

Windows into Safety and Quality in Health Care 2009



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Foreword

The Australian Commission on Safety and Quality in Health Care reports annually on the state of healthcare safety and quality in Australia.

In 2007, the Commission and the Australian Institute of Health and Welfare jointly published a report on sentinel events in Australian public hospitals. In 2008, the Commission published *Windows into Safety and Quality in Health Care 2008*, a much broader review dealing with safety and quality issues in a number of areas, as well as sentinel event data from both public and private sector hospitals.

This year's *Windows into Safety and Quality in Health Care 2009* provides additional windows onto a range of safety and quality issues and continues to report on sentinel events. It offers safety and quality insights in a number of settings and from various perspectives.

Improving healthcare safety and quality is a vital activity because it has a real and powerful impact for patients. A number of chapters reflect on the role of measuring and reporting in improving healthcare safety and quality.

This report emphasises the three key elements of our proposed National Safety and Quality Framework that safe high quality care is always:

- patient focused
- driven by information, and
- organised for safety.

The National Safety and Quality Framework will inform and guide the Commission's work over the coming year.



Bill Beerworth Chairman
Australian Commission on Safety and Quality in Health Care

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Executive summary

The Australian Commission on Safety and Quality in Health Care (the Commission), in consultation with clinicians, consumers, public and private hospitals, and other healthcare provider organisations, has identified the priority national safety and quality areas for action in Australia. Throughout 2009, the Commission has continued a comprehensive work plan to address these priority areas. This report examines a number of the key issues.

Windows into Safety and Quality in Health Care 2009 is the second in a series of reports by the Commission. It includes a brief update on topics considered in the first report and expands to reflect the additional activity undertaken in other identified priority areas.

The *Windows into Safety and Quality in Health Care* series is intended to provide a focus for discussion and a flavour of the activity being undertaken by the Commission. Each edition does not attempt to cover every aspect of Commission activity. Future reports will address major evolving work such as healthcare accreditation reform, implementation of the clinical handover guide and the surgical safety checklist, aboriginal healthcare services, and medication safety.

1 Introduction

The establishment of a national framework for safe and high quality health care in Australia is a vital step forward. The proposed National Safety and Quality Framework (the Framework) offers a vision for safe and high quality health care for Australia and is predicated on the principle that safe high quality health care is always:

- patient focused
- driven by information, and
- organised for safety.

The Commission has undertaken a comprehensive public consultation, which has revealed a high level of support for the proposed Framework.

2 Retrospective

This chapter reflects on developments and progress in many of the topics featured in the *Windows into Safety and Quality in Health Care 2008* report. Promotion of patient rights through increasing use of the Australian Charter of Healthcare Rights has continued, as have advances in clinical safety in the areas of patient identification, medication safety and clinical handover.

There is ongoing work in system solutions such as effective open disclosure when things go wrong, agreement on surveillance and reporting of healthcare associated infections, and progress in the National Hand Hygiene Initiative. The detailed work surrounding the national reform process for accreditation of healthcare service organisations also continues.

3 Recognising and responding to clinical deterioration

A crucial question for patient safety is 'Will patients be safe if their clinical condition deteriorates in hospital?'

Over the last decade, there has been an increasing move nationally and internationally towards the systematic promotion and implementation of systems to improve the recognition of, and response to, the clinical deterioration of patients.

Patients being cared for in hospitals are sick, and deaths in hospitals will always occur. Ideally, the only deaths that should occur in hospitals are those that are expected — preventable deaths should not occur. Warning signs often precede serious adverse events such as unexpected death, cardiac arrest and unplanned admission to intensive care units. There is evidence that these warning signs are not always identified and, if they are, they may not be acted on appropriately.

Systems including the development of rapid response teams and the use of standardised observation charts are being used more and more often. They are also being refined to reduce preventable deaths and serious adverse events. These approaches increase the likelihood that signs of deterioration are recognised early and that they are responded to appropriately.

4 Antimicrobial stewardship

Inappropriate use of antimicrobials leads to the emergence of antimicrobial-resistant bacteria, and an increase in the risk of patient harm from side effects and unnecessary cost. Published work has indicated that as many as 25–50% of antimicrobial regimens prescribed in hospitals may be considered inappropriate.

This inappropriate antimicrobial use leads to the emergence and selection of resistant bacteria and their subsequent transmission among hospital patients. The end result is a significant impact on morbidity, mortality and treatment costs due to prolonged hospital stays and the need for more expensive drugs. Patients with resistant infections are twice as likely to die. If there was optimal antimicrobial use and containment of antimicrobial resistance, \$300 million of the Australian national healthcare budget could be redirected to more effective use every year.

Effective antimicrobial-management programs, often referred to as antimicrobial stewardship, have been demonstrated to decrease inappropriate antimicrobial use and improve patient care. The Commission is leading a program aimed at providing practical guidance for hospitals in the development and implementation of antimicrobial stewardship and will continue to work with clinicians, the health care system and governments to advance this approach.

5 Learning from complaints

What can patient complaints tell us about the safety and quality of health care?

Patient complaints are a valuable and important source of information about the experience of patients with the

healthcare system. One way of achieving a greater patient focus in the improvement of healthcare safety and quality is to use patient complaints as a catalyst for service improvement.

The increasing implementation of the Australian Charter of Healthcare Rights provides a mechanism to align the complaints received by Australasian Health Complaints Commissioners (HCCs) with the rights recognised by the healthcare system. This alignment offers a good opportunity to use the experience of patients when designing changes to the healthcare system and its processes.

Using the categories for complaints designed by the HCCs, patient complaints were mapped to the Australian Charter of Healthcare Rights. This demonstrated that the largest number of the complaints received related to the rights of safety and communication.

The Open Disclosure approach offers a possible model for encouraging effective and responsive clinician-patient communication. Open Disclosure represents an ongoing conversation between patients, clinicians and the healthcare service, which is focused on preventing similar incidents. Open Disclosure recognises that patients not only have a right to be heard, but that they can provide valuable insights into the standard of care.

6 Safety and quality in general practice

Much of the focus of early patient safety and quality work has been limited to issues that were particularly relevant to hospital-based practice. Most health care in Australia is, however, provided in primary care settings, particularly in general practice, and information regarding the risks to patient safety in this area is limited.

This year, the Commission funded an increase in the Australian sample size for the 2009 Commonwealth Fund survey. This survey focused on the characteristics, attitudes and practises of general practitioners (GPs) in 11 countries. The increased sample size allowed for a more detailed analysis of the survey results. It also provided valuable information regarding the organisation of Australian general practice, and of some of the systems that exist within practices to support safe and high quality health care.

The results of the survey indicate that general practices in Australia perform well on international comparisons in terms of practice organisation for safety and quality, and have many important systems and processes in place. The main area where the Australian performance was consistently below international comparators was in the area of measurement of practice improvement. For

example, only 24% of the surveyed general practices routinely received and reviewed data about their clinical outcomes. The survey also demonstrated that safety and quality systems in general practice varied according to location and size of practice.

These results highlight areas of potential improvement in patient safety in primary care. Approaches such as those in the Draft Primary Health Care Strategy will provide opportunities for targeted action.

7 Sentinel Event and other reporting for patient safety

Understanding patient safety and implementing appropriate measures are complex tasks, but are essential for the delivery of safe, high quality patient care. There is a great deal of data recorded in the current Australian healthcare system, including detailed funding information, and performance measures such as access times and screening rates. Nationally, there are also systems in place for the reporting of clinical incidents. However, among all of this activity, there is little direct measure of patient safety.

National Sentinel Event reporting in Australia is now in its fourth year. This chapter considers the issues around incident reporting and also includes the report of Sentinel Events for both public and private hospitals for 2007–2008. To keep with the previously stated intent of identifying events that ‘...result in the death or serious harm to a patient’, this year, Health Ministers approved the revision of the definition of Sentinel Event 1. This revision ensures that a Sentinel Event 1 only referred to procedures involving the wrong patient or body part that resulted in death or serious harm.

Results for public hospitals are presented. Data voluntarily supplied by private hospitals are also presented and these now cover more than 80% of all private hospital beds. The Commission recognises that although the count of Sentinel Events is of public interest, there is no capacity to develop a standardised rate of incidence of these events. As a consequence, it is not possible to use these figures in any comparative way as measures of healthcare system performance.

In the five years since Sentinel Event reporting was agreed, there has been considerable further development in the evidence and practical experience with using safety measurements for improvement. Several approaches are being developed for signalling and measurement systems that include the use of hospital-level outcome indicators,

analyses of coded inpatient data, bedside and chart audits, and structured adverse event analysis.

8 Measuring hospital mortality: using Hospital Standardised Mortality Ratios in Australia

The key reason for measuring hospital mortality is to use this information to improve the safety and quality of the care that hospitals provide. Hospital mortality statistics allow both the staff who work in hospitals, and current and future hospital patients to be better informed about the outcomes of health care. Mortality statistics in the form of Hospital Standardised Mortality Ratios (HSMRs) can also be used to monitor the impact of measures taken to improve safety and quality.

In work funded by the Commission, the Australian Institute of Health and Welfare developed a report that reviewed the established mechanisms for measuring hospital mortality and provided an analysis of Australian data.

The chapter illustrates the fact that HSMRs are a reliable screening tool with effective risk adjustment. As a consequence, they represent an approach that indicates where detailed analyses may be worthwhile to understand why higher or lower death rates are occurring. Techniques of data presentation will have an impact on how effectively this information is used by hospitals. The mortality rates in hospitals across Australia are used to illustrate some data presentation approaches.

The analysis of the Australian data resulted in two important findings. The first is that the routinely collected data within the Australian National Morbidity Database are acceptable sources of information on which to base an analysis of HSMRs. The second is that the HSMRs of Australian hospitals do differ from each other; however, within-hospital variation over time is small in comparison to differences between hospitals, and generally accounted for no more than 15% of overall variability. In other words, mortality rates in Australian hospitals are generally stable over time and random variation can be discounted as a source of difference between Australian hospitals.

The Commission is now working with health jurisdictions to develop the capacity for routine generation of HSMRs and their routine use as one of a core set of hospital-based outcome indicators for safety and quality.

9 Measuring and reporting on safety and quality in hospitals

The availability of timely, useful information is an essential component of high-performing healthcare systems. Across Australia, many clinical and safety indicator programs

operate at the levels of private or public hospital networks, jurisdictions or private hospital ownership groups. These include Queensland Health's clinical indicators and Variable Life Adjusted Display reporting methodology, and Victoria's Australian Patient Safety Indicators.

The identification and development of these safety and quality indicators are important early steps in the process of measuring and reporting on safety and quality in hospitals. The difficulty of making comparisons between hospitals that provide different types of care and in which patients have different ages, health profiles, and procedures (this is known as 'casemix') has been noted. The key to effectively use this information lies in the use of robust investigation approaches.

A number of issues need to be considered when measuring and reporting on the safety and quality of health care, which include the use of administrative and other data sources, comparability and risk adjustment, the level of reporting and the relative merits of measuring process and outcome. Each of these issues is considered within this chapter.

The Commission has recommended a core set of hospital-based outcome indicators for safety and quality to Health Ministers to be used across public and private hospitals. The indicators and their potential use within a report–review–act cycle at hospital level are discussed.

Hospitals should receive regular reports on a range of indicators of their safety and quality. These reports would be generated in a timely manner, risk adjusted and plotted against peer hospitals.

10 Impact of clinical registries

Clinical registries can have a key role in monitoring and improving the quality and safety of Australian health care. They have the potential to provide a strong evidence base for determining the efficacy, safety and quality of healthcare providers, interventions, medications, devices and treatments.

The Commission is piloting operating principles and technical standards for Australian Clinical Quality Registries. The focus will be on how such registries can play a key role in monitoring and improving the quality and safety of care received by Australian patients.

The development of these approaches will enable registries to be major sources and destinations for information and analysis in the coming electronic health-enabled healthcare environment.

A photograph of a middle-aged man with short grey hair, wearing a light blue button-down shirt and a patterned tie. He is looking intently at a large medical monitor on the right side of the frame, which displays a chest X-ray. He is holding a small object, possibly a pen or a pointer, near the screen. The background shows a hospital corridor with other people and medical equipment, slightly out of focus. A large white number '1' is overlaid on the left side of the image.

1

Introduction

One of the key roles for the Commission is to report publicly on the state of safety and quality. The annual *Windows into Safety and Quality in Health Care* report is one way in which the Commission achieves this. It is not intended to function as a scorecard or to set benchmarks for any aspect of the Australian healthcare system. Rather, it offers insights into particular aspects of safety and quality in Australian health care. The Commission has proposed a framework for safe and high quality health care that will allow us to start mapping the way ahead.



The National Safety and Quality Framework

During 2009, the Australian Commission on Safety and Quality in Health Care undertook an extensive public and health care provider consultation of its proposed National Safety and Quality Framework (the Framework).¹

The Framework encompasses a vision for safe and high quality care for Australia and describes what making safety and quality central to health care would mean for patients. The Framework is predicated on the statement that safe high quality care is always:

- patient focused
- driven by information, and
- organised for safety.

The Framework is designed to guide action to improve the safety and quality of the care provided in all healthcare settings over the next decade. The proposed framework would:

- be used as the basis of strategic and operational safety and quality plans
- provide a mechanism for refocusing current quality improvement activities, reviewing investments for safety and quality, and designing goals for health service improvement, and
- promote discussion with consumers, clinicians, managers, researchers and policy makers about how they might best contribute to safety and quality improvement.

Patient focused

Patient focused means providing care that is respectful of and responsive to individual preferences, needs and values. It means a partnership between consumers, families, carers and their healthcare providers, and that processes of care are designed to optimise the patient experience.

In the last couple of years, there has been much attention paid to health care and how it may be reformed. This conversation has been taking place in Australia and internationally. A recurring theme has been the central role of the patient and consumer. For example, in the United Kingdom (UK) Lord Darzi, stated in his review of the National Health Service that 'High quality care is care where patients are in control, have effective access to treatment, are safe and where illnesses are not just treated, but prevented'.²

In Australia, a key feature of this reform debate has been the National Health and Hospitals Reform Commission (NHHRC). In its final report, the NHHRC argued forcefully that an agile health system is one that has 'strengthened consumer engagement and voice' and this aligns with the patient focused orientation of the Framework.³

The patient focus does not apply only to the delivery of health care. It is the placing of the patient as the focus of all aspects, including discussions of policy and reform. It means ensuring the debates we have about health

care, the policies that are adopted and the decisions that are made truly focus on the patient. As Productivity Commissioner Gary Banks argues, evidence-based policy necessitates genuine inclusion and transparency, requires consultation with those who will be 'affected by the policy, whose reactions and feedback provide insights into the likely impacts and help avoid unintended consequences'.⁴

Using this broader focus on patients, it is readily appreciable that much of this report has a patient focus, albeit indirectly in some cases. Most of this report is framed around how the safety and quality of health care that Australians receive can be maintained and enhanced.

Driven by information

This is a focus on enhancing knowledge and evidence about safety and quality. It means that safety and quality data are collected, analysed and fed back for improvement. It means that this information leads to action to reduce unjustified variation in standards of care and to improve patients' experiences and clinical outcomes.

In the 2008 report, the Commission indicated that future reports would include additional information as part of its public reporting on the state of safety and quality, including performance.⁵ This 2009 report includes a number of chapters demonstrating how information can be used to identify and respond to safety and quality issues.

They include the use of complaints and medical indemnity information to identify safety and quality issues. How information from incident reporting and Sentinel Events can be used to further understand safety and quality of care issues is also examined. There are also chapters on how information can be used as a flag to draw attention and to precipitate investigations. Examples include the use of hospital mortality rates and indicators of variation within hospitals. In a chapter examining safety and quality in general practice, the results of a multi-national survey offers valuable insights. An examination of the impact of clinical quality registries demonstrates the value of information to maintaining and enhancing care.

The utility and value of information are themes that emerge repeatedly in the considerations of healthcare systems and redesign them for the future. In the UK, the final report of the Next Stage Review of the National Health Service recognises that 'making data on how well we are doing widely available to staff, patients and the public will help us understand variation and best practice and focus on improvement'. The National Health Service has taken this further:

Evidence shows that high-performing teams are characterised by the use of measurement to support improvement. . . . Our vision is for an NHS where teams consistently measure what they do, using good and timely information as a basis both to improve the care they provide and to compare themselves with other teams. Measurement should guide local innovation and improvement efforts — it is not an end in itself, only a means to the end of better quality care. At the same time, patients should be able to use some of this information to have greater control over their care and support decisions they make with their clinicians.⁶

In the Australian context, the NHHRC has asserted that for long-term sustainability, the health system must be agile and self-improving and that a key element in achieving such self-improvement is the 'smart use of data, information and communication'. The NHHRC was 'keen to promote a culture of continuous improvement through health performance reporting' with specific recommendations including:

- systems to provide comparative clinical performance data back to health services and hospitals, clinical units and clinicians, and
- publicly available information on health services to assist consumers in making informed choices.³

The 'smart use of information' can have significant value in achieving the reform of health care and to ensure that health care is both safe and of high quality. But, the 'driven by information' theme has even greater implications because it connects with wider debates and policy developments. For example, it can relate to the drive for the use of evidence and the role of the evidence in evidence-based policy and medicine.

Organised for safety

The proposed Framework states that being organised for safety means that safety is a high priority in the design of healthcare. It means that organisational structures, work processes and funding models recognise and reward taking responsibility for safety.

Chapters that consider how health care settings can be organised for safety include those on antimicrobial stewardship, recognising and responding to deteriorating

patients, and on how general practices in Australia are organised to ensure safe and high quality care.

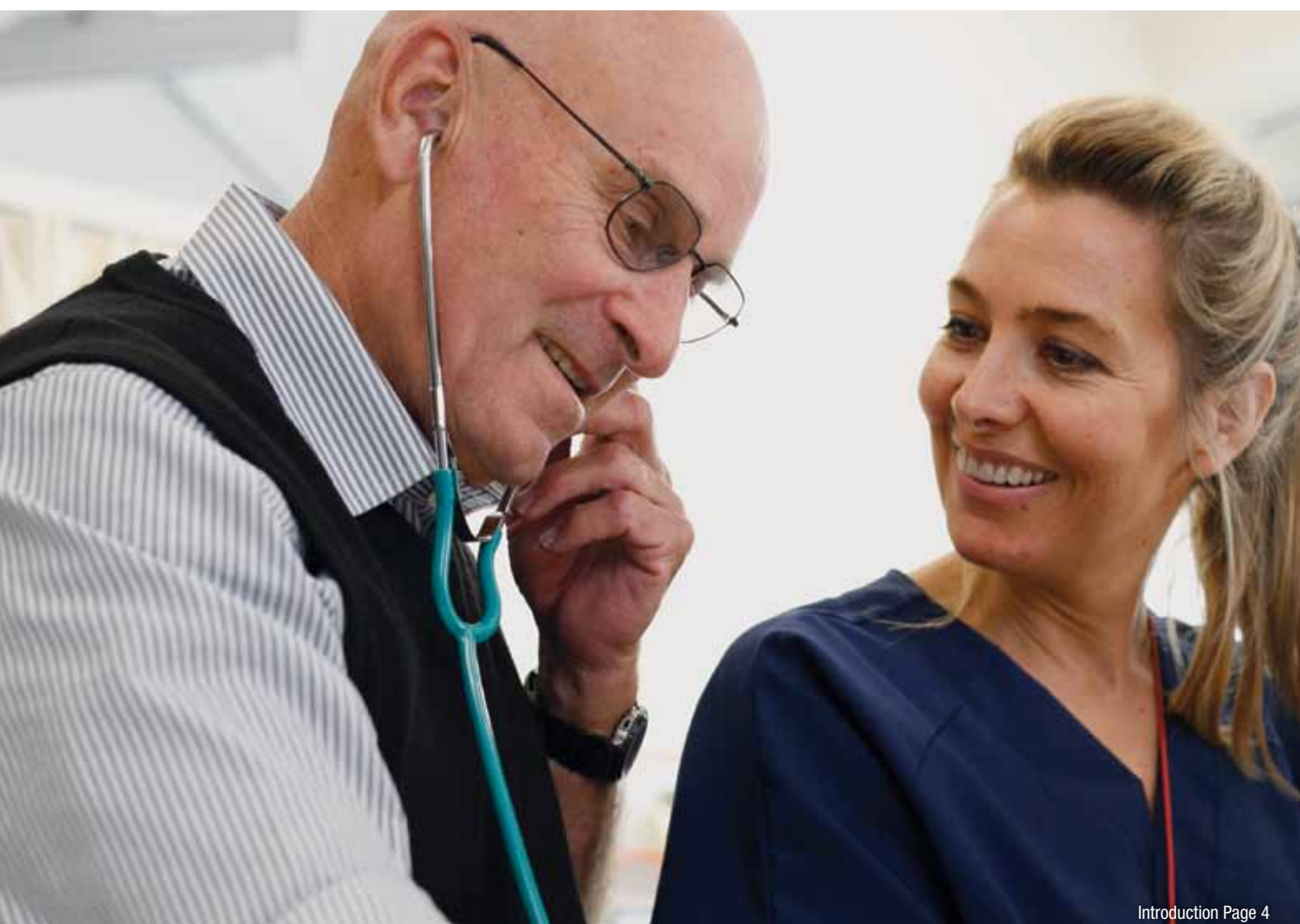
The real challenge in discussing reform comes in implementation. Here the need for information is by no means reduced as implementation needs to be context specific and appropriate for local realities. Monitoring and refining will always be necessary because attaining and maintaining high quality care is a continuous process.

There is considerable Australian and international impetus to reform health care as indicated by reports such as those of the NHHRC and Lord Darzi. But as the Chair of the Productivity Commission noted, that while major reform of the Australian health system may be desirable, this is only conceivable as incremental reform and the 'challenge with an incremental approach to reform... is to ensure that it is consistent with a coherent strategy for improvement of the system as a whole'. Furthermore, the fundamental reason for reform is not about cost containment, it is 'about changes that can lead to improvements in people's wellbeing'.⁷

Sustainable and meaningful improvements to our healthcare system require a health system that is receptive to evidence, driven by information, organised for safety, and patient focused.

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2

Retrospective

Many of the improvements in the safety and quality of health care can take time: time to research and compile the evidence, time to establish the most effective solutions, time to test and validate, time to embed and time to become part of the culture. This report follows and builds upon the *Windows into Safety and Quality in Health Care 2008* report. While each report provides a 'snapshot' of, or a 'window' into, an aspect of health care in Australia, they are not intended to cover the same areas or report sequentially on given topics. This chapter offers a brief retrospective on a number of the topics featured in the 2008 report.

Further information is available from the Commission's website at www.safetyandquality.gov.au



Healthcare rights

The Australian Charter of Healthcare Rights (the Charter) was developed by the Australian Commission on Safety and Quality in Health Care (the Commission) to provide a nationally agreed statement of the rights of patients across the health system. The Charter allows patients, consumers, families, carers and services providing health care to share an understanding of the rights of people receiving care. This gives the basis for a genuine partnership to achieve the best possible outcomes.

The Australian Charter of Healthcare Rights was endorsed by Australian Health Ministers in July 2008. The Commission has developed a range of resources to support use of the Charter by healthcare providers and health service organisations in Australia. These resources include translated versions of the Charter in a range of community languages, audio and Braille versions, brochures about the Charter for patients and their families, as well as healthcare providers, and guidance for health service organisations about how to use the Charter.

Since the Charter was endorsed, public and private health services and hospitals, and other organisations have been active in putting the Charter in place in their organisations. Examples of some of the activities that have been undertaken include:

- The Department of Health in Victoria has developed the *Australian Charter of Healthcare Rights in Victoria*, that adds specific information to the Charter that is relevant to health services in Victoria. Other states and territories are taking a similar approach in updating their public patient charters.
- Palliative Care Australia has included details of the Australian Charter of Healthcare Rights in consumer information about the National Standards Assessment Program for palliative care.
- Australian Health Complaints Commissioners have agreed to map the complaints they receive against the rights in the Charter. The results of this mapping process are presented in this report. In addition, the Queensland Health Quality and Complaints Commission worked with the Commission in the development of a code of rights and responsibilities. This was presented to the Queensland Minister for Health in 2008. Because there was such strong alignment between the code and the Charter, the Queensland Health Quality and Complaints Commission recommended that Queensland



adopt the Australian Charter of Healthcare Rights. This recommendation has been supported.

- The Australian Dental Association has developed a policy statement about partnerships between dentists and patients that includes a requirement that the Australian Charter of Healthcare Rights and the complementary rights and responsibilities of patients and dentists be recognised by dental boards in appropriate professional standards.
- Ramsay Healthcare began to roll out the Charter across all of its Australian facilities from July 2009. Patient and provider fliers were distributed, and posters located in hospital foyers and at bedside tables, lockers and reception areas.
- Professional colleges including the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the Royal Australian and New Zealand College of Ophthalmologists and the Australian and New Zealand College of Anaesthetists have publicly expressed support for the Charter. Activities that have been undertaken by colleges include publishing the Charter in their members' journal, examining how the Charter fits within their training curriculum and making reference to the Charter in policy statements about care processes.

The Australian Charter of Healthcare Rights is only one part of a larger drive towards a more patient focused healthcare system. Despite the strong and positive

response to the Charter further work is needed both to embed the Charter, and to ensure that the healthcare system is patient focused. The Commission will need to maintain its role promoting the Charter nationally. Other drivers may be needed to ensure that the Charter is used across the health system, particularly in areas where penetration has been low. This may include requirements in standards and accreditation processes, formal accountability and reporting mechanisms or the introduction of incentives.

Patient identification

The prevention of mismatches between patients and their care remains an international and Australian patient safety challenge in 2009. Recognising that mismatches can occur in all types of clinical processes, and for many different reasons, work to prevent these errors continues across a wide range of different areas.

In 2008, the Australian Health Ministers endorsed specifications developed by the Commission for a standard national patient identification band. Use of these specifications will reduce variation in patient identification bands and ensure that bands that are used are designed to make it easy to identify the patient. Since the specifications were endorsed by the Health Ministers, public and private hospitals have started work to review their existing patient identification bands, and where necessary, procure new bands that comply with the specifications. This process has required significant work providing education to staff about the importance of patient identification, and how the new bands can reduce mismatches.

In 2008, the World Health Organization released a surgical safety checklist that was developed as part of its Safe Surgery Saves Lives Global Patient Safety Challenge. The Surgical Safety Checklist (the Checklist) includes a core set of safety checks for use in any operating theatre environment. The Checklist is designed to improve safety by focussing on anaesthetic safety practice, ensuring correct site surgery, avoiding surgical-site infection and improving communication within the operating team.

There has been strong support for the Checklist in Australia. The Checklist was launched by the Australian Minister for Health and Ageing on 19 August 2009 with the Royal Australasian College of Surgeons, the Australian and New Zealand College of Anaesthetists, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the Royal Australian and New Zealand

College of Ophthalmologists and the Australian College of Operating Room Nurses. The Commission has been liaising with these professional organisations and is also supportive of the Checklist. In November 2009, Health Ministers endorsed the Checklist as the national strategy for surgical safety in Australia, and agreed that the principles of the checklist should be implemented by 1 July 2011.

