. Membership approximately 22,000, mainly GPs.	Reports from health professionals' perspective. Gives detailed information about medicines involved. Little information on outcome for the patient.
Pharmacists' Defence Association (PDA)	January 2005 to December 2005	198	Open, closed and settled claims. Represents more than 9,000 pharmacists, primarily working as employees or locums.	Reports from health professionals' perspective. Gives detailed information about medicines involved. Little information on outcome for the patient.
Chemists' Defence Association (CDA)	January 2001 to May 2006	1,950	Open, closed and settled claims. Represents 3,806 members who own 10,784 pharmacies. It is a subsidiary of the National Pharmacy Association.	Reports from health professionals' perspective. Gives detailed information about medicines involved. Little information on outcome for the patient.

What the data show

Reporting profile

A total of 59,802 (8.3 per cent) patient safety incidents reported to the NRLS between January 2005 and June 2006 were medication incidents (table 2). This makes medication incidents the second most frequent type of incident reported to the NRLS after patient accidents during this time period. Data from the NHSLA showed that between April 1995 and June 2006, 8.2 per cent of clinical negligence claims had a medication error as the cause.

Table 2: The 10 most common types of patient safety incident

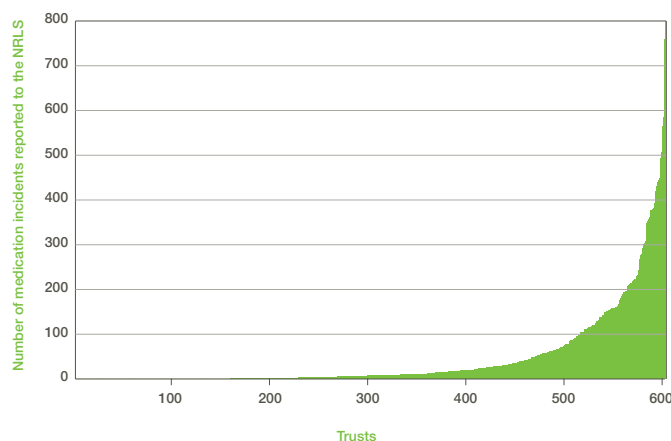
Type of patient safety incident	Number	Percentage
Patient accident	278,886	38.8
Medication	59,802	8.3
Treatment, procedure	58,921	8.2
Access, admission, transfer, discharge (including missing patient)	55,710	7.8
Infrastructure (including staffing, facilities, environment)	46,122	6.4
Documentation (including records, identification)	35,533	4.9
Disruptive, aggressive behaviour	34,944	4.9
Clinical assessment (including diagnosis, scans, tests, assessments)	31,644	4.4
Consent, communication, confidentiality	28,723	4.0
Medical device/equipment	23,389	3.3
Total	653,674	91.0

Note: For 173 incidents (0.02 per cent) the incident type was not reported.

Source: Incidents successfully imported into the NRLS analytical database between January 2005 and June 2006.

Reporting to the NRLS has increased greatly over time. Over four times more incidents were reported in June 2006 compared with January 2005. Despite the overall increase, some trusts are still reporting very few incidents and some are reporting very few medication incidents. Just under a third of NHS trusts reported no medication incidents to the NRLS during the first six months of 2006 (chart 1).

Chart 1: Number of medication incidents reported to the NRLS by trust



Note: Based on 607 NHS organisations that were in existence as at 1 January 2005.

Source: Medication incidents successfully submitted to the NRLS between January 2006 and June 2006. A shorter time period was used than for the rest of the report, to include only the most recent data and therefore more accurately represent reporting patterns.

A large proportion of the non-reporting and low-reporting trusts consist of primary care organisations. Half of all primary care organisations (162 of 324 organisations) reported a total of three or fewer medication incidents to the NRLS between January 2006 and June 2006 (table 3). Only ambulance trusts (31 organisations) reported a lower average (median) number of medication incidents.

Table 3: Average number of medication incidents reported to the NRLS by type of NHS trust

NHS trust type	Number of trusts in cluster	Minimum	Average (median)	Maximum
Acute specialist trusts	21	0	14	379
Acute teaching trusts	25	0	268	759
Other acute trusts	140	0	65.5	448
Ambulance trusts	31	0	0	13
Learning disabilities and mental health trusts	66	0	9.5	242
Primary care organisations	324	0	3	175

Note: For 279 incidents (1.0 per cent), the trust code was not reported. This is because these incidents were reported directly to the NRLS, and the reporters chose not to share the incident with their trust. In addition, 884 incidents (3.1 per cent) reported by community pharmacy chains are not included in this table. Only 38.8 per cent of medication incidents reported between January 2005 and June 2006 indicated the age of the patient. Based on 607 NHS organisations that were in existence as at 1 January 2005.

Source: Medication incidents successfully submitted to the NRLS between January 2006 and June 2006. A shorter time period was used for this analysis than for the rest of the report to include only the most recent data and therefore more accurately represent reporting patterns.

There is scope for even acute trusts, which have a longer history of incident reporting compared with primary care organisations, to increase their levels of reporting of medication incidents. For example, half of acute specialist trusts sent 14 or fewer reports of medication incidents during the first six months of 2006. Furthermore, at least one trust of each different type did not report any medication incidents to the NRLS during the first six months of 2006.

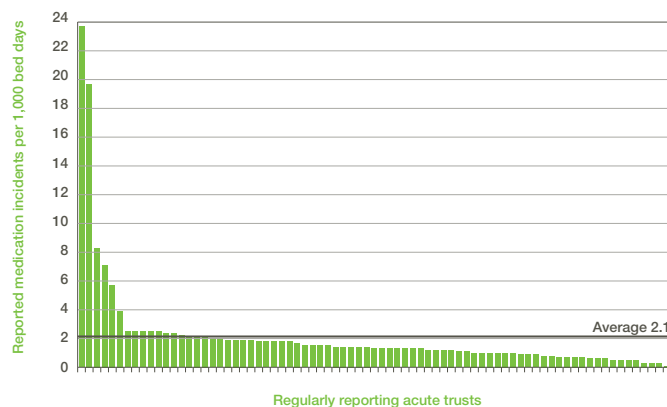
However, there are many trusts reporting a greater number of medication incidents. For example, half of acute teaching trusts each reported more than 268 medication incidents between January 2006 and June 2006. One acute teaching trust reported 759 medication incidents during this time period.

There will always be a gap between the numbers of safety incidents that actually occur and the numbers that are reported – the well-known ‘reporting gap’.⁵⁰ A recent systematic review of international literature included 37 studies from 12 countries that provided a numerical estimate of under-reporting of ADRs.⁵¹ The average rate of under-reporting across all of the studies was 94 per cent. There were no significant differences between the rates of under-reporting in general practice and hospital-based studies. The average (mean) under-reporting rate was lower (87 per cent) for the 19 studies investigating specific severe and serious ADRs.

Although high numbers of reports do not necessarily indicate safer care for patients, a recent study conducted for the NPSA found a correlation between trusts with higher reporting rates and trusts achieving the Clinical Negligence Scheme for Trusts (CNST) Risk Management Level 3.⁵² It is clear that trusts with more open reporting cultures will be in a better position to identify risks and act on them.

Data from trusts that consistently reported over a number of months were used to more accurately examine the rate of reporting of medication incidents. It was found that medication incident reporting rates, for consistently reporting trusts, ranged from 0.1 to 19.7 medication incidents per 1,000 bed days (average 2.1) (chart 2). The two highest rates were from Welsh trusts. These figures are not outside the expected range, reflecting the profile of bed usage and positive reporting culture in Wales. The Healthcare Commission found an average of 0.9 medication incidents reported per 1,000 patient days (the number of inpatient bed days plus the number of first outpatient and accident and emergency attendees).³ Given the different denominators, it is difficult to compare the rates. However, from both sources, it is clear that – even for trusts reporting consistently – there is still a substantial reporting gap. Voluntary reporting systems will never provide complete information, but they are a valuable tool for organisations to identify risks and learn from errors.

Chart 2: Reported medication incident rates for consistently reporting acute trusts



Source: The rate of reporting and the number of trusts reporting to the NRLS has increased over time. Trusts were therefore included if they reported consistently (defined as 100 or more reports every month based on date of incidents) between December 2005 and May 2006. Hospital episode statistics on occupied bed days from 2004/05.

Settings where medication incidents occur

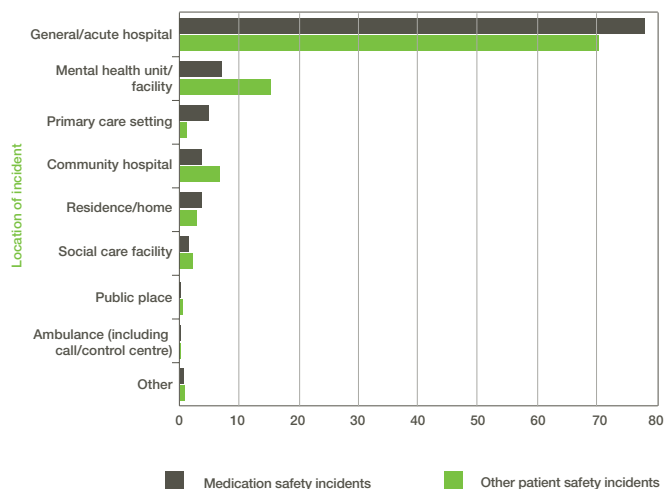
The majority (78.0 per cent) of medication incidents reported to the NRLS between January 2005 and June 2006, as for all incidents reported, occurred in general or acute hospitals (chart 3). Of these, 40.6 per cent occurred in medical specialties and 20.9 per cent in surgical specialties. In total, 81.7 per cent of medication incidents reported to the NRLS in this period occurred in a general, acute or community hospital.

As described in section 1, the majority of medicines activity takes place in non-acute settings. There is significant under-reporting to the NRLS of medication incidents that occur in community settings. Only 4.9 per cent (2,949) of the medication incidents reported to the NRLS between January 2005 and June 2006 occurred in a primary care setting

(including community pharmacies) (chart 3). Although the total number of reported medication incidents occurring in a primary care setting was low, they were the most common incident type in these settings (29.5 per cent of all incidents reported to the NRLS). This is a much larger proportion compared with all other settings.

In addition, data from acute settings can reveal some issues about medicines safety in the community, because some hospital data will reflect errors originating in the community (see discussion of hospital admissions data on page 11-12).

Chart 3: Incidents reported to the NRLS by location



Note: The location of 310 medication incidents (0.5 per cent) and 2,859 other patient safety incidents (0.4 per cent) was either reported as unknown or not applicable, or was not reported.

Source: Incidents successfully imported into the NRLS analytical database between January 2005 and June 2006.

A smaller number of reported medication incidents occurred in mental healthcare settings compared with non-medication incidents. The issues associated with medication in mental healthcare settings have been addressed in the second Patient Safety Observatory report, *With safety in mind*.¹³

Patient groups who are vulnerable to medication incidents

The age of the patient was indicated in 38.8 per cent of medication incidents reported to the NRLS between January 2005 and June 2006 (the NRLS is limited in the information it contains on patient details – see appendix 1). Children aged between 0 and 4 years were involved in 10.1 per cent (2,081) of the reported medication incidents in which a date of birth was reported (chart 4). However, this age group only accounted for 5.6 per cent of all bed days in the NHS. Therefore the proportion of reported medication incidents that involve this age group is higher than expected, given the proportion of hospital activity they constitute. The particular risks relating to medicines given to very young children are examined in more detail in section 4.

Chart 4: Comparison between the proportion of patients who experienced a medication incident and all patients, by age group



Source: Incidents successfully imported into the NRLS analytical database between January 2005 and June 2006, where age reported and within a valid range (20,594 incidents, 38.8 per cent of total) for medication incidents occurring in a general, acute or community hospital or a mental health unit. Hospital episode statistics on occupied bed days from 2004/05.

Medication incidents and stage of the medication process

Just under 60 per cent of reported medication incidents were related to the administration of medicines (table 4). Nearly 18 per cent were associated with preparing medicines in all settings, including dispensing in pharmacies, and almost 16 per cent of incidents involved prescribing, with only around five per cent associated with monitoring.

In all known locations except primary care settings, the largest proportion of reported medication incidents occurred during administration. In primary care settings (including community pharmacies) the majority (62.9 per cent) of reported incidents occurred during preparation or dispensing.

Table 4: Breakdown of medication incidents by stage in the medication process

Stage in medication process	Number	Percentage
Administration/supply	35,487	59.3
Preparation/dispensing	10,615	17.8
Prescribing	9,377	15.7
Monitoring	2,894	4.8
Other	1,349	2.3

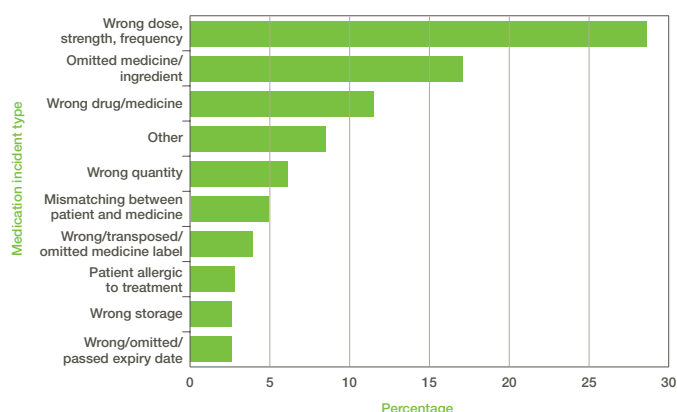
Note: For 80 medication incidents (0.1 per cent) the stage in the medication process when the incident occurred was not reported.

Source: Medication incidents successfully imported into the NRLS analytical database between January 2005 and June 2006.

Medication incidents and type of medication error

Three types of medication error accounted for over half (57.3 per cent) of all medication incidents (chart 5). These were the wrong dose (28.7 per cent), omitted medicines (17.1 per cent) and wrong medicine (11.5 per cent). These and other types of error are reviewed in more detail in the following sections.

Chart 5: The 10 most common types of medication error reported to the NRLSⁱ



Note: For 73 medication incidents (0.1 per cent) the type of error was not reported.

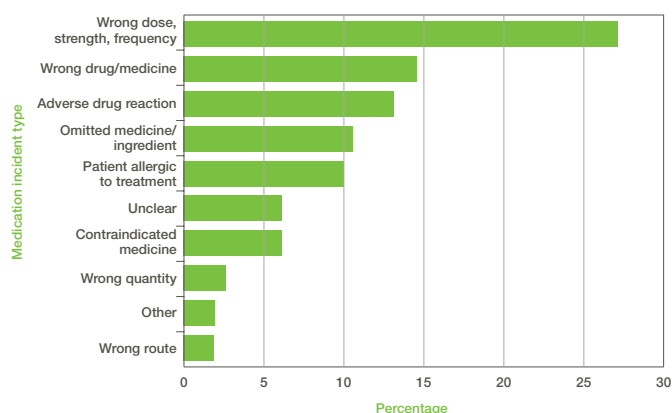
Source: Medication incidents successfully imported into the NRLS analytical database between January 2005 and June 2006.

The 10 most common types of error associated with clinical negligence claims with a cause of medication error made to the NHSLA showed some similarities to the NRLS data (chart 5), with wrong dose, strength or frequency and wrong medicine being the two most frequent error types (chart 6). There are, however, some differences. In particular, known patient allergy was associated with more medication incidents in litigation data (10.1 per cent as opposed to 2.8 per cent in NRLS data) and omitted medicines with fewer (10.7 per cent as opposed to 17.1 per cent in NRLS data). This may reflect the nature of clinical negligence claims, which tend to relate to incidents where patients experienced severe harm.

Most claims (86.9 per cent, 603 claims) made to the NHSLA that were caused by medication error occurred in an acute trust. This reflects the patterns for all claims administered by the NHSLA, as most claims are made against acute trusts.⁵³

ⁱ Medication incidents reported as 'wrong quantity' refer to errors in the number or volume of the correct medicine (e.g. 60 tablets dispensed when the prescription ordered 30 tablets). Medication incidents reported as 'wrong dose, strength or frequency' relate to errors in an individual dose of the correct medicine (e.g. 20 mg tablets dispensed instead of 10 mg or 20 mg tablets administered twice a day instead of once a day).

Chart 6: Claims to the NHSLA (April 1995 and June 2006) caused by medication error, by the 10 most common types of medication error



Source: NHSLA data from April 1995 to June 2006. Claims in which cause of claim was recorded as medication error (n=694). See appendix 3 for further information about the NHSLA data.

Outcome of error for patients

A report to the NRLS not only describes the incident but also, importantly, indicates the outcome for the patient with regards to the degree of harm that occurred.ⁱⁱ It should be noted that the definitions of the categories of harm are strict and based on the physical harm to the patient (see appendix 2). For instance, there must be evidence of permanent harm to the patient for a harm to qualify as severe.

A higher proportion of medication incidents reported to the NRLS were reported as resulting in no harm compared with all other patient safety incidents that were reported (82.8 per cent and 66.8 per cent, respectively) (table 5). Furthermore, the proportion of medication incidents reported as resulting in death was also lower compared with all other patient safety incidents reported as resulting in death (0.1 per cent and 0.4 per cent, respectively).

Table 5: Reported degree of harm to patients

	Number		Percentage	
	Medication safety incidents	Other patient safety incidents	Medication safety incidents	Other patient safety incidents
No harm	49,494	439,859	82.8	66.8
Low harm	7,459	172,573	12.5	26.2
Moderate harm	2,311	36,673	3.9	5.6
Severe harm	458	6,100	0.8	0.9
Death	58	2,800	0.1	0.4

Note: For 24 medication incidents (0.04 per cent) and 138 other patient safety incidents (0.02 per cent) the degree of harm was not reported.

Source: Incidents successfully imported into the NRLS analytical database between January 2005 and June 2006.

ⁱⁱ Definitions for the harm categories used are given in appendix 2.

A medication incident reported as resulting in 'no harm' does not necessarily mean the incident is of no consequence to the patient. Reports indicate that the same medication incident can lead to different outcomes for different patients (see example incidents below). In addition, there is considerable learning from the 'no harm' category, which includes serious incidents that, by chance, did not result in harm to the patient.

Patient was given amoxicillin, when they were allergic to penicillin. (Reported as resulting in no harm)

GP on call administered amoxicillin to the patient. A short time later the patient collapsed in cardiac arrest. An ambulance was called and a CPR [cardiopulmonary resuscitation] protocol followed. Whilst CPR was being completed, it was ascertained that the patient had been prescribed an antibiotic ... which a relative stated the patient had told the GP that they were allergic to. (Reported as resulting in death)

All the medication incidents reported as resulting in death or severe harm in the data used for this report were reviewed and their degree of harm confirmed based on the available evidence. Degree of harm is consistently reported to be more severe than the description of the incident indicates. This is often because the potential for harm has been reported rather than the actual degree of harm (see 'interpreting medication incident reports' opposite). For example, over 80 per cent of the incidents reported as resulting in severe harm did not give evidence of the permanent harm caused to the patient. Following review,ⁱ fewer incidents were classified as resulting in death or severe harm. Section 3 examines these confirmed deaths and severe harm incidents in more detail.

Between January 2005 and June 2006, 58 medication incidents were reported to the NRLS as resulting in death. After review it was decided that, based on the available evidence, only 19 of the 58 incidents had actually resulted in the death of a patient (table 6). Another 19 medication incidents that resulted in the death of the patient, but were reported as resulting in a lower degree of harm, were found by searching the database for keywords and reviewing incidents reported as resulting in severe harm. The number of medication incidents resulting in severe harm also decreased from a reported 458 incidents to 54 after review.

In 16.0 per cent of claims made to the NHSLA where medication error is cited as a cause, the incident resulted in death (111 of 694 claims made between April 1995 and June 2006). This is a higher proportion of all medication related claims compared with the proportion of medication incidents reported to the NRLS (0.1 per cent) that resulted in death. However, these comparisons should be treated with caution as this higher proportion in the NHSLA data probably reflects the serious nature of the claims made to the NHSLA (an incident which results in no harm would probably not be the subject of a clinical negligence claim).

ⁱ All incidents reported as death or severe harm were independently reviewed by at least two pharmacists according to strict criteria and using all the information provided in the reports to agree the confirmed degree of harm, which was in line with the rigorous NPSA definitions.

Table 6: Medication safety incidents by confirmed degree of harm to patients

Confirmed degree of harm	Number	Percentage
No harm	49,714	83.1
Low harm	7,552	12.6
Moderate harm	2,391	4.0
Severe harm	54	0.1
Death	38	0.1

Note: For 29 medication incidents (0.05 per cent) reported as resulting in severe harm or death the report did not contain enough information in the incident description for the degree of harm to be confirmed. In another 24 incidents (0.04 per cent), the degree of harm was not reported.

Source: Medication incidents successfully imported into the NRLS analytical database between January 2005 and June 2006, incorporating revised data on the number of incidents with an outcome of death or severe harm as a result of the review described above.

Interpreting medication incident reports

Considerable learning can be gained from data on the incidence of errors and descriptions of incidents. However, some aspects of reports to the NRLS need to be interpreted with caution, particularly the degree of harm that incidents cause to patients.ⁱⁱ The NPSA definitions of degree of harm are based on the physical harm the incident results in for the patient. However, because the information is reported at the point at which the incident happened and the report is reliant on the perception of the staff member, the actual outcome of the incident for the patient may not yet be accurately known, may be over-estimated or may not be caused by medicine as first thought.

There are also issues around missing data in the reports to the NRLS. The NRLS is able to collect a wide range of data items. However, it is not mandatory to report many of these items and completion levels are low. For instance, patient characteristics (age, sex, ethnicity, weight) and medicine details (name, *BNF* class, route, form) are helpful in the analysis of and learning from incidents, yet these have low completion rates.

