AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

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AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

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Safety+Quality
COUNCIL

July 2002

Second National Report On Patient Safety

Improving Medication Safety

AUSTRALIAN COUNCIL FOR SAFETY AND QUALITY IN HEALTH CARE

Second National Report on Patient Safety
Improving Medication Safety

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The Australian Council for Safety and Quality in Health Care was established in January 2000 by all Australian Health Ministers to lead national efforts to improve the safety and quality of health care, with a particular focus on minimising the likelihood and effects of error. The Council reports annually to Health Ministers.

This document is an attachment to the Council's third report to Health Ministers, *Safety through Action — Improving Patient Safety in Australia, Third Report to the Australian Health Ministers' Conference 19 July 2002*.

Further information on the work of the Council can be found on the Council's website at www.safetyandquality.org or email safetyandquality@health.gov.au

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Preface

Safety is the dimension of quality that is most valued by patients and their families when they receive health care. Yet developing a culture of safety requires significant effort. Safe patient care is a result of safe systems of care, not just the responsibility of individuals within the system. It requires an understanding of the complexity of the health care system — which is not amenable to simple fixes — and action at all levels of the system.

We know that unsafe care is costly. Adverse events are more likely the result of error prone situations rather than error prone people. Fundamental changes are needed to achieve a just health care culture where individuals feel more secure and are encouraged to report errors and system failures and to act on opportunities for system improvement.

The Australian Council for Safety and Quality in Health Care has listened to these important messages and is taking forward a body of work to build a 'safety net' for health care. As medication error remains one of the most common causes of unintended harm to patients, improving medication safety is a high priority within this safety net. Much of this harm could be prevented through effective interventions and systems to improve safety in health care.

This report on medication safety is the second in a series of national patient safety reports produced by the Council. The *First National Patient Safety Report*, published in August 2001, aimed to improve community understanding of the nature of risk in health care and the importance of a systems focus. The Report also discussed current issues and efforts and the challenges ahead for safety improvements in Australia.

This *Second National Patient Safety Report* reinforces these messages while focusing on one important area - improving medication safety for patients. The Report provides a valuable guide to understanding medication safety in Australia and discusses strategies that have been found to be effective in improving medication safety.

Australia is fortunate in having innovative national policies and programs for improving patient safety through better use of medicines. However there is a need for continued national leadership, collaboration with all stakeholders and more focused planning to ensure a greater uptake of proven strategies to improve medication safety.

A key Council strategy in this area has been to establish a Medication Safety Taskforce to develop and drive a 'platform for action' to accelerate improvements in medication safety for patients in Australia.

I would like to encourage all stakeholders to work collaboratively with this Taskforce to assist in achieving its mission.

Bruce Barraclough

Chair, Australian Council for Safety and Quality in Health Care

Executive summary

Medicines are part of most people's lives - in any two-week period, around seven in ten Australians (and nine in ten older Australians) will have taken at least one medicine. Like any form of treatment, however, use of medicines are not without risks. Things may not always turn out as expected. This may only happen in only a small proportion of cases, but because use of medicines is so common, this can translate into a large number of problems overall.

Problems with medicines are often referred to as *medication incidents*. People's experiences of harm as a result of medication incidents can vary widely. This can depend on the particular situation and how, when or whether the problem was picked up. A very small number of medication incidents may lead to serious injury or death. Some incidents can lead to less serious problems. Both these occurrences are often referred to as *adverse drug events*. Many more medication incidents are 'close calls' which do not result in patient harm. These are warning signs that systems are less than fail safe or not robust.

Mistakes with medicines usually result from system failures or breakdowns which increase the risk of something going wrong. For example, in hospitals, storing medicines with similar packaging next to each other increases the risk that the wrong one will be selected. Not all medication incidents are related to a mistake. Someone may react badly to a medicine properly prescribed, even when there were no previous signs of such a reaction.

Medication incidents are significant in Australian health care. We know that as the use of medicines increases, the rate of medication incidents also rises. We know that the number of problems that people experience also increases with the number of medicines they are taking. We know less about the types of errors that occur and underlying contributing factors.

What do we know about medication incidents in hospitals?

Available data suggest that between 2 and 3 per cent of all hospital admissions are related to problems with medicines which may originate within the community or within the hospital. Medicines most commonly involved include medicines for cancer chemotherapy, for treatment of pain and inflammation and for heart conditions and high blood pressure. People aged over 65 years have higher rates of medication incidents, partly because they are more likely to be taking one or more medicines.

A range of errors and system failures can occur in hospitals including errors in prescribing, administration and dispensing. Factors commonly linked to adverse drug events in hospitals include not having effective systems to check doses of medicines and check patient identities.

What do we know about medication incidents in the community?

Every year there are over 100 million general practice encounters in Australia, with around 400,000 of these thought to involve adverse drug events. It is not known how many of these are related to medication errors. Community pharmacies in Australia dispense over 190 million prescriptions every year. While the actual incidence of pharmacy errors in Australia is not known, they appear to be relatively uncommon.

In general practice, the most common medication incidents are the use of an inappropriate medicine or dose and errors in prescribing or administering medicines. Many of these are thought to be preventable. The most common types of dispensing errors involve selection of the incorrect strength of a medicine or selection of the incorrect product, which can occur when different products have similar packaging or names that sound alike.

After a hospital admission, a patient's usual healthcare professionals need to know about changes to the patient's medications, particularly if they take a number of medicines. Factors contributing to medication incidents include poor communication between patients and health professionals, between different health professionals treating the same patient and a lack of appropriate consumer information about medicines and how to manage them safely.

What can we do to improve medication safety?

The different types of medication incidents show that this is a complex area and no single factor is responsible. In Australia and around the world, a systems approach is being developed to improve use of medicines and reduce medication incidents. Successful implementation of change requires a number of building blocks such as:

- strong leadership from governments, health care managers and professionals and all players to make improving patient safety a priority;
- practical tools and approaches which help to build safer processes and work practices to reduce medication incidents and support safer patient care, such as simplifying processes to reduce the risk of error;
- education and organisational support for safe systems of work;
- partnerships between consumers and health professionals — improvements will be made through consumers knowing more about their medicines and how to use them safely.
- supporting strategic research which addresses gaps in current knowledge and practice and helps to identify new issues; and
- integrating activities with the National Medicines Policy and the National Strategy for Quality Use of Medicines.

Key strategies based on the published evidence are briefly described in the box below**. The evidence suggests that careful implementation of computerised prescribing with clinical decision support systems should be a priority.**

Consumers can help to prevent problems with medicines by being as involved as possible in their own health care. Suggested 'tips for consumers and health professionals' are included in the 'Key Messages: an abridged version of this report'.

Strategies that have been shown to reduce medication incidents include:

- Use of computerised prescribing with clinical decision-support systems by doctors — information about medicines for health care providers on-line or in prescribing/dispensing software.
- Computerised adverse drug event alerts — these hold information about the patient's medical record and medication record, and automatically signal the presence or possibility of an adverse drug event when a medicine is prescribed.
- Individual patient medication supply in hospitals — medicines are labelled, supplied and stored for each individual patient, reducing the risk of wrong medicine or wrong dose.
- Clinical pharmacy services — pharmacists in hospitals can support systems to reduce medication incidents, through patient and staff education, monitoring and medication review.
- Transfer of information between hospital and community settings — complete list of current medications held by the patient and better transfer of information between hospital and community health professionals.
- Community based medication management services and case conferencing — assisting patients considered at high risk of medication-related problems through review of their prescribed, over-the-counter and complementary medicines, and discussion of their overall health care.
- Discharge medication management services — range of services for people at risk of medication incidents, including discharge and medication summaries to patients and health care providers.

Key messages: an abridged version of this report

The safest possible health care for all Australians — that is the aim of the Australian Council for Safety and Quality in Health Care.

The Council is working in many different ways to build a 'safety net' for health care. Improving medication safety is a priority within this safety net, because problems with medicines are one of the most common causes of unintended harm to patients.

The Council's work particularly focuses on looking at how systems within and between health care services can be redesigned and simplified to make the use of medicines safer.

This report seeks to increase general understanding of:

- things that can go wrong with medicines and which have the potential to cause patient harm;
- what we know about the size and nature of the problem in Australia;
- some strategies that have been shown to make a difference; and
- some national directions that are being taken to improve medication safety.

The report concentrates on medicines that have been approved for use in Australia. It does not look at the systems that aim to ensure that medicines are safe and effective before they are approved for use.

Why focus on medication safety?

Medicines are part of most people's lives — in any two-week period, around seven in ten Australians (and nine in ten older Australians) will have taken at least one medicine.

Medicines can help us to stay healthy, relieve symptoms of diseases, cure some diseases, and improve our quality of life. Like any form of treatment, however, medicines are not without risks. Things may not always turn out as expected.

All medicines have the potential for side effects. As well, despite the commitment and best planning of the people involved, mistakes sometimes happen. Things go wrong in only a small proportion of cases — but because use of medicines is so common, this small proportion can translate into a large number of problems overall. Every person is important, and it matters every time someone is unintentionally harmed by their health care.

What causes problems with medicines?

Mistakes with medicines usually result from system failures or breakdowns which increase the risk of something going wrong. For example, in hospitals, storing medicines with similar packaging next to each other increases the risk that the wrong one will be selected by mistake.

Not all medication incidents are related to a mistake. Someone may react badly to a medicine although it has been properly prescribed, even when there were no previous signs of such a reaction.

Problems with medicines are often referred to as *medication incidents*. People's experiences of harm as a result of medication incidents can vary widely. This can depend on the particular situation and how, when or whether the problem is picked up. A very small number of medication incidents may lead to serious injury or death. Some incidents can lead to less serious problems. Both these occurrences are often referred to as *adverse drug events*. Many more are 'close calls' which do not result in patient harm. These are warning signs that systems are less than fail safe or not robust.

Adverse drug events are typically difficult to track, define and measure. Not enough is known currently about how common they are, what causes them or how we can prevent them.

Because human beings are fallible, and not all problems with medicines can be prevented, we will probably never achieve completely 'risk-free' use of medicines. We need to redesign and simplify systems within and between health care services so that mistakes are less likely in the first place. We need to make sure that if problems do occur, they are noticed quickly by those working in the system, and can be corrected before they cause harm to patients.

What do we know about problems with medicines in Australia?

Studies confirm that medication incidents are significant in Australian health care.

But what do we know about what is going wrong, where it is happening and why? We know that system failures contribute to problems with medicines, and that medication incidents can happen at many different points in processes related to the use of medicines. We know that as the use of medicines increases, the rate of medication incidents also rises. We also know that the number of problems that people experience also increases with the number of medicines they are taking.

We know less about the types of errors that occur, and less about the underlying problems that make these errors likely to happen.

Like most international studies, most Australian research studies rely on self-reporting of medication incidents by health professionals. This includes incident reporting systems and a national adverse drug reaction reporting system. Both of these systems collect information about the types of things that go wrong.

There can't be a single source of information that gives a comprehensive picture of the kinds of problems that occur with medicines because there are so many different types of medication incidents and so many different settings in which health care is provided. What we can do is gather information from a number of sources in both hospital and community settings, and use it to paint an overall picture.

What do we know about medication incidents in hospitals?

Information from studies in hospitals and from national data collections can tell us about medication incidents in hospitals:

- between 2 and 3 per cent of all hospital admissions are related to problems with medicines which may originate within the community or within the hospital (this includes over-use and under-use of medicines, and adverse drug events);
- medicines most commonly involved are medicines for cancer chemotherapy, for treatment of pain and inflammation; for heart conditions and high blood pressure; medicines that are anticoagulants (that affect blood clotting); antibiotics; central nervous system medicines (for example medicines for anxiety, sleep or depression); and corticosteroids (medicines used to reduce inflammation or suppress the immune system); and
- people aged over 65 years have higher rates of medication incidents. This is partly because they are more likely to be taking one or more medicines.

Types of errors and system failures in hospitals

Studies have identified a range of commonly reported errors in hospitals, including:

- errors in prescribing, for example, when the inappropriate medicine is prescribed, or prescriptions are transcribed incorrectly from one chart to another;

- errors in administration, for example, where a dose of medicine is given to the wrong patient;
- errors in dispensing by the hospital pharmacy, for example, when the wrong medicine is dispensed and sent to the ward; and
- errors in documentation, for example, where previously known adverse drug reactions or allergies are not recorded on the patient's chart.

Factors most commonly linked to adverse drug events in hospitals include not having systems in place to check doses of medicines and patient identities and failure to properly read patients' charts.

What do we know about medication incidents in the community?

Much less is known about medication-related problems in the community than in hospitals. These are more difficult to track and measure. Some current information includes the following:

- Every year there are over 100 million general practice encounters in Australia. Extrapolating from smaller research studies suggests that around 400,000 of these involve adverse events associated with medicines. It is not known how many of these are related to medication errors.
- Community pharmacies in Australia dispense over 190 million prescriptions every year. While the actual incidence of pharmacy errors in Australia is not known, they appear to be relatively uncommon.

Errors and system failures in the community

Studies of medication incidents in general practice and pharmacy practice suggest the following:

- In general practice, the most common medication incidents involving medicines are the use of an inappropriate medicine, errors in prescribing or administering medicines, and use of an inappropriate dose of a medicine. Most of these medication incidents are thought to be preventable. Doctors consider communication problems, errors in judgement or assessment, and procedural problems such as lack of protocols or inadequate review of patient history to be the major contributing factors.
- The most common types of dispensing errors in the community involve selection of the incorrect strength of a medicine or selection of the incorrect product, which can often occur when different products have similar packaging or names that sound alike. Community pharmacists report that overwork, fatigue, interruptions and similar or confusing drug names are major factors contributing to dispensing errors.

Transition between hospital and the community

After people are admitted to hospital, the types or dosages of their prescribed medications are likely to change. When they leave hospital, it is important that their usual GP, pharmacist and community healthcare professionals are informed about the changed medications. This is especially the case for older people who are likely to have more complex problems and take a number of different medicines.

Factors contributing to medication incidents may be summarised:

- poor communication between patients and health professionals, and between different health professionals treating the same patient (for example, change of medication as a result of their hospital stay);
- problems that can occur when consumers see more than one health professional (for example, a doctor may prescribe a medicine for a person, unaware that a different doctor has prescribed it separately) — the consumer may not pick this up, especially if the medicines have different names; and
- lack of appropriate consumer information about medicines and how to manage them — common problems include difficulty in understanding medication labels, confusion about generic and trade names of the same medicine and storing and taking medicines past their expiry dates.

What can we do to improve medication safety?

The different types of medication incidents show that this is a complex area and no single factor is responsible. In Australia and around the world, a systems approach is being developed to improve use of medicines and reduce medication incidents.

In health care, making changes to systems requires a range of solutions. Some strategies that have been suggested for reducing medication incidents are briefly described in the box below. The evidence for their effectiveness is discussed in Chapter 4 and Appendix II.

Strategies that have been shown to reduce medication incidents include:

- Use of computerised prescribing with clinical decision-support systems by doctors — information about medicines for health care providers on-line or in prescribing/dispensing software.
- Computerised adverse drug event alerts — these hold information about the patient's medical record and medication record, and automatically signal the presence or possibility of an adverse drug event when a medicine is prescribed.
- Individual patient medication supply in hospitals — medicines are labelled, supplied and stored for each individual patient, reducing the risk of wrong medicine or wrong dose.
- Clinical pharmacy services — pharmacists in hospitals can support systems to reduce medication incidents, through patient and staff education, monitoring and medication review.
- Transfer of information between hospital and community settings — complete list of current medications held by the patient and better transfer of information between hospital and community health professionals.
- Community based medication management services and case conferencing — assisting patients considered at high risk of medication-related problems through review of their prescribed, over-the-counter and complementary medicines, and discussion of their overall health care.
- Discharge medication management services — range of services for people at risk of medication incidents, including discharge and medication summaries to patients and health care providers.

What is being done nationally in Australia?

Already much is being done at many levels to improve health care systems and make problems with medicines less likely.

At a national level, the National Medicines Policy has been in place for over a decade with a framework for improving use of medicines in Australia which involves consumers, health care professionals, health educators, health care facilities, the media, the medicines industry and governments working together to develop strategies at different levels. The Policy, which includes a Quality Use of Medicines component, was set up in response to calls by consumers groups about the need to improve use of medicines.

The Australian Council for Safety and Quality in Health Care is the lead organisation promoting and coordinating action to improve the safety of health care. Medication safety is a priority and action is being taken in a range of areas. These areas include planning for a national collaborative project to assess different ways of reducing adverse drug events and supporting safer patient care and piloting a mechanism for direct consumer reporting of medication incidents.

The different types of medication incidents show that this is a complex area and no single factor is responsible. In Australia and around the world, a systems approach is being developed to improve use of medicines and reduce medication incidents.

Successful implementation of change requires a number of building blocks such as:

- strong leadership from governments, health care managers and professionals and all players to make improving patient safety a priority;
- practical tools and approaches which help to build safer processes and work practices to reduce medication incidents and support safer patient care, such as simplifying processes to reduce the risk of error;
- education and organisational support for safe systems of work;
- partnerships between consumers and health professionals — improvements will be made through consumers knowing more about their medicines and how to use them safely.
- supporting strategic research which addresses gaps in current knowledge and practice and helps to identify new issues; and
- integrating activities with the National Medicines Policy and the National Strategy for Quality Use of Medicines.

Ongoing priorities within a national approach include:

- wider implementation of computerised prescribing with clinical decision support systems and adverse drug alert systems;
- developing processes to ensure consistent standards for computerised decision support systems which include high quality information about medicines;
- promoting the use of individual patient medication supply systems in hospitals;
- further exploring standard Australian coding systems for medicines;
- raising awareness and reducing risks of medicines that are commonly associated with look-alike or sound-alike errors;
- improving the completeness of individual's medication records through implementation of strategies such as the Better Medication Management System;
- making best use of existing hospital, clinical and community pharmacy services, as part of a team approach to health care;

- further developing discharge liaison services in Australian hospitals; and
- action research which focuses on gaps in our current knowledge and better ways of ensuring widespread uptake of proven strategies across Australia.

What can consumers and health professionals do?

What does all this mean for consumers? Consumers can help to prevent problems with medicines by being as involved as possible in their own health care. This is facilitated when health care professionals provide environments in which consumers and their carers can have access to information and ask questions, and can participate in decision-making.

The tips overleaf are adapted from the Council's booklet *Safer Health Care — What it Means for You,* with extra advice on medicines added where relevant.

Tips for consumers

1. **Be actively involved in your own health care.** Taking part in every decision that is made about your treatment is the single most important way to help prevent things from going wrong. Research shows that people who are more involved with their care tend to get better results. For example, if you are prescribed a medicine that you are not familiar with, ask about it. You need to know all about your medicines so that you can manage them properly.

2. **Speak up if you have any questions or concerns.** Choose a doctor who you feel comfortable talking to about your health and treatment. Remember that you have a right to ask questions and to expect answers that you can understand. The doctor or other health professional wants to answer your questions but can only answer them if you ask. Ask a family member, friend or interpreter to be there with you if this will help. If you want to, you can always ask for another professional opinion.

3. **Learn more about your condition or treatments by asking your doctor or nurse and by using other reliable sources of information.** Ask your doctor if your treatment is based on the best available evidence. It's also a good idea to find out why a test or treatment is needed and how it can help you. Most medicines in Australia have a Consumer Medicines Information leaflet that explains in plain English all about the medicine. Always ask for a Consumers Medicines Information leaflet.

4. **Keep a list of all the medicines you take.** This includes prescriptions and over-the-counter medicines, and complementary medicines such as vitamins and herbs. You can use the list to let your doctor and pharmacist know about everything you are taking, and about any drug allergies you may have. Take the list with you each time you see your doctor or pharmacist and ask them to change it as your medicines change. If you are going to hospital, take the list with you. When you are discharged from hospital, make sure you have a list of all the current medicines you are taking. Use it next time you see your doctor or pharmacist.

5. **Make sure you understand the medicines you are taking.** When you get your medicine, read the label, including the warnings. Make sure it is what your doctor ordered for you. If you have any questions about the directions on the label, ask the pharmacist. You should also ask the doctor or pharmacist about side effects, possible interactions with other medicines, and what foods or other things to avoid while taking the medicine. Ask the pharmacist for written information about the medicine, to help you recognise problem side effects if they occur.

6. **Before you leave hospital, ask your doctor or other health carer to explain the treatment plan you will use at home.** This includes learning about your medicines and finding out when you can get back to your normal activities and when you need to see a doctor for follow-up care. Research shows that when people are discharged from hospital, doctors think that they understand more than they really do about their continuing treatment and follow-up.

Tips for health care professionals

These tips are intended for health care professionals to help facilitate an environment in which patients can be as active as possible in ensuring safe use of their medicines.

1. **Actively involve consumers in their own health care.** It's one of the most important ways to help prevent things from going wrong. Health care professionals should provide an environment in which consumers and their carers can ask questions, have access to information and participate in decision-making.

2. **Set aside time to allow consumers to talk about any concerns that they have.** Let them know from the beginning that it is okay for them to ask questions and that you will do all that you can to give them the information that they need. Encourage the participation of family members and carers.

3. **Provide information for consumers in a language and format that is easy to understand.** Have access to printed information in plain English and facilitate the use of interpreter services and other services for people who do not have English as a first language**.**

4. **Take a complete medication history, including over-the-counter and complementary medicines.** Check for contraindications, allergic reactions and interactions between medications.

5. **Provide oral and written information about medications in plain language.** Explain side effects and tell the consumer what to do if side effects occur. Explain the need to take the full course of medications and help the consumer to work our ways to ensure that they can adhere to medication regimes. Offer Consumer Medicine Information leaflets for each medicine prescribed.

6. **Develop strategies to make sure that consumers get the results of their tests and investigations.** Take time to explain the meaning of the results and be prepared to repeat this information on several. Ask questions.

7. **Set out options for consumers.** Provide them with choices and encourage them to be involved in decision-making.

What can you do if you have concerns about your medicines or overall health care treatment?

If you have concerns about your health care treatment or suspect that you have experienced an adverse drug event, you may wish to follow-up using one or more of the following avenues.

- Talk to your doctor or other health professional about your concerns. Most health professionals will welcome the opportunity to discuss your health concerns.
- Ask for another professional opinion.
- Contact the relevant area of the hospital or health care setting with your concern. Most hospitals have a complaints officer to assist people with concerns about the health care treatment they have received. Dispensing errors can be notified to Pharmacy Boards.
- Contact the independent health care complaints body in your state or territory. Your health department can give you the contact details.

Second National Report on Patient Safety
Improving Medication Safety

July 2002

Introduction

Everyone seems to have a story to tell about medicines. Most of the stories are good stories, about people feeling better as a result of taking medicines, or staying well because medicines have helped to prevent illness. Sometimes, however, the stories are about problems with using medicines, or even worse, about harm that results from taking medicines.

It's not surprising that so many people have stories about medicines. Every year in Australia almost 200 million prescriptions are dispensed — that's about 10 prescriptions per year per person (Commonwealth Department of Health and Aged Care 1999). People also use over-the-counter medicines and complementary medicines. The country's national survey about health tells us that in any two-week period, 69 per cent of the population have taken at least one medicine and that 91 per cent of older people will have taken a medicine (ABS 1999).

Medicines can help us to stay healthy, cure some diseases, relieve symptoms of disease and improve quality of life. But, like any form of treatment, medicines are not without risks and things may not always turn out as expected. All medicines have the potential for side effects. As well, despite the commitment and best planning of the people involved, mistakes sometimes happen. Things go wrong in only a small proportion of cases — but because use of medicines is so common, this can translate into a large number of problems overall.