Identifying patients correctly and consistently is one of the key requirements for avoiding mismatches between patients and their care. In 2009, the National E-Health Transition Authority has been working on the development of unique health identifiers for patients, and for healthcare providers and organisations. These identifiers are designed to facilitate accurate and secure electronic recording and communication of patient health information between a patient's healthcare team. It is expected that these identifiers will be in use by mid-2010.

Medication safety

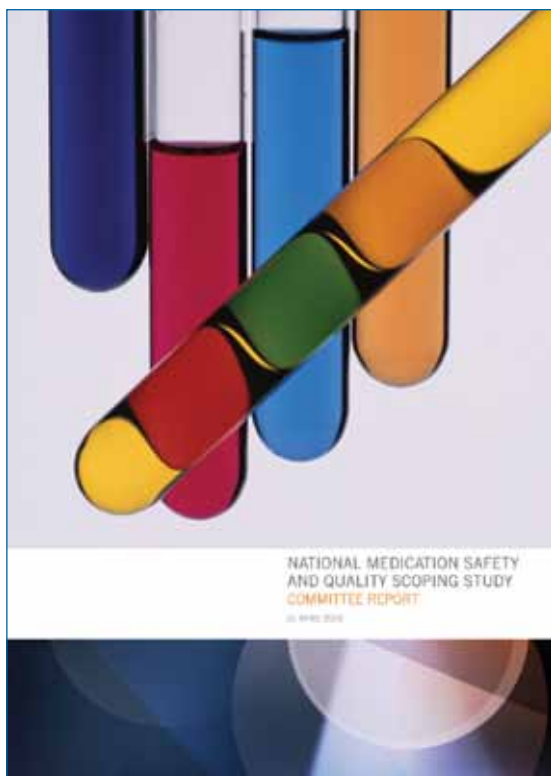
The Commission's work on medication safety has expanded following the release of the *National Medication Safety and Quality Scoping Study* (the Study) in April 2009. The Study recommended four key actions for the Commission, on which it has acted, as well as forty-five other actions for the Commission and other organisations, to improve national medication safety and quality.

The Commission analysed the forty-five recommendations and has recast its medication safety program to reflect the priorities that informed the Study. Additional work is already being undertaken under the new program, which is organised along five key themes:

1. improving continuity of care
2. standardisations and system improvements
3. reducing gaps in practice
4. using technology, and
5. advocating safety and quality.

For example, the Commission is developing national recommendations for user-applied labelling of parenteral medicines, lines and fluids to reduce the high error and harm rate from unlabelled or inadequately labelled medicines. The recommendations will be available in April 2010.

The Study will also inform the Commission's future work in medication safety.



Possibly the most important piece of work recommended by the Study, and one that the Commission has already started, is the development of guidelines for Australian hospitals specifying and commissioning electronic medication management (EMM) systems. The guidelines will consist of the following:

- user requirements and procurement guide for hospital EMM systems incorporating essential safety features
- a toolkit for hospitals to aid in safe implementation during commissioning, and
- an optimal look-and-feel user interface, building on the National Inpatient Medication Chart (NIMC), and resulting in a common user interface between EMM systems nationally.

Many hospitals are already planning for implementation of EMM. However, while Australian hospital pharmacists have been managing inventories and dispensing using computer systems for some years, there are few examples of full EMM systems integrating electronic prescribing, dispensing and drug administration in Australian hospitals. Those involved in implementation projects invariably speak of critical success factors such as the changes to culture and practice, and the need for detailed planning. Reflecting this experience in the guidelines as a learning exercise for other hospitals is critical.

Underlying the project is the proposition that a lot of the complex work — developing tools to assess and procure EMM systems, building up a strong implementation and planning study and defining what optimal EMM screens look like — should be informed by best practice and the experience of Australian hospitals that have already been through the process of acquiring and implementing EMM systems, rather than each hospital starting from scratch. The Commission will make the guidelines available in early 2010.

Consistent with its medication safety program objectives, the Commission will give a high priority to medication reconciliation throughout 2009–2010. This will be through development of a common medication reconciliation form and also through its involvement in the World Health Organization's High 5s Medication Reconciliation Program.

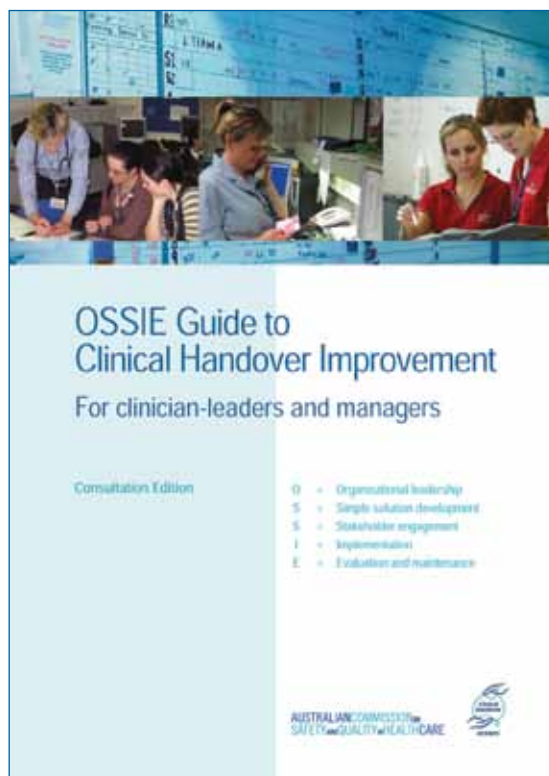
Clinical handover

Clinical handover refers to the transfer of professional responsibility and accountability for some or all aspects of care for a patient, or group of patients, to another person or professional group on a temporary or permanent basis. Clinical handovers can occur at shift change, when patients are transferred between health services or wards, on the telephone, and during admission, referral or discharge. Clinical handovers can occur in a number of forms such as: face-to-face, via telephone, written, and/or aided by electronic handover tools. Approximately 28 million clinical handovers occur annually in Australia.

The Commission's National Clinical Handover Initiative (the Initiative) was established in February 2007 with the aim of improving handover communication across all healthcare settings. Since publication of the *Windows into Safety and Quality in Health Care 2008* report, the National Clinical Handover Initiative has undertaken a number of activities:

1. A pilot program run over the last two years as part of the Initiative has involved 14 projects that developed and trialled practical and transferable tools for improving clinical handover. Development of these tools was based on workplace research and involved more than 30 hospitals in six jurisdictions as well as some primary and residential aged care services. These tools are now freely available for use from the Commission's website, including:
 - protocols for improving medical and nursing shift-to-shift handover

- materials on using the briefing techniques (SBAR, ISBAR, ISOBAR, SHARED) at handover
 - tools to help clinicians redesign their own handover practices
 - online education modules
 - tools for handover from aged care facility to hospital and for inter-hospital transfers, and
 - materials on team communication.
2. In March 2008, a consultation edition of the *OSSIE Guide to Clinical Handover Improvement*, was released to assist clinician-leaders and managers to improve clinical handover practices. The guide offers an approach to change management, measurement and use of standardised processes for handover. The guide was developed based on workplace research conducted at the Royal Hobart Hospital — University of Tasmania and the Western Australia Country Health Service — Royal Perth Hospital pilot projects. OSSIE stands for:
- O = Organisation leadership
 - S = Simple solution development
 - S = Stakeholder engagement
 - I = Implementation
 - E = Evaluation and maintenance.



3. In June 2009, *Clinical Handover: Critical Communications*, a supplement issue of the *Medical Journal of Australia*, was published. The supplement, sponsored by the Commission, contains 14 articles and represents a substantial contribution to the evidence base on clinical handover both nationally and internationally. *Clinical Handover: Critical Communications* is available at www.mja.com.au.
4. Four workshops to assist clinicians to use the practical tools developed by the pilot projects have been held in Adelaide, Brisbane, Perth and Melbourne over the past year. These workshops have allowed the Commission to translate the lessons and tools developed by the pilot projects across health services in Australia into practise.

Last year's *Windows into Safety and Quality in Health Care 2008* included a handover chapter titled, *How is patient care transferred safely?* It aimed to provide readers with a greater understanding of the processes and risks associated with clinical handover. The Commission's clinical handover program is focused on developing resources to assist with handover improvement. But is this work making a difference?

The lead author of last year's chapter, Professor Elizabeth Manias, Faculty of Medicine, Dentistry and Health Sciences, University of Melbourne, has had many conversations with clinicians from a variety of backgrounds about handover processes in their hospitals. Professor Manias believes the Commission's work is reaching clinicians at the bedside, leaders and managers. From her observations at the coalface, clinicians are talking about the importance of handover and attempting to make changes in their work practices. Professor Manias reflected that these 'clinicians are able to converse in very critical ways about how handover affects their patient care activities and to make crucial links between handover processes and patient safety'.

Several clinicians have informed her that they were impressed with the relevance and importance of the work covered in the workshops. In particular, Professor Manias noted that 'there have been clinicians with managerial and leadership responsibilities who have used aspects of the OSSIE Guide as well as the content from workshops to assist them in improving current handover practices in clinical settings'.

Momentum and interest in handover improvement in Australia is growing. The Commission is committed to ensuring effective, consistent and agreed processes for clinical handover are applied whenever accountability and responsibility for patient care is transferred.

The successful improvement of handover processes requires the extensive inclusion of staff who participate in handover in the redesign process. To support staff through changes in clinical handover, it will be necessary to implement a robust change management framework. The goal of a standardised process for clinical handover is improving the flow of critical information between healthcare professionals that ensures patient safety and continuity of appropriate care.

Open Disclosure

In 2008, Australian Health Ministers agreed to work towards the implementation of the Open Disclosure Standard in all healthcare facilities. Adherence to the Open Disclosure Standard requires that all patients who are harmed during health care receive:

- an expression of regret (or an apology) for the incident
- a factual explanation of what happened
- an explanation of the potential consequences of the incident, and
- a discussion of the steps being taken to manage the incident and to stop it from happening again.

In 2009, incidents that result in harm to patients were openly discussed in many health care facilities across Australia. Work continues to help ensure that all incidents are openly and compassionately discussed with patients and their families, in every state and territory and in the public and private sectors. More states, territories and some private health services have moved to train and support staff to participate in Open Disclosure, and increasing numbers of patients will be told about things that go wrong during their health care.

However, research undertaken for the Commission in 2009 has shown that many professionals on the front line of care are unsure about the medico legal framework surrounding open disclosure. This confusion may be due in part to the fact that laws governing incident investigation and apology vary between every state and territory. This perception causes uncertainty and can make health professionals appear to be reluctant or unable to express regret, apologise or share the results of investigations.

The Commission has engaged further research to add to the relatively little information available on patient perceptions of Open Disclosure. The '100 patient stories project' involves exploring one hundred patients' experiences of Open Disclosure, and using

the information obtained to develop survey instruments to measure the effectiveness of Open Disclosure, as perceived by patients and healthcare staff, and indicators of effective Open Disclosure.

The 100 patient stories project is due for completion in June 2010. This will constitute the world's largest evidence base on patients' experiences of Open Disclosure.

Accreditation

The 2008 report outlined the Health Ministers' reform process for accreditation of health service organisations being led by the Commission. The reforms include the development of new standards in areas where there is potentially a high risk of harm to patients, an expansion of the number of health services being accredited; and improved public access to standards and information to consumers on the performance of health services.

Over the last 12 months, the Commission has actively progressed the first phase of accreditation reform. This has focused on the development of draft National Safety and Quality Healthcare Standards for:

- Governance for Safety and Quality in Health Service Organisations
- Healthcare Associated Infection
- Medication Safety
- Patient Identification and Procedure Matching, and
- Clinical Handover.

A detailed analysis of the regulatory options to put these reforms in place has been completed and a recommendation on the scope of accreditation has been developed. Work on a data collection model, supporting processes to underpin the future national accreditation system, a cost-impact analysis on the implementation and rollout of the model, and processes to support coordination with regulatory authorities are underway. The Commission reported back to Australian Health Ministers in November 2009, providing an update and recommendation on the next steps for implementation.

Healthcare associated infections

In December 2008, the Commission presented two papers to Health Ministers on a national approach to the prevention of healthcare associated infection (HAI). Health Ministers noted that to significantly reduce HAI a multi-faceted approach is necessary and that the

components of this include national infection control guidelines, improving rates of hand hygiene compliance, antimicrobial stewardship, building clinician capacity and surveillance of HAI.

Health Ministers approved the following actions for implementation of a national approach to the prevention of HAIs:

- all hospitals establish HAI surveillance
- all hospitals monitor and report through their relevant jurisdiction into a national data collection:
 - *Staphylococcus aureus* (including methicillin-resistant (MRSA)) blood stream infection
 - *Clostridium difficile* infection
- a national approach to hand hygiene standards.

During 2009, the Commission has worked with the jurisdictions and private hospital sector to develop agreed definitions for the collection of *Staphylococcus aureus* (including methicillin-resistant (MRSA)) blood stream infection and *Clostridium difficile* infection. Data standards for national surveillance and a data dictionary have been developed to assist hospitals and jurisdictions. The Commission will continue this work for ongoing national data collection.

The National Hand Hygiene Initiative

Last year's report noted that the World Health Organization has developed a standardised conceptual approach to teaching and promoting a new hand hygiene culture in healthcare facilities, which was applicable in Australia. In Australia, the National Hand Hygiene Initiative has now started in all states and territories and the private sector, through Hand Hygiene Australia, under contract with the Commission. The following resources have been provided:

- a manual has been adapted for Australia from the WHO Guidelines on clean hands
- workshops on the '5 moments for hand hygiene' have been attended by over 750 healthcare workers
- more than 1,000 DVDs for training auditors of hand hygiene compliance have been distributed
- a website with access to the educational resources has received over 30,000 hits from Australian users, and
- an online learning package on hand hygiene has been undertaken by over 32,000 healthcare workers. In some hospitals and regions (including the private hospital sector), all healthcare workers

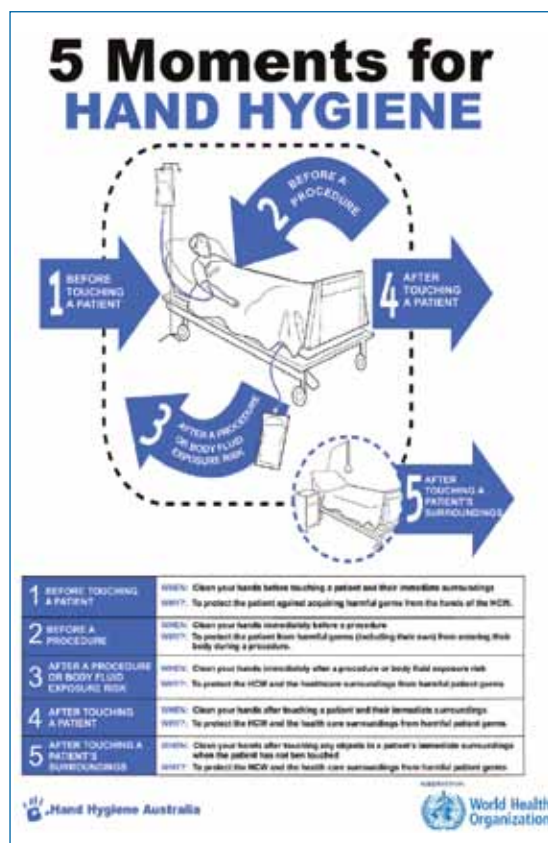
are now expected to complete the package prior to starting employment.

Collection of hand hygiene compliance data

Hand hygiene compliance is measured at specified intervals during the program, with the number of acute in-patient beds at each facility dictating the number of areas required to be audited and the number of observations to be undertaken. A standardised hand hygiene compliance assessment form is used for all assessments with training in the hand hygiene compliance assessment tool, data collection, data entry and data analysis provided for all participating hospitals.

The 5 Moments for Hand Hygiene program is an educational approach, which is proven to improve the overall rate of clinician hand cleaning. Measuring and reporting compliance with the steps of the 5 Moments program, is a powerful contributor to the success of this program, and all states and territories are now doing this. Rates of compliance with the 5 Moments program are assessed and reported according to a number of specified criteria, including by healthcare professional category, and type of activity performed.

The underlying reason for undertaking the Hand Hygiene Initiative is to reduce the risk of healthcare providers inadvertently spreading infections between patients. It is



known from overseas experience that the risk of this happening is lowest when the compliance rate with this particular program stays above 70%.

Data have been collected nationally from a total of 182 hospitals from both the public and private sectors. The average compliance rate was 63.5% (range across jurisdictions was 50.1% to 70.8%). Queensland has undertaken a successful hand hygiene initiative in state public hospitals for some years using a different compliance measurement process. Queensland will be using the 5 Moments measurements from 2010.

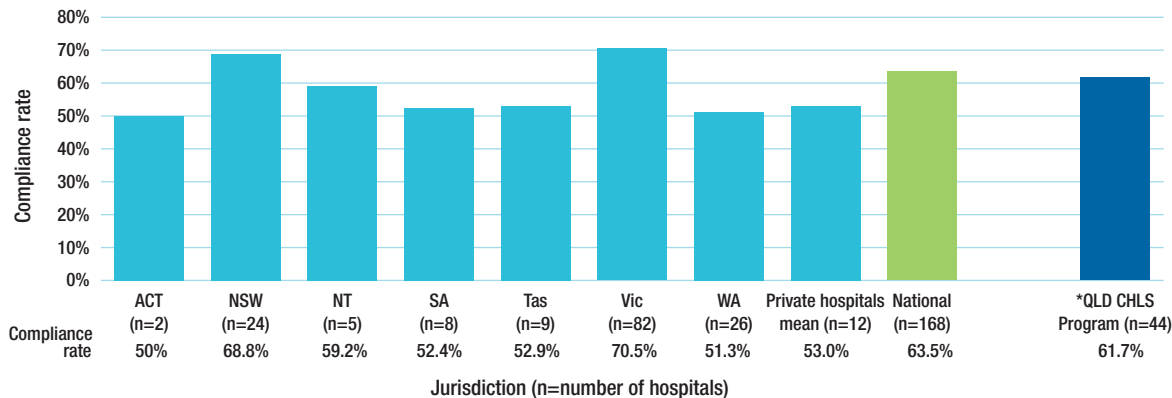
Figure 2.1 depicts the compliance rates and number of hospitals for each of the jurisdictions that submitted data for the second audit period in August 2009. The highest compliance rate and the largest number of hospitals submitting data was Victoria (70.5% from 86 hospitals). This demonstrates the benefit of using the program over several years, as Victoria began the process well before the start of the national program.

Figure 2.2 depicts the compliance rates for each of the 5 Moments. The highest rates of compliance were after touching a patient (73%) and after completion of a procedure (71%). Figure 2.3 depicts the compliance rate by healthcare worker professional group. The highest compliance rates were nurses (69% for student nurse and 68% for Registered Nurses).

The National Hand Hygiene Initiative is continuing. Measurement and reporting of compliance with the 5 Moments program will remain a key part of the initiative and the Commission will make the national results available through its website (www.safetyandquality.gov.au). The number of hospitals providing data in this second round of reporting has increased and it is anticipated to continue to increase for the subsequent data periods. This ongoing initiative will remain a valuable step in the national efforts to reduce the risk of healthcare acquired infections in Australia.

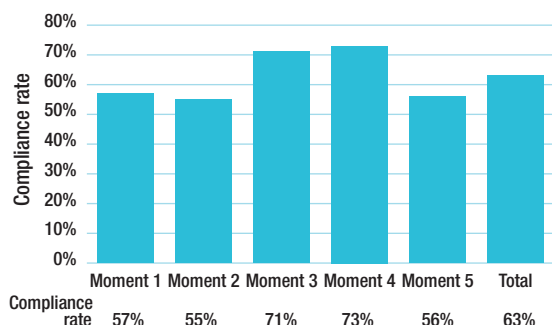
Figure 2.1 Hand hygiene compliance rates by jurisdiction Audit period 2 – 2009, Hand Hygiene Australia

(jurisdictional data from public facilities only)



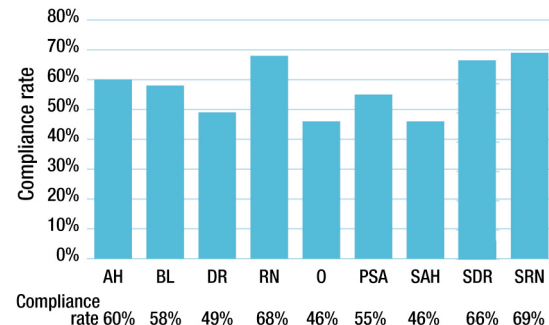
*The QLD CHLS Program did not audit using the 5 Moments tool. This rate cannot be directly compared to rates in other jurisdictions.

Figure 2.2 National Hand Hygiene compliance rates by Moment Audit 2



Moment 1 = Before touching a patient; Moment 2 = Before a procedure;
Moment 3 = After a procedure or body fluid exposure; Moment 4 = After touching a patient;
Moment 5 = After touching a patient's surroundings

Figure 2.3 National Hand Hygiene compliance rates by healthcare profession Audit 2



AH = Allied Health; BL = Pathology; DR = Medical Officer; O = Other, not specified;
PSA = Patient Support Assistant SAH = Student Allied Health; SDR = Medical Student
SRN = Student Nurse



3

Recognising and responding to clinical deterioration

The characteristics of patients are changing, both in Australia and internationally. Acute care hospitals now have an increasing proportion of patients who have complex problems and who are more likely to be or become seriously ill during their hospital stay.^{1,2} Warning signs often precede serious adverse events such as unexpected death, cardiac arrest and unplanned admission to intensive care units (ICUs).^{3,4} However, there is evidence that these warning signs are not always identified, and if they are, they may not be acted on appropriately.^{5,6}

Ensuring that patients who deteriorate in hospitals receive appropriate and timely care is a key safety and quality challenge. These patients should receive the care they need irrespective of where they are in the hospital or the time of day. However, survival rates from cardiac arrest are lower on weekends and at night. Mortality rates of patients admitted to intensive care from general wards are higher than those admitted from emergency departments or operating theatres, suggesting that these patients are not receiving optimal care prior to their admission to ICU.^{7,8}

This situation has been known for some time, and the need to provide consistently safe and high quality care to patients who deteriorate in hospitals is well-recognised. Australia was the first country to take a systematic approach to managing the needs of these patients, and has been at the forefront of much of the early research and innovation in this area.^{9,10} One of the first models introduced was the medical emergency team (MET) in 1990, which was developed at Liverpool Hospital in Sydney.⁹ The MET is traditionally based in the ICU and is a team of medical and nursing clinicians who provide specialist emergency assistance to patients who are deteriorating wherever they are in the hospital. The use of METs and similar models has spread rapidly in Australia and internationally. In 2005, approximately 60% of hospitals in Australia and New Zealand with an ICU had a MET service in place.¹¹

Despite work over almost two decades, significant problems remain. These problems can be seen in reports of serious and sentinel events (Box 3.1),¹² in media

Box 3.1 Sentinel events involving patients who have deteriorated in hospital reported by New Zealand District Health Boards

- A patient was admitted to hospital with pneumonia. The patient's deterioration was not recognised and the existing systems to identify early warning signs were not used. Resuscitation of the patient was delayed and the patient died.
- A cardiac patient in a non-cardiac ward had a fast, irregular heart rate and low blood pressure. This was identified by a nurse who paged a junior doctor. The junior doctor later reported not receiving the page. The nurse did not feel able to escalate care to a more senior doctor when there was no response to the page. After some delay, the patient was eventually transferred to coronary care, and no permanent harm was experienced.
- A patient with significant co-morbidities needed resuscitation. Staff had difficulty accessing the contents of the resuscitation trolley, and had limited knowledge of how to use resuscitation equipment and the resuscitation process. Not all of the equipment and information on the resuscitation trolley was correct nor was additional essential equipment readily available. The patient died.



Box 3.2 Australian media reports regarding patients who have deteriorated in hospital

Death of a Berkeley man avoidable, inquest told

'The death of a Berkeley man at Wollongong Hospital could have been prevented had his deterioration after surgery been better recognised by senior medical staff, a coronial inquest heard yesterday.'

Illawarra Mercury, Veronica Apap, 30 October 2008

Vanessa, 16, killed by a sick system

'[The Deputy State Coroner] said Vanessa died needlessly in the worst possible case he had seen ... due to lack of communication, poor management, staff inexperience and poor record-keeping.'

Sydney Morning Herald, Natasha Wallace, Alexandra Smith, Malcolm Brown, 25 January 2008

Nurse trial halted as kill charges dropped

'It was alleged [two nurses] had not raised the alarm soon enough when [the patient's] oxygen saturation levels (SATS) became critical after a simple back operation.'

Courier Mail, Jason Gregory, 22 April 2008

reports that appear when people die unexpectedly in hospitals (Box 3.2), and in research showing the continuing occurrence of serious adverse events, such as avoidable cardiac arrests.¹³ Because of this, work has continued to develop and embed systems to properly recognise and respond to clinical deterioration. In Australia, there are now programs in place in a number of states and territories, as well as at a national level.^{14–16}

How common is deterioration in hospitals?

Knowing how many patients in hospitals are deteriorating and may be at risk of serious adverse events is important as it helps determine what sort of organisational resources are required to care for these patients, such as the potential use of METs. It also provides information about how often deterioration is *not* recognised, and therefore can be an

Box 3.3 Example of calling criteria for a medical emergency team⁵

The MET should be called if you are concerned about any of the following issues:

Airway

If threatened

Breathing

All respiratory arrests

Respiratory rate <5 breaths per minute

Respiratory rate >36 breaths per minute

Circulation

All cardiac arrests

Pulse rate <40 beats per minute

Pulse rate >140 beats per minute

Systolic blood pressure <90 mm Hg

Neurology

Sudden fall in level of consciousness (fall in Glasgow coma scale of >2 points)

Repeated or extended seizures

Other

Any patient you are seriously worried about that does not fit the above criteria

indication of how many people may be experiencing serious adverse events that could be prevented.

Clearly, the prevalence of deterioration in hospitals depends on how deterioration is defined. Traditionally, the focus has been on deterioration that is sufficient to trigger a call to the MET or equivalent service. Although calling criteria for METs vary, they are usually based on the occurrence of serious physiological or clinical abnormalities (Box 3.3).

Both prospective and retrospective methods have been used to study the prevalence of patients with signs of deterioration. One Swedish study recorded the physiological measurements of all the adult patients in one hospital (excluding patients in intensive care and psychiatric wards) on two separate days.¹⁷ This study found that 4.5% of patients demonstrated abnormal physiological measurements that were sufficient to trigger a call to a MET. An Australian study retrospectively

Box 3.4 Responding to medical Emergencies: System Characteristics Under Examination (RESCUE)

Prof Tracey Bucknall, Cabrini-Deakin Centre for Nursing Research; Dr Daryl Jones, Austin Hospital; Dr Jonathon Barrett, Cabrini Hospital; Prof Rinaldo Bellomo, Austin Hospital; Dr Rasa Ruseckaite, Cabrini-Deakin, Centre for Nursing Research on behalf of the RESCUE investigators

A total of 1,688 patients from four private and six public hospitals were included in the RESCUE point prevalence study (76.8% participation). Patients who refused to be assessed or were unavailable during the data collection period (23.2%) were excluded. There were 1,043 public patients and 645 private patients included in the study, with an average age of 65 years. Patients were mostly female (52%), non-elective (49.6%) medical admissions (48.3%).