Only 26.8 per cent of medication incident reports included the medicine name as a separate data field. Without this information, it is necessary to search the free text description of the incident to identify the medicine involved. This process can impede accurate identification of the risks to patients and actions to minimise those risks. Some trusts are taking action to improve data quality, with impressive results.

ⁱⁱ The strengths and limitations of the NRLS reporting system are set out in appendix 1.

Practice example: Improving the quality of medication incident reporting

Organisation: Sheffield Teaching Hospitals NHS Foundation Trust

Objective(s): To improve the quality of medication incident reports by increasing the number of reports which include the medicine name.

Action taken

For the first six months of 2005, this teaching hospital found that only 35 per cent of reported incidents included the name of the medicine. Knowing which drugs are involved in safety incidents helps pharmacists and clinical staff to target their efforts appropriately. The importance of providing this information was supported by the trust risk forum, Datix user group and pharmacy staff. Therefore, guidelines were produced for completion of the medication field on the Datix system and an automatic prompt was added to the Datix system when a new entry was coded as a medication incident. In addition, the trust incident form was amended to include a section to record medication details. The report for May–November 2005 showed the proportion of medication incidents reported with a medicine name have increased to 76 per cent.

This report shows how reported incidents can reveal weaknesses and risks in current medicines practice and systems. However, at present, there is considerable under-reporting, particularly from certain sectors (such as primary care). In addition, reports are not always complete – for instance, only one in four include the drug name – which is essential for learning and taking action.

In December 2006, the Department of Health published a report, *Safety first*,⁹ which reviewed the organisational arrangements currently in place to support patient safety. It concluded that more could be done to make patient safety a priority at a local level and to maximise impact. The report's recommendations include a review of current arrangements for reporting safety incidents, with a view to making reporting easier and sharing the information obtained in the most effective way. Following the publication of *Safety first*, work is underway to implement these recommendations in order to maximise the impact of lessons learned from patient safety incident reports in the NHS.

Conclusion

Medication safety is an important aspect of patient safety. Medication safety incidents were the second largest group of patient safety incidents reported to the NRLS between January 2005 and June 2006. Even though there is substantial under-reporting by NHS organisations, a significant amount of learning can be gained from the data that are reported.

Wrong doses, omitted medicines and wrong medicines make up the majority of medication errors reported the NRLS. Most of the reported incidents occurred during the administration of medication. A large number of reported medication incidents involved children aged between 0 and 4 years old and issues for this patient group are explored further in section 4.

The fourth report from the Patient Safety Observatory

Section 3 Learning from medication incidents leading to severe harm or death

Summary

A review by the NPSA confirmed that 92 medication incidents reported to the NRLS between January 2005 and June 2006 caused severe harm to patients or resulted in death.

The detailed review of incidents resulting in severe harm or death contributes to understanding of how incidents occur and can inform initiatives to minimise preventable harms at a local and national level.

Most incidents confirmed as leading to severe harm or death were caused by errors in drug administration and, to a lesser extent, prescribing.

Types of medication errors resulting in severe harm or death included: wrong dose, omitted medicines, wrong medicine, contraindicated medicine, known patient allergy to medicine and wrong route.

In an analysis of errors related to route of administration, injectable medicines were most commonly associated with severe harm or death, although these make up a small proportion of medicines used overall.

Types of drugs most frequently associated with incidents resulting in severe harm and death include: opioids, anticoagulants, insulin, antibiotics (patient allergy), chemotherapy, antipsychotics and infusion fluids.

This section explores the analysis of medication incidents that are confirmed to have caused severe harm to patients or resulted in death.

Between 1 January 2005 and 30 June 2006, the NRLS received 92 reports of medication incidents that resulted in severe harm or death (54 severe harm and 38 deaths).¹ These numbers are substantially lower than the estimates from research studies.⁷ As discussed in section 2, there is substantial under-reporting of medication incidents to the NRLS. Moreover, estimates from research studies are based on small number of events. Despite the small numbers of such reports in comparison with the actual numbers likely to be occurring in England and Wales, they provide considerable learning for developing initiatives to minimise preventable harms at local and national levels.

When in the medication process do severe harm incidents occur?

Most of the reported incidents resulting in severe harm or death related to administration (56.5 per cent, 52/92). A substantial proportion (29.3 per cent, 27/92) related to prescribing error (table 7).

Table 7: Medication incidents by stage in the medication process, for incidents confirmed as resulting in severe harm or death

Stage in medication process	Confirmed degree of harm		Total (% of total)
	Severe harm	Death	
Administration/supply	28	24	52 (56.5%)
Prescribing	18	9	27 (29.3%)
Monitoring	4	3	7 (7.6%)
Preparation/dispensing	3	1	4 (4.3%)
Other	1	1	2 (2.2%)
Total	54	38	92 (100%)

Source: Medication incidents successfully imported into the NRLS analytical database between January 2005 and June 2006.¹

Types of medication errors leading to severe harm or death

Several types of medication error were associated with the reported incidents confirmed as resulting in severe harm or death.¹ The most common error was wrong dose, strength or frequency of medicine (table 8).

¹ The reported degree of harm may not always be in accordance with the NPSA's definition of that degree of harm (see appendix 2 for the NPSA definitions of degree of harm). Therefore all incidents reported as death or severe harm were reviewed independently by at least two pharmacists, using all the information provided in the report and strict criteria to ensure that the degree of harm reported was in line with the NPSA's definitions. It was found that 19 of the 58 medicine incidents reported to the NRLS as resulting in death had that outcome. A keyword search of the database revealed that 19 medication incidents that were reported as resulting in a lower degree of harm also resulted in death. Of the 458 medication incidents reported to have resulted in severe harm, 54 fulfilled the NPSA's criteria for this category of harm after review.

Table 8: Medication error type, for incidents confirmed as resulting in severe harm or death

Type of medication incident	Confirmed degree of harm		Total (% of total)
	Severe harm	Death	
Wrong dose/strength/frequency	19	16	35 (38%)
Adverse drug reaction	9	6	15 (16.3%)
Omitted medicine	10	3	13 (14.1%)
Contraindicated medicine	5	5	10 (10.9%)
Wrong medicine	6	4	10 (10.9%)
Patient allergic to treatment	2	3	5 (5.4%)
Wrong route	3	1	4 (4.3%)
Total	54	38	92 (100%)

Source: Medication incidents successfully imported into the NRLS analytical database between January 2005 and June 2006ⁱ

Most claims to NHSLA (between 1995 and 2006) which cited medication error as a cause and where the patient died were related to the administration of medicine (29.7 per cent, 33/111 deaths) and wrong dose/strength/frequency of medicine (10.8 per cent, 12/111 deaths). This reflects the findings from the NRLS.

As discussed in section 1, all preventable harm from medicines is of interest to the NPSA. This includes ADRs where the harm was preventable. The descriptions of the medication incidents reported as ADRs that resulted in severe harm or death did not contain enough information to discern whether the incidents were preventable (see section 1 for explanation of preventable and non-preventable harms). Therefore incidents confirmed as resulting in severe harm or death which were recorded as ADRs were not reviewed in-depth here but are included in the numbers presented in this section.

Wrong dose

The reported medication incidents involving wrong dose errors that resulted in severe harm or death underscore the importance of routine activities such as documentation, monitoring of medicines, and communication with carers and other healthcare providers. Wrong dose errors in children can be particularly harmful (see page 32-34).

ⁱ The reported degree of harm may not always be in accordance with the NPSA's definition of that degree of harm (see appendix 2 for the NPSA definitions of degree of harm). Therefore all incidents reported as death or severe harm were reviewed independently by at least two pharmacists, using all the information provided in the report and strict criteria to ensure that the degree of harm reported was in line with the NPSA's definitions. It was found that 19 of the 58 medicine incidents reported to the NRLS as resulting in death had that outcome. A keyword search of the database revealed that 19 medication incidents that were reported as resulting in a lower degree of harm also resulted in death. Of the 458 medication incidents reported to have resulted in severe harm, 54 fulfilled the NPSA's criteria for this category of harm after review.

A child awaiting heart surgery was discharged from hospital on an unlicensed paediatric strength of a diuretic furosemide liquid containing 5 mg in 5 ml. When the patient's parent requested further supplies of the diuretic the GP prescribed a licensed product containing 10 mg in 1 ml. The parent was not informed of the change and continued to give the child 5 ml at each dose instead of 0.5 ml. After receiving the wrong dose at home for several days the baby was rushed to hospital and died from hypoxic ischaemic brain damage, hypovolaemia and furosemide toxicity. (Death)

Omitted medicines

Omitted medicines can have serious consequences. The NRLS received reports of deaths and severe harm occurring when medicines had not been prescribed, dispensed or administered to patients.

A patient was advised to discontinue aspirin and clopidogrel prior to an outpatient appointment for a pain relieving epidural injection. This was only one month after placement of a coronary stent. As a result the stent became blocked and the patient suffered a myocardial infarction. (Severe harm)

A patient taking regular carbamazepine to control seizures was admitted to hospital. During the inpatient stay the supply of carbamazepine ran out. This was not identified by the pharmacy technician responsible for the medicine supplies on the ward. The patient was without medication for three days and as a result had a generalised seizure of several minutes' duration followed by disorientation. (Severe harm)

Patient with hypoadrenalism secondary to pan-hypopituitarism, dependent on hydrocortisone replacement therapy, was too sleepy to take the tablets for 24 hours. No attempts were made to give the medicine by injection. Overnight the patient had a presumed aspiration due to their already poor swallow reflexes and was unable to mount an effective circulatory response to this insult. The patient became profoundly hypotensive and hypoxic. (Severe harm)

Wrong medicine

Medication incidents involving the wrong medicine being dispensed, prepared or administered and resulting in severe harm or death were reported to the NRLS.

A patient with acute renal failure had been vomiting for one week and was dehydrated. They became bradycardic. Fluid replacement was not effective. Their condition deteriorated and they died. Bumetanide had been prescribed but bisoprolol had been dispensed by pharmacy in error. The patient took this medicine for four days up to the day before their death. (Death)

Isoprenaline was drawn up into a syringe but labelled as metaraminol in error. This was administered to the patient by the anaesthetist. The patient had a serious adverse reaction requiring resuscitation and cardioversion. The patient's condition stabilised after 40 minutes, surgery was cancelled and the patient was transferred to ICU [intensive care unit]. (Severe harm)

Contraindicated medicine

Medicines may be contraindicated because of the possibility of interactions with other medicines (drug–drug interactions) or due to the presence of other disease states (drug–disease interactions). In either situation, severe harm or death may result.

A patient admitted with supraventricular tachycardia was treated with intravenous verapamil followed later by intravenous metoprolol. After the metoprolol was administered there was a drop in heart rate (33 beats per minute). The [patient's condition] deteriorated further overnight. Efforts to reverse the effects of the interaction between these two drugs were not effective and the patient died. (Death)

A patient was commenced on the anticoagulant low molecular weight heparin. The following day the nurses noted that the patient had melaena, possibly due to aspirin. The aspirin was discontinued but a further dose of low molecular weight heparin was given. As a result of over-anticoagulation the patient experienced a haemorrhagic stroke and subsequently died. (Death)

Patient allergy to treatment

Allergy to medicine is a specific type of contraindication for the use of a medicine or other medicines from the same therapeutic class. As noted previously, if a patient experiences an ADR when taking a medicine for the first time the incident should be reported to the MHRA.²⁴ In addition, the name of the medicine and the patient's reaction should be prominently recorded in the patient's medical record to ensure they do not receive that medicine again. If the patient is given the medicine again despite this known reaction, the incident should be reported to the NPSA and categorised as 'patient is allergic to treatment'.

The clinical notes of a patient showed a record of penicillin allergy but amoxicillin had been prescribed in the past. From these old prescriptions it was assumed that amoxicillin would be safe and it was prescribed again. The patient died later that day as a result of the anaphylactic reaction. (Death)

A patient reported a possible allergy to an antibiotic beginning with the letter 'T'. Several medicines beginning with 'T' were suggested but the patient was still not sure. They had received amoxicillin in the past without problems. Cefuroxime was prescribed and administered but immediately after the dose was given the patient complained of difficulty breathing and itchiness. The patient was immediately assessed by the doctor who diagnosed anaphylaxis. Attempts at resuscitation were unsuccessful. (Death)

Wrong route

Wrong route errors include incidents where oral liquid medicines and feeds have been administered via the intravenous route. These types of error occur owing to the inclusion of universally compatible Luer connectors on devices used to administer medicines by any route.

A patient was given a liquid enteral feed down a Hickman line in error. This caused severe back pain, reduced blood saturation levels and an increased pulse as fat emboli entered the subclavian vein leading to the heart and eventually to the lungs. (Severe harm)

Route of administration for incidents confirmed as severe harm or death

Injectable medicines are associated with the greatest number of incidents confirmed as resulting in severe harm or death: 53/92 incidents (57.6 per cent, see table 9). This is not surprising as injectable medicines are often potent medicines, requiring complex dose calculations, methods of preparation and administration, and systems for monitoring treatment (see section 4 for a discussion of issues related to injectable medicines).

Table 9: Medication incidents by route of administration, for incidents confirmed as resulting in severe harm or death

Route of administration	Confirmed degree of harm		Total (% of total)
	Severe harm	Death	
Injectable	28	25	53 (57.6%)
Oral	23	12	35 (38%)
Inhaled	1	0	1 (1.1%)
Rectal	1	0	1 (1.1%)
Not stated	1	1	2 (2.2%)
Total	54	38	92 (100%)

Source: Medication incidents successfully imported into the NRLS analytical database between January 2005 and June 2006.

ⁱ The reported degree of harm may not always be in accordance with the NPSA's definition of that degree of harm (see appendix 2). Therefore all incidents reported as death or severe harm were reviewed.

A critically ill patient had an intraoperative cardiac arrest and therefore intravenous fluids were administered quickly as part of the resuscitation. It was noted after the patient was stable that 500 ml of five per cent glucose with 0.4 per cent lidocaine had been administered intravenously rapidly instead of 500 ml of a colloid six per cent. The patient died 48 hours later with clotting and suspected liver problems. (Death)

A patient with low blood potassium (potassium 3.1 mmol/l) was prescribed an infusion containing 40 mmol potassium in 100 ml. The rate of the infusion was not controlled by an electronic infusion device. When turning the patient to wash them, the infusion rate increased. The resulting cardiac arrhythmia was promptly detected by staff at the bedside and the patient was successfully resuscitated by the crash team. (Severe harm)

A patient who was being resuscitated from a cardio-pulmonary arrest required infusions of sodium bicarbonate. When the second infusion was set up, glucose with lidocaine infusion was given instead of sodium bicarbonate. (Severe harm)

A prescription for prostacyclin infusion was written in error for a baby when prostaglandin infusion was intended. This resulted in an excessively high dose of prostacyclin being infused, which is known to cause hypotension. The baby, who was critically ill, exhibited hypotension that was relatively resistant to other treatments. The baby died later. (Death)

Medicines implicated in incidents confirmed as severe harm or death

The medicines involved in the reported medication incidents which resulted in severe harm to or death of a patient can be grouped into several key therapeutic groups (table 10).

ⁱ The reported degree of harm may not always be in accordance with the NPSA's definition of that degree of harm (see appendix 2 for the NPSA definitions of degree of harm). Therefore all incidents reported as death or severe harm were reviewed independently by at least two pharmacists, using all the information provided in the report and strict criteria to ensure that the degree of harm reported was in line with the NPSA's definitions. It was found that 19 of the 58 medicine incidents reported to the NRLS as resulting in death had that outcome. A keyword search of the database revealed that 19 medication incidents that were reported as resulting in a lower degree of harm also resulted in death. Of the 458 medication incidents reported to have resulted in severe harm, 54 fulfilled the NPSA's criteria for this category of harm after review.

Table 10: Medication incidents by therapeutic group, for incidents confirmed as resulting in severe harm or death

Therapeutic group	Confirmed degree of harm		Total (% of total)
	Severe harm	Death	
Opiates	5	7	12 (13%)
Anticoagulants	8	2	10 (10.9%)
Anaesthetics	3	2	5 (5.4%)
Insulin	6	2	8 (8.7%)
Antibiotics	2	3	5 (5.4%)
Chemotherapy	0	4	4 (4.3%)
Infusion fluids	1	2	3 (3.3%)
Antipsychotics	2	0	2 (2.2%)
Other	27	16	43 (46.7%)
Total	54	38	92 (100%)

Source: Medication incidents successfully imported into the NRLS analytical database between January 2005 and June 2006.¹

The two therapeutic groups most commonly associated with reported incidents confirmed as resulting in severe harm or death were opioids (12/92, 13 per cent) and anticoagulants (10/92, 10.9 per cent). Where the medicine name was recorded in NHSLA data, the therapeutic group most frequently associated with the death of a patient was anticoagulants (22/69, 31.8 per cent of claims).

These results reflect the findings from the literature, which suggest that opioids, anticoagulants, insulin, antipsychotics and chemotherapy are the therapeutic groups most frequently associated with preventable medication errors that result in severe harm.^{7,47}

Reports to the NRLS suggest that antibiotics can also cause severe harm or death because they are associated with preventable anaphylactic reactions (see section on medicine given despite known patient allergy, page 31-32). Most of the reported incidents related to anaesthetics were ADRs, which are outside the scope of this report.

Opioids

Nine of the 12 reports of severe harm or death due to opioids were associated with overdose. It is imperative that every patient receives the appropriate dose of opioid and that patients receiving opioids are monitored regularly.

A patient died following an intravenous dose of 30 mg of diamorphine. A 5 mg dose had been intended. (Death)

On arrival at a hospice, a patient was oversedated and had a respiratory rate of four per minute having been given a bolus injection 40 mg diamorphine at home. This dose was equivalent to the total dose given in the previous 24 hours. The recommended bolus dose should have been one sixth of this dose. This placed the patient at great risk. The patient was assessed and closely observed. No further opioids were administered for approximately 10 hours after which the appropriate dose was recommenced. (Severe harm)

A patient was admitted to the intensive care unit with respiratory depression following an apparent opioid overdose on [the] ward. The patient had been receiving opioids by three different routes concurrently: an infusion epidurally, fentanyl via a skin patch and morphine orally as sustained release tablets. (Severe harm)

It was noticed that a client had been given the wrong medication at 8.30 am (slow release oxycodone 80 mg, lansoprazole 30 mg and lactulose 10 ml). The client was found to be unrousable with a respiratory rate of four breaths per minute. The client was resuscitated by the crash team and transferred to a medical admissions unit where a further arrest occurred. (Death)

Chemotherapy

The complexity of chemotherapy regimens and the need to allow patients to recover from one chemotherapy course before receiving the next course were implicated in the reported incidents involving these medicines.

A patient with acute myeloid leukaemia completed their second course of chemotherapy. Eight days later course three was commenced. Two days later the blood count showed reduced numbers of white cells and platelets. The third course of chemotherapy should not have commenced until the blood count had recovered following the second course. (Death)

A patient newly diagnosed with multiple myeloma was prescribed idarubicin and dexamethasone orally. The patient was prescribed and received four times the intended dose of idarubicin (240 mg instead of 60 mg) and developed protracted myelosuppression. The patient subsequently died from neutropenic sepsis and renal failure. (Death)

A dose of 10 mg idarubicin was given on days 2, 4, 6 and 8 of a chemotherapy course. The usual dose of 7 mg per metre squared should be halved if renal function is impaired indicated by a raised serum creatinine. The dose should have been 6.5 mg on days 1, 2, 3 and 4. (Death)

Insulin

The reported medication incidents confirmed as resulting in severe harm and death involving insulin illustrate the importance of the timing of insulin doses in relation to food intake and other therapy, and the accuracy of the dose to be administered (other issues relating to insulin are described on page 36).

A patient required a dose of dextrose and insulin prescribed for high potassium levels (6 mmol/litre). The dose was not given and the patient later had a cardiac arrest as a result of the high potassium and died. (Death)

A patient who had undergone bowel surgery was having TPN [total parenteral nutrition] and insulin. When the TPN infusion was finished it was switched off but the insulin infusion was not. The patient experienced a profound hypoglycaemic episode (blood glucose 0.1 mmol/l) requiring transfer to intensive care for urgent treatment. (Severe harm)

A patient unexpectedly became hypoglycaemic with a blood glucose of 1.2 mmol. Oral glucose was administered with good effect. However, the [patient's condition] suddenly deteriorated and [they] later died. Subsequently their drug chart showed that they had been given a dose of 24 units of insulin which should not have been given until the following day. (Death)

A patient was prescribed soluble insulin to treat high potassium levels in their blood. The dose prescribed was too high causing a deterioration in their general condition (Severe harm)

A patient was found unresponsive at 6:40 am. The crash team was called but the highest blood glucose measured during the arrest was 1.2 mmol. The previous day the patient had received two doses of long-acting insulin analogue at 11:50 and 21:00, instead of a single dose in the morning. (Severe harm)

Anticoagulants

The reports to the NRLS showed that (i) effective communication between hospital staff, the anticoagulant clinic, GPs and patients taking anticoagulants and (ii) systems for monitoring such patients are essential for safe anticoagulant therapy.

A patient was discharged from hospital on warfarin. The anticoagulant clinic was not informed of the patient's discharge so no follow-up appointment was made. The patient was re-admitted with an INR [international normalised ratio] of 18.1 (compared to an expected INR of between 2 and 4) and GI [gastro-intestinal] bleeding. (Severe harm)

A patient admitted for orthopaedic surgery ... should have had their anticoagulant therapy stopped seven days prior to surgery. This was not done and the patient ... [had a haemorrhage] during surgery, needing transfusion of 12 units of blood and transfer to a higher level of care. (Severe harm)

A patient on warfarin for atrial fibrillation was treated with antibiotics and steroids for an exacerbation of COPD [chronic obstructive pulmonary disease]; recognising that steroids could interfere with INR, the GP arranged a blood test for the following day. The result was high at 6.2 so the GP recommended that the patient stopped their warfarin therapy until the INR had dropped to 5 or below and another INR test was arranged. The patient's condition deteriorated and [they] subsequently died from a cerebral bleed. (Death)

Antipsychotic medicines

The risk of interactions with other medicines and the importance of safe monitoring and storage were highlighted by the reported incidents involving antipsychotics and that were confirmed as resulting in severe harm or death.

