

Building a safer NHS for patients

IMPROVING MEDICATION SAFETY



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A report by the
Chief Pharmaceutical Officer

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Foreword by the Parliamentary Under Secretary of State for Health

Improving quality of care and patient safety has always been at the heart of the Government's strategy for the NHS. Over the last six years, we have progressively built the capacity and framework to deliver this important objective. Our modernisation programme introduced the concept of clinical governance and set out a coherent vision of quality improvement for the first time in the history of the NHS.

The Chief Medical Officer's report to Ministers in 2000, *An Organisation with a Memory*, set out a challenging agenda for improving care by reporting and learning from adverse events. This innovative approach has attracted attention in health care systems throughout the world. We have moved swiftly to implement its key recommendations.

The National Patient Safety Agency, established in 2001, has the responsibility of improving the safety and quality of patient care through reporting, analysing, and disseminating the lessons of adverse events and 'near misses' involving NHS patients. It is the first truly national agency of its type anywhere in the world.

Our overriding aim is to embed a culture of safety in all NHS treatment, whether in hospitals or in primary care. Ensuring that drug treatment is safe is central to this strategy.

A prescribed medicine is the most frequent treatment provided for patients in the NHS. GPs in England issue more than 660 million prescriptions every year, and there are an estimated 200 million prescriptions in hospitals. Standards of prescribing in this country are high and the majority of drug treatment is provided safely.

However, mistakes do occur. They can arise in the prescribing, dispensing or administration of medicines. And the consequences can be serious for patients, their

family and friends – and for the health professionals involved. We are therefore committed to making drug treatment as safe as possible. This report from the Chief Pharmaceutical Officer is a further step towards this aim. It provides guidance for health professionals and NHS organisations, drawing on experience and good practice within the NHS and worldwide.

With the developing work programme of the National Patient Safety Agency, and as part of our overall drive to improve quality and safety of care, these recommendations will help make drug treatment safer for NHS patients.

A handwritten signature in black ink that reads "Norman Warner". The signature is written in a cursive style with a prominent initial 'N' and a trailing slash at the end of the name.

Lord Norman Warner

Executive summary

- Medication errors occur in all health care systems. Serious errors harm patients and expose health professionals to civil liability and sometimes criminal prosecution. They occur too frequently and they are preventable. Health systems throughout Europe and North America are putting considerable effort into strategies for safer medication use. In the NHS the Government is committed to reducing by 40% the number of serious errors in the use of prescribed drugs, an aim first set out in the Chief Medical Officer's Report, *An Organisation with a Memory*.
- This report explores the causes and frequency of medication errors, highlights drugs and clinical settings that carry particular risks, and identifies models of good practice to reduce risks. The NHS is already rich in examples of good practice, and the report draws on these, together with experience in North America and elsewhere, to describe a wide range of measures that will drive down the risk of medication errors. It contains good practice recommendations in areas which are known to be error prone. These are intended to help NHS organisations and professionals examine current practice to make medication safer for patients.
- The National Patient Safety Agency (NPSA) has been established by the Government to collect, collate, review and analyse error reports and produce and disseminate solutions to ensure that we learn from errors and so reduce risk. Medication errors are an early priority for the NPSA.

Organisations such as the NPSA, the Medicines and Healthcare Products Regulatory Agency (MHRA) and the National Programme for Information Technology in the NHS (NPfIT) should take appropriate issues forward on a national basis.

- Many side effects or adverse reactions to medicines are predictable and are accepted risks of treatment; they can be avoided or minimised by careful medicine prescribing and use. Some adverse reactions are unpredictable and therefore unavoidable. In contrast, medication errors – mistakes, slips or lapses made when medicines are prescribed, dispensed or used – are always avoidable.
- It is important to keep the problem of medication errors in perspective. Most drug treatment in the NHS is provided safely and effectively. For example, more than 660 million prescriptions are written by GPs in England each year, but the defence organisations report less than 200 claims involving medicines against GPs annually. Similarly, there are only about 400 claims against community pharmacists each year for dispensing errors. However, there are no grounds for complacency. As the case examples in this report show, serious errors do occur and they can have devastating consequences for patients.
- Medication errors occur when human and system factors interact with the complex process of prescribing, dispensing and administering drugs to produce an unintended and potentially harmful outcome. Attention is usually focussed on the actions of individuals who are considered to be the cause of error. But latent conditions within an organisation and triggering factors in clinical practice are important causes of error. Checks and error traps should therefore be built in to all medication processes.
- Current guidance and standards on prescribing, dispensing and administration of medicines are fragmented and divided between a range of professional and NHS regulatory bodies. Overarching national standards should be developed linking the various strands of medicines use within the NHS. The NPSA, together with the National Institute for Clinical Excellence, should consider how this can best be taken forward.

The medication process: prescribing, dispensing and administration

- The report sets out the risks of error at all stages of the medication process. Prescribing errors occur for many reasons including inadequate knowledge of the patient and their clinical condition, inadequate knowledge of the drug, calculation errors, illegible handwriting, drug name confusion and poor history taking. Factors such as fatigue and workload may contribute to the risk of error. Key steps for safer prescribing are outlined including:
 - Active management and review of long term repeat prescribing
 - Implementation of the electronic care record and effective electronic prescribing systems
 - Clear treatment plans, shared with all professionals involved in the patient's care
 - Double checking of all complex dose calculations
- Dispensing errors can also cause serious harm to patients. Many dispensing errors are due to drug name confusion, failure to clarify an ambiguous or badly written prescription, similar packaging or lack of a check by a second person. Measures to reduce risk include:
 - Formal dispensary checking systems and procedures
 - Appropriate training and assessment of competency to dispense and check prescriptions accurately
 - Checking medicines with the patient when issued and providing patients with the opportunity to ask questions about their medicines
- Accurate administration of medicines is critically dependent on the quality of all previous steps in the prescribing and dispensing processes. Safe administration cannot be entirely delegated to those actually giving the drug – risk management must be built into the whole medication process. In hospitals drug administration is the final step in a multidisciplinary process. Professionals should work together to integrate the various steps so that the patient receives medicines safely. The report describes a range of measures to ensure safe administration of medicines including:
 - Appropriate training for all staff involved in the handling of medication

- Clear drug administration procedures in all settings where medicines are given
- Double checking by a second person in defined, high risk circumstances, e.g., intravenous infusions, complex calculations
- Discussing medication with patients or carers at the time of administration and involving them in checking where appropriate
- Storing all medicines safely and in such a way that the risk of drug selection errors are minimised, and controlling the availability of high risk drugs
- Utilising information technology to support prescribing, dispensing and medicine administration

Safer use of medicines in people with allergies

- Serious harm has occurred when patients have been prescribed drugs – mainly penicillins – to which they have a pre-existing allergy. Prevention of such errors relies on patient and medicines information being available and acted on at the time of prescribing, dispensing and administration. The patient's allergy history is not always easily accessible with manual prescribing systems. Key measures to reducing the risks include:
 - Clear procedures for the documentation of allergies
 - Staff awareness of their responsibilities in allergy documentation, including updating the allergy record if a new allergy is identified
 - Implementation of electronic prescribing systems with automatic alerts
 - Readily distinguishable wristbands for patients with known allergies
- In addition, the Medicines and Healthcare products Regulatory Agency (MHRA) and NPSA should work with manufacturers to ensure that labelling of penicillins explicitly indicates the nature of the product and carries an appropriate warning.

Safer use of medicines in seriously ill patients

- The complexity of drug treatment in the seriously ill patient carries an increased risk of medication errors, particularly of drugs being given by the wrong route. Such errors may have catastrophic consequences. Oral medications and nebuliser solutions may be inadvertently given by the intravenous route. Intravenous medications may be given by the intrathecal route and *vice versa*. Key measures to reduce the risk include:
 - Using devices for the administration of infusions and feeds only for the purpose for which they are designed
 - Preventing oral and intravenous drugs being taken to the patient's bedside at the same time
 - Labelling the distal ends of all lines to allow positive identification of the site of access
 - Confirming the route of administration during the checking process

Safer use of medicines in children

- A medication error in a child may be more serious than the same error in an adult. The risk is often compounded by the need for additional calculations to determine the dose. Many medicines prescribed for children are only available as adult dose forms. Sometimes complex manipulations are necessary to prepare doses for very small babies. Action to reduce the risks in paediatrics should focus on:
 - Training and competence assessment in paediatric drug therapy including dose and infusion rate calculations
 - Availability of standardised charts or aide-memoires or, preferably, validated computer software for calculating doses and infusion rates for potent drugs, e.g., digoxin and opiates
 - Double checking and documentation of all dose calculations
 - Including the child's age, weight and the intended dose in mg/kg on all prescriptions

Reducing the risks with specific groups of medicines

- The report also identifies a number of medicines where repeated serious errors have occurred and particular effort needs to be made to improve medication safety. These include anaesthetic drugs, oral anticoagulants, cancer chemotherapy, intravenous infusions, methotrexate, opiate analgesics and potassium chloride. This list is not exhaustive and serious errors have occurred with other drugs (for example, insulin). Chapter 5 describes the risks and sets out specific recommendations for improving safety in these areas. In particular:
 - Operating theatre procedures, particularly for the use of anaesthetic drugs in pre-filled syringes and user-applied labels, need to be standardised and strengthened.
 - All patients taking oral anticoagulants should be monitored carefully, the responsibilities of different members of the health care team in anticoagulant therapy should be clearly defined, and there should be regular service audits.
 - There should be a structured multidisciplinary approach to cancer chemotherapy, a standardised approach to dose calculations and national standards for safe medication practice.
 - The range of infusion devices used in hospitals should be standardised, preferably through centralised equipment libraries, and support and training in their use provided for staff.
 - There should be clear and explicit communication about methotrexate dose regimes, and dispensing and prescribing computer systems should incorporate alerts to prevent inappropriate daily dosing.
 - The range of opiate analgesics used in primary and secondary care should be limited. Patients receiving injectable or high-dose oral opiates should be monitored carefully; the antagonist naloxone should be available where appropriate and staff trained in its use.
 - Availability of concentrated potassium solutions in hospitals should be restricted and ready-made bags should be used as widely as possible, in line with NPSA guidance. A national standard should be developed for hazard warnings on ampoules and packs.

Safer medication through improved information management and technology

- The case examples of serious errors contained in this report virtually all involve failure to receive, recognise, interpret or act on drug or patient data. Well-designed and implemented information management solutions therefore offer great potential to reduce the scope for mistakes and lapses. The NHS has, over many years, failed effectively to deploy information management and technology to handle clinical information, including prescribing processes and drug administration.
- In *Delivering the NHS Plan* the Government renewed its commitment to taking forward the NHS information strategy and providing the necessary investment for implementation. Introduction of the national electronic care record is central to this strategy and will ensure that any health professional treating a patient will have access to essential clinical information, including the medicines they are taking. This will provide increased safety in the prescribing, dispensing and administration of medicines. Greater use of electronic prescribing in hospitals, bar-coding technology and robotic dispensing have the potential to reduce further the risk of medication errors.

Safer medication through improved labelling and packaging

- There can be no substitute for carefully reading the label. However, in busy clinical practice other visual cues may be used to aid drug selection. Inappropriate labelling or packaging can be latent conditions that predispose to dispensing and administration errors. The report contains examples of similar drug names and labelling that can lead to selection of the wrong drug
- A working group of the Committee on Safety of Medicines reviewed this area in 2001 and made a range of recommendations to improve the clarity of labelling and packaging. In particular, the working group recommended that five elements of safety-critical information should be brought together in a prominent 'number plate' area of the label. Building on these recommendations, the former Medicines Control Agency (now the MHRA) and other interested parties agreed good practice guidelines which were published in March 2003.
- The information leaflets provided with medicines are important additional checks for patients on the drug and its usual dose and route. It is a legal requirement that a leaflet is provided with all medicines dispensed in primary care, to hospital outpatients or to patients being discharged.

Medication safety at the interface between care settings

- Many medication errors occur at ‘handover points’ within the health care system. The report therefore stresses the critical importance of effective communications when patients move from one care setting to another. Accurate information about current therapy is essential when patients are admitted to hospital to enable a complete clinical assessment and to plan future treatment.
- On discharge, the patient’s drug regimen and treatment plan need to be communicated in a timely and reliable way to ensure safe and seamless transfer of care back to the primary care team. Staff should ensure that patients understand their discharge medicines and can take them properly. Shared care protocols should address medication issues comprehensively – this is particularly important when they include ‘high risk’ drugs such as methotrexate.
- When patients are transferred from home to a care home, or between care homes, the patient may be transferred to the care of a different GP. Effective communication in advance of such transfers will ensure continuity in the supply of medicines.

Education and training for medication safety

- Prescribing, dispensing and administration of medicines are complex and skilled tasks. Health professionals need to be aware of the causes and risks of medication errors and strategies for their prevention. Undergraduate programmes do not always adequately develop the knowledge or skills needed for safe medication. The report contains many examples of good practice and innovation in teaching safe medication at undergraduate and postgraduate level.
- Undergraduate teaching in pharmacology and therapeutics should be strengthened where appropriate. Case studies should be used to teach the risks, causes and prevention of medication errors. Medication safety should be covered comprehensively in induction programmes for new NHS clinical staff, and regularly updated through continuing professional development programmes.

Managing medication safety in NHS organisations

- The report shows how medication errors occur and highlights many examples of good risk reduction practice already in place. But the overall approach has been piecemeal and NHS organisations now need to develop comprehensive strategies to improve medication safety if they are effectively to reduce the incidence of serious errors. PCT and NHS Trust boards should ensure that local strategies are in place, including:

- Systems for reporting and learning from medication errors
 - Building error traps into medication processes
 - Education and training for medication safety
 - Improved communications at the interface
 - Implementation of IM&T solutions
 - Formal structures for managing medication safety
 - Specific measures in high risk areas
- Some NHS trusts have created posts responsible for medication safety across the organisation. Medication safety should be a part of regular clinical audit and PCTs should require information from health care providers on error rates and risk reduction strategies.
 - The direct cost of medication errors in NHS hospitals may be £200-400 million per year. To this must be added the unknown cost of errors in primary and community care, and also indirect costs such as those arising from litigation. The potential savings from reducing serious medication errors are therefore substantial.

Conclusions: safer use of medicines in the NHS

- Awareness of the causes of medication errors and how they can be prevented has been growing in the NHS in recent years. The publication of *An Organisation with a Memory*, the commitment by Government to the aim of a 40% reduction in serious error rates and establishment of the NPSA have, for the first time, provided a systematic focus on medication safety in the NHS.
- This report sets out the scope of the problem and ways of learning from and preventing medication errors. The majority of drug treatment is already provided safely and effectively. But by systematically building on the many examples of good practice contained in the report, professionals and NHS organisations can make significant improvements in the prescribing, dispensing and administration of medicines.

1

Introduction: medication safety – a worldwide health priority

Medication errors occur in all health care systems. Improving safety in the prescribing, dispensing and administration of medicines is a priority for health services in Europe, North America, Australia and many other countries. The Government has set out, for the first time, a clear agenda for improving patient safety in the NHS in England with, as a key element, the aim of a 40% reduction in the incidence of serious medication errors. This is the first truly national patient safety strategy to be developed anywhere in the world. This chapter describes the background to the Government's strategy and the need for action to reduce the frequency of errors. It highlights the repeated pattern of many medication errors and the need to learn from experience to improve patient safety. It sets out the content of the main report, which describes the range of good practice measures that NHS organisations should implement to improve medication safety for their patients.

"I believe in our proverbs. There's one that says 'Everything that happens once can never happen again, but everything that happens twice will surely happen a third time'."

Paulo Coelho, *The Alchemist*

- 1.1** There is evidence from the international literature that medication errors occur in all health care settings. Some errors occur repeatedly not just within one healthcare system, but across healthcare systems worldwide.

In the United States it is estimated that 7,000 deaths each year are caused by medication errors, and that the number of deaths attributed to medication errors has increased 2.57-fold from 2876 in 1983 to 7391 in 1993.¹

The Adverse Drug Event Prevention Study Group in the United States reported that harmful medication errors occurred in 1.8% of admissions.²

Studies in Australian hospitals show that about 1% of all admissions suffered an adverse event as a result of a medication error.^{3,4}

In the UK, 216 claims against GPs handled by the Medical Defence Union between 1995 and 2001 were directly related to errors in prescribing, monitoring or administering medicines.⁵

Of 1000 consecutive claims reported to the Medical Protection Society from 1st July 1996, 193 (19.3%) were associated with medication and prescribing.⁶

- 1.2** The introduction of clinical governance as a key component of the Government's modernisation strategy provided, for the first time, a coherent framework for quality improvement in the NHS. Clinical governance also provides a new imperative for NHS organisations to tackle the problem of adverse events in patient care. The Chief Medical Officer's report *An Organisation with a Memory*, commissioned by Health Ministers, focussed on the scale and nature of serious failures of care and, critically, on how the NHS can learn from service failures to make care safer for patients in the future.⁷
- 1.3** *An Organisation with a Memory* confirmed that, as in most health care systems, there had been little systematic learning from adverse events and service failures in the NHS. As a result, patients suffer unnecessary and avoidable harm because the lessons from past experience have not been heeded. In particular, some specific, rare but very serious adverse events occur time and again, despite repeated inquiries that conclude that 'the lessons must be learned.' The recurrent spinal maladministration of vinca alkaloids is the most notable example. However, similar patterns of repeated errors are seen with other medicines, for example, therapeutic overdoses of digoxin in children, of methotrexate and of opiate analgesics.
- 1.4** Too often, incident enquiries have been characterised by passive learning – where lessons are identified but not carried through into practice – and this is seen in the medication errors that occur repeatedly with 'high risk' drugs. In contrast, patients' interests are best served by active learning – where the lessons are embedded in the organisation's culture and practice. *An Organisation with a Memory* identified a number of barriers which prevented active learning from taking place in the NHS, and concluded that the service needed to develop:

- unified mechanisms for reporting and analysis when things go wrong,
- a more open culture, in which errors can be reported and discussed,
- mechanisms for ensuring the lessons are put into practice, and
- a wider appreciation of the value of the system approach to preventing errors.

1.5 In 2001, *Building a Safer NHS for Patients* set out in more detail the Government's plans for improving patient safety.⁸ It stressed again that repeated patterns of error are seen, which need specific action to reduce risks to patients. It set out steps to be taken in four key areas of serious recurring error.

- To reduce to zero the number of patients dying or being paralysed by maladministered spinal injections
- To reduce by 25% the number of instances of harm in the field of obstetrics and gynaecology which result in litigation
- To reduce by 40% the number of serious errors in the use of prescribed drugs
- To reduce to zero the number of suicides by mental health patients as a result of hanging from non-collapsible bed or shower curtain rails

1.6 The National Patient Safety Agency (NPSA), a special health authority, has been established to collect and analyse information from NHS organisations, assimilate safety related information from reporting systems both in the UK and abroad, learn lessons and ensure that they are fed back into service delivery. It has already issued a Patient Safety Alert to raise awareness of risks and safety precautions associated with concentrated potassium solutions (*see chapter 5.7*). The NPSA has also piloted collection and analysis of data on adverse events, and will be rolling out a National Reporting and Learning System for the NHS in 2004.⁹

1.7 Mandatory national guidance on intrathecal chemotherapy was issued in November 2001 and updated in October 2003. It has now been implemented in all NHS Trusts providing this treatment. This report aims to help NHS organisations and health professionals achieve the much wider aim of a general reduction in serious medication errors. The report draws on the good medication practice that is already in evidence in the NHS, and also on experience from North America and elsewhere. However, the research base in this field is patchy. There are many observational studies that provide data on the

nature and frequency of medication errors, predominantly from the United States. In addition, there is now a growing British literature.

- 1.8** Medication errors carry human costs for the patient, their family and friends, and for the professionals concerned. They also impose a financial burden on the NHS. To date, most estimates of the financial costs come from studies in the hospital sector, particularly in North America. For example, a study of more than 4000 admissions in two US tertiary care centres found that in almost 2% there was a preventable adverse drug event, resulting in a mean increased hospital stay of 4.6 days and additional costs of \$5857. The total cost of preventable adverse drug events in a 700-bedded teaching hospital was estimated to be \$2.8 m per year.¹⁰
- 1.9** A study of 1014 admissions in two London teaching hospitals found that 10% of patients experienced an adverse event, of which half were preventable, adding a mean 8.5 days in hospital with additional costs of £290,000.¹¹ In a broad extrapolation of these findings to the NHS in England, the Department of Health has estimated that adverse events generate up to £2 billion of direct costs in additional bed days.¹²
- 1.10** Medication errors are consistently reported to account for between 10 and 20% of all adverse events. It follows that the direct cost of medication errors in NHS hospitals may be £200-400 million per year. To this must be added the unknown cost of errors in primary and community care, and also indirect costs such as those arising from litigation. The potential savings from reducing serious medication errors are therefore substantial.
- 1.11** We know something of the factors that cause medication errors, particularly in hospitals. But there is little robust research evidence on the effectiveness of interventions to reduce errors – careful studies are needed to evaluate, for example, possible information technology solutions and how checking systems might be improved. The NPSA is working with the NHS Patient Safety Research Programme to commission research into medication errors and their prevention.^{13, 14}
- 1.12** This report is therefore not intended to be prescriptive on the detail of how to reduce medication errors – it is a guide to current knowledge of the frequency, nature and causes errors, the risk factors inherent in current medication processes, and to risks specific to some medicines and patient groups. It provides empirical solutions and also interventions based on clinical experience in the UK and elsewhere. Improving medication safety must be locally driven by health professionals and managers at the front line of patient care. The recommendations and the many examples of current good practice are aimed at

helping NHS organisations and professionals to examine their local practice to make medication safer for patients.

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2

Medication errors: definitions, incidence and causes

2.1 What is a medication error?

While in the vast majority of cases medicines are prescribed and used safely, patients may be harmed by unwanted effects. Many side effects or adverse reactions are predictable and are accepted risks of treatment; they can be avoided or minimised by careful prescribing and use. Some adverse reactions are unpredictable and therefore unavoidable. In contrast, medication errors – mistakes or lapses when medicines are prescribed, dispensed or used – are avoidable. Until the Government established the National Patient Safety Agency in 2001, there had been no attempt to establish a unified mechanism across the whole NHS, including primary and secondary care, for reporting and analysis of medication errors, and no unified system for disseminating the lessons learnt and changes implemented.

2.1.1 Most medication errors do not result in harm to the patient. However, the use of any medicine carries an inherent risk. Patients can experience adverse reactions or side effects from medicines but not all such adverse effects are due to error.

2.1.2 An adverse drug reaction (ADR) has been defined by the World Health Organisation (WHO) as:

“Any response to a drug which is noxious, unintended and occurs at doses used for prophylaxis, diagnosis or therapy.”¹

2.1.3 Adverse drug reactions can be considered to fall into two broad groups – those which can be predicted from knowledge of a drug’s effects on the body (Type A), and adverse drug reactions which are unpredictable, unusual reactions that occur in particular individuals (Type B).² Type B reactions are less common but can be more serious than type A reactions. Adverse drug reactions are reported to the Committee on the Safety of Medicines using the voluntary Yellow Card Reporting Scheme.³

2.1.4 The term medication error has been defined in many ways. The NPSA has adopted the terminology of the US National Co-ordinating Council for Medication Error Reporting and Prevention:⁴

“A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of health professional, patient or consumer.”

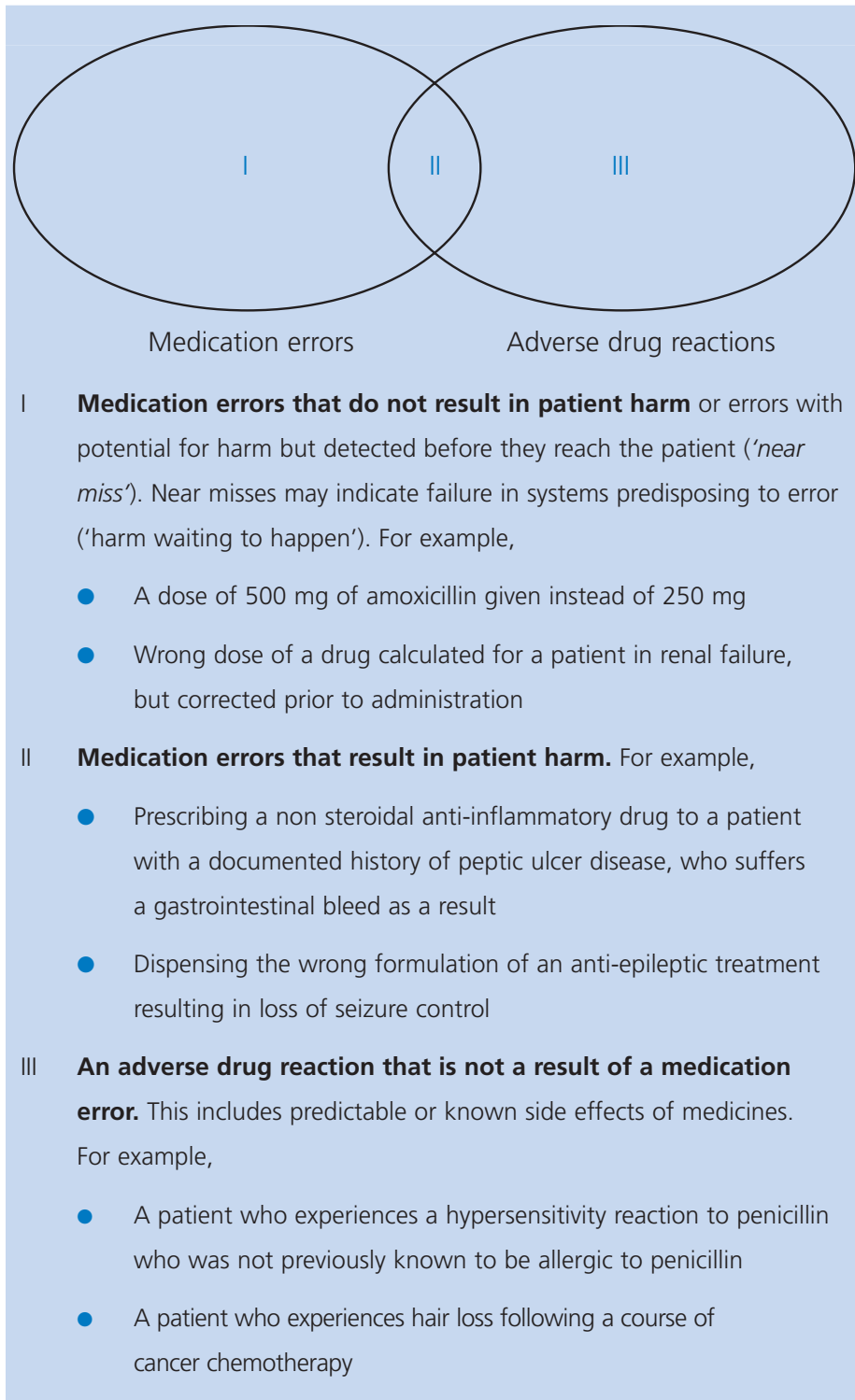
Medication errors may be related to professional practice, products, procedures, environment or systems. They may involve prescribing and ordering; dispensing and distribution; preparation and administration; labelling, packaging and nomenclature; communications and education; or use and monitoring of treatment.

2.1.5 Medication errors are, by definition, preventable. Most errors do not result in harm to the patient. However, the overall incidence of errors is an important indicator of medication safety in an organisation and therefore cannot be ignored. Some medication errors cause serious adverse drug reactions or side effects in patients. Adverse drug reactions which occur following a medication error are therefore preventable.

2.1.6 Figure 2.1 shows the relationship between adverse drug reactions and medication errors. The relative sizes of each category will vary according to the actual rates of medication errors and adverse drug reactions in any healthcare setting.