Data were collected using two approaches:

- documentation from observation charts for the 24-hour period prior to the day of the survey, and
- one set of observations gathered by a data collector on the day of the survey using a standard format.

Observations included heart rate, respiratory rate, blood pressure and oxygen saturation. The preliminary analysis identified the total proportion of patients who fulfilled the MET criteria on the day observations were taken as 3.31%. Figure 3.1 shows the total percentage of patients fulfilling MET criteria in the preceding 24-hour period and on the day of data collection, as well as differentiating between public and private hospital point prevalence.

Figure 3.1 Percentage of patients fulfilling MET criteria

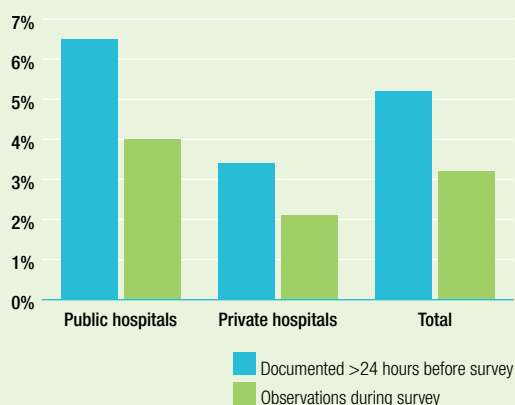


Figure 3.2 presents the percentages of elective and non-elective patients who fulfilled the MET criteria, as well as differentiating between private and public hospitals. Figure 3.3 shows the percentages of medical and surgical patients fulfilling MET criteria at the time the observations were collected. Similar to other studies, non-elective, medical patients were most frequently identified as fulfilling MET criteria.

Figure 3.2 Admission characteristics of patients fulfilling MET criteria during survey

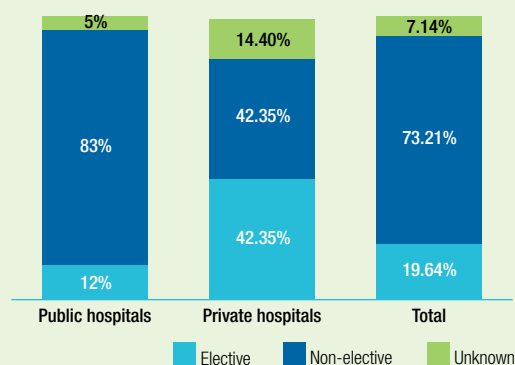
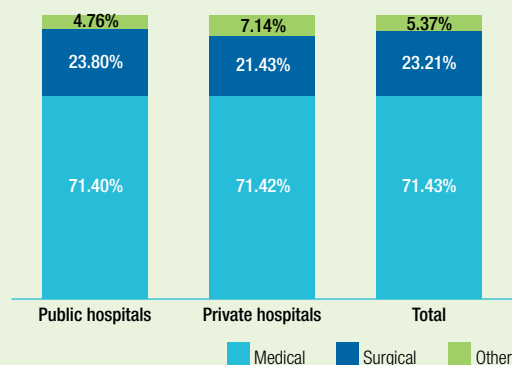


Figure 3.3 Unit characteristics of patients fulfilling MET criteria during survey



The RESCUE investigators are: Tracey Bucknall, Principal Investigator RESCUE study, Cabrini-Deakin Centre for Nursing Research; Daryl Jones, Austin Hospital; Jonathon Barrett, Cabrini Hospital; Rinaldo Bellomo, Austin Hospital; Rasa Ruseckaite, Cabrini-Deakin Centre for Nursing Research; Mari Botti, Epworth Health Care; Trisha Dunning, Barwon Health; Trish Livingston, Eastern Health; Bev O'Connell, Deakin University; Judy Currey, Alfred Hospital; Julie Considine, The Northern Hospital; David Green, Barwon Health.

reviewed the case notes of all eligible inpatients in five hospitals over a two-week period.¹⁸ This study found that 6.4% of patients had recorded physiological abnormalities that were sufficient to trigger a call to the MET. Also, over half of these patients had at least one recording of less serious abnormalities that were considered as early signs of critical conditions.

Australian researchers have recently conducted the largest study that has been done to date to determine the prevalence of these conditions among patients at a given point in time. This study was undertaken at ten hospitals in Melbourne and aimed to:

- determine the prevalence of patients at risk of a medical emergency in acute care settings by assessing the prevalence of cases where patients fulfil commonly used criteria for MET activation
- assess the frequency of failed and delayed MET activation by relating the number of cases where MET criteria are reached to the number of actual MET activations, and
- determine whether the presence of MET criteria is associated with an increased 30 or 60-day mortality, unplanned admissions to intensive care and cardiac arrests.

The results of this study will be submitted for publication in 2010. Some preliminary findings are now available and are reported in Box 3.4.

Why is deterioration not managed properly?

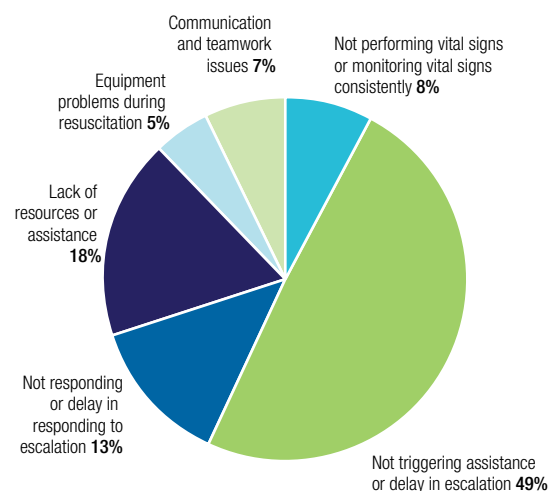
The factors that contribute to a failure to recognise and respond to a deteriorating patient are complex and overlapping. Information about the reasons why these occur comes from analyses of reports of adverse events, audits of documentation and medical records, surveys and interviews of staff providing care, and observation of care processes. Contributing factors that have been identified include:^{4 19–23}

- not monitoring vital signs consistently or not understanding observed changes in vital signs
- lack of knowledge of signs and symptoms that could signal deterioration
- failing to recognise the significance of the apparent deterioration
- uncertainty about whether assistance should be called for, or reluctance to call for assistance

- delays in notifying medical staff of the signs of deterioration
- delays by medical staff in responding to such notification
- lack of skills and knowledge about managing deteriorating patients among ward medical and nursing staff
- failure of ward staff to promptly seek supervision or advice
- failure to communicate with other staff about concerns, including in handover situations
- failure of essential equipment such as resuscitation trolleys, and
- lack of clarity about roles and responsibilities for care of deteriorating patients.

As part of the development of its Recognition and Management of the Deteriorating Patient Program, Queensland Health analysed the incidents that had been reported to its state-wide incident reporting system between January and August 2008.¹⁵ Of the 61 incidents identified, 43 related to a failure to identify deteriorating patients and 18 related to a failure to manage these patients appropriately. The most common contributing factor identified for these incidents was not triggering assistance or a delay in escalation of concerns (Figure 3.4).

Figure 3.4 Contributing factors attributed to incidents identified as relating to a failure to identify or manage acutely deteriorating patients reported to Queensland Health PRIME Clinical Incident Reporting system, January–August 2008



Systems for improving recognition of and response to deterioration

Much of the development of recognition and response systems to support the care of patients who deteriorate has come from bottom-up processes. This has meant that a range of different systems has evolved to meet the specific needs of individual hospitals. As noted earlier, the use of systems to respond to deteriorating patients is increasing and METs are becoming common. However, the use of a MET is only one aspect of the recognition, response and organisational supports that are required to provide effective care to patients who deteriorate. The limited anecdotal information that is available about the wider use of these systems suggests that their implementation and effective use is variable.

Because of the large number and wide range of possible factors that can contribute to failures in this area, formal coordinated systems are needed that operate across the entire hospital. As part of its work in this area the Commission worked with clinicians, researchers and policy makers to develop a Consensus Statement that

describes the elements that are essential for properly recognising and responding to patients who deteriorate in hospitals (Box 3.5). This statement can provide the basis for strategic policy in this area and also guide health services in developing their own systems for recognising and responding to clinical deterioration.

Recognising deterioration

Frequently, there are observable physiological and clinical abnormalities prior to an adverse event, and this provides the impetus to put systems in place to identify deterioration early, lessen the intervention required to stabilise the patient and attempt to prevent any possible later adverse events. For effective recognition of deterioration there needs to be:

- reliable and timely monitoring of vital signs
- recording of vital sign measurements in a way that can be easily understood and which prompts recognition of deterioration
- understanding by staff of the importance of measuring vital signs and the meaning of observed abnormalities

Box 3.5 Consensus Statement: Essential elements for recognising and responding to clinical deterioration

A. Clinical processes

1. *Measurement and documentation of observations:* To recognise clinical deterioration regular measurement of physiological observations is required. Observations should be documented in a structured tool such as an observation chart.
2. *Escalation protocols:* A formal documented escalation protocol that sets out the organisational response for different levels of abnormal physiological measurement is required. This applies to the care of all patients at all times.
3. *Rapid response systems:* A system that provides emergency assistance or advice quickly is required to provide appropriate care to patients who are deteriorating.
4. *Clinical communication:* Structured communication processes should be used at handover and as part of ongoing patient management to support the identification of patients who are deteriorating and communication of information about their management.

B. Organisational prerequisites

5. *Organisational supports:* Formal systems are needed to support effective recognition of, and response to, clinical deterioration. These need organisational support and executive and clinical leadership for success and sustainability.
6. *Education:* Having an educated and suitably skilled and qualified workforce is essential to provide appropriate care to patients who deteriorate.
7. *Evaluation, audit and feedback:* Evaluation of new systems is needed to establish their efficacy and determine what changes might be needed to optimise performance. Ongoing monitoring is necessary to track changes in outcomes and check systems keep operating as planned.
8. *Technological systems and solutions:* Systems for recognising and responding to clinical deterioration should consider the inclusion of technological solutions based on evidence of efficacy and cost.

- clear specifications of what level of physiological abnormality or clinical disturbance triggers a call for emergency assistance, and
- clear communication channels for staff to call for assistance, and support for them to do so.

The use of technology in supporting recognition of deterioration has been increasing, and systems have been developed in Australia (Patientrack™) and the United Kingdom (VitalPAC™) that allow nurses to directly record physiological observations into a personal digital assistant (PDA).^{24 25} Although technology such as this will probably become commonplace in hospitals in the future, it is likely that this will take some time. At the moment, paper observation charts are the primary tool for recording information about vital signs and other physiological measures, and therefore have a critical role in the identification of patients who are deteriorating.

Observation charts are an important tool for recognising deterioration

Factors that contribute to a failure to provide safe and high quality care to patients who are deteriorating include vital signs not being recorded, not understanding the significance of recorded physiological abnormalities and not calling for assistance based on these abnormalities. The way in which observation charts are designed and used can affect these issues.

There is an increasing focus on the use of observation charts to assist in recognising deterioration. This can be seen in efforts internationally and within Australia to revise and improve charts, and to incorporate specific features in them to support this recognition process.^{26–28} Some of this work has been conducted or coordinated by state and territory health departments, but much of it is also taking place in individual hospitals or wards.

One study from the United Kingdom examined five different charts used within just one hospital and found that the design of the charts had a significant effect on the ability of medical and nursing staff to detect patient deterioration, with detection rates for physiological parameters showing deterioration ranging from 0% to 100%.²⁶ Based on this analysis, a new chart was designed, and significant improvements were found in detection rates of parameters that were poorly identified initially, with rates of detection of abnormalities in respiratory rate and oxygenation increasing by 41% and 45%, respectively.

For an observation chart to be effective in improving the identification of patients who are deteriorating, it is important the chart:

- includes physiological measures that predict or are associated with the occurrence of critical illness or serious adverse events
- includes features, systems or algorithms that are effective in identifying patients who are deteriorating and in prompting action in response to identified deterioration, and
- displays information in a way that facilitates early and easy recognition that the patient is deteriorating.

Evidence about some of these issues exists, but it is patchy and findings are not always consistent. There is evidence about predictors of deterioration and the use of scoring systems to identify patients who are deteriorating. However, research about vital signs and observation charts is limited. Decisions about observation charts and measurement of vital signs are frequently based on clinical experience, intuition and tradition.^{25 29}

To support efforts in this area, the Commission is working in partnership with Queensland Health and the University of Queensland to conduct a research project to provide new knowledge about the design and use of observation charts that will assist staff to better identify clinical deterioration. This project will:

- compare existing patient observation charts to identify which charts are best in terms of recording vital signs, detecting deterioration and responding appropriately to deterioration
- examine performance in using the different charts under different situations
- create and evaluate a new chart that takes into account the best features of existing charts, and
- recommend the best patient observation chart for clinical use based on empirical evidence.

This research is currently underway. Preliminary results from the first phase of the project are summarised in Box 3.6.

Responding to deterioration

There are a number of different models for providing timely emergency advice or assistance to patients who are deteriorating in hospital. These vary mainly in terms of the composition of the teams responding to the patient who is deteriorating (led by doctors or led by nurses), the

skills of the responding team (eg whether the team is able to intubate patients) and the role of the responding team (some teams have a structured educative role as well as responding to an immediate clinical need). At this stage, there are no studies that demonstrate any difference in outcomes between these approaches.³⁰ The different models that have been developed reflect the different circumstances of organisations, particularly in terms of issues such as workforce and staffing mix. Some of the most common models are:

Medical emergency team: A MET is led by a doctor and generally includes an intensive care physician, ICU nurse and possibly other medical or nursing staff. Medical emergency teams were first developed in Australia and are the most common emergency response model used here.

Rapid response team: The terms 'rapid response team' and 'medical emergency team' tend to be used interchangeably in Australia. However, in the United States, rapid response teams tend to refer to nurse-led teams.³⁰ One study from the United States reported on a rapid response team led by a physician's assistant that included a critical care nurse and a respiratory therapist. Results for this team were similar to those found in studies of METs in terms of decreased rates of cardiac arrest.³¹

Critical care outreach: Critical care outreach teams have been primarily used in the United Kingdom. There is considerable variation among these critical care outreach teams; they are generally led by ICU nurses, sometimes with medical input.^{30 32} The role of critical care outreach teams is mainly focused on the provision of critical care services to patients on general wards, follow-up of patients from ICU, and the formal and informal education of ward staff.³²

Intensive care liaison nurse: The use of ICU liaison nurses is increasing in Australia as another way of responding to clinical deterioration. This model overlaps with the United Kingdom (UK) critical care outreach team in that it is a nursing role focusing on staff education and support, ward assessment and liaison, patient care and support, and family education and support.³³ In some cases, the ICU liaison nurse works with a MET.³⁴

Two-tier models: The first tier of this model involves a call to a member of the team with primary clinical responsibility for the patient; if there is no response or if further help is required, a second call is made to a MET or other ICU-based service. The rationale given for this

approach is that it is more appropriate that emergency care is provided by the team primarily involved (who know the patient). However, concerns have been raised that this approach could embed the problems that led to the initial development of models such as MET.

The models described here for responding to deterioration usually include either nursing or medical staff from an ICU. However, this model is not practical in facilities where intensive care services are not available, or where there is not full-time medical coverage. The types of small facilities that may need alternative models for responding to deterioration include those in rural and remote areas, some outer metropolitan hospitals and sub-acute facilities such as rehabilitation hospitals.

The way in which deterioration is recognised should not change according to the type of facility: appropriate monitoring of vital signs and interpretation of this information should always occur. It is the response to deterioration that is more likely to change based on the type or location of facilities. Staffing, skill mix and external resources all affect the way in which deterioration is managed in rural and remote health facilities.³⁵ Sometimes care is provided by short-term medical locums, and in other cases nurses are the main providers of care. Assistance from local GPs or ambulance services may need to be called. It is important that staff have the skills and authority to deliver care to deteriorating patients until further assistance is available.

One Australian hospital has claimed to have successfully implemented a rapid response system using staff from the emergency department, and there are reports of the introduction of rapid response systems in community hospitals in the United States.^{31 36 37} Despite these individual reports, there has been little specific attention paid to the needs of smaller facilities and those in rural and remote areas.

Implementing systems to improve the recognition of, and response to, patients who are deteriorating

It has been noted that 'the introduction of rapid response systems in hospitals is a complex, multi-component intervention — essentially a process of social change. The effectiveness of these systems is sensitive to an array of influences: leadership, changing environments, details of implementation, organisational history and much more'.³⁸ For this change to be effective, all of the essential elements listed in Box 3.5 need to be implemented in a coordinated way, and effort and resources need to be applied over the long term.

Box 3.6 Human factors in adult general observation chart design

Dr Mark Horswill, Ms Megan Preece, & Mr Andrew Hill, School of Psychology, The University of Queensland; Dr Rozemary Karamatic, Queensland Health Skills Development Centre; Dr David Hewett, Queensland Health Skills Development Centre & School of Medicine, The University of Queensland; Associate Professor Marcus Watson, Queensland Health Skills Development Centre & Schools of Medicine & Psychology, The University of Queensland

A three-phase project is currently being carried out by the Commission, Queensland Health, and The University of Queensland to examine human factors aspects of observation chart design. The aims of the project are to:

- (1) develop a patient observation chart that minimises user error in detecting deteriorating patients by incorporating best human factors practise
- (2) generate recommendations and guidelines for the development and evaluation of clinical charts.

The first phase of this project involved reviewing 25 charts from Australia and New Zealand. A team of evaluators with human factors and clinical backgrounds identified a total of 1,189 usability problems in the 25 charts that could potentially lead to errors while recording data or detecting deterioration (or increase the time taken to perform these tasks). The team found a dramatic variation

in the usability of different charts and that all the charts had some issues that could be improved through redesign.

Some examples of usability problems encountered are:

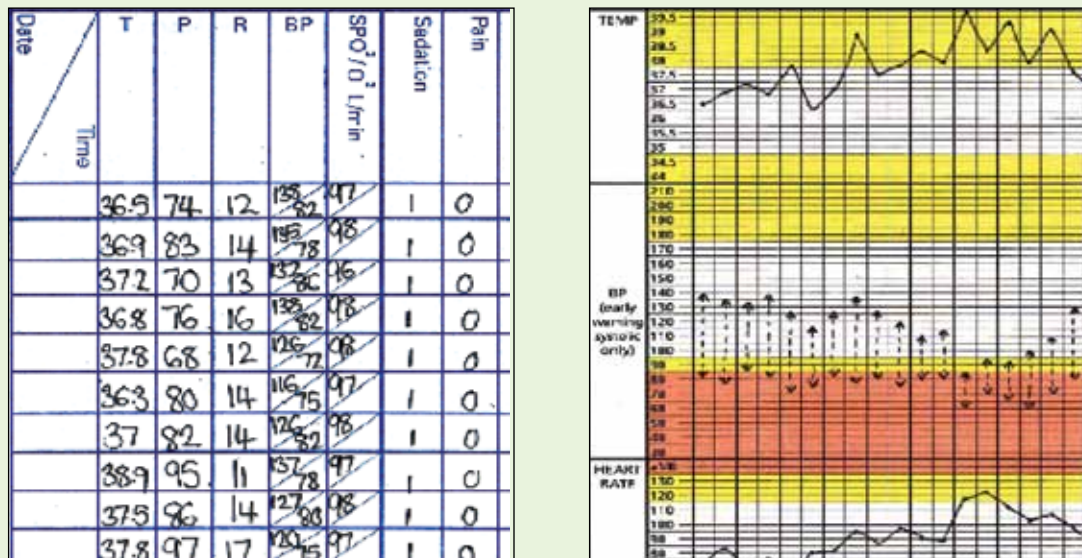
- Many charts presented vital sign data numerically where graphical presentation was considered superior for detecting deterioration (see Figure 3.5).
- Some of those charts that did use graphs required users to plot multiple overlapping vital signs on the same graph rather than plotting each vital sign on a separate graph (see Figure 3.6). This was considered to make deterioration potentially harder to detect.
- Some charts were considered to put an unnecessary burden on users' memory (eg having to turn over a page to access a look-up table in order to interpret a particular vital sign) or introduce unnecessary cognitive load (eg requiring users to add up numbers from different locations across a page to calculate a track-and-trigger measure).
- Only about one-third of the charts took advantage of the use of colour to improve chart usability.
- Many of the spaces provided for writing were too small for information to be recorded legibly by users and many of the font sizes used were too small to be easily read in low-light conditions.

Because METs and other systems have now been in place for some time in Australia and elsewhere, reports are now emerging of the success of these long-term efforts, and the elements that are needed to support implementation.

Factors that have been identified as being associated with successful implementation of these systems include:^{39–42}

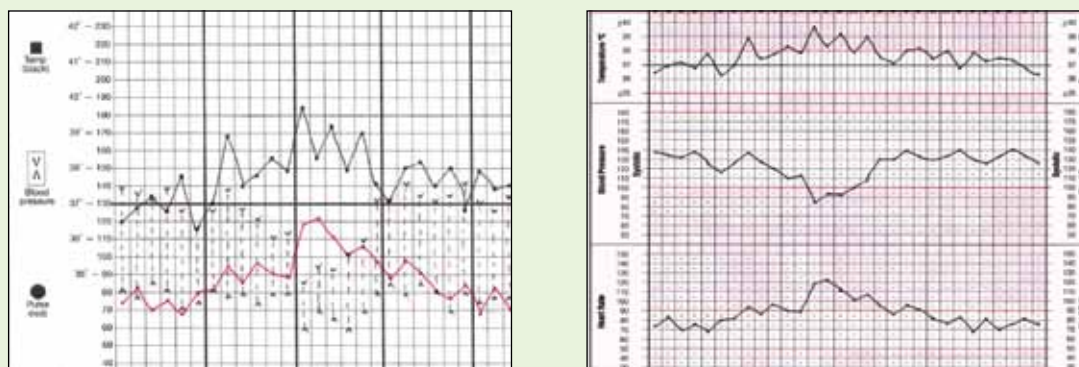
- strong, visible and unqualified support from executives and clinician managers
- actively seeking input from ward staff and making changes to systems to address their concerns
- clear, consistent and continual messages to call for emergency assistance in all circumstances
- using clear, objective criteria for calling for emergency assistance
- effective initial training and ongoing reinforcement regarding calling criteria and procedures
- ensuring staff providing the emergency assistance are competent, and have a positive approach to managing a call, including working with ward staff
- using multi-faceted communication strategies to inform staff about the new systems
- nursing staff with a positive attitude towards and high level of understanding of the MET
- conducting ongoing audits of the success of the new systems, and reviewing the results
- providing feedback to staff who call the MET, and those providing the response about individual calls, as well as trends over time, and
- committing sufficient time and resources to prepare for the introduction of new systems.

Figure 3.5 Comparison between different ways of displaying vital signs



The chart on the left displays vital sign data in numerical, the chart on the right displays the same data in graph form. It was argued that the deterioration is easier to detect in the graph form.

Figure 3.6 Comparison between different ways of plotting vital signs



The chart on the left has three vital signs plotted on the same graph, the chart on the right displays the same data on separate graphs. It was argued that the trends in the data are clearer when the plots are separated.

The team then developed a draft of a new chart intended to avoid as many of these design problems as possible by combining the best elements of existing charts.

The second phase of this project involves an online survey that will canvas the opinions and preferences of health professionals regarding chart design. For example, respondents will be shown a number of different methods for displaying vital sign data and asked which they prefer. The results from this survey will be used to identify current preferred representation of clinical information. Where appropriate, this information will be used to improve the design of the new chart.

The third phase of the project involves a series of simulation studies examining the extent to which the design of charts influences the potential for documentation and process errors. In order to discover which chart leads to the fewest number of errors in recording data and detecting deterioration, the team will be asking novice and experienced chart users to fill in and interpret a number of charts in the ward simulation suite at the Queensland Health Skills Development Centre. Participants will be given the task of monitoring the vital signs of a number of simulated patients in the ward over a period of hours under realistic workload and their errors will be analysed to see which charts lead to a better rate of correct recognition of deterioration.

Box 3.7 The Early Recognition of the Deteriorating Patient Program in the ACT

Dr Imogen Mitchell, The Canberra Hospital & Ms Heather McKay, ACT Health

The Early Recognition of the Deteriorating Patient Program (ERDP) in the ACT aimed to improve the documentation and recognition of deteriorating vital signs and the timeliness of medical review. The ERDP is a multi-faceted intervention that includes a track-and-trigger system, a new observation chart and a locally developed COMPASS® education package, which aims to bring physiology to the bedside and provide an understanding of why we measure vital signs. The initial pilot on four wards at two hospitals showed improvements, including an increase in vital sign measurement, a decrease in unplanned ICU admissions and cardiac arrests, an increase in MET reviews and a reduction in the number of hospital deaths. Success of the pilot rollout has occurred across inpatient areas. Current audits of the program include monthly documentation audits in all clinical areas, as well as analysis of the vital signs in the 24 hours prior to each MET callout.

Evaluation post-rollout of the program has demonstrated sustained improvements in several

areas. There has been an increase in frequency of measurement of all vital signs in the 24 hours prior to a MET callout with a particular improvement in respiratory rate documentation. The accuracy of a correct modified early warning score (MEWS) has improved since the first audits from 49% to 82%, and the time to medical review from the initial communication reduced from 76 minutes to 31 minutes.

Sustainability of improvements is achievable, however, ongoing auditing, support and education are essential. A clear governance structure is crucial, as well as executive level support and stakeholder involvement. The delivery of the educational component of the program at the local undergraduate educational institutions has also been beneficial in changing the culture of how vital signs are interpreted. The program has proven to be easily adaptable to facilities within the ACT as well as in rural hospitals. There continues to be ongoing commitment to the program within ACT Health and resources have been made available to other facilities, at no cost, on the program's website www.compass.act.gov.

Are patients safer because of the introduction of these systems?

There have been numerous studies published about the impact of systems introduced to improve the care of patients who deteriorate in hospitals. Most of these studies have looked at the number of adverse events, such as cardiac arrests, unexpected deaths and unplanned admissions to intensive care before and after the introduction of new systems.^{10 34 43–47} Generally, these systems have been found to be beneficial in terms of reduced deaths, cardiac arrests, hospital length of stay, length of stay in intensive care and cost.³⁰

However, only two randomised controlled trials in this area have been published.^{5 48} One Australian study found no difference between hospitals randomised to introduce a MET service and those without a MET in terms of rates of occurrence of cardiac arrest, unplanned admission or unexpected death.⁵ The other study examined the introduction of a critical care outreach team at ward level in a single hospital in the UK.⁴⁸ This study found

a reduction in hospital mortality for patients in the intervention wards.