Patient had been having lithium treatment for several years. They were admitted to an acute hospital for cardiac reasons and started on various medicines including bumetanide (a diuretic). They were discharged on this treatment and had become increasingly confused. The community psychiatric nurse and general practitioner were concerned and a lithium level was done. The level was 4.1 mmol/l, which is potentially fatal. The patient was admitted to hospital for urgent treatment. (Severe harm)

The patient was admitted to ICU from a ward. On cleaning the patient's ward locker, an empty box of clozapine 100 mg with 30 tabs missing and amlodipine 5 mg with four tablets missing was discovered. The patient may have taken an overdose from their bedside medicine locker. (Severe harm)

Conclusion

Medicine errors do not often result in severe harm or death. However, as this section has shown, a wide range of medicine errors can lead to severe harm or death. The actions recommended in section 6 focus on what can be done locally to address medicines safety in relation to the errors which have been discussed here.

The fourth report from the Patient Safety Observatory

Section 4 Medication incidents in hospitals

Summary

Hospitals can take action to prevent harm to patients from several types of medication error: wrong dose, omitted medicines, wrong medicine, wrong route, mismatched patient and drug, and wrong formulation.

NRLS data show patient groups that are vulnerable to medication error in hospital; people with known allergies to medicines and children aged 0 to 4 years.

Particular risks have also been identified in relation to injectable medicines. Insulin is provided as an example of a commonly used medicine that highlights a range of medication safety issues.

Documentation and communication issues were implicated in many of the incidents reviewed.

Some hospitals are working to improve medicines safety where they have identified local issues. This section presents examples of practice to reduce risk of harm from medicines in hospitals.

The majority of reports of harm or potential harm from the reported medication incidents came from hospitals (see section 2). This section describes the results of a qualitative analysis of reports of different types of medication incidents reported to the NRLS that occurred in a hospital.

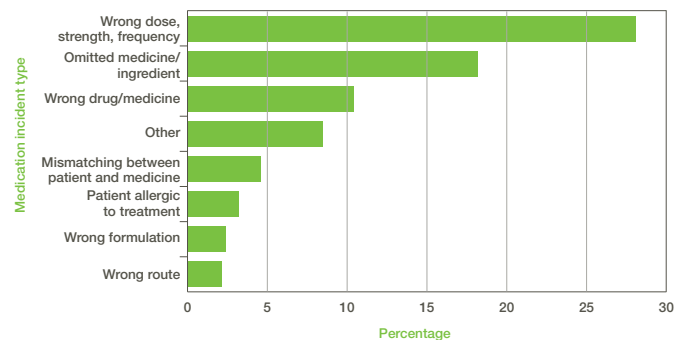
Just over 48,000 medication incidents reported to the NRLS between January 2005 and June 2006 occurred in a hospital. Most of these occurred in an acute/general hospital (95.6 per cent) with reports from community hospitals accounting for 4.4 per cent.

*Building a safer NHS for patients*² highlighted that certain patient groups may be vulnerable to particular safety risks in hospital. The reports from hospitals analysed here confirmed the risks for two of these groups: children and people with allergies to medicines. In addition, particular issues were identified in relation to injectable medicines and insulin. Problems with communication and documentation were an underlying theme in many of the reported incidents reviewed.

Samples of eight types of reported medication incident that occurred in an acute, general or community hospital were analysed. These eight incident types accounted for just over three-quarters (77.5 per cent) of all hospital-based medication

incidents reported to the NRLS and were those that occurred most frequently (chart 7) and had a high potential for harm (chart 8). For example, although reported incidents where the patient was allergic to the treatment only accounted for 3.2 per cent of all reported medication incidents occurring in a hospital (chart 7), 30.9 per cent of them resulted in some harm (chart 8). The learning from the reported incidents is described in detail below.

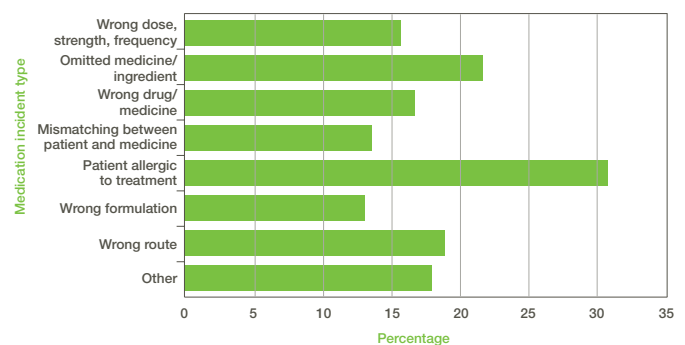
Chart 7: Percentage of all reported medication incidents occurring in hospitals, for the eight key types



Note: For 49 (0.1 per cent) reported incidents the medication incident type was missing.

Source: Medication incidents successfully imported into the NRLS analytical database between January 2005 and June 2006.

Chart 8: Percentage of reported incidents within each of eight key medication incident types resulting in harm



Note: For 49 (0.1 per cent) incidents the medication incident type was missing. Also, 21 incidents (0.04 per cent) that were reported as resulting in severe harm or death did not contain enough information in the incident description for the degree of harm to be confirmed.

Source: Medication incidents successfully imported into the NRLS analytical database between January 2005 and June 2006 that occurred in an acute, general or community hospital.

Stages of the medication process at which incidents occur in hospitals

Although medication incidents occur at all stages of the medication process in hospitals, many of the incidents relate to the administration of medicines. Medicines administered outside normal working hours or during the medicine round present a particular risk for error. Some hospitals have developed active working relationships between pharmacists and nurses in order to improve medication safety on the wards and other clinical areas.

In addition to identifying incidents relating to the prescribing, dispensing, preparation and administration of medicines, the analysis of reported incidents revealed issues with the supply system of medicines in hospitals. Incidents may occur when a hospital medicines supply system fails or when hospital pharmacy opening/closing times lead to a delay in the right dose and medicine being administered to the patient. Supply issues are particularly serious in certain clinical areas (for example, anaesthesia) and for vulnerable patients (for example, those experiencing cardiac arrest). Incidents might occur in relation to ward medicines stock control and housekeeping, as well as pharmacy re-ordering, monitoring and contingency planning (for example, for manufacturer supply shortages).

A ward needed a supply of methadone for an addict admitted on a Sunday but pharmacy was closed.

Lorazepam was requested urgently by staff in Accident and Emergency as stocks were getting low. However, replacement stock had not arrived by the time it was needed to treat a patient with epilepsy so an alternative medicine had to be administered.

Communication between wards and hospital pharmacies is important in ensuring the appropriate, safe and timely supply of medicines.

A ward ordered IV [intravenous] paracetamol and disodium pamidronate for a patient and were assured that they would be sent the next day. However they had still not arrived three days later. The patient was in pain and pyrexial.

Clearly, there are practical policies and procedures that can be put in place to address the supply of medicines in hospitals. Guidance on the safe and secure handling of medicines has recently been revised.⁵⁴ Some hospitals are taking steps to ensure that medication practice on wards is as safe as possible, particularly in relation to the storage of controlled drugs.

Practice example: Controlled drugs stock lists

Organisation: King's College Hospital NHS Foundation Trust

Objective: To use a systematic process to agree new systems to improve the monitoring of stocks of controlled drugs held on wards and increase consistency in the use of these medicines across wards.

Action taken

An audit in November 2004 at this London teaching hospital showed that the numbers of different drugs and preparations held on wards differed widely. Nearly half of the medicines had not been used for more than a month and cupboards were overcrowded. A system of controlled drug stock lists was developed and piloted in the paediatric and women's services wards. The pharmacy department divided the controlled drugs into three 'risk' categories; low strength drugs commonly used on most wards (green), high-strength drugs routinely prescribed in certain situations (yellow) and high-strength opioids rarely prescribed first-line (red). Ward stock lists for green and relevant yellow drugs were agreed with the ward manager and pharmacist. Orders for 'non-stock' yellow and red category drugs were screened and authorised by a pharmacist.

Evaluation of the pilot showed that the total number of controlled drugs stored on the wards was reduced by a third. There was a 61 per cent reduction in the number of non-routine (and higher risk) drugs inappropriately stored on the wards. Feedback from staff on the wards was positive, and they felt that drugs were still available when needed.

Unauthorised use of medicines

The analysis of reports from hospitals revealed safety issues in relation to medicines (including illicit substances) that are prescribed, supplied or administered to a patient without the knowledge or consent of the healthcare team, by health professionals, by patients' relatives or by patients themselves. This type of incident should be investigated locally to identify root causes.

A patient had been receiving fentanyl 100 microgram patches, a controlled drug, prescribed by a pain clinic for chronic back pain. The patient's partner had been bringing these patches into hospital for the patient to use. These had not been prescribed in the hospital so there was no record that the patient was using this medicine, no record that it was being administered, and no record in the controlled drugs book.

Types of medication error occurring in hospital

Wrong/unclear dose or strength, or wrong frequency

The most common type of medication incident, accounting for 28.2 per cent of all reported medication incidents in hospitals, involved the wrong dose, strength or frequency. These errors were reported at all stages of the medicine process, from prescription to monitoring. Wrong dose incidents may be overdoses resulting in toxicity, or underdoses, where the patient does not benefit from taking the medicine.

The incidents reviewed reported misunderstandings due to the use of abbreviations or illegible, incomplete or ambiguous prescription instructions. The use of the abbreviations 'u' and 'iu' when referring to medicine doses is discouraged as these abbreviations can be misinterpreted as numbers resulting in 10-fold overdoses.

A prescription for insulin was written as 6iu. However this was read by the nurse as '61 units' and this dose was given to the patient. The nurse quickly realised the mistake and the GP referred the patient to the hospital.

An inpatient being treated for renal failure had a high potassium level and was prescribed insulin 10 units and dextrose. This was misread and 100 iu were drawn up and given causing the patient to lose consciousness. The patient became unconscious due to hypoglycaemia and was transferred to intensive care.

It is important for staff administering medicines to cross-check the dose and frequency of medicines, as incidents may occur where the right medicine is given but the dose or dosing frequency differs from the prescription.

Dispensing errors occur when the medicine dose, strength supplied or instructions on the medicines label differ from the prescription. Many of these errors are identified and prevented through checking either by dispensary staff before the medicines leave the pharmacy department or by the patient or nurse before a dose is administered. However, harm has occurred when such errors have been missed and patients have taken or been given the wrong dose of their medicine.

A patient attending the anticoagulant clinic was found to have a high INR of 8.7 indicating that they were over-anticoagulated and at risk of bleeding. The patient [had] experienced some bruising but no bleeding. An investigation identified that the patient had been dispensed 50 mg phenindione (anticoagulant) tablets instead of the prescribed 25 mg tablets.

Some medicine doses require complex calculations that may be difficult to determine or perform, particularly in urgent situations or environments where there are distractions and time pressures, such as busy wards.⁵⁵ Because the calculations are complex, errors may not be immediately identified.

Many 'wrong dose' incidents involve medicines that require the calculation of an individualised patient dose, such as cancer chemotherapy where doses are expressed as milligram per square metre of body surface area, or for patients with heart problems requiring inotropes where doses are expressed as micrograms per kilogram per hour. There are also particular issues relating to calculation of doses for children (see page 32-34).

Omitted medicines

Omitted medicines were the second most commonly reported type of medication incident in hospitals. Reports reviewed describe incidents that involve entirely missing a medicine from an intended medicine regimen, or missing one or more doses of a medicine. In most cases, short term medication omissions are unlikely to cause harm to patients. However, for patients who rely on taking medicines regularly to stay well, such as people with diabetes, epilepsy or transplants, missed doses may result in severe harm. Similarly, for patients who are acutely unwell and require immediate treatment, the omission of a medicine, for example, intravenous antibiotics over a weekend, may cause harm.

In the sample of reports examined, incidents reporting omitted medicines were associated with medicines prescribed, dispensed or administered outside routine times (for example, the medicine round).ⁱ Certain medicines need to be prescribed in response to the patient's latest laboratory result. If the result is delayed or not available or suitably experienced medical staff are not available, to prescribe the medicine, the prescription may not be written by the time the dose is due and the patient may not receive critical treatment.

Prescribing omissions may occur when the medication history of a patient is either unavailable or incomplete, resulting in essential medication being left off the patient's prescription. This is more likely to occur at transfer of care, when patients are admitted to or discharged from hospital (see also section 5, page 44-47).

Medicine omissions can be identified and corrected by pharmacists who regularly review medicine charts in hospitals and record medication histories. Studies by the Audit Commission and Healthcare Commission show that more hospital pharmacists are now spending time on wards doing activities such as this.^{3,16} However, omitted medicines are still an issue and additional safeguards may be required to ensure patients receive all their essential medicines.

ⁱ This is congruent with research, for example: Ridge KW et al. Medication errors during hospital drug rounds. *Quality and Safety in Health Care*. 1995; 4: 240-243

Practice example: Nurse-led audit and initiatives to engage nurses in improving medication safety

Organisation: Oxford Radcliffe Hospitals NHS Trust

Objective: To assess practice and understanding of medication safety, and the nurse's role in this, and improve practice and procedures for medication safety.

Action taken

Medication safety had been identified as a trust priority. Practice development nurses planned a programme of work to engage clinicians, which was supported by senior nursing and pharmacy staff.

The first phase (over three months) involved a series of initiatives to gather information on current safety issues: observational audit of nurses' practice and work environment (for example, interruptions and completing drug charts), staff surveys to assess knowledge of medication safety, a review of incident reports and clinical governance reports, and focus groups with nurses to identify key issues and possible solutions. Results of the audit were presented to local directorates.

In the second phase, clinical managers and their teams developed local action plans focused on making specific changes, such as the re-design of the drug administration area on particular wards. More detailed work was carried out by the Practice Development Nurses on certain areas, such as the role of healthcare assistants in drug administration, and competences for newly qualified nurses and midwives.

There are plans to repeat the audits and focus groups to evaluate any changes in practice and culture.

Wrong medicine

Incidents where the wrong medicine is prescribed, dispensed or administered can occur as a result of confusion between two medicines that look-alike or sound-alike.¹ The main causes of selection errors in the reports reviewed included: similar medicine names, similar packaging for different medicines, similar class of medicine, poor storage of medicines (for example, removing ampoules from the manufacturer's boxes) and preparation of medicines in a busy or stressful environment.

Inappropriate labelling and packaging of medicines can contribute to this type of incident, especially where two different medicines are produced by the same manufacturer and packaged in similar coloured boxes. Many examples of pairs of medicine names which had been confused were identified in the sample analysed. Often the medicines that were confused were also available in the same form and strength. For example, bisacodyl and bisoprolol, which have similar names, are both presented as 5 mg tablets. Examples of medicines whose names have been confused and which were reported to the NRLS are shown in box 1, opposite.

¹ This is congruent with published research, see: Roberts DE et al. An analysis of dispensing errors in NHS hospitals. *International Journal of Pharmacy Practice*. 2002;10(suppl): R6

Practice example: Use of local audit to identify risk and reconcile medicines

Organisation: South Staffordshire Healthcare NHS Foundation Trust

Objective: To establish the extent of medicines reconciliation in transition between wards and improve on medication reconciliation activity.

Action taken

When beds are not available within adult mental health services for emergency admissions, patients who are at the recovery stage of their treatment sleep in an alternative ward. The National Prescribing Centre's measure of medicines reconciliation was used to assess this procedure. It was found that all medications were unreconciled during this transition period. Staff were transferring service users as per protocol and medication for the evening was being dispensed and transferred with them, but it was impossible for the receiving ward to reconcile these with a medicines card, compromising patient safety. This practice and the protocols were therefore changed so that the medication is either administered prior to transfer or the medication accompanies the patient along with the medicine card. Alternatively, if the medication is available on the receiving ward it can be administered there. This change was effective in reconciliation of all medicines.

Box 1: Examples of medicines whose names have been confused

vinblastine	and	vincristine	cefotaxime	and	cefuroxime
morphine	and	diamorphine	adrenaline	and	amiodarone
hydroxyzine	and	hydralazine	amiodarone	and	allopurinol
prostacyclin	and	prostaglandin	bisacodyl	and	bisoprolol

Examples of incidents relating to look-alike and sound-alike medicines are found throughout the medication process in hospitals.

The NPSA is working with industry and design partners to improve packaging and labelling to help minimise the risk of 'look-alike' packaging.

A patient was prescribed quetiapine 25 mg at teatime and at night, and quetiapine 150 mg in the morning. The pharmacist queried the 150 mg dose and discovered that the prescription should have been for ranitidine 150 mg twice daily. The prescription was amended.

OxyContin® 5 mg three times a day was prescribed in error when oxybutynin 5 mg was intended. Several doses were given before the error was identified. The patient was also taking regular morphine sulphate. The error meant that the patient was receiving two different opioid analgesics with potential for toxicity.

A patient was commenced on bladder irrigation early in the morning. When the irrigation needed replacing with a full container it was discovered that a bottle of glycine and ethanol had been used to irrigate the bladder instead of sodium chloride 0.9 per cent solution. The glycine and ethanol bottles had been mixed up on the shelf with the bottles of sodium chloride.

A patient was prescribed hydralazine 25 mg. The pharmacy dispensed hydroxyzine 25 mg tablets but labelled them as hydralazine. Three tablets were administered before the error was identified.

Mismatching between patient and medicine

Incidents which are reported as a mismatch between two patients ('wrong patient') occur at all stages of the medicine process. Many of the incidents in the sample analysed related to administration, but these errors may also happen at the monitoring stage, for example, if doses of a medicine are adjusted according to the wrong patient's laboratory results.

A 50 mg dose of morphine sulphate modified release tablets prescribed for one patient was administered to another patient in error.

A patient attended the nuclear medicine department for a thyroid scan. The patient responded to the wrong name and received a dose of a radioisotope intended for a different patient who was due to have a bone scan.

At the end of their inpatient stay, patients may be given medicines to take home. These are commonly issued from the ward and may include medicines supplied by the pharmacy department and medicines from the patient's bedside locker.

The pharmacist received a call from a patient asking why they had methotrexate in their discharge medication. The pharmacy computer was checked and it was confirmed that none had been dispensed for this patient. The name on the label on the medicine bottle was that of the patient in the bed next to the caller on the ward.

All hospital inpatients should wear identification wristbands to help to ensure that the right patient receives the right care. Patient details recorded on the wristbands should correspond to details recorded on the patient's medicine chart and these should be confirmed whenever medicines are administered. Patients receiving medicines with a high potential for severe harm (for example, chemotherapy, injectable contrast media for scans, radioisotopes, haemodialysis), especially in day care and outpatient departments, should be positively identified by both verbal and written means.

Wrong formulation

Medicines are available in a variety of forms for example, injections and infusions for intravenous administration, modified release tablets or liquid medicines for oral administration. Some medicines are manufactured in a form which is ready to administer, but others may need reconstitution or dilution to prepare individual doses. In the review, 2.4 per cent of medication incidents from hospitals reported the right medicine given in the wrong form for example, modified release instead of immediate release. Some injectable medicines are formulated as different salts or in different diluents depending on the route by which they are administered; it is often critical that the correct product is given by the correct route.

Methylprednisolone sodium succinate 120 mg for intravenous injection was prescribed for a patient but three vials of methylprednisolone acetate for intramuscular or intra-articular injection were dispensed. The error was identified before the dose was administered.

Modified release oxycodone was administered to a patient instead of immediate release oxycodone on several occasions.

Practice example: Nurse tabards for protected medicine rounds on wards

Organisation: Christie Hospital NHS Trust

Objective: To introduce new procedures to reduce medication administration errors during medicines rounds on wards.

Action taken

This large cancer centre reported a high proportion of incidents relating to medicines administration on wards. Observational studies have shown that interruptions and distractions are common during medicines rounds.

In November 2005, one medical oncology ward introduced a set of procedures to reduce the possibility of nurses being distracted while administering medicines. Nurses were asked to wear red aprons to administer medication and notices were put up advising patients, relatives and staff that nurses wearing these aprons should not be disturbed. In addition, the treatment room on the ward was locked while nurses prepared the medicines.

After six months, there was a decrease in reported incidents relating to administration of medicines on that ward compared with similar wards. Compliance with new policy is generally good. This practice is being considered for roll out to other wards in the trust.

Wrong route

Wrong route errors occur when a medicine is prescribed or administered:

- by a route other than that intended by the manufacturer of the product;
- by an inappropriate route for the patient;
- by the correct route but to the wrong site.

Wrong route incidents with particular potential for severe harm involve the prescription or administration of a medicine by a route different from its licensed use. The most well-known example of a hazardous route error is the accidental intrathecal administration of the cytotoxic medicine vincristine, which has resulted in a number of deaths in the UK and worldwide. Other examples of such incidents include inadvertent parenteral administration of a medicine intended for oral use, and administration of an injection intended to be given intramuscularly by the intravenous route. Despite the known risks, wrong route errors are still reported to the NPSA.

A patient was prescribed omeprazole to be given via a nasogastric line. The dose was prepared in a syringe which was inadvertently connected to the central (intravenous) line. The patient became bradycardic and hypotensive but was resuscitated and recovered without immediate ill effect.

One of the causes of confusion between enteral and parenteral routes of administration is the design of the devices used to give feeds and medicines by these routes.⁵⁶

Wrong route incidents may also occur when a medicine is administered by the correct route for that medicine, but not as intended by the prescriber. For example, a patient is

prescribed a dose of an injectable medicine to be given by the intravenous route but the medicine is given as a tablet by the oral route.