2.1.7 Many published studies have not clearly defined medication error and do not therefore distinguish between errors and adverse drug reactions. Additionally, the World Health Organization’s International Statistical Classification of Diseases and Related Health Problems (ICD-10)⁵ does not make this distinction. It is important that error reporting schemes clearly differentiate between adverse events that are the result of medication error and those that have occurred during correct therapeutic drug use.

Figure 2.1 Relationship between medication errors and adverse drug reactions

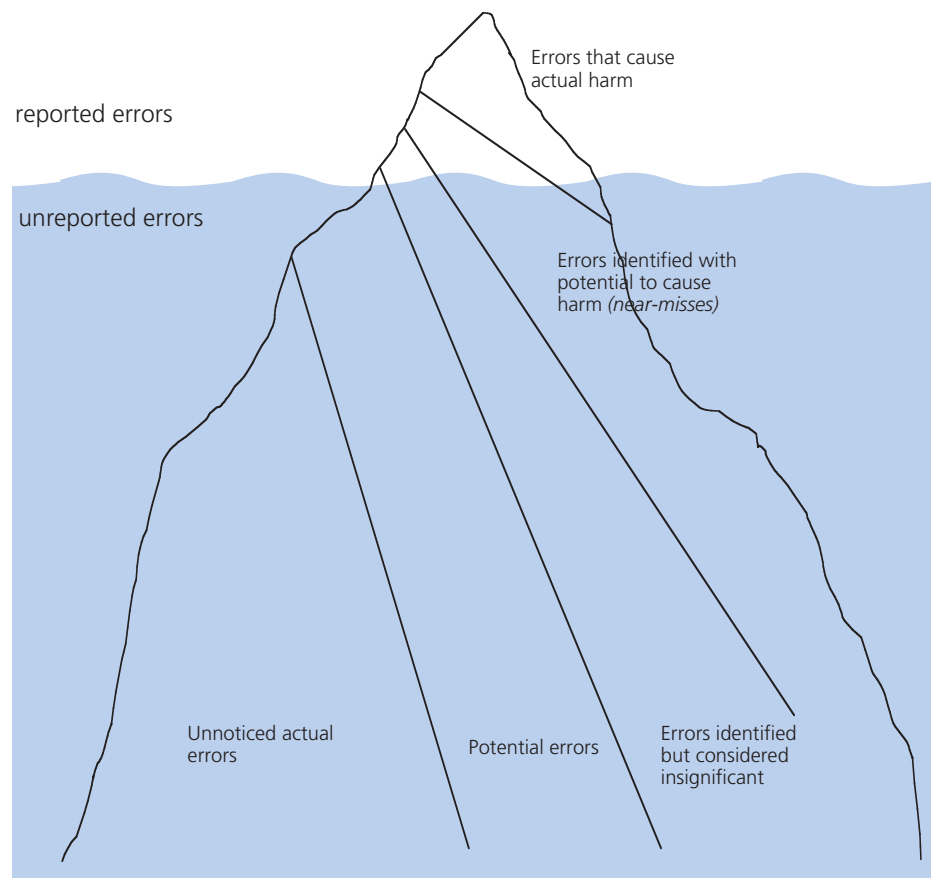


2.2 How often do medication errors occur?

Because of low reporting rates the incidence of medication errors within the NHS is not known. There are many barriers to error reporting. Low reporting rates deny organisations and the NHS as a whole the opportunity to learn from mistakes. The National Patient Safety Agency has been set up to collect, collate, review and analyse error reports and produce and disseminate solutions to reduce risk.

2.2.1 The incidence of medication errors in the NHS is unknown. Errors may be intercepted before they reach the patient. Errors that do reach the patient may be unnoticed. Some errors that are noticed may not be reported where the patient has not come to any harm. In cases where a patient has experienced an untoward event as a result of an error the incident is more likely to be reported.

Figure 2.2 The medication error iceberg



2.2.2 Error reporting is a voluntary and reactive process. Under-reporting may therefore occur for a number of reasons. Reporting relies on error awareness and willingness to report. Fear of discipline may deter the use of incident reports. Because the process is reactive there may be a tendency not to report 'near misses' or potential errors. However, as much can be learned from reporting near misses as from actual errors, and both should be reported.

2.2.3 Heinrich has estimated that, in industry, there is a ratio of one major injury and 29 minor injuries to 300 no-harm accidents.⁶ Analysis and learning from near misses or no-harm accidents can help prevent serious injury. Experience from the aviation industry indicates that a successful reporting system will record an increasing proportion of minor incidents compared with serious events.

2.2.4 Some barriers to the reporting of adverse events and 'near misses' are:

- lack of awareness that an error has occurred
- lack of awareness of the need to report, what to report and why
- perception that the patient is unharmed by the error
- fear of disciplinary action or litigation, for self or colleagues
- lack of familiarity with reporting mechanisms
- loss of self esteem
- staff feeling they are too busy to report
- lack of feedback when errors are reported

“In the great majority of cases the causes of serious errors stretch far beyond the actions of the individuals immediately involved.”

Organisation with a Memory, 2000

2.2.5 In the past the focus of incident analysis has tended to be on the events immediately surrounding an adverse incident and, in particular, the acts or omissions of the people involved. *An Organisation with a Memory* acknowledges that individuals must be accountable for their actions but stresses that serious errors are often caused by wider defects in systems (latent conditions) which lie dormant until they combine, possibly with human error, to precipitate a serious incident. Identification of these defects and conditions through active management of patient safety and effective reporting systems enables them to be removed before they can cause harm to patients.

2.2.6 There are already some systems within the NHS for reporting and learning from medication errors.^{7,8,9} Many organisations have developed their own systems for reporting and reviewing errors to raise awareness of risks. However, these developments have not been integrated, systematic or comprehensive across all NHS organisations.

2.2.7 Until the Government established the National Patient Safety Agency there had been no attempt to establish a unified mechanism across the whole NHS, including primary and secondary care, for reporting and analysis of medication errors, and no unified system for disseminating the lessons learnt and changes implemented. The actual number of injuries and deaths that can be attributed to medication errors in the NHS is therefore unknown.

However, 9% of incidents reported to the NPSA in its pilot data audit (PDA) involved medicines.¹⁰ And we know that in the UK, 216 claims handled by the Medical Defence Union over a six year period arose from medication errors,¹¹ and of 1000 claims reported to the Medical Protection Society, almost 20% arose from medication errors.¹²

Medication errors occur in other health care systems; it is estimated that harmful errors occur in 1.8% of hospital admissions in the United States,¹³ leading to about 7,000 deaths each year.¹⁴ Similarly, an Australian study showed that 0.8% of inpatients suffered a harmful medication error.¹⁵

2.2.8 Despite uncertainty about the baseline frequency of medication errors, it is clear from international research studies and reports from NHS organisations that the incidence of errors causing serious harm to patients can be significantly reduced. *Building a Safer NHS for Patients*¹⁶ therefore set out clear aims for reducing error rates.

2.2.9 The Government established the National Patient Safety Agency¹⁷ in July 2001 as a special health authority. In 2004 the NPSA will implement a national reporting and learning system to enable the NHS to report all types of adverse incidents including those involving medicines. The core purpose of this system is to improve patient safety. The NPSA will identify patterns and trends in avoidable adverse events so that the NHS can change practice and management to reduce the risk of recurrence.

2.2.10 NHS boards should actively promote incident reporting within their organisations. The emphasis should be to identify risks and propose solutions to avoid future errors. Whilst individuals involved must be accountable for their actions they should not be inappropriately blamed for errors that occur. The NPSA is developing an Incident Decision Tree to assist managers in deciding the most appropriate course of action to be taken following a serious incident.¹⁸

2.3 Why do medication errors occur?

In order to reduce the risks, it is important to understand what causes medication errors. Errors occur when both human and system factors interact in a chain of events – often complex – resulting in an undesirable outcome. Too often it is only the actions of individuals which are considered to be the cause of error. Latent conditions within an organisation and triggering factors in clinical practice should also be considered as important causes of error.

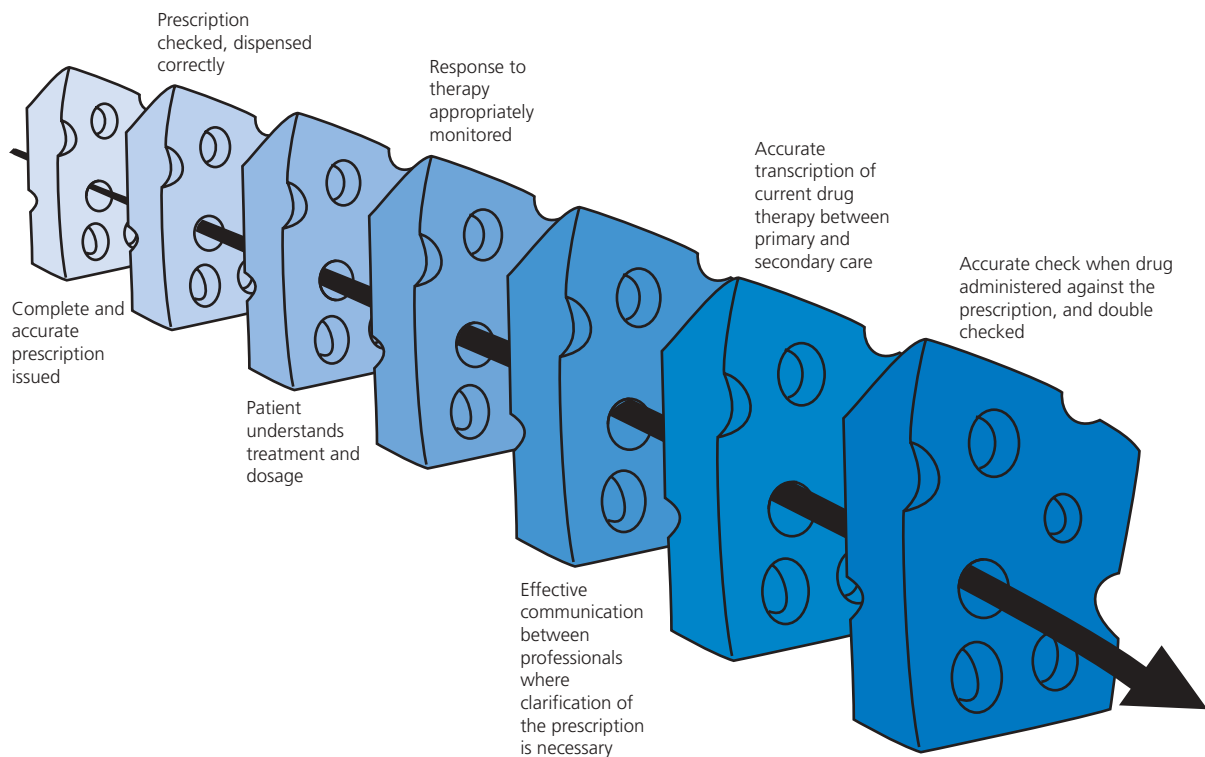
“Human beings make mistakes because the systems, tasks and processes they work in are poorly designed.”

Lucian Leape

- 2.3.1** The majority of medication is prescribed, dispensed and administered safely. The overwhelming majority of NHS staff are highly motivated individuals who work together as a team to achieve the best outcomes for their patients. However, the risk of error is inevitable in any industry or profession and mistakes do occasionally occur. Errors that result in serious harm to patients are always distressing, not just for the individual or family affected but also for staff and organisations associated with the error. Harmful medication errors are particularly distressing as they occur at a very personal level and confound the aim of treatment, which is to improve health.
- 2.3.2** NHS organisations and health professionals have put in place a range of systems and checks to prevent medication errors. However, recent experience has shown that in certain situations those safeguards have not been adequate and have failed to prevent serious error and harm to patients.
- 2.3.3** Current guidance and standards on prescribing, dispensing and administration of medicines are fragmented and divided between a range of professional and regulatory bodies. They are often written from a unidisciplinary perspective to meet professional rather than organisational aims.
- 2.3.4** The ‘Swiss cheese model’ of system failure can be readily applied to medication errors.¹⁹ Each slice of cheese represents a defence, barrier or safeguard against error. Ideally all the defences should be intact, but in reality the layers are full of holes.
- 2.3.5** An error may get through holes in one or more layers of defence but be stopped at another stage in the process. The more layers of defence there are and the lower the likelihood of holes in those defences opening up, the lower the risk of a damaging error or accident occurring. Therefore in a well-designed system,

with inbuilt and robust safeguards and defences, an error would rarely be able to get through to cause harm.

Figure 2.3 Swiss cheese model of error prevention: some layers of defence against medication error. In a number of recent fatal medication errors effective operation of any one of these defences would have saved a life.



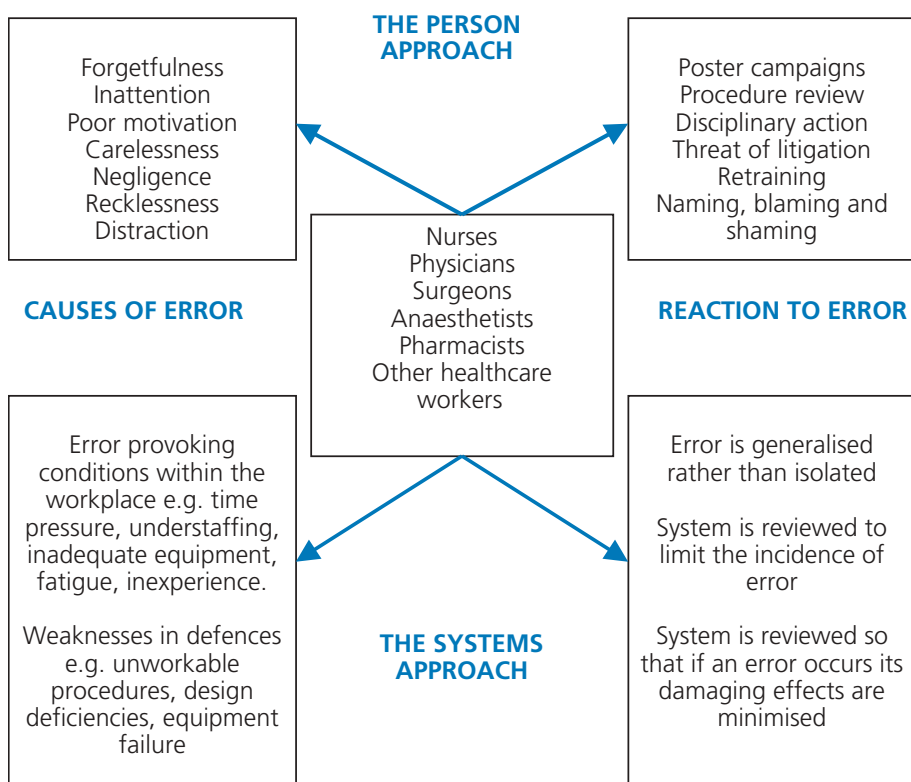
Holes in the defences open up as a result of active failures and latent conditions. The active failures are unsafe practices of the people working with a system, for example the prescriber failing to double check a prescription, or the pharmacist failing to identify an incorrect dose on a prescription. Latent conditions reflect the structure of the organisation, its resources, management and processes which, either alone or in combination with an active failure, can result in error. For example, the lack of a computerised prescribing system with inbuilt systems to highlight an erroneous prescription or the lack of an effective communication system between primary and secondary care.

2.3.6 Two approaches to human error have been described:²⁰ the person approach and the systems approach. The person approach focuses on the errors made by individuals. The reaction to these errors tends to be to name, blame and shame. Although professionals must take responsibility for their actions, blaming doctors, pharmacists or nurses for errors does not encourage a culture of

reporting or learning. In order to function safely an organisation needs to understand its risks so that it can minimise them by building in defences and safeguards. These risks can only be identified if there is commitment to an open culture of reporting throughout the organisation.

2.3.7 The systems approach accepts that humans are fallible and therefore errors can be expected to occur – and may recur regardless of the competence of individuals working within the system. Rather than focusing on the individual it focuses on the conditions under which individuals work and how those conditions can predispose to errors. Understanding the conditions that may predispose to error enables system defences to be developed such that the errors are avoided.

Figure 2.4 The person and systems approaches to medication error



2.3.8 An error occurs when a planned action fails to achieve a desired outcome. Reason described two basic types of error:²¹

- **Slips and lapses**, where the actions do not go according to plan, for example; omitting to administer a prescribed drug to a hospital patient, *intending* to write a prescription for 100 mg of a drug but writing 300 mg instead.

- **Mistakes**, where the plan itself is inadequate to achieve its objectives; failing to prescribe a drug that is indicated in a patient, writing a prescription for 300 mg of a drug *not knowing* that the usual dose is 100 mg.

2.3.9 In order to design safe systems it is essential that the causes of errors are understood. Systematic analysis of incidents must be carried out to gain that understanding. In ‘high risk’ industries such as aviation, oil and nuclear power formal investigation of incidents is well established. In these industries and in medicine studies of accident causation have highlighted the complexity of the chains of events leading to adverse outcomes. Such a chain of events leading up to the inadvertent administration of vincristine by spinal injection has been described.²²

2.3.10 In any analysis it is important that all contributory factors are considered. These include the actions of individuals, the clinical context and patient factors at the time, the conditions in which the error occurred and the wider organisational context.²³ The National Patient Safety Agency is developing a process for analysing reported incidents retrospectively, including root cause analysis.²⁴

Identifying and addressing the risks

A prospective technique of ‘failure mode and effects analysis’ has been developed in non-healthcare industries. A process is analysed to identify possible or likely errors and predict what their impact might be. Action can then be taken to minimise the risk or ameliorate the consequences when a potential error cannot be eliminated. This technique has been applied in healthcare by tracking the medication process from start to finish by a multidisciplinary group. Each element of the process is listed and the potential for error is identified at each stage. Error preventing actions or ‘error traps’ can then be designed into the process.^{25,26}

2.3.11 Examples of error traps that can be established using failure mode and effects analysis include:

Removing the hazard

- Eliminate high risk items or procedures, e.g., prepare all dilutions of strong potassium chloride in the pharmacy rather than on wards
- Limit use or access, e.g., intravenous vincristine
- Control storage, e.g., separate drugs with similar packaging in the dispensary or on the ward
- Design systems to avoid look-alike containers, names, computer abbreviations, poor labelling

Alerting staff to imminent error

- Hazard warnings and signs, e.g., prominent documentation of allergy status
- Warning messages in electronic prescribing systems
- Alarms on infusion pumps
- Warning labels on potentially hazardous drugs, e.g., vincristine, potassium, penicillins

Preventing completion of hazardous action

- Failsafe devices, e.g., infusion pumps that will not deliver outside a defined rate
- 'Lock and key' design, e.g., use of oral syringes incompatible with intravenous access, use of non-luer spinal connectors
- Information technology, e.g., electronic systems which prevent prescribing of a penicillin to a patient with known allergy

Minimising the consequences of error

- Availability of extravasation kits with staff trained to use them
- Automatic co-prescribing of antidotes with hazardous drugs, so that they can be given quickly if needed, e.g., naloxone with intravenous opiates
- Availability of flumazenil in all locations where midazolam is used

NHS Trusts in Yorkshire have collaborated in a human error risk reduction programme. The ERR[®] programme has been designed to help pharmacy staff develop the capability to reduce risk within their operations. Training aims to:

- **increase understanding of human error**
- **develop practical knowledge of how to identify vulnerable activities and investigate incidents**
- **develop ways of reducing effects of risk factors**

The programme provides a combination of ‘classroom’ activities and live project work focused on the problems likely to be met in practice, and helps the Trust to develop a knowledge base that will enable staff to systematically, progressively and proactively reduce the incidence of error.^{28,29}

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3

The medication process: prescribing, dispensing and administration of medicines

3.1 Safer prescribing of medicines

About 1.8 million prescriptions are written by general practitioners in England every day and an estimated 0.5 million in hospitals.¹ The standard of prescribing is generally high but patients are too frequently harmed through avoidable errors. Prescribing errors occur for a variety of reasons including inadequate knowledge of the patient and their clinical condition, inadequate knowledge of the drug, calculation errors, illegible handwriting, drug name confusion, and poor history taking. Personal and environmental factors such as fatigue and workload are also important contributory factors. Prescribing error is potentially the most serious of all types of medication error as, unless detected, it may be repeated systematically for a prolonged period.² It is important that all prescribers, whether doctors or, increasingly, nurses, pharmacists and other health professionals are aware of the principles of safe prescribing and of potential risks.

How often do prescribing errors occur?

- 3.1.1** Research studies have used varying definitions of prescribing error, and published data are drawn mainly from hospital practice. However, many of the principles affecting the quality of prescribing are common between primary and secondary care.
- 3.1.2** There is no generally accepted definition of what constitutes a prescribing error. Published studies using different definitions cannot be compared or generalised

to estimate prescribing error rates in different healthcare settings. A recent UK report³ adopted the following definition:

“A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant reduction in the probability of treatment being timely and effective or an increase in the risk of harm when compared with generally accepted practice.”

- 3.1.3** The absolute frequency of prescribing errors leading to patient harm is not known. Almost all studies have involved detection of errors by pharmacists, and avoidance of harm to patients.

A study in two US hospitals found that preventable adverse drug events, including medication errors and adverse drug reactions, occur in 1.8% of patients admitted to hospital.⁴

Over 1 year in a US hospital 2103 clinically significant prescribing errors were identified and averted by pharmacists, representing an overall prescribing error rate of approximately 0.4%. Forty-three of these were classified as potentially fatal or severe – corresponding to about 1 in 10,000 of all prescriptions.⁵

In a study of 550,000 prescriptions written by GPs in the UK pharmacists identified and averted potentially serious errors in 54 cases (1 in 10,000, 0.01%).⁶

In one UK hospital, potentially serious errors which were identified and averted by pharmacists, occurred in 0.4% of prescriptions. The majority of errors (54%) were associated with choice of dose and most serious errors originated in the prescribing decision.⁷

What are the causes of prescribing errors?

- 3.1.4** Prescribing errors may arise in the decision making process or in prescription writing. Errors in decision making may be due to lack of knowledge about the patient, drug or both. Monitoring of treatment may be inadequate or lacking. Errors in prescription writing may be due to poor communications, inaccurate transcription, or unsigned or illegible prescriptions.
- 3.1.5** Errors may be due to person or systems factors or a combination. Typically, many factors contribute to any prescribing error.

Human error theory was used to investigate the causes of 44 prescribing errors in a UK hospital. Forty-one doctors were interviewed to assess reasons for the prescribing error. A questionnaire was used to investigate the factors which may have contributed to the error. Most mistakes were made because of slips in

attention, or failure to apply relevant rules. Risk factors identified included work environment, workload, whether they were prescribing for their own patient, communication with the team, physical and mental well-being, and lack of knowledge. Organisational factors including inadequate training, low perceived importance of prescribing, a hierarchical medical team and an absence of self-awareness of errors were also identified.⁸

- 3.1.6** A particular error may recur but be caused by a different set of circumstances. Two examples of how different factors may contribute to the administration of 10-fold overdoses of heparin are described.

Figure 3.1 Different causes of erroneous administration of a 10-fold overdose of heparin

Cause	Error
The abbreviation 'o' is used to denote a unit of blood. Some medicines are also prescribed in units, for example, heparin and insulin. If the abbreviation 'o' is used when prescribing medicines it may be read as a zero resulting in a 10-times overdose.	Heparin 500 o IV was prescribed as a flush for a patient who was receiving medicines through an intravenous line. The prescription was misread by the nurse as 5000 units and this dose was administered.
Heparin, 5000 units, is prescribed widely on medical and surgical wards to prevent the formation of blood clots in veins. Less often, 500 units is prescribed to flush intravenous lines. Nursing staff, unfamiliar with this dose and route of administration, may misinterpret the prescription in favour of the dose and route they are most familiar with.	Heparin 500 units IV was prescribed. This was intended to be a flush for an intravenous line. The nurse was unfamiliar with this dose and route and gave 5000 units subcutaneously ⁹

Lack of knowledge and information about the patient

Lack of knowledge and lack of timely access to patient information have been identified as major root causes of medication prescribing errors.¹⁰

- 3.1.7** In hospitals junior doctors who have the least experience do most prescribing. Often they will be prescribing in complex clinical situations they have not seen

before. They may be working in new surroundings with unfamiliar systems as part of their rotational training and, like people in all occupations, are subject to stress, tiredness and distractions.

- 3.1.8** They have to make decisions based on the information available to them at the time – their own knowledge of the disease and its treatment, and their knowledge of the patient. In many instances, unable quickly to access information from case notes, doctors rely on memory when prescribing. Where admission to hospital is unplanned there may be delays in retrieving patients' case notes from storage in medical record libraries. Therefore, important information about the patient's previous medical history may not be available until the case notes are available.
- 3.1.9** Examples of situations in which errors may occur include:
- being called to a ward to prescribe for a female patient without being aware that she is pregnant
 - prescribing a low-molecular-weight heparin for a patient without knowing the patient's weight, which is needed to calculate the dose
 - prescribing a non-steroidal anti-inflammatory drug to a patient without knowing that the patient has a history of peptic ulcer disease.
- 3.1.10** Errors may similarly occur within primary care. When a service user is admitted to a care home there is a possibility that the medical care will be transferred to a different GP. The care home staff will make an early request for any prescribed medication and the GP may face the dilemma of being asked to prescribe without adequate information about the patient or their clinical condition.
- 3.1.11** Errors in prescribing may occur in the care home environment due to prescribing decisions being inadequately recorded. Decisions made by the GP during a visit to a care home must be incorporated into the patient's records in a timely manner to prevent medication error.
- 3.1.12** Failure to consider relevant clinical information may make it impossible for the prescriber to take into account the effect of the disease and physiological status on drug handling. These are well recognised as risk factors for drug toxicity.

Lack of knowledge and information about the drug

- 3.1.13** Lack of drug knowledge can lead to prescribing of drugs that are contraindicated or combinations that may cause harmful drug interactions. Lack of knowledge of drug metabolism and elimination may result in failure to adjust a dose in the light of the patient's condition. For example:

- prescribing a usual adult dose of digoxin, which is normally excreted by the kidney, to a patient with severe renal failure, when the dose should be lowered to reduce the risk of toxicity
- prescribing a combination antibiotic e.g., co-amoxiclav (Augmentin®), for a penicillin allergic patient without being aware that the combination includes a penicillin
- prescribing a beta-blocker for an asthmatic patient without realising that the drug is contraindicated in asthma
- prescribing the cholesterol-lowering drug simvastatin to a patient taking regular warfarin without realising that there is a risk of overanticoagulation

Calculation errors

3.1.14 Most medicines are available in formulations that correspond to their usual dose. However, for some potent medicines prescribed for adults and many medicines for children, the dose, volume or rate of administration needs to be calculated. These calculations can be complex and are major sources of prescribing error. The risk of error may be compounded by the different ways in which concentrations of drugs in solutions may be expressed; for example dilution (1 in 1000), mass concentration (1 mg in 1 ml) and percentage concentration (0.1 %).

In an American study more than 1 in 6 errors involved miscalculation of doses, wrong decimal point placement (10 fold errors), incorrect expression of unit of measurement or concentration, or incorrect administration rate.¹¹

In a British study 150 doctors in a teaching hospital were asked to complete a written questionnaire about drug dilution and concentration. About half were unable to convert doses correctly from a percentage concentration or dilution to the more conventional mass concentration. Recognising this as a cause for concern the authors suggested that all drugs should be measured in a standard way – as a mass concentration.¹²

3.1.15 Calculation errors occur commonly in paediatric practice where doses used can vary widely according to the body weight of the child.