Medication safety is one of the Australian Council for Safety and Quality in Health Care's priority areas for action, because of the impact that problems with medicines can have on consumers, and because of the potential to make a difference. The Council's work particularly focuses on how systems can be redesigned to make the use of medicines safer.

This report on medication safety is the second in a series of national patient safety reports. The first *National Report on Patient Safety*, published in August 2001 (ACSQHC 2001), aimed to improve community understanding of the nature of risk in health care, the importance of a systems focus, and current efforts and challenges for safety improvements in Australia. This second report aims to reinforce these messages, while focusing on a specific and important area of health care.

This report was commissioned by the Council to examine published literature and draw together knowledge about:

- things that can go wrong with medications and which have the potential to cause patient harm;
- the extent of the problem in Australia;
- some high level strategies that have been shown to make a difference; and
- the direction that is being taken in Australia to improve medication safety.

The report includes:

- a summary, which includes tips for consumers and for health professionals about safe use of medicines (this is also available separately);
- the main part of the report, which draws together knowledge about what can go wrong with medicines and why, and explores some solutions to the problem;
- a technical appendix, which discusses the literature in more detail;
- a glossary, which defines the terms used in the report;
- a bibliography, which lists the references cited in the report.

1 An overview of medication safety

This chapter aims to set the scene for the report, by outlining the steps involved in the selection and use of medicines, giving an overview of a systems approach to safer health care as it applies to medicines, and discussing the terminology used to describe the things that can go wrong with medicines.

Why focus on medication safety?

The Council's aim is for all Australians to have the safest health care possible. It is focusing on medication safety for a number of reasons, including the following.

- *The size of the problem* — while measuring the exact size of the problem is difficult for a number of reasons, it is estimated that around 140,000 hospital admissions each year are associated with problems with the use of medicines (including harmful side effects). We know that problems with medicines may make up about 20 per cent of all the things that go wrong in health care, and that a considerable proportion of these events may be preventable.
- *The cost* — we know that unsafe care is costly, with inappropriate use of medicines in Australia costing approximately $380 million per year in the public hospital system alone (AIHW 2002a).
- *The potential to make a difference* — while there are gaps in our knowledge, we know enough about the extent of the problem and possible solutions to put into place a range of initiatives to improve medication safety.

What are the steps in the medication process?

Use of medicines is shaped and informed by a range of factors from social attitudes to legislative regulations. Players who have an impact on making medicines use safer include governments – Commonwealth, States and Territories – health educators, health practitioners, and other health care providers and suppliers, the medicines industry healthcare consumers and the media (National Medicines Policy 2000).

The report concentrates on medicines that have been approved for use in Australia. It does not look at the systems that aim to ensure that medicines are safe and effective before they are approved for use.

In order to recognise what can go wrong with use of medicines, we need to understand the processes that are involved. There are many different steps, from diagnosis and prescription through to when the medicine reaches a consumer. Partnership and good communication between consumers/patients, doctors, nurses, pharmacists and other members of the health team is an essential element of safe care. In a hospital, there are many players involved in the direct medication process, including doctors, clerks, pharmacists, technicians, nurses and the patient/consumer themselves. Figure 1.1 shows the typical pathway for medicines in hospitals. At each stage, multiple factors influence whether the task will be performed without error.

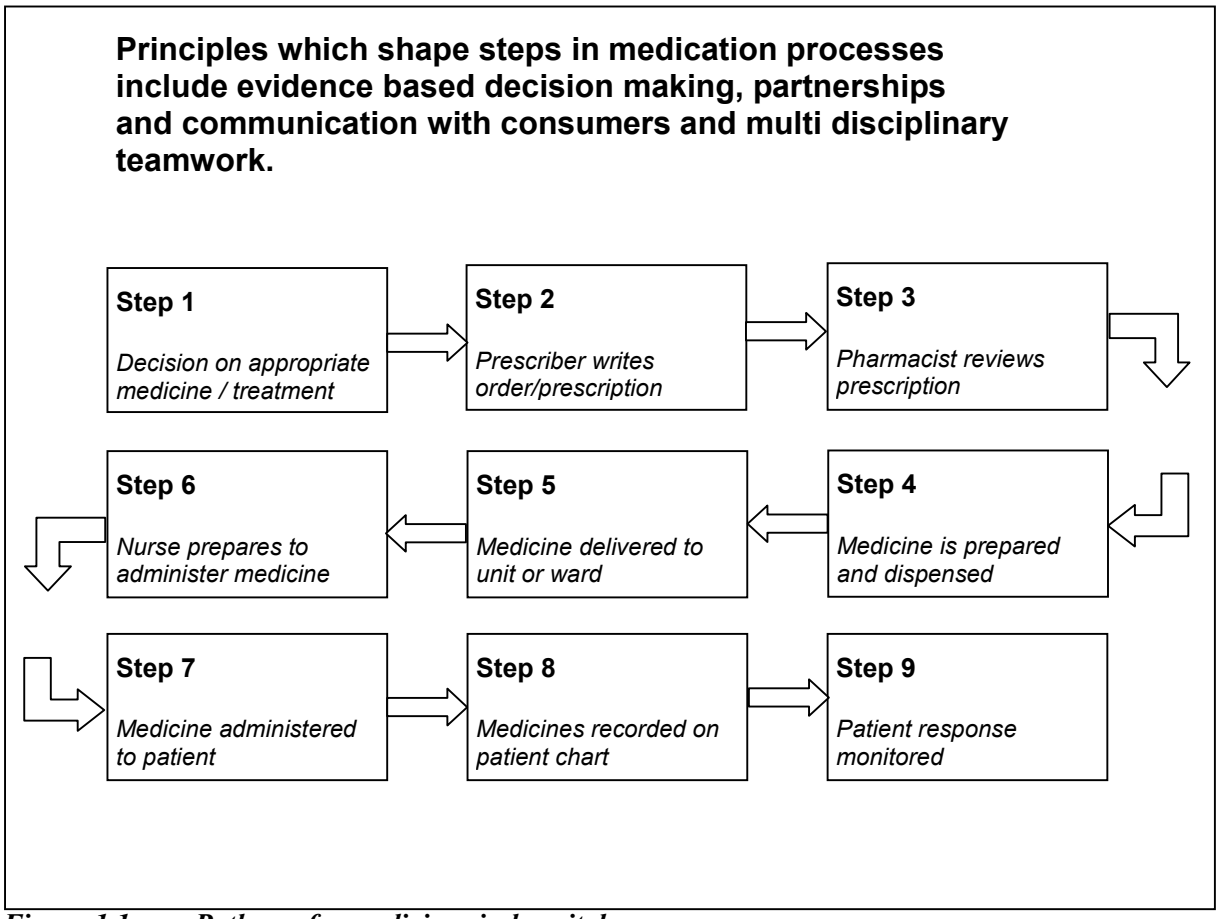


Figure 1.1 Pathway for medicines in hospitals
Source: Modified from Leape et al (1998).

Taking a systems approach to medication safety

What are system failures and errors?

Doctors, nurses, pharmacists and other health carers are human. No matter how well trained, expert and committed they are, sometimes they make mistakes. Mistakes are more likely to happen when people are tired, stressed or very busy but they also happen randomly in ordinary situations. Approaches to patient safety internationally stress that as human beings we can't usually operate at 100 per cent capacity 100 per cent of the time.

Mistakes usually result from system failures. A system failure can be defined as a fault or breakdown in any part of a system, or a lack of support in a system, that increases the risk of something going wrong. Factors such as poor design of processes, communication pressures, lack of standardised procedures and reliance on memory can all contribute to system failures. These factors can become even more significant in complex, multi-step processes such as use of medicines.

What are adverse events?

Not surprisingly, mistakes and system failures can lead to medication errors. In this report, these are included in the term 'medication incidents'. Medication incidents include problems which could have or did cause unintended patient harm and where the medication is likely to have been an important contributing factor. Most medication incidents do not result in patient harm and are sometimes referred to as 'near misses' or 'close calls'.

Medication incidents which lead to patient harm are called 'adverse drug events'. An adverse event can be defined as *an incident in which harm results to a person receiving health care*.

Patients' experiences of adverse drug events vary widely, depending on the particular situation and how, when or whether the error was picked up. In a small number of cases, adverse events may lead to death or serious injury. There are also less serious problems — and many more 'close calls' which do not result in patient harm but are warning signs that systems are not fail safe or robust.

All these incidents can be difficult to define and measure. Table I in the Glossary outlines in more detail some of the common terms and definitions.

Not all adverse drug events are related to a mistake — for example, a patient may react badly to a medicine even though it has been properly prescribed and there were no previous signs of such a reaction. This type of adverse event is usually less preventable. It is also important to understand that the disease process itself can lead to a poor outcome, despite the best care and appropriate use of medicines.

Because not all adverse events are preventable, and human beings are fallible, problems can never be eliminated altogether. To help prevent problems and mistakes, we need to redesign and simplify systems so that they reduce the likelihood of error in the first place and are safer for patients. A safe system also needs to make errors apparent quickly to those working in the system, with barriers in place so that the errors do not happen so frequently and can be corrected before causing harm to patients.

This requires strong leadership at all levels of health care to promote a systems perspective. It is also vital to encourage people to 'search out' error prone situations and ways of improving work processes without fear of being blamed or 'shooting the messenger'.

How do errors and system failures occur in the medication process

Errors and system failures can occur at any point in the medication process. Some examples of common reasons for errors include:

- handwritten prescriptions that are difficult to read;
- selection of incorrect strength/dosage;
- medication names that sound alike;
- medication packages that look alike;
- medicine administered to wrong patient;
- patient or carer misunderstands the directions;
- medication use not adequately monitored; and
- potentially harmful medicine interactions not recognised.

The following examples illustrate how system failures can lead to medication errors which sometimes lead to patient harm. Our knowledge about how often these happen in Australia and why is discussed in Chapters 2 and 3.

Example 1.1

In one of Australia's large hospitals a patient incorrectly received a dose of metronidazole (an anti-infective) which had been prescribed for the patient who had previously been in that bed.

Another patient incorrectly received a dose of insulin (used to manage diabetes) because a different patient's medication chart was located at the end of his bed. Fortunately neither patient suffered any ill effect.
Source: Thornton (2001).

Example 1.2

*A patient was prescribed Melphalan **5mg** (1 tablet) daily. This is a cytotoxic medication used for treating some types of cancer. The directions were written on the prescription as 5mg daily. The pharmacist typed on the label "take 5 tablets daily" instead of one (5mg) tablet daily. This resulted in the patient taking a dose of **25mg** daily. The patient died as a result of taking too high a dose of this medication.*
Source: Pharmacy Board of Victoria.

Comment: This is an example of a simple error with a tragic result. These types of errors can occur in a busy environment. This situation may have been avoided by the presence of safeguards to detect and correct the error. This could include a computer-based dispensing system designed to alert the pharmacist to possible inappropriate doses of high-risk medications. A less technological approach may be to establish a protocol that ensures that instructions on high-risk medicines are verified by a second person.

Example 1.3

A nurse was preparing an antibiotic injection at a large teaching hospital. The necessary equipment was gathered, including a plastic ampoule of solution to reconstitute the vial of antibiotic. During the checking process, it was discovered that the plastic ampoule contained 1g of potassium chloride in 4mL, rather than water for injection. The error was detected prior to the patient coming to any harm. The nurse pointed out that there had been no advertising to highlight that the red labelling of the potassium chloride plastic ampoules had been changed to blue, making the ampoule appear similar to the water for injection ampoule.
Source: Thornton (2001a).

Understanding the terminology

System failures and adverse events are terms used when talking about patient safety generally. There are also many terms used to describe the things that can specifically go wrong with medicines. For example, the terms 'medication incident', 'side effect', 'adverse event' 'adverse drug event' and 'adverse drug reaction' are all used to describe things that go wrong with medication use. Key terms such as these are associated with the effect or potential effect the medicine itself has on the person. The terms are related to each other and have slightly different meanings. The Safety and Quality Council is developing a list of the main safety and quality terms, with agreed definitions, to increase consistency in how the words are used. These and other terms used in the report are included in the Glossary.

The following diagram illustrates how the various terms are related and how they are used in this report. Each of the main terms is discussed in Table I of the Glossary.

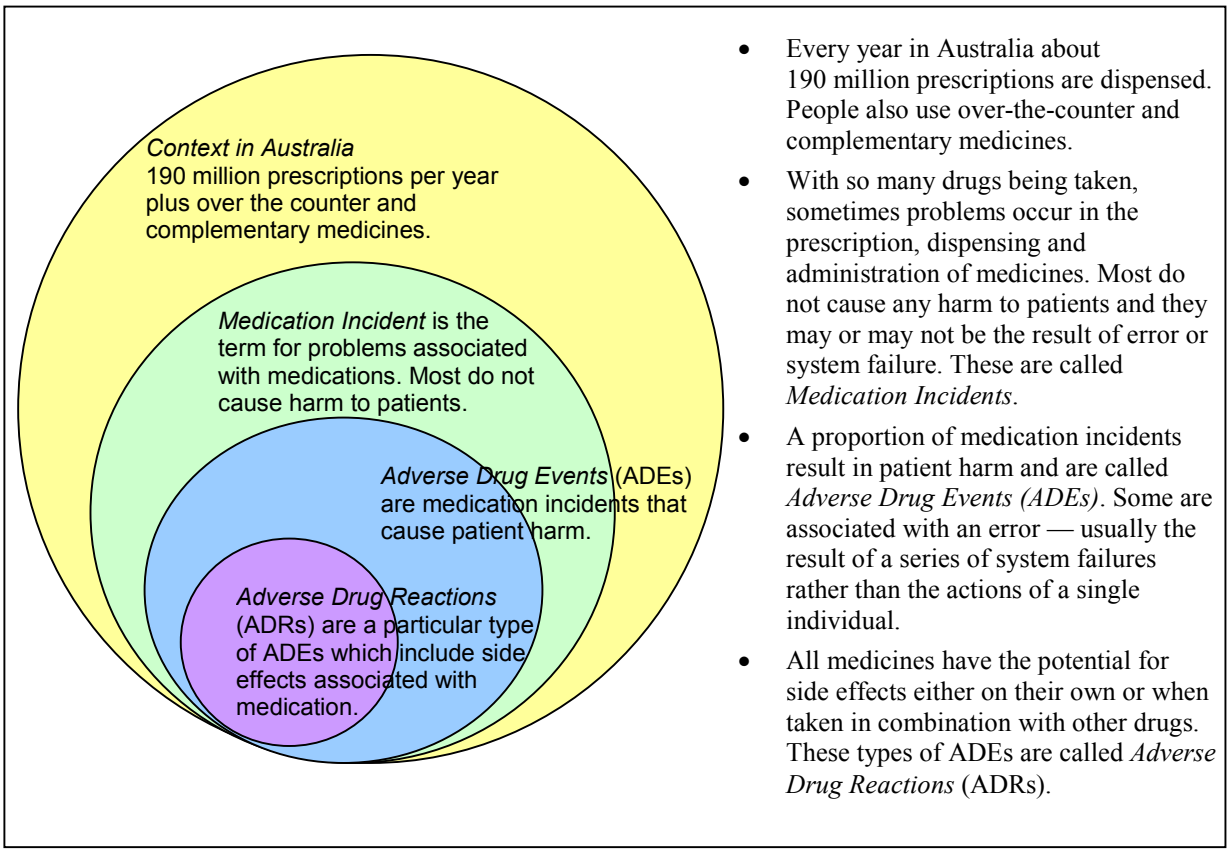


Figure 1.2 Relationship between medication incidents, adverse events and adverse drug reactions

2 Medication incidents in Australia: what do we know about the problem?

Medication incidents can happen anywhere in the health system. In this chapter, we examine what is known about medication incidents in different settings across the health system. There is no single source of data that gives a complete picture of the kinds of problems that can happen with medicines and where they occur. This would not be possible, because of the range of different types of medication incidents and the many different settings in which health care is provided. What we can do is obtain data and information from a number of sources. From this we can infer the overall picture.

Medication incidents in the hospital setting

Information on medication incidents treated in hospitals comes from a number of different sources, ranging from small studies based in hospitals to national data sets. Some studies have looked at hospital admissions (these include events that occurred both in and out of hospital, but are treated in hospital), while others have focused on adverse drug events or adverse drug reactions. Despite the differences between the studies, they give us an indication of the numbers of people going to hospital as a result of problems with their medicines and the types of problems that occur. Certain results are consistent across the studies (see box). The results are discussed in more detail below.

What do we know about medication incidents in the hospital setting?

- Medication incidents in the hospital setting are relatively common. These include events that occur both in and out of hospital, but are treated in hospital.
- Overall, results suggest that between 2 and 3 per cent of all hospital admissions may be medication-related — this translates to over 140,000 hospital admissions in Australia in 1999–2000. This includes admissions resulting from over-use and under-use of medicines as well as those related to adverse drug events.
- The medicines most commonly involved in medication incidents are medicines for cancer chemotherapy, medicines used to treat pain and inflammation, medicines for heart conditions and high blood pressure, medicines that affect blood clotting, antibiotics, central nervous system medicines and corticosteroids.
- Older people have higher rates of medication incidents. This is partly because they are more likely to be taking one or more medicines, and partly because they are more likely to be admitted to hospital (and so be represented in hospital statistics).
- It is likely that a considerable proportion of hospital admissions related to medication incidents may be preventable.
- No reliable and complete data on patient deaths associated with adverse drug events are available.

Hospital-based studies of medication-related admissions

There have been at least 20 Australian studies since 1988 that have looked at the numbers of people being admitted to hospital as a result of problems with medicines (Figure 2, also Table 1 in Appendix I). These may include admissions resulting from over-use and under-use of medicines as well as admissions resulting from other adverse drug events.

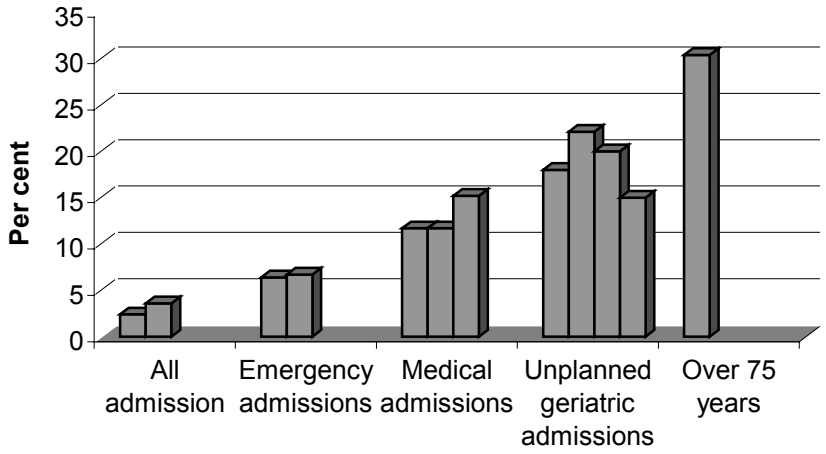


Figure 2.1 Types of medication-related hospital admissions: Results from Australian studies 1988 to 2001

When the same groups of patients are compared across the studies, the results are remarkably consistent. Overall, they suggest that between 2 and 3 per cent of all hospital admissions are medication-related. In older people (those over 65 years), approximately one in five unplanned admissions to hospital are medication-related. One study found that 30 per cent of unplanned admissions in people aged over 75 years were related to medicines (Chan et al 2001). This may be partly because older people are more likely to be taking one or more medicines, and partly because they are more likely to be admitted to hospital (and so be represented in hospital statistics).

Children also appear to experience higher rates of medication incidents. One study in three different hospitals found approximately 4 per cent of all admissions in children (under 18 years) were medication-related (Easton-Carter 2001). These figures take in over-use and under-use of medicines, including accidental poisonings.

The medicines most commonly involved in medication-related admissions were medicines for cancer chemotherapy, medicines used to treat pain and inflammation (commonly known as non-steroidal anti-inflammatory drugs or NSAIDs), medicines for heart conditions and high blood pressure, anticoagulants (medicines that affect blood clotting), antibiotics, central nervous system medicines (for example medicines for anxiety, sleep or depression) and corticosteroids (medicines used to reduce inflammation or suppress the immune system).

These studies were nearly all undertaken in single hospitals, usually with pharmacists and doctors assessing whether the admissions were related to use of medicines. For this reason, they are the most accurate studies we have. However, they usually involve less than 1,000 cases, which is considered a small sample. The findings may not represent what is happening across the country.

National and state level information

There are two main sources of information that help us to understand what may be happening nationally:

- *The Quality in Australian Health Care Study* (Wilson et al 1995) — this study aimed to find out the incidence in Australian hospitals of adverse events that resulted in disability, death or prolonged hospital stay. Overall, 14,179 case notes from 28 hospitals were reviewed. The main findings relating to medicines were (Day et al 1995):
  - — just under 2 per cent of hospital admissions were associated with adverse drug events (adverse drug reactions and medication errors causing harm);
  - — the medicines most commonly involved were medicines for heart disease and high blood pressure, antibiotics, anticoagulants, non-steroidal anti-inflammatory drugs and medicines for cancer chemotherapy; and
  - — 43 per cent of adverse drug events were considered potentially avoidable.
- *The National Hospital Morbidity Database* — this database is maintained by the Australian Institute of Health and Welfare and holds information about hospital admissions. This includes information on admissions associated with adverse drug reactions that caused the admission to hospital and those that occurred during hospital stay, therefore providing information about only one aspect of medication incidents. The main findings for the year 1999–00 include:
  - — 69,766 adverse drug reactions were associated with hospital admission;
  - — the medicines involved were very similar to those identified from the hospital admission studies and the Quality in Australian Health Care Study (see Tables 2 and 3 in Appendix I).
  - — older people have the highest rates of adverse drug reactions (Figure 2.2).

State based information can also provide some valuable insights. Data from South Australia for example shows that the rate of adverse drug reactions increased four-fold between 1988–89 and 2000–01 — while we can't be sure how much of this is avoidable, there seems to be a strong link between increasing use of medicines and increasing rates of adverse drug reactions (see Figure 2.3). Some of the increase may be due to better recording of data.

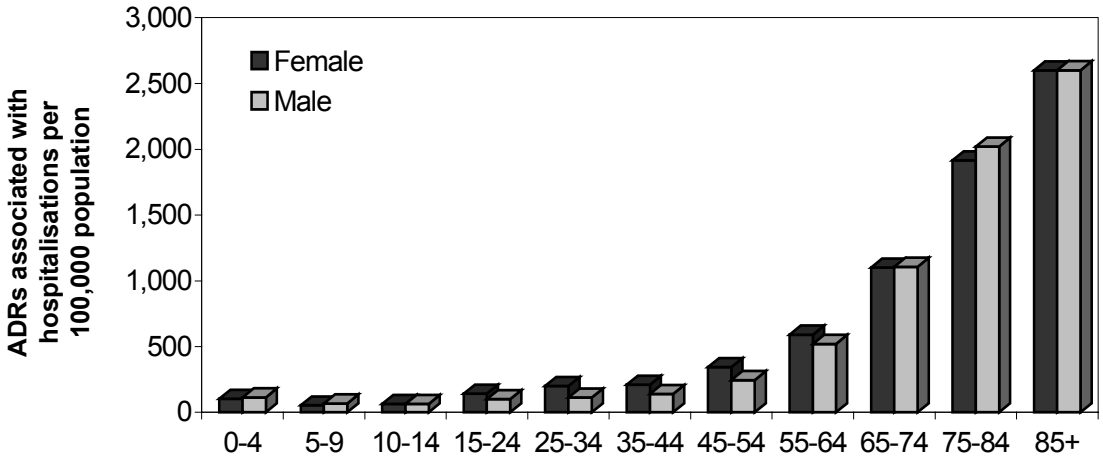


Figure 2.2 Rate of adverse drug reactions associated with hospitalisations by age and gender— Australia, 1999–2000

Note: ADR = adverse drug reactions
Source: Figure compiled from data from AIHW and ABS.