Three systematic reviews of rapid response systems have concluded that there is insufficient evidence to conclusively state that the introduction of systems such as MET are effective.^{49–51} The reasons for this conclusion are associated with the fact that most of the studies that have found improvements are uncontrolled 'before and after' studies that are not as methodologically strong as randomised controlled trials.

Despite these findings, there is a consensus that the evidence that exists is sufficient to support the use of systems for recognising and responding to deterioration, particularly given the face validity of the concept, lack of adverse outcomes and modest cost implications.^{30 52} Also, some proponents consider that randomised controlled trials are not the best model to examine the impact of the introduction of organisational systems such as these, and that evaluation approaches that can be used in complex social systems may be more effective.^{38 53} Furthermore, studies are now being

published that demonstrate the effectiveness of systems such as METs in different ways. Two recent studies have demonstrated that patients for whom a MET call is delayed experience greater mortality,^{54 55} and another study has demonstrated that an increase in the number of MET calls is associated with a decrease in overall cardiac arrests and unexpected deaths.⁵⁶

Where to next?

Over the last decade, there has been an increasing move internationally towards the systematic promotion and implementation of systems to improve the recognition of and response to deterioration of patients by health departments and other institutions that support safety and quality.^{57–59} The use of formal systems to support the recognition of, and response to, deterioration of patients in hospitals is now being recommended in clinical guidelines.⁶⁰

This has been mirrored in Australia where there are now programs in place in a number of states and territories, as well as at a national level.^{14–16} These programs will support a coordinated and consistent approach to the recognition of, and response to, deterioration of patients in hospitals.

Research regarding the recognition of, and response to, clinical deterioration is continuing, and there is an active and growing international community of researchers that is contributing to the evidence base. As demonstrated by the presentations at the 5th International Rapid Response Systems Conference in May 2009 (rapidresponsesystems.org/), the focus of much of this new research is on identification of patients at risk of deterioration, implementation of systems to improve the recognition and response to clinical deterioration, examination of ways existing systems can be improved and refined, and exploration of the reasons why there continue to be failures in this area. This type of research will improve the way that these recognition and response systems operate. Innovative approaches to examining human behaviour, such as human factors and sociological analysis, will also assist in understanding how people use the systems and why failures may occur.

Patients being cared for in hospitals are sick, and deaths in hospitals will always occur. Ideally, the only deaths that should occur in hospitals are those that are expected (such as those for patients with a not-for-resuscitation or similar order): preventable deaths and other preventable adverse events should not occur. This ideal has not been,

and possibly cannot ever be, achieved. However, the systems that have been discussed in this chapter are helping to reduce preventable deaths and serious adverse events by ensuring that signs of clinical deterioration are recognised early, and that they are responded to appropriately.

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4

Antimicrobial stewardship

Antimicrobials are chemical substances that inhibit or destroy bacteria (antibiotics), viruses (antivirals), fungi (antifungals), yeasts or moulds. The introduction of antimicrobial agents must be considered as one of the most significant milestones in modern medicine and a major contributor to the demise of infectious diseases as the major cause of premature death in the latter half of the 20th century. Previously feared and often fatal infections became 'miraculously' curable and the treatment seemed so safe and effective that doctors often prescribed antibiotics for dubious indications and for longer than necessary — in case they may help — with little concern for adverse effects. For many years, the development of resistance by some bacterial species caused little alarm, because new, more effective agents with broader antibacterial spectra were being developed.

However, over the last 40 years, the prevalence of multi-drug resistant bacterial pathogens such as methicillin-resistant *Staphylococcus aureus* (MRSA) has risen alarmingly. Initially, the prevalence rose mainly in hospitals, but now it is increasing in the community. Few truly novel antibiotics have been developed recently. Also, there is little incentive for pharmaceutical companies to invest in development of new agents whose use is now increasingly (and appropriately) restricted.

The consequences of antimicrobial resistance are now well known. Patients with infections due to resistant bacteria experience delayed recovery, treatment failure or even death.¹

There is good evidence that overall rates of antibiotic resistance correlate with the total quantity of antibiotics used, as determined by the number of individuals treated, prior exposure and the average duration of each treatment course.^{2,3} Some antibiotics promote the development of resistance more readily than others, depending in part on the breadth of their antibacterial spectrum. In individuals, the risk of colonisation and infection with multi-drug resistant bacteria correlates strongly with previous antibiotic therapy.

Unnecessary antimicrobial use for self-limiting or non-infective illness, and inappropriate antibiotic choice, dose or duration of therapy drive the selection of resistant bacteria, disrupt normal bacterial flora and increase the risk of colonisation with resistant organisms with the risk of subsequent transmission to others. Inappropriate antimicrobial use increases morbidity and mortality due to avoidable drug toxicity, sub-optimal treatment of the original infection or subsequent infection with multi-resistant bacteria or fungi.^{4–6} When multi-resistant pathogens are prevalent, clinicians are forced to use broader spectrum and usually more expensive agents to treat seriously ill patients with sepsis. All of these effects contribute to increasing healthcare and societal costs.¹

Studies have demonstrated that as many as 25–50% of antibiotic regimens prescribed in hospitals are considered inappropriate.^{7,8} The reasons for the continued unnecessary or inappropriate use of antibiotics, in the face of increasing antibiotic resistance and availability of well-established evidence-based treatment guidelines, are varied.

Antibiotic resistance develops slowly and although much is known about the causes, it is difficult to attribute the effects to specific actions or decisions. Doctors may be

unaware that guidelines are available, may be too busy to consult them, may be confident that they know the best antibiotic choice, or may remain unconvinced of the risks entailed in their inappropriate use. Many are unwilling to withhold antibiotic therapy if the diagnosis is uncertain or risk treatment failure by using a narrow spectrum agent, which may not cover all possible pathogens.

Courses of antibiotics are often continued for longer than necessary because the prescription was not time limited and no-one has remembered to cancel it.⁹ Consumers can also contribute to the overuse and inappropriate use of antimicrobials by applying pressure on their doctor to prescribe antibiotics, for example, for a viral infection such as the common cold.¹⁰

As antimicrobial resistance increases and development of new antimicrobial agents declines, it is critical that we use those that are still effective wisely and judiciously.

An antimicrobial management program — known as antimicrobial stewardship — involves a systematic approach to optimising the use of antimicrobials. Effective hospital antimicrobial stewardship programs have been shown to decrease antimicrobial use and improve patient care.⁴ Along with infection control, hand hygiene and surveillance, antimicrobial stewardship is considered a key strategy in local and national programs to prevent the emergence of antimicrobial resistance.

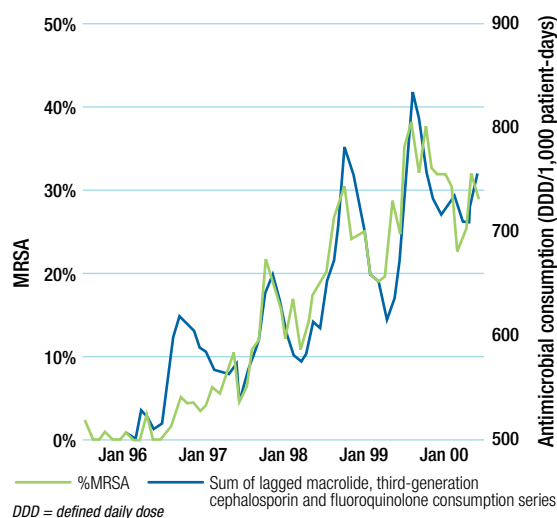
The problems

We know that the inappropriate use of antimicrobials leads to the emergence of resistant bacteria, an increase in the risk of patient harm from side effects, infection with multi-resistant bacteria or *Clostridium difficile*, and unnecessary costs.

Antimicrobial usage in Australia

Prior patient exposure to antimicrobials is a key risk factor for colonisation and infection due to antibiotic resistant bacteria and *Clostridium difficile* infection. These infections usually add to the overall infection load of a patient rather than merely replacing existing cases of infection caused by less resistant pathogens. Evidence from community and hospital practice shows that use of systemic antimicrobials is often indiscriminate or ineffectively targeted against the likely or proven pathogen.

Figure 4.2 Monthly rates of methicillin-resistant *Staphylococcus aureus* (MRSA) and monthly antimicrobial use (Aberdeen Royal Infirmary, Scotland, January 1996–December 2000)¹³

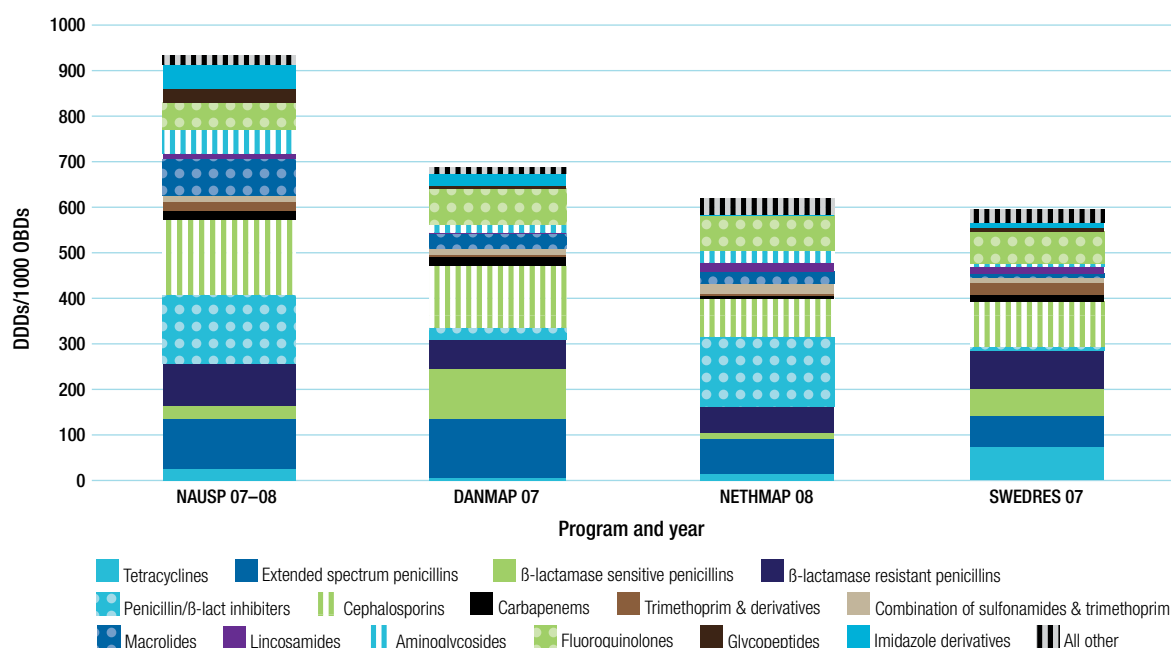


Data collected through the National Antimicrobial Usage Surveillance Program (NAUSP) over 12 months in 2007–2008 demonstrates a higher overall rate of inpatient antimicrobials in Australian hospitals compared to hospitals in northern Europe (Figure 4.1). Although it is acknowledged that these data are incomplete (representing only 48% of Australian major city centres), comparison with international data shows that Australian antimicrobial usage rates in hospitals are particularly high for some antimicrobial classes.

In Australian hospitals reporting data to NAUSP, the use of antimicrobials such as cephalosporins and macrolides appears to be higher than in other countries. There is good evidence that there is a dynamic, temporal relationship between monthly prevalence of MRSA in hospitalised patients and the use of macrolides, third-generation cephalosporins and fluoroquinolones in previous months. Figure 4.2 shows the total monthly use of these antibiotics in a Scottish hospital (taking into account their respective lags for direct effects) plotted against monthly MRSA prevalence.^{12, 13} The relationship between the use of these specific antibiotic classes and MRSA prevalence is striking.

The monitoring and analysis of antimicrobial usage are critical to understanding antibiotic resistance. Comprehensive, integrated surveillance programs operate in the United States and Europe, where programs include the European Surveillance of Antimicrobial Consumption, the Danish Integrated Antimicrobial Resistance Monitoring and Research Program, a surveillance program for antimicrobial consumption and resistance in the Netherlands, and the Swedish *Antimicrobial Utilisation and Resistance in Human Medicine* report. In Europe, reports on antimicrobial consumption and resistance are published annually. Currently, Australian hospital antimicrobial use data are incomplete and are not linked with resistance surveillance data. This limits their potential use.

Figure 4.1 Comparison of aggregate antimicrobial usage rates in Australian hospitals (National Antimicrobial Usage Surveillance Program data) with international bench marks



DANMAP = Danish Integrated Antimicrobial Resistance Monitoring and Research Program; DDD = defined daily dose; NAUSP = National Antimicrobial Utilisation Surveillance Program; NethMap = surveillance program for antimicrobial resistance in the Netherlands; OBDS = occupied bed days; SWEDRES = Swedish Antibiotic Utilisation and Resistance in Human Medicine
Source: National Antimicrobial Utilisation Surveillance Program, Annual Report 2007.

Impact on patients

Inappropriate antimicrobial use increases the risk to patients of colonisation and infection with resistant organisms and subsequent transmission to other patients. Patients with antimicrobial-resistant infections experience the consequences of ineffective treatment, recurrent infection, delayed recovery or even death.¹ Turnidge et al reported that one in five Australian and New Zealand patients diagnosed with *Staphylococcus aureus* bacteraemia died and that patients with MRSA infection had a higher mortality rate than those without.¹⁴ Roberts et al reported that twice as many patients with antimicrobial-resistant infections died compared with patient with non-resistant organisms.¹

Antimicrobials can cause serious harm from avoidable adverse drug reactions and interactions with other drugs. Some examples include life-threatening hypersensitivity reactions with penicillins; cardiac arrhythmias with macrolides, some antifungals and most fluorquinolones; and kidney damage with aminoglycosides and amphotericin B. Inappropriate use can also increase morbidity and mortality due to suboptimal treatment of the original infection or subsequent infection with multi-resistant bacteria, fungi or *Clostridium difficile*.⁴⁻⁶

Costs

The emergence and selection of resistant bacteria and other organisms, driven by inappropriate antimicrobial use

and subsequent transmission among hospital patients have a significant impact not only on healthcare costs but also on societal costs. Additional healthcare costs of infections caused by resistant organisms include:

- the need for more expensive antibiotics to treat the infections
- the need to isolate patients colonised with resistant organisms in order to prevent cross-infection, and
- increased length of stay resulting from delayed recovery.

In 2009 in the United States medical costs attributable to antimicrobial-resistant infections were estimated at US\$18,500 to US\$29,000 per patient and an excess length of stay of 6.4–12.7 days. Roberts et al also estimated significant societal costs resulting from mortality and the cost of lost productivity.¹

Another cost is the inappropriate prescribing of expensive broad-spectrum antibiotics. The existing NAUSP data demonstrates an unexplained wide variation in usage rates for these agents.¹¹ Although this variation may be due to differences in patient-mix and acuity, the degree of variation seen across 23 large tertiary hospitals suggests that different approaches to controlling antibiotic usage are also in use and, presumably, some are more effective than others.



In Australia, it has been estimated that \$300 million of the Australian national health budget could be re-directed to better use if there was optimal antimicrobial use and containment of antimicrobial resistance.¹⁵ These savings incorporate improved treatment outcomes for patients, improved productivity through fewer sick days, and reduced use of costly antimicrobials to treat resistant infections.

What the Commission is doing about these problems

Improving the safe and appropriate use of antimicrobials is an important component of patient safety in hospitals.¹⁶ Along with infection control, hand hygiene and healthcare associated infection (HAI) surveillance, antimicrobial stewardship is a key component of a multi-faceted, multi-disciplinary approach to preventing emergence of antimicrobial resistance and decreasing preventable HAI. One of several initiatives in the Commission's HAI Program⁴ to prevent and contain antimicrobial resistance will be the publication of *Reducing Harm to Patients: The Role of Antimicrobial Stewardship Programs in Australian Hospitals*.¹⁷

The publication, designed for clinicians and health administrators, describes the elements of an antimicrobial stewardship program and the evidence to support its inclusion in hospital quality and safety programs to improve the selection and use of antimicrobial therapy

and to reduce adverse outcomes from inappropriate use. Restrictive and educational strategies are described, along with guidance on developing and introducing a stewardship program, the cultural changes required and the resources needed for an effective program.

Antimicrobial stewardship

Antimicrobial stewardship programs have been defined as 'an ongoing effort by a health-care institution to optimise antimicrobial use among hospital patients in order to improve patient outcomes and reduce adverse consequences of antimicrobial use (including antimicrobial resistance and unnecessary costs)'.¹⁸

Stewardship programs aim to change antibiotic prescribing behaviour to reduce unnecessary use and promote the use of agents less likely to select resistant bacteria, in line with guidelines and demonstrated incidence of antibiotic resistance.¹⁹

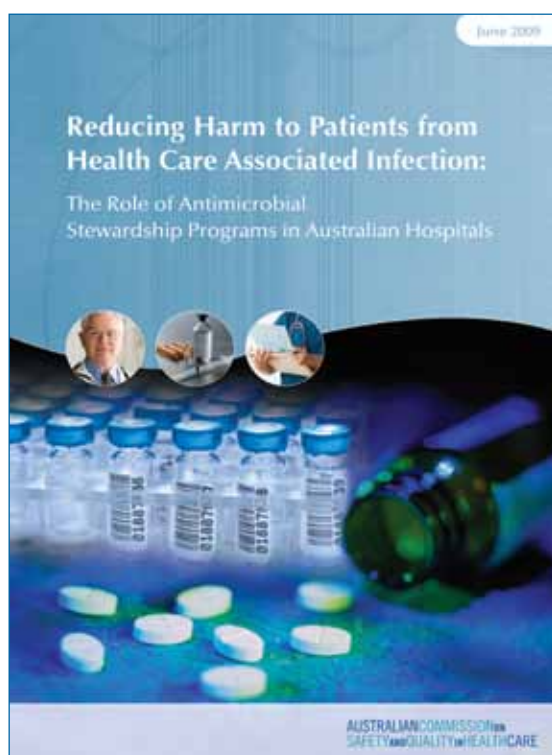
Comprehensive programs have demonstrated an overall reduction in antimicrobial use by 22–36%⁶ and substantial pharmacy cost savings.^{4, 8} Successful programs have been shown to improve the appropriateness of antibiotic use, reduce institutional resistance rates as well as morbidity, mortality and health care costs.^{11 18 20} Although data on the economics of antimicrobial stewardship programs are limited, maintaining an antimicrobial stewardship team to optimise treatment of bacteraemia has been shown to be cost effective.⁸

Stewardship programs are multi-disciplinary; they utilise the expertise and resources of infectious diseases physicians, clinical microbiologists and pharmacists. Their success depends on the explicit support of the hospital administration, the allocation of adequate resources and the cooperation and engagement of prescribers.

Case study 1 is a good example of the costs and benefits of a successful antimicrobial stewardship program in an Australian hospital.

Elements of antimicrobial stewardship programs

The requirements for successful antimicrobial stewardship programs in hospitals are well described in the literature.^{18 20 9 21 22} Minimum antimicrobial stewardship measures have been developed²³ and evidence-based guidelines⁴ and recommendations for good antimicrobial



Case study 1 Effect of an active antimicrobial stewardship program in a large tertiary hospital

A large tertiary teaching hospital in New South Wales has had an active approach to antimicrobial stewardship for many years, underpinned by locally relevant antimicrobial guidelines and enthusiastic staff in the areas of pharmacy, infectious diseases and microbiology. Clinical teams are regularly engaged in guideline review, development, and implementation at local and national levels. Specific discussions about patients are prompted by an online anti-infective registration (approval) system, where clinicians who prescribe broad-spectrum agents register the indication for use and are advised on correct dosage. Twice-weekly infectious diseases and microbiology patient rounds take place in intensive care units (ICUs). These frequently lead to changes in antimicrobial therapy, generally to early cessation.

A drug usage evaluation (DUE) pharmacist regularly audits antimicrobial use for particular agents, and clinical syndromes or situations (mainly community-acquired pneumonia and surgical prophylaxis). These audit data are used to provide feedback to clinicians to encourage more appropriate use.

Monthly data on usage are supplied to the NAUSP. This allows for benchmarking of ICU and non-ICU use against 22 other large Australian hospitals. A study of usage of selected high-cost (predominantly broad-spectrum) antibiotics in 2006 indicated that, for most agents, use in ICU and non-ICU situations in this hospital was far lower than the national average. Based on purchase cost alone, the net cost difference in 2006 was \$278,000 (\$59,000 of this was for ICU use lower than the national average).

practice in hospitals published.²¹ All contain a range of common elements, some core strategies that should be included in all programs, activities to complement core strategies, and the structure and authority required to implement a successful antimicrobial stewardship program.

Through its HAI program, the Commission has developed evidence-based recommendations, which include the following strategies for antimicrobial stewardship programs in Australian hospitals.

Essential strategies for all hospitals

The Commission has developed four essential strategies for all hospitals:

- Implementation of clinical guidelines that are consistent with the latest version of *Therapeutic Guidelines: Antibiotic*²⁹ and incorporate local microbiology and antimicrobial-susceptibility patterns.
- Formulary restriction and approval systems that include restriction of broad-spectrum and later generation antimicrobials to patients for whom their use is clinically justified.
- Clinical microbiology laboratory reporting of restricted susceptibility-testing results that are consistent with institutional antimicrobial treatment guidelines.
- Review and audit of antimicrobial prescribing with intervention and direct feedback to the prescriber.

Activities according to local priorities and resources

The Commission recommends the following five activities in relation to local priorities and resources:

- Effective education of prescribers and pharmacists about antimicrobial use, the development of antimicrobial resistance and the sensible prescribing of antimicrobials.
- Point of care interventions including:
 - streamlining or de-escalation of therapy
 - dose optimisation, and
 - parenteral to oral conversion.
- Use of information technology, such as electronic prescribing with clinical decision support and online approval systems.
- Monitoring performance of antimicrobial prescribing by collection and reporting of unit- or ward-specific antimicrobial-dispensing data; directed evaluations of antimicrobial use and application of Quality Use of Medicines antimicrobial indicators.
- Annual publication of facility-specific antimicrobial susceptibility data.

Structure and governance of the program

The Commission recommends that the following structure and governance strategies be put in place for an antimicrobial stewardship program:

- Support and collaboration of hospital administration including dedicated resources for stewardship activities, education, and measuring and monitoring antimicrobial use.
- A multi-disciplinary antimicrobial stewardship team with core membership of an infectious diseases physician, clinical microbiologist or other nominated clinician (lead doctor) and a clinical pharmacist.
- Antimicrobial stewardship resides within the hospital's quality improvement and patient safety governance structure with strong links between the stewardship team, and drug and therapeutics and infection control committees.

Antimicrobial usage data

One of the key components of successful antimicrobial stewardship programs is measuring the effectiveness of the program activities. In antimicrobial stewardship, this is usually achieved by measuring antimicrobial use, auditing the quality of prescribing and monitoring processes, and monitoring outcome measures. The information is used to provide feedback to prescribers and inform the local antimicrobial stewardship team and the drug and therapeutics committee of the effect of stewardship initiatives on antimicrobial use and resistance patterns.

The monitoring and analysis of antimicrobial usage is critical to understanding antibiotic resistance. It is also essential to identify trends in use that require further investigation through targeted audits and antimicrobial evaluation studies. It is also essential for the provision of feedback to prescribers as part of educational programs to influence prescribing behaviour. Surveillance data can be used to identify changes in use that may be linked to development of resistance and to measure the impact of antimicrobial stewardship programs.

The three key components of an effective surveillance system for collecting antimicrobial use and resistance data are:

- integrated and standardised surveillance methods
- automated data collection and recording, and
- data comparison and feedback.

Methods of antimicrobial data collection in Australia differ across the states and territories. Data are obtained from pharmacy computer records and are not linked to patients or to prescribers. This limits their use in measuring the quality of prescribing. Computerised decision-support systems for antimicrobial prescribing have been developed and are in use in several Australian hospitals.²⁴ These systems can be used to measure adherence to hospital guidelines for prescribing antimicrobials and provide information on the appropriateness of prescribing.

Despite its limitations, broad-scale surveillance of antimicrobial-use data obtained from hospital pharmacy systems is useful on many levels. It currently provides the most accurate indication of which antimicrobials are being used and where, it brings trends in prescribing into focus and may allow more time-efficient use of drug usage evaluation (DUE) resources to be directed towards real changes in prescribing volumes. In Australia, the national antimicrobial data collection is undertaken by NAUSP, which provides monthly reports on hospital inpatient antibiotic use to contributing hospitals, and reports every two months to the Australian Commonwealth Department of Health and Ageing. Data are contributed by 48% of major city hospitals from six states. Corresponding national rates, calculated from aggregate data, are included in the reports for comparison.⁵

Those hospitals contributing data to NAUSP use the information to monitor stewardship interventions. Case study 2 demonstrates the usefulness of surveillance of antimicrobial use.

Analysis of usage data from NAUSP for 2004–2008 shows total aggregate antimicrobial consumption has remained relatively static.¹³ However, there are both upward and downward trends in use of individual antimicrobial classes and agents within classes. Increasing use of antimicrobials has been demonstrated in some hospitals, providing targets for possible intervention programs. Comparison with international data shows that Australian usage rates in hospitals are high for some antimicrobial classes; however, unlike the individual country surveillance programs described earlier, Australian data are not linked to resistance data. This limits their use in identifying areas for intervention or measuring areas of improvement.

Conclusion

Antimicrobial resistance contributes to poor patient outcomes and threatens to undermine the great advances in treatment of infectious diseases that have occurred over the past 40 years.

Comparison with international data demonstrates that Australian usage rates in the contributing hospitals remain high for some antimicrobial classes.

The emergence and selection of resistant bacteria and other organisms, driven by inappropriate antimicrobial use and subsequent transmission among hospital patients, have a significant impact on morbidity, mortality and treatment costs due to prolonged hospital stays and the

need for more expensive drugs.²⁵ Patients with resistant infections are twice as likely to die and \$300 million of the Australian national health budget could be re-directed to more effective use every year if there was optimal antimicrobial use and containment of antimicrobial resistance.^{15 26 27 28} The estimated savings incorporate improved treatment outcomes for patients, improved productivity through fewer sick days and reduced use of costly antimicrobials to treat resistant infections.

The elements of an effective hospital antimicrobial stewardship program for this country have now been defined, but further work is required to expand and optimise the use of antimicrobials in Australian hospitals.