Case 1. Death of a premature baby as a result of a morphine overdose

A junior doctor miscalculated a dose of intravenous morphine resulting in the administration of a 100 times overdose. The dose was calculated as 0.15 milligrams but the decimal point was inserted in the wrong place and a dose of 15 milligrams was prescribed. The dose was administered to a premature baby who tragically died despite treatment with the antidote, naloxone.¹³

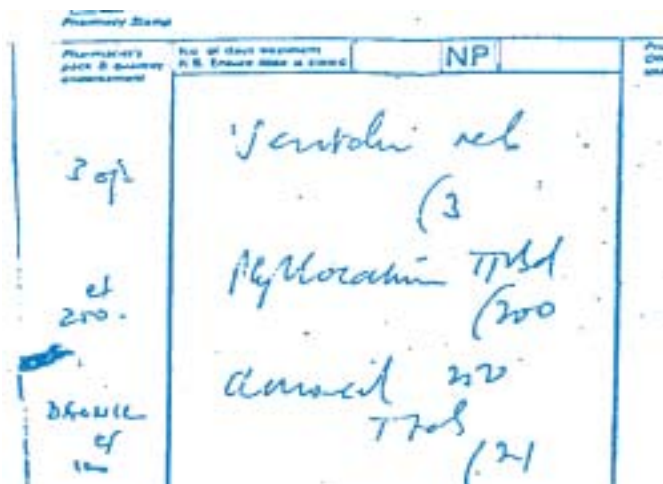
Illegible prescriptions

A study assessing the quality of written inpatient prescriptions found that of 4,536 prescriptions 4 to 10 percent were illegible or ambiguous.¹⁴

- 3.1.16** Illegible prescriptions are a major cause of medication error. They force the person reading the prescription to make their own interpretation. If that interpretation is wrong the drug may be incorrectly transcribed by another doctor, incorrectly dispensed by the pharmacist or incorrectly administered by a nurse. In all instances the patient is at risk. The prescription should always be clear, unambiguous and leave no doubt as to the prescriber's intentions.

Case 2. Antidiabetic drug dispensed instead of antibiotic resulting in harm

A man suffered irreversible brain damage after a pharmacist misread his doctor's prescription. The patient had been prescribed the antibiotic Amoxil® (amoxicillin) for a chest infection. The prescription was badly written and the pharmacist misread the drug name as Daonil® (glibenclamide) a drug used to lower blood sugar in people with diabetes. As a result of taking the wrong medicine the patient went into a coma and was hospitalised for 5 months. He suffered blunted intellect and poor short-term memory as a direct result of the medication error.¹⁵



Case 3. Illegible prescription results in fatal dispensing error

An American example illustrates how drugs which look alike when hand written can be confused. A pharmacist dispensed the antihypertensive felodipine (Plendil®) 20mg four times a day having misread a prescription for 'Isordil', used to treat angina, 20mg four times a day. The patient died following a cardiac arrest.¹⁶

Case 4. Thyroxine on illegible prescription dispensed as methotrexate

A man was prescribed thyroxine 25 micrograms daily on discharge from hospital. The prescription was badly written and read and dispensed as methotrexate 2.5 mg. The patient developed an abnormal blood count and died following an associated infection.¹⁷

- 3.1.17** Illegible prescriptions make it difficult to interpret doses. There are many cases where this has resulted in 10-fold overdoses and serious harm to patients.

Case 5. Ten-fold error leading to fatal overdose of epidural diamorphine.

A patient died at a leading private hospital after a prescription was misread. An epidural infusion of diamorphine was prescribed for post-operative pain relief. The prescription was misread as 30 mg in 10 ml instead of 3 mg in 10 ml by both a nurse and a junior doctor.¹⁸

Case 6. Ten-fold error in insulin dosing as a result of misinterpretation of prescription

Two patients in different nursing homes received incorrect insulin doses. In both cases the word 'units' had been abbreviated to 'IU', meaning international units, on the label and on the medicine administration record. The doses were misread as 61 U instead of 6 IU. The patients required hospital admission as a result of the ten-fold overdoses.¹⁹

Drug name confusion

- 3.1.18** Medicines with similar sounding names and drug names that look alike when hand-written may result in prescribing or transcription errors.

Case 7. Fatal confusion between 'Losec'® and 'Lasix'®.

A 59 year old woman in a Belgian hospital suffered a cardiac arrest which was attributed to low serum potassium. Review of the medical record revealed a transcription error. A poorly written prescription for 'Losec'®, an ulcer-healing medicine, had been misread and incorrectly transcribed by a nurse who instead gave the patient 'Lasix'®, a drug which is known to lower potassium levels.²⁰

- 3.1.19** Drugs in the same class may have similar prefixes or suffixes. While this may help with awareness of the clinical use of the drug (drugs within the same class often have a similar range of indications) it may also make them look similar or sound similar. This can be a source of error with potentially serious consequences especially if the doses in which the two products that have been confused vary widely, for example amlodipine and nimodipine.

The Royal Liverpool Children's NHS Trust conducts a formal risk assessment when new products are introduced into practice to ensure that risks from drug name confusion or other characteristics of the new drug are identified and addressed.²¹

In the US the Institute of Safe Medication Practices invites practitioners to conduct a confidential safety review on brand names being proposed for new pharmaceutical products. Comments on characteristics of the proposed name such as look-alike letters and names, sound-alike names, names that look like a common medical term or abbreviation, and dose ranges are invited. Handwritten examples of the proposed drug names are included.²²

- 3.1.20** Drugs with similar names sometimes have totally unrelated uses, for example, clomipramine (an antidepressant) and clomifene previously known as clomiphene (an anti-oestrogen used to treat subfertility), chlorpromazine (an antipsychotic) and chlorpropamide (an antidiabetic drug). They are likely to be adjacent to each other in drug indexes, on computer systems and on dispensary shelves. Confusion between these drugs has led to a number of serious errors.

At least seven such errors are known to have harmed patients leading to clinical negligence claims.^{23,24}

3.1.21 The 'Co'- nomenclature used to denote drug combinations may also cause confusion, for example; coprenozide and coproxamol, coflumactone and cofluampicil.

3.1.22 European medicines legislation requires the adoption of recommended international non-proprietary names (rINN).²⁵ New names for a small number of medicines could present an additional risk during the transitional period.

Dosage formulation

3.1.23 Health professionals may not appreciate the important distinguishing properties of different dosage forms available for certain medicines (e.g., controlled-release versus immediate-release tablets). This can lead to inappropriate use of dosage forms and potential risk to the patient. Errors associated with dosage forms account for up to 15% of prescribing errors.²⁶ Dosage formulations at particular risk of error include:

- Medicines with a wide dose range and multiple tablet/capsule size
- Oral controlled release forms
- Dosage forms with unusual frequency of administration
- Oral liquid formulations requiring reconstitution, dilution or dose measurement
- Oral liquids where multiple concentrations are available
- Multiple dose injectables
- Injectables with more than one concentration or size of vial
- Injectables with complicated or unusual preparation processes
- Non intravenous injectables
- Complex and/or difficult to use delivery devices

Use of abbreviations

3.1.24 Abbreviation of drug names can lead to significant error. Abbreviations are sometimes used for brevity but risk being misinterpreted. Some abbreviations used as a convenient short cut to prescribing long generic drug names may be confused with shorter trade names for different drugs; for example , the

abbreviation 'ISMN' for isosorbide mononitrate has been read as Istin®, the proprietary name for amlodipine.

Case 8. Istin prescribed instead of isosorbide mononitrate

A patient was discharged from hospital with a supply of isosorbide mononitrate tablets. The referral letter sent to the GP following the patient's discharge requested that 'ISMN' was to be continued. This was misread by the GP as Istin® (Amlodipine) which was subsequently prescribed and dispensed. The error was identified by the patient who suffered no ill effects.²⁷

The US Institute for Safe Medication Practices has issued a bulletin entitled 'do not use these dangerous abbreviations or dose designations'. This includes a table listing the abbreviation, intended meaning, misinterpretation and best practice for writing the drug name.

Examples listed include:

- **M₄SO₄, intended to mean morphine sulphate but misinterpreted as magnesium sulphate**
- **ARA^oA intended to mean vidarabine but misinterpreted as cytarabine (ARA^c)**
- **HCT intended to mean hydrocortisone but misinterpreted as hydrochlorothiazide**
- **AZT intended to mean zidovudine but misinterpreted as azathioprine**

Use of zeros and decimal points

3.1.25 Positioning of zeros and decimal points is a frequent cause of serious prescribing error. 'Trailing' zeros should never be used. For example 1.0 mg, intended to mean 1 mg, may be misread as 10 mg if the decimal point is not seen, resulting in a 10-fold overdose. Leading zeros should always be used. Otherwise a prescription for .1 mg may be misread as 1 mg with the same serious consequence.²⁹

The British National Formulary (BNF) provides guidance on prescription writing.³⁰

- Unnecessary use of decimal points should be avoided e.g. 3 mg not 3.0 mg
- Quantities of 1 gram or more should be written as 1 g etc.
- Quantities less than 1 g should be written in milligrams, e.g. 500 mg not 0.5 g
- Quantities less than 1 mg should be written as micrograms, e.g. 100 micrograms not 0.1 mg
- When decimals are unavoidable a zero should be written in front of the decimal point where there is no other figure, e.g. 0.5 ml, not .5 ml.
- Use of the decimal point is acceptable to express a range e.g. 0.5 to 1 g.

Unusual routes of drug administration

3.1.26 Some products are intended for administration by only one route. The dose of the drug may vary according to the route of administration, for example; up to 160 mg of propranolol, a drug for angina and hypertension, may be given by mouth but only 1 mg intravenously. Drugs may therefore be administered incorrectly if the route of administration is not clear or the dose prescribed is for the wrong route. When prescribing for an unusual route, care should be taken to ensure that the correct formulation of the drug is specified.

Uncommon dosage regimens

3.1.27 Drugs are usually prescribed to be administered once or several times daily. Occasionally drugs are taken less frequently, e.g., methotrexate is prescribed to be taken weekly in the treatment of rheumatoid disease and psoriasis; some medicines taken by travellers for malaria prophylaxis are taken weekly. Because a doctor will only rarely prescribe this regimen it is easy to write 'daily' on the prescription, especially if the prescription is written by a junior doctor or a doctor acting outside his area of expertise. This can have catastrophic consequences as highlighted in the recurring problem of prescribed methotrexate overdoses (*see chapter 5.5*)

Case 9. Prescribed overdose of alendronate

A patient was prescribed Fosamax (alendronate) 70 mg once a week for prevention of osteoporosis as a hospital inpatient. Fosamax 70 mg daily was prescribed on the discharge prescription, potentially exposing the patient to a high risk of adverse effects. The error was corrected by the pharmacist prior to dispensing.³¹

Complicated dosage regimens

3.1.28 Drugs may be prescribed in unusual or complex regimens, e.g., gentamicin in renal impairment, chemotherapy infusion regimens. Prescribers should ensure that they understand the rationale behind such dosing regimens and ensure that the prescription is written in a way that their intention is clear and fully understood by other members of the clinical team.

Case 10. Prescribed overdose of cyclophosphamide

A 39 year old woman received a drug overdose during treatment for metastatic breast cancer at a US hospital. The protocol stated that the cyclophosphamide dose was 4 g/m² over four days. The patient received 4 g/m² daily for four days. She died as a result of the toxic effects of the cyclophosphamide on her heart.³²

Poor history taking

3.1.29 An accurate medication history is essential for safe prescribing. Patients may already be taking drugs that interact with, or duplicate, new treatments. Often they do not take all the drugs that are prescribed for them. They may self-medicate with over-the-counter (OTC) medicines, herbal or complementary remedies. Additionally they may be taking medicines from a previous course of treatment that is no longer appropriate. Establishing an accurate medication history is particularly important when patients have been transferred between primary and secondary care (*see chapter 6.3*).

In a study in older people at the University Hospital of North Durham, a structured review of patients' medication was conducted after admission. An average of almost 1 drug per patient was found to be inappropriate and stopped. An average of approximately 1 drug per 2 patients was started following identification of omissions in the drug history.³³

Repeat prescribing

3.1.30 Repeat prescribing in primary care may be a source of error, especially in the absence of a protocol. Repeat prescribing systems may make it difficult to ensure that therapy is adequately monitored or reviewed. Patients may continue to be prescribed medicines which are no longer necessary.

A study in general practice in 1996 found that 66% of repeat prescriptions showed no evidence of authorisation by a doctor, and 72% of repeat prescriptions showed no evidence of having been reviewed in the previous 15 months.³⁴

The Medical Protection Society is developing a toolkit for General Practice to promote safer prescribing. It will contain resources such as repeat prescribing guidelines and guidelines on prescribing controlled drugs.³⁵

3.1.31 In general practice the practice manager or receptionist often initiates repeat prescriptions. Administrative staff involved in repeat prescribing arrangements should receive appropriate training and should work to clearly defined procedures.

Reducing the risk of prescribing errors

- Adverse drug reactions should be reported to the Committee on the Safety of Medicines, and prescribing errors should be reported through the NPSA national reporting and learning scheme.
- In accordance with General Medical Council Standards of Practice,³⁶ doctors should prescribe drugs or treatment, including repeat prescriptions only when they have adequate knowledge of the patients' health and medical needs.
- New prescribers, for example, nurses, pharmacists and, ultimately, other health professionals should prescribe in accordance with the relevant guidance.^{37,38}
- British National Formulary guidance should be followed when writing prescriptions, with particular attention to the use of abbreviations, decimal points and zeros. Calculations should be double-checked. The completed prescription should be reread to ensure it is correct.

- Experience of prescribing errors should be shared with colleagues in a critical incident review process.
- Prescribers should be aware of all patient characteristics that may affect the choice of drug or dosage regimen and adjust the treatment plan accordingly. They should review relevant drug-related information prior to prescribing.
- Prescribers should have ready access to therapeutic guidelines and pathways, especially for complex or potentially toxic treatments.
- If unsure about the choice of drug, dose or route for a patient, prescribers should always seek advice from a senior colleague or pharmacist.
- Electronic prescribing systems, linked to the patient record, may reduce the risk of many prescribing errors (*see chapter 6.1*).
- The treatment plan should include monitoring for therapeutic and adverse effects of drugs. The treatment plan and any subsequent changes should be documented in the patient's clinical notes. Wherever possible a pharmacist should be available to provide advice on the drug treatment plan.
- Prescribers should discuss proposed treatment with patients wherever possible, and check that they understand the aims and potential side effects. The instruction 'as directed' should never be used on prescriptions.
- Prescribers and NHS managers should be aware of the factors that predispose to error. The environment for prescribing should take these factors into account and minimise distractions.
- Prescribers should be made aware at induction of the need to comply with local and national prescription writing standards. Audit and feedback via the clinical governance structure within an organisation should be used to promote adherence to prescribing standards.
- All NHS organisations should take particular care when new drugs, formulations or drug names are introduced to assess whether these present new risks.
- The MHRA, the NPSA, NHS organisations and professional bodies should ensure that the potential risks of the transition to recommended international non-proprietary names (rINNs) are minimised through an active programme of awareness and education.

3.2 Safer dispensing of medicines

Data from hospitals suggest that dispensing errors occur less frequently than prescribing errors, but can nevertheless cause serious harm to patients. The nature of dispensing errors is unlikely to vary significantly between hospitals, community pharmacies or dispensing doctors. Many dispensing errors are a result of drug name confusion, failure to clarify an ambiguous or badly written prescription, similar packaging or lack of a check by a second person. There are few published data on the type, frequency and causes of dispensing errors. The collection and review of such data should be encouraged to enable causes to be identified and addressed.

3.2.1 To dispense safely the following steps are required:

- Prescription interpreted and any ambiguity or safety concerns clarified with the prescriber
- Label generated with accurate information about the patient, drug name dose, frequency and any precautions
- Label affixed to a container or package containing the correct drug, strength and formulation
- Correctly labelled medicine given to the correct patient with appropriate information and advice

3.2.2 Failure in one or more of these steps may lead to a patient receiving incorrect medication. When a dispensing error is made in primary care and is not immediately detected, the patient may continue to take the incorrect medicine for the entire duration of that prescription. Dispensing errors may therefore result in serious harm.

A study of more than 1 million dispensed items in British hospitals identified 178 errors (0.018%). The error rate was 0.01% when the dispensing of pharmacists and technicians was double-checked, compared with 0.035% when there was no double-check. 9 errors resulted in patient harm.³⁹

In 1994 a Dispensing Error Analysis Scheme (DEAS) was established in the Cardiff and Vale NHS Trust. Confidential dispensing error reports were supplied by 66 hospital pharmacies in England, 19 in Wales and 4 in Scotland. Analysis of 7000 errors reported to the database between 1991 and 2001 included:

wrong drug supplied	23%
wrong strength of the right drug supplied	23%
wrong quantity	10%
wrong warnings or directions	10%
wrong drug name or details on the label	9%
wrong strength on label	8%
wrong form	7%
wrong patient name on label	7%

These errors occurred on inpatient drug charts, discharge prescriptions and outpatient prescriptions.⁴⁰

3.2.3 Inexperienced staff, including staff who work infrequently in the dispensary, may be more prone to making dispensing errors.⁴¹

3.2.4 There are few data in the public domain on dispensing error rates in community pharmacy.

In 2001, 406 claims were made against community pharmacist members of the National Pharmaceutical Association (NPA) as a result of dispensing errors. NPA membership comprises the owners of around 11,000 pharmacies in the UK dispensing more than 600 million prescriptions each year.⁴²

What are the causes of dispensing errors?

3.2.5 A variety of factors can predispose to dispensing errors including personal and environmental issues. Common single causes of dispensing error include similar sounding and looking drug names, inexperienced staff, low staffing, transcription errors and high workload. Other causes include misreading the prescription, similar packaging, applying an incorrect dispensing label and relying on information on the electronic patient medication record rather than the prescription.

The UK Dispensing Error Analysis Scheme reported that 33% of errors were linked to look alike/sound alike drug names, 23% to high workload or low staffing, 20% to inexperienced staff, 14% to transcription errors including wrong key strokes on computerised labelling systems.⁴³

A North American study found that there was no direct relationship between workload and error rates. Factors other than workload made important contributions to dispensing errors. These included poor relationships with supervisors, overall job dissatisfaction, the perception that breaks were inadequate to meet their needs, inability to focus and attend to details, personality characteristics, not getting enough sleep, and perceptions that pharmacy lighting and equipment were inadequate. Presence of these factors creates mental tension and distractions that lead to a breakdown in cognitive functioning.⁴⁴

Drugs commonly involved in dispensing errors

3.2.6 The ten drugs most commonly involved in dispensing errors from the DEAS database⁴⁵ are:

- Prednisolone
- MST (morphine sustained-release)
- Isosorbide mononitrate
- Warfarin
- Aspirin
- Lisinopril
- Carbamazepine
- Diclofenac
- Co-codamol
- Flucloxacillin

3.2.7 Dispensing errors involving prednisolone, warfarin, lisinopril, morphine and carbamazepine are known to have caused serious harm to patients. Drugs less commonly involved in dispensing errors, but nevertheless occasionally causing serious patient harm include; ciclosporin, digoxin, methotrexate, and tramadol.

Case 11. MST dispensing error

A pharmacist supplied 100 mg MST (morphine sulphate sustained-release) tablets against a prescription for 10 mg tablets. When the patient's wife was unable to wake him the doctor realised there had been a mistake.⁴⁶

3.2.8 The pairs of drugs most commonly involved in 'wrong drug' or 'wrong strength' dispensing errors are:

- Amiloride and Amlodipine
- Fluoxetine and paroxetine
- Hydralazine and hydroxyzine
- Carbamazepine and carbimazole
- Omeprazole 10 mg and 20 mg
- Atenolol 100 mg and 50 mg
- MST 10 mg and 30 mg
- Paroxetine 20 mg and 30 mg
- Warfarin 3 mg and 5 mg
- Diazepam 2 mg and 5 mg
- Co-codamol 30/500 and 8/500

3.2.9 In addition to dispensing commercially manufactured medicines, pharmacists may need to compound a medicine from a formula. Such extemporaneous dispensing can take place in a community or hospital pharmacy or, for more complex medicines including those for intravenous administration, in a specialised unit. Serious errors have occurred in extemporaneous dispensing.

The National Pharmaceutical Association has introduced a book for members to keep a record of formulae used for products dispensed extemporaneously. The book also includes background information on pharmaceutical calculations.⁴⁷

- 3.2.10** Ingredients and quantities used to prepare the final product should always be documented. The formula, ingredients and quantities should, wherever possible, be double-checked. Pharmacists and their staff should follow guidance on the extemporaneous preparation of medicines issued by the Royal Pharmaceutical Society.⁴⁸

Case 12. Renal impairment following amphotericin confusion

Amphotericin is an antifungal agent used to treat severe infections. It is available in two forms; conventional amphotericin which is given in a dose of up to 1.5 mg/kg, and amphotericin B lipid complex which is given in a dose of 5 mg/kg. A renal transplant patient was discharged from hospital on amphotericin B lipid complex but the homecare pharmacy dispensed conventional amphotericin. The patient experienced severe side effects, including worsening of his renal function, and needed hospital readmission.⁴⁹

Case 13. Inappropriate use of concentrated chloroform water

A baby died after being prescribed peppermint water which was prepared extemporaneously in a community pharmacy. Concentrated chloroform water had been used as an ingredient when the formula required double strength chloroform water leading to a 20-fold overdose of chloroform.⁵⁰

Dispensing errors with Carbamazepine

- 3.2.11** Similar packaging and appearance of carbamazepine products and the range of dosage forms available contribute to high error rates with this drug. Dosing errors in epilepsy may lead to toxicity which may manifest as excessive sedation or, alternatively, to loss of seizure control and fitting if the dose is too low.

In a study of 30 medication errors involving carbamazepine, 17 were dispensing errors. 14 were a result of confusion between 200 mg and 400 mg modified release tablets, and one involved a hospital inpatient receiving standard formulation carbamazepine in place of the same dose of modified release carbamazepine. In two incidents patients were dispensed 200 mg tablets in place of 100 mg standard tablets.⁵¹

Figure 3.2.1 Similar packaging of five different proprietary dosage forms of carbamazepine



Reducing the risk of dispensing error

- The clinical appropriateness of prescriptions should always be reviewed prior to dispensing, and any ambiguity or potential risk clarified with the prescriber.
- Checking procedures should be in place to ensure accuracy of the dispensed medicine. This should include both individual self-check procedures and, wherever possible, an independent check by a second individual, especially for complex calculations
- Pharmacists, dispensing GPs and their staff need to be aware of the factors that contribute to dispensing errors and adopt a proactive approach to managing the risks.
- Pharmacists should ensure that their dispensing practice is in line with the Royal Pharmaceutical Society's Practice Guidance.⁵² Dispensing GPs should ensure that suitable guidelines are in place, including checking arrangements.
- Dispensing and checking the final product are increasingly being delegated to technicians, particularly in hospitals but increasingly in community pharmacies. All staff should be suitably trained and demonstrate competence to dispense accurately and check prescriptions for accuracy.

- Hospital and community pharmacists, and dispensing doctors, should report dispensing errors and near misses through the NPSA national reporting and learning scheme.
- The dispensing area should be designed to minimise errors. Environmental conditions, e.g., lighting, space, noise and air-conditioning should support safe and efficient working practices, and minimise fatigue and distractions. Resources, both facilities and staff, should be appropriate for the workload.
- The Royal Pharmaceutical Society of Great Britain has suggested some principles to be followed when carrying out the final accuracy check on a dispensed medicine.⁵³ The mnemonic ‘HELP’ stands for the following:

H	How much has been dispensed
E	Expiry date check
L	Label checks for the correct patient’s name, drug name, dose, and warnings
P	Product check, i.e., that the correct medication and strength have been supplied

As part of its ‘Ready-to-go’ series of audit resources for community pharmacy, the Royal Pharmaceutical Society of Great Britain has also developed an audit pack to help improve the dispensing process and reduce the risk of errors.⁵⁴

- Labels should be read at least three times to confirm the drug name, strength and formulation, e.g., when selecting the medicine, when packaging or labelling and when issuing the medicine to the patient or carer.
- On issue, a check should be made of the patient’s or carer’s understanding of the medicine they are expecting to receive. This will help verify the accuracy of prescription and dispensed medication. The name and appearance of the dispensed item should also be verified.
- Data on actual and potential dispensing errors should be collected as part of clinical governance and continuous quality improvement. Data should be shared with colleagues in a critical incident review process.

3.3 Safer administration of medicines

The vast majority of drug administration takes place in the home where patients usually take their own medicines. Error rates in this setting are unknown. Error rates in the administration of medicines on hospital wards are around 5%, although the majority of these are not harmful, typically involving missed or delayed doses. Anaesthetics, paediatrics, intensive therapy and all intravenous treatments carry high risks of serious administration errors. Accurate administration of medicines is critically dependent on the quality of all previous steps in the prescribing and dispensing processes. Drug administration errors may occur for the same reasons as prescribing or dispensing errors, for example, deficiencies in handwriting, labelling or packaging. Managing the risks in administration cannot be entirely delegated to those actually giving the drug – risk management must be built into the whole medication process. In hospitals drug administration is the final step in a multidisciplinary process in which professionals should work together to ensure that the various stages are properly integrated so that the correct medicine is safely administered to the patient.

3.3.1 About 80% of medicines are prescribed and dispensed in the community and are taken by patients in their own homes, or in care homes. In hospitals, medicines are administered by doctors and, mainly, by nurses. In addition, there is a growing trend for hospital patients to self-administer, in appropriate circumstances. Proper application of procedures, checks and defences in the process up to the point of administration will ensure that the right patient receives the right drug, in the right dose, by the right route, at the right time. However, a failure at any point in the medication process from prescribing to administration may cause a drug administration error.

3.3.2 In care homes most medication is administered by care staff. In a care home that provides nursing care medicine administration will be carried out by registered nurses. Other care homes employ social care staff who undertake this duty. The administration of medicines to a large number of NHS patients who reside in private care is undertaken by staff who may have had no formal training in safe practice. The application of procedures, checks and defences is especially important in these settings.

How often do administration errors occur?

In UK hospitals the total error rate for oral drug administration is approximately 5% of doses due.⁵⁵

Of 37,994 medication errors reported to the MedMARx error reporting programme by 184 U.S. healthcare provider organisations during 2000, 42% were associated with administration of the medicine. Of the errors that resulted in harm, wrong administration technique was the most frequent type.⁵⁶

- 3.3.2** Using the broad definition of an administration error as any discrepancy between the intentions of the prescriber and the treatment actually received by the patient, error rates of around 5% have been recorded in a number of observational studies in hospitals. Most studies have been limited to oral drug administration and have used small sample sizes. Findings are consistent between UK and North American hospitals. Most research on drug administration errors has been carried out in secondary care. The rates of administration errors in primary care and community healthcare settings are not known.

A study of acetylcysteine infusions identified calculation errors in 5% of doses, drawing up errors in 3%, and mixing errors in 9%. Doses in almost 1 in 10 infusions varied by more than 50% from the prescribed dose.⁵⁷

A study of the preparation and administration of intravenous drugs in two British hospitals found errors in almost half of drug doses. One per cent of doses had potentially serious errors.⁵⁸

An observational study of medication administration was carried out in the intensive care units of two Dutch hospitals. Two hundred and thirty three administrations were observed which included 77 errors (33%). Common errors included wrong dose preparation, wrong administration technique and omissions.⁵⁹

- 3.3.3** The precise rate of harmful drug administration errors in the UK is not currently known. Data collected by the NPSA reporting and learning scheme will help to establish this figure in due course. Most drug administration errors do not lead to patient harm.