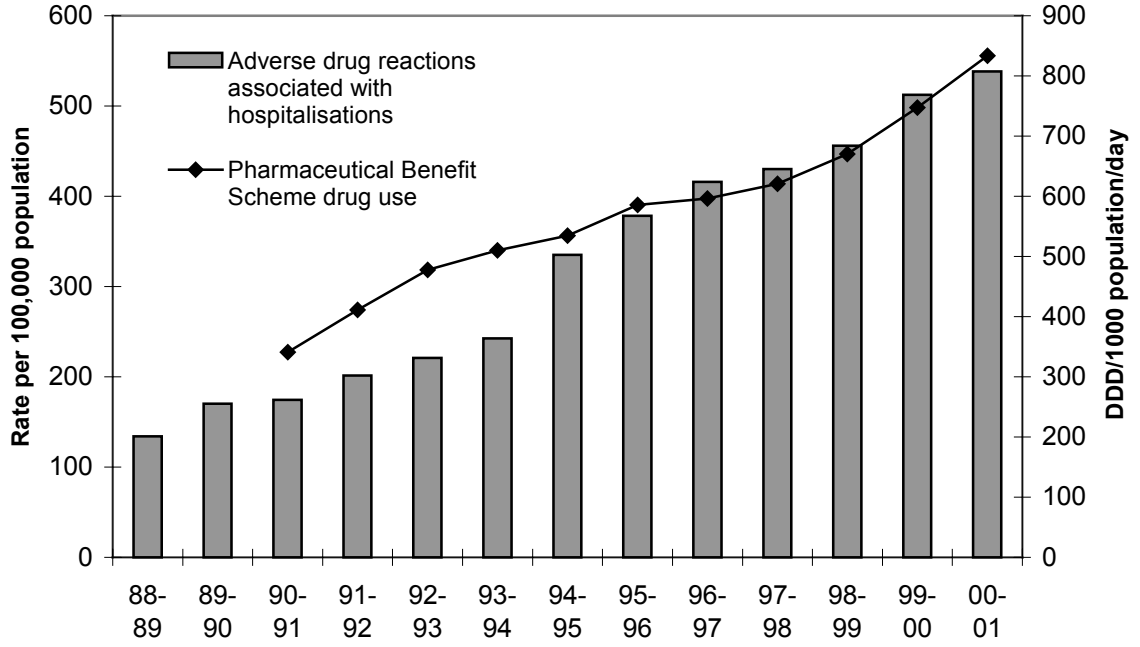


Figure 2.3 Annual rate of adverse drug reactions reported as associated with hospitalisations in South Australia and Pharmaceutical Benefits Scheme prescription dispensing in South Australia

Note: DDD = defined daily dose
Source: Figure compiled from data from the Integrated South Australian Activity Collection, South Australia; Drug Utilisation Sub-committee of Pharmaceutical Benefits Advisory Committee; and the ABS.

Understanding the extent of the problem

We can use the results of the hospital admission studies and national studies to help us understand the extent of the problems associated with medicines. If we assume that medication-related hospital admission studies are representative of what occurs nationally, then we can say that in 1999–2000, between 2 and 3 per cent (about 140,000) of the total 5.9 million hospital admissions across Australia may have been associated with problems with medicines. The findings of the Quality in Australian Health Care study (Wilson et al 1995) suggest that around 100,000 admissions may have been associated with adverse drug events.

To put these figures in perspective, we can compare them with numbers of hospital admissions for common diseases in the community — for example, in 1999–2000, there were 62,586 admissions for influenza and pneumonia, 60,759 for asthma and 41,708 for heart failure (AIHW 2002).

Medication-related hospital admissions are also costly, both economically and socially. Data from the Australian Institute of Health and Welfare (2002a) suggest that public hospital costs alone may be as high as $380 million.

There are no reliable data on deaths associated with medication incidents. The Quality in Australian Health Care Study reported 19 deaths associated with adverse drug events out of a total of 14,179 admissions reviewed (Day et al 1995). While extrapolating from one study must be done very carefully, applying these figures to hospitalisations in 1999–00 would suggest deaths associated with adverse drug events may be in the thousands per year.

Medication incidents in the community setting

Much less has been published about medication incidents in the community setting than in the hospital setting. The main sources of information are studies of medication management services, studies of people attending emergency departments but not admitted to hospital, and studies based on self-reporting by community pharmacists and general practitioners. A summary of the main findings from these studies is in the box below. We look at the types of errors that occur and the factors that contribute to them in the next chapter of the report.

What do we know about medication incidents in the community setting?

- Medication incidents in the community sector have not been studied as extensively as in the hospital setting.
- The number of medication-related problems that people experience increases with the number of medications taken.
- Approximately 400,000 adverse drug events may be managed in general practice each year (based on data from a survey of general practice).
- Rates of prescription errors and dispensing errors in the Australian community setting are not known.

Studies of medication management services

A review of case notes from a South Australian study, which involved 1,000 people considered to be at high risk of medication problems, identified 2,764 medication-related problems (2.8 problems per person). It is not known whether these problems resulted in medication incidents or adverse drug events. Thirty-seven per cent of the problems related to medication selection, 17 per cent related to the medication regimen, and 20 per cent related to patient knowledge and skills to manage their medicines and/or condition (Gilbert et al, in press). An earlier, smaller study identified 2.6 problems per person (March et al 1999). The medicines most commonly involved with these problems were medicines for the heart, central nervous system, digestive system and respiratory system. The number of problems people experienced increased with the numbers of medicines taken (see Figure 2.4).

Example 2.1

A 14-year-old male had been diagnosed with severe asthma which caused three hospital admissions within 12 months, and the loss of 10 school days during the school term. His mother was concerned about his progress at school. Upon assessment, the pharmacist discovered that the patient was not using his preventer medication regularly, was relying almost totally on his reliever medication, had a poor understanding of his condition and had a poor inhaler technique. The pharmacist educated both mother and patient about asthma and its appropriate management, including correct use of preventer and reliever medications. The pharmacist also demonstrated the correct inhaler technique. Two weeks later, the patient reported a reduction in symptoms. Two months later, there had been fewer asthma attacks, fewer school days lost and there had been no further admissions to hospital.
Source: Pharmacy Practice Research Group (1997).

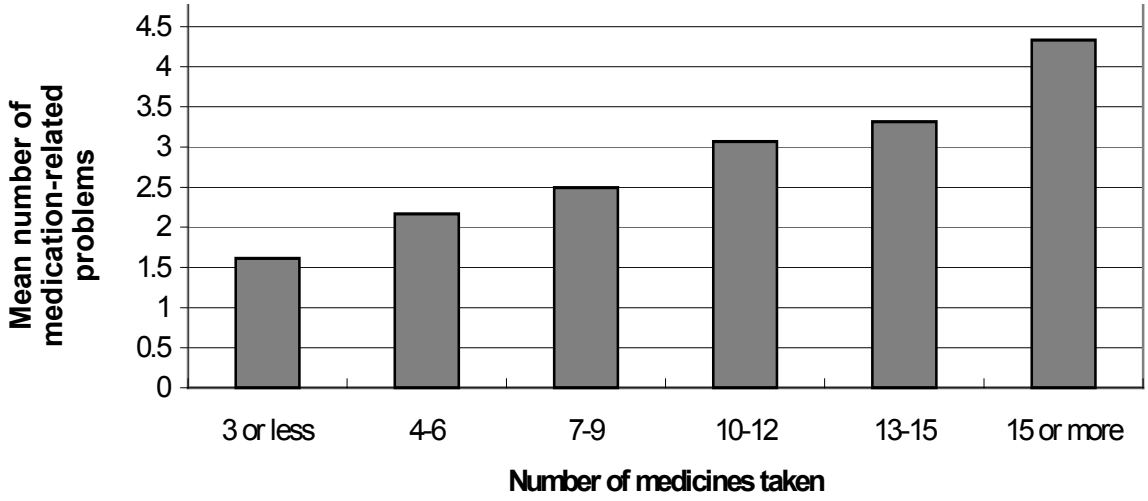


Figure 2.4 Numbers of medication-related problems compared with medication use

Source: Unpublished data, Quality Use of Medicines Implementation Trial, South Australia.

Studies of people attending emergency departments

A Melbourne study found that 7.3 per cent of emergency department attendances were medication-related, with 8.6 per cent of those not admitted to hospital attending the emergency department with medicine-related problems (Galbraith 1993). Another study found that 3.3 per cent of all emergency department attendances by children were medication-related (this includes children admitted to hospital as well as those who only attended the emergency department) (Easton-Carter 2001).

Studies of general practice and community pharmacies

Information on adverse drug events managed in Australian general practice is available from a survey of general practice, known as the BEACH survey (Bettering the Evaluation and Care of Health). In 1999–00, there were 4.1 adverse drug events recorded for every 1,000 visits to doctors (Hargreaves 2001). We know that there were over 100 million general practice encounters in Australia that year (HIC 2000) — extrapolating from the survey suggests that more than 400,000 adverse drug events may be managed in general practice every year.

Community pharmacies in Australia dispense over 190 million prescriptions each year — as an overall proportion of practice, dispensing errors appear to be relatively uncommon, although the actual incidence in Australia is not known. Information on the types of dispensing errors that occur is given in Chapter 3.

3 What factors contribute to medication incidents?

The evidence discussed in the previous chapter confirms that medication incidents are significant in Australian health care settings. However, we know much less about the factors that contribute to these incidents — about why systems fail and errors happen. None of the studies in Australian hospitals that were reviewed for this report identified systems failures that contribute to adverse drug events. Overseas, it has been estimated that changes to improve systems and reduce errors could help to prevent about three in every four adverse drug events (Leape et al 1995). Health systems differ across the world and we need to identify what causes medication incidents in Australia. More information is needed in this area.

Things can go wrong in any of the steps in the medication process. This chapter looks at what we know and don't know about the types of errors that occur in different settings, and the underlying problems that make these errors more likely to happen.

Information about the types of errors that commonly occur in hospitals and the community come from published studies and from incident monitoring systems (eg the Australian Incident Monitoring System maintained by the Australian Patient Safety Foundation). A summary of the results is given in the box, and the studies are described below.

What do we know about types of errors and why they occur?

- The published literature tells us relatively little about the factors contributing to medication incidents in Australia.
- Errors associated with the administration of medicines in hospitals range from 5–8 per cent to 15–20 per cent, depending on the type of medicine supply system used. Dispensing errors in hospital pharmacies have been reported at rates between 0.08 per cent and 0.8 per cent of all items dispensed. Incident monitoring data indicate that failure to read the chart and lack of robust systems for prescription/ordering are the most common factors linked to adverse drug events in hospitals.
- In general practice, the most common incidents involving medicines are the use of an inappropriate drug, prescribing errors, administration errors and use of an inappropriate dose of a medication. The majority of these medication incidents are considered to be preventable. Doctors considered communication problems, errors in judgement or assessment, and procedural problems such as lack of protocols or inadequate review of patient history, to be the major contributing factors.
- The most common types of dispensing errors reported in the community involve selection of the incorrect strength of a medicine or selection of the incorrect product, which can often occur as a result of 'look-alike' and 'sound-alike' errors. Community pharmacists reported the major factors contributing to dispensing errors as overwork, fatigue, interruptions and similar or confusing drug names.
- Problems with medications can also be caused by lack of communication, especially in the transition between the hospital and community setting, and when patients consult multiple health care providers who may not be aware of the patient's complete medication history.

What happens in hospitals?

Studies in hospitals have identified several common errors.

Errors in administration of medicines

These studies have mostly looked at error rates where different patient medication supply systems are used. The studies have found that:

- where patients are given medicines from common ward supplies, the error rates are between 15 and 20 per cent, compared with error rates between 5 and 8 per cent when individual patient medicines supplies are used (see Figure 3.1, also see Table 4 in Appendix I);
- many of the errors are 'timing errors' — these occur where a dose of a medicine has been given at least one hour before or after the scheduled time. Many timing errors occur because of busy schedules in hospital wards, and most are unlikely to cause harm to the patient. Timing errors have been found to occur at rates as high as 8 per cent of administered doses (see Table 4, Appendix I); and
- other commonly reported types of errors include errors of omission (where the patient does not get a prescribed dose of a medicine), wrong dose errors, errors in the type (formulation) of medicine given or an error in the route by which the medicine is given (eg by mouth when an injection has been prescribed).

Example 3.1

An infusion of dopamine 400mg in 100mL of glucose 5 per cent was prescribed for a patient. This is a medicine used to restore a critically low blood pressure. However, an infusion of dopamine 400mg in 50mL of glucose 5 per cent was administered (double the prescribed strength). The patient's blood pressure elevated rapidly. The error was detected and the infusion rate was adjusted to give the correct dose.
Source: Thornton (2002).

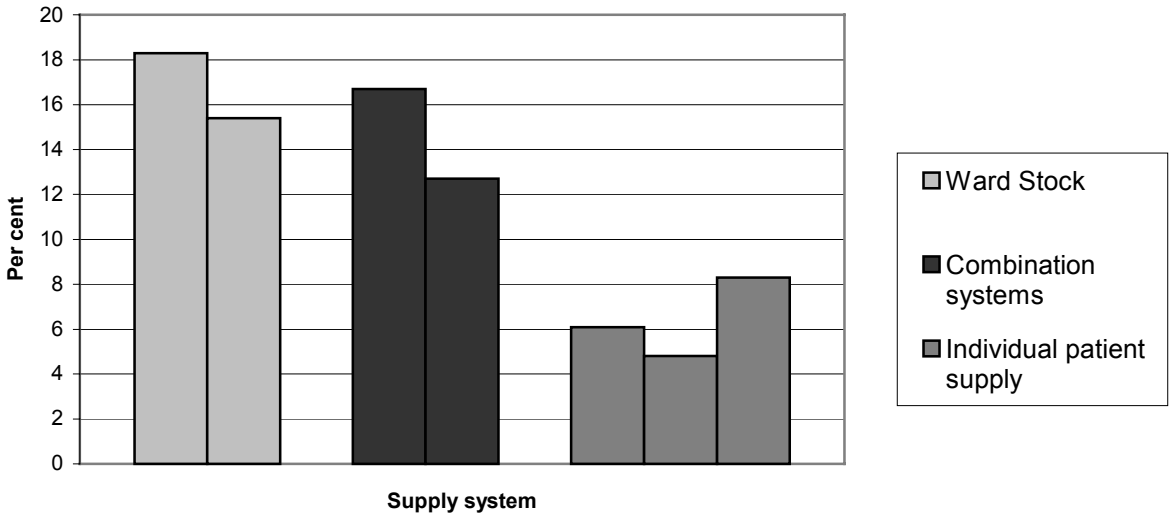


Figure 3.1 Medication administration errors: Australian hospitals 1988–2001. Differences in error rates where ward stock is used versus individual patient supply systems

Example 3.2

An intravenous infusion of Timentin 3.1g (containing the penicillin antibiotic ticarcillin and clavulanic acid) was administered to the wrong patient. The patient who received the dose had a known allergy to penicillin. The patient's allergy had previously resulted in a severe rash, but fortunately this event did not cause a life-threatening reaction.
Source: Thornton (2002).

There is a need for more information about the potential for administration errors to cause harm. In one study the medication error was judged to be 'clinically significant' in 10 (19.2 per cent) cases and potentially 'clinically significant' in 34 (65.4 per cent) cases. Another much smaller study, which only found 10 errors in total, estimated one (10 per cent) as clinically significant and six (60 per cent) as potentially significant (de Clifford et al 1994). Examples of errors judged to be clinically significant were those of giving 500mg of theophylline (a medicine to assist breathing) instead of 300mg, and omitting a dose of digoxin (a medicine for heart failure) (Rippe & Hurley 1988).

Prescription / medication ordering errors

Medication errors can also occur when prescriptions are written or transcribed from one medication chart to another. A majority of Australian hospitals require prescriptions to be written by the prescriber directly on to a chart which is also used to record medication administration, thus minimising or eliminating transcription.

There are not many studies assessing prescribing and ordering errors in Australia and all of them have used different methods, making it difficult to estimate an overall rate of prescription error. Also, not all prescribing errors lead to adverse drug events. Findings include:

- an Australian study of prescription errors and their likelihood to lead to adverse drug events examined 2,978 prescriptions and found that 71 (2.4 per cent) had the potential to cause an adverse drug event — these were usually because the dose was wrong or ambiguous (1 per cent), the dose was missing (0.6 per cent) or the directions for use were unclear or absent (0.5 per cent) (Coombes et al 2001);
- an earlier Australian study found a similar incidence of problems — of 10,562 prescriptions assessed, the strength was missing or incorrect in 0.7 per cent and the directions inappropriate or omitted in 0.4 per cent (Fry et al 1985; also see Appendix I, Table 5); and
- the outcome of these prescribing/ordering errors has not been studied extensively — one study in the intensive care unit (including both prescription and administration errors) found that in eight of the 68 medication errors the patient suffered harm of a mild to moderate nature. Medication error was judged to have the potential to cause mild to moderate harm to the patient on twenty-four occasions and substantial injury on seven occasions (Bordun & Butt 1992). It should be remembered that this study was conducted in the intensive care unit where patients were critically ill.

Dispensing errors

The incidence of dispensing errors in hospital pharmacies has not been studied extensively — one small study found the rate of dispensing errors from a hospital pharmacy department to be 0.08 per cent of all items dispensed (Thornton et al 1990), while another study found dispensing error rates of 0.4 per cent and 0.8 per cent of items dispensed (de Clifford 1993). The potential for these errors to lead to adverse drug events or patient harm was not reported.

Errors in the medication record

Lack of documentation about previous adverse drug reactions and allergies can result in adverse drug events (see case study below). For example:

- One hospital study found that previously known adverse drug reactions were not documented in 48 (77 per cent) of 62 cases (Coombes et al 2001).
- The same problem was observed in a New South Wales study where known adverse drug reactions were found to be documented in only 75 per cent of 117 cases where patients had reported a previous adverse drug reaction (Shenfield et al 2001).
- Another New South Wales study found that 8 per cent of medication histories omitted known allergic reactions (McCrudden et al 1995).
- The potential for these errors to lead to adverse drug events or patient harm was not reported.

Example 3.3

A patient, transferred from another hospital, was given an injection of metoclopramide 10mg (a medicine for nausea and vomiting) as ordered on the patient's drug chart. Later it was noted in a transfer summary from the previous hospital, that the patient had an adverse reaction to metoclopramide during her admission there. This had not been documented on the drug chart at the new hospital. The patient was closely monitored, but no obvious reaction to the metoclopramide occurred.
Source: AIMS database

Comment: Whenever a patient moves from one part of the health system to another (for example from the GP to the hospital, from one hospital to another or to a different part of the hospital), it is important to make sure all relevant information goes with the patient and is reviewed. If a problem is detected, corrective action should be taken where appropriate and the patient closely monitored.

Data from incident monitoring systems

Incident reporting systems have been implemented in many hospitals to collect information about factors that contribute to things that go wrong, as the basis for improving systems in the hospital. It is important to note that these systems are voluntary. While they can provide good information about why an incident occurred, they can't provide reliable information about the numbers of incidents that occur.

Incidents occurring within hospitals that use the Australian Incident Monitoring System (AIMS) are aggregated nationally. Figure 3.2 shows that most medication incidents include omission of therapy, overdose or administration of the wrong medicine. Failure to read or misreading of the chart accounted for most of the errors, with prescription or order errors and an unclear or incomplete order being the next two categories most commonly identified. Overall, 32 per cent of the medication incidents were considered to have no consequences, with a further 37 per cent having only minor consequences. Nineteen per cent were considered to have moderate consequences, while the consequences of 3 per cent were considered significant.

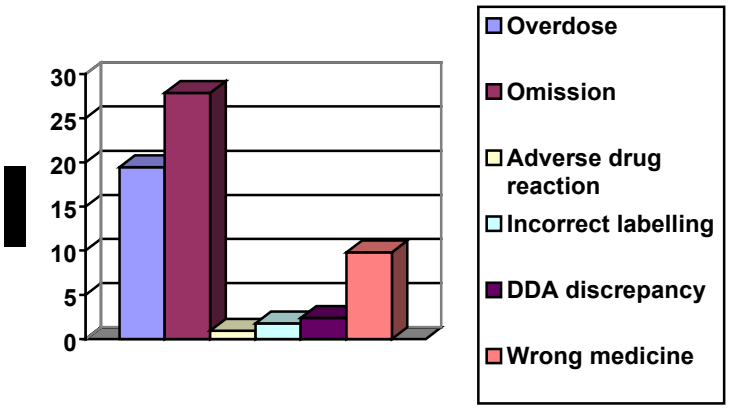


Figure 3.2 Types of medication incidents reported in the AIMS dataset

Note: DDA = drug of addiction.
Source: AIMS database.

Example 3.4

*A patient with breathing difficulty was supplied with the wrong strength medication from the pharmacy department at the time they were discharged from the hospital. The patient was given prednisolone **5mg** tablets (a medicine to reduce inflammation and improve breathing) instead of prednisolone **25mg** tablets. The container was labelled as "Prednisolone **25mg** tablets. Two tablets to be taken each morning with food". The manufacturer's label was not obscured. A nurse noted the discrepancy during a visit to the patient's home eight days after discharge from hospital and contacted the patient's doctor. Although the patient had been taking a lower dose of the medication they did not suffer any undue breathing difficulty. The patient was monitored closely and a new prescription for the medication was written by the patient's GP.*
Source: AIMS database.

What happens in the community setting?

Two Australian studies have assessed medication incidents in general practice and in community pharmacies. These studies asked GPs and pharmacists to provide their own explanation as to why the medication incidents occurred.

General practice

Medication incidents in general practice have been reported as part of an incident monitoring study of GPs (Bhasale et al 1998; Steven et al 1999). Detailed analysis of 807 of the total 2,582 reports found that incidents associated with medicines were the most frequent, accounting for 51 per cent of all incidents (Bhasale et al 1998). The GPs considered that (Bhasale et al 1998):

- 79 per cent of the medication incidents were preventable; and
- 23 per cent of the medication incidents had the potential to cause mild harm and 25 per cent had the potential to cause severe harm.

The types of medication incidents reported are shown in Table 3.1.

Table 3.1 Types of medication incidents in general medical practice

Type of incident	Rate per 100 incidents
Drug inappropriate	30
Prescribing error	22
Administration error	18
Dose inappropriate	15
Side effect	13
Allergic reaction	11
Dispensing error	10
Overdose	8
System inadequacies	7
Drug omitted or withheld	6

Source: Adapted from Bhasale et al (1998).

Doctors reported that communication problems, procedural, clinical and external problems all contributed to the incidents (Bhasale et al 1998). These factors are summarised in Table 3.2. External problems were considered those outside the GP's control, such as the action of others. Clinical problems usually related to errors in judgement or assessment. Procedural problems included lack of protocols, recall systems and procedures for review of medical records, while communication problems included poor communication between health professionals, as well as between health professionals and patients. Communication problems also included poor documentation, including whether records were up-to-date, complete and legible (Bhasale et al 1998). While these factors relate to all incidents reported in general practice, as most incidents involved medication it is likely the same factors contributed to medication incidents.