A patient developed chest pain. The nurse contacted the doctor who advised giving glyceryl trinitrate. The nurse set up an intravenous infusion according to the usual protocol. However the prescriber had intended that it should be given as a tablet sublingually.

The previous example shows the importance of understanding the options and suitability of different routes for medicines. Some patients are unable to receive medicines by certain routes because of their clinical condition. For example, the rectal route is unsuitable for patients susceptible to infection, the oral route is unsuitable for patients who cannot swallow, and some patients cannot be given intravenous medicines if they do not have the right type of line *in situ*.

A patient who had undergone bowel surgery was prescribed diclofenac suppositories for pain relief. However rectal medicine administration is not appropriate in this situation as it may delay healing of the surgical site.

Incidents where a medicine is prescribed or administered to the wrong site most commonly apply to medicines that are prescribed topically or intravenously. For example, eye drops prescribed for or administered to the wrong eye, or medicines administered intravenously but given peripherally into a small vein instead of centrally into a larger vein.

A concentrated infusion of 40 mmol potassium chloride in 100 ml sodium chloride 0.9 per cent was inadvertently given through a peripheral line rather than a central line.

Patient groups who are vulnerable to medication incidents

The analysis of all medication incidents reported to the NRLS between January 2005 and June 2006 showed that in medication incidents where age was reported, the proportion that involved children aged 0–4 years was higher than expected, given the proportion of hospital activity they represented (chart 4, page 16). In addition, 5/92 (5.4 per cent) of medication incidents resulting in severe harm or death were caused by patients being given medicines to which they were known to have an allergy (table 8, page 21). For this reason, an in-depth review was conducted of samples of incidents relating to patient allergy and children.

Patients allergic to treatment

In hospitals, it is the prime responsibility of the prescriber to ensure that the patient's allergy status is checked before any prescriptions are written. Other staff dispensing, administering and monitoring medicines can help prevent potential incidents by identifying the patient's allergy status if it has been overlooked. Three types of medicines commonly implicated in the reported incidents include antibiotics (mostly penicillins), opioids and non-steroidal anti-inflammatory agents.

A patient was prescribed and given a dose of amoxicillin. The patient developed itching and felt unwell, and later collapsed requiring antihistamine and adrenaline injection to treat the reaction. The patient was known to be penicillin allergic but this had not been transcribed onto the new medicine chart.

History of allergy is a core part of the patient history and incidents may occur where this is not accurately or clearly documented in patients' notes. Each time a prescription is written and a medicine dispensed or administered, a patient's allergy status must be checked.

A patient with a penicillin allergy documented on their medicine chart and who was wearing a red allergy alert wristband, was prescribed and given a dose of piperacillin.

It is important to discuss medication allergy with patients. Patients may state that they are allergic to medicines even if they have experienced what clinicians recognise as symptoms of medicine intolerance (for example, sickness, diarrhoea or headache). Such patients may safely receive related medicines without experiencing similar side effects. Therefore, when documenting a history of allergy the symptoms of the allergy should be included to differentiate between an allergy that is a contraindication to medicine therapy and medicine intolerance. Amongst the incidents reported to the NRLS, five confirmed incidents of severe harm or death were caused by patients being given medicine to which they were known to be allergic (see section 3).

In addition to the lack of knowledge about the patient, a lack of medicine knowledge can result in prescription of contraindicated medicines. To prescribe safely, prescribers must know the class of medicine they are prescribing. For example, cephalosporins may be contraindicated in up to 10 per cent of patients with penicillin hypersensitivity⁵⁷ and non-steroidal anti-inflammatory drugs may worsen asthma in susceptible individuals. These drugs are contraindicated in patients allergic to aspirin.

An asthmatic patient with renal colic was prescribed diclofenac for pain relief. The diclofenac caused wheezing and coughing.

A further analysis was undertaken of a sample of incident reports involving the prescription of penicillins or penicillin-containing medicines to patients with documented penicillin allergy. Approximately half the reported incidents were related to compound products whose names do not immediately indicate that the product contains penicillin. Some products containing penicillin have names that indicate this, such as amoxicillin, flucloxacillin and ticarcillin, but compound products may have other names. These were frequently associated with allergy incidents in reports to the NRLS.

co-amoxiclav – Augmentin®
 co-fluampicil – Magnapen®
 combination of ticarcillin and clavulanic acid – Timentin®
 combination of piperacillin and tazobactam – Tazocin®

Practice example: Actions to reduce incidents in patients with known allergies

Organisation: King's College Hospital NHS Foundation Trust

Objective: To improve recording of patient allergy status by prescribers.

Action taken

Patients with known allergy to penicillin are at risk of receiving contraindicated drugs if their allergy status is not clearly documented. This trust had a policy that prescribers should fill in the allergy status on the patient's drug chart. However, in April 2000 an audit showed that only 45 per cent of the allergy boxes on the charts were completed.

The trust introduced a campaign to improve recording of allergies by prescribers, which included a training and education programme and a re-design of the prescription form to make the allergy box more prominent. In addition, the trust produced a 'traffic lights' warning system which was displayed as a poster in clinical areas. In this system, products that are not safe for a patient with penicillin allergy are shown in red (for example, amoxicillin), those that may be unsafe are shown in amber (for example, cefuroxime), and those that are safe to use are shown in green (for example, erythromycin).

An audit in June 2006 showed that the recording of patient allergy status had improved, as 93 per cent of allergy boxes on drug charts were completed.

Children

For children aged 0–17 years, medication incidents were the incident type most frequently reported to the NRLS from hospitals (19.0 per cent). However, not all reports provided the patients' age, so this finding should be treated with caution.

Evidence from the USA suggests that severe errors may be three times more common amongst children than in adults.⁵⁸ Recent systematic reviews⁵⁹⁻⁶¹ and research⁶² have highlighted concerns about medication safety in children. To understand more about the types of medication error reported to the NPSA relating to children, a sample of reported medication incidents involving children was reviewed by paediatric pharmacists. The most commonly reported incident in the sample was wrong dose or frequency, followed by omitted medicines and wrong medicine.

A baby weighing 825 g was prescribed a daily dose of 16.4 mg of a glycopeptide antibiotic. The dose should be 8 mg/kg, equivalent to 6.6 mg for this baby. The error was discovered and rectified by the pharmacist before any doses were given.

A key factor contributing to medication incidents in children is the complexity of dose calculations, which need to be carried out individually based on the age, weight and clinical condition of the child. However, there may be little information available to guide staff making up doses for children from 'adult' preparations where only part of an ampoule, vial or tablet needs to be given. Some incidents reported errors in weighing the child or recording the weight, or where medicines are given at the wrong rate or frequency (particularly for injectable medicines).

A patient was weighed incorrectly on admission and their medicines were prescribed and administered according to the wrong weight. The patient was sent home with paracetamol and was later admitted via A&E [accident and emergency] to the ward with paracetamol overdose, requiring acetylcysteine infusion.

Complex dose calculations may result in 10-fold or greater dose errors as a result of misplacement of the decimal point and confusion when converting dose units between micrograms and milligrams. Errors made when calculating doses may be compounded when calculating the volume of liquids needed for the dose.

93 mg of noradrenaline was prescribed at a rate of 1 microgram/kg/minute instead of 9.3 mg at a rate of 0.1 microgram/kg/minute

310 micrograms of morphine was administered instead of 31 micrograms.

Practice example: Minimising the risk of error when administering oral morphine solutions to babies and children

Organisation: Royal Liverpool Children's NHS Trust (Alder Hey)

Objective: To develop a tool to minimise risk when calculating and administering oral morphine to children and neonates.

Action taken

The trust received a number of reports of incidents where the maximum oral dose of morphine had been exceeded. This was due to confusion over the dose prescribed, and measurement of the dose from the morphine oral solution 10 mg/5 ml.

Pharmacy staff have taken steps to minimise the risk of these potential errors. An oral morphine maximum dose checker card has been produced to help healthcare professionals check that doses are within an acceptable and reasonable range for individual patients. This card gives healthcare professionals a further check that the volume they are measuring is appropriate. The dose checker specifically directs staff to a separate section for babies weighing less than 5 kg and refers to the weaker (500 micrograms/ml) morphine solution which will allow small doses to be measured more accurately.

Practice example: Using information technology (IT) to calculate dilutions of intravenous infusions for neonates

Organisation: The Hammersmith Hospitals NHS Trust

Objective: To improve safety in calculation of medicine doses for neonates.

What happened?

Neonatal babies are frequently given intravenous medication that has to be diluted prior to infusion. The calculations on how to dilute the medication are complex and many calculation errors have been documented. In addition, there have been occasions where treatment has been delayed while these calculations are made and confirmed. A computer programme was developed to calculate and provide a print-out of the actual dilution required to supply the required dose for individual neonates.

Another theme which emerged from the analysis is the use of gentamicin in children. This may have been because of the complexity of dose calculations, the frequency of use of this medicine and its potential for harm. Gentamicin sometimes needs to be given at extended dosing intervals (36 or 48 hours) to compensate for the renal immaturity of neonates. Such dosing schedules can result in errors in the frequency of medicine administration, with potentially dangerous consequences.

Children may be at increased risk of medicine omissions, as they tend to be prescribed medicines at the time of admission (commonly antibiotics) and timings then follow six or four hourly from that point, rather than at standard medicine administration-round times.

It was identified at 08.15 that intravenous meropenem had not been given at the prescribed time of 04.00.

Nurse not informed that patient required pre-surgery medication so patient suffered unnecessary pain and distress.

Many of the reported incidents related to the wrong medicine being given, especially the administration of vaccines in primary care.

Pneumococcal polysaccharide vaccine (not recommended in children under 2 years) sent from pharmacy instead of pneumococcal polysaccharide conjugated but discovered by staff (not given to patient).

Both in primary and in secondary care, medication incidents involving children seemed to occur in clinical areas that do not specifically look after children and where specialist expertise may be lacking.

A patient [child] was given 1 gram of paracetamol rectally in accident and emergency. According to the patient's weight the dose should have been 520 mg or less.

A third party (adult) is often involved in the treatment and care of children. It is important that all people who might be involved in decisions about a child's care have appropriate information and understanding of the medicines being used and why.ⁱ Patients, parents and carers can be a valuable safeguard in accurate medicine administration.⁶³ However, incidents involving children have been reported to the NRLS where parents and carers have been implicated in medication incidents involving children.

The parents of twins were querying doses being given to their child as they had realised they were incorrect. Medicines were being given to the wrong twin due to taking parent's word instead of checking [the] name band.

Although it is helpful to empower parents and carers to administer medicines, this can also cause medication safety incidents.

A parent administered medicines into an intravenous catheter instead of the gastrostomy tube on a paediatric ward.

These incidents reinforce the importance of resources and procedures to ensure the competence, knowledge and support for patients, parents and carers.

Reducing the risk: cross-cutting issues

Analysis of reported medication incidents in hospitals identified two recurring issues concerning medicines: communication and documentation, and injectable medicines.

Communication and documentation

Documentation is a key way in which information about medication is communicated. Poor documentation may contribute to different types of medication incident at all stages of the medication process. Patients are given medicines in hospital according to instructions written by the prescriber on the medicines administration chart. Illegible or incomplete prescriptions and the use of abbreviations have resulted in error when medicines are administered or the prescription is transcribed onto another chart or onto the discharge prescription. Poor documentation may lead to discrepancies between the patient's intended and actual prescriptions, which could result in the wrong medicine or wrong dose being given, or omitted.

A patient was prescribed azathioprine (an immunosuppressant) 250 mg daily instead of azithromycin (an antibiotic) 250 mg daily. The patient was taking their own medication so did not take any of the wrongly prescribed medication.

Prescribing mismatch errors may occur where prescriptions are written from information relating to the wrong patient. Prevention of such errors depends on positive identification of the patient from all sources of information and the accurate storage and retrieval of written documentation.

ⁱ A specific British National Formulary for children has been developed to assist those prescribing or administering medicines to children in specialist and non-specialist settings. Available at: <http://bnfc.org/bnfc>

A patient was prescribed medicines intended for another patient who was admitted on the same day. The medicines included hydroxycarbamide [hydroxyurea] which may have prolonged the patient's neutropenia (low blood count and susceptibility to infection). In spite of being seriously ill with chest problems exacerbated by neutropenia, the patient recovered.

A patient was prescribed sodium valproate 300mg. This was queried as the patient had no symptoms, suggesting this medicine was needed. It was discovered that the prescription was intended for the patient in the next bed but had been written on the wrong patient's chart.

Practice example: Safer prescribing training

Organisation: Trafford Healthcare NHS Trust

Objective(s): To improve medical training regarding the principles and therapeutics of safe prescribing, and to increase doctors' awareness of the importance of reporting medication incidents and ADRs.

Action taken

Changes to pre-registration medical training, including defined objectives for medicines management training, provided the opportunity for pharmacy staff to review the in-house education provided to this group of doctors. This also allowed issues to be addressed that had been raised through medication incident reporting, changes to the trust's medicines policy and NPSA patient safety alerts. Junior medical training was re-designed to be more interactive and focused towards the core competencies.

Foundation year one doctors now receive an OSCE (objective structured clinical examination) teaching session which consists of four workstations that cover taking a drug history, inpatient prescription chart writing, discharge prescriptions using the electronic patient record, and controlled drug prescribing. The doctors attend in groups of three or four and are given 10 minutes per station.

In addition, there is a presentation on safe prescribing for fifth year trainees and a session on significant drug interactions for foundation year two doctors. Doctors new to the trust receive induction information including a standard operating procedure for prescribing on inpatient charts.

The organisation, storage and design of documentation featured in the medication safety reports. In many hospitals, medicines that are given at unusual times or that require specific monitoring are prescribed on separate charts. For example, doses of oral anticoagulants, which are prescribed according to the patient's blood clotting results, may be omitted if these prescriptions become separated from the main chart. Medicines that are given to the patient as a single dose ('stat' doses) are also often prescribed in separate sections of the chart, and the patient's allergy status might be recorded elsewhere in their notes, so may be overlooked.

A diabetic patient was receiving insulin by intravenous infusion using a 'sliding scale' regimen. When the insulin infusion was stopped [the patient] did not receive a prescribed dose of insulin and was left with no insulin for three hours. The patient had unacceptably high blood sugar levels as a result.

Reports to the NRLS also suggest that using different methods of documentation (for example, forms) across departments is a potential risk factor for medication error. For example, the use of multiple medicines charts or the use of separate medicine administration forms (such as in accident and emergency, intensive care and operating theatres) contributed to reported medication incidents involving children. Documentation organisation (storage and retrieval) is clearly important for patient safety and there are organisational and legal requirements for documentation and reconciliation, for example, maintaining controlled drugs records.

The controlled drugs administration register indicated a stock level of three ampoules of oxycodone injection 20 mg in the controlled drugs cupboard. However these could not be found when they were needed as staff had not noted that they had used the ampoules earlier to prepare a subcutaneous infusion.

Many hospitals are now taking active measures to improve the safety of controlled drugs, including in clinical areas other than wards, where there may be particular risks in current practice.⁵⁴

Practice example: Controlled drugs in theatres

Organisation: Cardiff and Vale NHS Trust

Objective: To reduce risk of error in operating theatres by identifying particular clinical features which made existing procedures not fit for purpose. To agree procedures and documentation relating to controlled drugs.

Action taken

A trust in Wales experienced a number of medication incidents involving controlled drugs in operating theatres and anaesthetic rooms. This led to a review of processes and documentation, which showed that the standard controlled drugs documentation and procedures that were in place reflected ways of working on wards and were not appropriate for theatres.

The trust decided to develop a tailor-made controlled drugs record book and procedure for theatres. The new record book and procedure was piloted and, after minor changes, rolled out to all anaesthetic rooms in the trust. This was accompanied by training and education for all staff including anaesthetists, nurses and operating department practitioners. Incidents involving controlled drugs from these areas will continue to be monitored.

Communication within and between teams is essential to ensure that the patient receives the right care. If plans are not effectively communicated, the patient's recovery and discharge may be delayed. When the inpatient prescription chart is being rewritten or when the patient is being discharged, the patient's medicines and doses need to be transcribed onto a separate chart or prescription. This is another point at which errors may occur.

An elderly patient had been taking 5 mg nitrazepam at night whilst on the ward. This was erroneously transcribed onto the discharge prescription as nitrazepam 5 mg twice a day. The error was not identified before the patient went home on wrong dose, subsequently falling and suffering a fractured hip.

Practice example: Dedicated theatres and anaesthetics pharmacist

Organisation: Oxford Radcliffe Hospitals NHS Trust

Objective: To reduce the risks associated with medication in theatre and anaesthetic areas.

Action taken

Theatres pose major medicines management issues but may receive little pharmacy input. At this trust, theatres were identified as a key medicines risk area due to many factors, including:

- frequent use of high-risk medicines for example, muscle relaxants, anaesthetic agents;
- frequent use of high-risk routes of administration for example, spinal, epidural;
- patient unable to communicate;
- numerous 'handovers';
- the scale of the problem (30 operating theatres within seven theatre suites, spread across three sites);
- little pharmacy knowledge of specialist medicines use in theatres;
- inadequate stock list control with widespread use of unlicensed medicines.

This was remedied by the introduction of a pharmacist to provide support to theatres and anaesthetists. Working closely with the multi-professional theatre staff, the pharmacist identified, assessed and prioritised risks to medicines safety. Actions taken as a result included rationalisation and standardisation of stock, reviewing unlicensed medicine use, developing medicines guidelines, reviewing medicines storage and auditing of the use of controlled drugs.

The theatres have benefited from the nominated pharmacy contact, who has become an integral member of the theatre team involved in teaching, providing advice and actively disseminating medicines information. This closer liaison has enabled action on medicines risks to be taken.

Injectable medicines

As shown in section 3, medicines that are administered by injection were associated with the highest proportion of reported incidents confirmed as resulting in severe harm or death (58 per cent, 53/92 incidents). Different types of medication error (for example, wrong dose, wrong medicine) can occur with injectable medicines just as with other routes of administration. However, the preparation of injectable medication is a highly complex process involving many steps at which errors can occur.⁶⁴

Use of an incorrect volume of diluent when preparing an infusion can result in the final medicine concentration being too high or too low. This particularly relates to injectable medicines that are either given over a long period of time or are irritant at the site of injection and so require dilution. Ideal volumes are recommended by manufacturers. If these are exceeded, the medicine may not be effective. If the medicine concentration is too high it may harm the patient.

A 500 mg dose of the antibiotic clarithromycin was administered to a patient as an IV bolus injection instead of diluted in 250 ml of sodium chloride 0.9 per cent infusion. The patient complained of severe irritation in arm above the site of injection and became sweaty.

The infusion fluid used to dilute injectable medicines must be chemically compatible with the medicine. If an incompatible infusion fluid is used, the medicine in the infusion will deteriorate. Occasionally, crystallisation may result which may cause harm to patients if infused intravenously, especially if a filter is not used.

An infusion of phenytoin in dextrose five per cent was prescribed. The infusion was prepared as prescribed. The solution in the giving set crystallised due to the incompatibility between the phenytoin and the dextrose five per cent.

In addition to preparation of the medicine itself, errors may occur related to the use of equipment to measure and deliver the dose.

Morphine patient controlled analgesia (PCA) background infusion was running at 5 mg/hour. This should have been 1 mg/hour. Patient became sedated, may have aspirated and was admitted to ITU [intensive care unit].

The use of equipment to administer injectable medicines is also an issue in community settings (see section 5).ⁱ

ⁱ The problems caused by different types of infusion pump are recognised in recent NPSA guidance. See: *Safety in doses: improving the use of medicines in the NHS. Safe medication practice work programme for 2007-08.* Available at: www.npsa.nhs.uk/health/alerts

Medication incidents involving insulin

The issues raised in medication incident reports relating to insulin may reflect similar issues for medicines management of other chronic conditions. The prevalence of people living with diabetes is increasing, and growing numbers of people are being prescribed insulin.¹⁹ Insulin is a complex medicine and regimens vary between patients. Close monitoring and management is required to ensure a patients' blood glucose (sugar) level is controlled. High levels of blood glucose as a result of too little insulin can lead to dehydration, coma and death, and low levels (hypoglycaemia) as a result of too much insulin can lead to coma and death.

Reviews of data showed that medication incidents associated with insulin occur throughout the medicines process, in hospitals and in the community, and they highlight the issues at the interface between these locations.

A patient admitted from a nursing home was prescribed Humalog® Insulin 20 units in the morning and 8 units in the evening according to the documentation from the nursing home. This looked unusual to the pharmacist who checked with nursing home and confirmed that the prescription should have been for Humalog MIX® 25 (25 per cent quick acting Humalog® and 75 per cent intermediate acting). The patient had been given the wrong insulin resulting in hypoglycaemia, which was reversed with intravenous dextrose.

Many types of insulin are available, supplied in different strengths and different types of device, the naming and labelling of which increase the potential for error.

Reviews of medication incidents involving insulin found issues similar to those described for the cross-cutting themes of injectable medicines and communication and documentation. For example, some patients require insulin infusions on a 'sliding scale' where doses are adjusted according to blood glucose monitoring. Problems with both intravenous insulin infusions and subcutaneous injections have resulted in patient harm.

Reports of incidents involving duplicate doses showed that a lack of documentation had led to administration of a second dose. For instance, where both the patient and the nurse administered a dose, or where health records were not checked before a dose was administered, or two doses were given as a result of distractions.

Many reports relate to the self-administration of insulin, and raise issues such as duplicate and unauthorised administration, and administration at the wrong time in relation to meals. It is important that patients are enabled to administer their own insulin if appropriate and that they receive adequate support to do this. For example, prescribers should clearly communicate changes to their prescriptions.

An insulin dependent diabetic patient was self-administering their own insulin. The doctors reduced the dose of insulin from 50 units to 45 units but the patient was not informed. The patient continued to self-administer the higher dose resulting in low blood sugars for several days.