Case study 2 Use of ceftriaxone at a hospital

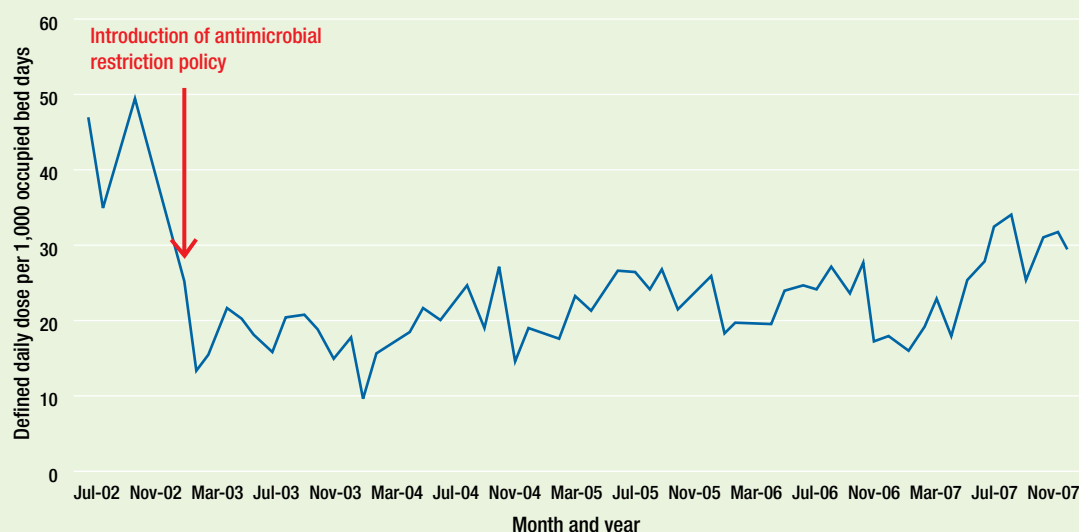
High usage of third-generation cephalosporins in South Australian metropolitan hospitals was noted in 2002 through data collection and analysis by the South Australian Antimicrobial Usage Surveillance Program. One hospital implemented an antimicrobial-restriction policy in January 2003, with a focus on community-acquired pneumonia treatment protocols, which had been identified through a pharmacy audit as an area that uses ceftriaxone inappropriately.

Figure 4.3 shows that the use of ceftriaxone decreased significantly following the implementation

of the new policy and that this level of use was sustained for about four years. However, ceftriaxone use appears to again be on the rise. This has been at least partly attributed to the lack of input from specialist antimicrobial pharmacists in recent years; a follow-up intervention is being considered.

This case study demonstrates the usefulness of surveillance of antimicrobial use. Surveillance allowed the detection of high usage of a specific group of agents; this stimulated investigation and the implementation of a targeted intervention, which was followed by monitoring of the effect of the intervention.

Figure 4.3. The use of ceftriaxone over five years following the introduction of an antimicrobial restriction policy



The challenge for Australian healthcare providers is now to actively work to reduce the growing and unnecessary adverse impact of antimicrobial resistance on patients by implementing strong and effective antibiotic stewardship programs. Failure in this endeavour will inevitably lead to increasingly limited treatment options for patients infected with resistant pathogens and a steadily increasing waste of limited health dollars in unnecessary treatment.

The Commission will continue to work with governments, healthcare professionals and the healthcare system to develop this important work further.

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5

Learning from complaints

With thanks to the Australasian Health Complaints Commissioners

Patient complaints have the potential to create a great deal of fear in the medical community. This fear is based on the unknown — where exactly will the complaint go and what will the repercussions be for both the healthcare facility and the clinicians involved? Incidents that lead to complaints have the potential to significantly alter the clinician–patient relationship, with many patients feeling anger and a loss of trust. But if complaints are dealt with effectively and address the patient's concerns, they can provide an opportunity for healing and an insight into healthcare delivery and how it may be improved. Currently, patient complaints represent one of the few mechanisms for the patient voice to be heard in health care.

Making health care more patient focused is an important aspect of improving its safety and quality.¹ One way of achieving a greater patient focus is to use patient complaints as a catalyst for service improvement. Informing patients of their rights forms the basis of a shared understanding of how health care will be provided.² However, patients do not always know and are not routinely advised of their rights. This can limit the effectiveness of a patient's participation in the management of their own health care.³

The majority of complaints can be fully resolved at the point of service, and many resources and policies have been developed to assist clinicians in handling complaints at the local level.⁴ Some jurisdictions track complaints and their resolution in their incident reporting and management systems.⁵ However, organisational responses to complaints are not always satisfactory and do not always involve the patient, even though patients can provide a unique perspective and can help identify safety and quality solutions that are innovative and important.⁶

If a patient or family member has a concern that has not been adequately addressed by the health practitioner or facility, they can make a complaint to the Health Complaints Commissioner (HCC). All states and territories of Australia have a statutory officeholder responsible for healthcare complaints. Although the legislation in each jurisdiction differs, HCCs share a common objective: the independent, impartial resolution of health complaints as one means of improving the safety and quality of health care.⁷

Common reasons for complaints

Not all adverse incidents result in a patient complaint. Patients and their representatives make complaints for a variety of reasons. However, there is a common thread that motivates complaints made to healthcare organisations: safety and quality improvement.

The three major reasons cited by those who have lodged a healthcare complaint are that they want an:

- explanation of the events leading to their complaint
- apology, and
- assurance that the same mistakes will not be made in the future.

There are many factors that must be considered by patients and their representatives before they complain

about an aspect of their health care. For instance, when an incident prompts a patient to complain, it may also affect their ongoing health care. Many patients report that they would never return to the health professional who was the subject of their complaint. This has implications for the continuity of their care. The reluctance to return to a healthcare professional or service after making a complaint may also inhibit a patient's willingness to complain in the first place.

Consequently, for a patient to make a formal complaint, they must feel strongly that their complaint will make a difference to the standard of care, both for themselves and for the community at large. Therefore, patient complaints should be viewed with respect and dealt with as a critical part of quality assurance. They provide both a window into patient expectations of the healthcare system and a unique perspective into how to improve healthcare delivery.

Patient expectations of the complaints process

Patients lodge complaints with the expectation that their complaint will be dealt with respect and that it will ensure that any systemic issues will be addressed. The markers of effective complaints management include, but are not limited to, being responsive to the concerns of the patients and their families, investigating and addressing systemic issues, and managing any identified standard of care problems.

Ensuring that patient expectations are met and that they are satisfied with the complaints process is challenging. It requires, from the outset, a clear explanation of what can realistically be achieved through the complaints process. New South Wales Health has determined that satisfaction for a complainant is achieved through:

- an objective mechanism for monitoring clinical processes as an alternative to reliance on peer review and self-regulation
- recognition and acknowledgement of the person's right to complain
- a demonstration of the health service's commitment to providing a quality service, and
- a demonstration of the health service's ability to respond effectively and efficiently.⁸

The ability to manage patient expectations of what the complaints process will deliver is fundamental to ensuring their satisfaction. It has been found that most

people who complained formally about their health care were not satisfied with either the complaints process or outcome.⁹ What is clear from research is that patients wanted stronger action taken. Such action ranged from disciplinary action for the clinician involved, to merely an acknowledgement of the harm that was done. It is of interest that only a small percentage of those who complained sought compensation. This may reflect the fact that those who take the time to complain are more likely to be motivated by quality assurance and altruism.

The Australian Charter of Healthcare Rights and patient complaints

The Australian Charter of Healthcare Rights (the Charter) was developed to underpin the provision of safe and high quality care and support a shared understanding of the rights of patients and consumers between those seeking health care, and those providing health care.¹⁰ In July 2008, Australian Health Ministers agreed that a single Charter would be identified as a clear statement of a minimum set of standards for healthcare rights, expectations and entitlements that is uniformly applicable across all states and territories.¹⁰ The Charter was the focus of a chapter in *Windows into Safety and Quality*

in *Health Care 2008*¹¹ and an update on progress with implementation of the Charter is included in the 'Retrospective' chapter of this report.

HCC complaints provide unique insights into the patient experience, patient-reported incidents, healthcare provider responses and lessons for improving health care.⁵ This chapter considers what complaints can reveal about the respecting of patients' rights, as stated in the Charter.

Complaints Commissioners are progressively adopting a uniform classification system for healthcare complaints. This system classifies complaints into 12 categories, each containing a number of core issues. At the request of the Australian Commission on Safety and Quality in Health Care (the Commission), the HCCs classified their data according to the seven rights in the Australian Charter of Healthcare Rights. This information was then compiled for this chapter (Figure 5.1).

This mapping demonstrated that the two Australian healthcare rights that had the most complaints categorised against them were safety and communication.

Case studyⁱ

An elderly woman suffered a fall at home. She was taken to the Accident and Emergency (A&E) ward by her daughter at around 11.00 am. She was not seen by a doctor until 5.30 pm. The daughter believed that her mother's condition had deteriorated while she was waiting. She reported that when she tried to advise nursing staff of her concerns she was told that her mother must wait her turn.

The mother remained in A&E until the next morning when she underwent a CT scan. The scan showed that she had suffered a stroke and she was admitted to the hospital. As she displayed signs of confusion, she was placed under mechanical restraint. The next day the restraint was removed and she subsequently suffered a fall, fracturing her right leg.

The daughter made a complaint to the Healthcare Complaints Commissioner. The issues considered by the Commissioner were: why it took so long for

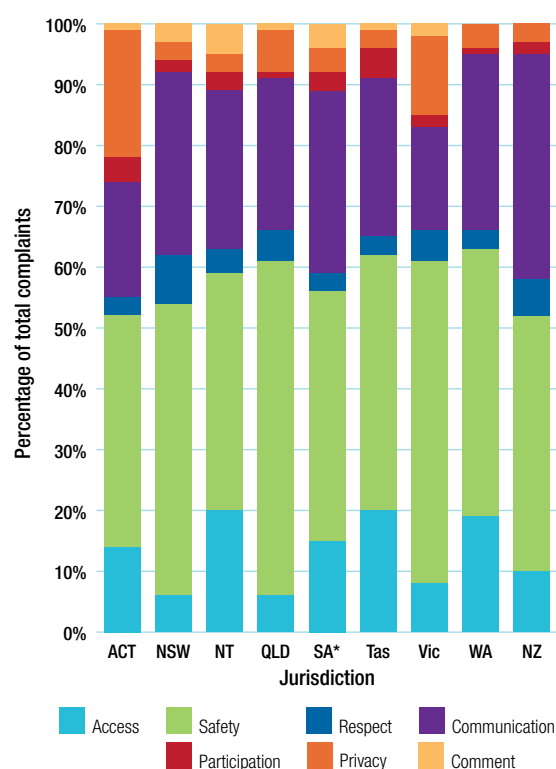
the woman to be seen in A&E, whether the delay compromised her recovery and why the restraints were removed.

As a result of the complaint the hospital chose to make a number of changes to practice.

These included:

1. amendment to the triage policy in A&E, to require the review of Category 3 patients every 30 minutes until they are seen by a doctor, and that each review is to be documented
2. signage in A&E to inform patients of the triage categories, to assist patients in understanding the reasons for delay in being seen and to advise them of the procedure to be followed if they have been waiting beyond the accepted time
3. the establishment of an aged care liaison team within A&E to perform assessment on elderly patients and to provide alternatives to inpatient hospital care.

Figure 5.1 Complaints to Australasian Health Complaints Commissioners, classified according to the rights in the Australian Charter of Healthcare Rights, 2008–09



ACT = Australian Capital Territory; NSW = New South Wales; NT = Northern Territory; NZ = New Zealand; SA = South Australian; Tas = Tasmania; Vic = Victoria; WA = Western Australian
 *SA data covers Oct.-Dec. 2008.

Safety

There are a number of possible implications from the prevalence of complaints about safety. It has been suggested that patients assume that basic standards are maintained and that all aspects of health care are safe.¹² When patients assume that care is safe and are then harmed during care, they are likely to feel anger, shock and betrayal towards the clinician and the healthcare system in general.⁹

Patients may also be disposed to complain about safety issues that they can observe. If the error is obvious to patients, they may worry about the errors they are not seeing (eg a lack of hand washing diligence may cause concern that sufficient care in other aspects of treatment may not be occurring).

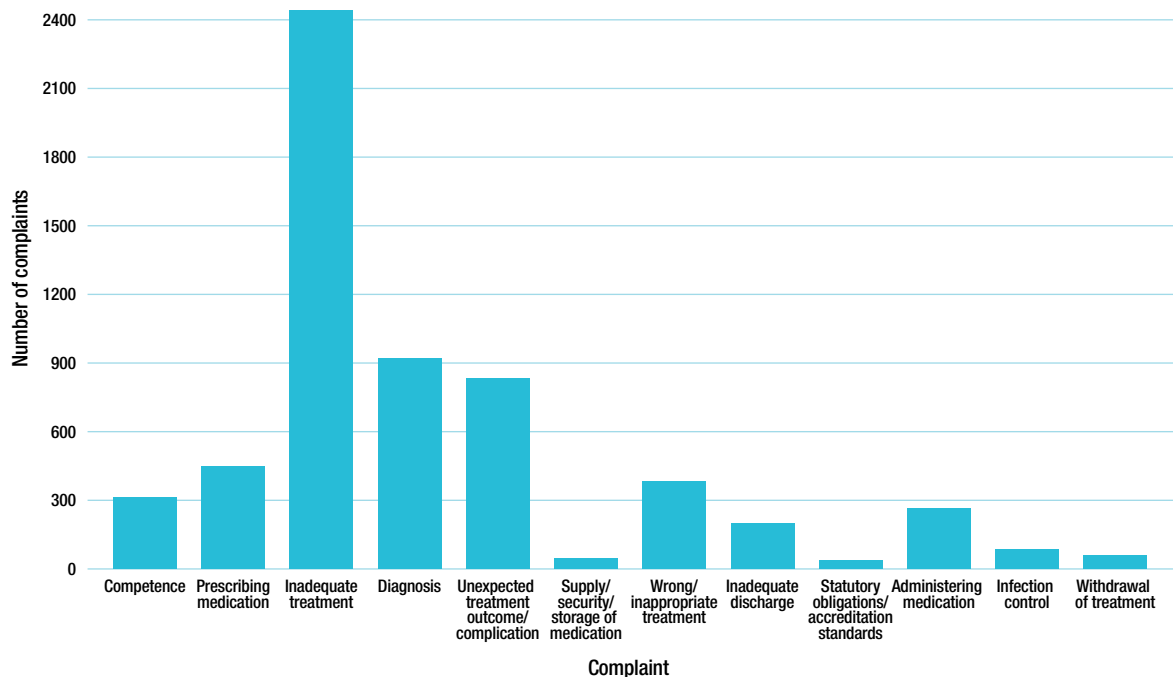
Conversely, only 34% of Australians surveyed by the Commonwealth Fund in 2007 were very confident that they would receive safe care. Of the remainder, 46% were somewhat confident and 20% were not very or not at all confident that they would receive safe care.¹³



Complaints identified as primarily relating to safety have been grouped into a number of issues by the HCCs. It is evident from this data that the leading complaint relates to 'inadequate treatment' (Figure 5.2). Although this may seem like a broad and potentially subjective category, it does exclude complaints relating to negligent treatment and clinician competence. It may be argued that this category then acts as a 'catch-all' for complaints that do not fit neatly into other more defined categories. However, what may be taken from the uniformity across jurisdictions is that patients were likely to make a complaint that fell under this category if their treatment or care was not satisfactory or adequate. There have been moves in some jurisdictions to look at separating this complaint category into 'inadequate treatment' and 'inadequate care', which may provide more focused data on the nature and cause of complaints about safety.

It is interesting to note that international studies suggest that while two-thirds of patient complaints relate to the safety of clinical treatment, such complaints rarely result from a clinical incident in isolation. Often a combination of perceived staff insensitivity, communication breakdown and concern about clinical treatment eventually motivates a patient to make a formal complaint.¹⁴ These findings are supported by the data provided by the HCCs which show the Australian healthcare right with the second greatest number of complaints categorised against it was communication. Generally, this was the poor attitude or manner of the healthcare professional when dealing with the patient.

Figure 5.2 Complaints to Australasian Health Complaints Commissioners about the right to safety, classified by complaint issue, 2008–09



Despite safety being the source of most complaints, it does not paint an entirely negative picture of the healthcare system. For example, it is positive to note that complaints about competence (a key component of the Charter's Safety healthcare right), negligence, wrong or inappropriate treatment, and the misadministration of medication were relatively uncommon (Figure 5.2).

Communication

It is critical to both healthcare delivery and the healing process to have strong and effective communication between patients and their healthcare professionals. Communication takes on another level of significance when there has been an adverse event experienced by the patient during care. Some experts suggest that patients often blame healthcare professionals not for their original mistake but rather for their lack of transparency or willingness to honestly explain what has occurred during treatment.¹⁵

A large proportion of complaints reported to the HCCs were made about health professionals' attitude and manner (Figure 5.3). The frequency of complaints about communication, and in particular regarding clinician attitude and manner, concurs with many other studies of patient complaints.^{16–20}

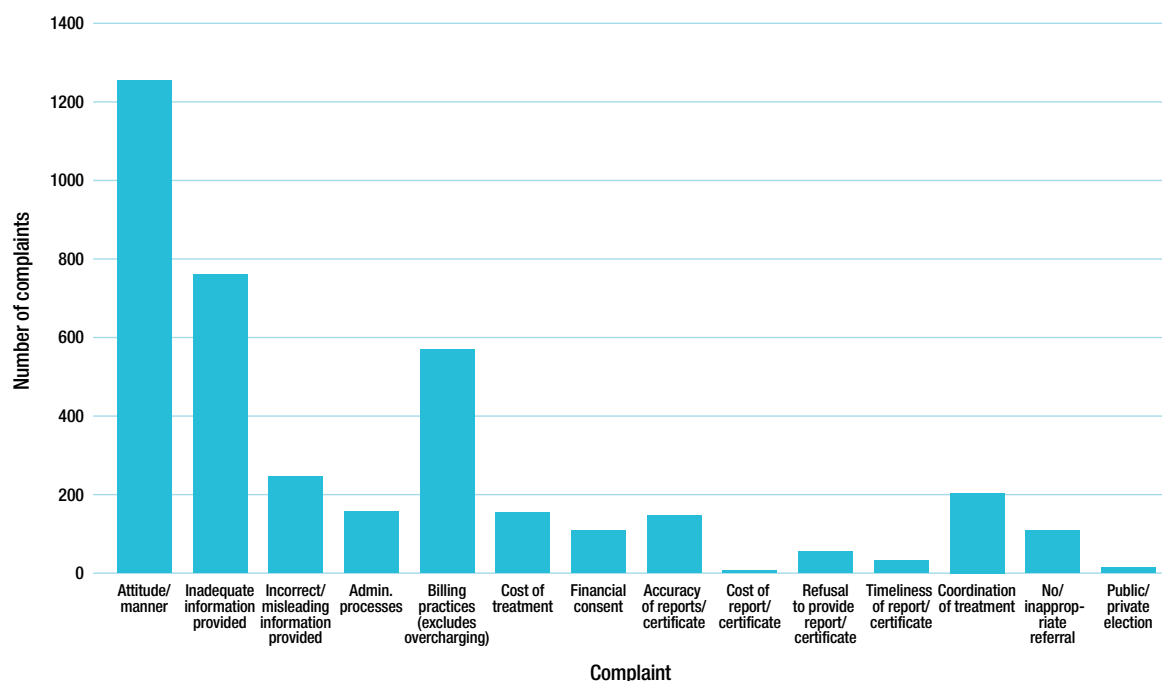
This result echoes international findings. For example, an independent review of complaints in the United Kingdom found that staff attitude was one of the main factors

influencing customer satisfaction with public services.²¹ Some experts have even suggested that communication problems may underpin the majority of complaints lodged. Research into Victorian complaints data found that appropriate explanation, information provision and resolution of misunderstandings contributed to a successful outcome for many patients.¹⁶ Researchers interviewing patients who had suffered an adverse event report that these patients express a need to be engaged and to receive a clearly articulated apology in addition to both emotional and medical support.²²

It has been suggested that complaints about the attitude and manner of healthcare professional–patient communication also represent a failure to appreciate that in some circumstances the emotional needs of patients may be as important as their physical state.¹⁵ If health care is to truly become responsive to the rights and perspectives of the patient (or more patient focused), then it will be necessary to investigate how healthcare professionals can improve their communication skills and focus on the needs (both clinical and emotional) of their patients. Given the number of complaints that have their foundation in poor communication and a lack of sensitivity, it is clear that this is an area that healthcare professionals need further support.

In order to address these fundamental communication issues, it will be important to consider the impact that targeting this area in clinician education and practice may

Figure 5.3 Complaints to Australasian Health Complaints Commissioners about the right to communication, classified by complaint issue, 2008–09



have for healthcare professionals. It has been suggested that strategies to address communication skills and the appropriate sharing of information may have a profound impact on clinician–patient interaction.¹⁶ In the United States, a checklist for physician behaviour has been proposed, which is designed to teach doctors to behave in ways that will result in the patient feeling well treated.ⁱⁱ Many of the actions suggested are generally considered to be ‘good manners’ (ie asking permission before entering a patient’s room, introducing oneself, smiling where appropriate).

Although the effects of behaviour modification techniques and etiquette checklists on patient satisfaction are yet to be evaluated, checklists have been successfully used to address other complex problems involving cultural change, such as infection control.²³ As a complementary method, it has even been suggested that customer service training should be made mandatory for all healthcare professionals.^{24 25} Such training would give healthcare professionals the appropriate words, stress recognition and management, and negotiation and people skills to interact effectively with a patient — particularly following adverse events.ⁱⁱⁱ This type of training would need to be appropriately tailored to healthcare professionals’ work and should provide reassurance to them that they are delivering quality care, but that things can be done better.

Communication, health literacy and vulnerable populations

National survey results suggest that a majority of adult Australians have relatively low levels of ‘health literacy’ and may not know how to complain.²⁶ Health literacy is ‘the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.’²⁷

An important aspect of healthcare literacy is the knowledge and understanding of one’s healthcare rights and avenues through which patients can have their concerns regarding their health care heard. Patients do not always know how to access avenues for complaints or redress, or know how they could participate in improvement processes.²⁸

This can be compounded in rural and regional Australia. On a per capita basis, rural residents are under-represented by about 25% in the complaints received by HCCs.^{29 30} There are a range of factors beyond merely health literacy that contribute to this under-representation. The nature of rural health care may play a critical role. In many parts of rural and regional Australia, there are strong incentives to keep a medical professional resident in the town and this may mean that incidents go unreported in order to keep the area’s medical practice open. In addition, the demographics of rural and

regional Australia may also be relevant, with many older Australians not feeling empowered to even question healthcare professionals, let alone formally complain about them.

Patients with limited English may also be reluctant to draw attention to adverse events, and thus appear to be satisfied and content despite problems with their health care.^{31 16 iv} However, patients from non-English speaking backgrounds are disproportionately at risk of experiencing adverse events. This reluctance to assert one's healthcare rights has been termed the 'happy migrant effect'. Factors that contribute to the 'happy migrant effect' include 'extreme powerlessness related to being unable to communicate, a positive comparison of health care in the new country compared with the old, patriotism for the new country, cultural norms that proscribe acceptance, politeness or social desirability, self-denigration for not having learnt English and, for a few, a fear of reprisals if they spoke out in complaint'.³¹ Whatever the reasons may be, the reluctance of patients from non-English speaking backgrounds to complain suggests that healthcare organisations have much to learn from listening to the stories of those patients with limited English who do complain.

Patient complaints and Open Disclosure

In Australia, the concept of Open Disclosure focuses on transparency and good communication with a patient and their family following an adverse event. Open Disclosure is the open discussion of incidents that caused harm to a patient. If a patient has been harmed during their treatment, then a senior healthcare professional should talk about it with the patient and their family. When this discussion takes place, the healthcare professional should:

- express regret (or apologise) for the incident
- explain what is known about what went wrong
- explain the consequences of the incident for the patient and their ongoing care, and
- inform the patient what is being done to investigate the incident and to minimise the possibility of it happening again.

If the adverse incident is serious, there will be a formal meeting in which the patient (and their family or carers) meet with relevant healthcare professionals from the hospital or healthcare service that provided their care.

Open Disclosure does not affect a patient's right to take the matter further in any way. For instance, the patient and their family can use the complaints process of the healthcare facility or the HCC in their state or territory. Open Disclosure was introduced to improve patient care and to prevent the same mistakes from happening again, which reflects the common desire that patients and their families have, that is, that some good comes from adverse events. It is grounded in the Charter's 'communication' and 'comment' healthcare rights. Open Disclosure is patient focused and responsive, therefore, once it is established across the country, it is hoped that the need for patients to complain about their health care will be diminished.^{v vi} To that end, the Commission has taken an active role in moving towards a consistent and national implementation of the Open Disclosure program, one that is responsive to individual patient needs.

Clinician-patient communication

The '100 patient stories project' was developed by the Commission and a team led by Professor Rick Iedema at the University of Technology, Sydney, as part of an overall strategy to support and encourage healthcare staff and facilities to undertake open disclosure in a manner that is most effective for patients. It was endorsed by the Australian Health Ministers' Conference (AHMC) in April 2008, when AHMC agreed to work towards the



implementation of the Open Disclosure Standard in all healthcare facilities. The project will involve:

1. collecting 100 Australian patients' narratives of both their experience of adverse events and their experience of Open Disclosure. Some patients will be asked to participate in video interviews, so that their stories can form part of training for healthcare staff
2. developing and validating two survey instruments (one for staff and one for patients and families) that can be used by healthcare facilities to monitor and continually improve the effectiveness of their Open Disclosure practices, and
3. developing patient focused indicators of effective Open Disclosure.

The 100 patient stories project has begun interviews with patients and families who have experienced an adverse event and undergone Open Disclosure. While only a small number of patients have been interviewed thus far, there have been some interesting comments regarding effective and ineffective clinician-patient communication. While the data from the project is still raw and has not yet been fully analysed, it is clear that patients are comforted by effective communication from their treating healthcare professionals. What a healthcare professional says and, often more importantly, how they convey it (through their body language and general manner) provides a significant measure of comfort (or even further distress) to the patient and their family, depending on the communication skills of the healthcare professional involved.

Improving care following complaints

There are a number of barriers that patients face in making a complaint against a healthcare professional or service. These range from a lack of knowledge of healthcare rights and avenues for redress to a fear that complaining may have a detrimental impact on their health care. Therefore, when a patient or their family complain, it provides a unique opportunity to review both the incident and systemic issues that lead to the incident.

A patient or their family must be motivated to pursue a healthcare complaint and the prevalent motivation reported is quality assurance and altruism: to ensure that no other family has to endure a similar adverse event. Both empirical studies and HCC data suggest this, indicating that patients seek a resolution to their complaint that involves addressing any systemic or performance-based issues that are uncovered. As a

The 100 patient stories project

Individual examples of good communication

'[The adverse event] happened, [the clinician] told us what's going to happen next, we can now get on with this part of it, and we'll hear from him about that part of it, you know what I mean, so it felt like we were going away with a clear mind of what the procedure was that we had to follow through on next'. (Family member)

'[The clinician] went through all the steps of what would happen, he gave us his number, he told us to contact him any time... he was wonderful really and he did the follow up stuff where he rang me, asked how my [family member was] going and [...] he needed me to do something and he asked [whether it] would be better if I did it or my [family member]. [The clinician] talked to me at great length about what my [family member] was going through and the kind of support she would need and all that kind of thing'. (Family member)

Individual examples of poor communication

'[After the adverse event] nobody came to us and gave us [or] offered an explanation, it was just over and you leave the room and everybody goes home and it was just like it was a horrible feeling'. (Family member)

'[The clinician] didn't want to talk about it anymore, her whole body language changed where she became defensive and it's like, well as she says: "there's nothing we can do about it, she's dead". And when she made that statement I turned to [another family member] and I said I just want to get out of here. I just wanted to get out of there, because she wasn't... she wasn't sorry anymore'. (Family member)

'[The adverse event] just [felt] like bad luck and that's how [the clinician] described it, you know, it was like Swiss Cheese Syndrome. I just shook my head and he said "what it is, you know the Swiss Cheese Syndrome, all the holes line up and she just fell through the holes" and I just thought [sarcastically] that was really great, bad luck Mum sort of thing'. (Family member)

result, complaint handling that does not result in change is unlikely to meet patients' expectations.³²

The issue of communication works both ways. Patients need to be aware of and understand that things may go wrong in health care. Patients can no longer view their healthcare professionals as infallible. Clear and comprehensible explanation of the risks involved both informs and empowers a patient.