Table 3.2 Factors contributing to incidents in general practice

Contributing factor	Rate per 100 incidents
Poor communication between patient and health professionals	23
Action of others (not GP or patient)	23
Error of judgement	22
Poor communication between health professionals	19
Patient consulted other medical officer	15
Failure to recognise signs and symptoms	15
Patient's history not adequately reviewed	13
Omission of checking procedure	10
GP tired/rushed/running late	10
Patient misunderstood their problem/treatment	10
Inadequate patient assessment	10

Source: Bhasale et al (1998).

The incident monitoring study also showed that prescribing errors contributed to medication incidents. Very little other data are available on the rate of prescribing errors in general practice. One report documented error rates among two GPs where hand written or computer generated prescriptions were used (Jones et al 1988). As only two doctors were evaluated, we

can't draw conclusions about error rates. A study is currently underway looking at error rates with computerised prescribing systems (personal communication M. Kidd, May 2002)

Example 3.5

"After about six months I was staggering around like a drunken geriatric and a couple of days ago I got around to reading the fine print on the box and all the warnings were there. It said 'Avoid excessive exposure to sunlight or sunlamps while undergoing treatment. This medicine may affect mental alertness and/or coordination.' and boy does it!"
Source: Waller (1999).

Pharmacies

Some information on the types of dispensing errors that occur is available from Pharmaceutical Defence Limited, the company that provides professional indemnity insurance for pharmacists. The company is notified by pharmacists of known errors in dispensing. The most common types of errors are the selection of the incorrect strength of the medicine, the incorrect product or an incorrect interpretation of the prescription (Table 3.3). The selection of the incorrect strength or incorrect product often occurs as the result of a 'look-alike' or 'sound-alike' error. This can occur where two products have a similar name or packaging design (See Figure 3.3 for examples of similar packaging).

Example 3.6

*A patient was prescribed **Lanoxin PG** (containing digoxin **62.5 microgram per tablet)** for a heart condition. In error, the pharmacist dispensed **Lanoxin**, containing digoxin **250 microgram per tablet** and labelled it as Lanoxin PG, with the directions intended for the Lanoxin PG. The patient ended up in hospital as a result of taking too high a dose.*

This dispensing error has been reported to the Victorian Pharmacy Board on eight occasions over the last three years.
Source: Pharmacy Board of Victoria

Examples of 'look-alike' or 'sound-alike' dispensing errors

Dispensing errors recently reported to the Pharmacy Board of Victoria which have resulted from look-alike and sound-alike names include:

- *Imdur (a medicine for chest pain or 'angina') confused with Imuran (a medicine which effects the immune system)*
- *Prozac (a medicine for depression) confused with Provera (a hormone therapy)*
- *Roaccutane (a medicine for acne) confused with Rocaltrol (a medicine for osteoporosis).*

Source: Pharmacy Board of Victoria.

Figure 3.3 Examples of similar packaging. There are many others that could be provided.

The factors contributing to dispensing errors in Australia were assessed in a survey of 209 community pharmacists. Pharmacists thought the major factors contributing to dispensing errors were high prescription volume, overwork, fatigue, interruptions to dispensing and similar or confusing ('look-alike', 'sound-alike') drug names. Some things that pharmacists thought would minimise dispensing errors were: having systems for checking their dispensing procedures; having a systematic work flow for dispensing; checking the original prescription when dispensing repeats; improving the packaging and labelling of drug products; having distinctive drug names; and improving patient counselling (Peterson et al 1999).

Other factors contributing to medication incidents

Inadequate continuity of care

When people are very sick they often end up in hospital, away from the care of their usual GP and pharmacist. It is essential for patient care that information about a patient's medicines is communicated to the hospital when the patient is admitted and back to their community health professionals when they are discharged. Poor communication at the time of discharge from hospital or errors in prescribing or transcribing at discharge can contribute to medication incidents.

Information on hospital discharge prescriptions was examined at one hospital. Review of discharge prescriptions for 68 patients found that 49 (15 per cent) of the 329 regular medications intended to be continued were omitted (Coombes et al 2001). Another study undertaken to assess the accuracy of medication-related information in the medical record found on average one medicine was omitted from the discharge prescription. There were also problems with the medication history on admission with, on average, one medicine not being documented on the medication history for every two patients (Stowasser et al 1997). How often these omission errors lead to actual adverse drug events or patient harm has not been reported.

Example 3.7

In one case a 45-year-old woman with unstable angina was discharged from hospital with only aspirin and amlodipine (medicines for her heart condition). Other medications she was intended to continue — isosorbide mononitrate SR (her dose had been doubled during admission), gliclazide, metformin, ranitidine and conjugated oestrogens — were all omitted. These medicines are for heart disease, diabetes, indigestion and menopausal symptoms (Coombes et al 2001).

Comment: On discharge it is important that the patient clearly understands their medication regime and that this information is also sent to community health care professionals who manage the patient's ongoing care. This is particularly important for patients with complex health care needs who may be taking a number of different medications.

Another study examined how discharge information was communicated to GPs. One-hundred and six GPs answered questionnaires about the type of information they had received from the hospital about 203 of their patients. In 44 cases (22 per cent) the hospital directly notified the GP of the patient's admission to hospital. In 54 (27 per cent) the patient notified the GP. In the remaining 55 cases (52 per cent) there was no notification given to the GP. A change to the patient's medicines was made in hospital in 87 per cent of the 203 cases, with the patient's medicine at discharge differing from what the GPs understood the patient to be taking before they went to hospital in 72 per cent of cases. When the patients were discharged from hospital, the mean time taken for GPs to receive the discharge summary from the hospital was three days, although the range extended from one to twenty-one days (Mant et al 2001). The extent to which these communication problems lead to adverse drug events and patient harm is not known.

There are also problems with communication between hospitals. A study in a regional hospital in Queensland looked at the medical records of patients referred to the oncology unit of the hospital. These patients had chemotherapy (medicines for cancer) which had been started at another hospital. Of the 100 referral medical records reviewed, 72 per cent had the potential for one or more errors associated with the patient's medicines. The most common faults were: not enough documentation to allow doses to be confirmed; handwritten or illegible medication orders; and lack of instruction about the length of time between cycles of chemotherapy (Gilbar 1999).

Example 3.8

A 79 year-old woman was seen at home by a pharmacist. The patient had urinary incontinence which appeared to be linked to the use of spironolactone (a medicine which can be used to help remove fluid from the body). The pharmacist contacted the prescriber, who expressed surprise that the patient was still taking the medication as she had been advised to cease it. When the woman stopped taking the medication, the incontinence problem resolved.
Source: Pharmacy Practice Research Group, 1997.

Multiple health care providers

The Australian health system allows consumers to see GPs and pharmacists of their choice. Each health professional keeps individual records, so they don't always have details of what actions and decisions other health professionals may have made, unless formal correspondence has been sent. In this situation, it is easy for medication errors such as duplication of treatment or drug interactions to occur — for example, one health professional may prescribe a medicine, being unaware that a different health professional has prescribed it separately. The consumer may not be in a position to pick up the mistake if the medicines have two different names or if they don't know that the medicines interact.

Use of more than one health professional appears to be common. In one study involving 204 people, 48 per cent had medicines prescribed by more than one doctor and 28 per cent had medicines dispensed from more than one pharmacy (Sorensen et al 2000). No data are available on the extent to which this causes problems for consumers.

Keeping unnecessary medications

Keeping medications that are no longer in use or are past their expiry dates can contribute to medication errors. In a small study where pharmacists visited people at home to provide medication management services, 21 per cent of people were found to be keeping medicines no longer in use, and 20 per cent of people were keeping expired medicines (Sorensen et al 2000). No data are available on the extent to which this practice leads to adverse drug events or patient harm.

Example 3.9

An elderly woman asked a pharmacist if he could look at some medicines which her daughter suggested she get rid of. The pharmacist eventually took away a large bag containing forty-seven medicines that had expired in the last 12 months.
Source: QUMCIT (1999a)

Generic names/trade names

Pharmacists are now able to dispense generic medications where these are available, shown to have the same effect at the same dose, and the prescriber has not indicated this is not allowed. It is important that consumers are aware of this practice and know if they are dispensed a generic medication that it is the same as the branded medication. One study found that consumers did not understand the difference between the generic and trade name of a medication in 29 per cent of cases (Sorensen et al 2000). While this has the potential to lead to adverse drug events that result in patient harm, no data are available on the extent to which this occurs.

Example 3.10

Paracetamol *is the generic name for a kind of pain relief medicine.* ***Panadol*** *and* ***Herron*** *are examples of brand or trade names that are used for paracetamol.*

Understanding the label

Difficulty in understanding medication labels can lead to medication errors. A survey of 100 older consumers found that consumers sometimes have difficulty understanding medication labels. The instruction ‘take one tablet every 6 hours, 1 hour before food (four tablets per day on empty stomach)’ was correctly interpreted by 16 per cent and misunderstood by 84 per cent of consumers, whereas the label ‘take one tablet twice a day’ was correctly understood by 83 per cent of consumers (Adamson et al 1988). It has not been reported how often difficulty in understanding the label results in adverse drug events and patient harm.

Example 3.11

A study assessing the interpretation of medication labels by people from a non-English-speaking background found that the label

"Take TWO tablets, FOUR times a day when necessary for pain relief (MAX: 8/day)"

Could be interpreted as

"Tablets should be taken for a maximum of 8 days only" *OR*…

"Take 4 tablets when in pain" *OR*…..

"Take 4 tablets a day only for pain over a period of 8 days"

Source: Stewart et al (1998).

Example 3.12

An 18-year old woman took a dose of a friend's medication (nizatidine) for an upset stomach. About one hour after taking the dose she experienced an allergic reaction to the medication including shortness of breath, wheezing and mild swelling of her neck. She was taken to a hospital emergency department. After treatment at the hospital she improved rapidly.
Source: Hamilton-Craig & McNeece (2000).

4 What works to improve medication safety?

The previous chapter highlighted the things that can go wrong with medicines and their use, as well as some of the factors that contribute to problems. In this chapter we look at a number of strategies to reduce medication incidents. Each strategy is discussed individually — however, we know that to build a safer system, a combination of strategies will be required.

This chapter particularly focuses on initiatives that have been tested for reducing medication incidents and making patient care safer. There have been many other initiatives tested that focus on improving use of medicines, rather than specifically reducing adverse drug events. Some strategies include academic detailing, case studies, clinical audit and feedback programs, use of medication management aids and consumer education and awareness campaigns. While they are relevant to the overall strategy for improving use of medicines, these initiatives are not the focus of this report and are not discussed further.

It is clear that medication safety is a complex area and that no single factor is responsible for adverse drug events. For this reason, in Australia and around the world, a systems approach is being used to reduce medication incidents. This means that we need to pay attention to the environment in which we work and live, as well as think about individual behaviour to address problems. We need to build into our health systems and work practices processes to make system failures nearly impossible, or to detect and correct errors and failures before they cause patient harm. We also need to provide education strategies and organisational support to help people to work safely. This means providing strong leadership to make patient safety a priority, using resources that reduce error, and implementing practices that promote safety.

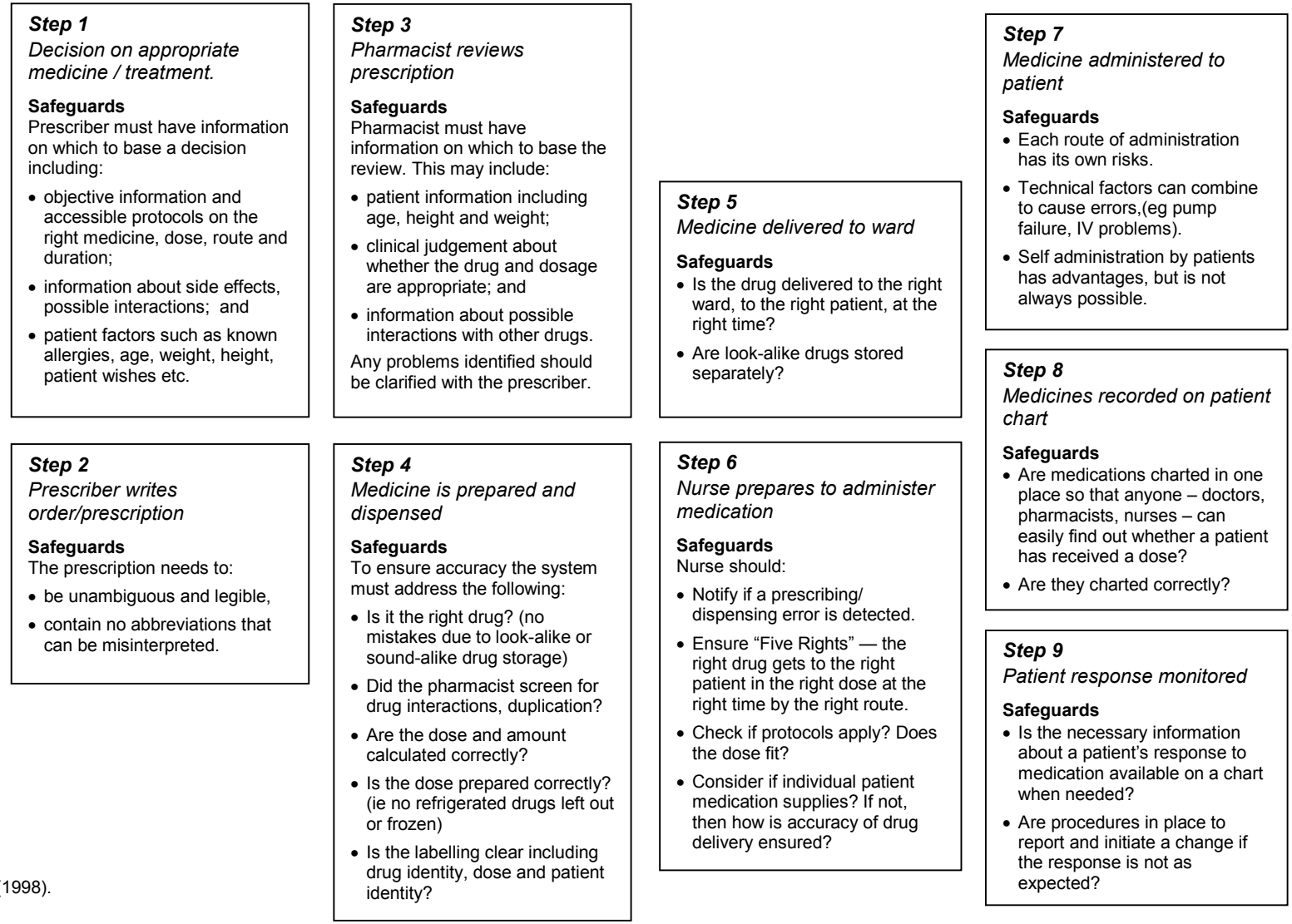
As an example of a systems approach, Figure 4.1 (below) takes the medication pathway outlined in Chapter 1 and shows how safeguards in the system can help to prevent medication incidents and patient harm at each step.

Figure 4.1 Example of a medication pathway in the hospital setting

This is an example of a typical pathway of medicines in hospitals, at the level of patient care.

The pathway that a medicine travels from diagnosis and prescription through to when it reaches a patient involves many different steps and there is a risk of error at any point in the process. Wherever possible, the health care system must have safeguards built in to detect and correct errors before they cause patient harm.

Key redesign factors include reducing reliance on memory, simplifying and standardising processes, use of protocols and checklists.



Source: Modified from Leape et al (1998).

Table 4.1 highlights some of the basic elements of a safe medication process, particularly within hospitals. These are important building blocks for building safer systems, which recognise that human beings cannot operate at 100 per cent accuracy all the time. These strategies have been developed and tested by the Institute of Healthcare Improvement, whose breakthrough collaborative work with hospitals in the United States has demonstrated measurable reductions in patient harm from medication use (Leape et al 1998).

Table 4.1 Basic elements of systems which have successfully reduced medication errors in US hospitals using the Breakthrough Collaborative Method

Process improvements to reduce medication errors within hospitals
• Strong leadership commitment to achieving improvements through systems redesign
• Improve direct communication — to reduce possible misunderstandings
• Drive out fear so that staff reporting of error prone situations occurs in a non-punitive way
• Train for teamwork — experience in other industries shows that effective teams produce fewer errors
• Increase feedback
• Optimise the work environment for safety
• Automate carefully
• Differentiate — eliminate look-alikes and sound-alikes
• Decrease multiple entry to record information
• Reduce hand over points
• Decrease reliance on vigilance — reduce requirements for extended focused attention beyond normal human duration
• Improve access to information
• Use protocols and checklists wisely
• Standardise and simplify processes as much as possible
• Reduce reliance on memory

Which strategies have been shown to reduce medication incidents?

Strategies that have been shown in the published literature to reduce medication incidents are summarised in the box below. Most of the evidence comes from an overseas systematic review, but there have also been Australian studies in several areas. The evidence for a range of strategies is discussed in this section, with more details of the studies in Appendix II. Current use of the strategies in Australia is discussed in Chapter 5.

Strategies that have been shown to reduce medication incidents include:

- Use of computerised prescribing with clinical decision-support systems by doctors — information about medicines for health care providers on-line or in prescribing/dispensing software.
- Computerised adverse drug event alerts — these hold information about the patient's medical record and medication record, and automatically signal the presence or possibility of an adverse drug event when a medicine is prescribed.
- Individual patient medication supply in hospitals — medicines are labelled, supplied and stored for each individual patient, reducing the risk of wrong medicine or wrong dose.
- Clinical pharmacy services — pharmacists in hospitals can support systems to reduce medication incidents, through patient and staff education, monitoring and medication review.
- Transfer of information between hospital and community settings — complete list of current medications held by the patient and better transfer of information between hospital and community health professionals.
- Community based medication management services and case conferencing — assisting patients considered at high risk of medication-related problems through review of their prescribed, over-the-counter and complementary medicines, and discussion of their overall health care.
- Discharge medication management services — range of services for people at risk of medication incidents, including discharge and medication summaries to patients and health care providers.

Systems to promote improved prescriber decision-making

Automating prescribing and clinical decision -support systems

Lack of knowledge about medicines or lack of access to information about medicines when it is needed can contribute to adverse drug events (Leape et al 1995). Clinical decision-support systems may be a way of addressing this deficiency. Clinical decision-support means that relevant, objective, accurate and balanced, up-to-date information is provided to health care providers. It can include guidelines or protocols for administration of medicines (either as print or electronic versions). It can also include information services, such as drug information and advisory services or poisons information services.

Computer-based decision-support systems can be stand-alone, on-line reference systems that provide accessible drug information and guidelines (Weekley et al 2000). Other computer-based decision-support systems have the medicines or therapeutics information embedded in software for prescribing and dispensing. The advantage of these systems is that the information can be accessed when it is needed (for example, when the prescription is being written). These systems can also work as adverse drug alerts. For example, checking the prescription for interactions with other drugs already listed in the medical record, checking that the dose is in the recommended range, providing alerts against known allergies and providing alerts for recommended tests and their results. (Hunt et al 1998).

A review of the international literature found that the use of guidelines and protocols, usually together with other strategies, improves medication use (Grimshaw & Russell 1993). Computerised decision-support, combined with electronic prescribing systems, is an effective strategy for reducing medication errors, including errors which could cause patient harm (Shojania et al 2001). These clinical decision-support systems appear to prevent a range of different medication errors and have beneficial effects on patient outcomes.

A review of evidence for the use of computer models to help prescribers determine appropriate medication doses found 'some of the most compelling evidence' that these systems improve patient safety and reduce medication errors (Shojania et al 2001). The

international review only included studies that had demonstrated an effect on health outcomes or medication errors. There have only been a limited number of studies of this type undertaken around the world, mostly limited to single systems within one institution and not compared to commercially available systems.

Computerised decision-support systems in Australia are still being developed (see Chapter 5). However, there is strong evidence from the international literature that these systems improve patient safety.

Computerised adverse drug event alerts

Computer systems are increasingly used for maintaining medical records and for prescribing. Alert mechanisms have been developed to go into these computer systems, designed to automatically signal the presence or possibility of an adverse drug event for a particular patient. Most systems do this by scanning the patient's laboratory results, medication record and medical history. So, for example, if the scan finds a record of an abnormal laboratory value in a patient's medical file plus a record for a medicine that may cause the abnormal test results, an alert will be issued so that the health care provider can check whether the two are related (Shojania et al 2001).

Internationally, these systems have been shown to be beneficial overall. However, most of the systems tested were 'home-grown' applications, developed for use in a particular institution. There are no Australian studies looking at the effectiveness of computerised adverse drug event alert systems for reducing error or improving patient outcomes. However, Australian studies assessing the use of manual alert systems in the community setting for improving use of medicines (eg stickers placed on medical records or therapeutic 'flags' that highlight issues for particular medications) have shown a beneficial effect (Litt et al 1996; Bonner et al 2001).

Systems to promote accurate dispensing of medicines

Automated dispensing devices

Automated dispensing devices are computer-based devices that store and dispense medications and maintain records of medication use. There are a number of different devices available (Benrimoj et al 1995).

In the United States, automated dispensing devices are increasingly used in hospitals, to try to make the dispensing process more efficient as well as to reduce medication incidents. Automated dispensing systems may improve efficiency and provide cost savings to the health system, because pharmacists are released from dispensing and can concentrate on clinical issues. The review of the international literature, however, revealed that there is no clear evidence that current automated dispensing devices reduce medication errors or improve patient outcomes (Shojania et al 2001). Likewise, in Australia, there is no clear evidence to support their use for reducing medication incidents (Coombes et al 1999; Martin et al 2000).

Systems to promote accurate administration of medicines

Individual patient medication supply

Methods used for distributing medicines in hospitals can contribute to medication incidents (Leape et al 1995). As we saw in Chapter 2, error rates are higher where ward stock supply systems are used (Figure 3.1; See also Appendix I, Table 4).

Individual patient-based medicine distribution methods can include:

- supply of individual doses, separately packaged and labelled for the patient and kept in an individual patient store (unit dose system); or

- supply of individual medicines labelled for the patient (so more than one dose is supplied) and kept in an individual patient store (individual patient medication supply).

The advantage of this method is that all medicines are labelled, supplied and stored for individual patients. Other methods often involve the use of common stock of medicines supplied to the ward. The likelihood of error is greater, because staff must select the right dose of the appropriate medicine for the right patient at the time of administration, from the range of medicines provided for all patients.

An international review of the literature found that unit dose supply methods reduce errors occurring during administration of medicines. This review did not include any Australian studies. Australian studies that have directly compared different medicine distribution methods and errors associated with administration also suggest that individual patient medication supply reduces error rates associated with administration of medicines (See Figure 3.1; McNally et al 1997; Boyle et al 1998).

Systems to improve management of medicines

Information transfer between hospital and community settings

Accurate, well-timed transfer of information between hospital and community settings is important for ensuring appropriate medication use. This includes information about a patient's current medicines, any changes that were made in hospital and why, as well as allergies and relevant medical history. This information needs to be transferred between hospital and community pharmacies, as well as between hospitals and general medical practices.

An international review of studies aiming to improve the transfer of information between hospital and community pharmacies found that written care plans held by the patient and the transfer of patient information by facsimile between hospital and community pharmacists on hospital admission and at discharge were both useful for improving information transfer (Shojania et al 2001).