Conclusion

This section has reviewed when medication errors happen in hospitals and what these errors are. Although the focus has been on ward areas, other clinical areas in hospitals, such as diagnostic areas or theatres, might face particular medication risks. Some hospitals are tackling certain high-risk clinical areas with dedicated pharmacy input to improve safety.

Injectable medicines and other forms of high-risk medicines featured in the medication incidents reviewed. Section 6 outlines local actions that can be undertaken to minimise risks from particular types of medicine, including injectable medicines.

Many errors relate to poor documentation and gaps in communication. Good record-keeping is essential and the reported harms relating to omitted medicines and known patient allergies, for example, illustrate the need for vigilance in this area. Developments in electronic prescribing and patient records may make some of these errors less likely. As section 6 suggests, hospitals should review current practice now to identify areas for improvement, particularly for known risks such as controlled drugs.

This section has highlighted potential weaknesses in current hospital medication practice and many hospitals are taking innovative steps to improve practice for patients under their care. Pharmacy teams with dedicated time on wards and clinical areas are working with doctors and nurses to improve patient safety. Hospitals tend to have sicker patients who need medicines that may have a small therapeutic window and potential for harm. There is great potential and need for close working between and across staff groups to improve safety when using medicines.

The fourth report from the Patient Safety Observatory

Section 5 Medication incidents in the community and at the interface between the community and hospital care

Summary

Most medication activity – the prescribing, dispensing, taking and monitoring of medicines – happens in the community, although most information on medication safety (for example, literature, reported incidents) relates to hospitals.

This section features reported medicine safety incidents occurring in general medical practice, community pharmacy and patients' own homes (including care homes).

Overall, the volume of patient safety incidents that occurred in community settings and were reported to the NRLS is small, but this is supplemented by data from other sources and published literature.

The two most common types of medication incident reported to the NRLS that occurred in the community were wrong dose and wrong medicine. Errors relating to medicines with sound-alike or look-alike names were common in both prescribing and dispensing in the community.

As with all other reported medication incidents, the vast majority of incidents resulted in no harm.

Several themes emerged from the analysis of medication incidents in the community, including communication and documentation (for example, in relation to vaccines), and the transfer of care between the community and hospitals raised specific medicines safety issues.

The majority of healthcare in England and Wales is carried out in primary care (the community), away from acute (hospital) settings.⁵⁰ For the purposes of this report, the following locations were considered as community settings:

- general (medical) practice
- community pharmacy
- patient's own home (private house, residential care home or nursing home).ⁱ

This section explores the types of medication safety incidents occurring in these community settings and during patient transfers between these settings and acute care (the primary–secondary care interface).ⁱⁱ

ⁱ 'Patient's own home' refers to reports which recorded the location of the incident as a place that is generally considered to be a person's permanent residence, including nursing and residential care homes, but not hospices.

ⁱⁱ As there were very few reports from general dental practice and there is little published research on medication safety in general dental practice, these data are not analysed in depth here. A brief review found that most incidents reported from dental surgeries related to the administration of anaesthetics and ADRs (especially to penicillin-based antibiotics) that could not have been anticipated.

The data presented here are mainly from the NRLS but due to the relatively low level of reporting from primary care (compared with the acute sector) they are augmented with evidence from published research and data on clinical negligence claims provided by the Medical Defence Union (MDU), Pharmacists' Defence Association (PDA) and the Chemists' Defence Association (CDA) (see appendix 3).

Reporting of medication incidents in primary care

Levels of reporting to the NRLS from community settings are generally low.⁶⁵ Just over four-fifths (81.7 per cent) of all incidents reported to the NRLS occurred in acute, general or community hospitals. This may be indicative of the complex, mixed economy of providers and the different relationships between organisations. It might also reflect differences in reporting cultures among healthcare professionals. The NPSA is working to increase the accessibility of reporting to the NRLS in the light of the Department of Health publication *Safety first*.⁹

There may be belief among healthcare practitioners working in the community that, by reporting errors, they might damage their relationship with other practitioners providers with whom they may have a business relationship, or they might be leaving themselves open to disciplinary action by employers and healthcare regulatory bodies, or even face criminal prosecution.⁶⁶ The NPSA is working with others to dispel these misconceptions and to assure practitioners of the confidentiality of NRLS data.

Community settings reporting to the NRLS

In the analysis of incidents reported to the NRLS between January 2005 and June 2006 from community settings, patient's home was the most common (52.4 per cent) location in which medication incidents occurred. The second largest number of incidents occurred in community pharmacy (36.1 per cent) and the third largest number in general medical practice (11.5 per cent).

Some of the community pharmacy chains that have their own internal reporting systems have agreed to share their reports with the NPSA. The NPSA is also working with other community pharmacy chains to enable direct reporting to the NRLS via head offices.

Furthermore, as incident reporting is a requirement in the new pharmacy contract, many pharmacies are working with the NPSA to develop consistent and accurate reporting.³⁰

Reporting of all incidents occurring in general practice to the NRLS is generally low.¹¹ However, in the data analysed for this report, medication incident reports accounted for one in five of all incidents occurring in general practice. Many practices are engaged in significant event audits (SEA) to learn from things which have gone wrong, which may include medication incidents. Practices could report incidents investigated as part of these audits to the NRLS, in order to share the learning nationally (through the NPSA) as well as locally.

Incidents in people's own homes, hospices and residential or nursing care homes are believed to be reported by visiting healthcare staff (for example, district nurses or health visitors). At present, organisations that provide care for patients, but are not part of the NHS (for example, local authority or voluntary sector-run day centres) are not connected to the NRLS. For this reason, the NPSA is working closely with other organisations, such as the CSCI.

Outcomes of medication incidents in the community

The vast majority (83.1 per cent) of medication incidents occurring in the community were reported as resulting in no harm to the patient, reflecting the pattern of medication safety reports from other settings (see section 2). As noted previously, incidents reported as 'no harm' are not necessarily of no consequence to patients (see page 9–12).

Stages of the medication process at which incidents occur in the community

A third (32.3 per cent) of reported medication incidents that occurred in general medical practice related to prescribing (see table 11). Many of these reported incidents cited communication issues or the prescribing of antibiotics to which the patient was known to be allergic, particularly penicillins. Data from the MDU show that 65 per cent of claims were related to prescribing. As non-medical prescribing increases, the volume of prescribing incidents reported from other professional settings might increase. It is therefore vital that prescribing incidents are reported to allow understanding of the causes and to share learning.

Table 11: Percentage distribution of stage in medication process by community location

Stage in medication process	Location of incident			Total
	General practice	Community pharmacy	Patient's own home	
Preparation/dispensing	12.4	92.8	10.4	40.4
Administration/supply	41.7	1.3	64.4	39.0
Monitoring	10.5	0.4	13.5	8.5
Prescribing	32.3	4.1	6.7	8.7
Other	2.9	1.2	4.7	3.2

Note: For 10 (0.2 per cent) incidents occurring in a GP surgery, community pharmacy or patient's own home, the stage in the medication process was not reported.

Source: Medication incidents successfully imported into the NRLS analytical database between January 2005 and June 2006.

Most reported medication incidents occurring in general medical practice related to medicines administration (41.7 per cent, table 11). The incident descriptions showed that this was particularly related to administration of vaccines. This is often carried out by practice nurses in whom the reporting culture is far more developed than it is in GPs.^{67,68}

Some of the administration and supply errors occurring in general medical practice may have originated from dispensing practices, and hence may be related to dispensing rather than administration. In these situations the main types of medication error are likely to be similar to those reported from community pharmacy.

Most reported community pharmacy medication errors related to the preparation or dispensing of medicines, which is consistent with research from the UK.³⁴ This is unsurprising, as this activity still constitutes most of a community pharmacist's work, although this may change as new roles for pharmacists begin to be accepted by the professions and their patients. Data on the stage of the dispensing process where an incident occurs are not routinely collected through the NRLS, although research suggests that errors occur most frequently in selection (60 per cent), followed by labelling (33 per cent) and bagging (6.6 per cent).⁶⁹

The analysis showed that in patients' own homes, the most commonly occurring reported medication incidents were related to administration of medicines (64.4 per cent). Empowering patients to understand their medicines and take them safely has the potential to enhance patient care. Although the issues of concordance and compliance are outside the remit of this report, the expert patients programme⁷⁰ and other initiatives to promote these values make an important contribution to patient safety.

Practice example: Community pharmacy domiciliary visiting scheme for housebound older people

Organisation: Cambridgeshire Primary Care Trust, Cambridgeshire County Council and the LPC (Local Pharmaceutical Committee)

Objective(s): To identify people taking complex medications and living in their own homes and to provide extra support to them.

Action taken

'At risk' patients are referred to the trust's scheme co-ordinator by any practitioner working with the patient, such as their GP, district nurse or health visitor, as well as practitioners from other organisations, such as social services and hospital discharge teams. The co-ordinator contacts a suitably trained community pharmacist who undertakes a home visit. A suggested care plan is written and sent to the patient's GP, who is responsible for acting on the suggestions in consultation with the patient.

Supervised administration of medication (for example, where home care workers prompt patients to take their medicine) emerged as an issue in the community reports. This not only highlights the importance of initiatives to facilitate medication concordance, but also demonstrates the uncertainty amongst community-based staff about responsibilities, policy and protocols regarding medication administration.

On a routine visit to the patient, the CSN [community staff nurse] observed that the morning tablets were still in the monitored dosage system. Carers had not offered them prior to the nurse's visit.

Administration of vaccines also emerged as a theme in the reports reviewed. Incidents included reports of patients being given repeat doses of a vaccine in error or patients receiving the wrong vaccine. Issues regarding the management of vaccination programmes were also evident, particularly relating to cold storage, documentation and information for practitioners and the public.

Another area of concern is the monitoring and follow-up of medicines use. The NPSA is also carrying out specific pieces of work relating to the monitoring and follow-up of high-risk medicines.⁵⁶

Types of medication error occurring in the community

Incidents relating to the wrong dose, strength or frequency were the most frequently reported type of medication incident across the three community settings presented in this section (table 12). The most common incident types reported in the community were also similar to those reported in hospitals.

Table 12: Percentage distribution of medication incident type by community locations

Medication incident type	Location of incident			Total
	General practice	Community pharmacy	Patient's own home	
Wrong dose/strength/frequency	26.0	32.2	30.4	30.5
Wrong medicine	24.0	33.2	7.6	18.7
Omitted medicine/ingredient	5.8	1.3	20.6	12.0
Wrong quantity	5.1	6.5	12.3	9.4
Mismatching between patient and medicine	5.4	5.1	5.6	5.4
Wrong formulation	1.9	8.0	0.8	3.5
Wrong/omitted/past expiry date	2.4	2.2	3.3	2.8
Wrong/transposed /omitted medicine label	2.0	4.5	1.8	2.8
Contra-indicated medicine	5.3	0.6	0.9	1.3
Wrong method of preparation/supply	1.4	1.1	1.4	1.3
Wrong storage	2.4	0.2	1.3	1.0
Adverse drug reaction	2.2	0.4	0.7	0.8
Patient allergic to treatment	2.6	0.3	0.4	0.6
Wrong route	0.3	0.1	0.9	0.5
Wrong/omitted verbal patient directions	1.7	0.1	0.5	0.5
Wrong/omitted patient information leaflet	0.7	0.2	0.3	0.3
Other	9.0	0.9	9.9	6.5

Note: For 101 (2.0 per cent) medication incidents occurring in a GP surgery, community pharmacy or patient's own home, the medication incident type was not reported.

Source: Medication incidents successfully imported into the NRLS analytical database between January 2005 and June 2006.

Types of medication error in general medical practice

Most prescribing incidents in general medical practice reported to the NRLS concerned either the wrong dose or strength (26.3 per cent), or the wrong medicine (21.6 per cent). This is consistent with published research.^{33,69,71-73}

Incidents reported as wrong medicine, dose or strength in this review were often related to the confusion caused by medicines with similar names, rather than medicines from the same therapeutic group. This indicates that incidents where the wrong medicine, dose or strength are prescribed may be due to mis-selection from a list (for example, on a computer

screen). This was corroborated by data from the MDU, which also indicated that the main problem was with look-alike or sound-alike names.

Possible claim regarding three prescriptions for chlorpropamide instead of chlorpromazine.

Prescribing error of clomipramine instead of clomifene.

Pregnancy following administration of Depo-Medrone® instead of Depo-Provera.®

Developers of prescribing software should consider the potential for mis-selection carefully when designing user interfaces.

Reports of incidents where the wrong frequencies for medicines in general medical practice were prescribed give cause for concern as, depending on the nature of the medicine involved, the consequences may be quite serious. For example, giving methotrexate daily rather than weekly could lead to potentially fatal blood dyscrasias.

Data from the MDU are rich in detail on the type of medication involved in patient safety incidents. Some of the most common groups of medicines in claims settled by the MDU are shown below.

- Contraceptives and hormone replacement therapy (both contraindication and wrong drug).

Pregnancy following prescribing of Micronor® instead of Microgynon.®

Pregnancy following prescription of Monacor® instead of Micronor.®

Prescribing of a combined hormonal contraceptive to patient with family history of vascular problems resulting in deep vein thrombosis.

Ectopic pregnancy following prescribing of a progestogen only contraceptive to patient already taking carbamazepine for epilepsy resulting in psychological problems.

Claim that endometrial cancer was due to erroneous prescribing of conjugated oestrogens following total abdominal hysterectomy.

Communication difficulty resulting in prescribing of estradiol/norethisterone acetate patches to menopausal patient.

Side effects following erroneous insertion of testosterone instead of oestrogen implant.

- Antibiotics, particularly penicillin.

Trimethoprim and amoxicillin prescribed to patient with known co-trimoxazole and penicillin allergy.

Anaphylactic shock following the prescription of a penicillin based antibiotic to a patient with known allergy.

Severe rash following the prescription of penicillin during a home visit to a patient with pneumonia resulting in death – note of known allergy on patient's record was unreadable.

Types of error in community pharmacy

In common with findings from published research,⁶⁹ incidents reported to the NRLS suggest that 'picking' errors are common. These are incidents where the wrong medicine (particularly look-alike or sound-alike medicines) or wrong strength/formulation of a medicine is selected.

Atenolol 100 mg tablets were prescribed and labelled but allopurinol 100 mg tablets dispensed. Patient took allopurinol once daily for six days. Patient felt unwell and disorientated. Patient admitted to hospital: spent two days in coronary care unit and then moved to ward for rest of week.

Supplied 56 x amiodarone 100 mg tablets against a script for 56 x atenolol 25 mg tablets.

Humalog® 100 u/ml supplied instead of Humalog® Mix 25.

Patient received Voltarol® in place of Valoid® tablets.

Zyban® 150mg tabs (P.I.) Parallel import was nearly supplied instead of Zantac® 150 mg tabs. The package looks similar to the old style Zantac® pack. The picking error was spotted before issue to the patient.

Patient presented prescription for lorazepam 1 mg tablets, the prescription was labelled as lorazepam 1 mg tablets but lormetazepam 1 mg tablets were dispensed.

Flecainide 100 mg tablets given out instead of 50 mg.

The patient was prescribed citalopram 10 mg and was given the 40 mg tabs. The patient has been taking three tablets daily for a week and has experienced some side effects.

Data from the PDA and the CDA confirmed the findings from the NRLS that wrong dose, strength or frequency and wrong medicine are amongst the common errors seen in community pharmacy.

Incorrect medication dispensed - baclofen given instead of Buscopan.®

Patient given 100 mg instead of 50 mg atenolol – labels correct.

Patient received wrong strength of lisinopril (lower strength than normal).

These examples suggest that selection errors may be linked to similar packaging or poor dispensary layout. The NPSA is working closely with the pharmaceutical industry to increase the safety elements of pack redesign, and has also undertaken projects looking at safe dispensary design and layout, and safe dispensed products.

Wrong quantity of medicines supplied accounted for 6.5 per cent of the errors in community pharmacy reports. These incidents may be related to miscalculation, misinterpretation or the use of split packs, and may be an indicator of a prescribing error.

Additional themes identified from the NRLS reports and details of claims made to the PDA and CDA include:

- Incidents are associated with commonly used medicines.

Atenolol 100 mg tablets were assembled instead of thyroxine 100 mcg tablets.

Patient received a box of amlodipine 5 mg tablets (28) labelled as atenolol 25 mg tabs and a box of correctly labelled atenolol 25 mg tablets. It seems that this occurred due to the very similar yellow boxes used for both products.

Patient was prescribed 3 x 28 amlodipine 10 mg. They returned a week later with 2 x 28 of ramipril 10 mg capsules. Patient hadn't taken any medicine because they were expecting tablets. Both the amlodipine 10 mg and ramipril 10 mg caps are in very similar in packaging. The ramipril must have been placed with amlodipine.

- Modified release preparations implicated in incidents, particularly in relation to picking the wrong formulation of the same medicine.

Dihydrocodeine 30 mg tablets supplied instead of dihydrocodeine 60 mg SR [sustained release] tablets

Co-careldopa 100/25 dispensed against owing for same. However, original prescription was for M/R [modified release] form. Original dispensing was correct but label incorrect.

Doxazosin 4 mg MR tablets requested. Doxazosin 4 mg tablets supplied (non MR).

Supplied and labelled Dilzem XL® 120 mg caps instead of Dilzem SR® 120 mg caps. Dilzem XL® is a one-a-day preparation.

- Reports often involve medicines with greater capacity for causing harm for example, cardiovascular drugs, insulin and central nervous system medication.

Amlodipine 10 mg dispensed and labelled as atorvastatin 10 mg. Patient had taken some tablets.

A prescription for atenolol 50 mg tablets was received and amitriptyline 50 mg tablets were supplied in error.

Patient was dispensed 5 x 3 ml NovoMix 30 *Penfill*® labelled as 5 x 3ml Mixtard 30®. Patient had used three *Penfill* before they realised the error. They had been starting to have regular stomach pains each evening.

Patient telephoned into the diabetes centre stating that insulin received from the pharmacy is clear and is usually cloudy. Patient was advised to read out exactly what was printed on the dispensed insulin cartridges. NovoRapid *Penfill*® had been dispensed instead of NovoMix 30 *Penfill*®.

Locum dispensed fluoxetine 20 mg capsules against a prescription for furosemide 20 mg tabs.

Customer received incorrect medication and took them until side-effects occurred. The customer went to see their GP who identified that a dispensing error had taken place.

Prescription dispensed on [date]. Patient took first dose on [date – one week later] of risperidone which had been dispensed in error. Ropinirole should have been dispensed. After the second dose the patient felt unwell and went to bed. The patient's partner contacted the surgery out of hours and was directed by NHS Direct. A doctor was sent to the patient's home and an ambulance called at 10:15. Patient was admitted at 10:45.

Mismatching between the patient and medicine accounted for 5.1 per cent of community pharmacy incidents reports analysed. This suggests mis-selection of a name from a software interface, mis-bagging of prescription items, or, as CDA data suggest, it could also be associated with labelling. In all cases, more work needs to be done to make software interfaces clearer and to improve standard operating procedures to reduce the chance of these types of errors occurring.

Among the extended roles being undertaken by community pharmacy is the monitoring and follow-up of patients, and supporting other healthcare professionals working in the community.

Practice example: Community pharmacy anticoagulant service

Organisation: Canterbury and Coastal Primary Care Trust (PCT)

Objective(s): To improve monitoring of anticoagulants and keep patients within recommended therapeutic (INR) levels.

What happened?

A new service involving seven community pharmacies has been set up to enable pharmacists to take the lead in supply and concordance checking of anticoagulant medicines. Patients are invited to a 'brown bag' review where the pharmacist checks their medication and the scheme is explained to them. Patients are then asked to return each month and bring their Yellow Book to discuss dosage and changes with the pharmacist (once blood tests have been received) as well as to collect supplies.

The service has been developed locally to link with the Advanced Services Medicines Use Review of the new pharmacy contract and allows resources to be directed, as well as providing protected time for pharmacists to manage this complex and high-risk medication. Information on indicators such as patients within recommended INR range and suffering bleeds will be monitored over time locally to identify any changes after introducing this service.

Discussion of incidents relating to over-the-counter (OTC) medicines is outside the scope of this report. However it is clearly an important part of community pharmacists' work and has implications for patient safety. The culture of recording, sharing and reporting incidents relating to OTC medicines needs to develop alongside reporting and learning concerning prescription medicines. The increased use of IT systems may have a part to play so that practitioners have a full understanding of the medicines a patient may be taking before additional medication is prescribed.

Types of medication error in patients' homes

The types of incident reported as occurring in patients' homes reflect the variety of methods used for administering medication in the community. Incidents reported from nursing homes and residential care homes reinforced the finding from a recent CSCI report that medicines administration is a key area of concern.⁵ The CSCI found that almost half the care homes in England – 210,000 places – failed to meet the National Minimum Standards for Medication. The annual report from the Care Standards Inspectorate for Wales also highlighted concerns over the management of medication, with requirements made in 44 per cent of a sample of inspection reports.⁷⁴

The administration of injectable medicines, especially the use of syringe drivers, emerged as an issue within private residences, reflecting the complexity of this route of administration (see section 4). The incidents reported in the community described errors or confusion in calculating the rate of infusion, monitoring and proper use of the device.

On checking, the nurse found the syringe driver still full with the previous 24 hours' medication. A clamp was found on and the giving set was closed. The driver did not alarm. It was not the usual driver being used. It was unclear why the giving set was closed.

Issues surrounding the use of devices have been tackled locally in some cases, such as where agreement has been reached across primary care trusts to use the same device to reduce the risk of practitioners using unfamiliar devices.

Omitted medicines constituted the second largest proportion (20.6 per cent) of the errors reported in a patient's home. This is similar to the findings of the analysis of reports from hospitals and is in contrast with other community settings, although the actual incidence of omitted medicines in the community is unclear due to the small numbers of incidents reported.