- 3.3.4** Many different types of drug administration error may occur:⁶⁰

- A patient does not receive a dose of medicine by the time the next dose is due
Example: a patient is prescribed flucloxacillin 500 mg four times a day. The morning dose is incorrectly omitted
- A patient receives the wrong dose of a medicine
Example: a patient is prescribed aspirin 75 mg in the morning but is incorrectly given a 300 mg tablet instead of a 75 mg tablet

- A patient receives a medicine which has not been prescribed (wrong drug or wrong patient)
Example: a patient is prescribed co-amilozone but is incorrectly given co-amilofruse

Example: a dose of insulin was administered to a patient because the patient's identification was not properly confirmed.
- A drug is administered in a dosage form different from that prescribed
Example: Morphine sulphate SR 10 mg (MST) is prescribed but morphine sulphate 10 mg (Sevredol) is incorrectly administered
- A patient receives a medicine at the wrong time
Example: Warfarin is prescribed for a patient to be taken at 6 p.m. but the dose is incorrectly administered at 6 a.m.
- The correct form of a medicine is administered but by the wrong route
Example: Vincristine for administration intravenously is incorrectly administered via the intrathecal route
- The physical or chemical integrity of the medicine has been compromised (e.g., date expired drug)
Example: A vaccine is incorrectly administered when the expiry date has been exceeded
- An infusion is given at wrong rate
Example: an infusion was intended to be administered at 2 mls per hour but was incorrectly administered at 20 mls per hour
- Inappropriate procedure used during administration of drug
Example: an incorrect inhaler technique is used and the patient receives an inadequate dose
- Incorrectly making up or manipulation before administration
Example: an injection is incorrectly reconstituted using lidocaine instead of saline
- The patient receives a dose of a medicine in addition to that prescribed
Example: a second dose of a drug is administered by a person unaware that the dose has already been given

3.3.5 The incidence of each type of error will vary according to the clinical setting and the type of drug distribution system in operation. Drugs given by the intravenous route have the greatest potential for serious harm if given incorrectly (see chapter 5.4). For oral drug administration the most common type of error is omission.⁶¹

Causes of drug administration errors

3.3.6 Poorly hand-written prescriptions, verbal orders, transcription errors and inadequate labelling are frequent causes of drug administration errors. Personal factors, such as lack of knowledge, fatigue, illness, personal or work stress and distractions also contribute to administration errors. Low nurse to patient ratios make it difficult for nurses to know the patients to whom they will administer drugs and in care homes the increasing use of agency staff who are unfamiliar with the service users and drug regimens may increase risks.

3.3.7 Preparation of doses prior to administration is an important step in the medication process, particularly for injectable drugs. This is sometimes undertaken by someone other than the person giving the drug. This step is frequently associated with medication errors. Risks associated with the preparation of injections include:⁶²

- incorrect dosage calculation
- selection of the wrong drug or diluent
- mislabelling of syringes
- incorrect method of preparation
- incompatibility of constituents
- instability of the final product
- microbial contamination
- particulate contamination

Many health professionals have little training in the safe preparation of medicines. Procedures for checking drug administration should include checking all the stages of dose preparation.

3.3.8 The risk of error may be increased when drugs are being prepared in busy, cluttered clinical rooms. Where drug storage facilities are untidy and crowded the risk of selecting an incorrect drug may be increased. Storage of drugs intended for administration to one patient at that patient's bedside reduces the range of drugs from which selection can be made and may therefore reduce the risk of medication error.

Figure 3.3.1 Overcrowded clinical rooms may predispose to drug error



3.3.9 Pharmacy in the Future – Implementing the NHS Plan⁶³ promotes the re-use of the medicines that patients bring into hospital, where appropriate. As well as reducing waste, the use of patients' own medicines and, where appropriate, self-administration can reduce administration errors and help patients prepare for self-care after leaving hospital. This principle has been incorporated into the National Service Framework for Older People.⁶⁴

A study at the Wirral Hospital NHS Trust compared the rate of medicine administration errors using traditional ward medicine trolleys with a re-engineered system using patients' own drugs in bedside lockers. There was an overall reduction in the medication administration error rate of 75%⁶⁵

Figure 3.3.2 Drug storage in an overcrowded medicines trolley



Figure 3.3.3 Storage of patient's own medicines in a bedside medicines locker



3.3.10 High rates of dose omission may be a result of hospital drug distribution systems being unresponsive to clinical demands. The time delay between the prescription being written and the medicine being available can lead to doses being missed. This is particularly a problem when drugs are prescribed outside normal pharmacy opening hours. The Audit Commission⁶⁶ reported that up to half of all inpatient prescriptions are written outside traditional weekday pharmacy

opening hours. To ensure that patients receive safely prescribed medicines in a timely way hospital pharmacies need to consider extended opening hours. The situation may be more acute within primary care where there may be a significant delay in procuring a new treatment for a service user within a care home.

The American Society of Health-System Pharmacists⁶⁷ have described common causes of drug administration errors as:

- *Ambiguity in the way the strength appears on labels or in packaging*
- *Drug product nomenclature (look alike or sound alike names, use of lettered or numbered prefixes and suffixes in drug names)*
- *Equipment failure or malfunction*
- *Illegible handwriting*
- *Improper transcription*
- *Inaccurate dosage calculation*
- *Inadequately trained personnel*
- *Inappropriate abbreviations used in prescribing*
- *Labelling errors*
- *Excessive workload*
- *Lapses in individual performance*
- *Medication unavailable*

3.3.11 Many medicines are administered to patients in care homes, or in their own homes by social care staff. Monitored dosage systems (MDS) and compliance aids, where medicines are dispensed in blister packs or boxes divided according to the time of day the dose should be taken, may simplify administration. However, not all medicines can be put into the MDS, which may give rise to error. There is also the potential for care staff to place undue confidence in a system rather than employ safe practice. An additional source of error arises when care staff elect to dispense medicines into compliance aids for convenience.

3.3.12 Errors may occur in the care home setting through non-availability of the prescribed medication. The lack of an organised system to request repeat

prescriptions, and processes that are subject to delay at the point of prescribing and dispensing may be the cause.

3.3.13 Errors may occur in care homes if additional remedies are administered which may be unsuitable for the patient, or where inadequate records are maintained. Although the use of well-designed medication administration records (MARs) may reduce the risk of administration errors in care homes this is wholly dependent on the standard of record keeping within an individual care home. Printed computerised MAR charts may only be relied upon on the date of issuing the prescribed medicines. The Royal Pharmaceutical Society of Great Britain has offered guidance to pharmacists that duplicate labels should not be provided to care home staff for the purpose of adding to the MAR chart. Further errors may be caused by:

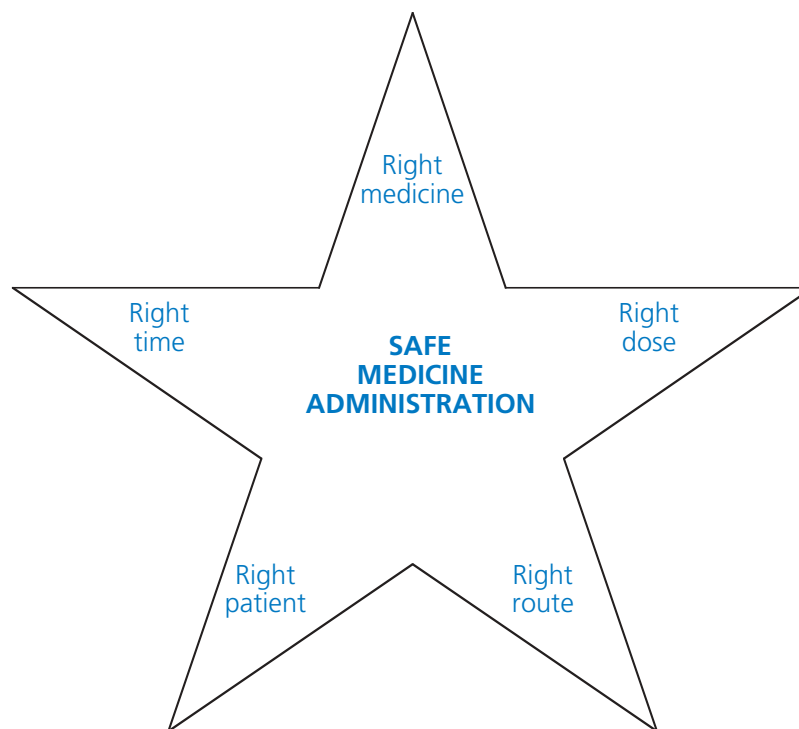
- failure to remove a medication from the MAR when no longer appropriate
- failure to add a medication to the MAR when a new prescription is initiated
- failure to alter the dose and frequency when a prescription is altered
- directions included in the MAR chart differing from the label instruction
- medication missed from the MAR chart because it has not been recently requested

3.3.14 Patients who are helped to take their medicines in their own homes by social service or independent formal carers can also be at risk from error. Carers may not be aware of the full list of medicines the patients take. They are unlikely to be aware of the need to seek advice before purchasing medicines on behalf of the patient. Medicines may also be transferred to unlabelled containers by carers, relatives or the patients themselves in an attempt to simplify medicine taking, but with the loss of important dosing information.

Reducing the risks of drug administration

- The following checks should be performed immediately prior to medication administration: right medication, in the right dose, to the right person, by the right route, at the right time. Particular attention should be paid to injections and infusions where the risks associated with error are higher.

The Five Rights



- Pharmacists, doctors, nurses and others involved in the administration of medicines should work together to ensure accurate and safe drug administration. Each has a role in improving the quality of drug administration and in monitoring the quality of other groups' contributions to the medication process.
- Pharmacy departments should be proactive in ensuring that sufficient, easily accessible information is available for nurses and doctors. Medicines information services should review how best to provide information support for safe prescribing and drug administration.
- Complex calculations may need to be carried out to prepare drug solutions and to determine the rate of administration. These should be carried out by staff who have demonstrated practical skills in dose/rate calculations. Where staff do not feel confident they should seek confirmation of accuracy.

- To reduce the frequency of omission errors pharmacists must promptly clarify unclear or inappropriate prescriptions and ensure timely availability of newly prescribed medicines. The times at which pharmacists are available to support prescribing and drug administration may need to be reviewed.
- Systems should be in place to ensure that all serious administration errors and near misses are reported to the NPSA through the national reporting and learning scheme, in addition to being reviewed locally.
- For adults, doses of oral medicines are typically one or two tablets or capsules, or 5 ml or 10 ml of liquid. Some injectable medicines are also presented in ampoules or vials corresponding to their usual adult dose. If an unusually large number of dose units appears to be needed this should alert staff to a potential error.
- Particular care needs to be taken when administering medicines to children when adult formulations are used to prepare doses. A significant overdose to a small child may be contained within one adult dosing unit (*see chapter 4.3*).
- NHS trusts should ensure that staff administering drugs understand the indications, risks, precautions and contraindications to each medicine, and are competent to perform any calculations necessary.
- Staff administering drugs should know the expected outcomes of the treatment, monitor the response to treatment, and be able to inform the team caring for the patient of any relevant changes in the patient's condition. They should know about potential interactions with food or other medication, and what action to take when adverse effects occur.
- New clinical staff should be provided with guidelines covering medicines administration. Safe administration of medicines should be addressed in continuing professional development programmes for all clinical staff (*see chapter 6.4*).
- The Nursing and Midwifery Council produce guidelines to establish principles for safe practice in the management and administration of medicines.⁶⁸ Trust drug policies, detailing specific actions to be taken to minimise the risk of medication error based on local risk assessment, should be promoted to all staff.
- Staff administering medicines in care homes or in patients' homes should be trained in the safe handling and administration of medicines, including documentation, in line with the requirements of the National Care Standards Commission.⁶⁹

- Staff should only administer medicines that are properly labelled. During the administration process the label should be read and reread at each stage of the preparation of the dose. Where possible, patients or carers should be involved in the checking process. Discussing the name, route and purpose of the medication at the time of administration can be an important additional safeguard.
- Linked automated systems, e.g., electronic prescribing, computerised medication administration records or bar-coding, will facilitate review of prescriptions and may increase the accuracy of administration, and reduce transcription errors (*see chapter 6.1*).
- Conventional methods of storage on wards often allow similarly packaged drugs, for example, lidocaine, furosemide and saline ampoules, to be adjacent. Hospitals should ensure that storage facilities minimise the risk of selection or reconstitution errors. There may be merit in storing medicines by BNF category, which should be an additional defence against error. This may require additional support at ward level from pharmacy staff.
- Medication safety considerations should be taken into account in the design or refurbishment of hospital wards, theatres or departments.⁷⁰ NHS Estates, in consultation with the NPSA, should review the Health Building Note to ensure that medicine storage facilities reflect current requirements for patient safety.
- Many doses for administration by injection or infusion are prepared in sub-optimal conditions at ward level. The amount of intravenous dose preparation on nursing units should be minimised by centralising aseptic dose preparation within the hospital or by using outside sources. Hospitals should use commercially available premixed intravenous solutions wherever possible (*see chapter 5.4*).

The Clinical Resource and Audit Group in Scotland have produced a good practice statement for the preparation of all injections. The document provides all staff who prepare injectable medicines for patients, in hospitals and in the community, with clear guidance about how to minimise the risks and improve the safety of patients.⁷¹

- High-risk drugs should be restricted. They should be withdrawn from ward stock where appropriate and dispensed from pharmacy against individual prescriptions, for example, concentrated potassium chloride solutions (*see chapter 5.7*). Staff should be accredited to order, prepare or administer high-risk drugs to reduce errors due to lack of knowledge or inexperience. This approach has already been adopted in the NHS to reduce the risk of maladministration of vinca alkaloids
- Alternative validated methods for double checking dose calculations should be developed and made available on wards and clinical departments, e.g., dose checking charts and computer programmes. However these should supplement, rather than replace, sound skills in dose calculation.
- If a person administering a drug is unsure of the drug, dose or regimen it should be confirmed with a second individual, preferably the prescriber or a pharmacist, prior to administration. If a drug cannot be administered for any reason the prescriber should be notified.
- The use of patients' own medicines and, where appropriate, self-administration by hospital inpatients should be promoted.

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4

Reducing the risks: challenges with specific patient groups

4.1 Safer use of medicines in people with allergies

Serious harm has occurred when patients have been prescribed drugs to which they have a pre-existing allergy. In a number of incidents staff have been unaware that a combination product contained a penicillin that was potentially – or actually – lethal to a susceptible patient. Prevention of such errors relies on patient and medicines information being available and acted on at the time of prescribing, dispensing and administration. The patient's allergy history is not always easily accessible with manual prescribing systems. This type of error could be prevented with electronic prescribing systems linked to the electronic national care record.

4.1.1 Anaphylaxis is a serious allergic drug reaction that causes laryngeal oedema, bronchospasm and hypotension. Severe anaphylaxis may be fatal. Blood products, vaccines, antibiotics, aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs), heparin, muscle relaxants used in anaesthetics and many other drugs have the potential to cause anaphylaxis in susceptible individuals.

4.1.2 Drugs frequently associated with anaphylactic reactions reported to the Committee for the Safety of Medicines¹ include:

- Amoxicillin (an antibiotic)
- Vaccines

- Suxamethonium (a muscle relaxant used in anaesthetics)
- Allergen extract (used for allergy testing)
- Trimethoprim (an antibiotic)
- Atracurium (a muscle relaxant used in anaesthetics)
- Ciprofloxacin (an antibiotic)
- Intravenous iron
- Intravenous vitamins
- Lidocaine (a local anaesthetic)
- Propofol (an intravenous sedative)
- Thiopental (an intravenous sedative)

4.1.3 In addition to the active drug itself, additives used in the formulation of medicines, for example, colourants or preservatives, may also cause severe reactions. Severe anaphylaxis is more likely after intravenous administration of drugs.²

Twenty-five of 234 claims to the Medical Defence Union by hospital doctors,³ and 11 of 193 claims to the Medical Protection Society by General Practitioners⁴ involved allergic drug reactions.

4.1.4 Inadvertent prescribing and administration of medicines where the patient has a documented allergy have occurred with devastating consequences. In many cases the allergy history of the patient was not available at the time of prescribing. This information is usually documented in the patient's medical record but also needs to be prominent within the prescribing system to prevent accidental prescribing of a contraindicated medicine.

Computerised prescribing in a large tertiary care hospital in the United States reduced the rate of serious allergy errors by 56%. However, serious errors continued to occur where clinicians did not enter information about newly detected allergies during a hospital inpatient episode, and the offending drug was subsequently re-prescribed.⁵

4.1.5 In some instances, even when the allergy status of the patient has been available, patients have been given a combination product containing a contraindicated medicine, where the both the prescriber and the person administering the drug were unaware of the constituents of the product.

- 4.1.6** The nomenclature of penicillins can be confusing. Many products have names that do not immediately suggest that they contain a penicillin.

Some penicillins and penicillin-containing antibiotics

Benzylpenicillin (Penicillin G)
Procaine benzylpenicillin (procaine penicillin)
Phenoxyethylpenicillin (Penicillin V)
Flucloxacillin
Ampicillin
Amoxicillin (amoxycillin)
Co-amoxiclav (amoxicillin with clavulanic acid) = Augmentin [®]
Co-fluampicil (flucloxacillin with amoxicillin) = Magnapen [®]
Ticarcillin with tazobactam = Timentin [®]
Piperacillin
Piperacillin with tazobactam = Tazocin [®]
Pivmecillinam

- 4.1.7** There is currently no requirement for labels to include the warning ‘CONTAINS A PENICILLIN’. While it is essential that staff handling these products understand their constituents, clear and explicit labelling can be an important visual reminder of the class of product being handled, adding another safeguard against potentially harmful errors.

Case 14. A fatal allergic reaction to a penicillin-containing antibiotic

A 63 year old woman recovering from a hysterectomy died after receiving a dose of intravenous penicillin. She was documented to be allergic to penicillin on the front of her medical notes, although the prescribing doctor had not seen this warning when the prescription was signed. She was also wearing a red wrist-band labelled “penicillin sensitive”. She was given Augmentin[®], a proprietary combination product which contains amoxycillin.⁶

Case 15. Anaphylaxis due to penicillin administration to an allergic patient

A 36 year old patient was admitted to hospital for drainage of an abscess on her leg. Her allergy to penicillin was documented in her medical notes, and her GP also wrote to the hospital to warn them of the allergy when he referred the patient. Because of the severity of the allergy the patient wore a medical alert bracelet to warn healthcare providers. Despite these warnings she was prescribed and administered an intravenous dose of Magnapen®, a combination of penicillins to which she had a severe anaphylactic reaction and cardiac arrest, resulting in a persistent coma.⁷

- 4.1.8** Penicillin-sensitive patients may also be allergic to cephalosporins and other beta-lactam antibiotics, which are structurally related to the penicillins.

Cephalosporins	cefaclor, cefadroxil, cefalexin, cefamandole, cefazolin, cefixime, cefotaxime, cefoxitin, cefpirome, cefpodoxime, cefprozil, ceftazidime, ceftriaxone, cefuroxime
Other beta-lactam antibiotics	aztreonam, imipenem with cilastatin, meropenem

Reducing the risk of allergic reactions

- Trusts should implement a written standard for the documentation of drug allergies, including roles and responsibilities of different health care professionals involved in the medication process.
- Allergy documentation should be audited against this standard. The results of the audit should be fed back to staff through clinical governance processes.
- The allergy status of patients should be written in a prominent position in the medical notes and be referred to each time the patient is reviewed by a member of the clinical team. This should be done even when the patient has no known allergies.
- In general practice all drug allergies should be recorded on the computer in a way that will trigger an alert if an attempt is made to prescribe these drugs in future.

- The allergy status of the patient should be documented on all hospital charts used for prescribing medicines so that it is visible at the point of prescribing, dispensing and drug administration.
- Consideration should be given to a universal symbol denoting penicillin allergy which could be used on medicine packaging, patient's case notes, hospital inpatient identity bands, and medical alert bracelets. This would make the allergy status readily distinguishable.
- In order to distinguish between serious allergy and less harmful drug intolerance, the symptoms of any reported allergy should be documented. If a patient develops an allergy during the patient's hospital stay the medical record must be updated to reflect the current allergy status.
- Manufacturers should share responsibility for the safe use of drugs commonly associated with severe allergic reactions. The MHRA and NPSA are working to ensure that labelling and packaging of penicillin products carries the warning '*contains penicillin*'.

4.2 Safer use of medicines in seriously ill patients

The complexity of drug treatment in the seriously ill patient has increased the risk of medication errors, particularly of drugs being given by the wrong route. Such errors happen rarely but may have catastrophic consequences. Oral medications and nebuliser solutions may be inadvertently given by the intravenous route. Intravenous medications may be given by the intrathecal route. The risk of these wrong route errors is compounded by the widespread use of Luer connectors in medical practice. Work is in hand to commission a new spinal connector for the NHS and to seek long term standardisation of connectors used in medical practice across Europe.

4.2.1 Drugs may be given by one of several routes including:

- oral
- nasogastric
- gastrostomy
- jejunostomy
- sublingual
- rectal
- topical
- subcutaneous
- intramuscular
- intraocular
- intravenous – peripheral
- intravenous – central
- epidural
- intrathecal
- transdermal

4.2.2 With the increasing complexity of drug administration, particularly in the high technology environments of critical care and surgery, patients may have multiple lines accessing various sites for drug administration greatly increasing the risk drug administration by the wrong route.

4.2.3 Giving a drug by the wrong route is a frequent administration error highlighted in studies from the US and Europe.

The Massachusetts Coalition for the Prevention of Medical Errors has described examples of wrong route errors and proposed recommendations for system changes to minimise the risks of such errors.⁸ Examples of errors described include:

- oral drugs given intravenously
- intravenous drugs administered intrathecally
- intramuscular drugs administered intravenously
- epidural and intravenous lines being mixed up

- 4.2.4** The United States FDA reported that wrong route accidents caused 12% of fatal medication errors:

A review of 469 medication error related deaths reported to the US FDA between 1993 and 1998 identified giving the drug by the incorrect route as the third most prevalent type of error, involving 57 patients. Fourteen patients died as a result of an intravenous drug being administered intrathecally, eight deaths were associated with an oral product being given intravenously, four patients died as a result of an intramuscular injection being given intravenously and one died as a result of an IV injection being given intramuscularly. Thirty other wrong route incidents were not categorised further.⁹

Thirty errors associated with the wrong route of administration were reported to a Swedish database of medication errors.¹⁰ These included injection of oral drugs (11), injections given at the wrong injection site (7), inhalation of oral drugs (2), oral drugs being applied topically (2), a rectal drug given by injection (1).

- 4.2.5** Confusion between two different sites of administration can be fatal, most notably the administration of drugs intended for oral administration being administered intravenously, and confusion between spinal and intravenous injections.

Cases 16 & 17: Fatalities associated with accidental intravenous administration of epidural bupivacaine

There have been two reports, from different hospitals, of similar errors involving the administration of bupivacaine, intended for epidural administration, by the intravenous route. In both instances the 500 ml infusion bag containing bupivacaine was mistaken for a bag of almost identical appearance containing an intravenous fluid to help to maintain blood volume. The same type of giving set is used to administer both intravenous and epidural infusions and this may have compounded the risk of error.¹¹

- 4.2.6** There is a risk of oral drugs being administered intravenously if the dose is measured in an intravenous syringe. This risk is further increased if syringes containing oral and intravenous drugs are taken to the patient's bedside at the same time, especially if the nurse administering the medicine is not the nurse who prepared the doses.
- 4.2.7** In the past solutions for injection were presented as clear liquids. However, some drugs intended for intravenous administration are now presented as white

emulsions, for example propofol and diazepam. Therefore the appearance of the contents of the syringe does not necessarily trigger the thought that the drug at hand is only for administration via the enteral route.

Case 18: Inadvertent intravenous administration of oral morphine

A doctor requested 5 mg of morphine to be drawn up for intravenous administration to a patient. The nurse drew up 2.5 ml of Oramorph 10 mg/5 ml (formulated for oral administration) from a plastic unit dose vial into an intravenous syringe. The nurse made an entry in the controlled drug register but this was not countersigned. The contents of the syringe were then given to the patient intravenously without a second check. The nurse later realised that a mistake had been made. The patient experienced no adverse effect.¹²

- 4.2.8** Drugs in syringes for administration by the intravenous route may be given in error by any other route. Intrathecal medication errors are particularly hazardous. These belong to a class of misconnection hazard arising from the wide application of the Luer connector.¹³
- 4.2.9** Limiting the use of Luer connectors can significantly reduce the risk of serious wrong route errors. Introducing a dedicated intrathecal connector would prevent inadvertent administration of intravenous drugs by this route. This is an example of a ‘lock and key’ error trap which designs out the possibility of misconnection.

Reducing the risk of wrong route errors

- Intravenous syringes should not be used to prepare or administer oral medicines. Oral syringes, whose tips are designed to be incompatible with Luer connectors, should always be used.
- Drugs to be given by the oral route and drugs to be given by the intravenous route should not be taken to the patient’s bedside together.
- The use of Luer connectors should be restricted.

As part of the strategy to eliminate intrathecal medication errors, the Department of Health has begun a tendering exercise for the design and supply to the NHS of a new medical connector, for all spinal procedures, that cannot be connected to a standard Luer syringe. The NPSA and MHRA are working with professional groups and practitioners to assess new connector solutions.

The European Committee for Standardisation (CEN) issued a report on Luer connectors which assessed the dangers arising from incorrect connection between medical devices which could result in substances being delivered to the patient by an inappropriate route. The report recommended the development of alternative connectors for certain applications. This work is currently being undertaken by a CEN committee.¹⁴

- Pumps that are used to deliver intravenous medications should not be used for enteral fluids.
- Staff giving any medicine from a syringe should satisfy themselves that the drug, dose and route of administration are all correct. When administering medicines to seriously ill patients with multiple lines, particular attention should be made to confirming the route of administration.
- The distal ends of all lines should be labelled to ensure that the site of access for drug administration can be positively identified.

A line labelling policy has been developed in a UK hospital to promote the safe administration of fluids, feeds and medicines and minimise the risk of errors and infection, especially for patients with multiple lines. The policy ensures a consistent approach to the labelling of all lines across the trust.¹⁵

- Ideally, all intravenous drug administration should be checked by two qualified practitioners. This check should include confirming the route of administration to the patient.
- Clear, written protocols of the dose ranges of medicines commonly prescribed for seriously ill patients in critical care situations should be in place. These protocols should include standardised dilutions for use in infusion devices.

4.3 Safer use of medicines in children

A medication error in a child may be more serious than the same error in an adult. The risk of error in children is often compounded by the need for additional calculations to determine the dose. Many medicines prescribed for children are only available as adult dose forms. Sometimes complex manipulations are necessary to prepare doses for very small babies. Ideally, small doses for intravenous administration should be prepared centrally in the pharmacy. Staff prescribing or giving drugs in paediatrics and neonatology should demonstrate competence in calculation skills. The National Patient Safety Agency will review medication processes in children and neonates, in collaboration with key stakeholders. Safe use of medicines in children will be further addressed in the forthcoming National Service Framework for Children, Young People and Maternity Services.

4.3.1 Drug dosing for children is often complex because of the need to take body weight or surface area into account and also because of variations in metabolism or elimination of drugs by the body. Weight-based dosing is common so more calculations need to be made during the prescribing, dispensing and administration of drugs. The impact of errors in children, especially neonates, may be more clinically significant as they may not have the necessary metabolic reserves to buffer the consequences of any error.

A study of 1120 children admitted to 2 teaching hospitals in the United States during April and May 1999 identified an error rate of 5.7 per 100 prescriptions. Wrong doses were the most common (28%). These were caused by errors in prescribing, transcription (prescriptions were transcribed by nurses on to the drug administration record) or administration. The most common drugs involved were antimicrobials, analgesics and sedatives, electrolytes and fluids, and bronchodilators. The intravenous route was most commonly implicated. Serious errors were most frequent in neonatal intensive care.¹⁶

4.3.2 Errors in prescribing for children frequently arise because of poor handwriting, misinterpretation of decimal points and calculation errors. Misplaced decimal points can result in 10- or 100-fold dosing errors. Despite widespread awareness of the risk, decimal point errors involving potent drugs, notably digoxin and opiates, continue to occur. These can be fatal.