A number of strategies have been investigated in the Australian setting, including continuum of care guidelines, discharge liaison services by pharmacists and/or nurses, as well as hand-held medication records.

Discharge liaison services aim to improve medication management for people as they move from hospital back to the community. The service can include activities such as:

- providing discharge and medication summaries to the patient and their local doctors and pharmacists;
- developing and coordinating care plans to assist medication management;
- educating the patient about their medicines; and
- where necessary, home visits after discharge from hospital.

Controlled studies in Australia to assess the impact of discharge medication management services implemented by pharmacists or by pharmacists and nurses have shown this service improves patient outcomes (Collins & Stowasser 1998; Stowasser et al, in press; Stewart et al 1998a; Stewart et al 1998b) and reduces medication incidents (Spurling et al 2001).

A study in New South Wales involved GPs and hospital staff working together to identify barriers to communication about a patient's medications between hospitals and the community. Participants identified system changes required to overcome these barriers, and put in place action plans to implement these changes (Mant et al 2001a). This process improved the way that discharge information was provided to GPs (through the use of fax

machines), and that information about medicines was provided by GPs to hospital staff (for patients at risk of medication incidents).

Medication management services and case conferencing

Medication management services typically involve review of a person's prescribed, over-the-counter and complementary medicines. The review is undertaken to optimise the consumer's health and wellbeing, minimise medication-related problems and promote quality use of medicines. The service is provided to people who are considered at high risk of medication-related problems. The medication management service involves the consumer, along with their GP and pharmacist, and, where appropriate, medical specialists and nurses. The service enables the consumer and their health care team to identify, resolve and prevent medicine-related problems. Case conferencing is similar to medication management services, but often has a broader health care focus. Multidisciplinary case conferencing involves health care providers from different disciplines discussing and planning health care for individual patients.

Controlled studies assessing medication management services as part of a discharge liaison strategy have confirmed that this service is effective in improving patient outcomes (Collins & Stowasser 1998; Stewart et al 1998a ; Stewart et al 1998b) and reducing medication incidents (Spurling et al 2001). Implementation trials assessing medication management services in the wider community also show that these services contribute to improving medication use and reducing medication-related problems (Gilbert et al 2002, Bennett et al 2000, Roberts et al 2001). Controlled trials of multidisciplinary case conferencing in Australia have also been shown to improve medication use, although these latter trials did not assess medication incidents as an outcome (King and Roberts 2001; Gailer et al 2001; Crotty 2001).

Example 4.1

At the time of the case conference Rose had difficulty walking and had experienced a number of falls. She had pain in her hip and leg and was on many medicines, including medicines for Parkinson's disease. The many medicines meant there was potential for them to interact with each other. The medicines for her Parkinson's disease did not seem to be working properly.

At the case conference, it was decided two of her medicines were unnecessary and may have been contributing to her falls. These medicines were stopped. Her medicines for her Parkinson's disease were changed to ones that had worked over a longer time period, with a second faster acting medicine recommended, if needed. Regular paracetamol was recommended for the pain in her legs and hips. Source: Crotty (2001).

Medication management services and case conferencing to facilitate the flow of information between hospitals and community services are funded by the Commonwealth to support people considered to be at risk of medication problems including those who are chronically ill with complex care needs. The results of Australian trials suggest these services can improve patient outcomes.

Other systems to promote accuracy of the medication process

Bar coding

Sometimes errors occur because the wrong drug is provided to a patient or the right drug is given in the wrong way. Bar coding of medicines and a bar code on the identification bands worn by patients in hospitals are considered ways in which these errors may be prevented. The bar code would be scanned, in the same way that items are scanned at supermarket checkouts. Bar coding can be used to check that the right drug has been selected for the right patient when medicines are dispensed or administered (National Coordinating Council for Medication Error Reporting and Prevention 2001). The use of bar coding for medication

administration is still being developed and has not been well studied. Despite this, some observational studies overseas suggest that bar coding may reduce error rates. More studies of this technology are needed, particularly in the Australian setting.

Clinical pharmacy services

The work of clinical pharmacists in hospitals can support system processes known to reduce medication incidents:

- their educational activities assist in the dissemination of knowledge about medicines;
- their role in monitoring, medication review and drug use evaluation assists medication distribution and checking procedures; and
- activities such as providing medication records can also assist information transfer.

The international literature shows that the activities of clinical pharmacists reduce adverse drug events. Australian studies also support the role of clinical pharmacists in improving patient safety. The case study in the box below illustrate how clinical pharmacists can make a difference.

Example 4.2

A patient was known to be allergic to penicillin but was prescribed flucloxacillin (a type of penicillin antibiotic) for an infection. The clinical pharmacist detected that an incomplete clinical history had been taken about the patient's allergies, and negotiated for a different antibiotic to be prescribed.
Source: Alderman & Farmer (2001).

5 Implementing strategies to reduce medication incidents — a national approach

Available evidence points to a number of strategies to redesign medication systems that have been shown to reduce medication incidents (discussed in Chapter 4). In this section, we examine what we know about the current state of their implementation in Australia. We also look at some of the mechanisms already in place to facilitate and coordinate action in this area.

Systems do not get redesigned by themselves. A culture of safety does not develop by itself. If we are to reduce the risk to patients associated with medicines, action is required at all levels of the health care system. This includes national and state policy formulation, macro-management and performance monitoring, operations management and governance in health care services and changes in clinical service provision at an individual health care provider level.

Mechanisms to facilitate and coordinate action

There is much activity already underway in Australia to facilitate and coordinate action to improve all aspects of medicines including their use and safety. Table 5.1 describes some of the existing government-initiated bodies involved in medicines.

Table 5.1 Examples of mechanisms in Australia to facilitate and coordinate action

Body	Purpose
National	
Therapeutic Goods Administration (TGA)	TGA assesses all new prescription and over the counter medicines for their efficacy, quality and safety. Product labelling, packaging and appearance are also assessed. Only those products for which the benefit has been show to outweigh the risk are approved. Complementary medicines are also regulated and assessed for quality and safety. TGA also conducts post-marketing product surveillance.
Adverse Drug Reaction Advisory Committee of TGA (ADRAC)	Responsible for facilitating adverse drug reaction reporting.
Pharmaceutical Health and Rational Use of Medicines (PHARM) Committee	Expert committee which oversees the development, implementation and evaluation of the Quality Use of Medicines component of the National Medicines Policy.
Australian Pharmaceutical Advisory Council (APAC)	Representative body, which provides the primary forum for the engagement of all stakeholders in discussion, debate and resolution of issues arising from the National Medicines Policy.
National Prescribing Service (NPS)	Supports quality prescribing and the facilitation of quality use of medicines. National Prescribing Service facilitators are employed at the local level to assist general practitioners along with other local health care professionals in their efforts to improve use of medicines.
Medication Safety Taskforce of the Australian Council for Safety and Quality in Health Care	Leads national initiatives to measurably reduce patient harm from medication use.

Body	Purpose
State and Territory	
Pharmaceutical sections of State and Territory Health departments	The service and functions of these units varies significantly in the different states and territories. Drugs and Poisons legislation is a state /territory responsibility and all health departments have units managing this legislation. Additional quality use of medicines services vary depending on resourcing with the most developed being the Quality Use of Medicines area of the Queensland Improvement Enhancement Program in Queensland Health.
State and territory drug therapeutic committees or programs, such as • NSW Therapeutic Assessment Group • Victorian Drug Usage Advisory Committee • Queensland Hospitals Drug Advisory Committee • South Australian Drug Usage Advisory Group • Tasmanian Statewide Drug and Therapeutics Committee	Support and lead quality use of medicines in State/territory programs and networks. Clinical pharmacologists, pharmacists and clinicians who represent the hospital drug and therapeutic committees in their state/territory are members and leaders in these organisations.
Local	
Drug and Therapeutics Committees and Risk Management Committees (individual hospitals)	These committees are well established in Australian hospitals. A 1996 study reported 287 drug and therapeutics committees or their equivalents operating in Australia, out of 303 hospitals with pharmacy services. (Weekes & Brooks 1996).
Medication Advisory Committees (individual aged-care facilities)	In aged-care facilities it is recommended that Medication Advisory Committees be established to improve medication management (APAC 2000). These organisations could be supported to promote and facilitate the implementation of strategies to reduce medication incidents in this setting. Where area-wide medication advisory committees are operating, this role in supporting safer patient care could extend across the whole community.

Improving systems of care

This section briefly outlines the current status of initiatives in Australia to improve medication safety and possible future directions. Figure 5.1 (on page 52) gives a summary overview.

Simplifying medication processes

In Australia, there has been little systematic, nationally coordinated effort to apply the available evidence about improving systems of care to medication safety particularly within hospitals and across the continuum of care. An important initiative to build capacity for change at a local level is the use of the Institute for Health Improvement Breakthrough Collaborative Methodology to improve medication safety. This methodology achieves improvement in a short time by using existing knowledge about the nature and causes of adverse drug events and the mechanisms for addressing them. In the 1996 Institute for Health Improvement Collaborative on Reducing Adverse Drug Events in America, three-quarters of the 43 participating organisations made substantial progress in reducing adverse drug events

(and one-third exceeded their goal of achieving a 30 per cent reduction within 12 months (Leape et al 1998).

Adverse drug event alert systems

Many doctors in the community and all pharmacists in Australia use computer systems to assist them with prescribing or dispensing medicines. Many of these systems have in-built alerts, such as checking for drug interactions, but how these systems are used and how effective they are have not been well studied. Many of the barriers that limit the wider implementation of computerised clinical decision-support systems (see below) also apply to adverse drug event alert systems.

Individual patient supply systems

It is clear from the evidence that individual patient medication supply can significantly reduce the incidence of medication incidents. Individual patient supply systems are the recommended way to supply medicines in Australian hospitals (SHPA 1996). The extent of this practice in Australian hospitals is currently unknown, but anecdotal accounts suggest that it is patchy. Strategies to promote greater uptake should be a priority.

Bar coding

Bar coding has not been widely implemented in Australia. A major barrier to bar coding for medications has been the lack of a universally accepted system, as well as the need for consistent application of bar coding to all medication packaging (National Coordinating Council for Medication Error Reporting and Prevention 2001). Steps are being taken to help this to happen. In Australia, a collaborative group called the Medicines Coding Council of Australia is working to implement an Australian standard coding system for medicines. A national coding system is required to allow electronic transmission, storage and use of information about medicines.

As well as facilitating the use of bar coding technology, a standard Australian coding system for medicines will allow other technologies to be further developed, including electronic reporting of adverse drug reactions, and the development and maintenance of decision-support systems (MCCA 2002).

Labelling and packaging

Dispensing and administration errors sometimes occur because products have similar names or are in similar packaging and the health professional inadvertently selects the wrong product (‘look-alike’ and ‘sound-alike’ errors). The Pharmacy Board of Victoria has produced a list of medicines that are commonly associated with ‘look-alike’ or ‘sound-alike’ errors to raise awareness of this issue (see Part III of the technical appendix). Pharmacy computer systems also have inbuilt alert mechanisms for highlighting potential errors of this type. Also, guidelines for good dispensing practice have been developed in an effort to minimise dispensing errors (Pharmaceutical Society of Australia 2002).

Brand names of medicines are among the pieces of information approved at the time a product is registered in Australia. The Therapeutic Goods Administration can refuse registration if the presentation of the product is unacceptable, so there is potential to reject proposed brand names because of concerns that they are similar sounding or similar looking to names of products already on the market in Australia.

There are programs in use overseas which may be able to be adapted for use here. For example, in the United States, the Food and Drug Administration undertakes formal testing of brand names before products are registered. The program involves doctors, pharmacists and

nurses who work within the Food and Drug Administration reviewing and interpreting simulated outpatient and inpatient prescriptions with the proposed names (FDA 2001).

Clinical Pharmacy Services

Clinical pharmacy services have been shown to be effective in reducing medication error and system failures. These services are well established in Australia. A survey of the 309 Australian hospital pharmacy departments was undertaken in 1995. Of the 111 responses received, 87 per cent of the pharmacy departments were involved in activities to detect, correct and report medication errors. Almost 80 per cent of the departments had formal medication error reporting systems in place. Pharmacy departments also reported providing a number of other services that could assist in reducing adverse drug events. Ninety-six percent of departments provided medication chart review, 93 per cent kept records of clinical pharmacists' interventions, 88 per cent provided patient education and counselling and 86 per cent provided nurse education (Tenni & Hughes 1996).

While clinical pharmacy services are well established in Australia, there is currently a national shortage of both community and hospital pharmacists. There have been increased student intakes into pharmacy courses to address this issue. It is currently estimated that the hospital pharmacy workforce shortage may not be overcome until 2010 (Health Care Intelligence Pty Ltd 1999 cited in AIHW 2000).

Discharge Liaison Services

Discharge liaison services are an effective mechanism for improving transfer of information and reducing medication-related problems when patients move from hospitals back to the community. Guidelines for medication management across the continuum of care have been developed by the Australian Pharmaceutical Advisory Council (APAC 1998). However, it appears that this service is still under-developed in Australia. The 1995 survey of pharmacy departments found that only 18 per cent of the 111 pharmacy departments responding were able to offer a discharge liaison service (Tenni & Hughes 1996).

Individual medication records

The effectiveness of decision-support and alert systems also depends on access to a patient's complete and current medication record. As noted in the earlier chapters, studies have shown that at times, medication records are incomplete. Many people in Australia use multiple providers which can also lead to fragmentation of the medication record. The Better Medication Management System is being developed to overcome this.

The Better Medication Management System has been funded by the Federal Government and aims to create a centralised database containing an individual's medication record. Participation in the initiative will be voluntary for individuals, their doctors and pharmacists. The advantage of this system is that even if consumers see different doctors or pharmacists, their medications, including prescription, over the counter and complementary medicines, can still be added to one centralised record This has the potential for providing a complete medication record. The Better Medication Management System is currently under development. The complete system would roll out nationally from 2004, after successful completion of the Field Test, which is expected to commence towards the end of 2002.

Medication management services and case conferencing

Collaborative medication management services have been shown to be effective in improving use of medicines and reducing medication problems. This is a relatively new practice and delivery of the service requires awareness of the service among consumers, general practitioners and pharmacists and appropriate training, including accreditation of pharmacists.

Funding for the service in Australia has been available for residents in aged-care facilities since 1998, with funding for people living in the community commencing in 2002.

In 2000, 1,926 (63 per cent) of residential aged-care facilities in Australia had active medication review services and over 97,000 residents received a review of their medications. Guidelines have been developed by the Australian Pharmaceutical Advisory Council to assist medication management in aged-care facilities (APAC 2000). An important recommendation of these guidelines is to establish medication advisory committees to facilitate and coordinate initiatives to improve medication management.

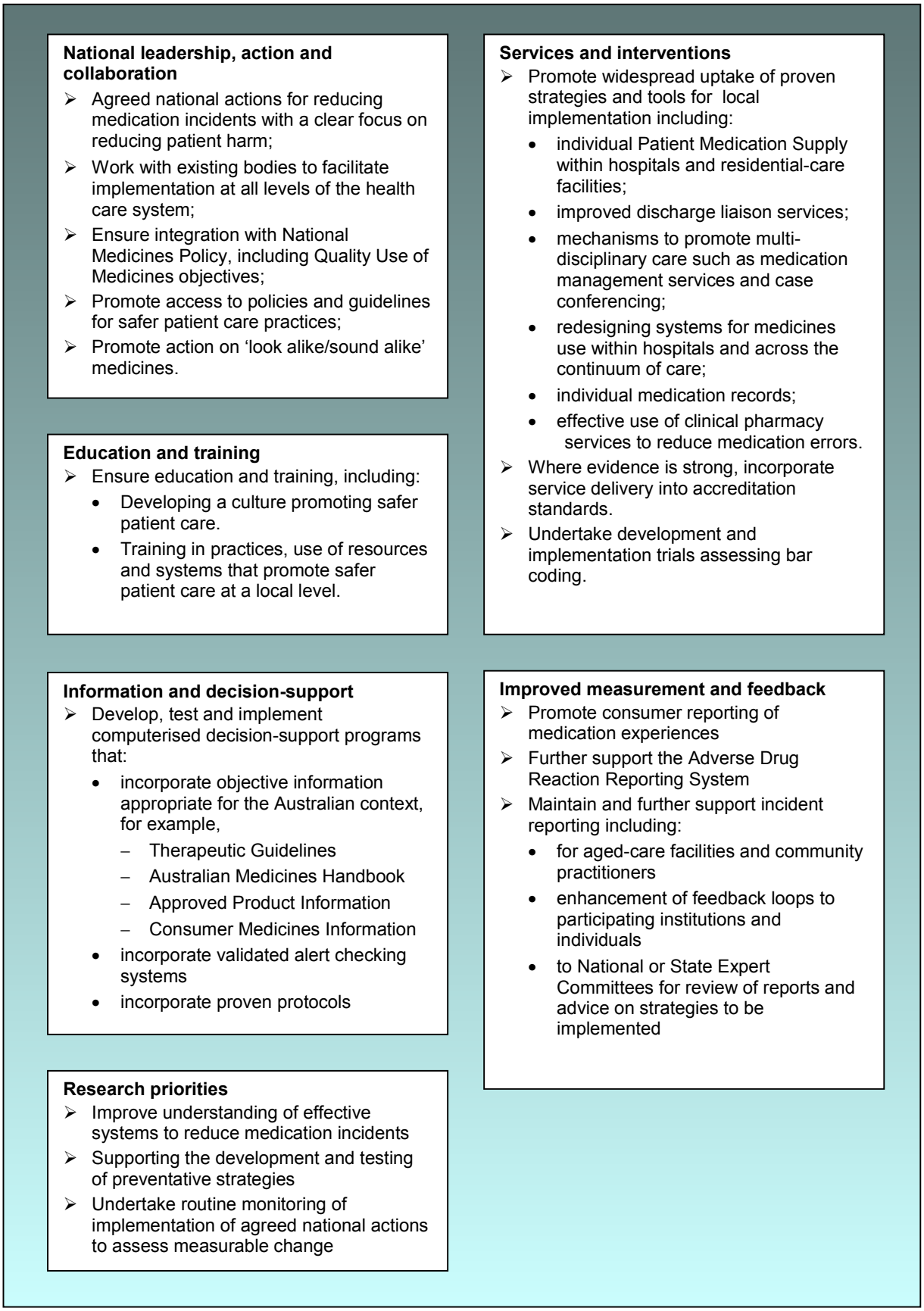


Figure 5.1 Overview of elements of national approach to reducing medication incidents

What are our resources for change?

Resources cannot be used effectively unless people know they exist, where to get them and how to use them easily. We need to improve the promotion and use of existing proven resources, guidelines and policies so that people do not need to 'reinvent the wheel'. Professional groups and health care services have already developed policies and guidelines that promote safer patient care and aim to reduce medication incidents. For example, guidelines for drug distribution in hospitals have been produced by The Society of Hospital Pharmacists of Australia Committee of Specialty Practice in Drug Distribution (SHPA 1996). Criteria for safe storage of medicines on wards are currently being tested (personal communication P Thornton May 2002).

Decision-support and objective information

In Australia, there are several sources of objective information about appropriate use of medicines. These include Therapeutic Guidelines, Australian Medicines Handbook, Approved Product Information and Consumer Medicines Information. These are supported by publications such as Australian Prescriber, the Australian Adverse Drug Reactions Bulletin and the National Prescribing Service News. Protocols supporting the appropriate use of 'problem' medicines (such as anticoagulants) have also been developed. All of these are available in print versions and many are also available in electronic versions.

The challenge now is to make this information easier to access and use, by incorporating information into computerised prescribing and decision-support systems. In Australia, computerised systems with objective decision-support that can be used at the time of prescribing are still in the developmental phase.

Most GPs and all pharmacists in Australia use computer systems for prescribing or dispensing purposes, which provides an enormous opportunity for implementation. However, while projects are underway in Australia to further develop computerised decision-support systems, there are also barriers to widespread implementation. For example, the software for prescribing and dispensing is produced by different agencies, using different coding systems, computer language and messaging systems, as well as different databases for medicines information.

The use of different sources of medicines information means that different systems may provide different alerts or different advice. A system is required that ensures consistent standards for developing computerised decision-support, including the incorporation of high quality medicines information. There has been a recommendation that "a single national entity be established to determine national governance arrangements for electronic decision-support systems in health care settings" from the major stakeholders in this area (NICS 2002).

The first step in this process is being taken forward by the National Institute of Clinical Studies and the National Health Information Management Advisory Council. A taskforce has been established to develop governance arrangements to ensure systems will be developed to consistent standards. This will address some of the barriers to implementation.

Education, training and organisational support

Education and training in safety issues and systems is important for making and sustaining change. When new systems are introduced, education and training must be part of their implementation. The use of clinical decision-support, individual patient supply and alert systems, bar coding, electronic medication records and other services will not be successful without adequate training and support. Appropriate education and training systems will be an integral part of developing a culture of safety in health care.

How can we improve measurement and feedback?

Effective measurement is an essential part of improving medication safety. There are mechanisms to collect data on adverse drug reactions and medication incidents in Australia. However, there are continuing challenges in promoting improved reporting of incidents, making sure that feedback is available across the health care system (particularly about identified risks and hazards) and more broadly, measuring how well we are doing in improving patient care.

Adverse drug reactions

Information about adverse drug reactions mainly comes from the national adverse drug reaction monitoring system operated by the Australian Drug Reactions Advisory Committee (ADRAC). The system holds information on all suspected adverse drug reactions that have been reported in Australia since November 1972 (over 160,000 adverse drug reaction reports) and receives about 1,000 reports per month. Issues of concern are routinely reported in the Australian Adverse Drug Reactions Bulletin, which is published four times a year.

While reports to ADRAC are voluntary, participation by general practitioners and hospitals (usually from hospital pharmacists) is good, with Australia having one of the highest reporting rates in the world. As a result, ADRAC has generated new knowledge about a number of adverse drug reactions. For example, liver reactions associated with some antibiotics were first identified worldwide by Australian reports. It is estimated that 50 per cent of marketed medicines have serious adverse drug reactions first detected after marketing (Moore et al 1998).

Continued and increased participation in ADRAC needs to be encouraged.

Incident reporting

The Safety and Quality Council is developing a national Incident Reporting and Management Specification to support the identification and reporting, analysis and dissemination of information. The aim is to find better ways to manage hazards and risks and improve systems of care. Incident reporting and management systems can collect information about medication incidents and their outcomes. Most are anonymous and/or confidential and voluntary. The systematic anonymous reporting of medication incidents can be used as a warning device, flagging problems that have an impact on quality of care. The development and implementation of interventions based on the information from the process can link incident reporting and management to broader safety and quality of care improvement.

An example of an incident reporting system is the Australian Incident Monitoring System (AIMS) which collects information on all health care incidents including medication incidents. The analysis of incident reports, however, is not routinely released publicly. The major strength of incident reporting is that it collects qualitative information about why medication incidents occur. The voluntary nature of incident reporting can result in under-reporting of incidents. Although the information collected is useful for safety improvement, it has limited value for determining actual rates of adverse events.

Greater feedback on the factors leading to medication incidents is needed. A regular bulletin, similar to the Australian Adverse Drug Reactions Bulletin or the Institute of Safe Medication Practices Alert (ISMP 2002) would be useful. Expert review committees with responsibility for reviewing incident reports may also assist the process. Incident reporting systems need to also encompass aged-care facilities, private hospitals and private practitioners, including general practitioners, pharmacists and nurses, because little is known about the types of problems occurring within these settings. Participation in incident reporting systems and the use of analysis for system improvement should be encouraged.