As in hospitals, problems with omitted medicines in patient homes can be caused by difficulties in accessing medicines. An analysis of a sample of incidents reported from community nursing settings (for example, patients' homes), which resulted in a severe level of harm, highlighted the issue of access to medicines out of hours, particularly the supply and management of controlled drugs for pain relief. Further research is required into these types of incidents and incidents where medicines are prescribed, dispensed or administered by someone unfamiliar with the patient and local policies or procedures (for example, locums).

Practice example: Medicines Training Partnership

Organisation: Middlesex Group of Local Pharmaceutical Committees

Objective(s): To support community-based practitioners, including home care workers, to administer and monitor medication.

Action taken

The Middlesex Group of Local Pharmaceutical Committees, covering most of north and west London, has established the Medicines Training Partnership. The organisation trains practising community pharmacists and arranges for them to deliver training on the safe handling, administration and recording of medicines to carers in a wide range of care settings, including home care, residential and day care. The Partnership liaises with local authorities, primary care trusts, care organisations (including charitable and voluntary bodies) and the CSCI on appropriate training for care workers.

Reducing the risk: cross-cutting issues

In the qualitative analysis of incident descriptions, two issues were identified that have an impact on all stages of the medication process and all types of error in the community: communication and documentation, and safety at the interfaces of care. Clearly these issues are interlinked and both have implications for medicines safety in hospitals too (see section 4).

Communication and documentation

In common with the analysis of reported incidents in hospitals, the review of medication incidents reported in the community found that errors relating to communication and documentation were prevalent throughout the medication process in primary care. However, there were some specific issues relating to documentation and communication in the community, for example, communication regarding repeat prescribing.

The patient brought back the repeat prescription because amlodipine tablets had been changed from 10 mg to 5 mg. The patient was not aware that the dose should have changed. The latest clinic letter indicated a strength of 5 mg. The surgery telephoned the outpatient clinic ... which said that the dose had not changed and it was an error on the clinic letter.

The documentation of prescribing is a key issue. Whilst electronic prescribing appears to have eliminated difficulties in deciphering handwritten prescriptions, this technology may have introduced the opportunity for different risks such as picking errors (see above). Changes to prescriptions, especially when carried out by another practitioner, are another area where communication seems to breakdown.

Reports to the NRLS show that doses are often omitted or duplicated because of the failure to follow protocols regarding communication or documentation.

A nurse visited a patient at home to administer the evening insulin dose. On completion the nurse entered the actions in the patient's record and left this in the patient's home with the prescribing card. At 20.00 the nurse received a call from a community rehabilitation assistant to say that when they had arrived at the patient's house a nurse from the twilight services was present and had just given the patient a second dose of insulin. The second nurse stated that they had been in a hurry and ... had not read the patient's notes.

A recent report published by the MDU gives a snapshot of the types of medication incident reported in general practice (but which are not necessarily subject to complaint by a patient).⁷⁵ The report confirms that communication breakdown is a key factor in incidents relating to the administration of medicines in general practice, particularly mix-ups with patient records (for example, records unavailable or immunisation records not checked before administration).

Many patients are visited by a number of different health and social care staff in the community and this introduces the potential for confusion. Staff involved might include out-of-hours services, specialist nursing teams (for example, palliative care or diabetes outreach staff) and staff from a range of other agencies.ⁱ Some local areas are developing policies to ensure a consistency of approach in medication.

Practice example: Medication policy – home care services

Organisation: City and Hackney Teaching Primary Care Trust and London Borough of Hackney Social Services

Objective(s): A policy was developed to clarify the role and responsibilities of the social services' and private providers' home care services when assisting service users with medicines management.

Action taken

Home care services enable service users to remain in their own homes, and this service includes helping people to take their medicines (when it is part of the agreed package of care). This policy was agreed between the trust and social services. It articulates the philosophy and principles of the service and training that should be provided for workers as well as practical guidelines about home care workers' responsibilities. The policy includes guidance on: how home care workers should liaise with health professionals; what to do when a patient does not take their medication; how to deal with medicines in different forms (for example, liquids, creams, patches) and the use of oxygen; documentation and recording medication use; dealing with non-prescription medication; and the safe disposal of medication.

The document also includes forms for use by home care providers. For example, there is a form for recording that home care workers have been shown by the district nurse how to administer eye or ear drops.

ⁱ This confusion may occur despite guidance which indicates that patients' community nursing records should be left in the home so that each professional knows what treatment has been prescribed and administered.

Several professional organisations have written information and guidance for their members on safe medication practice across all stages of the medication process.^{54,76-79} There are numerous medicines management initiatives, including a Medicines Management Services Collaborative, which produce guidance on safe medication practice in primary care and provide opportunities for sharing local learning and solutions.⁸⁰

Medicine safety at interfaces of care

The importance of maintaining continuity of care at points of patient transition has been acknowledged.^{81,82} The safe use of medicines is a key component in the continuity of care. Transitions occur at different interfaces, including between care providers (for example, admission to and discharge from hospital), practitioners (for example, GP and practice nurse) and work shifts (for example, handover). It is therefore unsurprising that medication error at these interfaces emerged as a theme throughout this review.

NRLS data from all care settings highlighted problems in communication and transfer at patient handover. The data include examples of problems in verbal and written communication (for example, prescriptions and patient records), using a variety of methods (for example, fax, email, telephone) and between a range of people (for example, patients, doctors, pharmacists, nurses). Effective communication encompasses accurate, detailed information about medicines. The exact nature of that information, and who should have access to it at various interfaces of care, is being developed by Connecting for Health.

Communication concerning medicines at admission and discharge from hospital is vital and can affect all stages in the medication process. On admission to hospital, an accurate assessment of the patient's current medication is essential to ensure that patients continue to take their regular medicines and that any drug-related problems can be identified. Similarly on discharge, information on changes in the medicines the patient takes, the rationale for these changes and any subsequent monitoring or follow-up requirements, need to be communicated back to the community team and the patient.

A range of incident types related to communication at interfaces between inpatient settings (for example acute and community hospitals) and the community were identified in the NRLS data. These can be grouped into four general themes:

- 1 incomplete or incorrect medication history on admission to hospital;
- 2 incorrect or incomplete discharge medicines;
- 3 poor information about medicine on discharge from hospital;
- 4 lack of monitoring or follow-up on discharge.

(1) Incomplete or incorrect medication history on admission

When patients are admitted to hospital, a full medication history is required so that medicines can be appropriately continued or discontinued according to the patient's clinical condition. If the medication history is incomplete, essential medicines may be omitted both during the inpatient episode and when the patient is discharged back to the community. Where critical drug therapy is omitted there is the potential for

patient harm. The documentation of this information is vital to ensure that medicines are taken safely.

As the staff member came to administer the patient's medications, they were unable to find the drug card. The patient had been admitted to the ward from home but no drug card was found in the medical notes. Staff member had been given no information about this from the staff nurse who had 'handed over' to them. The patient was asked if they had been given any medication in the previous shift and they replied "No".

Medication histories are usually taken by the admitting doctor and verified by a pharmacist as soon as possible after the patient is admitted, although pharmacists are increasingly playing a primary role in this activity. One way of helping to ensure consistent medication histories are obtained is described in the initiative below.

Practice example: Use of a minimum medication dataset for admissions to a medical admissions unit (MAU)

Organisation: Gateshead Health NHS Foundation Trust

Objective(s): To increase the number of patients admitted to the MAU with a minimum medication dataset as agreed by primary and secondary care.

Action taken

All 33 general practices in Gateshead use the EMIS computer system. For admissions resulting from a home visit, the GPs sent the EMIS download that they used on the home visit (which includes the patient's medication history) with the patients. However, for patients admitted out of hours or as emergencies, this rich source of information was not available. Therefore, a multidisciplinary group including representatives from Gateshead Primary Care Trust and the hospital agreed a minimum medication dataset and a process for implementing it, in consultation with practitioners and support staff. The dataset includes drug name, form, dose and route for all regular medications, allergies to medication and recent acute medicines prescribed.

Each GP's computer has been updated to provide easy access to the patient's list of medicines. This produces a single-page printout of the minimum dataset that practice staff can fax to the secure, designated fax machine held on the MAU, including for patients who are admitted out of hours or without a GP letter. The uptake of this fax system has been monitored and is gradually increasing. With the EMIS downloads the fax ensures a full medication history is available for the majority of patients admitted to the MAU.

(2) Incorrect or incomplete discharge medicines

Omissions may occur when the medication history of a patient is either unavailable or incomplete on admission or discharge, resulting in essential medication being left off the patient's prescription.

A patient who regularly took levothyroxine, a hormone to treat hypothyroidism, was admitted to hospital. During their hospital stay it was not noticed that their levothyroxine had been omitted from the hospital prescription and from the prescription when they were discharged. This was identified by the patient's GP who restarted levothyroxine as the patient was showing signs of hypothyroidism. However the patient, who had multiple medical problems, became unwell and was readmitted to hospital where they subsequently died.

A patient was admitted to an orthopaedic ward for a total knee replacement. The patient was not prescribed anticoagulants to prevent the development of a blood clot, known to be a risk of this type of surgery. The patient developed a pulmonary embolism post operatively.

The discharge prescription includes the medicines patients need to take after they have been discharged. Traditionally, these were all supplied by the pharmacy department and sent to the ward in a bag with a copy of the prescription to be issued to the patient immediately before they left hospital. With the increasing use of patient's own medicines in hospitals, along with dispensing for discharge, medicines to be issued to patients on discharge need to be assembled at ward level. If the medicines are not checked against the discharge prescription, patients may leave hospital with incorrect medicines or without all the medicines prescribed for them, or medicines that are inadequately labelled (see also mismatch between patients and medicines, page 30).

A patient under the care of the palliative care team was discharged with only paracetamol for pain relief. The patient's strong pain killers, morphine and tramadol, which had been prescribed had not been given to the patient and were found on the ward in the drug cupboard. When visited by the palliative care nurse the patient was found in great pain.

Patient was sent home with medication not prescribed for them and had another patient's name on their own medication. Patient did not realise this and took the tablet as prescribed on the box.

Patient was discharged with medication dispensed by the hospital pharmacy. The discharge letter said lisinopril 10 mg 1 tablet daily, but the actual medication dispensed was lisinopril 20 mg 1 tablet daily. The patient's blood pressure plummeted to 89/48. The GP reviewed all medication and prescribed the correct dose.

Medicines need to be carefully checked against the discharge prescription and with the patient, and bedside lockers need to be emptied when beds become empty. Discharge procedures are an area where hospitals can review local practice to improve safety.

Practice example: Dedicated pharmacy technician for intermediate care

Organisation: Barts and the London NHS Trust

Objective(s): To ensure the safe and effective administration and prescription of medicines on admission to, during and after a patients stay in intermediate care.

What happened?

The Tower Hamlets Thames House Intermediate Care service has 16 inpatient beds. Medicines management services are provided by a full time pharmacy technician who reviews patients' own medicines on admission, assesses, encourages and supports patients to take their own medicines whilst on the unit and identifies any needs to help the patient get the most out of their medicines. The technician is actively involved in medication aspects of discharge planning and is a member of the multidisciplinary team. The technician produces an individualised medication care plan and sets treatment goals empowering patients to achieve their maximum independence in managing their medication. The technician proactively co-ordinates all supply arrangements including referrals to locality and community pharmacists for follow-up, and liaises with social services and district nursing where further support is necessary. Medication to take home is prepared in advance, facilitating prompt discharge. Clinical input is provided by a pharmacist who reviews all medication with the GP on a weekly basis.

(3) Poor information about medicine on discharge from hospital

When patients are admitted to hospital, their medicine dose(s) may change, new medicines may be prescribed or medicines may be discontinued. It is important that the medication regimen and the rationale for any changes are adequately communicated to patients and the people supporting them (including their carers, GP and other health professionals). This is because, wherever possible, patients should be involved in decisions about their care. In addition, when patients understand their medication this can provide additional safety checks and empower them to take responsibility for their own care.⁷⁰

If care is being taken over by another healthcare professional, it is important that they understand why certain medication has been started, altered or stopped during previous episodes of care, otherwise they might re-prescribe medicines that are no longer indicated, or might not provide adequate monitoring or follow-up of medication use. To ensure this vital information was communicated consistently, one trust undertook the following initiative.

Practice example: Standardised discharge care planning communications sheet

Organisation: Essex Rivers Healthcare NHS Trust

Objective(s): To facilitate accurate information sharing about medication at discharge.

Action taken

This trust has updated its standardised discharge care planning sheet to include information about whether a medicine has been started or stopped in hospital and why. A copy of this sheet is sent to the community pharmacist and GP. Feedback from general practitioners indicates that the information is supplied in a timely, easy to read and concise manner.

Accurate information on the dose and formulation of medication is vital, and co-ordination is needed between care providers to ensure adequate supplies, and the equipment required for safe administration, are available.

The patient was discharged from the hospice late Tuesday evening with complex syringe driver *in situ* but no documentation about the set rate (60 mm/24 hours). Therefore the twilight nurses assumed this was an error and reduced the rate to 48 mm/24 hours. The patient therefore received less medication. The district nurse telephoned the hospice to talk about their concerns over the late discharge and lack of documentation. Twilight nurses were informed and care plans written with set rate clearly identified.

Patient discharged from the ward with two vials of insulin but no insulin syringes to give it. The patient usually uses an insulin cartridge administration device but this was not sent with the cartridges. As the patient is not familiar with using a vial and syringes (obtained from the ward), senior cover had to be called to administer the medication.

Practice example: Improving communication at the interface between primary and secondary care

Organisation: Calderdale and Huddersfield NHS Foundation Trust

Objective(s): To increase the quality of prescribing and communication between primary and secondary care.

What happened?

A local PCT carried out an audit of Calderdale and Huddersfield NHS Trust's medication and discharge summary to assess whether hospital doctors adequately completed it and how useful this information was to GPs. The audit showed that 39 per cent (32/83) of forms were considered to be incomplete. The main omissions were: medication changes not explained, clinical check not completed, place to which patient discharged missing and insufficient data on amount or duration of medication.

The trust held an interface stakeholder event in 2006 and a follow-up event in January 2007. These events brought together practitioners to identify and agree priorities for action to improve communication and medication issues at the interface between primary and secondary care. Four development areas were agreed at the first event: the development of a form containing all the medicines information required from the GP when the patient is admitted (compatible with the EMIS system); the introduction of a form to record changes made to medicines during the patients' stay; initiatives to increase the number of patients bringing their medicines into hospital with them; and improvements in electronic communication.

Initiatives undertaken include a twice-yearly campaign targeting prescribers (medical and non-medical) to coincide with junior doctors starting at the trust. All junior doctors attend lectures about medicines management, which covers prescribing practices and introduces prescribers to the web formulary and Trust Medicine Code. Nurses attend a mandatory medicines management training session. Written information for staff is produced, e.g. prescribing guidelines in 'Medicines management information for healthcare staff' (leaflet). The number of prescriptions that have to be referred back to prescribers for clarification prior to dispensing continues to reduce.

(4) Lack of monitoring or follow-up on discharge

When a patient is discharged on a new medicine, or the medicine regimen is changed, adverse incidents may occur if the patient's response to the medicine is not adequately monitored. Some medicines require close monitoring to avoid toxicity. If the need to monitor the medicine is not communicated, patients may not be adequately followed-up resulting in potential harm. This is especially important with drugs with narrow therapeutic indices such as lithium and warfarin.

Whilst reviewing a patient's medication in the general practice an error was noticed. The patient had been moved from a nursing home to another home and had changed GP. The home had requested a prescription for the patient: lithium carbonate 400 mg each day. It had been put on the computer records as one twice a day. So patient has been taking double dose. The error was not picked up by the home or community psychiatric nurse (CPN). Patient has been hospitalised twice due to lithium toxicity.

Some local areas have started initiatives to support high-risk patients on discharge from hospital and to ensure that their medication needs are being met safely.

Practice example: Pharmaceutical care for the vulnerable elderly scheme

Organisation: Hull and East Riding Primary Care Trusts

Objective(s): To facilitate communication about medication between hospitals and community services for vulnerable older people discharged from hospital.

Action taken

Patient hospital discharge information is faxed directly to community pharmacists for 'high-risk' patients (for example, people aged 75 or over on complicated dosage regimens, or if the patient's admission to hospital was due to a medication problem). The community pharmacist visits the patient at home for a medication review, liaises with the GP and then produces a care plan and continues to monitor the patient.

Practice example: The Colchester Risk Assessment Tool (RAT)

Organisation: Essex Rivers Healthcare NHS Trust

Objective(s): To focus pharmaceutical care planning on patients with the highest need for support after discharge.

Action taken

The RAT was developed as part of a pharmaceutical care planning service which was introduced in 1999. It aims to identify the patients most likely to benefit from a pharmacist home visit following discharge from hospital. The tool takes into account nine key factors that include side effects and compliance, and also social support for the patient. The most common problems identified were medicines requiring monitoring, patients unable to read labels and side effects from medication. An evaluation of the RAT found that it was effective at identifying patients who would most benefit from additional pharmaceutical care after discharge from hospital.

Further information see Ranson et al (2003)⁸³

Conclusion

The true picture of patient safety incidents will not be known until reporting rates increase. Without an investment in reporting, there will be limited learning and action to improve safety. The types of incident and potential opportunities for error, along with the examples of local initiatives presented in this section highlight the potential for improving medication safety in primary care.

The fourth report from the Patient Safety Observatory

Section 6 Taking action to improve medication safety

Summary

The NPSA has issued a challenge to NHS organisations and staff, setting out seven priority areas for action:

(1) Increase reporting and learning from medication incidents

(2) Implement NPSA safe medication practice recommendations

(3) Improve staff skills and competences

(4) Minimise dosing errors

(5) Ensure medicines are not omitted

(6) Ensure the correct medicines are given to the correct patients

(7) Document patients' medicine allergy status

Given the huge volume of medicines given each day in the NHS, even small improvements in safety can make a real difference to patient safety. By taking positive steps in these seven areas, all healthcare professionals can help to make medication safer for patients.

The role of healthcare commissioners in assisting with the implementation of these recommendations should not be underestimated.

This report highlights some weaknesses in current medication practice. Most medicines are prescribed and used safely, but sometimes errors happen. Although the proportion of reported harm is small, there is no room for complacency. The analysis of reports to the NRLS revealed some areas in which safety can be improved.

This report recommends seven actions that healthcare professionals, NHS organisations and healthcare commissioners can take to make medication practice safer.

- 1 Developing a culture of reporting and learning from medication incidents. Increased reporting will allow practitioners and NHS trusts to identify the risks associated with medicines, and track progress in addressing these risks to improve patient safety.
- 2 Section 3 identified the therapeutic groups associated with high risk (opioids, anticoagulants) and the medication practices (injectable medicines) that led to severe harm or death. The NPSA has issued safer

practice advice on these and other high risks with medicines.⁵⁶ Implementing and evaluating this advice will help to make medication practice safer.

- 3 Healthcare professionals whose duties involve the prescribing, dispensing, preparing, administering or monitoring of medicines should have appropriate training to ensure that they are able to carry out their duties safely. Recent NPSA patient safety alerts have identified a range of work competences required to use medicines safely for high-risk topics. Healthcare staff and NHS organisations should identify other work competences that could be improved by training.
- 4–7 Wrong dose, omitted medicines, wrong medicine, mismatching between patient and medicine, and patients with history of allergy being given medicines accounted for 65.0 per cent of all reported medication incidents. This report recommends four safer practice initiatives that can assist healthcare organisations and staff whilst addressing these important risks.

1. Increase reporting and learning from medication incidents

Recommendations for healthcare professionals

- Report medication incidents to the NRLS either via the local risk management system or, where this is not possible, directly via the NPSA website.ⁱ When reporting via the NPSA website, the reporter has the option to share the report with the NHS trust in which the incident occurred.
- Include reporting medication incidents as an objective in personal development plans.
- Use reflective learning from a medication incident that you have been involved in to improve one aspect of your medication practice as part of your continuing professional development in the coming year.

Recommendations for NHS organisations

- Ensure that there is an organisational commitment at Board level to improving patient safety, including through the safer use of medicines.
- Increase reporting of medication safety incidents to identify risks and challenges to products and systems.
- Ensure that a quality assurance process is in place, where the senior pharmacist in the organisation takes the lead on improving medicines safety, with the support of the chief

ⁱ www.npsa.nhs.uk

executive, medical director and nursing director, reviews the incident reports, and ensures that incident details are complete and that the NPSA incident codes have been applied accurately.

- Appoint a multidisciplinary group that reviews medication incidents and audits data concerning medication practice on a regular basis. This group should be responsible for the quantity and quality of medication incident reports, prioritising risks, initiating action to minimise these risks and evaluating the effectiveness of these activities.
- Provide regular feedback to healthcare professionals of case studies, summary data and progress with actions to improve medication systems.
- Produce an annual report summarising learning from incident reports, audit and other sources such as the NPSA's safer practice recommendations. This report should highlight what work has been done and is planned in the future to improve the reporting system, minimise risks and evaluate the effectiveness of these initiatives. It should be widely available within the organisation and to external organisations such as commissioners, healthcare insurers and other stakeholders.

2. Implement NPSA safe medication practice recommendations

The national guidance produced by the NPSA to help minimise risks associated with high-risk therapeutic groups and medication practices⁵⁶ are as follows:

Safer use of anticoagulants (March 2007)ⁱ

Key issues

Use of safety indicators to identify risks in anticoagulant services. Management of those risks by better compliance with national therapeutic guidelines; effective communication with patients and across care interfaces; therapeutic monitoring; co-prescribing; management of anticoagulants in dental patients; workforce competences.

Safer use of injectable medicines (March 2007)ⁱ

Key issues

Use of a risk assessment tool to identify high-risk practices and products. Reducing high risks by using ready-to-use and ready-to-administer preparations; labelling of syringes; use of closed systems, single-use products, technical information, dosage charts and dose calculation tools, double-checking systems and infusion monitoring forms.