Errors reported to the pharmacy department of a paediatric hospital in Canada between April and November 2000 were reviewed. Twenty errors by a factor of 10 were reported. Nineteen different medicines were involved. The errors could have resulted in death (6 cases), life threatening toxicity (9 cases) or moderate

toxic effects (1 case). In 4 cases toxicity was unlikely to result. Only five of the errors reached the children – 15 were intercepted. These errors occurred despite the use of a computerized prescribing system.¹⁷

Case 19. Fatal digoxin overdose in a neonate

A 3.2 kg baby was prescribed intravenous digoxin to control his heart rate, shortly after his birth by Caesarean section. A paediatric cardiologist advised a dose of 10 micrograms/kg and this was written in the patient's notes. When writing the prescription the junior doctor, who admitted to having 'no real experience' of prescribing intravenous cardiac drugs, failed to include the decimal point. This omission was not identified and the nurse gave 320 micrograms instead of 32 micrograms as intended.¹⁸

- 4.3.3** Errors may also be caused by different ways of expressing doses, which can vary between reference sources. For example, a dose may be expressed as 10 mg/kg/*day* or 10mg/kg/*dose*. The risk of this error occurring is increased when staff use different formularies, particularly when moving between hospitals.

Figure 4.3.1 A range of paediatric formularies are available



One hundred and ninety five medication errors were reported over a period of five years in a UK children's hospital. Fifteen errors involved a tenfold error in dose; five were due to calculation error, four were due to incorrect or unclear prescribing and five were due to incorrect infusion pump settings.¹⁹

- 4.3.4** The weights of children should be expressed as kilograms. Staff need to be aware that some carers may still use pounds to measure weights of small children. If a weight in pounds is mistakenly recorded in kilograms a 2.2-fold dosing error may result.
- 4.3.5** Prescriptions for intravenous infusions in children involve more than one calculation since both the dose and the rate of administration need to be calculated. Prescriptions should describe the drug, concentration, dose/kg/time, actual dose/time, route and rate per unit time so that the prescription can be thoroughly checked. Overdoses may be prescribed if the child's weight is more than the cut-off for a weight-based dose calculation. Awareness of maximum safe doses is essential.

Case 20. Fatal calculation error on a neonatal unit

A premature infant on a neonatal intensive care unit was prescribed 7.4 mg aminophylline to be administered intravenously. Instead of 0.3 ml of a 250 mg/10 ml solution, 7.4 ml was given. The baby developed clinical signs of theophylline toxicity and the blood theophylline level was greatly elevated. The baby died within 36 hours of the incident.²⁰

- 4.3.6** The dose may vary according to the clinical indication which may make a double check of the prescriber's intentions difficult. Many drugs used in children are prescribed outside their licensed indications, so dose information may not be readily accessible unless a paediatric formulary is used.
- 4.3.7** Dispensing errors may occur because of the limited number of drugs provided in formulations suitable for children. Dose ranges can vary between 0.1 ml and 10 ml, and fractions of tablets may need to be administered.
- 4.3.8** Inaccuracies in dosing can have serious consequences when very small volumes are being administered. Errors may occur when a dose of hundredths of a ml (e.g. 0.03 ml) is required but it is erroneously measured as tenths (e.g. 0.3 ml).²¹ Because of the wide variations in volumes needed for doses in children all doses should be double-checked against the mg/kg dose.
- 4.3.9** Formulation characteristics need to be considered carefully when prescribing for children as these may contribute to adverse drug events. Additives in some products may be harmful and need to be considered especially if the product is not licensed for use in children. Examples include chloroform, ethanol (intoxication), dyes and preservatives (allergy or intolerance).

Following the introduction of a new formulation of alfacalcidol solution (One-Alpha drops®), containing alfacalcidol in a concentration 10 times stronger than the previous, discontinued formulation, the Medicines Control Agency received 13 reports of accidental overdose as a result of prescribing or dispensing errors.²²

- 4.3.10** Liquid medicines are available in a wide variety of formulations, for example, solutions, suspensions, and oils. Occasionally solutions made for injection are given by mouth. Some liquids, e.g., ciclosporin are supplied with special devices for measuring the dose and special instructions for mixing with drinks. Suspensions must be shaken properly before measuring the dose to ensure an even distribution of the active drug in the bottle. Oral syringes of appropriate size should be used to administer all liquid medicines when the dose does not correspond to a 5 ml spoonful. Parents and carers should understand how to measure and administer doses of liquids to small children.

Reducing the risk of medication errors in children

- Dose, volume and rate calculations should be carefully checked and documented prior to administration of the medicine. To ensure that accurate double checks can be made the patient's age and, where the dose is weight dependent, the child's weight in kg and the intended dose in mg/kg/dose should be included on the prescription.
- *'Medicines for Children'*²³ published by The Royal College of Paediatrics and Child Health, and recently updated, is a valuable reference source. There would be considerable merit in also developing a single, approved national paediatric formulary which should be readily available to all staff involved in the prescribing, dispensing and administration of medicines for children.
- The provision of timely drug information to staff and parents on paediatric units is key. Pharmacists should participate in child health teams to identify and prevent errors, monitor adverse drug reactions, support doctors and nurses dealing with complex paediatric drug therapy, and teach parents and carers how to handle and administer drugs safely.
- All medical, nursing and pharmacy staff should demonstrate competence to calculate paediatric drug doses prior to prescribing, dispensing or administering medicines.
- Oral syringes should be used where appropriate.
- Ideally, small or difficult to measure doses should be prepared centrally in pharmacy.
- Calculation processes for continuous infusions should be simplified by standardising concentrations and diluents.
- Infusion rate charts and validated computer programmes to aid calculation should be available for use in paediatric units, particularly for potent drugs such as digoxin or opiates.

During the early 1990s at the Hospital for Sick Children in Toronto, Canada, several systems were put in place to reduce the risk of medication error. A computerised prescribing system was introduced to reduce handwriting and transcription errors. Hazardous drugs not required for immediate administration, including digoxin, heparin, insulin and potassium were removed from ward stock. All medical trainees participated in a test on the calculation of drug doses. A computer system to calculate dose volumes was implemented on the intensive care unit. The total number of reported actual medication errors reduced from 1006 in 1992-3 to 548 in 1998-99. The number of errors categorised as severe reduced from 11 to 3 over the same time period.²⁴

- Particular care must be taken with decimal points in paediatric prescribing. Trailing zeros must be avoided (e.g., 5 mg not 5.0 mg) and decimal points must be preceded by a digit (e.g., 0.5 micrograms not .5 micrograms).
- Dispensed prescriptions (for example, for outpatients or children being discharged) where a calculation has been made it should be double checked before being issued to the patient.
- Medication processes in neonates and children will be reviewed by the NPSA, in collaboration with the National Service Framework for Children, the Royal College of Paediatrics and Child Health, and the Neonatal and Paediatrics Pharmacists Group.

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5

Reducing the risks: challenges with specific groups of medicines

5.1 Drugs in anaesthetic practice

Anaesthetic practice requires the use of combinations of potent drugs, often in conditions of some stress in operating theatres. Drugs may need to be given urgently, and are often therefore prepared in advance by appropriately trained operating theatre staff. Local colour coding schemes used to assist quick drug identification may cause 'wrong drug' administration errors. The risk of errors can be reduced by formalising procedures and by regulating the use of colour coding in the labelling of anaesthetic medicines.

5.1.1 The incidence of errors in anaesthetic rooms is not known. However, the potential for serious drug errors in anaesthetics is greater than in other specialities. Because of the number of different drugs and syringes in use at any one time, including potent muscle relaxants and opiates and their respective antagonists, there is a high risk of 'wrong drug' incidents.¹

In 64 anaesthetic incidents reported to the Medical Defence Union there were 19 wrong drug errors, 16 wrong dose errors and 14 incidents where drugs were administered to patients with known allergies.²

5.1.2 It can be easy to mistake one drug for another in anaesthetic rooms or operating theatres. Misidentification of drug syringes or ampoules is an important cause of medication errors in anaesthetics.

The Australian Incident Monitoring Study reported that 144 out of 2000 anaesthetic incidents involved situations in which the wrong drug was given or almost given.³

- *33% of incidents involved ampoules*
- *Just over 40% involved syringes*
- *In more than half of the incidents involving syringes, the syringes were the same size*
- *In over half of the cases involving syringes they were correctly labelled*
- *In 81% of the 144 cases the wrong drug was actually given*
- *The risk of actual administration of a wrongly selected drug was higher if the drug was in a syringe (93%) rather than an ampoule (58%)*

5.1.3 Coloured adhesive labels are often applied to syringes to aid rapid identification of their contents prior to administration. However, there has been no agreed standard for colour coding of such labels and there is a significant risk of error if syringe contents are identified solely by colour, rather than by drug name. Because there is no standard, different colours may be used for the same drug within one hospital.

5.1.4 Multiple systems of colour coding pose a serious threat to patient safety in anaesthetics. Staff moving between hospitals in the UK may come across different colours for the same drug. Overseas anaesthetists coming to work in British hospitals and British anaesthetists working overseas may find this particularly confusing.

The Australian and New Zealand Joint Technical Committee have prepared a standard for user-applied labels in anaesthetics.⁴ Similar standards have been developed in the US by the American Society for Testing and Materials (ASTM). The standards specify label size, background colour, generic name, use of colour on labels for agonists and antagonists, and adhesion.

Case 21. Accidental administration of suxamethonium pre-operatively

Suxamethonium, a muscle relaxant, was administered to a patient instead of fentanyl as part of the anaesthetic induction regimen. The patient complained of difficulty in breathing but was unharmed as the error was discovered. A local colour coding system was thought to have contributed to the error.⁵

- 5.1.5** Ampoules are often removed from their original packaging and stored in alternative containers or on procedure trays until needed. They may then be inadvertently mixed up, resulting in selection of an incorrect drug, especially if the label styles are similar and the drug names contain similar words or character strings. Unused ampoules may be returned to the wrong pack.

Case 22. Misidentification of midazolam during premedication

Midazolam and suxamethonium were prepared for use by drawing up into syringes. The contents of one syringe, assumed to be the midazolam, were administered. The syringe actually contained suxamethonium. The patient experienced difficulty in breathing as a result. A recent change in supplier of midazolam within the hospital had resulted in the packaging, ampoule size and colour of both suxamethonium and midazolam being identical.⁶

Anaesthetists in New Zealand have developed an injectable drug administration and automated anaesthetic record system (IDAARS) with the aim of reducing medication error. All drugs, including ampoules and pre-filled syringes, are identified by pre-printed, colour-coded labels following an international colour-coding standard. The drug class and name are displayed in a large clear font (e.g. "Opioid" and "Fentanyl") and all labels are bar-coded. At the time of use the bar-code is read, the name of the drug appears on the computer screen in large font, and the drug name is announced by a voice file. Thus there are auditory and visual identity checks before drugs are administered. The impact of the system on medicine safety is yet to be evaluated.⁷

5.1.6 Operating Department Practitioners (ODPs) and nurses assist in the preparation and administration of anaesthetic drugs and their role in ensuring safe practice should be recognised. They should be trained and be competent to prepare doses of medicines, which should be double-checked by the anaesthetist prior to administration.

Reducing the risk of errors in anaesthetics

- Anaesthetists, theatre nurses and operating department practitioners should be aware of the risks and causes of medication errors and should ensure that checking procedures are in place and adhered to, even for routine procedures. They should recognise that errors occur especially in situations of haste, distraction or fatigue.
- Lighting of the theatre environment is critical for all aspects of safety. Where imaging technology requires reduced lighting, specific arrangements need to be made for selecting and checking anaesthetic drugs.
- Drug storage arrangements should be consistent in each theatre suite, and should be adequately stocked to ensure that any drugs required are readily available.
- Drugs, including water for injection and normal saline, should always be stored in the manufacturer's original packaging. Unpacking ampoules from these packs removes an important visual cue in the identification process. Arrangement by BNF category would be an additional defence against wrong drug or reconstitution errors.
- Ampoule labels should be read and re-read before drugs are drawn up into a syringe. Errors are unlikely to be detected once the drug is in the syringe.
- Ideally, drugs should only be drawn up into a syringe by the person who will administer the drug, immediately before use.
- However, syringes may sometimes need to be prepared in advance. They should then be labelled with the approved name of the drug and the strength of the drug in mg/ml, or international units (IU)/ml, using a national standard labelling system.
- There should be a written procedure for drawing up and checking drugs prior to administration.

- Syringes of drugs intended for use in an emergency should be immediately available but stored in an area away from the immediate work area (for example, general anaesthetics for failed regional anaesthesia in obstetrics, where drug errors may occur as a result of proximity of emergency drugs).
- The Royal College of Anaesthetists, The Association of Anaesthetists of Great Britain and Ireland, The Faculty of Accident and Emergency Medicine and the Intensive Care Society have recently agreed to adopt the international system of syringe labelling already in use in Australasia and North America.⁸ These organisations should work with the NPSA and MHRA to take this forward.
- Wherever possible pre-filling of syringes should be carried out in a pharmacy unit to assure quality of the contents and clear, accurate labelling.
- A pharmacist should regularly visit operating theatres and anaesthetic rooms to work with theatre staff to ensure safe drug use and storage and to maintain adequate supplies.
- When drug manufacturer, packaging or formulations change, theatre staff should be alerted before the drug becomes routinely available in the operating theatre.

5.2 Oral anticoagulants

Warfarin and related anticoagulants are frequently involved in serious medication errors. Most patients are treated safely with oral anticoagulants. However, if therapy is not monitored properly, or the patient's clinical condition or concurrent drug therapy changes, over- or under-anticoagulation can result, with potentially fatal consequences. Safe anticoagulant therapy is a multidisciplinary process involving healthcare professionals in both primary and secondary care. The need to inform all health professionals that they are taking warfarin should be explained to patients.

- 5.2.1** With greater evidence of benefit, for example in stroke prevention, the number of patients on long term anticoagulant treatment is increasing. Warfarin is the most frequently prescribed agent. Other, less commonly prescribed oral anticoagulants include phenindione and acenocoumarol (formerly nicoumalone).
- 5.2.2** Anticoagulants have a narrow therapeutic margin and are safe only if monitored closely and if the patient's clinical condition remains stable. Drugs in this class frequently cause preventable adverse effects. In primary care, anticoagulants are one of the three classes of drugs most commonly associated with fatal medication errors.⁹ In secondary care warfarin is one of the ten drugs most frequently associated with dispensing errors.¹⁰ The NHS Litigation Authority reports that oral anticoagulants are one of the ten most common errors resulting in claims against NHS Trusts.¹¹ The Chief Medical Officer has recently highlighted the death of a patient from a warfarin overdose caused by misinterpretation of a doctor's handwriting.¹²
- 5.2.3** The International Normalised Ratio (INR) is a measure of the blood's clotting properties. The risk of bleeding increases significantly when the INR is greater than 5. Careful monitoring of the INR is necessary to ensure safe use of anticoagulants.
- 5.2.4** The increasing numbers of patients being prescribed oral anticoagulants and requiring monitoring places considerable pressure on hospital outpatient clinics. As a result anticoagulation services are being devolved to primary care as satellite clinics, pharmacist or nurse led clinics and, in some areas, patient self-testing.¹³ Local testing of anticoagulation control may increase the safety of therapy by allowing frequent testing and improved communications between the patient and the primary care team. Where schemes for local testing of patients are set up there should be regular quality assurance of the service.

- 5.2.5** Oral anticoagulants interact with a wide variety of other medicines (for example, antibiotics and analgesics which are commonly prescribed in primary care) in most cases leading to an increased anticoagulant effect. Patients taking anticoagulants should be aware of the risks of taking other prescribed or purchased medicines without first seeking advice. Some people are particularly sensitive to warfarin, and in these individuals small increases in dosage, or introduction of interacting drugs, can cause catastrophic increases in anticoagulant effect.
- 5.2.6** The dose of warfarin must be carefully adjusted for each patient. The dose is therefore recorded in an anticoagulation booklet which is given to all patients. Patients are often given tablets of each of three strengths; 1 mg, 3 mg and 5 mg to enable doses to be adjusted. Recently, 0.5 mg tablets have been introduced to enable more accurate dose adjustment.
- 5.2.7** Supply of warfarin tablets of more than one strength may increase the risk of accidental overdose, especially in confused, older people.¹⁴ Particular care should be taken to avoid potentially catastrophic confusion between 0.5 mg and 5 mg tablets.

Case 23. Fatal outcome of azapropazone/warfarin interaction

A 66 year-old man with ischaemic heart disease was treated with warfarin for atrial fibrillation. He developed acute arthritis, diagnosed as gout by his general practitioner, and was prescribed the anti-inflammatory drug azapropazone. The dose was subsequently increased in response to an exacerbation of his arthritis. The patient then developed signs of bleeding. The general practitioner arranged for a full blood count, but did not check the INR. Before the results were available, the patient suffered a massive intracranial haemorrhage, was admitted to hospital, and died. On admission his INR was greater than 10.¹⁵

Case 24. Warfarin dosing is critical

While abroad, a 78-year-old woman underwent emergency surgery to remove a clot from her leg. She was prescribed warfarin tablets 2.5 mg once a day. This strength is not available in England, and on her return her GP prescribed warfarin tablets 3 mg once a day, and arranged an appointment in an anticoagulant clinic. There was a delay in her being seen in the clinic, and she developed bleeding, with an INR greater than 10. In spite of treatment with Vitamin K, an antidote, she died. The 20% increase in dosage was enough to cause a fatal haemorrhage.¹⁶

- 5.2.8** Errors can occur in care homes. Staff need to be aware that the dose of anticoagulant is critical and is listed in the patient-held record.
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Reducing the risks with oral anticoagulants

- The British Society for Haematology has published guidelines on oral anticoagulation.¹⁷ These should be reflected in local anticoagulant policies.
- When anticoagulants are prescribed on a shared care basis, the responsibilities of primary and secondary care professionals should be clearly defined.
- When prescribing other drugs for a patient on oral anticoagulants, a non-interacting drug should be chosen whenever possible. After any drug therapy changes the need for adjustment of the anticoagulant dose should be carefully evaluated.
- Patients should always receive an anticoagulant booklet on discharge from hospital, and should have their INR reviewed within 7 days.
- Staff should ensure that patients understand the need for anticoagulation, the possible side effects of treatment, and their own role in ensuring safe and effective management of their condition.
- Patients should be made aware of the importance of informing other healthcare professionals that they are on anticoagulant therapy before starting any other treatment or taking over the counter medicines, including herbal remedies.
- Staff managing anticoagulant clinics should undertake routine audits and review all over- and under-anticoagulated patients.

Staff at Basildon Hospital have developed an automatic voicemail system which calls patients at home with their INR result, dose and clinic appointment times. The system has been in operation for more than two years, transmitting over 60,000 reports by telephone. There were no clinical incidents during this period.¹⁸

- Wherever possible, prescribers should use computer decision support systems that have been designed to standardise anticoagulant control. Such systems can reduce the risks associated with anticoagulation by standardising dosage recommendations, providing information on clinic attendance, and alerting the prescriber to potential drug interactions.
- Pharmacy staff should confirm that the strength of tablets supplied corresponds to the patient's current dose.
- Pharmacists and dispensing doctors should ensure that all dispensary staff are aware of the risks and consequences of dispensing errors with warfarin. Warfarin dispensing should be double-checked whenever possible.
- The National Patient Safety Agency will review medication errors involving anticoagulants to identify system solutions to improve their safe use.

5.3 Cytotoxic chemotherapy.

Cytotoxic chemotherapy is complex with several stages at which errors can occur. Errors that lead to patients receiving higher doses or longer courses of treatment than intended can be fatal. Safety of cytotoxic chemotherapy can be improved through a structured multidisciplinary approach to the management of both in- and outpatients. Training in the risks of medication error is essential for all staff working within the specialty.

- 5.3.1** Cytotoxic drugs used in the treatment of cancer are invariably highly toxic with considerable potential for damage to normal tissues. They are often used in combinations and in complex dose regimens designed to achieve the maximal anti-cancer effect balanced against acceptable toxicity.
- 5.3.2** Errors involving these drugs can have devastating consequences. Recent cases of spinal maladministration of vinca alkaloids have highlighted the hazards of errors with cytotoxic chemotherapy.^{19,20}
- 5.3.3** Cytotoxics are frequently prescribed in doses close to the threshold of toxicity and serious harm has been caused by overdoses of many anticancer drugs. Errors may be due to the complexity of the calculations associated with surface area based dosing, or because algorithms for calculating doses, for example, in patients with renal failure, have not been fully understood by the staff using them.

Case 25. Severe renal failure as a result of carboplatin toxicity

A patient was prescribed carboplatin as part of a high dose chemotherapy regimen for metastatic breast cancer. Carboplatin is mainly excreted by the kidneys and the dose is therefore based on renal function. Because the patient was heavy, weighing 100 kg, the formula for calculating renal function overestimated her ability to excrete the drug. The carboplatin therefore accumulated resulting in acute renal failure and coma.^{21,22}

- 5.3.4** The complex nomenclature of chemotherapy regimens and drug names has been 'simplified' by clinicians into a series of abbreviations. While the abbreviations may appear simple they may be another source of medication error if they are misinterpreted. Confusion may occur between drugs with similar sounding names resulting in error. For example, giving cisplatin instead of carboplatin at the same dose in milligrams would result in a 4-8 fold overdose. Other cytotoxic drugs with similar sounding names include:

- vincristine and vinblastine

- paclitaxel and docetaxel
- doxorubicin and daunorubicin

5.3.5 Use of the numerical prefix '6' in the drug names 6-mercaptopurine and 6-thioguanine (tioguanine) may result in confusion leading to 6 times the dose being given.

5.3.6 Cytotoxic doses are not always expressed consistently. Toxicity may be critically dependent on the way in which doses are divided. Doses may be expressed in different ways in different protocols or regimens; as individual doses, as total daily doses or as the total dose for that course of treatment. This has led to misinterpretation and serious errors.

Case 26. Death due to cisplatin toxicity

Cisplatin was prescribed at a dose of 100 mg/m² as a continuous infusion days 1-4. The prescription was misinterpreted as 100 mg/m² daily for 4 days, instead of 100 mg/m² over the four-day period. The patient died as a result of the four-fold overdose.²³

Case 27. Prescribed overdose of vindesine

A patient was due to receive vindesine 3 mg/m² on days 1 and 8 of a 14-day chemotherapy regimen. Instead he received vindesine daily for eight days resulting in fatal haematological and neurological toxicity.²⁴

5.3.7 Increasing numbers of people are receiving cancer treatments as outpatients or in the day-care setting. Clinical pharmacy services are not normally structured to support outpatient departments. New models of service may need to be developed to improve pharmaceutical support for these patients and to provide support for staff prescribing and administering these potent medicines.²⁵

5.3.8 Most cancer chemotherapy is administered intravenously. Many of the drugs can cause devastating extravasation injuries if they are not correctly administered. Cancer nurse specialists play an important role in ensuring safe chemotherapy administration.

5.3.9 The range of cytotoxic drugs available for oral use is increasing. For example, capecitabine (for advanced colorectal cancer) and imatinib (for chronic myeloid leukaemia) have recently been introduced in oral forms. This may reduce the risks associated with intravenous treatment, and be more convenient for the patient. However, it may introduce new risks if it is wrongly perceived as safer

and is therefore not supervised as closely as intravenous chemotherapy. Between hospital visits, patients may be under the care of GPs with less specialist knowledge and less of a supporting infrastructure.²⁶

Case 28. Fatal bone marrow depression as a result of melphalan overdose

A patient was receiving chemotherapy for a lymphoma. She was discharged from hospital with a copy of the hospital prescription which she gave to her GP:

Melphalan 7 mg daily for 4 days

Prednisolone 30 mg daily for 4 days

Allopurinol 100 mg three times a day for 14 days

The GP issued a repeat prescription for all three drugs not realising that the melphalan and prednisolone should only have been continued for 4 days.

The repeat prescription for melphalan was issued as follows:

*'Melphalan 5 mg + 2 mg **twice** daily'*

The GP failed to notice the error. The prescription should not have been continued but the patient continued to take melphalan in a dose that was twice the dose in the original short course. She died as a result of bone marrow depression caused by the melphalan overdose.²⁷

Reducing the risks of cancer chemotherapy

- Cytotoxic chemotherapy should only be prescribed by a clinician who has received training in the speciality, and who has demonstrated competence to prescribe. All staff working in oncology should be trained in the risk of medication errors.
- The same method for calculating body surface area should be used by all staff involved in calculating or checking doses which are based on body surface area. Nomograms or algorithms used for dose calculations should be appropriate for the purpose, validated and applied correctly.
- Simplification of dosing calculations will reduce the potential for calculation error. Some specialist centres are developing 'dose banding' systems for some drugs where individual doses are automatically rounded up or down within pre-agreed limits.

Professor Kent Woods has reported on the general issue of preventing intrathecal medication errors.²⁸ Professor Brian Toft conducted the external enquiry into the incident at the Queen's Medical Centre, Nottingham in 2001.²⁹ Drawing on the recommendations made in these reports the Department of Health issued comprehensive national guidance in 2001 on the safe administration of intrathecal chemotherapy.³⁰ This was updated and re-issued in 2003 together with a training pack.³¹ All NHS trusts providing intrathecal chemotherapy must comply with this guidance. Oncology staff and service managers must be aware of the guidance and regular audits should be undertaken to ensure adherence.

The website 'Management and Awareness of the Risks of Cytotoxics' provides an online information and support service for oncology and healthcare professionals seeking to improve the standards of safety in the handling, administration and monitoring of cytotoxic drugs. The guidelines have been developed from a full literature search and expert review of the evidence base, and offer guidance on over 20 topics related to safe handling and monitoring of cytotoxic drugs.³²

- All injectable chemotherapy should be prepared centrally within the pharmacy and be labelled according to agreed protocols. All calculations should be double-checked as part of this process.
- National guidance on intrathecal chemotherapy should be implemented rigorously.
- All supplies of oral cytotoxic drugs should be double-checked before being issued to patients. For short courses or intermittent therapy labels should always specify the course length.
- Pharmacists should be an integral part of the team caring for cancer patients both in the inpatient and outpatient setting, so that advice on dosage and side effects is available to staff and patients.

- If patients receiving oral chemotherapy are being cared for by their GPs in the community, the GP, nurse, pharmacist and patient should have sufficient information about the treatment plan to be able to identify adverse effects quickly.
- All patients undergoing cancer chemotherapy should carry a card to alert doctors unfamiliar with them to the possibility of immunosuppression, lowered white blood count or septicaemia. Consideration should be given to the design of a national standard patient held 'immunosuppression card'.

The American Society of Health-System Pharmacists has produced a series of recommendations for preventing medication errors in cancer chemotherapy.³³ These focus on the following key areas:

- **Education of health care professionals**
 - **Procedures for verifying prescribed doses**
 - **Establishment of dosage limits**
 - **Standardisation of prescribing vocabulary including drug names and expression of dosage units**
 - **Working with drug manufacturers**
 - **Patient education**
 - **Effective communications**
- The NPSA should work with oncology practitioners to develop national standards for the safe prescribing and administration of cancer chemotherapy.

5.4 Intravenous infusions

Medication errors involving the intravenous route have particularly high potential for patient harm. Administration of drugs by infusion often uses complex equipment. Errors may occur when staff use inappropriate or unfamiliar equipment, when equipment fails or when staff training has not been adequate. Standardising the range of equipment used locally, training, and device maintenance programmes may reduce the risk of infusion related error. The National Patient Safety Agency is working with manufacturers, the NHS Purchasing and Supplies Agency and NHS trusts to develop a package of measures to reduce errors with infusion devices.

- 5.4.1** Infusion devices are used widely to administer drugs at a controlled rate via the intravenous route. Infusions are used for continuous administration of potent medicines, or where medicines given intermittently need to be diluted to reduce irritation to the vein at the site of administration.
- 5.4.2** If the administration rate is not adequately controlled the patient may receive too little medicine or too much. Administration of a continuous infusion too rapidly may result in serious toxicity.
- 5.4.3** Problems associated with medical devices such as infusion pumps are reported to the Medicines and Healthcare products Regulatory Agency (MHRA) who investigate adverse incidents, issue safety warnings and provide advice on the development of national and international standards for equipment design, including equipment used for medicines administration.
- 5.4.4** Adverse incidents associated with infusion devices can occur for a number of reasons, including failure of the device itself, user error, inadequate servicing and maintenance, inappropriate device selection and inadequate instructions for use. User error is the most frequent cause.