Addressing the communication skills of healthcare professionals may seem, at first glance, to be simple, but this would involve changing the communication culture that has developed in clinical practice. Such cultural changes are inherently difficult and any initiatives aimed at improving communication must engage healthcare professionals in a non-threatening way to maintain trust.

Open Disclosure provides a potential road map for encouraging effective and responsive clinician-patient communication. It provides a patient-focused format in which a clear, honest and apologetic explanation of adverse events can be conveyed to patients and their families. Open Disclosure represents an ongoing conversation between patients, clinicians and the healthcare service that is focused on preventing similar incidents. As such, it recognises that patients not only have a right to be heard, but that they can provide valuable insights into the standard of care. When Open Disclosure is used appropriately and in line with the Standard,^{33 34} it seems to address many of the concerns that lead patients to lodge formal complaints. Open Disclosure is not the panacea to the issues raised by patients through their complaints. However, the principles of clear, honest and patient-focused communication may have wider application at every stage of health care.

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6

Safety and quality in general practice

The field of patient safety emerged following research showing that a large number of harmful, but potentially preventable, incidents occur in hospitals,¹⁻³ and following a number of high-profile inquiries into incidents at specific hospitals.^{4,5} These origins mean that the focus of much of the early patient safety work was limited to issues that were particularly relevant for hospital-based care settings; there was limited examination of the patient safety risks that exist for care provided in the community.

Most health care in Australia is provided in primary care settings, particularly in general practice. Almost one in five people visit a general practitioner (GP) in any given two-week period,⁶ and it has been estimated that 85% of the population see a doctor at least once a year.⁷ Given the size and importance of this sector, it is essential that attention is paid to ensuring care provided in general practice is safe and of a high quality.

The characteristics of general practice affect the way that care is provided and the nature of the patient safety risks that exist. Some of the differences between acute and primary care settings, and the potential impact of these differences on patient safety are described below:^{8–11}

- Patients in general practice are typically not as sick as those in acute-care settings, and any procedures that are performed tend to be less invasive. Although this may limit the opportunities for harm from the provision of treatment, there are a large number of occasions of treatment in general practice, meaning that the cumulative risk is still high.
- The contribution of patients, their families and carers has a significant impact on the outcomes of care provided in general practice. This means that while there are patient safety risks associated with the skills and knowledge of the healthcare professional, the actions and knowledge of patients, families and carers can also have an impact on safety and quality. For example, lower levels of literacy among patients is associated with a greater misunderstanding of prescription medicine labels, which may effect adherence to medication regimens and the occurrence of adverse drug events.¹²
- In hospitals, the care tends to be provided within the one organisation. While some patients may receive care from only one GP, others may attend multiple practices, receive care from specialists and allied healthcare providers, and may also need to have tests done by external laboratories and imaging centres. This means that a general practice is part of a dispersed network, and communication with other healthcare providers and sites is particularly important.
- In general practice, there tends to be fewer resources allocated to quality and safety infrastructure than in acute care settings. Although larger practices may have a practice manager, in many cases the doctors, nurses and clerical staff are the only resources available to support safety and quality in addition to their existing roles. This means that processes to support safety and quality such as incident reporting,

data collection, audit and feedback will not necessarily be established and routine.

- In general practice, the longer term relationships between patients and healthcare providers may support the provision of quality care. On the other hand, the episodic nature of this relationship can mitigate against the maintenance of patient safety.

Information about quality and safety in general practice is limited.¹³ There is no comprehensive source of information about the quality of care provided in general practice, or the safety of care processes; different types and sources of data provide different parts of the picture (see Box 6.1).

General practice safety and quality information — 2009

Each year the Commonwealth Fund, a not-for-profit organisation based in the United States, conducts an international health policy survey. In 2009, the survey examined the characteristics, attitudes and practises of GPs in 11 countries, including Australia (see Box 6.2). The survey examined how GPs perceive the quality of care in their country, the resources that exist, the activities undertaken and the perceived barriers to, and facilitators of, high quality, efficient, patient-centred care.

This year, the Australian Commission on Safety and Quality in Health Care (the Commission) funded an increase in the sample size of the survey in Australia from 500 to 1,016 GPs. The results of this survey add to the existing knowledge about Australian general practice by providing information from a national, representative sample of GPs using a robust, well-respected survey. The increased sample allowed for more detailed analysis of the data than would have been possible otherwise. The existence of a similar survey of GPs conducted previously by the Commonwealth Fund also enabled comparisons over time.

The complete international comparative results of this survey have been published elsewhere by the Commonwealth Fund.¹⁹ This chapter focuses on the responses of Australian GPs, looking particularly at the way that their practices are organised to provide safe and high quality care.

With the emergence of patient safety there has been an increasing emphasis on the importance of organisational systems to ensure that practises that are known to improve safety and quality are implemented properly and routinely.²⁰

Box 6.1 What do we know about safety and quality in general practice?

Examples of some of the different Australian sources of quality and safety information and the knowledge they provide are:

- Interviews with GPs have been used to obtain information about quality of care. One study of 247 GPs in 97 practices found that most GPs were not managing asthma in line with national guidelines.¹⁴
- Audits of patient records provide information about the care that patients receive and the potential outcomes of that care. One study of 230 patient records at GP practices found that adherence to diabetes guidelines improved once care plans had been introduced.¹⁵ Outcomes, including measures of cholesterol and blood pressure, also improved following introduction of the care plans.
- The Bettering the Evaluation and Care of Health (BEACH) program has collected information over 10 years about individual patient encounters from a constantly changing random sample of GPs. Over this period, management of conditions such as diabetes, cancer and asthma has changed in accordance with guidelines, associated with the introduction of government policies and incentives.¹⁶
- Information is available from Medicare regarding the use of specific item numbers and incentive payments. For example, the Enhanced Primary Care item numbers support annual voluntary health assessments for older Australians, and care planning and case conferencing services for people of any age with chronic conditions and complex needs.⁷ In 2006, 90% of GPs claimed these items, suggesting that a high proportion of GPs are involved in continuity and coordination of care.⁷
- A study of 433 reports of errors from a random sample of 84 GPs found that errors relating to the processes of care are the most common type of error. These included errors relating to practice systems, investigations, medications, other treatments and communication.¹⁷
- General practice patients can provide information about the care they receive. One study asked 7,505 patients with chronic conditions to rate their practice in terms of factors such as access, continuity of care, communication, inter-personal care and the doctor's knowledge of the patient. Patients from smaller practices reported better access to care compared to larger practices. Practices in urban areas were more likely to be rated as more 'patient-centred', possibly reflecting increased choice of healthcare providers and greater choice of healthcare practices.¹⁸

The examination of the capacity of organisations and the need for systems to support safety and quality began in the acute care sector and are now increasing in general practice. Capacity is one of the domains of the Royal Australian College of General Practitioners (RACGP) Quality Framework.²¹ In the RACGP framework, capacity includes consideration of general practice workforce and personal capacity, as well as practice capacity and safety and quality systems.²²

There is evidence that better patient outcomes are associated with the presence of organisational structures such as clinical information and tracking systems, use of non-medical practice clinicians to follow-up patients, and formal cooperation with dietitians.²³⁻²⁴ There is also recognition that more attention needs to be paid to the organisational capacity of Australian general practice in areas such as practice governance and business

management, teamwork, support for information management and technology systems, and links with other organisations, particularly regarding the care of patients with chronic conditions.²⁵

There are a number of models of safety and quality that can provide indications about the characteristics and activities required for general practices to provide safe and high quality care.²⁵⁻²⁷ In this chapter, the framework for examining data from the Commonwealth Fund survey comes from the proposed National Safety and Quality Framework (the Framework) developed by the Commission. The three dimensions identified in the Framework for safe and high quality care are: patient focused care, care that is driven by information, and care that is organised for safety (for more information about the Framework refer to the Introduction).

Box 6.2 How the survey was conducted

The survey was conducted by the Minter Group in Australia, under the guidance of Harris Interactive, the United States-based company contracted by the Commonwealth Fund to conduct the survey. The survey was conducted between February and May 2009.

A random sample of GPs was drawn from a national list provided by the Prospect Shop (a commercial provider of direct marketing lists). This list was stratified by region according to the Australian Standard Geographical Classification (major cities, inner regional, outer regional, remote or very remote).

Potential respondents were recruited and screened by telephone. To be eligible to participate, GPs needed to spend at least 50% of their time in active practice. GPs who agreed to participate were asked

to complete a paper-based survey. A reminder call was made to GPs to return the completed survey.

The final sample was 1,016 GPs, and a response rate of 52% was obtained.

The details of the sample are as follows:

Gender: male 63%, female 37%

Age: <35 4%, 35–49 39%, 50–64 48%, 65+ 9%

Location: major cities 59%, inner regional 20%, outer regional 11%, remote or very remote 10%.

To ensure the respondent sample reflected the population it was intended to represent, the sample was weighted in the analysis according to the age, sex and location of the GP.

The other countries participating in the survey were the United States, United Kingdom, Canada, New Zealand, France, Germany, Italy, Netherlands, Norway and Sweden.

Table 6.1 Questions from the Commonwealth Fund survey discussed in this chapter

National Safety and Quality Framework dimension		Commonwealth Fund survey questions
Patient focused care		Access to after hours services
		Provision of written information regarding medications and self-care instructions
		Email communication with patients
Driven by information		Routine use of guidelines
		Ability to generate information about patients from existing medical records systems
		Review of clinical and practice performance
Organised for safety		Use of non-medical healthcare providers to manage patient care
		Use of information technology for clinical purposes
		Work practices to support high quality care
		Processes for identifying adverse events

Each of the three dimensions in the proposed National Safety and Quality Framework includes a number of evidence-based strategies and actions that provide direction for how general practices could be organised to provide safe and high quality care. Many of the questions in the Commonwealth Fund survey overlap with these strategies and actions. Table 6.1 lists the survey topics that have been identified as key strategies in the Framework, and will be the basis for discussion in this chapter.

The following sections provide information about the Australian results of the Commonwealth Fund survey in these areas. In some cases, comparisons are made between GPs in Australia and other countries, between GPs in different locations and in practices of different sizes. In addition, where possible, the 2006 Commonwealth Fund survey of Australian GPs is used to demonstrate relevant changes.

Patient focused care

Patient focused care is care that is respectful of and responsive to the preferences of an individual patient, needs and values. It means a partnership between consumers, family, carers and healthcare providers. Where care is patient focused, processes are designed to optimise the experience of patients.

There is increasing evidence that supporting greater patient involvement in their own care can have safety benefits in areas such as infection control and adherence to treatment regimes, as well as improved self-care and self-management.²⁸

In Australian general practice, three aspects of patient focused care have been identified:²⁶

- taking a patient centred approach to the consultation
- ensuring general practice meets the expectations of consumers about what constitutes patient centredness, and
- the role of general practice in addressing health inequalities.

In the Commonwealth Fund survey only a small number of questions related to patient focused care. The results of these questions indicate that while Australian GPs are strongly patient focused in some aspects of the care they provide, others are less positive.

Only half of GPs in the survey said that their practice had arrangements in place where patients could see a doctor or nurse after hours without going to an emergency department. Australia ranked below other countries in the survey in this regard (8th of 11 countries participating in the survey), with 97% of GPs in the Netherlands and 89% in New Zealand having such arrangements in place (Figure 6.1). In contrast, in 2006, 81% of Australian GPs surveyed reported that they had such arrangements in place. The reason for this change is unclear, as there have been no changes since 2006 to the program that provides incentive payments to GPs for ensuring after hours care is available to their patients,²⁹ and access to care outside normal opening hours remains a criterion in the standards for general practices from the RACGP.³⁰

Most Australian GPs surveyed reported that they provided written material to their patients: 80% reported they either routinely or occasionally gave patients a list of medications, and 93% reported that they either routinely or occasionally gave patients with chronic conditions

instructions about how to manage their own care at home. Australia performed better on these measures, and was ranked second among participating countries with regard to providing written instructions to patients with chronic conditions (Figure 6.1).

Only 17% of Australian GPs reported that their practice communicated with patients by email for clinical or administrative purposes. Although this figure was low, Australia ranked 4th on this question behind Sweden (35%), the Netherlands (31%) and the United Kingdom (19%). This figure has increased since 2006 when only 8% of Australian GPs reported that they communicated with their patients by email regarding treatment (Figure 6.1).

There were minimal differences in the results of these questions according to the size or location of the practice.

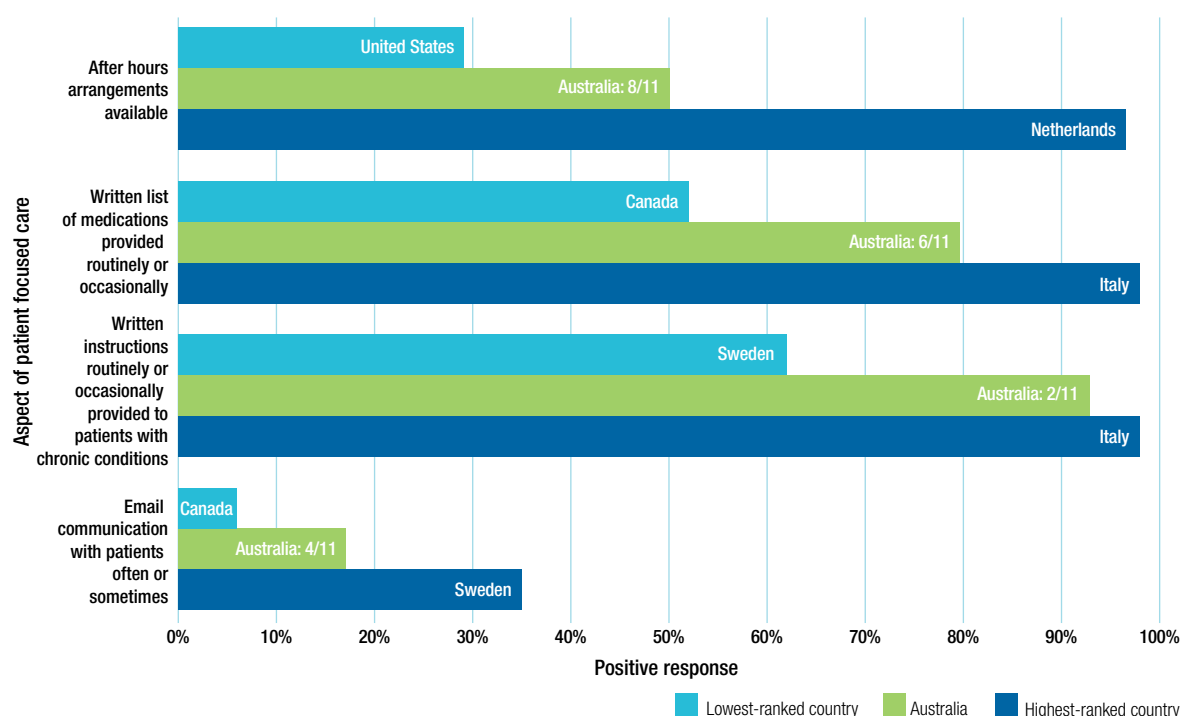
Driven by information

When care is driven by information, it means that safety and quality data are collected, analysed and fed back in order to promote improvements. Action is taken to reduce unjustified variation in standards of care, and to improve patients' experiences and clinical outcomes based on this feedback.

The gap between what is known about the treatment people should receive and the treatment they actually receive is well known.³¹⁻³² Studies in Australia and internationally show that only about half of patients receive care in accordance with known evidence and guidelines.³¹⁻³⁴ One factor contributing to this situation is the lack of practice infrastructure, including multi-disciplinary teams and effective decision-support systems and information use.³⁴ There is evidence that practice characteristics and organisational capacity can improve compliance with guidelines. For example, one study has found that compliance with asthma guidelines in general practice was associated with better teamwork and organisation of care processes.³⁵

Recognition of the importance of knowledge management in general practice is increasing.³⁶⁻³⁷ Knowledge management is a process by which people in organisations find, share and develop knowledge for action.³⁶ Databases, decision support and retrieval systems, review and feedback systems, informal and formal communication, and training processes are important supports for effective knowledge management in general practice.³⁶

Figure 6.1 Performance of Australian general practitioners and patient focused care



Most Australian GPs reported that they routinely followed written evidence-based guidelines for common conditions such as diabetes (87%), depression (70%), asthma or chronic obstructive pulmonary disease (COPD) (85%) and hypertension (82%). Following guidelines was less common for attention deficit hyperactivity disorder (ADHD) (36%). Although only 34% of GPs reported that they routinely followed guidelines in all of these areas, Australia was ranked second internationally on this measure, only behind New Zealand (37%). There was some variability between GPs regarding reported compliance with guidelines: GPs in medium-sized practices tended to be more likely to report that they routinely used guidelines (Figure 6.2). The high rate of reported use of guidelines in this survey contrasts with research showing that a large proportion of patients is not receiving care that corresponds with accepted guidelines.^{31 32}

Most GPs reported that with the medical record system that they currently have they could generate a list of patients by diagnosis (61%), by laboratory result (52%), by being due or overdue for tests or preventive care (63%), as well as a list of medications for individual patients (71%). Forty-three per cent of GPs reported that they could easily generate all of this information, and Australia ranked second on this measure behind the United Kingdom (65%). GPs in larger practices tended to be more likely to report that it was easy to generate this

information; GPs in remote areas tended to be less likely to do so (Figure 6.3).

GPs in Australia tended to be ranked lower on the questions relating to the measurement of practice improvement than other countries in the survey. Only 24% of GPs reported that their practice routinely received and reviewed data on clinical outcomes; however, over half reported that they received and reviewed information about patient satisfaction. Half of GPs reported that they reviewed areas of their clinical performance against targets at least annually, and 43% reported that they received information about how the clinical performance of their practice compared to others (Figure 6.4). The same trends regarding variability associated with the size and location were observed for these questions as for use of guidelines; that is, GPs in remote locations and in smaller practices were less likely to report that these activities occurred.

Organised for safety

When care is organised for safety, it means that safety is a high priority in the design of health care. Organisational structures, work practices and funding models recognise and reward taking responsibility for safety.

As was noted earlier, there is increasing evidence that the introduction of organisational systems supports the provision of high quality care that complies with

Figure 6.2 Performance of Australian general practitioners and the use of written guidelines

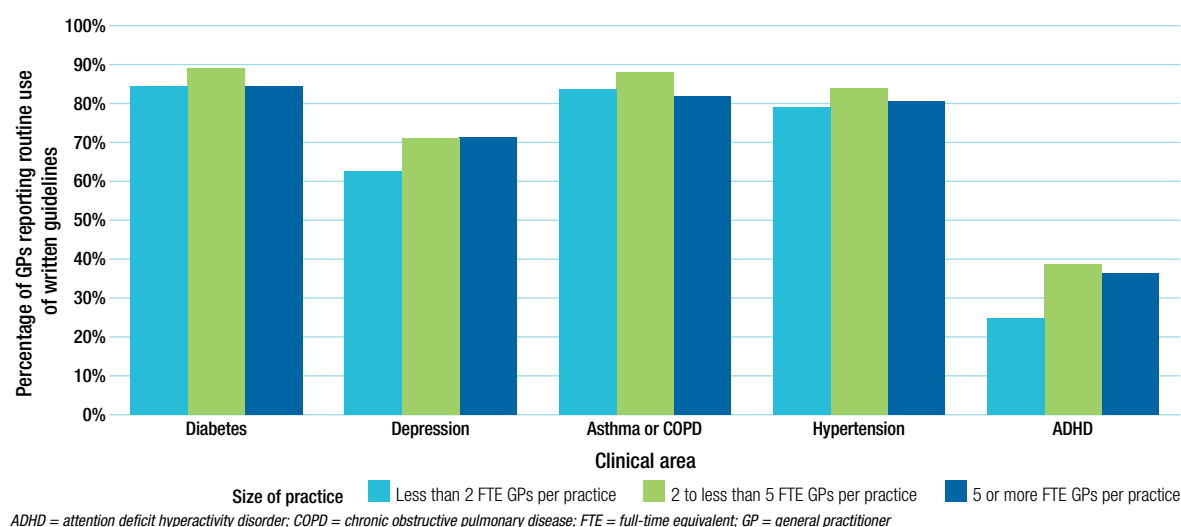


Figure 6.3 Performance of Australian general practitioners and the use of medical record systems to generate patient information

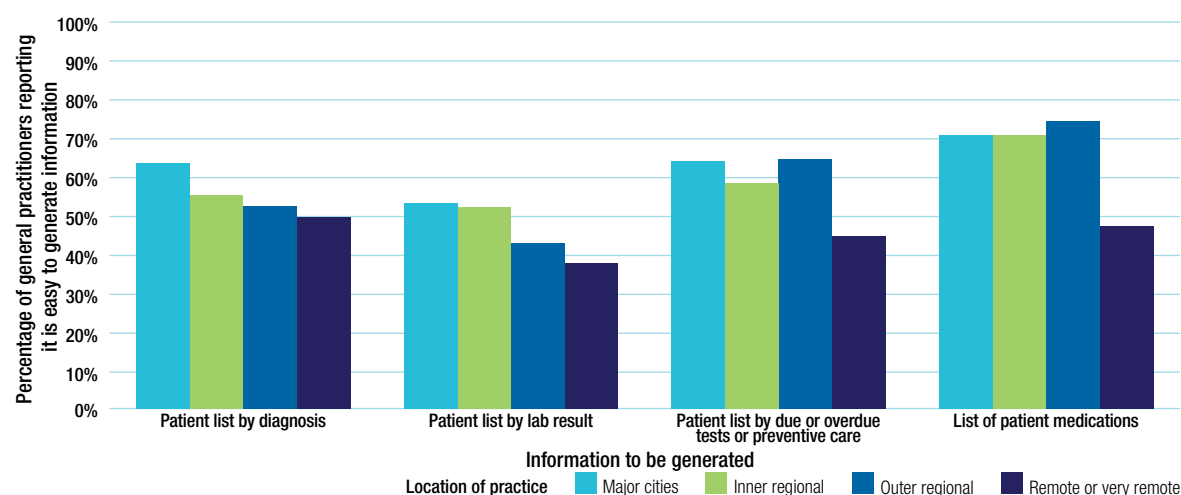
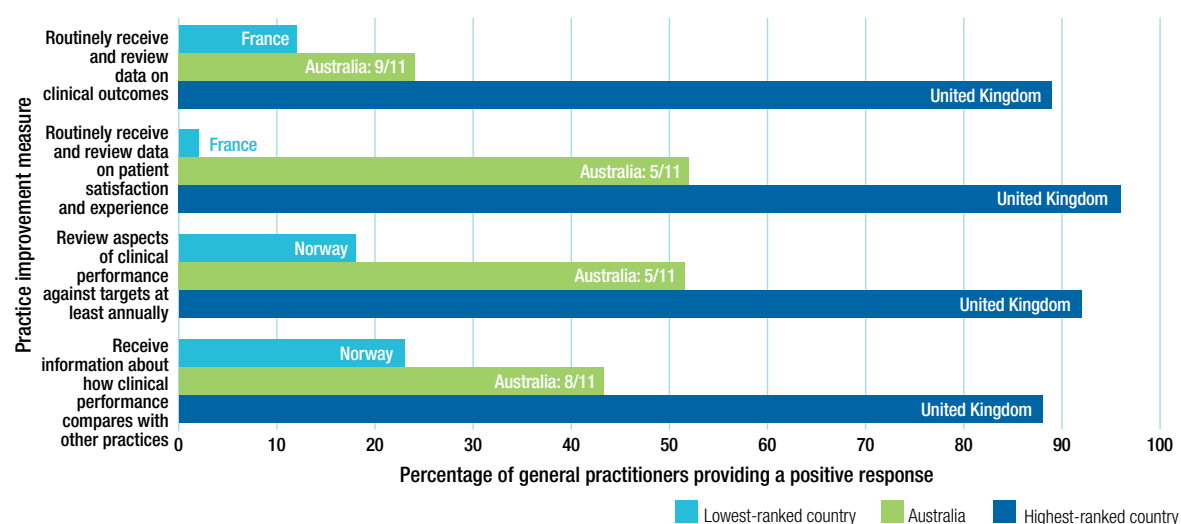


Figure 6.4 Performance of Australian general practitioners and practice improvement



clinical guidelines.³⁸ For example, there is evidence that quality of care (although not necessarily improved patient outcomes) is associated with the introduction of computerised systems for screening, preventive care, and decision support, as well as systems that support enhanced professional roles of non-medical clinicians.^{38–41}

Most Australian GPs surveyed reported that other healthcare providers (such as nurses, nurse practitioners and allied healthcare professionals) in their practice shared responsibility for patient care (88%). The main roles these providers had were to educate patients about managing their own care, providing health promotion counselling to patients, calling patients to check on medications and symptoms, and helping to coordinate care between visits.

There was a high rate of use of electronic medical records, and other information technology in general practices in Australia. Ninety-five per cent of GPs reported that they had electronic medical records in their practices, and there was also a high rate of using electronic systems for ordering laboratory tests (90%), accessing laboratory test results (96%), providing alerts or prompts about potential drug doses or interactions (96%), entering of clinical notes (95%) and prescribing (95%). While there was some variability in these results according to the location of the practice, there was a clear trend that larger practices were more likely to have these electronic systems in place (Figure 6.5). Overall, the percentage of GPs reporting use of electronic systems for clinical purposes has increased since 2006 (Figure 6.6).

Australian general practices also performed well in international comparisons regarding activities that were performed to support the delivery of quality care. Australia was the highest ranked country for the presence of systems for tracking of laboratory results until they reach clinicians (79%), receiving alerts or prompts to provide patients with test results (76%) and receiving reminders for guideline-based interventions and screening tests (73%). Australia also ranked third when it came to having systems to send patients reminder notices for regular preventive or follow-up care (89%). Again, there was a tendency for larger practices to be more likely to report these activities are undertaken routinely. Practices in more metropolitan areas were also more likely to report that they occurred (Figure 6.7).

Most GPs reported that they had a process in place for identifying adverse events and taking follow-up action (85%). Of these GPs, only 38% considered that this

process worked well; the others felt that it could use improvement. These results indicate an improvement since 2006 when only 35% of GPs reported that they had a documented process for follow up and analysis of all adverse events. In 2006, 21% reported that they had such a process for adverse drug reactions only.