Promoting safer measurement and administration of liquid medicines via oral and other enteral routes (March 2007)ⁱ

Key issues: Oral to intravenous route

Use of oral/enteral syringes incompatible with intravenous ports; use of enteral feeding systems incompatible with intravenous syringes.

Key issues: Epidural to intravenous route

Storing epidural infusions separately from intravenous infusions; rationalising the range of epidural infusions used; use of ready-to-administer epidural infusions; labelling of epidural medicines, administration sets and infusion.

Reducing the risk of hyponatraemia with intravenous infusions in children (March 2007)ⁱ

Key issues

Minimise the use of sodium chloride 0.18 per cent and glucose four per cent infusions in children; minimise the use of these infusions as ward stock in general paediatric areas; use of therapeutic guidelines, training, fluid prescriptions and charts.

Reducing risks with high-dose morphine and diamorphine injections (May 2006)

Key issues

Manage the risks of mis-selection errors of high-dose products (30 mg and greater) for low-dose products (less than 30 mg) by improving storage, labelling, use of guidelines and training; availability of naloxone.

Ensuring safer practice with Repevax and Revaxis vaccines (April 2005)

Key issues

Manage the risks of mis-selection errors with these look-alike and sound-alike vaccines by improving the design of labelling, supply procedures, storage and checking procedures.

Safer practice with oral methotrexate (July 2004 and June 2006)

Key issues

Manage the risk of prescribing oral methotrexate therapy once daily instead of once weekly by improving the design of electronic prescribing systems, the labelling and packaging of products, medicines storage and patient information.

Safer practice with potassium chloride concentrate injections (July 2002)

Key issues

Manage the risks of death from fast-bolus doses of potassium chloride concentrate; remove concentrate product from ward stocks outside critical care areas; increase the use of ready-to-administer infusions; store concentrate product and other intravenous injectables in separate cupboards in critical care areas to avoid mis-selection errors.

Recommendations for healthcare professionals

- Review and implement guidance produced by the NPSA to help minimise risks from a range of medication practices.

ⁱ See NPSA, *Safety in doses: improving the use of medicines in the NHS. Safe medication work programme 2007-08*. Available at: www.npsa.nhs.uk/health/alerts

Recommendations for NHS organisations

- Monitor implementation of the pieces of NPSA guidance listed above by building evaluation into the organisation's business and work plans. Trusts should evaluate improvement in these areas and include this information in their annual medication safety report. The NPSA has provided safety indicators and audit forms to assist organisations in evaluating safe medication practice initiatives.
- Share the results of any evaluation via the Annual Medication Practice Report, and with healthcare commissioners, the Healthcare Commission and NHS litigation organisations to indicate the effectiveness of these initiatives.

3. Improve staff skills and competences

Work competences are statements of good practice that help measure performance outcomes. They can be used by:

- healthcare professionals to help develop their knowledge and skills, improve their performance and gain credit for their achievements.
- NHS organisations to identify individual learning needs and define the learning outcomes that individuals need to achieve, and by doing so improve the safety and quality of the services they offer.

The process of preparing work competences has been established by Skills for Health.ⁱ Work competences are intended to be multidisciplinary and outline safe practice for all staff undertaking these responsibilities, including medical staff.

The NPSA has developed work competences for anticoagulant therapy, the use of injectable medicines and paediatric infusions. These competences and e-learning modules to help healthcare professionals acquire the essential knowledge relating to these topics are available from the NPSA website.ⁱⁱ

A range of other work competences for the safe use of medicines can be found in the completed framework section of the Skills for Health website including competences in chemotherapy, children's services, coronary heart disease, diabetes, long-term conditions, older people, and palliative medicine.

Recommendations for healthcare professionals and NHS organisations

- Use the proposed work competences and e-learning packages developed by the NPSA as part of recent patient safety alerts.
- Identify other work competences required for the safe use of medicines that need to be improved by training and education.

ⁱ www.skillsforhealth.org.uk

ⁱⁱ www.npsa.nhs.uk

4. Minimise dosing errors

Dosing errors are the most frequently reported type of medication error. In the reports to the NRLS, the greatest number of reported incidents of deaths and severe harms from dosing errors related to opioids, anticoagulants and insulin products. Children and older people are more commonly involved in dosing errors than other patients.

Recommendations for healthcare professionals

- Ensure that when prescribing, dispensing, preparing, administering or monitoring medicines you are fully aware of, and have easy access to, essential information regarding medicine dosing. In particular, help minimise dosing errors in children by making full use of the *BNF for Children*.⁸⁴
- Always undertake the required checks on dosage. Do not assume that some other member of staff will have undertaken the safety check.
- If dosage calculations are required, where possible, ask another healthcare professional to also calculate the dosage independently.
- Ensure arrangements are in place for all the required clinical monitoring and dosage adjustments to be made as required.
- When prescribing, dispensing or administering medicines ensure that you are aware of the previous dose, any change in the patient's clinical condition and any laboratory data that may indicate a change is required in the dose of the medicine.

Recommendations for NHS organisations

- Undertake an analysis of dosing error incidents to identify the risk most commonly associated with dosing error locally. Consider undertaking audits to complement this analysis.
- Ensure that when staff are prescribing, dispensing, preparing, administering or monitoring medicines, they have easy access to essential information about medicines dosing, such as national and local medicines information services and therapeutic protocols.
- Review local medicine-related policies to identify whether they provide the necessary guidance to minimise risks, whether they require updating or whether failure to follow procedures is contributing to patient safety incidents.
- Provide help for staff in the form of dosage charts and calculators, dose checking software in infusion pumps and syringe drivers, and ready-to-use products, where appropriate, to avoid complex dose calculations.

5. Ensure medicines are not omitted

This report has identified omitted medicines as the second largest cause of reported medication incidents. The data showed that for some kinds of medicines, such as anticonvulsants, insulins or anticoagulants, a missed dose can have serious and even fatal consequences. Research studies support this finding, although it is not widely recognised as a risk.

Recommendations for healthcare professionals

- Report all serious omissions or delays as a medication incident. Do not ignore omissions caused by prescribing, dispensing or administering errors.

Recommendations for NHS organisations

- Assess incident reports and periodically audit all omissions and delays. The results of these audits should be used to inform system improvements to minimise these omissions, particularly in areas that frequently report these types of error.
- Review medicine storage and medication supply chains regularly.

6. Ensure the correct medicines are given to the correct patients

Mis-selection errors related to look-alike and sound-alike medicines can occur when prescribing, dispensing, preparing or administering medicines. Any healthcare professional can make a mis-selection error irrespective of qualifications, experience or seniority.

At a national level, the NPSA has worked with other organisations to improve the packaging and labelling of drugs to prevent confusion, and has developed design guidance for industry.⁸⁵

There is an important subset of incidents involving misidentification of patients and these patients receiving medicines intended for another patient.

Recommendations for healthcare professionals

- Be aware of the risks of mis-selection errors due to look-alike and sound-alike medicines. Alert your colleagues and the pharmacy when you identify a medicine that has a high risk of being mis-selected.
- Where a medicine is likely to be mis-selected, change your practice to minimise this risk:
 - o Store such medicines in different locations to avoid mis-selection.
 - o Use alert labels in medicine storage locations to remind staff of the risk of mis-selection.
 - o Where necessary, ask another healthcare professional to confirm the correct medicine has been selected.
 - o Work with your pharmacy service to identify and use medicines with safer designs that minimise risks of mis-selection.
- Avoid misidentification of patients by checking the patient's identity by using the patient's name in full and one or more of the following: hospital number, NHS number, date of birth, address. Check the information on the patient's wristband where this is available (see NPSA guidance on wristbands for hospital inpatients).⁵⁶
- If the NHS trust has supplied auto-ID technology, use it to confirm the identity of the patient and the prescribed medicine when dispensing or administering medicines.

Recommendations for NHS organisations

- Be aware of the risks of mis-selection errors related to look-alike and sound-alike medicines. Improving the medication system is the best method to prevent these errors.
- Review incident reports concerning wrong medicine and wrong patient selection. Focus safer practice initiatives on medicines that are most frequently mis-selected. Audits of methods of checking patient identity are also helpful.⁸⁶ Results of these audits should be used to inform system improvements to minimise patient mis-selection.
- Develop purchasing for safety policies for medicines. These policies should recognise the risks of look-alike and sound-alike medicines in practice. Risk assessment of labelling, packaging and presentation of medicines should form part of the procurement process. Trusts should avoid purchasing products with a high risk of being mis-selected and try to purchase products designed to promote safer practice. The MHRA and the NPSA has issued guidance on the labelling and packaging of medicines.⁸⁷ A useful risk assessment tool that assesses the error potential of medicines has been developed by the NHS Pharmaceutical Quality Assurance Committee. This tool should be used for contracting purposes.⁸⁸
- Have policies in place for the use of segregated storage, alert labelling and double-checking systems in medicine procedures to help minimise mis-selection errors.
- Consider implementing the use of auto-ID technology to make dispensing and administration of medicines safer.

7. Document patients' medicine allergy status

A significant number of reported incidents involved patients with a known allergy to the medicine. In some cases, severe harm or death from anaphylaxis occurred due to these types of error.

Recommendations for healthcare professionals

- Ensure that the medicine allergy status for all patients is documented, including 'No known medicine allergy'.
- Do not prescribe, dispense or administer medicines to patients if you do not know their medicine or allergy history and it has not been documented.

Recommendations for NHS organisations

- Audit the frequency of incidents reports involving medicine allergy and the extent to which the allergy status (including 'no known medicine allergies') is documented on all patient medication records.
- Ensure that all electronic prescribing and dispensing systems include a record of the patient's medicine allergy status and that this information is complete before any medicines are prescribed or dispensed. Electronic systems should alert the user to a patient's allergy status if they attempt to prescribe or dispense a medicine that may cause harm.
- Consider the use of a wristband incorporating the colour red to alert healthcare professionals to the allergy status of the patient when administering medicines.

- Develop local systems to alert health professionals that the following examples and other penicillin-containing products should not be used in patients with penicillin allergy.

co-amoxiclav – Augmentin®

co-fluampicil – Magnapen®

combination of ticarcillin and clavulanic acid – Timentin®

combination of piperacillin and tazobactam – Tazocin®

Recommendations for healthcare commissioners

Healthcare commissioners are in an ideal position to lead on medicines safety and monitor progress on medication safety issues through the commissioning process. Their role in reducing patient safety incidents should not be underestimated.

The NPSA recommends healthcare commissioners take two actions that will help NHS organisations and healthcare professionals with the seven recommendations described in this report:

- Ensure that reporting and learning of medication incidents is an explicit requirement for all commissioned services involving the use of medicines.
- Require all commissioned NHS organisations to submit an Annual Medication Practice Report.

An annual Medication Practice report should include:

(i) a summary of the number, type and quality of medication incident reports, identify clinical areas and services that have reported and those that have not, and describe what work has been done and is planned to improve the medication reporting system; and (ii) a summary of information from audits and complaints from patients involving medication practice.

The report should describe (i) actions and initiatives that have been taken to minimise medicine-related harms from locally identified risks and those identified by the NPSA; and (ii) how these actions and initiatives have been evaluated, to determine whether they have been implemented as planned and whether they have reduced harm to patients. A safe medication practice work programme for the next year should form the final section of the report.

The NPSA has issued a challenge to all staff to implement these seven priority areas for action now to improve medicine safety.

Safer medication is everybody's business and small changes will make a real difference in reducing harm to patients.

The fourth report from the Patient Safety Observatory

Appendix 1: National Reporting and Learning System

The NRLS dataset is designed to collect a notification report of a single patient safety incident soon after it occurs. It focuses on what happened, when and where it happened, the characteristics of the patient(s) involved (such as age, sex and ethnicity), and the outcome for the patient(s). The dataset also includes contributory factors, and factors that might have prevented harm. Reports also contain free text that explains what happened in varying degrees of detail. Additional detail is provided in reports involving medication and medical devices.

How to interpret NRLS data

There are a number of notes of caution in interpreting the data from the NRLS:

- NHS organisations have provided data to the NRLS for varying lengths of time, so data included within this report may not be representative of the rate of incidents across all of England and Wales.
- International research suggests that there is significant under-reporting of incidents.
- Reports made to local risk management systems may not capture all types of incidents that occur.
- The data are confidential. The NPSA does not seek to hold information on the identities of individual staff or patients, and this means that the data are not routinely checked with the reporter. However, steps are usually taken to maximise the quality of the data by, for example, checking for duplicate reports and feeding back to individual trusts if there are problems with their reports.
- Incident reports are often made soon after the incident, but before the incident has been investigated locally. Hence, the reports to the NRLS may not contain complete information about the incident, especially findings of more detailed investigations such as root cause analysis.
- There are no reports from the public or patients included in this analysis, although, since April 2006, the public and patients have been able to report incidents via a dedicated reporting form.
- A higher number of reported incidents from a trust, specialty or location, does not necessarily mean that the trust, specialty or location has a higher number of incidents; it may instead reflect greater levels of reporting. Organisations reporting higher numbers of patient safety incidents may have a better developed safety culture, resulting in greater reporting and learning from reports.
- Some incidents recorded in local risk management systems, and subsequently forwarded to the NRLS, may not technically be patient safety incidents. For example, deaths from natural causes that occurred in hospital, and also deaths where patients died unexpectedly, are sometimes reported to local risk management systems, for local audit purposes, and hence reported to the NRLS.
- The data are likely to include incidents where the impact on the patient, or whether the incident could have been avoided, is not clear. For example, suicides are often reported to local risk management systems in cases where the event could not have been prevented by health services.
- The level of detail collected locally varies. For example, some organisations and local data collection systems do not currently collect information on contributing factors or the ethnicity of the patient(s) involved. At the present time, there is insufficient information on the age and gender of patients involved in incidents to allow analysis of this information, but the quality of demographic data is improving.

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Appendix 2: NPSA definitions of degrees of harm

Harm	NPSA definition
No harm	<i>Impact prevented:</i> any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to the person(s) receiving NHS-funded care. <i>Impact not prevented:</i> any patient safety incident that ran to completion but no harm occurred to the person(s) receiving NHS-funded care.
Low harm	Any patient safety incident that required extra observation or minor treatment, and caused minimal harm to the person(s) receiving NHS-funded care.
Moderate harm	Any patient safety incident that resulted in a moderate increase in treatment, and which caused significant but not permanent harm to the person(s) receiving NHS-funded care.
Severe harm	Any patient safety incident that resulted in permanent harm to the person(s) receiving NHS-funded care.
Death	Any patient safety incident that directly resulted in the death of the person(s) receiving NHS-funded care.

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Appendix 3: Data sources and analysis

Table A: An overview of the data collected from various organisations

Source	Time period of data analysed	Volume of reports	Number of relevant incidents reviewed in depth*	Description
NHSLA	1 April 1995 to 30 June 2006	815	694 claims with medication error as cause	All claims notified to NHS trusts in England via the Clinical Negligence Scheme for Trusts (CNST).
MDU	1 January 1996 to 30 June 2006	218	194 upheld claims	Settled claims from the largest medical defence organisation in the UK. Membership of the MDU is approximately 22,000, mainly general practitioners.
PDA	January to December 2005	209	198 claims reported to the PDA	A mixture of open, closed and settled claims reported to the PDA. The PDA represents more than 9,000 pharmacists, primarily working as employees or locums.
CDA	January 2001 to 27 May 2006	2,048	1,950 claims reported to the CDA	Anonymised data was a mixture of open, closed or settled cases. The CDA represents 3,806 members who own 10,784 pharmacies. It is a subsidiary of the National Pharmacy Association.

*This figure is after exclusions (for example, due to insufficient information describing the incident or because the incident is not a medication safety incident).

A key role of the Patient Safety Observatory is to bring together information from a range of sources for a more robust understanding of patient safety. Besides the NPSA's NRLS, other organisations also report on medication safety issues. For example, the Audit Commission published a report on medicines management in hospitals in 2001, and the Health Service Ombudsman's reports to Parliament (1997–2004) have described medication safety incidents within the synopses of completed investigations.

It has been recognised for some time that clinical negligence claims can provide information about patient safety incidents and harm to patients. During the preparation of this report, data provided by the NHSLA, MDU, the PDA and the CDA were analysed to supplement the data from the NRLS. The aim was to triangulate findings from published research and NRLS data, particularly in relation to (a) types of incident and (b) emerging themes.

Table A shows the supplemental data included in this report and the source of the data collected by each organisation.

Interpreting the data

Comparisons between clinical negligence and NRLS data must be treated with caution for two reasons. First, the primary purpose of clinical negligence databases is to support claims management and therefore information relevant to improving patient safety is sometimes missing.⁸⁹ Second, the data from clinical negligence cases come from claims made by or on behalf of patients, whereas patient safety incidents are reported by staff. Nevertheless, analysis of information from

claims, alongside reports to the NRLS, may help build a more complete picture of patient safety issues.

The data used from different sources cover different time periods, and different settings and geographical regions (for example, NHSLA data only include CNST claims made to trusts in England). Therefore direct comparisons between these data and the reports to the NRLS with regard to the volume of medication-related incidents cannot be made. However, the data are useful for qualitative, thematic analyses.

In contrast with the MDU and PDA data, claims made to the NHSLA and CDA are made against an organisation and not individual clinicians. Of the NHSLA claims reviewed in detail, almost 87 per cent were made against acute trusts;⁹⁰ it was not possible to discern which organisations were involved in claims described in CDA data. The data from the MDU and PDA were obtained specifically because of the dearth of data reported from community settings to the NRLS. The data from the MDU provided information regarding medication error in general practice, and data from the PDA and CDA provided greater understanding of medication incidents in pharmacies. However, as the location of the incident is not recorded in the PDA database, it was not possible to discern whether claims were against community pharmacists, although the membership of the PDA suggests this is likely.⁹¹

The method followed for selecting data from each dataset is described below. None of the datasets include identifiable information such as patient or trust names.

Data sources

NHSLA data

A search of relevant cause categories and keywords was conducted to extract all the medication-related claims. A total of 3,096 claims were found, representing 8.2 per cent of all claims notified to the NHSLA. All claims (for all years) notified to trusts where the cause of the claim was recorded as 'medication error' were reviewed further. Out of the 815 claims that were notified to trusts with a cause of medication error between April 1995 and June 2006, 121 (14.8 per cent) were excluded from in-depth review. Most of the remaining claims (531, 76.5 per cent) were closed, 148 were open (21.3 per cent) and 15 (2.2 per cent) were potential claims.

Data on the costs of the claim were available from the NHSLA dataset, unlike the other datasets. The NHSLA data on cost of claims used in calculating the costs of medication error to the NHS (appendix 5) included the total cost of claims that were closed between 2001 and 2005 and in which the cause was cited as medication error.

MDU data

The MDU is the largest medical defence organisation in the UK, working primarily with general practitioners to provide indemnity insurance, as well as guidance and support. A keyword search of all claims brought since 1 January 1996 and settled by 30 June 2006 was conducted by the MDU. This identified 218 upheld claims, of which 194 were then reviewed in depth by two reviewers (one pharmacist) at the NPSA. A particular strength of these data is their richness regarding medicine names, although there are no data on the degree of harm caused by the incident.

PDA data

The PDA represents more than 9,000 pharmacists who primarily work as locums or employees.^{92,93} Data on a mixture of open, closed and settled cases were shared with the NPSA. This covered claims notified to the PDA between 2000 and 2006. Claims notified in 2005 were selected for review (209 claims) by two reviewers at the NPSA (one pharmacist) and 198 cases were included in the in-depth analysis.

CDA data

Data obtained from the CDA were a mixture of open, closed and settled cases covering the period 2001 to 27 May 2006 (it was not possible to tell the status of individual claims). As the date of the claim was not included in the dataset, all claims except those reported as 'OTC advice' (69 out of 2,048) were included in the analysis.

Data analysis

Data from all four organisations were reviewed in a similar way to identify themes and emerging issues. All of the datasets include a free text description of the incident leading to the claim. This description was reviewed in detail by at least one pharmacist at the NPSA and mapped against the NRLS typology for stage of medication process and medication incident type. In addition, where medicine names were described this was recorded and categorised by *BNF* medicine type. If there was a clear indication that the patient had died as a result of the incident, this was also recorded.

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Appendix 4: Advisory group members and members of other consultation groups

Advisory Group members:

Professor Tony Avery (GP and Nottingham University), Professor Nick Barber (School of Pharmacy, University of London), Ms Sophia Bhatti (General Medical Council), Dr Declan Chard (Royal College of Physicians Trainees' Committee), Dr Stephen Green (Medical Defence Union), Professor Matt Griffiths (Royal College of Nursing), Ms Sadia Khan (Royal Pharmaceutical Society of Great Britain), Ms Liz Plastow (Nursing and Midwifery Council), Dr John Scarpello (University Hospital of North Staffordshire), Richard Seal (National Prescribing Centre) and Ms Heidi Wright (Royal Pharmaceutical Society of Great Britain).

NPSA Hospital Pharmacists' Reference Group:

Kate Appleby (Derby Hospitals NHS Foundation Trust), Darrell Baker (Cardiff and Vale NHS Trust), Bryony Dean Franklin (The Hammersmith Hospitals NHS Trust), Sandie Fairclough (Royal Liverpool Children's NHS Trust – Alder Hey), Steve Gage (Cardiff and Vale NHS Trust), Neil Gammack (Gateshead Health NHS Foundation Trust), Tom Gray (Derby Hospitals NHS Foundation Trust), Sarah Hepburn (United Bristol Healthcare NHS Trust), Don Hughes (Conwy & Denbighshire NHS Trust), Jeanette Knight (University Hospitals Coventry and Warwickshire NHS Trust), Una Laverty (The Leeds Teaching Hospitals NHS Trust), Malcolm Partridge (Nottingham University Hospitals NHS Trust), Jillian Redpath (The Craigavon Area Hospital Group Trust), Margaret Stone (Nottingham University Hospitals NHS Trust), Nicky Thomas (Sheffield Teaching Hospitals NHS Foundation Trust), Steve Williams (University Hospital of South Manchester NHS Foundation Trust).