Between 1990 and 2000, 6773 adverse incident reports associated with infusion and transfusion devices were received by the Medical Devices Agency.³⁴ These included 85 fatalities. A detailed investigation of 1495 adverse incident reports involving infusion pumps was carried out. In just over half of the reports the cause of the error could not be established. The remainder of the cases were attributed to:

- *user error (19%)*
- *equipment performance (8%)*
- *design/labelling (5%)*

- *quality assurance (5%)*
- *damage (5%)*

In an analysis of 700 infusion errors 70 % were associated with syringe pumps and a large proportion of these were due to user error rather than failure of the equipment. Due to underreporting it is likely that the actual number of medication errors associated with infusion devices is at least five times the number actually reported.³⁵

5.4.5 Typical user errors with infusion devices include:

- misloading the giving set or syringe
- setting the wrong rate
- confusing primary and secondary rates
- not confirming the set rate
- not confirming the pump type or syringe size
- not stopping the pump correctly
- allowing free-flow of fluid when lines are removed or fitted
- unskilled or irregular servicing
- inadequate testing after servicing
- interference by patients or visitors

Case 29. Death due to an incorrectly set infusion pump

A patient died after receiving an overdose of diamorphine by infusion as a result of a misunderstanding around whose responsibility it was to set the infusion rate. The pump had been returned from servicing set at a rate 50 times that required to deliver the prescribed dose.³⁶

Case 30. Emergency caesarean section as a result of over-infusion

Oxytocin is administered as a controlled infusion to induce labour. While a nurse was setting up an oxytocin infusion the infusion device indicated a warning. She went to get help but failed to close the clamp on the giving set and the drug flowed freely into the patient. As a result of the over-infusion the baby needed to be delivered by emergency Caesarean section.³⁷

Reducing the risk of infusion errors

- Devices should be designed to be simple to set up, easy to use and have good safety features and alarms that alert users to problems.
- The device used should be appropriate for the drug being administered and the patient receiving the drug.
- Purchasers should note the advice given by the NHS Purchasing and Supply Agency and the MHRA.

The MHRA classifies infusion devices into risk categories.

Infusion devices are evaluated by performance characteristics, such as long term accuracy, consistency index, time to alarm, bolus following occlusion, and other suitable parameters for delivering infusions safely.

This classification informs clinicians of the most appropriate infusion device to use according to the clinical situation and intended treatment³⁸

- The MHRA recommends that hospital trusts establish multidisciplinary infusion systems committees who should advise on standardisation of infusion equipment, procurement, methods of use, training, maintenance and other issues with the objective to improve patient safety. The committee should include representatives from medical engineering, pharmacy, supplies and medical and nursing representatives from a range of clinical specialities.

Some NHS Trusts have established equipment libraries where infusion devices are procured, serviced and stored centrally. Devices are issued to clinical areas when required and returned after use. Centralisation in this way can ensure that a range of appropriate, well-maintained devices is available for use, supported by appropriate training and advice.³⁹

- Staff should be trained in proper use of infusion devices, supported by good user manuals. All suppliers provide training in the correct use of their equipment.

The Clinical Negligence Scheme for Trusts (CNST) Clinical Risk Management Standard 5: Induction, Training and Competence requires NHS Trusts to ensure the competence and appropriate training of all clinical staff. Standard 5.1.5 states that there should be a system in place which identifies any equipment for which the operator is required to have specialist training, and for each piece of equipment users and their training needs should be identified. These should be achieved through equipment controllers or, where appropriate, an equipment library.⁴⁰

- Managers should ensure that training in infusion devices is made available to all staff. Staff should ensure that they have received adequate training and are confident that they know how to use the devices safely.
- Staff should know how to set the device up, how to get air out of the system and know what the alarm systems mean and how to respond to them. They should not be obliged to set up a pump that they have not been trained to use.
- Any actual or suspected damage to a device must be reported so that the device can be serviced to ensure that it is still accurate.
- The NPSA is working with stakeholders to develop and evaluate a range of measures to improve safety with infusion devices. These include a checklist to support purchasing, a user evaluation questionnaire, support for the development of equipment libraries and a web-based training tool.

5.5 Safer use of methotrexate

Methotrexate is a cytotoxic and immunosuppressant drug that is not commonly prescribed outside the specialist areas of oncology, dermatology and rheumatology. Low-dose oral methotrexate for psoriasis or rheumatoid arthritis is prescribed for once a week administration, and care is often shared between GPs and hospital consultants. Prescribing, dispensing and administration errors have led to inappropriate daily dosing with methotrexate, resulting in a number of fatalities. The National Patient Safety Agency is working with health professionals, patient groups, the pharmaceutical industry and software suppliers to develop measures that will improve safety of methotrexate treatment.

5.5.1 Methotrexate is a cytotoxic agent used in the treatment of some cancers and as an immunosuppressant in the treatment of psoriasis and rheumatoid arthritis. In the vast majority of cases methotrexate is used safely and effectively. However, its potential toxicity includes bone marrow suppression, and the dose and side effects need to be monitored closely during treatment.

5.5.2 Medication errors with methotrexate can occur in both primary and secondary care and may involve prescribing, dispensing, administration or a combination of causes. The outcome is usually serious and often fatal. The NPSA has identified 25 deaths and 26 cases of serious harm linked to the use of methotrexate in England over a 10-year period.⁴¹ The problem is also well documented in the USA and Australia. Cambridgeshire Health Authority has published a comprehensive analysis of the causes of a fatal methotrexate error:

Case 31. Fatal toxicity as a result of daily methotrexate dosing

A woman prescribed methotrexate for the treatment of rheumatoid arthritis died as a result of receiving 10 mg daily, instead of a weekly dose of 17.5 mg. The overdose of methotrexate severely depressed her blood count which resulted in infection and gastrointestinal bleeding.⁴²

5.5.3 The primary causes of these serious errors are the dose and/or frequency prescribed or dispensed. In some instances this is due to confusion between the 2.5 mg and 10 mg strengths of methotrexate where both have been available. In others, errors have occurred when patients have been admitted to hospital for a primary diagnosis other than rheumatoid arthritis, and prescribing errors were made by house officers that do not routinely prescribe this drug.⁴³

5.5.4 These issues have been highlighted by the Committee on Safety of Medicines (CSM)⁴⁴ and in the British National Formulary.⁴⁵

5.5.5 Lack of patient information and poor understanding of the importance of weekly dosing are also important contributory factors.

A study in 93 patients attending rheumatology outpatient clinics found that many patients had insufficient knowledge about methotrexate side effects and interactions. Many patients were unsure of their dose and unaware of their tablet strength, leaving them vulnerable to adverse effects and prescribing and dispensing errors. Some patients had not read the information provided. The authors suggest that key messages about methotrexate toxicity be reinforced regularly, possibly by including essential information on a patient-held monitoring and dosage card, and through advice from pharmacists. Such information needs to be available for non-English speaking patients.⁴⁶

Reducing the risks of methotrexate treatment

- Doctors should be cautious when changing the treatment of chronic disease states which are being managed by specialist colleagues. If changes are made they must be appropriately communicated and documented.
- Procedures and prompts, both computer based and manual, should be put in place in primary and secondary care to reduce the risk of incorrect dosing of methotrexate. A warning prompt indicating a weekly dose should be linked to methotrexate.

To minimise the risk of confusion, some hospitals have taken the decision to stock only one strength of methotrexate tablets⁴⁷

- The CSM Working Group on the Labelling and Packaging of Medicines⁴⁸ has recommended that manufacturers should include an additional warning statement on the front face of the packaging reminding health care professionals to:

“Check dose and frequency. Methotrexate is usually taken once a week”

- Prescribers, pharmacists and nurses should ensure that they are familiar with weekly dosing regimens and should take an active role in ensuring that patients taking methotrexate understand their dose and regimen.

- They should also ensure that patients know how to recognise signs of toxicity and the importance of referring themselves to their doctor if any of these signs develop.

Barts and the London NHS Trust has established a high risk drug monitoring service to minimise the risk to patients taking medicines such as methotrexate, particularly when they move between primary and secondary care.⁴⁹ Patients are seen by a pharmacist in the clinic, who provides education about medicines, monitors laboratory tests and advises on dose changes. Patients are followed up into primary care with careful attention to communications and shared care guidelines. The service has reduced risk, increased clinic capacity, and improved patient satisfaction by reducing hospital attendance time.

- Patient held records should be used to provide information for patients about their treatment and dose. These should be available to clinicians who do not have immediate access to the patient's medical record.
- The NPSA is working with health professionals, patient groups, the pharmaceutical industry and software suppliers to develop a package of measures. These include a patient treatment diary, improved packaging and patient information and IT flagging mechanisms to minimise prescribing and dispensing errors.⁵⁰

5.6 Opiate analgesics

Potent opiate analgesics are frequently involved in serious medication errors, often because of incorrect dose calculations.

A wide range of products with differing potencies and release characteristics are available. This can be confusing to inexperienced staff and contributes to medication errors. In particular, confusion between different strengths of oral morphine has caused a number of fatalities. Hospitals and general practices should limit the range of opiates used and establish clear guidelines for their prescribing and use.

5.6.1 Opiate analgesics are widely used for moderate to severe pain. They are administered orally, rectally and by injection. They have a narrow therapeutic margin and in overdose cause respiratory depression and hypotension. There are many reports of fatal medication errors where patients have inadvertently received an excessive dose of opiate.

Case 32. High dose of morphine given to wrong patient

A 77 year old man with chronic respiratory disease was being cared for in a nursing home. He was given a dose of 300 mg sustained release morphine tablets which was intended for the person in the next room. He was found unconscious and died three days later from pneumonia. The nursing home's written medicine policy, which required double-checking of controlled drugs, had not been followed.⁵¹

5.6.2 Morphine is one of the drugs most commonly involved in medication errors reported to both US and Swedish databases.^{52,53} Opiates are designated “high alert medications” by the US Joint Commission on Accreditation of Healthcare Organisations,⁵⁴ which identified ward stocks and drug name confusion as common risk factors. Patient controlled analgesia (PCA), unless properly managed, may also present risks.

5.6.3 Opiates feature prominently in serious errors reported to the NHSLA,⁵⁵ the MDU⁵⁶ and the dispensing error analysis scheme.⁵⁷ (*see Chapter 3.2*)

- 5.6.4** Because many opiate preparations are derivatives of morphine their names often contain a common stem. This can lead to confusion, particularly when drugs with similar sounding names have greatly differing potencies. For example,

morphine

diam**m**orphine

hydrom**m**orphone

- 5.6.5** Many oral opiates are available in a variety of dosage forms. Oral immediate-release and controlled-release products are available from several manufacturers. Serious errors have occurred as a result of confusion between different formulations of the same drug.

Table 5.6.1 Range and complexity of formulations of oral morphine containing products

Immediate release	Controlled release
2 manufacturers	3 manufacturers
7 products	26 products
5 strengths (10 – 100 mg)	12 strengths (5 – 200 mg)

- 5.6.6** If oral morphine sulphate is prescribed for administration to patients in hospital without specifying the dosage form, there is potential for confusion between sustained-release products, which are usually prescribed every 12 or 24 hours (MST[®] or MXL[®]), and immediate-release products, (Oramorph[®] or Sevredol[®]) which are usually administered every four hours.

Confusion between MST and Sevredol was reported 11 times between 1993 and 2001 to the anonymous error reporting scheme in an NHS Trust.⁵⁸ An alert was issued to all staff to raise awareness of the risks.

- 5.6.7** For example, if a patient prescribed morphine sulphate 60 mg every 12 hours is given an immediate-release preparation of morphine sulphate instead of a controlled release preparation they are very likely to experience the effects of morphine overdose. A similar situation may arise with oxycodone where two formulations for administration at different frequencies exist.

Case 33. Over-sedation as a result of confusion between morphine sulphate tablets

A patient was prescribed morphine sulphate slow release tablets (MST®) 60 mg regularly twice daily for pain relief in addition to quick acting morphine sulphate 10 mg (Sevredol®) as required for breakthrough pain. Sixty mg Sevredol® was given in error when MST® was due. The patient became heavily sedated, although no active intervention was required.⁵⁹

- 5.6.8** This is more likely to be a problem in hospitals where prescriptions on the inpatient drug administration record do not need to comply with the regulations for Controlled Drug prescribing in the same way as outpatient prescriptions.
- 5.6.9** Errors have occurred with injectable opiates as a result of confusion between the packaging of ampoules of morphine and diamorphine.

Case 34. Diamorphine overdose in migraine attack

A patient suffering with migraine, with severe headache and vomiting, was prescribed diamorphine and metoclopramide by the Emergency Doctor Service. The doctor intended to administer 5 mg of diamorphine from a 10 mg ampoule, but 15 mg was inadvertently administered from a 30 mg ampoule. The patient, an otherwise fit young woman, died of diamorphine toxicity. Similarity between the ampoule sizes and the appearance of the labels contributed significantly to this tragic event.⁶⁰

Figure 5.6.1 Use of colour to differentiate strengths of diamorphine



Figure 5.6.2 Similarities in diamorphine ampoule labelling have led to serious error



Figure 5.6.3 Similar labelling on outer packs of morphine may also cause confusion



A retrospective review of medication errors at the Royal Hospital for Sick Children in Glasgow identified that five errors associated with morphine sulphate had occurred up to July 1998. The hospital implemented two strategies to reduce the risk of recurrence

- **Only one strength of morphine sulphate ampoules would be stocked in the hospital instead of three**
- **The neonatal intensive care unit changed to using syringes of morphine sulphate made up by the pharmacy department at a concentration of 50 micrograms/ml.**

There were no further errors reported during the two years following implementation of these changes.⁶¹

5.6.10 Specialists in pain management working in multidisciplinary teams can ensure that protocols are in place for prescribing, dosage, administration, device selection and patient monitoring to reduce the risks with opiates. When strong opiate analgesics are used for post operative pain relief, by patient controlled analgesia (PCA) or continuous epidural analgesia with a local anaesthetic, the involvement of acute pain teams and specialist 'pain' nurses can minimise the risks.

Reducing the risks of errors with opiates

- NHS organisations should have local guidelines in place to ensure safe prescribing, dispensing, administration and monitoring of strong analgesics. Where appropriate this may include pre-printed prescriptions.
- The range of products available for administration should be limited to minimise the risk of confusion. High strength ampoules of opiates should not be held routinely in general ward areas or by community practitioners.
- Medical, nursing and pharmacy staff should be familiar with the range of oral morphine products available and the usual frequencies in which they are prescribed and administered.
- Patients receiving injectable or high-dose oral opiates should be monitored carefully. The opiate antagonist, naloxone, should be available and staff should be trained in its use. It should be prescribed in advance or be subject to a Patient Group Direction to allow its administration in an emergency.

- All acute hospitals should have a multidisciplinary pain team to advise on good practice, establish safe systems and train other staff in the safe use of strong analgesics.⁶²

A Pain Control Team at King's College Hospital⁶³ has developed standard prescriptions for epidural analgesia and patient-controlled analgesia to ensure that prescriptions are unambiguous and that naloxone is concurrently prescribed for use if necessary. The adhesive stickers have been designed to be fixed to the patient's drug chart.

Figure 5.4 Proforma prescriptions for strong opiate infusions

EPIDURAL			
Diamorphine 5mg in Bupivacaine 0.25% 50ml			
Rate			
1-5ml/hour			
Anaesthetist's Signature		Start Date	Pharm.
Naloxone			
Dose		If respiratory rate less than 7/min or patient difficult to rouse	
100 micrograms			
Max. Frequency	Route	Inform Doctor after administration	
2 min	i.v		
Signature		Start Date	Pharm.
SUBCUTANEOUS PCA			
PATIENT CONTROLLED ANALGESIA			
Diamorphine 100mg in N/Saline 50ml			
Bolus dose		Lockout	
2 mg		10 minutes	
Signature		Start Date	Pharm.
Naloxone			
Dose		If respiratory rate less than 7/min or patient difficult to rouse	
100 micrograms			
Max. Frequency	Route	Inform doctor after administration	
2 min	i.v		
Signature		Start Date	Pharm.

- Oral sustained-release opiates are a particular source of error and care should be taken to avoid any possible ambiguity when prescribing these drugs. Including the brand name on the prescription and dispensing label will aid in the identification of the correct formulation to be dispensed or administered.

- All dose calculations and drug administration of strong analgesics on hospital wards should be double-checked.
- Prescriptions dispensed for individual patients to take at home should be double-checked for accuracy.
- Ideally, doses of opiates for administration to neonates and small children should be prepared centrally in the pharmacy or supplied in small dose units.

5.7 Potassium chloride

Rapid administration of concentrated potassium chloride solution causes cardiac arrest and is frequently fatal. Injection of concentrated potassium chloride solution has occurred where the ampoules have been confused with other drugs or diluents. Such errors can be avoided if these ampoules are not routinely stored on hospital wards. The availability of potassium solutions on wards in NHS hospitals was the subject of the first NPSA Patient Safety Alert.

5.7.1 Potassium chloride (KCl) is cardiotoxic and is part of the lethal cocktail of drugs used to carry out the death penalty in some countries. It is used therapeutically to correct hypokalaemia (a low level of potassium in the blood) when it is administered as a dilute solution by infusion.

5.7.2 In patients who are fluid restricted, more concentrated infusions may be administered via a central venous line with cardiac monitoring. In these cases infusions may be made by diluting concentrated potassium chloride solution to a suitable volume.

5.7.3 Administration of potassium chloride by the intravenous route is inherently hazardous. Both the concentration and rate of administration of the infusion solution are critical. There are multiple reports both from the United States and the United Kingdom of fatal errors. Potassium chloride was mentioned in 40 incidents reported in the NPSA pilot data audit.

5.7.4 Errors have occurred when ampoules of concentrated potassium chloride solution, containing 10% or 15% potassium chloride solution, stored on wards to prepare dilute solutions, have been accidentally injected at full strength instead of water or saline.

Figure 5.7.1 Striking similarity between strong potassium chloride and sodium chloride ampoules: confusion can be lethal



“The way to prevent tragic deaths from accidental intravenous injection of concentrated KCl is excruciatingly simple – organisations must take it off the floor stock of all units. It is one of the best examples I know of a ‘forcing function’ – a procedure that makes a certain type of error impossible”⁶⁴

Lucian Leape

The US Joint Commission on Accreditation of Healthcare

Organisations highlighted the risks of KCl in a Sentinel Event Alert in 1998.⁶⁵ In eight of ten fatal cases the availability of concentrated KCl on the nursing unit was a contributing factor. In six of the eight cases the KCl was mistaken for some other medication e.g. sodium chloride, heparin or furosemide. The Commission recommended that KCl should not be available outside pharmacy without specific safeguards. Following publication of the alert the number of reported deaths due to maladministration of KCl fell from 12 in 1997 to only one in 1999.⁶⁶

Case 35. Inadvertent use of KCl to flush an intravenous cannula

A six-day-old baby girl was prescribed intravenous antibiotics during a hospital admission. The dose should have been followed by a saline flush. Immediately after the flush she became pale and stopped breathing. Her heart then stopped and a pulse did not return until resuscitation attempts had gone on for five and a half minutes. An ampoule of concentrated potassium chloride had been used in place of the normal saline intended for the flush.⁶⁷

Case 36. Inadvertent use of KCl to reconstitute an antibiotic

A 65 year old woman died after concentrated potassium chloride solution was used in place of water for injections to reconstitute a vial of cefuroxime injection. She had undergone a routine gastrointestinal investigation procedure in the operating theatre. Immediately after the injection she collapsed and could not be resuscitated. Two ampoules of concentrated potassium chloride solution had been used in place of the required water for injections to reconstitute the antibiotic.⁶⁸

- 5.7.5** A number of NHS trusts have implemented policies to reduce the risk of potassium chloride errors by restricting the availability of the concentrated solution.^{69,70}

The Guild of Health Care Pharmacists issued a statement on the storage and prescribing of strong potassium chloride solutions providing pharmacists with guidance on their responsibilities to reduce risks associated with its use.⁷¹

- 5.7.6** However, while the central distribution of potassium chloride can be controlled, it may be difficult to regulate the redistribution of ampoules within a hospital from areas that may need to hold stock, e.g., dialysis units, ITUs, theatres. Preventable errors still occur due to lack of effective risk management with this hazardous drug.

The Freeman Hospital, Newcastle Teaching Hospitals NHS Trust, has introduced a system of ordering concentrated potassium chloride ampoules which ensures that all stages in the ordering, supply, delivery and receipt of the ampoules are traceable by signature.⁷²

- 5.7.7** The risks associated with the availability of concentrated potassium chloride solution and measures to improve safety in the use of this drug were the subject of the first Patient Safety Alert issued by the NPSA in July 2002.⁷³

Reducing the risks of errors with strong potassium chloride

- All NHS organisations should implement policies and procedures to restrict the availability of ampoules of concentrated potassium chloride in clinical areas, in line with the NPSA safety alert. The availability of other injectable potassium salts, including potassium hydrogen phosphate and potassium di-hydrogen phosphate, should also be reviewed.
- Ampoules should not normally be stored at locations outside the pharmacy department apart from specialist theatre areas and critical care areas. The member of staff responsible for storage of medicines should demonstrate that systems are in place to prevent accidental misuse.
- A wide range of pre-prepared infusion solutions containing potassium chloride should be made available. Storage arrangements, both within pharmacy and at ward/department level, should be designed to avoid the risk of selecting the wrong concentration, or of confusion with other infusion solutions
- Potassium chloride should be prescribed whenever possible in concentrations available as ready-made infusions. Ideally prescriptions for potassium chloride in concentrations other than these should be dispensed on an individual patient basis by pharmacy to ensure that the prescription is safe.
- Ampoules of concentrated potassium chloride solution should be visually distinguishable from all other injectable preparations, especially commonly used ampoules such as sodium chloride and water for injections.
- The use of the word 'injection' on ampoules of concentrated potassium chloride solution should be discouraged.
- The CSM Working Group on the Labelling and Packaging of Medicines has recommended that ampoules and cartons of concentrated potassium chloride solutions should bear a large red 'K' on the labelling to highlight the need for caution.⁷⁴ This recommendation should be implemented urgently.
- Until such cautionary labelling is implemented nationally, pharmacists should ensure that dispensed potassium products bear a similar warning label.

- Some NHS Trusts use distinctive glass ampoules with a black cap, but there is no NHS or industry standard. The NPSA and MHRA should work with industry and practitioners to develop distinctive, standardised labelling and packaging of these products, as recommended in the report of the CSM Working Group.

Figure 5.7.2 Distinctive black cap on potassium chloride ampoule



- Potassium chloride ampoules should only be stored on wards where there is a specific clinical indication and there is no suitable ready-made dilute form. They should be stored in a separate locked drug cupboard used solely for the storage of potassium chloride.
- Concentrated potassium chloride ampoules should not be transferred between clinical areas. All supplies should be made directly from the pharmacy department
- Where it is necessary to prepare an infusion the addition of the concentrated potassium chloride solution should ideally be carried out centrally in the pharmacy, otherwise in a clinical room away from the patient. Extra care should be taken to ensure that additives made in this way are adequately mixed to avoid the risk of 'pooling' of the concentrate within the infusion.

- Risks associated with the storage, prescribing, preparation and administration of potassium chloride containing solutions should be highlighted in patient safety induction training for all staff involved in the medication process and should also feature in specific training programmes for intravenous drug preparation and administration.

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6

Reducing the risks: organisational and environmental strategies

6.1 Safer medication through information management and technology

Information technology has not been deployed to best effect to manage prescribing and drug administration in the NHS. The Government is now firmly committed to the investment needed to provide modern information management in the NHS, with £2.3 billion to be provided in 2003-06. The electronic national care record is central to this strategy and will ensure that any health professional treating a patient will have access to essential clinical information, including the medicines they are taking. This will provide increased safety in the prescribing, dispensing and administration of medicines. Greater use of electronic prescribing in hospitals, bar-coding technology and robotic dispensing have the potential to reduce further the risk of medication errors.

The National Programme for Information Technology in the NHS (NPfIT)

6.1.1 The NHS has, over many years, failed to make best use of information management and technology to handle clinical information, including prescribing processes and drug administration. The Government's information strategy is now committing significantly increased investment to the development of modern communications and information management in the NHS.

6.1.2 In *Delivering the NHS Plan*¹ the Government renewed its commitment to taking forward the IT strategy and providing the necessary investment for implementation. *Delivering 21st Century IT Support for the NHS*, published in June 2002, set out the strategy for electronic delivery of healthcare services.² Introduction of a national care record and electronic transfer of prescriptions in primary care are among the key elements in this strategy. The electronic care record will, for the first time, enable health professionals in any setting (subject to consent, confidentiality and security requirements) to access the patient data they need to deliver care safely, effectively and efficiently.

Using information technology to reduce medication errors

6.1.3 The case examples of serious medication errors given in preceding chapters virtually all involve failure to receive, recognise, interpret or act appropriately on drug or patient data. Well-designed and implemented information management solutions therefore offer potential to reduce the scope for human mistakes and lapses, and to eliminate completely some types of error.

*In a study of 317 general practitioners in Yorkshire, 17% said that lost paper records had led to wrong drugs being given. Sixty percent thought that the introduction of electronic records would improve standards of care.*³

6.1.4 There is already considerable experience in the United States with electronic prescribing and robotic drug management systems and there is now increasing evidence from a small but growing number of developments in the UK that appropriate application of IM&T can reduce error. These include electronic prescribing, computerised decision support, robotic pharmacy dispensing machines, bar-coding and computerised medication administration records.

6.1.5 The key benefit of computerising the prescribing, dispensing and administration of drugs is that information about the patient and the drug is centralised and available to each person who has to make decisions in these complex processes. Crucially, data about the patient and the drug being prescribed are linked, enabling cross checks to be made and problems such as contraindications and dosing errors to be identified and resolved.

6.1.6 However IM&T solutions have been developed to meet the requirements of particular medication systems, most notably in the United States. The benefits are not automatically generalisable to NHS settings. New systems have the potential to introduce new errors which can be more difficult to detect. For example, fast look-up codes may not differentiate similar drugs names (e.g., penicillamine selected when penicillin required⁴). Automated medication systems

therefore need rigorous design and user assessment before widespread implementation.

- 6.1.7** It is also important not to place undue reliance on automated solutions, which should not replace clinical skills and judgement. For example, patients have received incorrect doses of radiotherapy and chemotherapy when professionals failed to recognise erroneous dose recommendations from computer systems.⁵ Staff need to respond appropriately to drug interaction alerts⁶ and ensure that relevant information, for example, on allergies, is kept up to date so that alerts are triggered if an attempt is made to prescribe a contraindicated drug.

Electronic transfer of prescriptions (ETP) and electronic prescribing

- 6.1.8** The use of computers in prescribing is well established in primary care with the vast majority of prescriptions being generated electronically. However, there is significant variation in the functionality of GP systems for monitoring prescribing and medication review. Systems that do not comply with the Department of Health's accreditation (RFA) standards⁷ may be less effective in monitoring prescribing and patients' response to treatment.
- 6.1.9** However, although most GP prescriptions are now generated electronically, currently they have to be printed out and taken to the pharmacy for dispensing. Pilot projects have recently been concluded on electronic transfer of prescriptions between GP surgeries and community pharmacies. The pilots showed that prescriptions can be transmitted electronically in an accurate and secure manner. How best to implement ETP electronically, using the patient record spine as the vehicle for storing and transferring prescriptions, is now being taken forward within the NPfIT. ETP will provide great benefits for patients. In particular, it will remove the need for prescriptions to be re-keyed in the pharmacy, eliminating an significant potential for error.
- 6.1.10** Experience of electronic prescribing in UK hospitals is limited to a few sites. In contrast, there is extensive experience in the US, where electronic prescribing (often referred to as computerised physician order entry or CPOE) is routine practice in many hospitals.