Consumer partnership

Consumer input and feedback is central to attaining safe use of medicines. An active and respectful partnership between consumers and health care professionals is an essential element of safe care. Tips for improving consumer involvement can be found in the Appendices.

Consumers have consistently called for a consumer adverse event reporting system to be established. While consumers can report directly to the Australian Adverse Drug Reaction Reporting System and the Australian Incident Monitoring System, they are not set up for this purpose. Currently, consumers are encouraged to lodge reports through their health professionals. Consumers do not always feel confident that their reports to health professionals are adequately acknowledged, recorded or passed on.

Direct consumer reporting has been shown to add to our knowledge about the safe use of medicines and the extent of medication problems. A medicine information telephone line which has incorporated consumer reports of adverse events is demonstrating the value of this source of information (McGuire & Moses 2002; McGuire et al 2001).

What are some research priorities?

Strategic research into systems for reducing medication incidents is also important. The literature review undertaken for this report highlights the lack of published Australian research in this area. There is no system to reliably identify the number of medication incidents that occur. While there are some data in Australia that provide estimates about medication incidents, these are mostly in the hospital setting, with little work being undertaken in community settings. Also, Australian research into the cause of adverse drug events, particularly from a systems perspective is limited. So are rigorous trials to assess the effectiveness of interventions with the Australian health care system. We need to address these research gaps.

6 Conclusion

This report has examined what we currently know about medication incidents, the strategies that could be used to reduce medication incidents that can be prevented, and how those strategies are being used in Australia at the moment. Collectively, the studies tell us that medication incidents are common, cause significant illness and injury, and are costly in both human and economic terms. There is much to be done to improve this situation.

Medication safety is an area where there is a good basis for action. Not only has considerable data been collected about the size and extent of the problem, but studies in Australia and overseas have produced sound evidence about effective strategies to reduce medication incidents. To date, there has been little systematic, nationally coordinated work to apply the evidence to improve medication safety. The challenge now is to build on research and turn evidence into practice, coordinating and developing national programs to implement safer medication practices and reduce preventable patient harm in Australian health care services.

The different types of medication incidents show that this is a complex area and no single factor is responsible. In Australia and around the world, a systems approach is being developed to improve use of medicines and reduce medication incidents. Successful implementation of change requires a number of building blocks such as:

- strong leadership from governments, health care managers and professionals and all players to make improving patient safety a priority;
- practical tools and approaches which help to build safer processes and work practices to reduce medication incidents and support safer patient care, such as simplifying processes to reduce the risk of error;
- education and organisational support for safe systems of work; and
- partnerships between consumers and health professionals — improvements will be made through consumers knowing more about their medicines and how to use them safely.
- supporting strategic research which addresses gaps in current knowledge and practice and helps to identify new issues; and
- integrating activities with the National Medicines Policy and the National Strategy for Quality Use of Medicines.

Technical appendix

I Medication incidents

Table 1 Medication-related hospital admissions or re-admissions — Australia 1988–2001

	Total admissions reviewed	Total medication-related	Type of medication-related admission			
			Adverse drug reaction	Non-compliance	Over-dose	Other
All hospital admissions assessed						
Gleeson (1988)	947	34 (3.6%)	34 (3.6%)	N/A	N/A	N/A
Larmour et al (1991)	5,623	136 (2.4%)	90 (1.6%)	5 (0.09%)	40 (0.7%)	1 (0.02%)
Admissions via Emergency Department assessed						
Galbraith (1993)	751	48 (6.4%)	Unknown	Unknown	7 (0.9%)	Unknown
Dartnell et al (1996)	965	68 (7%)	26 (2.7%)	15 (1.6%)	13 (1.3%)	14 (1.5%)
Admissions to Medical Wards assessed						
Sarkawi & Daud (1995)	419	49 (11.7%)	21 (5%)	12 (2.9%)	14 (3.3%)	2 (0.5%)
Stanton et al (1994)	691	81 (11.7%)	21* (3%)	10* (1.4%)	26* (3.8%)	11* (1.6%)
Leishman & Vial (1998)[#]	217	33 (15.2%)	10 (4.6%)	8 (3.7%)	11 (5.1%)	4 (1.8%)
Unplanned re-admissions assessed						
Blackbourn (1991)	180	29 (16%)	12 (6.7%)	14 (7.8%)	1 (0.6%)	2 (1.1%)
Hewitt (1995)	131	46 (35%)	29 (22%)	1 (0.8%)	0	16 (12.2%)
Greenshields et al (1997)	63	17 (27%)	unknown	unknown	Unknown	unknown
Stowasser et al (2000)[**]	28	9 (32.1%)	unknown	unknown	Unknown	unknown
Paediatric admissions assessed — medical only excluding oncology						
Easton (1996)	1,682	58 (3.4%)	10 (0.6%)	29 (1.7%)	10 (0.6%)	9 (0.5%)
Easton-Carter (2001)	2,949	127 (4.3%)	29 (1.0%)	38 (1.3%)		

continued

	Total admissions reviewed	Total medication-related	Type of medication-related admission			
			Adverse drug reaction	Non-compliance	Over-dose	Other
Geriatric admissions via emergency departments assessed						
Ng (1996)	172	31 (18%)	18 (10.5%)	5 (2.9%)	1 (0.6%)	7 (4.1%)
Atkin et al (1994)	217	48 (22.1%)	41 (18.9%)	5 (2.3%)	1 (0.5%)	1 (0.5%)
Wong et al (1993)	245	49 (20%)	35 (14.3%)	13 (5.3%)	1 (0.4%)	N/A
Wong et al (1993)	541	81 (15%)	61 (11.3%)	19 (3.5%)	1 (0.2%)	N/A
Harding (1998)	16	6 (37.5%)	4 (25.0%)	1 (6.25%)	0	1 (6.25%)
Chan et al (2001)##	240	73 (30.4%)	32 (13.3%)	9 (3.8%)	1 (0.42%)	31 (12.9%)
Cardiac patients admitted to the coronary care unit or medical wards						
Lee & Oldenburg (1993)	112	37 (33%)	14 (12.5%)	11 (9.8%)	0	12 (10.7%)

N/A = Not assessed

* Only definite or probable medication-related admissions reported (all other results report definite, probable or possible medication- related admissions).

\# Medical and respiratory wards and endocrinology unit.

** Assessed by medical file review and examination of medication changes.

Patients aged >75 years.

Table 2 Adverse drug reactions associated with hospitalisations as identified by Y codes 40 to 59 — Australia 1999–2000

Y Code	ICD-10-AM definition	Number of adverse drug reaction reports	Per cent	Rate per 100,000 population	
				Male	Female
Y40	Antibiotics	7,643	11.0	45.18	34.57
Y41	Other anti-infectives	1,200	1.7	7.37	5.15
Y42	Hormones and synthetic substitutes	6,477	9.3	40.48	27.08
Y43	Primarily systemic agents (predominantly anti-neoplastics)	9,372	13.4	53.95	43.85
Y44	Agents primarily affecting blood constituents	6,756	9.7	35.78	34.75
Y45	Analgesics, antipyretics, and anti-inflammatory drugs	10,284	14.7	60.78	46.52
Y46	Antiepileptics and antiparkinsonism drugs	2,257	3.2	12.09	11.47
Y47	Sedatives, hypnotics and antianxiety drugs	958	1.4	5.11	4.89
Y48	Anaesthetics and therapeutic gases	1,351	1.9	8.07	6.03
Y49	Psychotropic drugs	4,525	6.5	28.82	18.38
Y50	CNS stimulants	88	0.1	0.45	0.47
Y51	Autonomic nervous system drugs	1,951	2.8	10.61	9.75
Y52	Cardiovascular system drugs	7,938	11.4	48.68	34.13
Y53	Gastrointestinal system drugs	667	1.0	4.17	2.79
Y54	Water, mineral, and uric acid metabolism drugs	2,962	4.2	18.84	12.06
Y55	Agents affecting smooth and skeletal muscles and respiratory system	657	0.9	4.69	2.16
Y56	Skin and mucous membrane, ophthalmological, otorhino-laryngological, and dental drugs	1,131	1.6	6.93	4.86
Y57	Other and unspecified drugs	3,159	4.5	18.14	14.83
Y58	Bacterial vaccines	135	0.2	0.65	0.75
Y59	Other vaccines & biological substances	255	0.4	1.38	1.28
	Total	**69,766**	**100.0**	**412.19**	**315.75**

Source: Table compiled from data from the AIHW and the ABS.

Table 3 Adverse drug reactions associated with hospitalisations as identified by the third digit Y codes — Australia, 1999–2000

Y code	International classification of diseases	Number of adverse drug reaction reports	Per cent of total reports
Y43.3	Antineoplastic antibiotics	7,444	10.7
Y44.2	Anticoagulants	5,080	7.3
Y45.0	Opioids and related analgesics	4,793	6.9
Y42.0	Glucocorticoids	3,564	5.1
Y52.0	Cardiac stimulant glycosides	2,523	3.6
Y40.0	Penicillins	2,479	3.6
Y45.3	Non-steroidal anti-inflammatory agents	2,298	3.3

Source: AIHW.

Table 4 Medication administration errors — Australian hospitals 1988–2001

	Total opportunities for error	Error rate (excluding minor timing errors)	Type of medication error				
			Timing error	Wrong dose	Omission	Wrong formul'n or route	Other
Ward stock -based systems							
Stewart et al (1991)	2,017	369 (18.3%)	75 (3.7%)	46 (2.3%)	82 (4.1%)	6 (0.3%)	160 (7.9%)
McNally et al (1997)	494	76 (15.4%)	22* (4.5%)	20 (4.0%)	13 (2.6%)	2 (0.4%)	19 (3.8%)
Combination systems							
Rippe and Hurley (1988)	312	52 (16.7%)	24 (7.7%)	6 (1.9%)	12 (3.8%)	3 (0.96%)	7 (2.2%)
Camac et al (1996)	370#	47 (12.7%)	25 (6.8%)	N/G	N/G	N/G	N/G
Individual patient supply							
de Clifford et al (1994)	164	10 (6.1%)	1 (0.6%)	2 (1.2%)	5 (3.0%)	0	2 (1.2%)
McNally et al (1997)	502	24 (4.8%)	12* (2.4%)	2 (0.4%)	7 (1.4%)	0	3 (0.6%)
Thornton & Koller (1994)	242	20 (8.3%)	2 (0.8%)	0	13 (5.4%)	0	5 (2.1%)

N/G = insufficient data given to calculate rate of individual error types.

* Major timing errors included, minor timing errors excluded — a deviation of two or more hours from the ordered time. All other studies define a 'timing error' as a deviation of one or more hours from the ordered time.

\# Total data using two different storage sites — ward bay medication drawer and patient's bedside locker.

Table 5 Types of errors: Prescription errors — Australian hospitals 1985–2001

Reference	Number of prescriptions or charts audited	Number of errors detected (rate)	Major findings
Inpatient and discharge prescriptions from medical and surgical wards assessed			
Coombes et al (2001)	2,978 prescriptions	71 errors with significant potential to cause an ADE (2.4%)	The most common error types found were wrong or ambiguous dose (1.0% of prescriptions), dose absent from prescription (0.6% of prescriptions), frequency absent from prescription (0.4% of prescriptions*)
Medication charts in a paediatric department assessed			
Dawson et al (1993)	212 medication charts#	52 major errors** (24.5% of med'n charts)	The most common error types were dose errors (12.3% of charts reviewed), error of administration frequency (5.7% of charts reviewed), error of administration route (5.2% of charts reviewed), error in drug name/formulation (1.4% of charts reviewed).
Dawson et al (1993)	325 medication charts#	35 major errors** (10.8% of med'n charts)	The most common error types were dose errors (4.9% of charts reviewed), error of administration route (2.5% of charts reviewed), error of administration frequency (1.8% of charts reviewed), error in drug name/formulation (1.5% of charts reviewed).
Errors in medical, surgical, children's wards and a critical care unit assessed			
Leversha (1991)	6,641 medication chart checks	241 (3.6% of chart checks)	The major types of prescribing errors detected were incorrect dose prescribed for patient's condition (1.2% of chart checks), no strength specified (1.0%), insufficient information (0.2%). It was also found that failure to record the patient's current (ongoing) medication on the chart occurred in 69 cases (1.0% of chart checks)
Prescriptions presenting to pharmacy department assessed			
Fry et al (1985)	10,562 prescriptions	574 (5.4%)	Included assessment of legal requirements, (eg patient name and address, doctor's signature) as well as clinical requirements (eg dose, frequency) The strength was missing or incorrect in 0.7%, the directions inappropriate or omitted in 0.4%, and the wrong drug in 0.06%.

ADE = adverse drug event

* Percentage of prescriptions for regular and 'as required" medications only.

** Major errors included errors in drug name, dose, formulation, route or frequency of administration.

Note: unit of analysis is medication chart, which may include one or more prescriptions.

II Evidence for the effectiveness of strategies for reducing medication incidents

USA Agency for Healthcare Research and Quality systematic review of practices to improve patient safety

The USA Agency for Healthcare Research and Quality (AHRQ) has recently completed an international systematic review of the evidence for processes and structures aimed at improving patient safety in the health care system (Shojania et al 2001). The strategies that were reviewed for reducing adverse drug events included computerised prescribing and clinical decision-support systems, clinical pharmacy services, adverse drug event alerts, protocols, unit-dose drug distribution systems, automated medication dispensing devices, and bar coding. The study also examined processes for improving information transfer, patient participation and educational techniques.

The AHRQ report, published in July 2001, was a rigorous review with strict inclusion and exclusion criteria. It included strategies that can be applied in the hospital setting or at the interface between hospital and the community. Only controlled observational or clinical trials, and systematic reviews or meta-analyses including controlled studies were included in the review. Further the studies were only included if they reported actual clinical outcomes including morbidity, mortality, adverse events or surrogate outcomes including errors or intermediate outcomes with a well-established connection to a clinical outcome of interest such as an adverse event. For practices other than diagnostic or therapeutic interventions, studies reporting other measurable variables connected to the targeted safety outcome were included.

The ARHQ review was used as the basis of evidence for the efficacy of various safety practices. It should be noted, however, that health systems differ around the world and the structure of the health system may influence whether a practice or strategy is effective. This appendix summarises the findings from the AHRQ review. Where possible, the evidence for the efficacy of these strategies in the Australian setting is also reported.

Systems to promote improved prescriber decision-making

Clinical decision-support systems

The AHRQ review included discussion of the evidence for clinical decision-support systems and electronic prescribing ('computerised physician order entry') in reducing medication errors and adverse drug events and improving patient safety (Shojania et al 2001). The reviewers concluded that there was evidence to suggest that electronic prescribing in combination with clinical decision-support systems is an effective strategy for reducing medication errors including errors with the potential to cause patient harm. The reviewers also concluded that the stand-alone clinical decision-support systems appear to prevent a range of different medication error types and have beneficial effects on actual patient outcomes.
A review of evidence for the use of computer models to determine appropriate medication doses found 'some of the most compelling evidence' that these systems improve patient safety and reduce medication errors. The reviewers commented that there is a need for more research comparing the various types of systems that are available including the commercially available systems.

Computerised decision-support systems in Australia are in the developmental phase and no controlled studies were located which have evaluated the use of clinical decision-support systems for improving patient safety or reducing medication errors or adverse drug events in the Australian setting.

Computer adverse drug event detection and alerts

The AHRQ review examined the international literature to evaluate the role of computerised adverse drug event detection and alert systems for improving patient safety (Shojania et al 2001). The reviewers identified five studies that met the criteria for the review. Four of these studies involved using a computer system to detect potential adverse drug events (such as abnormal laboratory results) and alert physicians or pharmacists if an event was detected. One study used a computer system that alerted the physician and also made recommendations about the action to take. The evidence showed these systems were effective in reducing time for changes to be made in response to abnormal laboratory values. One study showed a significant reduction in serious adverse drug events and allergic reactions when an alert system was used. Although the studies showed beneficial effects overall, the reviewers commented that the computer systems used in the studies were 'home-grown' applications devised for the particular institutions where they were used. Additionally they identified the need for more research measuring the benefits of these systems in terms of actual patient outcomes.

A review of the literature failed to identify any further studies evaluating the outcomes of using computerised adverse drug event detection and alert systems to reduce medication errors or improve patient safety in the Australian setting.

Systems to promote accurate dispensing of medicines

Automated dispensing devices

In the US, automated dispensing devices have been used increasingly in hospitals in an attempt to improve efficiency and cost savings in the dispensing process as well as to reduce medication error associated with dispensing and administration processes. For this reason, the evidence for error and adverse drug event reduction with automated dispensing devices was reviewed as part of the AHRQ report (Shojania et al 2001). In reviewing the evidence from the limited number of generally poor quality international studies available, the reviewers concluded that there was no evidence that automated dispensing devices reduce medication errors or improve patient outcomes. The reviewers suggested that there was a need for further studies to examine the effectiveness of newer, more advanced automated dispensing devices that can be integrated with additional information support systems that may improve patient safety.

A review of the literature located two studies that evaluated automated drug distribution in the Australian health care setting.

A study to evaluate an automated drug distribution device, the *Pyxis Medstation 2000 Rx,* was undertaken on four wards of a teaching hospital in Adelaide (Martin et al 2000). The only types of medication error that were investigated in this study were missed doses. The rates of missed doses before and after the implementation of the automated dispensing were compared by pharmacists reviewing patient medication charts. No significant reduction in missed doses was found with the automated dispensing system (missed doses accounted for 13 per cent of doses before and 12 per cent of doses after implementation).

Another study undertaken in a Brisbane hospital (Coombes et al 1999) was undertaken to assess the frequency and type of medication administration errors with two different medication distribution methods, a ward stock system and an automated system. Medication administration was observed for a period of seven days on two different wards of the hospital, each using one of the two different medication distribution methods. In the ward using the ward stock method, there was an error rate of 16 per cent (or 12 per cent excluding timing errors). In the ward using the automated method, there was an error rate of 12 per cent (or 9

per cent excluding timing errors). This study did not compare individual patient supply with the automated system. As it is known that more errors occur when the ward stock system is employed than when individual patient supply is used, the results of this study do not provide clear evidence of the efficacy of automated systems for reducing error.

Systems to promote accurate administration of medicines

Individual patient-based medication distribution

The AHRQ review found unit dose supply methods reduced errors occurring during medication administration. The reviewers commented, however, that there was a lack of studies evaluating the impact of unit dosing on actual adverse drug events. The review did not include any Australian studies. In Australia, there have been a number of studies assessing administration errors associated with different medication distribution methods (Figure 3.1, Appendix I Table 4).

Only two Australian studies were located that have directly compared different medication distribution methods and resultant errors associated with administration.

In a study undertaken in a Perth hospital, a pharmacist observed nurses administering medicines (McNally et al 1997). The study was undertaken in two separate wards and the medicines were supplied via two different systems, in what is called a cross-over design (ie the two different systems were used alternately in each ward). For one two-week period, medicines were supplied by a ward stock system. During another two-week period (and after staff had been trained in the different system) medicines were supplied as individual patient supply. Excluding minor errors of timing, the error rate was 15.4 per cent (76/494) when the ward stock system was used. When the individual patient supply system was used, the error rate was 4.8 per cent (24/502). This study did not assess harm associated with the errors.

A second study undertaken at four teaching hospitals in Sydney looked at the effectiveness of different distribution systems to reduce errors associated with missed doses (Boyle et al 1998). One of the hospitals employed individual patient supply, while the other three hospitals maintained ward stock. A pharmacist reviewed medication charts after administration to determine if any doses had been missed. The results did show a reduction in missed doses with the individual patient supply. In the three hospitals using the imprest system, 3,931 doses were reviewed of which 223 (5.7 per cent) were missed. In the hospital using the modified unit dose system, 3,287 doses were reviewed of which 136 (4.1 per cent) were missed. The study is not as well-designed as it uses pharmacists as direct observers of medicine administration, which limits conclusions that can be drawn from the results.

There is evidence for the effectiveness of individual patient supply in reducing medication errors. The findings from the two Australian studies that compared systems of medication supply, suggest this finding is also applicable to the Australian health care setting.

Systems to improve management of medicines

Medication Management Review Services

The only controlled Australian studies assessing medication management services have been undertaken as part of hospital-community discharge liaison studies (Collins & Stowasser 1998; Stewart et al 1998a ; Stewart et al 1998b; Spurling et al 2001: all described above) or within aged-care facilities (Quality of Medication Care Group 1998; Roberts et al 2001).

A study was conducted in nursing homes in south-east Queensland (Roberts et al 2001) to evaluate whether a 12-month pharmacy program involving medication review and staff education about medications could change medication use, mortality and hospitalisation rates, measures of disability and adverse events in nursing home residents. The pharmacy program

was introduced into 13 nursing homes. Other usual practices were continued in conjunction with the pharmacy intervention. There were 39 nursing homes that served as the control in which usual practice was continued. Analysis of the data for frequency of hospitalisation, annual mortality rate, number of residents for which adverse events was reported and changes in measures of disability for residents showed that there were no significant differences between the intervention and control groups. The clinical pharmacy intervention was, however, found to reduce overall medication use and improve the quality of medication use in the nursing homes. For example, a significant reduction in the use of benzodiazepine hypnotics, laxatives and non-steroidal anti-inflammatory drugs was associated with the intervention.

A controlled design to determine the efficacy of medication management services in the hostel setting involved 1982 residents from 38 hostels in south-east Queensland. The results revealed both decreases and increases in medication use which were dependent on the culture of the hostel. In those hostels where a decrease in medication use was seen, there was an average reduction of 13.8 per cent. No difference was seen between the intervention and control groups in terms of hospitalisations, overall mortality and disability. Significant improvements were seen in quality of life scores concerned with mobility, sociability and confusion in the intervention versus control groups. The intervention also reduced the number of mishaps reported by residents. There were 40 per cent of patients reporting mishaps in the control group compared with 30 per cent in the intervention group (Quality of Medication Care Group 1998).

The provision of medication management services in the community setting in Australia has been less well tested, with most studies using uncontrolled designs and others not employing independent panels for judging significance.

Medication management services were trialed in the practice setting within five community pharmacies in South Australia. Two hundred and five patients were enrolled. The service consisted of a comprehensive review undertaken by the pharmacist, usually within the pharmacy, with appropriate follow-up consultations where necessary. Case notes were kept for all service delivery. Upon completion of the project, independent researchers coded the case notes to identify medication-related problems, actions taken and outcomes. At baseline, 179 patients were considered to have at least one medication-related problem, with 526 medication-related problems identified in total. Over the 11 months of the study, 678 consultations were implemented. At follow-up, outcomes as recorded by the participating pharmacists were available for 432 problems. Overall, 75 per cent of problems were recorded as being well managed or resolved at follow-up; improving in 12 per cent and unchanged in the remaining 13 per cent (March et al 1999).

A trial to implement medication reviews by GPs, focused on patient's over 65 years and taking five or more medicines. Sixty-two GPs, from four divisions of General Practice, participated in the project. They in turn recruited 694 patients. Participating GPs were supported with continuing medical education, peer-review sessions, copies of the *Australian Medicines Handbook*, prescription pad inserts that contained quality use of medicines prescribing tips, and a GP resource kit, which included a medication checklist that outlined issues for consideration during the medication review. Patients were offered two medication reviews, six months apart, and 466 patients participated in both reviews. Changes in medication and quality of life measures, as measured by the SF-36, were monitored. Quality of life measures did not improve between baseline and follow-up, showing no-change or falling across that time frame. There were changes in medication use with the median number of medications for patients at the first review being nine and decreasing to eight by the second review. The dose of benzodiazepines was found to decrease across the two reviews, while use

of SSRI antidepressants increased. However, no assessment of appropriateness or clinical significance of these changes were made, nor was adverse events included as an outcome measure (Tipper et al 1999).