NPSA community pharmacy workshop attendees:

Laraine Clark (Eastern and Coastal Kent Primary Care Trust), Mary Clarke (City and Hackney Teaching Primary Care Trust), Hazel Evans (Stockport Primary Care Trust), David Green (Essex Rivers Healthcare NHS Trust), Sandra Llewelyn (Lloyds Pharmacy), Peter Magirr (South East Sheffield Primary Care Trust).

Examples of local practice provided by:

Darrell Baker, Principal Pharmacist, Head of Patient Services, Cardiff and Vale NHS Trust.

Gillian Cavell, Deputy Director of Pharmacy and Medication Safety, King's College Hospital NHS Trust.

Laraine Clark, Head of Prescribing and Medicines Management, Canterbury area of Eastern and Coastal Kent Primary Care Trust.

Mary Clarke, Director of Governance, Estates and ICT (Nurse Director), City and Hackney Primary Care Trust.

Dr Clare Crowley, Medicines Safety Pharmacist, Oxford Radcliffe Hospitals NHS Trust.

Sandie Fairclough, Head of Pharmacy, Royal Liverpool Children's NHS Trust – Alder Hey.

Katharina Floss, Critical Care, Theatres and Anaesthetics Directorate Pharmacist, Oxford Radcliffe Hospitals NHS Trust

Jo Foggo and Shahanara Rouf, Senior Pharmacy Technicians (job share), Intermediate Care, Barts and the London NHS Trust.

Gill Gamblin, the Middlesex Group of Local Pharmaceutical Committees.

David Green, Interface Development Pharmacist, Colchester General Hospital, Essex Rivers Healthcare NHS Trust (Associate Director, Community Health Services, London, Eastern and South East Specialist Pharmacy Services).

Karen Guy, Specialist Nurse, Medicines Management, Calderdale and Huddersfield NHS Foundation Trust.

Janet Hattle, Pharmacy Service Manager, Gateshead Health NHS Foundation Trust.

Graham Hill, Professional Development Pharmacist, East Riding and Hull Local Pharmaceutical Committee (LPC).

Alex Hodgins, Principal Pharmacist, Barts and the London NHS Trust.

Beryl Langfield, Principal Pharmacist, Computer Services, Pharmacy Department, Hammersmith Hospitals NHS Trust.

Michael Levitan, the Middlesex Group of Local Pharmaceutical Committees.

David Milligan, Deputy Director of Pharmacy, Trafford Healthcare NHS Trust.

Ruth McNamara, Corporate Professional Development Nurse, Oxford Radcliffe Hospitals NHS Trust.

Samantha Mortimer, Senior Nurse Quality/Standards, Medicines Management, South Staffordshire Healthcare NHS Foundation Trust.

Caroline Peet, Pharmacist Team Manager, Cambridgeshire Primary Care Trust, Cambridge Area.

Nicky Thomas, Clinical Governance Pharmacist, Sheffield Teaching Hospitals NHS Foundation Trust.

Carolyn Warburton, Primary Care Support Manager, Cambridgeshire Primary Care Trust, Cambridge Area.

Jackie Wrench, Modern Matron for Medical Oncology and Chemotherapy Services, Christie Hospital NHS Trust.

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Appendix 5: Calculation of costs to the NHS

Costs to the NHS of harms from medicines were estimated on best available evidence of rate of harm from different sources, against most recent hospital activity and costs data.

Cost of admissions for avoidable harm from medicines

The most robust, recent study from the UK indicated that 6.5 per cent of all non-elective admissions were related to adverse drug reactions (ADRs). Of these, 72 per cent were judged to be avoidable. Therefore 4.68 per cent of non-elective hospital admissions were related to avoidable ADRs. The average length of stay after an ADR related admission was eight days per admission.⁶ Hospital reference costs for general inpatient bed days for 2005/6 were £206 per day.

These figures were applied to the most recent number of non-elective admissions of 4,659,054 (excluding obstetrics as in the research study) for England (Hospital Episode Statistics 2005/06). Therefore the calculation of costs for admission for avoidable harms from medicines was:

$4.68 \text{ per cent [rate of avoidable harm]} \times 4,659,054 \text{ [total non-elective admissions]} \times £206 \text{ [cost of inpatient day]} \times 8 \text{ [average length of stay for admission]} = £359 \text{ million.}$

Cost of harm from medicines during inpatient stay

A systematic review suggested that the rate of ADRs in the UK and Europe was about seven per cent (although this did not include major areas of error, such as drug administration).⁴⁹ In the absence of other evidence on avoidability the same rate of 72 per cent, as calculated by Pirmohamed et al⁷ was applied, leading to a conservative avoidable rate of 5.04 per cent.⁹⁴

Wiffen et al estimated the range of additional days spent in hospital as a result of an adverse drug reaction to be between two and four, taking three additional days as being representative.⁴⁹ The same hospital reference costs as before were used.

These rates were applied to most recent total hospital admissions of 13,180,552 for England in 2005–06 as outlined in the Hospital Episodes Statistics. The calculation of costs for harms from medicines during inpatient stay was therefore:

$5.04 \text{ per cent [rate of avoidable harm]} \times 13,180,552 \text{ [total admissions]} \times £206 \text{ [cost of inpatient day]} \times 3 \text{ [average additional length of stay]} = £411 \text{ million.}$

Costs from litigation

The precise figure is not known, but a review of the claims data provided by the NHSLA for this report suggested that for claims settled during the period 2001–05 the total cost of medication-related cases was about £20 million in England (equivalent to about £4 million per year).

TOTAL

The total estimate of annual costs of up to £774 million therefore consists of most recent activity figures and the following calculations.

Estimate of avoidable admissions for harms from medicines	£359 million
Estimate of avoidable harms from medicines during inpatient stay (likely to be conservative as excludes administration errors)	£411 million
Additional litigation costs (annual)	£4 million
Total	£774 million

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Appendix 6: Selected literature on medicines safety (rates of medication error) in the UK

Prescribing error studies

By publication date, most recent study first

Reference	Site	Data collection period	Study design	Results
Chen YF et al. Incidence and possible causes of prescribing potentially hazardous/contraindicated drug combinations in general practice. <i>Drug Safety</i> . 2005; 28: 67-80.	Community (four general practices)	One year (1999–2000)	Review of patient records (n=37,940) to identify contraindicated drug combinations.	Incidence of 4.3 contraindicated drug combinations per 1,000 patients (1.9 per 1,000 patient-years), 70 per cent of which were judged to be unjustified. One-third of interactions were documented at the time of prescribing (two-thirds of the events identified involved medications which had been initiated by hospital doctors).
Mandal K, Fraser SG. The incidence of prescribing errors in an eye hospital. <i>BMC Ophthalmology</i> . 2005; 5: 4.	Specialist hospital (eye hospital)	Four weeks	Prospective study of number of prescribing errors by pharmacists. The errors were categorised as error of prescription writing or drug error.	Overall eight per cent (144/1952) prescription sheets had errors. Seven per cent of the total errors were errors of prescription writing whereas one per cent were drug errors. The outpatients department had the highest prevalence of errors.
Price-Forbes AN et al. A regional audit of the use of COX-2 selective non-steroidal anti-inflammatory drugs (NSAIDs) in rheumatology clinics in the West Midlands, in relation to NICE guidelines. <i>Rheumatology</i> . 2005; 44: 921-924.	Hospital outpatients	Two weeks	Questionnaire for all patients (2846 patients) attending clinics in 18 rheumatology units to audit the appropriateness of NSAIDs use in relation to NICE guidance.	Overall, 37 per cent of NSAID prescriptions were appropriate.
Mikuls TR et al. Suboptimal physician adherence to quality indicators for the management of gout and asymptomatic hyperuricaemia: results from the UK General Practice Research Database (GPRD). <i>Rheumatology</i> . 2005; 44: 1038-1042.	Community (general practice)	Not known	UK General Practice Research Database (GPRD) was used to investigate doctors' adherence to three validated indicators which assess the quality of allopurinol prescribing practice for the treatment of gout and asymptomatic hyperuricaemia.	25–50 per cent of all patients eligible for at least one of the three validated quality of care indicators were subject to possible allopurinol prescribing error.

Reference	Site	Data collection period	Study design	Results
Ridley SA et al Prescription errors in UK critical care units. <i>Anaesthesia</i> . 2004; 59: 1193-1200.	Critical care units	Four weeks	Review of all new and re-written prescriptions (21,589 new prescriptions).	15 per cent of prescriptions (3,141) had one or more error. 19.6 per cent of errors (618) were significant, serious or potentially life-threatening. The five most common medicines associated with incorrect prescriptions were: potassium chloride, heparin, magnesium sulphate, paracetamol and propofol.
Morris CJ et al. Indicators for preventable drug related morbidity: application in primary care. <i>Quality and Safety in Health Care</i> . 2004; 13: 181-185.	Community (nine general practices)	Two years three months	Pilot study applied 29 validated indicators for preventable drug-related morbidity (PDRM) to electronic patient records (all patients over 18 years old).	One per cent of records contained evidence of potential PDRM events (507/49,658 records). The three most common events related to: use of NSAIDs in patients with congestive heart failure or hypertension; lack of monitoring in patients prescribed angiotensin-converting enzyme inhibitors; and use of hypnotic-anxiolytic agents.
Rubin G et al. Errors in general practice: development of an error classification and pilot study of a method for detecting errors. <i>Quality and Safety in Health Care</i> . 2003; 12: 443-447.	Community (10 general practices)	Two weeks (June 2002)	An anonymous self-report form and self-completion questionnaire.	Six per cent of prescription errors were medication errors (22/397).
Chen YF et al. Prescription with potentially hazardous/contraindicated drug combinations presented to community pharmacies. <i>The International Journal of Pharmacy Practice</i> . 2002; 10(suppl): R29.	Community (11 community pharmacies)	One month (each pharmacy, between April 2000 and January 2001)	Samples of prescriptions were drawn from random dates in a month and screened in house using a standard drug interaction programme to trigger alerts. All alerts were fed back to pharmacists who checked to see if their own computer systems generated similar alerts.	Pharmacists reported 196 potential prescribing errors (0.6 per cent, 196/32,403 items dispensed). This included 17 drug interactions.
Dean B et al. Prescribing errors in hospital inpatients: their incidence and clinical significance. <i>Quality and Safety in Health Care</i> . 2002; 11: 340-344.	Hospital	Four weeks	Prospective chart review by pharmacists visiting wards covering 36,200 prescription items.	1.5 per cent of medication orders contained a prescribing error (95 per cent confidence interval [CI] 1.4 to 1.6). A potentially serious error occurred in 0.4 per cent (95 per cent CI 0.3 to 0.5). Most of the errors (54 per cent) were associated with dose of medicine. Error rates were significantly different for different stages of patient stay ($p < 0.0001$) with a higher error rate for medication orders written during the inpatient stay than for those written on admission or discharge.
Sanders J, Esmail A. The frequency and nature of medical error in primary care: understanding the diversity across studies. <i>Family Practice</i> . 2003; 20: 231-236.	Community	Not applicable	Literature review – includes three UK studies relating to medication error in primary care.	Studies in the UK have identified prescription and prescribing error rates between less than one per cent and 11 per cent of all prescriptions. The most common errors found in the studies reviewed were wrong dose and medicine interactions.

Reference	Site	Data collection period	Study design	Results
Shah SN et al. A survey of prescription errors in general practice. <i>Pharmaceutical Journal</i> . 2001; 267: 860-862.	Community. (23 doctors [three general practices] and three community pharmacies)	Two months	Chart review of prescriptions presented to community pharmacies.	7.46 per cent of prescription items contained errors (2,816/37,821 prescription items). The most common error detected related to directions (2.8 per cent, 1,056 items).
Fowlie F et al. Evaluation of an electronic prescribing and administration system in a British hospital. <i>Pharmaceutical Journal</i> 2001; 265: R16.	Hospital orthopaedic ward	17 months	Prospective chart review by pharmacists visiting ward. 2,230 hand written prescription items and 2,030 computer generated prescription items. 826 hand written discharge prescription items and 1,658 computer generated discharge prescription items.	4.7–7.4 per cent of inpatient prescriptions (4.7 per cent of computerised inpatient prescriptions, 7.4 per cent of hand written inpatient prescriptions). 5.9–7.7 per cent of discharge prescriptions (5.9 per cent of computer generated discharge prescriptions, 7.7 per cent of hand written discharge prescriptions). The study excluded the controlled drugs and intravenous medicines.

Medicine dispensing error studies

By publication date, most recent study first

Reference	Site	Data collection period	Study design	Results
Warner B, Gerret D Identification of medication error through community pharmacies. <i>International Journal of Pharmacy Practice</i> . 2005; 13: 223-228.	Community pharmacy (17 sites)	One year (October 2002 – 2003)	Pharmacists recorded medication error against specific categories in a diary-based reporting instrument.	987 medication errors in 485,940 prescribed items. 70 per cent (of 968) errors were classed as dispensing errors. (24.1 per cent of errors were prescribing errors). 25.2 per cent of errors concerned the wrong strength or form of medication 11 per cent involved the wrong drug being potentially or actually dispensed.
Ashcroft DM et al. Prospective study of the incidence, nature and causes of dispensing errors in community pharmacies. <i>Pharmacoepidemiology and Drug Safety</i> . 2005; 14: 327-332. Also: Quinlan P et al. Medication errors: a baseline survey of dispensing errors reported in community pharmacies. <i>International Journal of Pharmacy Practice</i> . 2002; (suppl): R68.	Community pharmacy	Four weeks	Prospective study of 35 community pharmacies (nine independent pharmacies and 26 chain pharmacies).	330 incidents were recorded relating to 310 prescriptions (125,395 prescribed items were dispensed during the study period). 280 (84.8 per cent) of the 310 incidents were classified as a near miss. 50 of the incidents (15.2 per cent) were classified as dispensing errors. Selection errors were the most common type of incident (199, 60.3 per cent).

Reference	Site	Data collection period	Study design	Results
Beso Aet al. The frequency and potential causes of dispensing errors in a hospital pharmacy. <i>Pharmacy World and Science</i> . 2005; 27: 182-190.	Hospital pharmacy	One year	Observational study of dispensing error identified at final check and all dispensing errors identified outside of the pharmacy.	Dispensing errors occur in about two per cent of all dispensed items. About one in 100 of these is missed by the final check. One or more dispensing errors were identified at the final check stage in 2.1 per cent of 4,849 dispensed items and outside of the pharmacy department in 0.02 per cent of 194,584 items. The majority of those identified at the final check stage involved slips in picking products, or mistakes in making assumptions about the products concerned.
Chua SS et al. A feasibility study for recording of dispensing errors and near misses in four UK primary care pharmacies. <i>Drug Safety</i> 2003; 26: 803-813.	Community pharmacy	Two x four weeks	Feasibility study with four community pharmacies to identify and evaluate the feasibility of a reporting system.	39 dispensing errors (0.08 per cent) and 247 near misses (0.48 per cent) were detected (a total of 51,357 items dispensed). The most common types of dispensing errors or near misses were incorrect strength of medication, followed by incorrect drug, incorrect quantity, incorrect dosage form and incorrect label.
Roberts DE et al. An analysis of dispensing errors in NHS hospitals. <i>International Journal of Pharmacy Practice</i> . 2002; 10(suppl): R6.	Hospital pharmacy (89 total, 66 in England, 19 in Wales, four in Scotland)	1991–2001 (most data collected before 1998)	Hospital chief pharmacists documented dispensing errors using a standard form (developed in previous study, see Spencer MG, Smith AP, 1993).	The two most common errors were wrong medicine and wrong strength, which both accounted for 23 per cent of reports (1,652/7,158 reports and 1,651/7,158 reports respectively). Nurses detected most errors (45 per cent, 3,221/7,158 reports), hospital pharmacists and patients each detected 17 per cent of errors (1,217/7,158 reports). Look-alike and sound-alike medicines were most commonly associated with errors where contributory factors were noted (33 per cent, 1,659/5,026 reports). Other key contributory factors were: high workload/low staffing (23 per cent 1,156/5,026 reports), inexperienced staff (20 per cent, 1,005/5,026 reports) and transcription (14 per cent, 704/5,026 reports). 92.5 per cent of errors had no/minor detrimental effects on patients (4,380 reports where outcome was recorded). There was one death as a result of error.
Spencer MG, Smith AP. A multicentre study of dispensing errors in UK hospitals. <i>Journal of Pharmacy Practice</i> 1993; 2: 142-146.	Hospital pharmacy (19)			An average incidence of 18.1 errors per 100,000 items dispensed. Study is by the same team as Roberts, et al (2002).

Medicine preparation and administration error studies

By publication date, most recent study first

Reference	Site	Data collection period	Study design	Results
Maidment ID, Thorn A. A medication error reporting scheme: analysis of the first 12 months. <i>Psychiatric Bulletin</i> 2005; 29: 298-301.	One English NHS and social care trust (including units for older adults, learning disability community homes and rehabilitation units)	One year	Descriptive analysis of first year of medication error reporting system.	76 per cent of errors related to the administration of medicines (50/66 reports). The two most common types of medication errors reported were wrong frequency (14/66) and mismatching of patient and medicine (16/66).
Taxis K, Barber N. Causes of intravenous medication errors: an ethnographic study. <i>Quality and Safety in Health Care</i> 2003; 12: 343-347. (Also: Taxis K, Barber N. Ethnographic study of incidence and severity of intravenous drug errors. <i>BMJ</i> 2003; 326: 684.)	One teaching and one non-teaching hospital – 10 wards	June – December 1999	Observation of intravenous preparation and administration on 10 wards including: intensive care, paediatrics, surgery, cardiology and nephrology.	One or more errors occurred in the preparation and/or administration of 49 per cent of intravenous doses (212/430 intravenous doses). Preparation errors occurred in seven per cent (32) of intravenous doses, administration errors occurred in 36 per cent (155) intravenous doses and both types of errors in six per cent (25) of doses. Errors were potentially severe in one per cent of doses, potentially moderate in 29 per cent of doses and potentially minor in 19 per cent of doses. 73 per cent of bolus doses (172/235) included an error, 95 per cent (163/172) of these related to bolus doses administered too quickly. There was an error rate of 14 per cent for medicines which required multiple steps to prepare (50/345 multiple step preparations).
Bruce J, Wong I. Parenteral drug administration errors by nursing staff on an acute medical admissions wards during day duty. <i>Drug Safety</i> 2002; 24: 855-862.	Hospital medical admissions ward	Four weeks (Dec 1998)	Observation of preparation and administration of intravenous medicine.	25.2 per cent of administration events included an error (27/107 events, CI 17 per cent to 35.5 per cent). The most frequently occurring type of incident was the medicine given at the wrong time. When wrong time errors are excluded from the analysis, the rate of administration error was 10.3 per cent (CI 3.8 per cent to 14.9 per cent).

Reference	Site	Data collection period	Study design	Results
Fowle F et al. Evaluation of an electronic prescribing and administration system in a British hospital. <i>The Pharmaceutical Journal</i> 2000; 265.	Hospital orthopaedic ward	17 months	Prospective chart review by pharmacists visiting ward.	5.4–9 per cent of medication administration events involved an error (5.4 per cent of computer generated prescriptions, 9 per cent of hand written prescriptions). The study excluded the administration of controlled drugs and intravenous medicines.
Barber ND, Dean BS The incidence of medication errors and how to reduce them. <i>Clinical Risk</i> . 1998; 4: 103-106.				Median 5.8 per cent medication administration error rate.
Hartley GM, Dhillon S. An observational study of the prescribing and administration of intravenous drugs in a general hospital. <i>Journal of Pharmaceutical Practice</i> . 1998; 6: 38-45.	Hospital 154 patients		Observation of the preparation and administration of intravenous doses.	26.9 per cent intravenous preparation and administration error rate. 4.7 per cent of errors classified as major; 17.3 per cent of errors classified as moderate; 77.9 per cent of errors classified as minor.
Ho CY et al. When do medication administration errors happen to hospital inpatients? <i>International Journal of Pharmaceutical Practice</i> . 1997; 5: 91-96.	Hospital care of the elderly ward		2,170 opportunities for error observed by independent observer.	5.5 per cent administration error rate. Omission errors were the main type of error.
Cavell GE, Hughes DK. Does computerised prescribing improve the accuracy of drug administration? <i>Pharmaceutical Journal</i> . 1997; 259: 782-784.	Two different hospitals – one medical ward in each hospital		Observational study of one medical ward in a hospital with computer prescribing and records and one medical ward in another hospital with manual prescribing and records.	18 per cent of administration events involved an error, including wrong time errors (5.5 per cent when wrong time errors are excluded). 40 per cent administration error including wrong time errors. 5.7 per cent excluding wrong time errors (there were 1,295 opportunities for error).
Ridge KW et al. Medication errors during hospital drug rounds. <i>Quality and Safety in Health Care</i> . 1995; 4: 240-243.	Six hospital medicine for the elderly wards	Four months (1993)	Covert observational study of drug rounds with intervention to stop administration error reaching the patient. 37 nurses performing 74 single nurse rounds.	Overall error rate of 3.5 per cent (CI 2.9 per cent to 4.1 per cent) (115 out of 3312 administrations). 68 per cent of errors were omitted medicines, 15 per cent wrong dose. In 98.2 per cent of cases the dose was given within two hours of the time indicated by the prescriber.

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The National Patient Safety Agency

We recognise that healthcare will always involve risks, but these risks can be reduced by analysing and tackling the root causes of patient safety incidents. We are working with NHS staff and organisations to promote an open and fair culture, and to encourage staff to inform their local organisations and the NPSA when things have gone wrong. In this way, we can build a better picture of the patient safety issues that need to be addressed.

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