Potential benefits of computerised prescribing

- All prescriptions include the drug name, dose, route and frequency (system prompts prescriber for these data elements)
- Prescriptions are legible and the prescriber is always identifiable
- Information about the patient is available to the prescriber at the time of prescribing
- Information about the drug is available to the prescriber at the time of prescribing
- Prescribers are alerted to anomalous dose and frequency selection
- Prescriptions are checked for allergies, drug-drug interactions, drug-laboratory interactions, contraindications or cautions in the patient, and the prescriber alerted.
- All relevant data about the patient and their drug regimen are available centrally
- Adverse effects can be documented and reported, audit and pharmacovigilance are facilitated
- Adverse drug events may be detected by capturing the use of antidotes such as vitamin K (warfarin overdose) or glucagon (insulin overdose), allowing review of events which led to their use.
- Relevant prescribing guidelines can be built into the prescribing system, helping achieve optimal treatment

In the US, RAND Health Communications is developing standards for electronic prescribing to help organisations select systems that optimise patient outcomes.⁸ These standards can guide the development of electronic prescribing to ensure that both benefits and problems with their application can be identified. The team is currently aiming to identify 'exemplar' systems which will be the basis for developing standards.

- 6.1.11** Electronic prescribing offers the additional benefit of releasing pharmacy staff time from routine prescription checking. Currently, prescribing errors are identified retrospectively, ideally before the patient receives the drug. The pharmacist then has to contact the prescriber to review the prescription.
- 6.1.12** Electronic systems have the potential to check automatically for dose errors, drug-drug and drug-disease interactions, and provide immediate alerts. Time can then be freed up from prescription checking to provide wider medicines management services and to advise on the more complex issues of drug selection, drug administration and monitoring of response to treatment.
- 6.1.13** Computerised prescription entry in the US has been shown to reduce the rate of serious medication errors by 55%⁹ and the rate of all errors by 83%.¹⁰

Computerised physician order entry (CPOE) at the Brigham and Women's Hospitals, Boston, eliminates the need for transcription of poorly legible orders and includes a dose selection menu, simple allergy and drug-drug interaction checking, and indicates routes and frequency of drug dosing. Introduction of the system prevented more than half of serious medication errors, with the rate declining from 10.7/1000 patient-days to 4.86/1000 patient days. Error rates were reduced in all stages of the medication process including prescribing, transcription, dispensing and administration.

- 6.1.14** However, caution needs to be exercised in translating this apparent dramatic improvement in prescribing quality into UK hospitals as traditional US practice involves extensive transcribing from case notes. To date, electronic prescribing has been implemented in only a small number of NHS hospitals.

In 1992 the Wirral Hospital introduced electronic prescribing using the TDS 7000 system (Technicon Data Systems, Atlanta). The effect on legibility and completeness of prescriptions was compared with hand-written prescriptions. A total of 2180 prescriptions for 267 patients on 5 wards (1217 before and 963 after computerisation) were assessed against the hospital standard for prescription writing as specified in the British National Formulary. Computerised prescribing significantly ($p < 0.0001$) improved the legibility and completeness of prescriptions compared with hand-written instructions.¹¹

A project at the Hammersmith Hospitals NHS Trust is evaluating the ServeRx system (MGD Medical Inc.). This provides electronic prescribing on a hand-held computer, linked to a ward workstation. The system maintains records of prescribing and administration, generates safety alerts, for example allergies, and controls drug storage and the drug trolley (which contains patient-specific drawers). Its impact on error rates is being evaluated.

Bar-coding

6.1.15 Bar-code technology is familiar through its widespread use in the retail sector. This technology has potential to improve patient safety by scanning codes on the drug, prescription and patient at the time of administration, reducing the risk of wrong drug errors. Pharmacy and ward stock management may be improved, reducing the risk of drugs becoming out of stock – one cause of omission errors.

6.1.16 Bar-coding is widely used in the US to manage medication in hospitals. The Department of Veterans Affairs (VA) has implemented a system in all 172 of its healthcare institutions:

“We now put medication bar-codes on our patients’ wristbands, on their IV tags and on their medication packages and then scan bar-codes before we give patients their medicine Initial reports show the system has eliminated two thirds of mistakes. This has potential to save countless lives”

Thomas L Garthwaite, VA Acting Under Secretary for Health¹²

6.1.17 The US Food and Drug Administration has now given notice of a proposal for mandatory bar-coding of all drugs and biological products, with the principal aim of reducing medication errors.¹³

Automated medication administration record

6.1.18 Medication administration records (MARs) in hospitals are prescription sheets on which details of each dose given are also recorded. In most UK hospitals these are hand-written. Ambiguous, incomplete or illegible records are a frequent cause of medication errors, and feature prominently in error inquiries. Transcription errors also occur when charts are rewritten.

Transcription may be perceived by doctors as a mechanical task rather than prescribing, especially during the night. "It's such a boring, thankless, tedious job that you're not going to sit there and use your clinical judgement..."

From Dean et al¹⁴

Figure 6.1 Example of a hand-written medication record – automation will improve legibility and make prescribing safer

REGULAR PRESCRIPTIONS													
DATE (YEAR/MONTH)	DRUG (Generic Name)	DOSE	TABLE OF ADMINISTRATION							METHOD OF ADMINISTRATION	SIGNATURE	NURSE	DATE
			0	01	02	03	04	05	06				
21/01	ROXITHROMIDINE	150mg								PO		05	
"	VONIPLEXIN	500mg								PO		05	
"	ASPIRIN	200mg								PO		05	
21/01	PARALIDONE	500mg								PO		05	
21/01	RECTALG	20mg								PO		05	
21/01	CIPROFLOXACIN	400mg								PO		05	
21/01	METRONIDAZOLE	500mg								PO		05	
21/01	HEPESIN	500mg								PO		05	
21/01	LOXALONE	150mg								PO		05	
21/01	BUSINEX A	T								PO		05	
21/01	Sylmet	T								PO		05	
21/01	Calixone	150mg								PO		05	
21/01	METRONIDAZOLE	500mg								PO		05	
21/01	CIPROFLOXACIN	500mg								PO		05	
21/01	Molital	150mg								PO		05	

- 6.1.19** Errors have occurred when drug administration has not been recorded and the dose has been given twice, and also when doses have been omitted. Omissions are often not recorded and clinicians are then unaware that the dose has not been given. Bar-coding, linked to an automated medication administration record, can ensure that all drug administration episodes and omissions are accurately recorded.
- 6.1.20** Bar-coding therefore offers the potential for coded drugs to be prescribed on coded electronic prescriptions for patients identified against their bar-coded medication record, and given by a bar-coded nurse. In this way the 'five rights' of drug administration (right drug, dose, patient, route and time (*see Chapter 3.3*)) should be ensured, with an electronic record of administration by an identified practitioner. When this is linked with an electronic patient record, the record of drug administration can readily be reviewed alongside changes in the patient's clinical and laboratory status.
- 6.1.21** There are already a number of examples of bar-coding in the NHS, for example in the blood transfusion service. For this technology to be applied to prescribing and administration of medicines, a number of technical issues need to be resolved, including the adoption of standard drug codes. And it cannot be assumed that success in reducing medication errors in a North American setting will necessarily translate to British hospitals. Nevertheless, the potential of this technology – and emerging techniques such as radio frequency tagging – should be evaluated in the NHS setting.

Robotic dispensing systems

- 6.1.22** Patient safety may be improved by automating routine technical functions that are prone to human error. Robotic automation of the dispensing process (again, widespread in the US) has been introduced in a few large hospitals in the UK, and also in a small number of community pharmacies. To date, however, there are only limited published data to demonstrate improved accuracy over traditional manual dispensing systems.
- 6.1.23** The dispensaries at St.Thomas's Hospital, London, the Royal London Hospital and Arrowe Park Hospital, Wirral, use the ARX ROWA robot to automate original pack dispensing for inpatients, outpatients and discharge prescriptions. The robot uses bar-code technology linked to dispensary labelling systems to select the items for dispensing and deliver them, via a chute, to the pharmacist or technician for dispensing.

Table 6.1 Some features of robotic dispensing systems

Task	Mode	Risk of error	Risk reduction
Stock allocated to shelf within robotic cabinet by bar code	Electronic	Drug placed at wrong location	Risk eliminated
Prescription screened by pharmacist	Manual	Inappropriate drug regimen not being recognised	No risk reduction
Label generated via pharmacy computer system	Manual	Wrong drug or dosage regimen entered	No risk reduction
Robot selects drug to be labelled using bar-code technology	Electronic	Wrong drug selected	Risk eliminated (assuming correct label entered)
Drug delivered by robot selected from chute by pharmacy staff for labelling	Manual	Wrong drug selected	Risk reduced but not eliminated. (At busy times many items can be delivered via chute creating a backlog)
Drug issued to patient/ward	Manual	Wrong drug issued to ward/patient	No risk reduction

A less quantifiable benefit of automation in the dispensary is that the environment is calmer as the need for staff to move about the dispensary is reduced.¹⁵

6.1.24 Dispensing error rates at Wirral Hospital NHS Trust fell by 50% in the first four months after introduction of this system¹⁶ but no data are available on the impact or nature and severity of errors.

6.1.25 Automated dispensing devices are also available for use on wards and clinical departments. They are widely used in the US but have not yet been evaluated in the UK. An evaluation of the ServeRx™ system which controls drug administration through a computerised cabinet on the ward, is now underway at the Hammersmith Hospitals NHS Trust.¹⁷ However, there is no evidence to date that such systems significantly reduce medication error rates.^{18,19}

Reducing the risks through information management and technology

- Modern information management and technology, implemented effectively, can contribute significantly to improving patient safety.
- The Government is already committed to the national care record and electronic transfer of prescriptions through the National Programme for Information Technology in the NHS. This will provide greater medication safety by greatly improving access to relevant patient data, and by reducing the need for prescriptions to be keyboarded in community pharmacies.
- Bar-coding technology, linked to electronic prescribing, has the potential to improve medication safety in hospitals but needs to be evaluated in the NHS setting. Robotic dispensing, in the pharmacy and on hospital wards, may also offer additional benefits.
- The NPSA and the Department of Health's Patient Safety Research Programme will further evaluate the effectiveness of these technologies in reducing medication errors.

6.2 Safer medication through improved labelling and packaging

Latent conditions that increase the likelihood of error can arise from the packaging and labelling of medicines. The design and appearance of packaging has become more important with the increasing use of manufacturers' original packs for the supply of medicines in the community and in hospitals. Similarities between the packaging of different strengths of the same product and different products produced by the same manufacturer are particular problems. A working group of the Committee on Safety of Medicines has made recommendations to improve patient safety through clearer packaging and labelling. Building on these recommendations the Medicines Control Agency (now the MHRA) and other interested parties agreed good practice guidelines for labelling and packaging which were published in March 2003.

- 6.2.1** There can be no substitute for carefully reading the label on a medicine. However, in busy clinical practice, other visual cues are sometimes used to aid drug selection, especially if the drug name is not the most obvious identifier on the packaging.
- 6.2.2** Confusing drug names, labels and packaging are important sources of medication errors. Sound-alike or look-alike drug names and similar packaging can lead staff to select the wrong drug.

Each year in the United States the Institute of Safe Medication Practice (ISMP) receives 1200-1500 reports of serious medication errors. Approximately 25% of these are related to name confusion and 25% to labelling and packaging issues. ISMP estimates that only 1-2% of events are reported. The total number of patients who are injured each year in the US because of drug name confusion is estimated to be at least 10,000. A similar number are injured as a result of errors caused by labelling and packaging confusion.²⁰

Confusing, inaccurate or incomplete labels and packaging contributed to 248 out of 1143 actual or potential drug errors (21%) reported to the US Pharmacopoeia Practitioners Reporting Network (USP/PRN) over a 1 year period.²¹

- 6.2.3** There are no comparable data for England but the incidence of such errors is likely to be similar.

Humalog® (insulin lispro) is a fast-acting insulin. Humalog Mix 25® (insulin lispro/insulin lispro protamine suspension) is a biphasic insulin. Administration of the fast acting insulin instead of the biphasic insulin may result in low blood sugar levels. Patients have needed hospital admission as a result of being

prescribed or dispensed the wrong insulin product marketed under the Humalog® name. As a result the CSM alerted NHS staff to the potential for confusion around the labelling and packaging of Humalog® products²²

The NPSA's national reporting and learning system includes codes for incidents caused by poor labelling and packaging. This will enable the frequency of these errors in the NHS to be determined.

- 6.2.4** The risk of such medication errors may be increased in emergency situations where health professionals are operating in stressful circumstances and rapid product selection is crucial.

Anaesthetists in New Zealand have developed a labelling system which helps to overcome the risk of error due to similarity of drug names and poor legibility of labels. Colour-coded, highly legible labels which include both the drug name and the indication are used. Dopamine and Dopram® have been confused as a result of similar names. With the new labelling system dopamine is labelled with "Inotrope, Dopamine" on a purple label, which is distinctively different from "Analeptic Agent, Doxapram" which appears on a white label (see Chapter 5).²³

- 6.2.5** In total 15 items of information are required by law to appear on the label of a medicine. Five of these (the name of the medicine, strength, route of administration, dosage and any special warnings) are vital for the safe use of the medicine. Special attention should be brought to these in the design of the packaging.

The Medicines Control Agency (now the Medicines and Healthcare products Regulatory Agency) has published best practice guidelines. These recommend that the five essential items of safety-critical information are brought together so that they are clearly and readily visible on a part of the pack where they are in one field of vision. This guideline has now replaced the previous NHS standard for ampoule labelling that required uniform black on yellow labelling for many medicines supplied as ampoules (for example, see Figure 5.1). All labelling of new products will be considered by the MRHA against this guidance document.

- 6.2.6** Once individual containers such as ampoules or vials have been removed from their original outer carton they often have limited, small font labelling information which further reduces the ease of identification.

Figure 6.2.1 Similarity between ampoules removed from their outer packaging



- 6.2.7** Environmental factors such as noise, interruption, sub-optimal lighting conditions and lack of space may also contribute to the incorrect selection of a drug.

Case 37. Maladministration of BCG vaccine

Potent percutaneous BCG vaccine was inadvertently administered intradermally to 19 teenagers, producing severe skin reactions. Similarity in the packaging of the different products intended for intradermal and percutaneous use was identified as the main cause of the accident. The same error occurred in a different health authority – again the packaging was thought to be the main cause of the mistake. As a result the manufacturers changed the packaging of the percutaneous product so that the text clearly read “for multipuncture technique only”.²⁴

- 6.2.8** Similarities in drug names and packaging have been identified as the two main contributory factors in dispensing errors. Traditionally, identification of tablets or capsules has been reinforced by an additional check on the appearance of the product. With most medicines now being supplied in the manufacturer’s original pack this visual cue is no longer available. Packaging and labelling are therefore a more important part of the checking process and, ideally, should be readily distinguishable.

- 6.2.9** Most medicines are used by patients in their own homes. Patients often have difficulty remembering the names of their medicines and clear labelling is essential. Patients may be confused by proprietary and generic names. They may have different supplies of the same medicine whose packaging will appear very different because the proprietary name is more prominent than the generic name.
- 6.2.10** Similarly, the medication administration record (MAR) in a care home may contain the proprietary name of the medicine and the product label may give the generic name. It is possible that untrained staff may write both onto the MAR thinking they are different medicines especially if the care home has received supplies from different providers e.g. from a community pharmacy and from a hospital on discharge. This may result in over-dosage of a medicine.
- 6.2.11** The patient information leaflets (PILs) provided with medicines can provide an important additional check on the nature of the drug and its usual dose and route. It is a legal requirement that the manufacturer's leaflet is provided with all medicines supplied to patients in primary care, as hospital outpatients and on discharge from hospital.
- 6.2.12** There is some evidence that patients may not fully understand cautionary labels on medicines. Further research is needed to establish how patient safety could be improved by clearer cautionary labelling.
- 6.2.13** Patients taking several medicines may be confused by their similar packaging. Doses may then be taken at the wrong time of day, in duplicate or missed completely.

Figure 6.2.2 Similar packaging of patient packs



6.2.14 Patients in their homes, care staff in care homes and nurses on wards may remove blister strips from their original containers and on occasions cut them up, leaving the blister strip with insufficient labelling information to identify the drug. Pharmacists may also sometimes need to cut blister strips when dispensing medicines in order to dispense the prescribed quantity.

Reducing the risks through clear labelling and packaging

- All medicine packs should be labelled legibly with essential information if medicines are to be correctly identified and used safely. Labelling should be subjected to readability testing.
- The MRHA's good practice guidance makes recommendations on general labelling and packaging principles which should be adopted for all medicines.²⁵
- The NPSA will review regularly reports of incidents caused by poor labelling and packaging and will work with the MHRA and industry to minimise errors of this type.
- Assessment of potential risks associated with the labelling and packaging of products should be a routine part of NHS procurement processes.

The North West Regional Pharmaceutical Quality Assurance Service is developing the concept of Medication Error Potential Analysis (MEPA) to apply to the contracting and purchasing of medicines. During the tendering process each product is assessed for error potential using a set of standard questions relating to all aspects of labelling and packaging. The results are scored to give a numerical value of risk around the use of that product. The MEPA is being piloted on a sample of about 90 medicines whose contracts are due to be renewed, with a view to identifying potential risks prior to committing to purchasing agreements.²⁶

- Pharmacists, dispensing doctors and out-of-hours service providers should ensure that a manufacturer's patient information leaflet is supplied with all medicines dispensed in primary care, hospital outpatient departments or for patients being discharged.
- Because of the potential for confusion when small containers are removed from their original containers, all small containers should be stored in the manufacturer's packaging until immediately prior to their use.
- Because of the reduced labelling on blister packs these should, where possible, be dispensed and stored in the manufacturer's original packaging.
- Where possible, blister strips should not be cut during the dispensing process in such a way that important labelling information is removed.
- Manufacturers should ensure that information on the reverse of blister strips is set out in such a way that important details remain visible when the strip has been partly used or cut.
- Labelling of dispensed medicines should comply with the Medicines Act and Regulations and with relevant professional guidance.
- Where medicines are prescribed by brand name, the dispensing label should also include the generic name.

6.3 Medication safety at the interface between health care settings

Effective communications are critically important when patients move from one care setting to another; many medication errors occur at such 'handover points'. Serious errors have occurred because of poor communications between primary and secondary care. Accurate information about current therapy is essential when patients are admitted to hospital to enable an accurate clinical assessment and to plan future treatment. And on discharge, the patient's drug regimen and treatment plan need to be communicated in a timely and reliable way to ensure safe and seamless transfer of care back to the primary care team.

- 6.3.1** When patients move between healthcare settings communication is often slow and incomplete. Delays in communicating information about the patient's hospital inpatient episode and discharge medication mean that this information is not always available to the general practitioner to support resumed prescribing for that patient, or to commence prescribing for a patient newly admitted to a care home.
- 6.3.2** Patients' therapies are often changed while they are in hospital. If they are unaware of the changes and then visit their GP before he receives information about the hospital episode, they can be inadvertently prescribed drugs that are no longer indicated, duplicate drugs, drugs that interact or are even contraindicated. The patient may become confused about which drugs they should actually be taking, and this can lead to readmission to hospital. Patients and carers should know about the medicines that they take. Any changes to their medicines should be explained to reduce the risk of confusion. Prescribing errors may also occur where information sent to GPs has been transcribed incorrectly.
- 6.3.3** Patients who are discharged from secondary care to a care home will be at risk if the discharge information is not simultaneously provided to the care home staff and the GP.

Case 38. Amlodipine overdose on discharge caused by poor communication

An elderly man was taking amlodipine 10 mg daily in hospital from his own supply which ran out just before he was discharged. He was given a supply of 10 mg tablets, correctly labelled, by the hospital pharmacy. However, as he was used to taking two 5 mg tablets he took two of the 10 mg tablets he had been given. He suffered dizziness and falls as a result of the overdose.²⁷

Case 39. Atenolol prescribed for wrong patient at discharge

Atenolol was added to the discharge regimen of a patient when it was intended for the person in the next bed. The patient, who already had heart failure, continued to take the atenolol for several weeks after leaving hospital. The error was not identified until after her death. The atenolol was judged to have contributed to her death from heart failure.²⁸

A pharmacy discharge letter scheme has been developed at Harrogate District Hospital. Each patient's medication is reviewed before discharge and an electronic discharge letter is produced in a clear, easy to read format. Each discharge drug is accompanied by an explanation of any changes (drugs started, drugs stopped, dose changes). Simple standardised wording is used and copies are sent to the patient/carer and the community pharmacist, as well as the GP. GPs agreed that the systems improved information exchange and reduced the number of medication errors across the interface.²⁹

- 6.3.4** Problems can occur after discharge with drugs that can only be prescribed by hospitals, drugs that are manufactured as 'specials', extemporaneously prepared products and drugs that are prescribed outside the manufacturer's product licence.

A European study found that half of the drugs prescribed to children in hospital were unlicensed or 'off-label'.³⁰

- 6.3.5** Increasing numbers of patients are cared for under 'Shared Care' arrangements between the primary care team and hospitals. There is a risk of medication errors unless there is clarity in the shared care plan about the patient's medication and the responsibilities of the various staff contributing to their care. Serious harm to patients has occurred because this clarity has been lacking and communications have been poor. For example, methotrexate errors are often due to a breakdown of shared care arrangements (*see Chapter 5*).

In the former Trent region a traffic light system was developed to clarify prescribing responsibilities across the interface:

- **Red drugs can only be prescribed by specialist consultants**
- **Green drugs can only be prescribed by GPs**
- **Amber drugs are prescribed under shared care arrangements where responsibilities are agreed depending on knowledge and experience.**
- **A standardised definition for each colour ensures uniformity in approach.³¹**

Case 40. Tacrolimus toxicity as a result of communication breakdown

A child, under the care of a tertiary centre and her local district general hospital, was on holiday in another NHS region when she became ill. Medical staff at the hospital to which she was admitted were unfamiliar with the medicine she was taking. Communications with her usual hospitals were confused and unsatisfactory. Altogether five different dosage regimens were communicated; by telephone and fax from the two hospitals near her home, by the parents on a piece of paper, and on the labels of the medicine containers. As a result the child was prescribed an excessive dose of tacrolimus, an immunosuppressant medicine.³²

A study in Glasgow asked whether GPs and community pharmacists wanted or received information on the reasons for drug therapy changes implemented in hospital. 96% of GPs and 94% of pharmacists said they would like information on changes in treatment to ensure continuity of care. 58% of GPs were not satisfied with the information they received about their patients' discharge drug therapy. The preferred method of receiving the information was via a modified hospital discharge prescription.³³

A UK study examined changes in drug therapy of patients discharged from an East London teaching hospital into the community. Patients in the intervention group were given a letter listing the drugs prescribed at discharge to be given to their community pharmacist. Patients in the control group were given no letter for their pharmacist. The discrepancy rate between their discharge prescription and medication subsequently prescribed by their GPs was 32.2% in the intervention group compared with 52.7% in the control group.³⁴

Safer use of medicines at the interface

- Timely, effective and unambiguous communications are essential to ensure medication safety as patients move between primary, secondary and tertiary care. The simple expedient of providing a copy of the discharge prescription for the patient's community pharmacist can significantly reduce errors following discharge.

The RPSGB has produced proformas to assist communication between hospital and community pharmacists on patients' admission and discharge.³⁵

- Patient's medication should be carefully reviewed on admission and discharge. Many hospitals have appointed pharmacists for this purpose.
- There should be a structured process at discharge to ensure that patients' medication is correct, and that they fully understand their treatment and any changes that have been made. When a patient is cognitively impaired and unable to assimilate the changes the primary carer should be fully informed.
- There should also be an early check by the primary care team to ensure that the medication is correct and that the patient is clear about the treatment.
- Ideally communications should be electronic, transferring information between hospital prescribing systems and GP and pharmacy systems. They should include doctors, pharmacists, the patient and carers.

At University Hospital, Lewisham, legible, electronic discharge prescriptions are transmitted automatically to the GP. The process of electronic transmission takes only 3 minutes.³⁶

At the Salford Royal Hospitals prescribing software developments have enabled immediate discharge summaries linked to the patient record to be written. Drug orders are generated from a pre-configured catalogue. The drug fields are customised to facilitate ordering of common drugs and dose regimens, and to restrict the options available for certain drugs, e.g., methotrexate is linked to a frequency dictionary that only allows weekly dosing. Order sets have also been established, e.g., an order set comprising aspirin, atenolol, pravastatin, GTN and lisinopril for patients post-myocardial infarction.³⁷

- In the short term, paper-based systems should be improved to provide more timely and reliable exchange of information, for example, patient-held record cards.
- There is evidence that the use of comprehensive patient-held records can improve the quality of care in chronic conditions, for example diabetes.³⁸ There is as yet no direct evidence of any effect on errors but such schemes are likely to help ensure safe medication.
- Ideally the patient-held record should be generated electronically to enable a single entry to be accessed by all health carers.
- Systems should be in place to ensure that changes to treatment made by telephone are documented, and that the patient's clinical notes and hand-held records are updated as soon as possible.
- Where GPs are required to prescribe specialised medicines under shared care arrangements, adequate monitoring facilities and communication arrangements with hospital colleagues should be in place before the medicines are prescribed.

6.4 Education and training for medication safety

Prescribing, dispensing and administration of medicines are complex and skilled tasks. Health professionals need to understand the actions, indications and contraindications and adverse effects of drugs. They must be able to relate that knowledge to the patient's clinical condition and select the most appropriate treatment regimen. They also need to be aware of the causes and risks of medication errors and strategies for their prevention. Undergraduate programmes do not always adequately develop the knowledge or skills needed for safe medication practice.

6.4.1 Professor Kent Woods' report on intrathecal medication errors highlighted the extent to which lack of knowledge contributes to adverse events.³⁹ More recently, the Audit Commission report "*A Spoonful of Sugar*" raised concern that junior doctors working in NHS hospitals do not receive adequate training in prescribing.⁴⁰ And a recent review⁴¹ highlighted "*the poverty of teaching medical students about therapeutics in general and prescribing in particular*"

6.4.2 Reforms of the undergraduate medical curriculum have sought to reduce the burden of factual knowledge that students are expected to learn. Some detailed knowledge previously taught at undergraduate level is undoubtedly better acquired during postgraduate specialist training. However, there is an essential core of knowledge and skills which all doctors need in order to prescribe, administer and monitor drugs safely.⁴²

"Learning about how to choose the dose seems to fall into a chasm between medical school (where, in our sample, the subject was not taught) and employment. This situation sends a message about the unimportance of doses Junior doctors are put in a position in which they have to prescribe without knowing how to do so."

Dean et al, 2002⁴³

6.4.3 It is therefore essential for patient safety that the undergraduate curriculum provides a good understanding of the clinical pharmacology of common drugs in therapeutic use, including contraindications, drug interactions and toxicities.⁴⁴ In addition, medical students need to develop the practical skills to prescribe and administer medicines safely, and an appreciation of the risks, causes and prevention of adverse drug events. These skills should be further developed during postgraduate training.

Traditional methods of assessing medical students examine therapeutic knowledge and not the skills required to practise. As a result of feelings among house officers that they lacked competence in practical skills in therapeutics, an objective, structured clinical examination (OSCE) has been designed to assess the skills of fifth year medical students at Birmingham University. Students are required to demonstrate competence in at least two practical procedures, in the management of a medical emergency, and in prescription writing through a series of six workstations. In two years the examination has been taken by 434 students, of whom 399 (91.9%) have passed. The OSCE has highlighted serious errors in key processes around drug prescribing and administration. Early identification of deficiencies in these core skills enables learning to take place prior to medical students practising as provisionally registered house officers.⁴⁵

In Modernising Medical Careers the UK Health Departments have set out plans to improve the quality of training for junior doctors ensuring that their training is streamlined for the benefit of themselves, the NHS and patients.⁴⁶ Newly qualified doctors will undertake a two-year foundation programme covering core clinical skills including patient safety, high standards of clinical governance and communication and time management skills.