Do general practices have systems to provide safe and high-quality care?

The results of the 2009 Commonwealth Fund survey of GPs provide a snapshot about the organisation of Australian general practice, and of some of the systems that exist within practices to support safe and high quality care.

The results of the survey indicate that general practices in Australia perform well on international comparisons in terms of practice organisation for safety and quality, and have many important systems and processes in place. There is a very high level of penetration of electronic systems into routine clinical care, although it is recognised that connection with hospital-based systems is limited. The use of guidelines and performance of tasks such as issuing reminders and providing written information to patients is reported to be common.

The main area where the performance of Australian GPs was consistently below international comparators was in the measurement of practice improvement. Of particular concern is that only 24% of GPs reported that their practice routinely received and reviewed data about clinical outcomes. This issue has also been identified in the Draft National Primary Health Care Strategy, and it is noted that knowledge support systems and information are needed to 'provide practitioners with information about their own performance and the capacity to compare themselves with their peers or against best practice'.⁴² Initiatives such as Australian Primary Care Collaboratives Program have also been developed to support use of practice information to improve quality of care (www.apcc.org.au).

This survey also identified variation in the systems in place in general practice according to the location and size of practice: GPs in smaller practices and in more remote areas were less likely to report the presence of systems and practices that may support the provision of high quality care. There has been little research on these topics in Australia. In the United Kingdom, there

Figure 6.5 Performance of Australian general practitioners and the use of electronic clinical systems

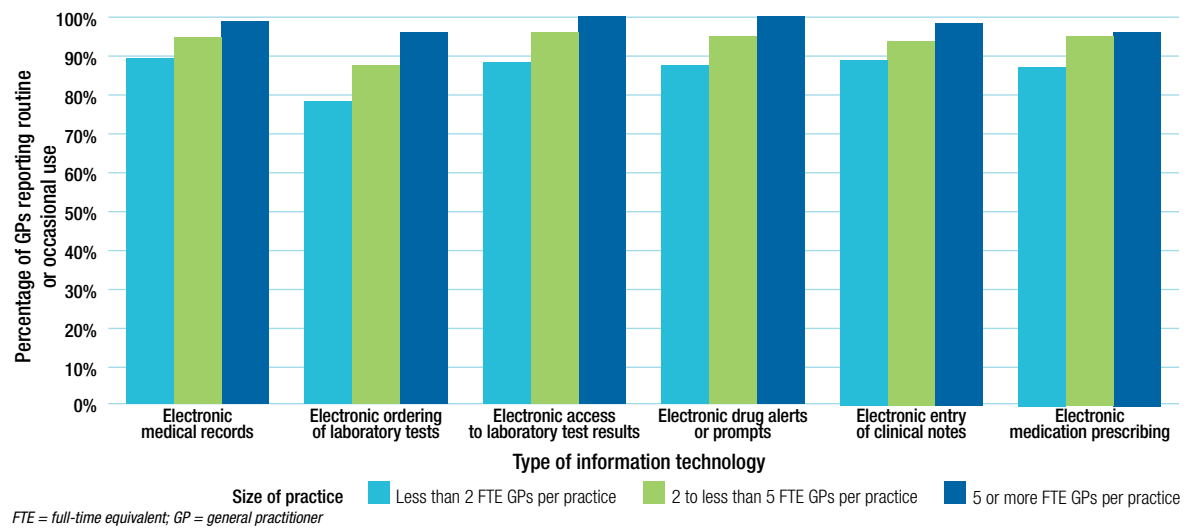


Figure 6.6 Change in performance of Australian general practitioners and electronic clinical systems over time

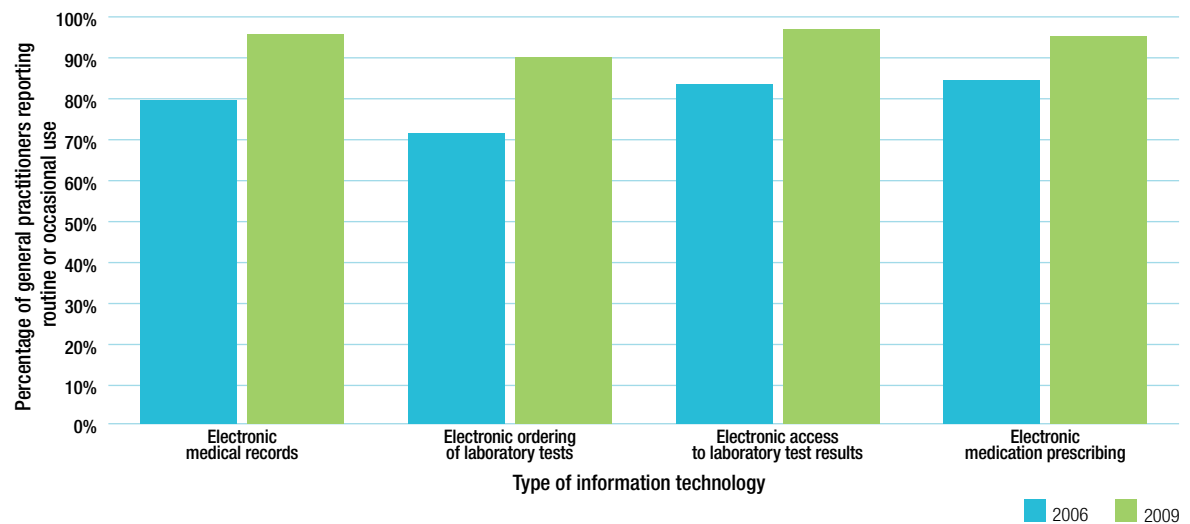
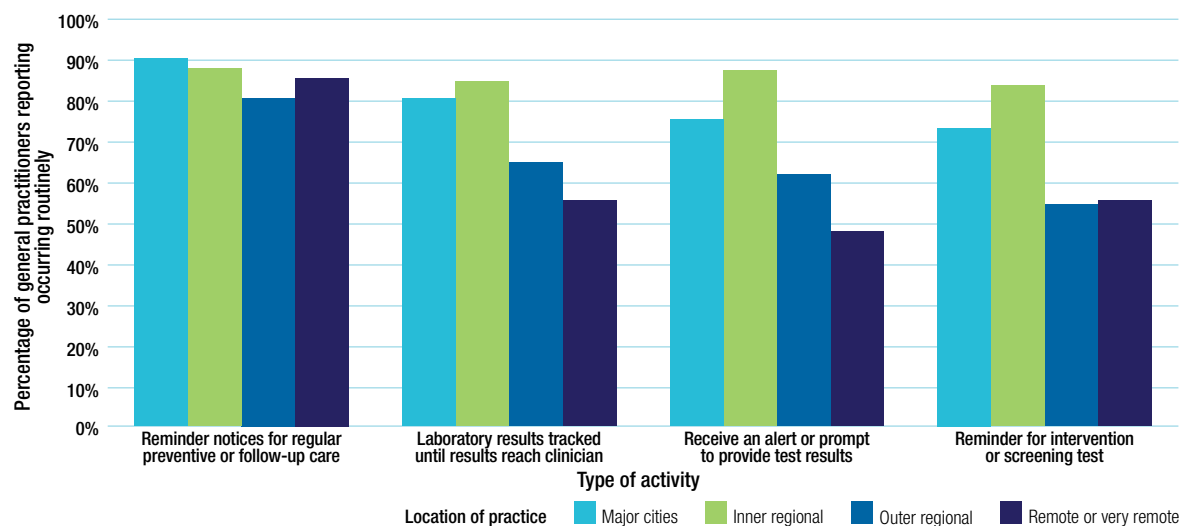


Figure 6.7 Performance of Australian general practitioners and practice activities to improve quality of care



is some evidence that larger practices provide higher quality care, but the results are not consistent.^{43–47} One study found that the reason larger practices performed better on an overall measure of quality was due to higher scores on organisational measures (such as management of records, information, medication and the practice), rather than clinical quality of care.⁴⁸ Another study in the United Kingdom found a tendency towards lower quality of care in more remote areas, but again, these results were not consistent.⁴⁹ It should be noted that the Commonwealth Fund survey did not include any assessment of the care provided by the GPs who participated, or the outcomes for their patients.

This survey found positive results regarding aspects of the organisation of general practice for safety and quality. There are, however, a number of ongoing challenges in general practice and primary care in Australia with a potential impact on safety and quality that are not addressed in the Commonwealth Fund survey. These include:⁴²

- primary care services that have traditionally been delivered in a fragmented and unplanned way
- disparities in access and outcomes across different parts of Australian and between different population subgroups
- lack of support for some people to understand the health system and be involved in decisions about the care they receive, and
- management of transitions across care settings.

Safety and quality has been recognised as a key direction for change in the Draft National Primary Health Care Strategy.⁴² Elements that have been identified as part of this direction include:

- access to information on safety, quality and performance that will drive improvement
- the need for tools to allow providers to reflect on the effectiveness of their services
- working within a performance framework that supports peer feedback and comparison as part of continuous quality improvement
- accreditation of publicly subsidised primary care services, and
- research that is timely, accessible and applicable to policy and service delivery.

The survey results presented in this chapter indicate that there are already good systems in general practice for safety and quality. The Draft National Primary Health Care Strategy sets a direction to build on this foundation to further improve safety and quality, including in other primary care disciplines. There is a large number of organisations in Australia that have a role in ensuring that primary care services are safe and of high quality, and the Commission will be working cooperatively with them to examine the nature of the patient safety risks in this sector and to identify the solutions that can be introduced to address them.

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7

Sentinel Event and other reporting for patient safety

Understanding patient safety and implementing appropriate measures is a complex task, but an essential one for the delivery of safe, high quality patient care.¹ There is a great deal of measurement done in the current Australian healthcare system. Funding, case-weighted separations, uptake of Medical Benefits Scheme and Pharmaceutical Benefits Scheme payments (as a reflection of service or therapy use), access times and screening rates are reported and analysed at local, state and national levels as funding bodies, providers, academics and the public seek to make sense of healthcare quality, value and areas of concern.

Much of this measurement is undertaken in hospitals, and reporting of this data has three purposes:

- *for accountability*: to provide system-level information to funding bodies, managers and clinicians
- *for transparency*: to provide important information to patients and consumers who are increasingly conscious of their right to know about their care and their care providers, and
- *to drive improvement*: by routinely providing information and timely performance feedback to clinicians and managers.

Nationally, there are systems in place for the reporting of clinical incidents. However, in all of this activity, there is little direct measurement of patient safety.

Learning from error

The World Health Organization (WHO) suggests that, in order to enhance patient safety, healthcare services need an 'increased ability to learn from mistakes, through better reporting systems, skillful investigation of incidents and responsible sharing of data'.²

The terms 'adverse event' (an incident that results in death or serious harm to a patient) and 'patient safety incident' (an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient) are often used interchangeably in discussions about error in healthcare. This chapter focuses on adverse events. The systems used to report and manage such adverse events are, however, often referred to generically as 'incident-reporting systems'.

The major benefits of incident-reporting systems include the:

- provision of a workflow approach to support effective incident management whereby logging of incidents provides a process for healthcare professional, and management accountability in incident resolution, and
- identification of system problems through routine investigation mechanisms that can then be corrected to reduce the likelihood of future error (for serious incidents this usually requires further investigation using techniques such as Root Cause Analysis (RCA)).

Incident reporting is not without its problems:

- Although formal systems provide the focus for systematic action within a healthcare service, it has been suggested that 'medical errors are not fundamentally due to a lack of knowledge — we

already know far more than we put into practice'.³ The value of incident-reporting systems in increasing our ability to learn from mistakes is not fully determined.⁴

- Incident-reporting systems can also be frustrating for those who use them for reporting⁵ and if they exist within a culture of 'shame and blame', clinicians will not be motivated to use them.^{6,7}
- The lack of visible feedback, or the perception that no action is driven by incident reporting, is also a powerful disincentive to report patient-safety incidents. Sometimes action will merely be the provision of information, but such information must be timely, credible and of use to clinicians.⁷

It is not the reports themselves, however, that are of the greatest potential value, but their capacity to lead to the development of coordinated solutions. Aggregated analysis of incident reports should generate signals for system-wide intervention. It has been suggested that: '...current approaches to mitigating risks are probably neither efficient nor effective. Local hospitals develop interventions to mitigate risks that have a low probability of achieving success. For example, errors involving devices are common, and the local intervention is generally staff re-education. The collective costs of re-education... would be substantial. A more effective and efficient approach would be to redesign the devices. Yet, individual hospitals and health care systems cannot do this alone. A collaborative effort is needed'.⁸

Approaches to incident reporting in Australia

Patient-safety incident reporting and investigation is now required in all healthcare jurisdictions in Australia. The legislative and policy basis for this requirement varies between states and territories, as do the mechanisms in place for reporting. There is no single national methodology but, nonetheless, the approaches are broadly consistent and include:

- policy or legal requirements of healthcare practitioners to report patient-safety incidents and mechanisms for training to support effective data collection
- use of a standardised risk-adjustment tools to classify the severity of the incident (generally a 'Severity Assessment Code (SAC)' or similar tool)
- use of an electronic reporting system that has the capacity to record actions taken to manage the incident, and
- specified actions required for the investigation of the most severe patient-safety incidents (most commonly RCA).

These approaches exist within interlocking requirements regarding open disclosure, complaint management and other mandatory reporting requirements. Across Australia, there are a variety of these other mandatory reporting systems focused primarily on patient deaths that may include the coronial system, maternal and perinatal death committees, and committees investigating deaths associated with anaesthesia and surgery.

In most jurisdictions, all events require some form of local grouping and consideration to see if there are any patterns to the incidents. Generally, the more serious of these events are required to be reported to a state level where further grouping and analysis are undertaken. Most jurisdictions now publish public reports of this jurisdictional-level work, and discussions have been continuing as to whether a national grouping of incidents would be of benefit.

Can incident reporting tell us more?

All of the factors outlined above that influence clinician use of an incident-reporting system will have an impact on the overall rate of clinician reporting, and hence on the overall proportion of all patient-safety incidents that is recorded. Incident reports have been described as ‘a non-random sample of identified hazards from a larger unknown universe of hazards that can focus our efforts on improving patient safety’.⁸ To make effective use of these reports, local clinician review of reported incidents is ideal.¹⁰

The contextualised knowledge required to make sense of an incident is held in the workplace, among those who are experts at their jobs. These are the same people the healthcare system hopes will possess the ‘error wisdom’ to avert accidents.¹¹

The capacity to glean appropriate information from the raft of reported patient-safety adverse events and the opportunity to recognise patterns of events, especially

Adverse event reporting in Victoria

In 2006, the absence of an integrated system to identify incidents directly impacting patient safety, primarily due to variation in reporting tools and terminology, made state-wide analysis of multi-severity incidents in Victoria impossible. Locally based incident-management systems had grown in response to the needs of the individual healthcare services. Lack of a central repository or link to the Department of Health (the Department) had resulted in good intelligence related to patient-safety incidents at the local healthcare service level, but with disparate data collections at the state level.

In considering the design and overarching concepts of its state-wide incident management system, the Department looked both nationally and internationally for examples of best practice. In 2006, the World Health Organization (WHO) Patient Safety Alliance had begun groundbreaking work on its Conceptual Framework for an International Classification for Patient Safety (ICPS).⁹ WHO aimed to define, harmonise and group patient-safety concepts into an internationally agreed classification in a way that would be beneficial to learning and for improving patient safety. Victoria’s incident management system principles and key concepts are based on the WHO ICPS conceptual framework.

The Victorian Health Incident Management System (VHIMS) is a standardised dataset and methodology for recording clinical, occupational health and safety and non-clinical incidents as well as consumer feedback. VHIMS will be implemented across all Victorian publicly funded healthcare services throughout 2010. In November 2009, Victoria will deploy VHIMS to a group of six healthcare services (and agencies) as a lead implementation.

Victoria will adopt a new strategy for the analysis of sentinel events following the rollout of VHIMS. Sentinel event-reporting analysis will focus on the most severe (ISR 1) clinical incidents, where the patient’s pre-existing condition was not identified as a major contributing factor, rather than focusing on the national sentinel event categories. ISR 1 events will be analysed to identify potential commonalities in incident or patient characteristics, as well as contributing and preventative factors that were identified by healthcare services in their review processes.

Lessons learned from these healthcare service reviews will be provided to all participating healthcare services. The degree of coded information within the extensive VHIMS code sets should enable Victoria to undertake trend analysis on the aggregated lower severity incidents annually.

(Courtesy of the Department of Health, Victoria)

where they may be uncommon in any one institution, still causes concern. This 'data overload' is recognised to be a potential problem with incident-reporting systems and to date, most of our 'comprehension' comes from individual case review⁸ or manual review of groups of small numbers of selected reports. Various managers of incident-reporting systems, generally at state and territory level, have given consideration to means of analysing larger groups of incident reports in order to identify findings that may be applicable at a whole-of-system level and are not visible at the individual patient or local institution level.

In order to support a national approach to this work, the Commission undertook the 'Learning from Patient Safety Incidents' project during 2009 to identify the potential for systemic learnings from adverse events recorded in Incident Reporting Systems (IRS). The project aimed to: identify key lessons that can be learned from incident information, develop a methodology for drawing together such information, and explore the value of this activity for national learning.

The work was undertaken for the Commission by a research team led by the Australian Patient Safety Foundation in collaboration with the Centre for Health Informatics of the University of New South Wales, the Human Factors and Safety Management Systems Group of the University of South Australia, and Communitio. The areas chosen for analysis were incident reports related to patient identification and clinical handover.

Overall, the project found that, currently, the analysis of large collections of clinical handover and patient identification incident reports provides no new information of substantial value.

Aggregate analysis techniques are still developing, and the quality of information contained in incident reports is likely to steadily improve as incident reporting becomes a routine, established practice for all clinicians. Calls for an aggregated, comprehensive national system cannot, however, be supported at present. Nonetheless, some risks span multiple healthcare organisations and this means that support for ongoing approaches to share the learning from current analyses is essential.

Reporting of Sentinel Events in Australia

In addition to the established processes of patient-safety adverse event-reporting in Australia, all hospitals, public and private, report separately a small set of severe events, called Sentinel Events. These may be considered as a group of 'never events', that is, events of a type that should never occur. National collection of Sentinel Events was agreed to by Health Ministers in 2004.

Results of the Learning from Patient Safety Incidents Project

Patient identification and clinical handover incidents from one jurisdiction were the subject of analysis in this project. The study used a variety of techniques to examine incident reports including machine-learning technology, incident analysis and human-factors analysis. In addition, root cause analysis reports were reviewed for selected incidents.

The project findings, such as 'patient identification incidents commonly involve errors with documentation, medication administration and procedures on the wrong patient' or that clinical handover incidents frequently involve 'inadequate or incomplete handover, with details pertaining to the clinical condition of the patient being omitted or inappropriate', are already established findings in the patient safety literature.

The project results suggest that aggregating clinical handover and patient-identification incidents reports for analysis does not provide new insights into the underlying causes of these types of incidents. The main limitation to harnessing learnings from the incident collections was the limited amount and variable quality of the information found within individual incident reports. This applies equally to the quality of the classification and quality of the narrative.

The project did, however, determine that machine-learning algorithms can successfully be used to accurately identify handover and patient-identification incidents for analysis.

A Sentinel Event report on public hospitals for 2004–05 was published in 2007.¹² Data from 2005 to 2007 were published in the Commission's *Windows into Safety and Quality in Health Care 2008* report¹³ last year and in the Productivity Commission's *Report on Government Services*. Private hospital sector data were voluntarily provided in 2008 for this reporting and have again been provided this year on the same voluntary basis. Sentinel Event reporting continues to be a part of the national safety and quality reporting framework for the Commission. However, it is recognised that using the count of Sentinel Events as a measure of 'performance' is misleading. Sentinel Events are simply a count of occurrence, and the absence of any capacity to determine a 'rate' for reporting means that results cannot be compared because.¹⁴

- Sentinel Events are extremely rare events within millions of hospital admissions and outpatient encounters. The differences between the crude numbers of Sentinel Events, typically presented by jurisdiction or over time, are unlikely to be statistically significant.
- There is no accounting for predisposing factors that may influence the likelihood of Sentinel Events; urgency, size, remoteness of facility and procedural complexity are not taken into account.

Incident data come from voluntary staff reports and overall reporting rates vary considerably. For rare and severe events, self-reporting is considered to be more valid.¹⁵ However, the use of these counts to measure and compare could possibly lead to decreased reporting, and thus reduce opportunity for analysis and improvement.

Higher reporting rates, in fact, are generally thought to be associated with safer care. In the United Kingdom, National Health Service organisations with high reporting rates performed better on safety culture (as assessed by staff survey) and received a lower rating for litigation risk than those with lower incident reporting rates.¹⁶

Development of the national model for reporting on patient safety by the Commission, which is discussed below, will eventually provide a more valid approach to understanding healthcare service safety performance and complement the Sentinel Event reports.

Defining Sentinel Events

As discussed in last year's report, the Australian national Sentinel Events list is arbitrary.¹⁷ The eight sentinel events represent about 10% of all serious adverse events, based

on published data of serious adverse events reported to central agencies in Queensland and New South Wales. These states, and other jurisdictions, require the central reporting of all healthcare-related events associated with death or permanent harm.

The definitions in the current Sentinel Event list do not all specify a consequence. The intent in choosing these Sentinel Events was to identify events that '...result in the death or serious harm to a patient'. Experience from the jurisdictions revealed that in the evolution of data gathering, application of Sentinel Event 1 (procedures involving the wrong patient or body part) had been inconsistent. Prior to 2007–2008, procedures involving far less harm, including wrong-site diagnostic radiography, had been included in the reporting process. Although this may have value at a jurisdictional level in order to identify system issues such as patient identification problems that may require a local solution, it was agreed that they should not be considered as Sentinel Events in the national reporting of these events.

Consequently, the Australian Health Ministers' Advisory Council (AHMAC) amended the definition of Sentinel Event 1 this year to ensure that it only relates to events that result in death or serious harm, bringing it into line with the other seven Sentinel Events. The revised definition now includes a clarifying phrase to specify which events should be included for national reporting:

Sentinel Event 1. 'Procedures involving the wrong patient or body part *resulting in death or major permanent loss of function*'.

The 2007–2008 tables have been adjusted in line with this new definition of Sentinel Event 1. There have been no other definitional changes.

Future patient safety reporting in Australia

To obtain a comprehensive picture of patient safety, a range of measures is required and a more strategic approach taken to the use of incident reporting and analysis. In the five years since Sentinel Event reporting was agreed to, there has been considerable further development in the evidence and practical experience with using safety measurements for improvement. In addition, government and the private sector have demonstrated increased interest in understanding and responding to safety 'metrics' beyond sentinel events.

Sentinel Events 2007–2008

Public sector

Sentinel Event type	2005–06	2006–07	2007–08*
Procedures involving the wrong patient or body part <i>resulting in death or major permanent loss of function</i>	66	159	21
Suicide of a patient in an inpatient unit	25	41	32
Retained instrument or other material after surgery requiring re-operation or further surgical procedure	28	28	34
Intravascular gas embolism resulting in death or neurological damage	2	3	1
Haemolytic blood transfusion reaction resulting from blood type ABO incompatibility	1	2	4
Medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs	5	11	21
Maternal death or serious morbidity associated with labour or delivery	12	13	22
Infant discharged to the wrong family	0	0	2
Total	139	257	137

* The 2007–08 figures reflect the revised national definition of the first sentinel event.

Private sector

The numbers of private hospitals voluntarily reporting sentinel event numbers has changed each year. Figures for 2007–2008 cover facilities operating 22,163 beds, which is a little more than 80% of the 27,641 private hospital beds in Australia.

Sentinel Event type	2005–06	2006–07	2007–08*
Procedures involving the wrong patient or body part <i>resulting in death or major permanent loss of function</i>	13	28	1
Suicide of a patient in an inpatient unit	5	4	8
Retained instrument or other material after surgery requiring re-operation or further surgical procedure	16	27	14
Intravascular gas embolism resulting in death or neurological damage	1	3	0
Haemolytic blood transfusion reaction resulting from blood type ABO incompatibility	2	1	2
Medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs	0	0	1
Maternal death or serious morbidity associated with labour or delivery	7	4	9
Infant discharged to the wrong family	0	0	0
Total	44	67	35

* The 2007–08 figures reflect the revised national definition of the first sentinel event.

Government support for the use of patient safety measures is demonstrated in the National Healthcare Agreements 2009–2013 (NHA), which are accompanied by a set of performance indicators. These include:

- selected adverse events in acute and subacute care settings, and
- unplanned or unexpected re-admissions within 28 days of selected surgical admissions.

The Commission is working to generate more reliable and comprehensive signalling and measurement systems for local hospital safety improvement. Ideally, it would include the following elements:

- *Hospital-level outcome indicators* for monitoring trends and variations in in-hospital mortality and re-admissions. Health ministers endorsed the Commission's proposal that hospitals routinely generate a core set of common outcome indicators that enable routine comparison of performance of a hospital over time, and against peer hospitals. Trends and 'spikes' in these indicators would be plotted with an appropriate risk adjustment. A model for responding to spikes and significant trends would include data review, case reviews, and at times further investigation. Queensland has implemented a comprehensive and sound governance and review process as part of the VLADs project¹⁸ and Victoria's AusPSI project¹⁹ has a similar intent and approach (refer to Chapter 9 for more information).

- *Analyses of coded inpatient data* to monitor trends and variations in high-volume, 'mundane' sources of harm. Associate Professor Terri Jackson (University of Queensland) was commissioned to study measurement and costing of hospital-acquired diagnoses from inpatient data. This project was reported in *Windows into Safety and Quality in Health Care 2008*, and demonstrates the usefulness of coded inpatient data, especially the 'condition onset' flag, to quantify the cost and additional bed days generated by in-hospital events including falls with fractures, infections, pressure ulcers and post-procedural metabolic disorders.²⁰
- *Bedside and chart audits or surveys*, rigorously sampled, to provide 'gold standard' baseline rates and understanding, of a discrete set of high-volume adverse-events (for instance, pressure ulcers).
- WHO, via the Australian Patient Safety Foundation, is developing a classification to support *structured adverse-event analysis*. Applying this tool to samples of specific types of adverse-event reports may enable better thematic learnings than analysis of raw IRS information.²¹

National reporting will provide information and signals for action to support priority setting for improvement in patient safety.



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A photograph of a hospital corridor. A person in a blue shirt and dark trousers is walking away from the camera towards an exit sign. The corridor has white walls, a tiled floor, and a ceiling with recessed lights. An 'EXIT' sign is visible above a doorway in the distance. A large white number '8' is overlaid on the left side of the image.

8

Measuring hospital mortality: using Hospital Standardised Mortality Ratios in Australia

The key reason for measuring hospital mortality is to use this information to improve the safety and quality of the care that hospitals provide. Hospital mortality statistics allow both the staff who work in hospitals, and the current and future patients of that hospital to be better informed about the outcomes of care. Mortality statistics can also be used to monitor the impact of measures taken to improve safety and quality.