A collaborative model for medication management services was trialed in Sydney. Overall, 179 patients received a medication review service. The service included a medication review undertaken by the pharmacist, a subsequent meeting between the GP and pharmacist to discuss findings and recommendations. Follow-up was undertaken three months later. A clinical panel comprising of a clinical pharmacist, GP, clinical pharmacologist and physician reviewed the case notes from the service and independently rated the clinical significance of the findings, recommendations and changes implemented using established criteria. The agreement of significance among panel members was poor, however, all four panel members judged at least 20 per cent of changes to result in a significant positive effect, while three panel members judged at least 40 per cent of changes to be significant (Krass & Smith 2000).

A South Australian trial also tested a collaborative model for delivery of medication management services. Overall, 119 GPs and 64 pharmacists provided medication management services to 1,000 patients as part of this trial. The service included a medication review with the patient undertaken by the pharmacist usually at the patient's home, a subsequent meeting between the GP and pharmacist to discuss findings and recommendations, and a follow-up visit to the patient to implement the recommendations. Case notes were kept for all service delivery, which included an assessment written by the pharmacist based on their initial home-visit, a subsequent plan which had been negotiated with the doctor as well as outcomes found at follow-up. Independent researchers coded the case notes to determine the nature of medication-related problems, actions taken and outcomes. Results indicated 90 per cent of people who received the service had one or more medication-related problems, with 2,764 problems identified. Follow-up data were available for 978 problems, with 61 per cent reported as resolved or well-managed and a further 20 per cent considered to be improving.

While the studies assessing medication management services in the community are less rigorously designed than those that have been undertaken in aged-care facilities and as part of discharge liaison services, collectively, the studies across all settings provide evidence that medication management services do contribute to improvements in patient outcomes. While most of the studies did not use adverse drug events or medication errors as an outcome measure, the studies that employed medication-related problems as an outcome measure provide some evidence that the service is likely to be effective in reducing adverse drug events.

A comparative study of two collaborative models for the provision of domiciliary medication review was undertaken in New South Wales. In this study, GPs identified patients at risk of medication-related problems and referred them to their preferred pharmacy for a medication review, the majority of which took place in the person's own home. Subsequent meetings were held between the GPs and pharmacists to discuss the review's findings and recommendations. Follow-up and reassessment was undertaken by the GP at three months. The comparative model was similar with the addition of a clinical audit undertaken by the GP prior to the referral to the pharmacist. The evaluation findings state that patients reported improvements in their health and understanding of their medications, although the instruments used to assess this do not appear to have used explicit criteria. . Assessment of medication use revealed an overall mean reduction in medication costs of 9.1 per cent as a result of implementing the service, with both models contributing to a reduction in medication costs. Adverse drug events and medication-related problems were not outcome measures reported for this study (Bennett et al 2000).

Case conferencing

A controlled trial in Canberra was conducted to determine whether multidisciplinary case conference reviews would improve health outcomes for nursing home residents (King & Roberts 2001). The reviews involved GPs, a project officer, a clinical pharmacist, senior nursing staff other health professionals such as a physiotherapist and occasionally the resident or their representative. Part of the review process involved discussion of the resident's medications and medication-related problems. Recommendations were made (as a result of the review) for 69 of the 75 residents who received reviews. A total of 170 recommendations was made, the majority of which (93 per cent) related to medications taken by the residents. There were 92 recommendations implemented, of which 37 (40 per cent) were assessed as being beneficial to the resident (in terms of health status or quality of life), 50 (54 per cent) resulted in no change, 4 (4 per cent) were "detrimental" and 1 (1 per cent) for which the outcome was unknown. "Detrimental effects" included relapses due to dose reduction or stopping medication, resident displeasure with rotation of injection sites, and a reversible adverse drug reaction. One month after completion of review, a comparison of medication use and mortality for residents who had reviews with those that did not was undertaken. This showed non-significant reductions in mortality and medication usage in the group receiving reviews. This study did not report the criteria or method used for assessing beneficial or detrimental effects. Adverse drug events and medication errors were not an outcome measure.

Another study conducted in five intervention and five control facilities assessed the impact of multidisciplinary case conferencing on the appropriateness of medication management of 'high-care' residents (Gailer et al 2001). The GP, pharmacist and residential care staff participated in the case conferencing, as well as a geriatrician and a behavioural specialist from the Alzheimers Association. Subjects in the intervention group received two reviews. Assessment of the Medication Appropriateness Index at baseline and at three months, revealed a significant improvement in the Medication Appropriateness Index score for residents receiving reviews, suggesting significant improvements in medication use. Adverse drug events were not a specific outcome measure in this study (Crotty 2001).

Information transfer at the hospital-community interface

In the AHRQ review of the international literature, the reviewers examined the evidence for practices aimed at improving the transfer of information between hospital and community pharmacies (Shojania et al 2001). Although the reviewers identified reports of a number of different strategies aimed at improving this process, only two controlled trials were found in the international literature. Both were randomised studies.

One study examined the use of written pharmaceutical care plans given to patients on discharge from hospital. At a follow-up visit, those who received the care plan were found to be significantly more compliant with their medication. Unintentional changes to medications were found for 50 per cent (14) of the patients who received the card, and 68 per cent (17) of patients in the control group. This difference was not statistically significant (Shojania et al 2001).

A second study involved the transfer of patient information by facsimile between hospital and community pharmacists on hospital admission and at discharge. It was found that more pharmacy interventions, such as dose changes or allergy checks were conducted by both the hospital and community pharmacists for those patients whose information was transferred by facsimile, compared to a control group who received the usual care (Shojania et al 2001).

The AHRQ reviewers concluded that these studies provided some evidence for the usefulness of these strategies for improving information transfer. They commented, however, that there is a need for more controlled studies examining the influence of these strategies on adverse drug

events and actual patient outcomes. Additionally there is a need to evaluate direct electronic communication of pharmacy data in controlled studies (Shojania et al 2001).

Discharge Medication Management Services: Controlled studies undertaken in Australia to assess the impact of discharge medication management services implemented by pharmacists or by pharmacists and nurses have shown this service improves patient outcomes and reduces medication incidents.

Two controlled studies conducted in South Australia evaluated the impact of discharge liaison services on the outcomes for patients discharged from an acute care hospital (Stewart et al 1998a; Stewart et al 1998b). This intervention involved counselling before discharge from hospital, followed by a pharmacist and nurse visiting a patient's home a week after discharge to optimise the management of the patient's medication, identify any early deterioration in the patient's condition and facilitate medical follow-up if required. The outcomes measured included the frequency of unplanned re-admissions to hospital and death within six months of discharge from hospital. The intervention was associated with a reduced frequency of hospital re-admission and death for patients with congestive heart failure (Stewart et al 1998a) and patients discharged from medical and surgical wards (Stewart et al 1998b).

A randomised controlled study of a discharge medication liaison service for patients discharged from medical and orthopaedic wards was undertaken in two hospitals, one in Queensland and one in New South Wales (Collins & Stowasser, 1998; Stowasser et al, in press). On the patient's discharge from hospital the medication liaison officer provided information to the patient's primary health care providers (GP and community pharmacist). This included information about the patient's discharge medications, changes to medications during hospitalisation, medication issues requiring attention after discharge and information to facilitate continued supply of any medications that may be difficult to obtain in the community. Patients in the control group received the normal discharge processing. Patients were followed up by a mail survey and medical record review 30 days after discharge. Outcomes measured included re-admission to hospital within 30 days of discharge, mortality, and functional status. There was a 20 per cent reduction in the total number of re-admissions to hospital within 30 days of discharge from hospital for the intervention group over the control group, however, this did not reach statistical significance. Change in functional status was measured, using the SF-36 model, at admission to hospital and 30 days after discharge from hospital. There were significant improvements in scores for bodily pain and physical functioning in the control group, while there were significant improvements in bodily pain, physical functioning and mental health scores for the intervention group. In general, the pattern of improvement in functional status was more consistent for the intervention group. There were insufficient patient numbers to assess the impact of the liaison service on patient mortality.

A study undertaken in South Australia evaluated the effectiveness of a medication liaison service to reduce the risk of medication incidents for patients making the transition between the hospital and community setting (Spurling et al 2001). A community pharmacist provided medication services for a group of patients discharged from an acute care hospital that were at risk of medication incidents. A control group received the standard discharge service from the hospital, while the intervention group received discharge counselling, home visits within 48 hours of discharge and the discharge summaries were forwarded to the patient's GP and pharmacist. The number of medication-related problems six weeks after discharge from hospital was compared for the two groups of patients. The group receiving the medication liaison service had significantly fewer medication-related problems six weeks after discharge from hospital.

Information transfer between hospitals and GPs: Another Australian study to promote information transfer at the hospital community interface focused on the transfer of information between GPs and hospitals at both hospital admission and discharge. This study conducted by Mant et al (2001a) investigated the impact of a project to improve communication between GPs and hospital staff in an Area Health Service in New South Wales. Stage one of the project had indicated that compliance with the Australian Pharmaceutical Advisory Council *National Guidelines to Achieve the Continuum of Quality Use of Medicines Between Hospital and Community* was poor, and that a number of barriers to effective communication between hospitals and GPs existed (Mant et al 2001).

Subsequently, a series of workshops were conducted to bring stakeholders together. At these meetings changes to systems that could be made to overcome these communication barriers were identified and participants agreed to commence implementation of these. In stage two of the project, surveys were conducted to review the progress using a series of specific indicators. Following this survey, a forum was held to review the results and to reassess action plans. Three months after the forum another survey was conducted. In comparison with stage one of the project, it was found that there were substantial and maintained improvements in faxing of discharge summaries from hospitals to GPs and provision of medication information to hospitals by GPs for patients at risk. Initiatives including updating of the directory of GP contact details by hospitals and provision of GP business cards to patients (to facilitate contact with the GP if a patient required an unplanned hospital visit) had been implemented at some sites. Some problems, however, had changed little including a poor rate of hospital notification to GPs of a patient's admission to hospital. This study did not use adverse drug events or medication error as an outcome measure.

Medication record cards: A randomised controlled study undertaken in outpatient clinics of a Melbourne Hospital assessed the impact of using a medication card in conjunction with medication counselling for improving knowledge about medications and compliance with regular oral medications (Lourens 1991; Lourens & Woodward 1994). The medication card contained written information about each of the patient's medications including generic and brand names, how the medication should be taken (including any special directions), the reason for taking the medication and any warnings (including interactions and known side effects). The intervention group received a medication card in addition to counselling from a pharmacist, while the control group received counselling only. Compliance and knowledge of medications was assessed at a second appointment three to four weeks later. A total of 97 patients completed the study, 49 were in the control group and 48 in the intervention group. The average age of participants in both groups was 71 years. There was a significant improvement in medication knowledge in the group using the medication card. There was an improvement in medication compliance in the group using the card, however, this did not reach statistical significance (Lourens & Woodward 1994). This study did not use adverse drug events or medication errors as an outcome measure.

Systems to promote accuracy of the whole medication process

Bar coding

The AHRQ review of the international literature found limited studies addressing the use of bar coding to improve patient safety or reduce medication error (Shojania et al 2001). One observational study conducted in a US hospital used hand-held scanners (as part of a medication management system) to identify the patient, the unit-dose medication for the patient and the nurse administering the medication. The medication error rate in the hospital decreased from 0.17 per cent before the system was introduced to a sustainable rate of 0.05 per cent after the system was implemented. However, because the scanning system was easily

bypassed and was frequently not used by the nurses, it was not possible to get a true indication of the impact of this intervention. Another observational study conducted in a pharmacy at a university hospital in the US assessed the impact of implementing bar code technology for drug dispensing. The dispensing error rate was reduced from 0.4 per cent (1 error in 250 doses) to 0 per cent (no errors in approximately 20,000 doses) with the implementation of bar coding when using a standard system. The reviewers concluded that use of bar coding technology warrants further investigation.

Systems providing clinical pharmacy services

Clinical pharmacists participate in a number of medication processes including medication review, ordering, dispensing, monitoring and education. As part of the AHRQ report, the evidence from the international literature supporting the role of direct pharmacist participation in clinical care as a strategy to reduce medication errors and adverse drug events in hospitals and other settings was reviewed (Shojania et al 2001). The reviewers found one study that provided strong evidence for the benefit of clinical pharmacist involvement in reducing adverse drug events for patients in a US hospital intensive care unit. Another controlled study performed in a UK hospital provided support for the role of ward-based pharmacists in reducing the rate of clinically significant medication errors. In the review of the evidence for the role of clinical pharmacists in the outpatient setting, the reviewers concluded that the evidence was less substantial. The reviewers identified a need for more research examining the impact of clinical pharmacy on outcomes relating to patient safety such as medication errors and adverse drug events.

A review of the literature examining the role of clinical pharmacists in improving patient safety and reducing medication errors or adverse drug events in the Australian setting located only one controlled study. Controlled studies provide a better indication of the usefulness of an intervention or strategy because they compare outcomes for a group of patients receiving the intervention with the outcomes for a group of patients not receiving the intervention.

A randomised controlled study undertaken at a hospital in Hobart evaluated the impact of full clinical pharmacy service for patients undergoing surgery who were considered at risk (Taylor & Peterson 2001). The full pharmacy service included medication review; conducting a medication history on admission; identifying documenting and attempting to resolve medication-related problems; review and discharge medication counselling. The control group received usual hospital pharmacy services during hospital stay and on discharge. Analysis of the results showed more medication-related problems were identified and resolved in the intervention group. The amount of chronic medication therapy on discharge was significantly lower in the group receiving the clinical pharmacy service. There were no significant differences in rates of re-admission to hospital, length of hospital stay or requirement for admission to the intensive care unit. This study is ongoing.

Some studies have assessed the impact of clinical pharmacists' interventions in conjunction with interventions from other health care professionals. An uncontrolled, pre-test, post-test design study examined the impact of clinical pharmacist and clinical pharmacologist activities on the rate of prescription errors in the children's ward of a Sydney hospital. Medication charts were audited for one month to establish a baseline rate of prescription errors in the ward. This chart audit was followed by a 12-month intervention strategy involving in-service education on prescribing conducted by a clinical pharmacologist and regular medication chart reviews conducted by a clinical pharmacist who indicated errors in writing and discussed them with the prescribing doctor. An identical audit was then conducted the following year. During each audit the presence of major and minor prescription errors was determined. Major errors were errors in drug name, formulation, dose, route or frequency of administration.

In the baseline audit there were 52 major errors in the 212 charts audited (24.5 per cent). In the audit following the intervention strategy there were 35 major errors in the 325 charts audited (10.8 per cent). There was a statistically significant difference in the number of major errors between the two audits (Dawson et al 1993).

Less rigorous evidence for the effectiveness of clinical pharmacy interventions is provided by studies in which interventions undertaken by clinical pharmacists have been independently reviewed in order to assess their clinical significance. The evidence obtained from these types of studies is not as strong as that obtained from controlled studies as there is no comparison group, nor pre-test, post test design, however, studies of this type were the most commonly undertaken in the Australian setting. For this review, studies were included that had documented clinical pharmacist interventions, the interventions were reviewed by an independent panel or reviewer and the clinical significance of the intervention was rated using pre-defined criteria or their impact on patient outcomes or medication error rate was determined. Studies using self-assessment or those that only judged the type of intervention, not its potential clinical significance were excluded.

Nine Australian studies assessing the effectiveness of clinical pharmacist interventions for reducing adverse drug events meeting the inclusion criteria were located. A summary of these studies appears in Table 1. The most recent multi-centre study quantified the impact of clinical pharmacist interventions, including changes to drug therapy or patient management on outcomes for hospitalised patients including length of hospital stay and potential for re-admission to hospital (Dooley et al 2001). Clinical pharmacist interventions in eight major Australian public hospitals over an average of 21 days were reviewed by an independent multidisciplinary panel. There was a total of 1,399 interventions, during 24,866 patient separations from the hospitals in the study period. Of these, 96 interventions (7 per cent) were considered to have reduced the patient's length of stay in hospital and 156 interventions (11 per cent) were deemed to have reduced the potential for the patient to be re-admitted to hospital. The clinical significance of the intervention was deemed to be life saving in 15 (1.1 per cent) of interventions, major in 351 (25 per cent) of interventions, moderate in 535 (38 per cent) of interventions and minor in 425 (30 per cent) of interventions. Seventy-three (5.2 per cent) interventions were considered to be of no clinical significance.

Table 1 Studies of interventions by clinical pharmacists in Australia*

Reference	Number of patients or charts reviewed	Number of interventions	Major findings
Interventions in acute care public hospitals reviewed			
Dooley et al (2001)	24,866 patient separations during study	1,399 pharmacist-initiated changes to drug therapy or patient management	There were 96 (7per cent) interventions deemed to have reduced the length of hospital stay for a patient, and 156 (11 per cent) interventions which reduced the potential for the patient to be re-admitted to hospital.
Hall et al (2001)	Number not given — interventions collected for one week per month for 6 months	2,342 interventions analysed; 7.4 per cent administrative, 92.6 per cent clinical	A potential for sequelae if the intervention did not occur was described as either "severe" or "catastrophic" in significance in 28 cases and "possible" to "almost certain" to have occurred without the intervention.

continued

Reference	Number of patients or charts reviewed	Number of interventions	Major findings
Tenni (1996)	115,408 chart reviews	62,132 clinical pharmacist services	Interventions associated with review of biochemistry results were classified as clinically significant in 92 per cent of cases, therapeutic drug monitoring interventions were significant in 90 per cent of cases, and patient counselling interventions were clinically significant in 74 per cent of cases. 69 per cent of the significant interventions involved dose changes.
Simioni & Brien (1996)	80 patients involved in a baseline phase, 77 patients involved in a trial phase involving implementation of pharmaceutical care plans on a medical ward	253 interventions (99 in baseline phase, 154 in study phase)	During the baseline phase (current clinical pharmacy practice at the hospital) there were 69 interventions (70 per cent) that were accepted by medical staff and resulted in a positive patient outcome. In the trial phase (using pharmaceutical care plans) there were 113 interventions (73 per cent) accepted by medical staff which resulted in a positive patient outcome. There were 15 interventions (15 per cent) in the baseline phase and 20 interventions (13 per cent) in the trial phase that prevented drug toxicity or exacerbation of an existing medical problem. One intervention in the baseline phase was ranked as "potentially life-saving".
Spencer et al (1994)	Number not given — interventions over a 6-month period recorded	611 interventions analysed	372 interventions were classified as being of "appreciable" or "major" clinical significance according to a published rating system.
Interventions in a repatriation hospital reviewed			
Alderman & Farmer (2001)	Number not given — all interventions considered to be of potential major significance over a 30-day period	67 interventions considered to be of potential major clinical significance	A total of 39 interventions were considered to be of major clinical significance. Most common category of medication-related problem addressed by the interventions was an inappropriately high dose of medication, which occurred in 17 (44 per cent) of interventions
Interventions in metropolitan and country hospitals assessed			
WA Clinical Pharmacists Group (1991)	4,328 charts reviewed	334 interventions recorded	Interventions were classified as potentially life-saving in 17 cases (5 per cent of interventions), preventing major toxicity or organ damage in 44 cases (13 per cent of interventions), optimising drug therapy in 189 cases (57 per cent of interventions) and minor in 84 cases (25 per cent of interventions).
Interventions in an oncology hospital reviewed			
McLennan et al (1999) ; McLennan et al (1999a)	Number not given — interventions associated with inpatient care collected over a 2-month period	674 interventions documented (corresponding to 295 episodes of inpatient care)	Activities were classified according to *International Diseases Classification – 10 (Australian modification*) (ICD-10-AM) taxonomy. Outcomes could be assessed for 10 per cent of the interventions reported. In 90 per cent of the assessed interventions clinical benefit was documented.

* Studies included if interventions were independently reviewed and clinical significance, impact on patient outcomes or medication error rate was determined.

III List of similar medication names that contribute to medication error

Similar names contribute to problems with medicines when they are confused due to poor handwriting, or they look-alike or sound similar when verbal instructions are given. Listed below are some examples where this may occur.

The following information has been collated from reports and complaints received by the Pharmacy Board of Victoria, Pharmacy Board of Tasmania and the Pharmaceutical Council of Western Australia together with the RGH, Daw Park, South Australia, Pharmacy E-Bulletin.

An increase in errors due to the product next to the intended item being selected has been noted this year (eg Lanoxin instead of Lanoxin PG, Luvox instead of Lovan, Avapro instead of Avapro HCT, Prozac instead of Provera). The use of scanners to cross check the selected container against the computer entry can minimise selection errors. Use of a pharmacy dispensing checklist is strongly recommended.