- 6.4.4** In modern practice prescribing decisions are often made by a team of clinicians caring for the patient. A multidisciplinary approach to medication safety should therefore be adopted where appropriate. This is particularly important as prescribing responsibilities are extended to nurses and pharmacists. Joint teaching at relevant stages within schools of medicine, nursing and pharmacy would help to foster an understanding of the contributions different professions make to medication processes.⁴⁷
- 6.4.5** All doctors, nurses and pharmacists starting work in a new environment need training and support during their period of induction. Joint induction training of new staff in safe medication practices should be encouraged. It may be appropriate at the end of this induction period to assess competence in the skills required by each discipline to practise safely.

- 6.4.6** The relative inexperience of junior doctors when they start working in NHS hospitals makes them particularly liable to make medication errors.⁴⁸

At the Wirral Hospital concerns were expressed whether preregistration house officers have the knowledge and skills to prescribe effectively from the first day of their first job. House officers have therefore been asked not to prescribe, except under close supervision, for the first six weeks.⁴⁹

During the induction programme for new nursing staff at King's College Hospital, nurses are required to complete a written assessment of skills and knowledge required for accurate drug administration.⁵⁰

King's College Hospital also introduced a prescribing skills training programme for preregistration house officers (PRHOs). The aims are to raise awareness of prescribing risk and to improve the quality of prescribing. All PRHOs are required to achieve a minimum standard in a written prescribing skills assessment before the end of their placement.⁵¹

- 6.4.7** However, following their initial induction period few professionals currently undergo any assessment of competence to ensure that they are able to carry out the tasks that they are expected to as part of their normal practice. Induction and supervision should be followed up with continuing professional development to ensure that knowledge and skills in safe medication practice are maintained and updated.

The Centre for Pharmacy Postgraduate Education holds workshops for pharmacists as part of a programme of Continuing Professional Development.⁵² The learning objectives are to enable participants to:

- identify common factors that contribute to medication errors and state practical steps to minimise them
- conduct a baseline risk assessment of their own dispensing process
- Implement necessary changes using practical tools
- analyse the contributors to, and learn from, dispensing incidents in their own practice
- name key local support contacts in risk management and clinical governance
- feel more confident about medication error recording

The Directors of Nursing and Pharmacy at the Hammersmith Hospitals NHS Trust have developed a “medication incidents roadshow”.⁵³ The 2 hour event, which takes place every 2 months, is aimed at nurses and pharmacists working within the Trust. The aims of the event are to increase knowledge of a range of issues relating to medication errors and to raise awareness of the importance of good practice in reducing error rates. Topics covered include:

- Why errors happen – human error theory and systems failure principles
- Common errors and changes that have been made as a result
- Good nursing practice
- Blood product and transfusion errors

6.4.8 Education and training of health professionals in medication safety would be greatly assisted by the development of core training materials. There would also be merit in a national framework for competence assessment in medication safety.

6.4.9 The safe handling of medication within care homes that do not offer nursing care will be determined by the extent of training for all staff who are responsible for the service users' medication. Since April 2002, training has been specified in the National Minimum Standards for Care Homes for Older People and Care Homes for Younger Adults.

Reducing the risks through education and training

- Undergraduate medical programmes in pharmacology and therapeutics should be strengthened to deliver the essential core of knowledge and skills that doctors need to prescribe and administer drugs safely. The British Pharmacological Society has developed a core curriculum which should form the basis of training in this area.⁵⁴
- The risks, causes and prevention of medication errors should be addressed in undergraduate and postgraduate programmes for doctors, nurses and pharmacists in both primary and secondary care. Case studies of medication errors are likely to be more valuable than a didactic approach in teaching the skills necessary for safe practice.
- The skills needed for safe prescribing, dispensing and drug administration should be assessed using an objective, structured, clinical examination (OSCE) as part of the relevant undergraduate programme.
- A multidisciplinary approach to training in safe medication practice should be adopted where appropriate.
- Medication safety should be covered comprehensively in induction programmes for new NHS clinical staff.
- All new prescribers should demonstrate that they can prescribe safely in practice before being allowed to do so without supervision.
- Knowledge and skills relating to medication safety should be regularly updated through formal programmes of continuing professional development.
- The NPSA is working with a number of Government and NHS organisations to take forward training and development in patient safety.

6.5 Managing medication safety in NHS organisations

Many NHS organisations have already established local systems to improve the safety of medicines use. These include schemes for reporting errors and disseminating learning points. Local schemes should be encouraged but must ensure reporting of errors through the National Reporting and Learning System. They should wherever possible tackle errors across primary and secondary care. Some NHS trusts have created dedicated posts to promote safe use of medicines across the organisation. This should be a part of regular clinical audit and PCTs should require information from providers on error rates and risk reduction strategies. There needs to be an overarching strategy on medication safety in NHS organisations. The National Patient Safety Agency is taking forward a comprehensive programme of work to improve medication safety in all organisations delivering NHS care.

6.5.1 The preceding chapters have shown how medication errors occur and how they can be prevented. *An Organisation with a Memory* stressed the need to encourage a reporting and questioning culture in the NHS in which professions and organisations can critically examine their actions and implement improvements in patient safety. All NHS organisations need to have formal structures that enable reporting and learning about medication safety, and which feed serious errors into the NPSA's national reporting and learning system.

6.5.2 The safe and secure handling of medicines is a fundamental element of clinical governance. The Controls Assurance standard for medicines management contains general principles which should inform strategies for reducing medication errors.

6.5.3 A number of medication error reporting schemes have already been set up in primary and secondary care. The aims of these schemes are similar:

- to report medication errors
- to review error reports collectively
- to provide feedback to staff involved in medicines use
- to reduce the risk of similar errors recurring

- 6.5.4** Such schemes may operate alongside 'Adverse Incident' reporting schemes, as they may identify non-serious errors or near misses which are not reported formally but which are nevertheless important in identifying process weaknesses that need to be improved.

Pharmacists at King's College Hospital operate an anonymous scheme for reporting medication errors on behalf of the Drugs and Therapeutics Committee. Errors reported are reviewed to identify trends in drugs and processes which have been implicated in errors. Alerts are issued to wards highlighting problems that have been identified, both locally and nationally, to staff involved in drug use.⁵⁵

Figure 6.4 Sure-Med Alert for penicillin allergy

King's College Hospital **NHS**
NHS Trust

sureMED

ALERT

Sure MED is a scheme for monitoring, reviewing and reporting medication errors. Its aim is to reduce medication errors. Alerts are circulated to raise awareness of the drugs involved in errors and reduce the risk to patients in the future

<p>DRUG</p> <p><i>Penicillins and Penicillin-containing products</i></p>										
<p>ERROR TYPE</p> <p><i>Contra-indicated drug</i></p>										
<p>POTENTIAL for ERROR</p> <p>The most important side effect of the penicillins is hypersensitivity, which causes rashes and anaphylaxis. Patients who are allergic to one penicillin will be allergic to all penicillins. About 10% of penicillin-allergic patients will also be allergic to cephalosporins. Penicillin-allergic patients should only be prescribed cephalosporins and other beta-lactam antibiotics, e.g. meropenem, imipenem and aztreonam with extreme caution.</p> <ul style="list-style-type: none"> • Administration of penicillins and penicillin-containing antibiotics to patients with allergies to penicillins may be associated with severe anaphylaxis and death. • Failure to document and consider a patient's drug allergy status may have catastrophic consequences. • The standard for drug allergy documentation, including 'nil known', on drug charts within King's College Hospital is 100% <p>The following penicillins and penicillin containing products are currently available in the Trust:</p> <table> <tr> <td>Amoxicillin/clavulanic acid = coamoxyclav (Augmentin®)</td> <td>Ticarcillin/clavulanic acid (Timentin®)</td> </tr> <tr> <td>Piperacillin/tazobactam (Tazocin®)</td> <td></td> </tr> <tr> <td>Amoxicillin</td> <td>Benzylpenicillin (Penicillin G)</td> </tr> <tr> <td>Flucloxacillin</td> <td>Phenoxyethylpenicillin (Penicillin V)</td> </tr> <tr> <td>Piperacillin</td> <td>Procaine penicillin (Jenocillin A®)</td> </tr> </table>	Amoxicillin/clavulanic acid = coamoxyclav (Augmentin®)	Ticarcillin/clavulanic acid (Timentin®)	Piperacillin/tazobactam (Tazocin®)		Amoxicillin	Benzylpenicillin (Penicillin G)	Flucloxacillin	Phenoxyethylpenicillin (Penicillin V)	Piperacillin	Procaine penicillin (Jenocillin A®)
Amoxicillin/clavulanic acid = coamoxyclav (Augmentin®)	Ticarcillin/clavulanic acid (Timentin®)									
Piperacillin/tazobactam (Tazocin®)										
Amoxicillin	Benzylpenicillin (Penicillin G)									
Flucloxacillin	Phenoxyethylpenicillin (Penicillin V)									
Piperacillin	Procaine penicillin (Jenocillin A®)									
<p>ACTION</p> <ul style="list-style-type: none"> • Ensure the patient's allergy status is completed on the drug chart <u>before</u> prescribing, dispensing or administering any drugs. • The patients allergy status must be considered prior to prescribing, dispensing or administering drugs • Ensure you are familiar with the components of combination products being prescribed, dispensed and administered 										

King's College Hospital and Southwark Primary Care Trust have piloted a scheme for anonymous reporting of prescribing and dispensing errors. The scheme, originally developed for use within the hospital, detected 38 errors and 10 near misses in the first 7 months. Common problems were seen including similar product names, poor handwriting and similar packaging. Reports are discussed at review meetings and prevention strategies agreed. Alerts outlining the strategies are sent to all community pharmacists.⁵⁶

The National Pharmaceutical Association is testing the concept of error and near miss reporting in community pharmacies in two pilot sites in Essex and Southampton. Two paper-based approaches to error reporting are being evaluated.⁵⁷

A medication error reporting scheme has been set up in Community Health South London NHS Trust which receives reports from all community health staff including district nurses, health visitors, community nurses, staff working in reproductive health and intermediate care. Areas associated with error which have been highlighted over the first four years of the scheme include

- Administration of vaccines
- Insulin administration by district nursing teams
- Use of tinzaparin injection following discharge from hospital
- Supply of oral contraceptives in reproductive health services
- Errors associated with poor communication and record keeping when care is provided through multiple health and social care agencies.⁵⁸

Boots Ltd introduced a dispensing incident action form several years ago. The form asks pharmacists to record the action they have taken on the patient's behalf, to reflect on the causes and to record preventive action taken for the future. The scheme was recently strengthened by the introduction of a dispensing incident management handbook to tackle the causes of near misses as well as errors.⁵⁹

Community pharmacists from the Pharmacy Development Group in Portsmouth recorded prescribing and dispensing errors for a 4 week period. 76% of errors recorded emanated from the GP surgery. Certain types of prescribing error recurred frequently. The results were fed back to GPs to initiate discussions about changes that might be made to reduce common errors.⁶⁰

- 6.5.5** There is much good medication practice in the NHS. However, many NHS processes have evolved to meet operational needs rather than being formally designed to deliver safe outcomes. Sources of error or unreliability have not usually been identified systematically in process design. ‘Capable’ processes, which reliably produce intended outcomes, making it more likely that the task is ‘right first time’, have not therefore been widely developed. Processes should be standardised, based on sound design, with built in error traps. This is increasingly important where staff move between organisations, e.g., agency and rotational staff. The NPSA is providing methodology and training in root cause analysis for NHS trusts to support them in developing solutions and error traps.

The Southern Derbyshire Acute Hospitals NHS Trust has established a dedicated committee to review policies, procedures and quality assurance systems for the safe use of medicines.⁶¹ Error reports are reviewed and action points disseminated. Recent action has included the development and implementation of:

- **an infusion monitoring form to ensure regular checks of administration via infusion pumps**
- **pre-printed prescription forms for chemotherapy and other complex treatments**
- **a trust-wide policy on anaphylaxis**
- **a system which ensures that gentamicin cannot be issued from the pharmacy until the latest blood level has been measured and the next prescribed dose checked**

The Luton & Dunstable Hospitals NHS Trust has introduced a collaborative programme to reduce medication errors. The scheme uses the 'Breakthrough Collaborative Model' developed by the Institute of Healthcare Improvement (IHI) in the US, and already adopted in the UK by, for example, the National Cancer Services Collaborative and the National Medicines Management Collaborative. The collaborative involves 30 multidisciplinary teams from ward and clinical departments working together intensively to monitor, audit and reduce preventable adverse drug events. The first year's experience has shown significant progress towards reducing the rate of prescribing, dispensing and administration errors.⁶²

- 6.5.6** Current guidance and standards on prescribing, dispensing, preparation and administration of medicines are fragmented and divided between a range of professional, NHS and regulatory bodies. There is a need for overarching national standards linking the various strands of medicine use within the NHS.
- 6.5.7** In some NHS trusts, pharmacists or nurses have been appointed with specific responsibility for medicine safety across the organisation.

Barts and The London NHS Trust has appointed a medicines risk management pharmacist, to work across the trust to identify, measure and reduce the risks associated with the use of medicines within the trust. The post holder works as part of the medicines risk team which includes a nurse medicines risk manager, linked with the school of nursing.⁶³

- 6.5.8** In the future all primary care staff will be required to report errors to the NPSA via local systems established by their Primary Care Trust. Systems need to be set up to enable multidisciplinary review of errors to help GPs, community pharmacists and nurses to learn from incidents.⁶⁴ Out-of-hours providers and care homes should be included. Local arrangements will continue to be of great value but must be fully integrated with reporting to the NPSA. Joint review across primary and secondary care should be encouraged, to tackle the problem of errors at the interface.

6.5.9 The nature and frequency of medication errors and their management by health care providers is a valuable indicator of quality of care.

The US Joint Commission for the Accreditation of Healthcare Organisations (JCAHO) sets medication use standards and requires health care providers to furnish evidence of ongoing quality improvement in drug use.⁶⁵

Reducing the risks through organisational change

- There are many elements to safe medication practice including:
 - Reporting and learning from errors
 - Building error traps into medication processes
 - Education and training
 - Improved communications at the interface
 - Information management and technology, and
 - A range of specific measures in high risk therapeutic areas
- Many of these approaches have been adopted, with some success, in the NHS. But the overall approach has been piecemeal. To tackle the continuing unacceptable incidence of serious medication errors, NHS organisations need an overarching strategy combining all of these elements with new themes that emerge from the NPSA's reporting and learning system.
- Local arrangements for reporting and learning from errors, such as those described above, will continue to be of great value, but need to be integrated into the NPSA reporting system.
- The NPSA should consider, together with the National Institute for Clinical Excellence (NICE) and professional organisations, how the development of multidisciplinary safe medication practice guidelines can best be taken forward.

The Clinical Negligence Scheme for Trusts (CNST) has developed a new standard on safe medicines practice which will be piloted from April 2004 and rolled out in 2005. This requires trusts to have a medicines management policy for the storage, prescribing and administration of medicines; and an annual report and programme, with defined objectives and progress.⁶⁶

- Primary care trusts should ensure that medication safety is addressed across primary and secondary care. An individual within the PCT, e.g., the pharmaceutical adviser or clinical governance lead should be responsible for medication safety. They should receive and review information from health care providers on error rates and risk reduction strategies.
- NHS Trusts should have dedicated machinery for organisation-wide management of medication safety. The chief pharmacist, whose post should be equivalent to that of clinical director, as recommended by the Audit Commission,⁶⁷ has a key role in this work. The results of such reviews should be a routine part of clinical audit, with findings being made available to commissioners.

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Dr Jim Smith

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January 2004

Annex 1

Summary of good practice recommendations

Recommendations for safer prescribing (chapter 3.1)

- All serious prescribing errors and 'near misses' should be reported to the NPSA
- Prescriptions should always carry patient directions and never be issued with the instruction 'as directed'
- Particular attention should be paid to checking the accuracy of complex dose calculations
- The patient's medical record should always be checked before a new prescription is written
- The treatment plan, including how the response to drug therapy is to be monitored, should be clearly documented in the patient's clinical notes
- Prescribers should have access to a pharmacist who is able to provide advice on the drug treatment plan
- Where possible aims and side effects of drug treatment should be discussed with the patient or their representative
- Prescribers should be trained and assessed as competent before being required to prescribe
- Prescribers should follow local and national prescribing standards
- Where available, electronic prescribing systems should always be used

- Actual and potential prescribing errors should be recorded and reviewed regularly to raise awareness of risk

Recommendations for safer dispensing (chapter 3.2)

- Prescriptions should be checked for clinical appropriateness by suitably qualified staff prior to dispensing
- Formal checking procedures should be in place, including double checking for complex calculations
- Serious dispensing errors and near misses should be reported to the NPSA
- All ambiguities or potential risks should be identified, and clarified with the prescriber before dispensing
- Staff should demonstrate competence to dispense and check prescriptions accurately
- The medicine should be checked with the patient when it is issued
- Patients should have the opportunity to ask questions about their medicines
- Actual and potential dispensing errors should be recorded and reviewed regularly to raise awareness of risk

Recommendations for safer administration of medicines (chapter 3.3)

- There should be clear procedures to ensure that the right patient receives the right drug, in the right dose, by the right route at the right time
- Staff giving drugs have should have access to appropriate reference sources to support safe administration, including local medicines information departments
- Particular attention should be paid to confirming the accuracy of complex dose calculations
- Serious administration errors and 'near misses' should be reported to the NPSA
- Staff should be trained and assessed as competent before being required to administer drugs

- The treatment plan should include information for staff administering and monitoring the effects of medicines
- Where possible medicines should be discussed with patients or their representatives at the time of drug administration
- All medicines should be stored safely and in such a way that the risk of drug selection errors are minimised
- Infusions of 'high risk' medicines should, where possible, not be prepared at ward level, i.e., they should be purchased or prepared centrally by pharmacy
- Actual and potential administration errors should be recorded and reviewed regularly to raise awareness of risk
- In care homes where staff are responsible for medicines administration, there should be a formal system for identifying patients or service users when medicines are given

Recommendations for safer use of medicines in people with allergies (chapter 4.1)

- A standard for the documentation of allergies should be in place
- All staff should be aware of their responsibilities in allergy documentation, including updating the allergy record if a new allergy is identified
- Compliance with the standard for allergy documentation should be audited regularly
- All paperwork used for prescribing medicines should include a section for allergy documentation
- Hospital inpatients with documented allergies should wear readily distinguishable wristbands
- The MHRA and NPSA should work with manufacturers to ensure that labelling of penicillins, particularly for combination products, explicitly indicates the nature of the product

Recommendations for safer use of medicines in seriously ill patients (chapter 4.2)

- Only oral syringes should be used to prepare doses of oral medicines
- Drugs to be administered orally and by injection should be prepared and given at different times
- Devices for the administration of infusions and feeds should only be used for the purpose for which they are designed
- Lines should be clearly labelled at each end to indicate the site of access
- Procedures for administering medicines to patients with multiple lines should include confirming the route of administration

Recommendations for safer use of medicines in children (chapter 4.3)

- All prescriptions for children should include the child's age and, where the dose is weight dependent the child's weight and the intended dose in mg/kg
- Dose calculations should be documented and, ideally, double-checked before dispensing and administration
- All staff involved in paediatric drug therapy should have access to an approved paediatric formulary; there should be a national paediatric formulary
- In local dosing guidelines doses should be expressed in the same way as in the approved formulary
- Parents and carers should be taught how to handle and administer drugs safely
- Staff should demonstrate their competence in paediatric drug therapy including dose and infusion rate calculations
- Guidelines should be in place for the standardisation of infusion concentrations
- Infusion rate charts or validated computer programmes to aid calculation should be available for use in paediatric units, particularly for potent drugs such as digoxin or opiates

Recommendations for safer use of anaesthetic drugs (chapter 5.1)

- Drugs should never be removed from the manufacturer's packaging for storage in clinical areas
- Ideally drugs administered during anaesthetic procedures should not be drawn up in advance by theatre staff
- Where this is unavoidable, all syringes containing drugs should be accurately labelled
- There should be a written procedure for drawing up and checking drugs prior to administration
- The National Patient Safety Agency should work with the MHRA and the anaesthetics and intensive care organisations to develop an agreed national system for user-applied syringe labels in the NHS practice.
- A pharmacist should regularly visit operating theatres and anaesthetic rooms to help to ensure safe drug use

Recommendations for safer use of oral anticoagulants (chapter 5.2)

- All staff expected to prescribe oral anticoagulants should be trained and competent to do so
- GPs should be informed promptly when their patients are started on oral anticoagulants
- All patients started on oral anticoagulants should be given an anticoagulant clinic referral and appointment within 7 days of discharge from hospital
- All staff prescribing anticoagulants should follow local policies based on the British Society for Haematology guidelines
- All staff should understand their roles, responsibilities and the systems for outpatient anticoagulant follow-up
- Where warfarin is prescribed for inpatients, the warfarin prescription should always be kept with the main drug chart
- Patients being started on anticoagulants should receive information to enable them to manage their treatment safely

- When patients are unable to manage their treatment safely themselves there should be clear communication with the primary carers. This includes communication with care home staff where appropriate.
- There should be a system in place to audit and review over- and under-anticoagulated patients
- All patients receiving anticoagulants should have an anticoagulant booklet
- Dispensed prescriptions for warfarin should be double-checked before they are issued from the pharmacy

Recommendations for safer use of cytotoxic drugs (chapter 5.3)

- Cytotoxic drugs should only be prescribed by clinicians trained in the specialty and who are competent to prescribe
- There should be comprehensive shared-care guidelines for patients receiving cancer chemotherapy being discharged into the community
- National guidance on the safe administration of intrathecal chemotherapy must be followed
- There should be a single method used by all staff for determining and checking body surface area within the organisation
- The patient's chemotherapy protocol should always be accessible by all staff involved in the patient's care
- All staff involved in cancer chemotherapy should be trained in the risks of medication error
- All injectable chemotherapy should be prepared by pharmacy and supplied to patients in such a way that it is ready to be administered
- Information on the method of administration, extravasation risk and other special precautions should be supplied with each dose
- All dispensed prescriptions for cancer chemotherapy, including oral therapy, should be double-checked before being given to the patient
- Patients should be provided with written information to assist in the identification of potentially life-threatening adverse effects of treatment

Recommendations for safer use of intravenous infusions (chapter 5.4)

- Advice given by the NHS Purchasing and Supply Agency and the MHRA should be followed when purchasing new devices
- Staff should be trained in the correct use of devices and have access to suppliers' user manuals
- Staff should report actual or suspected damage to a device so that it can be serviced to ensure that it is still accurate
- Devices should be designed to be simple to use and have good safety features including alarms
- The most appropriate device for the drug being administered should be used
- The range of infusion devices used should be standardised, preferably through centralised equipment libraries

Recommendations for safer use of methotrexate (chapter 5.5)

- There should be a robust mechanism for communications between care settings on treatment regimen for patients on methotrexate
- Prescriptions for methotrexate written by junior doctors should be checked by a pharmacist or senior colleague
- Prescribing systems should incorporate a warning prompt to highlight weekly dosing for methotrexate
- Dispensing systems should incorporate a warning prompt to highlight weekly dosing or default automatically to weekly dosing
- Pharmacists should review the need for both 10 mg and 2.5 mg tablets of methotrexate to be available for dispensing
- Staff should ensure that patients understand their dose regime, how to recognise the signs of methotrexate toxicity and the importance of self-referral if these develop
- Patients receiving methotrexate therapy should be provided with hand-held record cards containing information about their treatment

Recommendations for safer use of opiate analgesics (chapter 5.6)

- Ideally, the antagonist naloxone should be available wherever injectable or high-dose opiates are used
- Dose calculations should be double-checked, and all dispensing of opiate analgesics should be double-checked before issue to the patient
- There should be local guidelines to ensure safe prescribing, dispensing, administration and monitoring of opiate analgesics
- The range of opiate analgesics prescribed and stocked should be limited to minimise the risk of confusion
- All acute hospitals should have a multidisciplinary pain team to advise on good practice, establish safe systems and train other staff in the safe use of strong analgesics
- Oral sustained-release opiates should be prescribed by brand name to reduce the risk of dispensing and administration errors
- Dose preparation and administration of opiates in hospitals and other care settings should be double-checked

Recommendations for safer use of potassium chloride (chapter 5.7)

- NPSA Guidance on the storage and documentation of concentrated potassium solutions must be followed
- Where potassium chloride ampoules need to be readily available, e.g., in operating theatres or intensive care units, they should be stored in a separate locked cupboard
- Potassium chloride should be used in premixed bags wherever possible
- Ampoules of strong potassium chloride solution purchased should be visually distinguishable from all other ampoules especially frequently used products such as sodium chloride, frusemide and water for injection
- When potassium chloride needs to be added to infusion solutions this should be carried out in the pharmacy department, not on the wards
- Staff should be trained in the risks of rapid administration of potassium chloride solutions and in the management of maladministration

Recommendations for safer medicines use through information management and technology (chapter 6.1)

- Modern information management and technology solutions should be implemented to achieve safe medicines use
- Work already under way within the National Programme for IT in the NHS to develop the electronic care record will support wider implementation of electronic prescribing
- Bar-coding technology should be developed and evaluated for its potential to deliver integrated, safe hospital medication systems
- To facilitate this, a national standard bar-coding system for medicines should be developed, building on work already under way on a standard drug dictionary for the NHS
- Robotic dispensing systems should be introduced where appropriate. Their impact on patient safety and medication error reduction needs further evaluation

Recommendations for safer medicines use through improved labelling and packaging (chapter 6.2)

- All dispensed medicines should be labelled in accordance with the Medicines Act and Regulations and relevant professional guidance
- The CSM working group's recommendations for improved labelling by manufacturers should be implemented
- Patient information leaflets should be provided with all medicines dispensed for outpatients, patients being discharged from hospital, and in the community
- Assessment of potential risks associated with labelling and packaging should be incorporated into the NHS procurement process
- When medicines have been prescribed by brand name, the dispensing label should also include the generic name

Recommendations for safer medicines use at the interface (chapter 6.3)

- Communications with GPs, patients, carers and community pharmacists about discharge medication should be timely and comprehensive

- There should be a structured process for review of patients' medication on admission to, and discharge from, hospital: pharmacists should be available to participate in reviews
- Staff should ensure that patients or their primary carers understand their discharge medicines and are able to take/administer them properly
- Shared care protocols should address medication issues comprehensively
- Electronic systems should be used for information exchange wherever possible
- Patient-held, shared care medication records should be used where appropriate

Recommendations for safer medicines use through education and training (chapter 6.4)

- Undergraduate teaching in pharmacology and therapeutics should be strengthened where appropriate to provide the knowledge and skills needed for safe medicines use
- Case studies should be used to teach the risks, causes and prevention of medication errors
- Objective structured clinical examinations should be used to assess the skills needed for safe prescribing and drug administration
- Medication safety should be covered comprehensively in induction programmes for new NHS clinical staff, and regularly updated through continuing professional development programmes
- The safe handling of medication in private care homes by staff who have no nurse training should be supported through recognised training programmes

Recommendations for managing medication safety in NHS organisations (chapter 6.5)

- NHS PCT and Trust boards should ensure that an overarching strategy is in place to deliver safe medication practices
- Local schemes for reporting errors and disseminating learning points should be developed, and all serious errors and near misses reported to the NPSA

- PCTs should ensure that medication safety is addressed across primary and secondary care; and they should require information on error rates and risk reduction strategies from health care providers
- NHS trusts should establish dedicated machinery for organisation-wide review of medication safety, which should be a routine part of clinical audit

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