Generic names are shown in *italics.*

Achromycin	Aureomycin
Aclin	Zactin
Aclin	Alprim
Adalat	Aldomet
Advantan	Ativan
Aldactone	Aldomet
Aldactone	Aldazine
Aldazine	Amizide
Aldazine	Aldactone
Aldomet	Adalat
Aldomet	Aldactone
Alphamox	Amfamox
Alprim	Aclin
Amantadine	*Cimetidine*
Amfamox	Alphamox
Amiloride	*Amlodipine*
Aminophylline	*Amitriptyline*
Amitriptyline	*Aminophylline*
Amlodipine	*Amiloride*
Amizide	Aldazine
Amorolfine	*Aminophylline*
Amoxycillin	*Ampicillin*
Anafranil	Largactil
Anaprox	Aprinox
Anaprox	Avapro
Apomine	Avomine
Aprinox	Anaprox
Aratac	Aropax
Aropax	Aratac
Aropax	Aurorix
Arthrexin	*Cephalexin*
Atarax	Ativan
Ativan	Atarax
Ativan	Advantan
Atromid	Clomid
Aurorix	Aropax
Avandia	Avanza
Avanza	Avandia
Avapro	Anaprox
Avapro	Avapro HCT
Beclomethasone	*Betamethasone*
Beconase	Becotide
Becotide	Beconase
Becotide	Berotec
Becotide	Betaloc
Berotec	Becotide

Betaloc	Becotide
Betamethasone	*Beclomethasone*
Budesonide	*Bumetanide*
Bumetanide	*Budesonide*
Caltrate	Carafate
Capoten	Gopten
Carafate	Caltrate
Carbamazepine	*Carbimazole*
Carbimazole	*Carbamazepine*
Carboplatin	*Cisplatin*
Cardizem	Cardiprin
Cardiprin	Cardizem
Ceflin	Keflin
Cephalexin	Arthrexin
Chlorpromazine	*Clomipramine*
Cipramil	Ciproxin
Ciproxin	Cipramil
Cisplatin	*Carboplatin*
Clomid	Atromid
Clomiphene	*Clomipramine*
Clomipramine	*Clomiphene*
Clomipramine	*Chlorpramazine*
Clomipramine	*Imipramine*
Cordarone	Cortisone
Cortisone	Cordarone
Daonil	Deseril
Deseril	Desferal
Deseril	Daonil
Desferal	Deseril
Didrocal	Didronel
Didronel	Didrocal
Differin	Difflam
Difflam	Differin
Dothiepin	*Doxepin*
Doxepin	*Dothiepin*
Endep	Endone
Endone	Endep
Enoxacin	*Enoxaparin*
Enoxaparin	*Enoxacin*
Ergotamine	*Ergometrine*
Feldene	Teldane
Fluoxetine	*Paroxetine*
Glicazide	*Glipizide*
Glipizide	*Glicazide*
Gopten	Capoten
Hydralazine	*Hydroxyzine*
Hydrea	Hydrene
Hydrene	Hydrea
Hydroxyzine	*Hydralazine*
Imdur	Imuran
Imipramine	*Clomipramine*
Imipramine	*Trimipramine*
Imuran	Imdur
Keflin	Ceflin
Ketoprofen	*Ketotifen*
Ketotifen	*Ketoprofen*
Lamictal	Lamisil
Lamictal	Lomotil
Lamisil	Lamictal
Lanoxin	Lanoxin PG
Lansoprazole	*Omeprazole*
Largactil	Anafranil
Lasix	Losec
Lasix	Lescol
Lescol	Lasix
Lomotil	Lamictal
Losec	Lasix
Losec	Prozac
Lovan	Luvox
Luvox	Lovan

Maxolon	Moxacin
Midoride	Modizide
Modizide	Midoride
Moxacin	Maxolon
Neurontin	Noroxin
Noroxin	Neurontin
Olanzapine	*Omeprazole*
Omeprazole	*Olanzapine*
Omeprazole	*Lansoprazole*
Optimol	Optrol
Optrol	Optimol
Panafcort	Panafcortelone
Pethidine	Prothiaden
Pramin	Premarin
Prednisolone	*Prednisone*
Prednisolone	Risperidone
Prednisone	*Prednisolone*
Premarin	Pramin
Progout	Prograf
Prograf	Progout
Prothiaden	*Pethidine*
Prozac	Losec
Quinidine	*Quinine*
Quinine	*Quinidine*
Risperidone	Prednisolone
Rosig	Zomig
Sandimmum	Sandomigran
Sandomigran	Sandimmum
Tamoxifen	*Tenoxicam*
Teldane	Feldene
Tenoxicam	*Tamoxifen*
Terbinafine	*Terfenadine*
Terfenadine	*Terbinafine*
Thioriazine	*Thyroxine*
Thyroxine	*Thioridazine*
Tramal	Trandate
Trandate	Tramal
Trimeprazine	*Trimipramine*
Trimipramine	*Trimeprazine*
Trimipramine	*Imipramine*
Xenical	Xeloda
Xeloda	Xenical
Zactin	Aclin
Zantac	Zyrtec
Zestril	Zyrtec
Zinnat	Zinvit
Zinvit	Zinnat
Zocor	Zoton
Zocor	Zoloft
Zoloft	Zocor
Zomig	Rosig
Zoton	Zocor
Zyrtec	Zestril
Zyrtec	Zantac

Abbreviations and acronyms

ABS	Australian Bureau of Statistics
ACSQHC	Australian Council for Safety in Health Care
ADE	adverse drug event
ADEC	Australian Drug Evaluation Committee
ADR	adverse drug reaction
ADRAC	Australian Drug Reaction Advisory Committee
AHRQ	Agency for Healthcare Research and Quality (US)
AIHW	Australian Institute of Health and Welfare
AIMS	Australian Incident Monitoring System
APAC	Australian Pharmaceutical Advisory Council
BEACH	Bettering the Evaluation and Care of Health
CIAP	Clinical Information Access Project
DDA	drug of addiction
DDD	defined daily dose
FDA	Food and Drug Administration (United States)
GP	general practitioner
HIC	Health Insurance Commission
ICD-10-AM	International Classification of Diseases-Version 10-Australian Modification
IHI	Institute of Healthcare Improvement
ISMP	Institute of Safe Medication Practices
MCCA	Medicines Coding Council of Australia
NICS	National Institute of Clinical Studies
NPS	National Prescribing Service
NSAID	non-steroidal anti-inflammatory drug
PBS	Pharmaceutical Benefits Scheme
PHARM	Pharmaceutical Health and Rational use of Medicines
SHPA	Society of Hospital Pharmacists of Australia
SSRI	Selective Serotonin Reuptake Inhibitor
TGA	Therapeutic Goods Administration

What can consumers and health professionals do?

What does all this mean for consumers? Consumers can help to prevent problems with medicines by being as involved as possible in their own health care. This is facilitated when health care professionals provide environments in which consumers and their carers can have access to information and ask questions, and can participate in decision-making. The tips below are adapted from the Council's booklet *Safer Health Care — What it Means for You,* with extra advice on medicines added where relevant.

Tips for consumers

1. **Be actively involved in your own health care.** Taking part in every decision that is made about your treatment is the single most important way to help prevent things from going wrong. Research shows that people who are more involved with their care tend to get better results. For example, if you are prescribed a medicine that you are not familiar with, ask about it. You need to know all about your medicines so that you can manage them properly.

2. **Speak up if you have any questions or concerns.** Choose a doctor who you feel comfortable talking to about your health and treatment. Remember that you have a right to ask questions and to expect answers that you can understand. The doctor or other health professional wants to answer your questions but can only answer them if you ask. Ask a family member, friend or interpreter to be there with you if this will help. If you want to, you can always ask for another professional opinion.

3. **Learn more about your condition or treatments by asking your doctor or nurse and by using other reliable sources of information.** Ask your doctor if your treatment is based on the best available evidence. It's also a good idea to find out why a test or treatment is needed and how it can help you. Most medicines in Australia have a Consumer Medicines Information leaflet that explains in plain English all about the medicine. Always ask for a Consumers Medicines Information leaflet.

4. **Keep a list of all the medicines you take.** This includes prescriptions and over-the-counter medicines, and complementary medicines such as vitamins and herbs. You can use the list to let your doctor and pharmacist know about everything you are taking, and about any drug allergies you may have. Take the list with you each time you see your doctor or pharmacist and ask them to change it as your medicines change. If you are going to hospital, take the list with you. When you are discharged from hospital, make sure you have a list of all the current medicines you are taking. Use it next time you see your doctor or pharmacist.

5. **Make sure you understand the medicines you are taking.** When you get your medicine, read the label, including the warnings. Make sure it is what your doctor ordered for you. If you have any questions about the directions on the label, ask the pharmacist. You should also ask the doctor or pharmacist about side effects, possible interactions with other medicines, and what foods or other things to avoid while taking the medicine. Ask the pharmacist for written information about the medicine, to help you recognise problem side effects if they occur.

6. **Before you leave hospital, ask your doctor or other health carer to explain the treatment plan you will use at home.** This includes learning about your medicines and finding out when you can get back to your normal activities and when you need to see a doctor for follow-up care. Research shows that when people are discharged from hospital, doctors think that they understand more than they really do about their continuing treatment and follow-up.

Tips for health care professionals

These tips are intended for health care professionals to help facilitate an environment in which patients can be as active as possible in ensuring safe use of their medicines.

1. **Actively involve consumers in their own health care.** It's one of the most important ways to help prevent things from going wrong. Health care professionals should provide an environment in which consumers and their carers can ask questions, have access to information and participate in decision-making.

2. **Set aside time to allow consumers to talk about any concerns that they have.** Let them know from the beginning that it is okay for them to ask questions and that you will do all that you can to give them the information that they need. Encourage the participation of family members and carers.

3. **Provide information for consumers in a language and format that is easy to understand.** Have access to printed information in plain English and facilitate the use of interpreter services and other services for people who do not have English as a first language**.**

4. **Take a complete medication history, including over-the-counter and complementary medicines.** Check for contraindications, allergic reactions and interactions between medications.

5. **Provide oral and written information about medications in plain language.** Explain side effects and tell the consumer what to do if side effects occur. Explain the need to take the full course of medications and help the consumer to work our ways to ensure that they can adhere to medication regimes. Offer Consumer Medicine Information leaflets for each medicine prescribed.

6. **Develop strategies to make sure that consumers get the results of their tests and investigations.** Take time to explain the meaning of the results and be prepared to repeat this information on several. Ask questions.

7. **Set out options for consumers.** Provide them with choices and encourage them to be involved in decision-making.

What can you do if you have concerns about your medicines or overall health care treatment?

If you have concerns about your health care treatment or suspect that you have experienced an adverse drug event, you may wish to follow-up using one or more of the following avenues.

- Talk to your doctor or other health professional about your concerns. Most health professionals will welcome the opportunity to discuss your health concerns.
- Ask for another professional opinion.
- Contact the relevant area of the hospital or health care setting with your concern. Most hospitals have a complaints officer to assist people with concerns about the health care treatment they have received. Dispensing errors can be notified to Pharmacy Boards.
- Contact the independent health care complaints body in your state or territory. Your health department can give you the contact details.

Glossary

The key terms used in this report are defined in the tables below. The Council recognises that finding solutions to minimise risk and hazards in systems requires clear and unambiguous communication between everyone who is working to achieve system improvement. At present a variety of terms is in common use. To address this issue the Council is undertaking comprehensive consultation to more precisely define the terms used to describe health care safety issues. Information about this consultation is available on the *Shared Meaning* website at www.safetyandquality.org/definition/smhome.htm

This section includes:

- Table I — key terms discussed in detail, with examples
- Table II — other terms used in the report

Definitions are those that are considered most appropriate and informative to the way in which they are used in the report.

Table I Key terms discussed in detail, with examples

Term and definition	Discussion	Examples
Incident *An event or circumstance which could have, or did lead to unintended and/or unnecessary harm to a person, and/or a complaint, loss or damage.*	Incident is the overarching term used to describe problems that cause actual harm and 'close calls' where harm was averted either by the defences build into the system or by chance. Close calls are often indistinguishable from adverse events in all but outcome. These are the 'free lessons' that allow the system to develop preventive strategies.	An example of an incident is a situation when the incorrect placement of a decimal point on a prescription results in a dose of **62.5mg** of *carvedilol* (a medicine sometimes used for the management of high blood pressure and heart failure) being prescribed instead of **6.25mg**. If the error is not detected, the incorrect dose may be dispensed and administered to the patient resulting in serious harm. This would be an *'adverse event'*. It would also be an *'adverse drug event'* because the harm is caused by an error associated with a medication. *If the error is detected and the prescription amended to reflect the correct dose, patient harm is averted. This is a* 'close call'.
Medication incident *An incident associated with medication*	Medication incidents include problems which could have or did cause patient harm, and where medication is likely to have been a contributing or causal factor. Medication incidents can happen at any point in the processes for prescribing, dispensing and administering a medication.	The example above is a medication incident because the incident is caused by an error associated with a medication. A patient in hospital might not receive a dose of medication because the nurse caring for the patient forgot to read the medication chart and as a result was not aware that the medication was due. This is also a medication incident.
Adverse event *An incident in which harm resulted to a person receiving health care*	It is important to note that adverse events may be associated with various aspects of health care, including medication, and can occur for a variety of reasons. Even when a person is taking medication the cause of the adverse event may not be associated with the medication.[1]	A fall is an example of an adverse event. Someone may fall over and be injured for a variety of reasons such as a slippery floor, poor eyesight or a cluttered area. If a person is taking medication, it is not always clear if the medication has been the cause of the fall.

[1] In regard to medications, the World Health Organisation defines an adverse event as "Any untoward medical occurrence that may present during treatment with a medicine but which does not necessarily have a causal relationship with this treatment."

Term and definition	Discussion	Examples
Adverse drug event *An adverse event due to a drug/medicine*	An adverse drug event is a particular type of adverse event where a drug/medication is implicated as a causal factor in the adverse event. Adverse drug event encompasses both harm that results from the intrinsic nature of the medicine (an adverse drug reaction) as well as harm that results from medication errors or system failures associated with the manufacture, distribution or use of medicines.	(See example under Adverse Event) Some medicines can make a person more vulnerable to falling over (eg medicines that make a person dizzy when they stand up suddenly). If the medication is a factor contributing to the fall, it can be described as an adverse drug event.
Adverse Drug Reaction *A response to a drug which is harmful and unintended, and which occurs at normal doses. Or* *A reaction which is harmful and unintended and which occurs as doses normally used in humans for the prophylaxis, diagnosis or treatment of disease or the modification of physiological function.*	An adverse drug reaction will be said to have occurred when the right drug was used for the correct indication in the right dose given by the right route, but the patient suffered unexpected and unpreventable harm as a result.	A group of antibiotic medicines called the fluoroquinolones were reported to be associated with 60 cases of tendon inflammation, rupture or tearing in Australia. This was an unexpected reaction to this medication which caused patient harm in a small number of patients. (ADRAC, 1999) Adverse reactions can also occur with herbal or complementary medicines. The complementary medicine echinacea is used for prevention and treatment of cold and flu symptoms. Between July 1996 and November 1998 there were 37 reports of suspected adverse reactions in association with echinacea. These were allergic-like effects included difficulty breathing, rash, chest pain and swelling. (ADRAC 1999a)
Side effect *Any unintended effect of a medicine occurring at doses normally used in people which is related to the pharmacological properties of the drug.*	All medicines have the potential for side effects that may cause patient harm. Side effects are generally known risks and not the result of an error or system failure. Information about side effects is included in consumer information provided with the medication.	An example of a side effect is sedation or drowsiness caused by the antihistamine medicine called promethazine. When this medicine is used to treat allergy it causes sedation as a predictable 'side effect' which is related to the way the medicine works in the body.
Harm *Death, disease, injury, suffering and/or disability experienced by a person.*	Harm should be determined from the perspective of the patient. It includes physical, psychological or emotional harm.	Harm includes pain, the need for further treatment or an extended time in hospital, disability ranging from minor disability that will resolve in a short time (eg headache) to serious, permanent disability (eg paralysis), or death.

Table II Other terms used in the report

Administration	The process of giving a medication to a patient or a patient taking a medication.
Adverse drug event	An adverse event due to a drug/medicine. (See Table I)
Adverse drug reaction	A response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. (See Table I)
Adverse event	An incident in which harm resulted to a person receiving health care. (See Table I)
Antibiotic	A drug that destroys bacteria.
Anticoagulant	A medication that keeps blood from clotting (also called blood thinner.).
Antihistamine	a group of drugs that block the effects of histamine, a chemical released in body fluids during an allergic reaction.
Automated dispensing devices	Automated dispensing devices are computer-based devices that store and dispense medications and maintain records of medication use.
Case conferencing	Case conferencing involves health care professionals working together to discuss and plan health care for individual patients.
Clinical decision-support systems	Clinical decision-support means the provision of relevant, objective, accurate and balanced, up-to-date information that is accessible to practitioners. It can include a variety of resources such as guidelines or protocols for medication administration (either as print or electronic copies). It can also include information services, such as drug information and advisory services or poisons information services.
Complementary Medicine	Vitamins, mineral, homoeopathic, aromatherapy and herbal preparations. These may be practitioner only or non-prescription medicines. In Australia, these products are regulated as therapeutic goods. (ASMI)
Diagnosis	Determination of the cause and severity of a disease.
Discharge Liaison Service	This intervention involves counselling before discharge from hospital, followed by a pharmacist and nurse visiting a patient's home a week after discharge from hospital to optimise the management of the patient's medication, identify any early deterioration in the patient's condition and facilitate medical follow-up if required.
Dispensing	To put up and distribute medicine, especially on prescription.
Dose	The precise measurement of medication which must be adhered to as prescribed by a doctor and dispensed by a pharmacist.
Error	An error can be defined as failure in the (drug) treatment process that leads to, or has the potential to lead to, harm to the patient and includes an act of omission or commission. Errors rarely occur as the result of the actions of a single individual. They are usually the result of a series of system failures. (See Table I)
Event	Something that happens to or with a person. (ACSQHC)
Generic name	The established name of the medication. The name of the product itself, not the brand name. (ISMP) (See Example 3.10 on page 37)

Harm	Death, disease, injury, suffering, and/or disability experienced by a person. (ACSQHC) (See Table I)
Incident	An event or circumstance which could have, or did lead to unintended and/or unnecessary harm to a person, and/or a complaint, loss or damage. (ACSQHC) (See Table I)
Incident monitoring	A method of collecting detailed qualitative data about any unintended incident, no matter how seemingly trivial or commonplace, which could have or did harm anyone, patient, staff or visitor. (PIR)
Medication error	(see Error)
Medication incident	An incident associated with medication. (See Table I)
Medication management review service	A service which includes a review of individual patient's medication undertaken by the pharmacist, and liaison between the pharmacist and the patient's medical practitioner.
Morbidity	(1) Description of the outcomes of disease. (2) The relative incidence of a particular disease in a specific locality.
National Hospital Morbidity Database	The National Hospital Morbidity Database contains patient morbidity data from records of hospital separations for episodes of admitted patient care. Data for almost all hospitals, both public and private, are included.
Over-the-counter medicines	Health care products that can be purchased without a prescription.
Close call	An incident that did not cause harm. 'Close calls' are incidents where harm was averted either by the defences built into the system or by chance. Close calls are often indistinguishable from adverse events in all but outcome.
Prescribing	To designate or order for use, as a remedy or treatment.
Prescription	A direction, usually written, by a doctor to a Pharmacist for the preparation and use of a medicine or remedy.
Side effect	Any unintended effect of a medicine occurring at doses normally used in people which is related to the pharmacological properties of the drug. (See Table I)
System failure	A system failure can be defined as a fault or breakdown in any part of a system, or a lack of support in a system, that increase the risk of something going wrong. Factors such as poor design, lack of communication, lack of standardised procedures and poor management decisions can all contribute to system failures.
Trade name	The proprietary name or trade name of the medication.
Unit dose supply	In unit-dose supply, medication is dispensed in a package that is labelled with the patient's name and ready to administer to the patient. In some organisations pharmacists and technicians place drugs in unit-dose carts. The carts have drawers in which each patient's medications are placed by pharmacy technicians — one drawer for each patient. The drawers are labelled with the patient's name, ward, room, and bed number. (AHRQ)
Y code	Y codes describe the external causes of morbidity or mortality in the International Classification of Disease — Version 10 (ICD-10). For example the class of medicine associated with an adverse reaction.

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Australian Council for Safety and Quality in Health Care

Australian Health Ministers established the Australian Council for Safety and Quality in Health Care in January 2000 to lead national efforts to promote systemic improvements in the safety and quality of health care in Australia.

Priority action areas for the Council are:

- supporting those who work in the health system to deliver safer patient care;
- improving data and information for safer health care;
- involving consumers in improving health care safety;
- redesigning systems of health care to facilitate a culture of safety; and
- building awareness and understanding of health care safety.

The Council has 24 members with a wide range of skills and experience who are all committed to making a difference to the safety and quality of health care. All Council members are appointed for the full term of the Council. The full Council meets up to five times a year and reports annually to Health Ministers at the Australian Health Ministers' Conference. It also reports regularly to the Health Ministers' Advisory Council.

A six-member Council Executive ensures timely and transparent decision-making on behalf of the Council. The Executive meets approximately every six weeks and reports to Council after each meeting. The Council also has a number of Working Groups to coordinate and develop work plans and projects in priority areas. The Council's Management Group, located within the Commonwealth Department of Health and Ageing, provides operational and policy support for the Council, the Council Executive and the Working Groups.

Members

Professor Bruce Barraclough (Chair)
Immediate past President,
Royal Australasian College of Surgeons
Professor and Director of Cancer Services for the Northern Sydney Area Health Service

Dr Michael Walsh (Deputy Chair)
Chief Executive Officer,
Bayside Health, Victoria

Professor Lesley Barclay
Director, Centre for Family Health and Midwifery, University of Technology, Sydney

Dr Shirley Bowen (resigned December 2001)

Dr Heather Buchan
Chief Executive Officer,
National Institute of Clinical Studies

Associate Professor Kaye Challinger
Chief Executive Officer,
Royal Adelaide Hospital

Ms Marie Colwell
Director, Asoka Systems Pty Ltd

Professor John Horvath AO
Area Director, State-wide Renal Services,
Royal Prince Alfred Hospital

Professor Clifford Hughes AO
Head, Cardio-Thoracic Surgical Unit,
Royal Prince Alfred Hospital, Camperdown

Ms Betty Johnson AO
National Secretary,
Older Women's Network Australia

Professor Brendon Kearney
Executive Director, Statewide Services,
South Australian Department of Human Services

Dr Len Notaras
Director, Clinical and Medical Services,
Royal Darwin Hospital

Ms Jane Phelan
Consumer, with an extensive background in journalism

Professor Paddy Phillips
Department of Medicine,
Flinders Medical Centre, Adelaide

Professor Bill Runciman
Head, Department of Anaesthesia and Intensive Care, Royal Adelaide Hospital

Professor Nick Saunders (resigned May 2002)

Professor Richard Smallwood AO
Chief Medical Office, Commonwealth Department of Health and Ageing

Professor Bryant Stokes AM
Department of Neurosurgery,
Saint John of God Hospital

Dr Heather Wellington
Coordinator Health Practice,
Corrs Chambers Westgarth, Lawyers

Dr Ross Wilson
Director, Quality Assurance,
Royal North Shore Hospital

Dr John Youngman
General Manager, Health Services,
Queensland Health

Co-opted Members:

Dr Jenny Bartlett
Director, Quality and Care Continuity Branch, Metropolitan Health and Aged Care Services, Victorian Department of Human Services

Dr David Brand
Consultant, Client Solutions

Dr Paul Dugdale
Chief Health Officer, ACT Department of Health and Community Services

Ms Pat J. Martin
Chief Executive Officer,
Royal Hobart Hospital

Dr Vin McLoughlin
Assistant Secretary, Priorities and Quality Branch, Commonwealth Department of Health and Ageing

Professor Chris Silagy AO (1960–2001)

Medication Safety Taskforce

One of the key working groups of Council is the Medication Safety Taskforce. The role of the Medication Safety Taskforce is to develop, implement and monitor national initiatives to achieve measurable improvements in medication safety. The Taskforce was established in late 2001 and meets three times a year, with small working parties meeting more frequently. Membership of the Taskforce includes a range of key national stakeholders and organisations, as follows.

Members (as at June 2002):

Council Members

Associate Professor Kaye Challinger

Ms Betty Johnson

Dr Len Notaras

Ms Jane Phelan

Professor Paddy Phillips

Professor Bill Runciman

Dr Ross Wilson

Co-opted Member

Dr David Brand (Co-Chair)

Invited Members

Professor Ric Day (Co-Chair), Professor of Clinical Pharmacology, University of New South Wales

Chair, Pharmaceutical Health and Rational use of Medicines (PHARM)

Ms Di Aldous, Director of Pharmacists, Royal Hobart Hospital

Ms Jenny Bergin, Pharmacy Guild of Australia

Dr Ian Boyd, Secretariat Adverse Drug Reactions Advisory Committee, Therapeutic Goods Administration

Ms Mary Emanual, Australian Self-Medication Industry

Ms Janne Graham, Deputy Chair, Australian Pharmaceutical Advisory Council

Professor Maree Johnson, Royal College of Nursing Australia

Ms Roberta Lauchlan, Private Health Industry Quality Working Group

Dr Amanda Ling, Private Health Industry Quality Working Group

Ms Nancy Pierce, Consumers' Health Forum

Dr Peter Roush, Australian Divisions on General Practice

Dr Sepehr Shakib, Consultant, Clinical Pharmacology, Royal Adelaide Hospital

Dr Danielle Stowasser, Program Area Manager, Quality Use of Medicines, Queensland

Ms Penny Thornton, Society of Hospital Pharmacists of Australia

Dr Lynn Weekes, Chief Executive Officer, National Prescribing Service

Mr Guy Wilmington, Australian Pharmaceutical Manufacturers Association