It can be argued that for hospitals to be able to use mortality statistics to improve the safety and quality of their practices, they need to be able to compare themselves against the outcomes that might reasonably be expected given the kinds of patients they treat.

In 2009, the Australian Commission on Safety and Quality in Health Care (the Commission) funded the work that culminated in a report (*Measuring and reporting mortality in hospital patients*) from the Australian Institute of Health and Welfare.² The first part of that report consists of a review of the state of the art in measuring hospital mortality. The second part provides an analysis of Australian data. The report concluded that:

- throughout the world, hospitals vary in the rate at which patients, admitted for care for a variety of acute illnesses, die during their hospital stay
- hospital mortality is best reported as a Hospital Standardised Mortality Ratio (HSMR)
- risk adjustment (to compensate for variations in the demographic and clinical characteristics of patients treated within hospitals of interest) is best undertaken by applying a mathematical modelling process based on logistic regression
- little extra benefit is gained by adding clinical or laboratory information to data that are already present in administrative or morbidity datasets, and
- the common practice is to calculate mortality rates for those limited numbers of primary diagnoses responsible for 80% of inpatient deaths, and to exclude patients whose admission is primarily for the purpose of providing palliative care.

The following sections explain some of the issues in deriving measures of hospital mortality.

Understanding measures of hospital mortality

$$\text{HSMR} = \frac{\text{Observed deaths}}{\text{Expected deaths}} \times 100$$

Hospital mortality statistics, generated from existing hospital reporting processes, are always reported as rates; that is, as the number of deaths per 100 patients treated. The number of deaths within a group of patients can be identified by looking at a hospital's raw statistics. If the observed number of deaths is divided by an expected

number of deaths, a ratio is obtained. A ratio value of less than one is favourable, more than one unfavourable. Multiplying that ratio by 100 generates the most common method of reporting hospital mortality, an HSMR.

A hospital whose mortality rate is exactly at the overall expected level for a whole group of hospitals studied has an HSMR of 100. A HSMR of 120 implies a mortality ratio 20% higher than would be expected in the average hospital treating patients of similar complexity, and an HSMR of 80 implies a mortality ratio 20% lower.⁴ The most important issues in hospital-mortality analysis relate to how to calculate the numbers of expected deaths.

Variations in HSMRs are commonly a source of considerable interest in the community at large. However, it is less clear how exactly to link these variations to the processes of care in the hospitals concerned.

Risk adjustment

The mortality rates of patients treated in hospitals might vary for a number of reasons, many of which may not be related to the quality and safety of care. Most obviously, the severity of patients' illnesses may vary between hospitals. If patients treated in Hospital A are much more severely ill when they reach hospital than those patients treated in Hospital B, it is likely that the mortality rate of patients in Hospital A will be greater than that in Hospital B. By allowing for the differences in severity, it is possible to help both Hospital A and Hospital B to assess whether their outcomes are what might be expected, given the cases they treat.

This adjustment process is called risk adjustment. Risk adjustment is only possible if all the hospitals in a study of hospital mortality use a standard 'language' to describe those characteristics of their patients that might affect their outcomes. Those characteristics covered in the 'language' will include factors such as age, sex, the primary clinical condition, any secondary conditions, whether a surgical procedure was performed, whether patients were admitted as an emergency, and so on.

In the 1980s, the United States federal government promoted the development of such a language (the Diagnostic Related Group, or casemix, system) as part of its efforts to change the payment systems for patients whose health care was the responsibility of the federal government (eg United States Medicare and Medicaid recipients). With standardised ways to describe patients' demographic and clinical characteristics, it became possible to devise risk-adjustment processes for

hospital mortality statistics. The Australian government adopted the casemix system in the 1990s, leading to the development of Australian-specific diagnosis-related groups (AN-DRGs).

Over the years, casemix systems have been adopted by many different countries. In using them, or other equivalent systems, an international consensus has gradually emerged as to how to risk adjust hospital mortality statistics so as to provide a relatively 'level playing field' for assessing the extent to which the outcomes of care for hospitals within a group are what might be expected, given the specific characteristics of the patients treated in each hospital. There have been a great number of studies published in which risk adjustment has been undertaken to examine mortality rates of a variety of conditions.^{5 6}

Risk adjustment is a fairly complex process and a number of concerns in relation to risk adjustment are commonly raised. Some of these are discussed below.

Co-morbidities

Patients may go to hospital for treatment of a specific condition, but the outcome of their stay will be influenced by other conditions that they also have. There is an almost infinite number of combinations of primary conditions and co-morbid conditions. The consensus that has emerged is that the influence of those extra, or co-morbid, conditions is best analysed by first grouping them using an index derived by an American medical researcher, Mary Charlson (the Charlson Index), then assigning a similar value to all conditions within any one subgroup.⁷ The values reflect the relative severity of the conditions within each Charlson Index subgroup.

Sources of the data

Calculating hospital mortality rates requires access to large amounts of information. The only practical way to gather enough information is to use the data that are collected about every patient — these data are normally used for the broad purposes of managing a healthcare system. Such datasets are commonly described as administrative or morbidity datasets. The term administrative is rather misleading, as such datasets usually contain quite detailed information about diagnoses and procedures undertaken.⁹ Notwithstanding this, healthcare professionals have long been concerned that administrative datasets do not contain sufficiently detailed clinical information. They have assumed that datasets

gathered for clinical purposes will be better resources for predicting hospital mortality than administrative datasets.

A review of the existing scientific literature on this issue has shown these anxieties to be largely unfounded. An extensive series of studies in the 1990s used a large volume of patient records from which clinical information had been extracted in various ways (see Table 1 in Ben-Tovim D et al 2009).² These studies demonstrated that adding extra clinical information to administrative datasets did not improve the capacity of the risk-adjustment process to more accurately discriminate those patients who were, or were not, at greater risk of dying during their hospital stay.

In a number of areas of clinical activity, specialist groups in various hospitals record considerable details about their patients and provide those details to specialised registries that group records together. This allows those specialist groups to risk-adjust outcomes using the detailed clinical information supplied by the specialist services. A major study compared mortality risk adjustment using data from a series of registries against risk adjustment for the same patients using the data available in administrative, or morbidity datasets. No increase in discriminatory power was observed.⁹

Random error and reliability

Hospitals are large and complex places in which things do not always go to plan. From a technical point of view, the concern is that hospital mortality rates may be subject to substantial random variation; that is, as a result of all the chance happenings in a hospital, overall mortality rates may vary so much from year to year that any one outcome becomes uninterpretable. A hospital may report a result one year that is a source of concern the following but by the following year, everything will appear to have changed. But those changes may not be the product of specific actions to improve hospital processes, rather they may have occurred by chance alone.

A number of the early studies that raised this concern did so by extrapolating information from one year, using rather complex mathematical techniques. The best way to study this issue is to examine what actually happens to mortality rates over a period of years. This was done in a study of all the major hospitals in the Netherlands.⁸ The results were reassuring in that while hospitals certainly differed from one another, the mortality rates in particular hospitals did not differ greatly over time. The effects of random variation were not so great as to make the results uninterpretable.

It is important to note that studies that confirm the robustness of mortality measures over time are generally confined to large (>10,000 separations per annum) and medium-sized (2,000–5,000 separations per annum) hospitals. The impact of a small change in mortality may be disproportionately magnified in hospitals with low numbers of admissions, so mortality rate measures are much less meaningful for small hospitals (<2,000 separations per annum) because the impact of the play of chance is not 'smoothed out' by the larger numbers of patients treated in bigger hospitals.

Australian Hospital Standardised Mortality Ratios

There are generally two types of information on hospital mortality rates in Australia: the traditional publicly available reports (eg journal articles and published reports) and the grey (unpublished or informal) literature. A number of traditional publicly available sources of information on hospital mortality rates in Australia have been identified, as has an example of unpublished hospital mortality information from Queensland that subsequently was made public.²

For the first time, the *Measuring and reporting mortality in hospital patients* report publicly presented HSMRs for Australian hospitals, although the confidentiality of the included hospitals was preserved.² The report itself provided a basis for a discussion among stakeholders and other interested individuals on a way forward for public reporting of HSMRs in Australia.

The report analysed data for Australian public hospitals in order to investigate the application of HSMRs.² One of the issues is how to display the results most meaningfully. Once the hospital mortality rates for a group of hospitals have been calculated, how should those results be provided back to hospitals, or to the community at large? There are three common ways to present hospital mortality rates:

- league tables
- caterpillar plots, and
- funnel plots.

League tables

It might seem that the most obvious way to present the results would be in a table with the results going from the highest (eg least favourable) HSMR to the lowest. Although that allows the reader to easily locate the

relative position of any given hospital, there are a number of reasons to avoid presenting HSMRs as a simple league table or set of league tables. A league table necessarily puts results into a rank order. Yet most hospitals have very similar HSMRs, with values that differ by just decimal points or one or two percent. Differences of that size are not of practical significance, yet when hospitals are bunched together they can lead to apparent large differences in hospital rankings, leading to an undue emphasis on small differences.²

Furthermore, even when HSMRs remain fairly stable over time, the exact value can be subject to a certain amount of random variation. So it is usual to quote HSMRs with a confidence range or interval. For example, a hospital's HSMR for 2006 may be 100, but with chance, the result could have fallen anywhere between 96 and 104. In 2006, it happened to be 100. Another hospital, treating the same kinds of patients with similarly skilled staff, could have a result within the same range and end up with an HSMR of 104. A league table would infer that the second hospital had a much worse result than the first, but actually, they were very, very similar. Presenting information in simple leagues tables, even if they contain information about confidence limits, can lead to misinterpretation or over-emphasis on relative rankings of hospitals.

Caterpillar plots

A 'caterpillar plot' is the colloquial term for a form of graphical presentation of individual hospitals ranked by HSMRs. The HSMR for each hospital (and their confidence intervals) are displayed along the x-axis, and the actual value of the HSMR is shown on the y-axis.¹⁰ Figures 8.1 and 8.2 show the HSMRs for two groups of hospitals. Figure 8.1 shows HSMRs for 'A1' hospitals (major city hospitals with >20,000 acute casemix-adjusted separations and regional hospitals with >16,000 acute casemix-adjusted separations per annum). Figure 8.2 shows HSMRs for B1 hospitals (Major city acute hospitals treating between 10,000 and 20,000 acute casemix-adjusted separations per year). The HSMR is calculated in such a way that the overall average HSMR for the population of patients treated within all hospitals is 100 (shown as a red line in figures 8.1 and 8.2).

Figure 8.2 provides HSMR values for B1 hospitals. More of the HSMR values for the smaller hospitals in peer group B1 are below 100 than the larger hospitals in Figure 8.1. Are those hospitals safer than the larger hospitals? Because the risk-adjustment process was

undertaken using data from all hospitals, it is statistically appropriate to present the information as shown. But the apparently lower-risk hospitals are only low risk for the kinds of patients they treat. They would only be truly comparable with the larger hospitals if, when presented with an identical patient mix, they had the same mortality outcomes. This would almost certainly not be the case, and if all hospitals were put together in a single league table, inappropriate conclusions might be drawn. This

is a further argument against simple league tables as a reporting methodology.

When the confidence limits or intervals of a pair of hospitals do not overlap, then those two hospitals can be assumed to be statistically different in their outcomes. When the confidence limits of a hospital's HSMR are *both above 100* (the whole of the confidence interval is above 100), then that hospital is assumed to have a mortality outcome that is statistically significantly worse than the

Figure 8.1 Caterpillar plot of HSMRs for Australian hospital peer group A1, 2005–2006

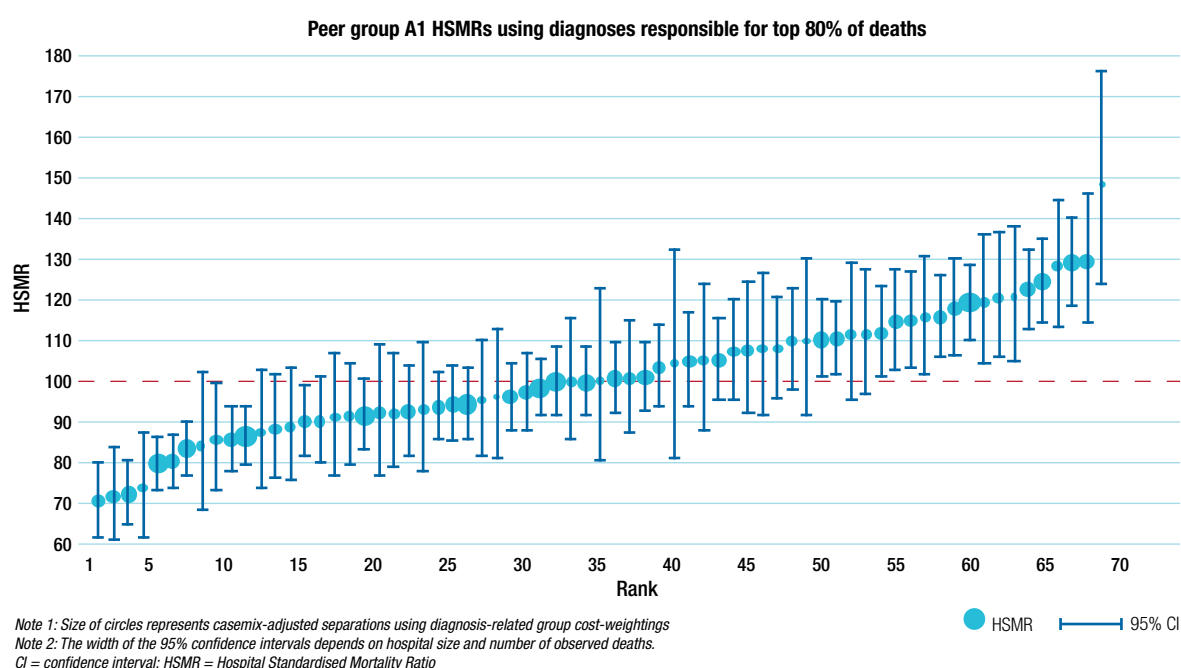
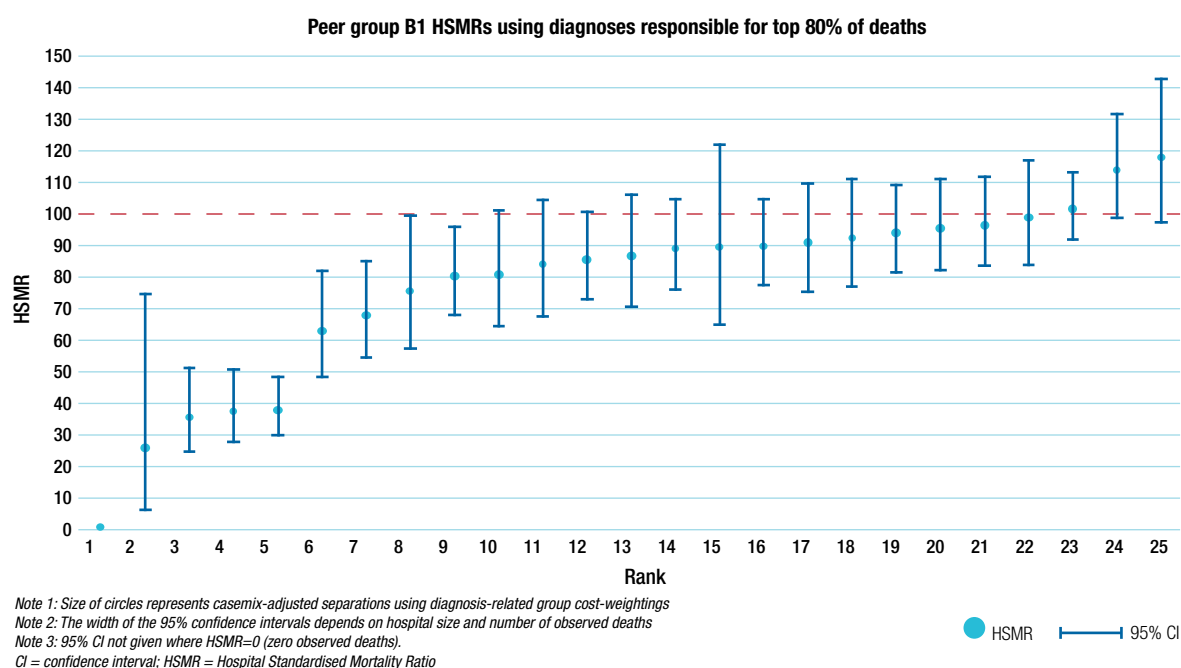


Figure 8.2 Caterpillar plot of HSMRs for Australian hospital peer group B1, 2005–2006



overall averages. When they are *both below* (or the whole of the confidence interval is below 100), that outcome is statistically better than the overall average.

Caterpillar plots are relatively easy to understand, and combine a straightforward graphical presentation with an appropriate statistical analysis. There are a number of different ways of presenting caterpillar plots that can emphasise different aspects of the results.

When analysing the outcomes from a national system, it is usual to group hospitals within that system in some way, for instance to group large general hospitals together, and separate them from smaller or more specialised hospitals. This increases the likelihood of comparing similar types of hospitals.

Funnel plots

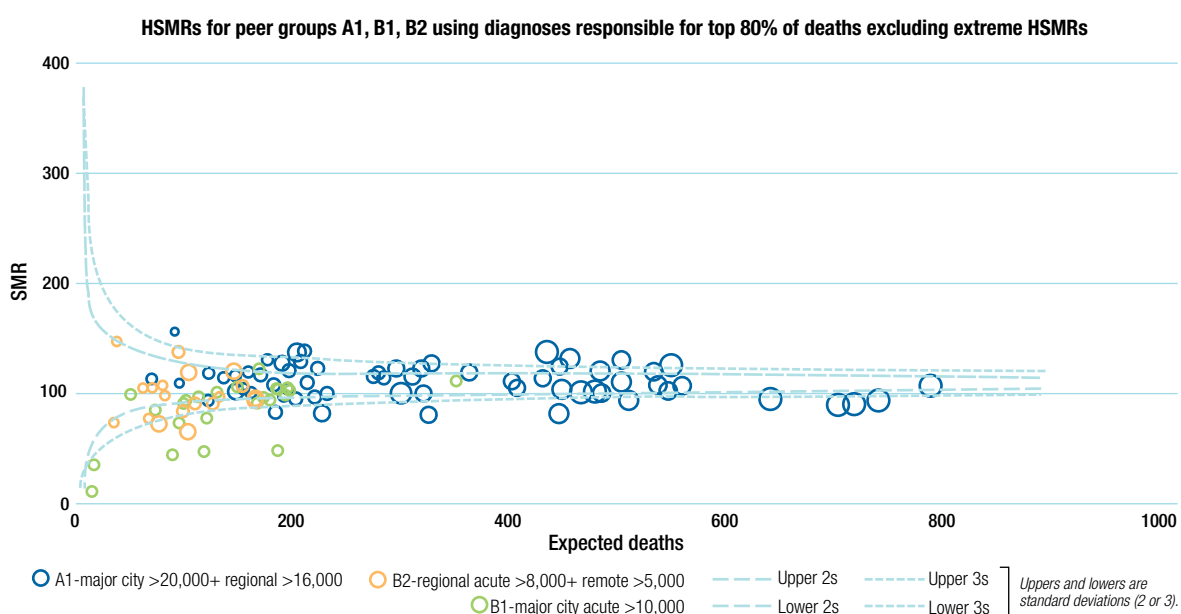
Funnel plots are a relatively recent innovation in the analysis and presentation of HSMRs.¹¹ They are a statistically sophisticated method for grouping hospital outcomes into bands that indicate the extent to which outcomes are or are not within a range of likelihoods. The term ‘funnel plot’ comes from the fact that the ‘width’ of the acceptable variation in the HSMR outcome bands forms a funnel shape, because smaller hospitals with smaller absolute numbers of deaths will have broader confidence limits for their mortality rates and as hospitals get progressively larger the intervals reduce.

The Lady of the Lamp

Florence Nightingale is rightly famous as the ‘Lady of the Lamp’. She played a vital role in establishing nursing as a profession, and dramatically improved care in nineteenth century military hospitals. It is less well known that she was an excellent mathematician and an early advocate for reporting hospital mortality statistics.¹

Florence Nightingale considered that the reporting of hospital statistics would ‘enable us to ascertain the relative mortality of different hospitals as well as of different diseases and injuries’. It was almost certainly at her urging that between 1861 and 1865 the *Journal of the Statistical Society* published a series of articles reporting English hospital-mortality rates. Interestingly, the criticisms that greeted those articles — ‘... the mortality of hospitals is mainly due to causes which determine the nature and severity of the cases admitted within their walls’³ — have continued to be echoed in comments on hospital mortality statistics up to the present day.

Figure 8.3 Funnel plot of Australian Hospital Standardised Mortality Ratios, 2005–2006



Note 1: Size of circles represents casemix-adjusted separations using diagnosis-related groups cost-weightings
 Note 2: Numbers in legends refer to total casemix-adjusted separations per year

Funnel plots provide a simple way to identify hospitals whose results are so extreme that it is unlikely to have occurred by chance (outliers). Figure 8.3 is an example of a mortality funnel plot. In most cases, the vast majority of hospitals lie inside the funnel. Only the hospitals with the most extreme results fall outside the funnel. Those falling above the funnel have HSMRs that are worse than expected, those below the funnel have HSMRs that are better than expected.

What do HSMRs tell us?

The literature on hospital mortality rates makes it clear that many of the anxieties about risk adjustment and the reliability of HSMRs can be allayed. But it is perhaps more problematic to decide how an observed mortality rate (that is or is not within the expected range) should be interpreted. If we take a safe hospital to be one that does a particularly good job of protecting the patients in its care from harm, then a hospital with a low HSMR might reasonably be said to be safer than one with a high HSMR. However, this is a 'whole of hospital' statement, and it says nothing about the efforts that individual units or clinicians make to provide the best possible care. It is also not yet clear whether high or low HSMR hospitals have factors in common that predict their mortality outcomes.

It is more problematic to simply assert that the care in hospitals with a high or low HSMR is of high or low quality. Finding a simple definition of hospital quality itself is not straightforward. Measures of quality are controversial and there is only a limited relationship between HSMRs and other measures of hospital quality. But what is the 'gold standard' of hospital quality? If it is mortality rates, then existing measures of quality are not good measures. If it is a process measure, such as the percentage of patients leaving hospital with evidence-based treatments for cardiac conditions, then the limited relationship between that measure and overall hospital mortality rates can be taken to mean that mortality rates are not great measures of quality.

There is no simple way to resolve this issue. The report advocates the use of mortality rates as a screening tool, rather than as definitive measures of safety or quality.² A screening tool is used to point towards a possible problem that requires further examination, rather than being used to definitively state that a problem may, or may not, be present. A screening process needs to be followed by a systematic investigation strategy for possible problem areas. This investigation begins

with the possibility of coding or other administrative issues, and works its way up to more serious issues of clinical concern. If a screening tool is to do its job well, the follow-up investigation will not always confirm an underlying problem. A certain amount of 'over calling' has to be tolerated if important issues are not to be missed, though the magnitude of extra work generated has to be carefully monitored.

Public or directed reporting?

There has been considerable debate as to whether hospital mortality rates should be publicly reported or whether they should be solely reported to hospitals and healthcare services. Hospitals and healthcare service staff may be concerned that their reputations will be unfairly damaged, and their patients unnecessarily alarmed, by public reporting of HSMRs. This could be particularly true if the reports are in the form of league tables that inappropriately emphasise small differences in HSMRs.

Although there is still some uncertainty in this area, accumulated experience seems to be that public reporting does prompt action on safety and quality more than restricted reporting does.¹⁰ Although healthcare professionals are sensitive to and respond to public reports, patients do not cease to seek care in those settings with reported higher mortalities. Furthermore, there are a number of case studies demonstrating impressive reductions in HSMRs as a result of efforts that were prompted by the public release of HSMR data.^{5 11}

Transparency in public reporting can aid in building and maintaining confidence and trust. National public reporting is now being undertaken in the United Kingdom and Canada.¹² Many healthcare systems in the United States provide mortality reports on their websites. Recently, a website set up by the United States Department of Health and Human Services allows self-selected comparisons between hospitals to be viewed online (www.hospitalcompare.hhs.gov). Other countries are likely to follow with national reports in the near future.

The Australian study of hospital mortality

The second part of the *Measuring and reporting mortality in hospital patients* report included a study of mortality rates in hospitals across Australia.² The primary objective of the study was to determine if administrative data, i.e. the National Hospital Morbidity Database (NHMD), generated by the states and territories and provided to the

Australian Institute of Health and Welfare (AIHW), contains sufficient information to create HSMRs for Australian hospitals. Initially, the mortality study examined a dataset of separations from all Australian hospitals (public and private) for the financial year 2005–2006. A separation is recorded whenever a patient is discharged from hospital inpatient (and some ambulatory) treatment facilities. These data were subjected to a cross-sectional analysis and then tested in a longitudinal study using data for three consecutive years.

Cross-sectional analysis methodology

The report's authors used the methodology published by the Canadian Institute for Health Information (CIHI) to calculate HSMRs.² The Canadian report details HSMRs for hospitals across Canada, and gives a well-documented model against which to test the adequacy of Australian hospital separations data.¹² Data from the NHMD were prepared for analysis in a similar manner to that reported by the CIHI.

Three subsets of analyses were undertaken. First, only those patients with those clinical diagnoses that accounted for 80% of in-hospital deaths were included (the groups of diagnoses with the greatest numbers of deaths). Second, only those separations with diagnoses that accounted for the remaining 20% of deaths were included. Finally, all records satisfying the selection criteria were included in the analysis. The report contains a detailed description of all three analyses, but here we shall focus on the analysis of those clinical diagnoses involved in 80% of hospital deaths, the group most commonly examined in other studies.

The criteria for separations to be included in the analysis were:

- admission to hospital for acute care
- age at admission from 0 to 120 years (neonates were excluded)
- gender recorded as male or female
- length of hospital stay up to 365 consecutive days
- admission category: either elective or emergency, and
- principal diagnosis at discharge — the proportion of in-hospital deaths was calculated for the set of cases with each three-character ICD-10-AM code and diagnosis codes were ranked in descending order of this proportion.

The criteria for separations to be excluded from the study were as follows:

- patients discharged against medical advice;
- palliative care patients, and
- neonates (infant age >0 and ≤ 28 days).

Table 8.1 summarises the composition of the sample population.

Table 8.1 Selective descriptive statistics for the high-risk case group (80% of in-hospital mortality in 2005–2006)

	Number of separations	Per cent
Gender		
Male	588,106	53.31
Female	515,169	46.69
Died in hospital	36,046	3.27
Healthcare sector		
Public hospital	744,481	67.48
Private hospital	309,064	28.01
Public psychiatric hospital	9	0.00
Private free-standing day hospital	49,721	4.51

Institutional issues

Australia has a number of highly specialised hospitals providing care for women and children. The specialised nature of these hospitals means that the factors influencing the mortality of patients treated within them are likely to be very different from those in general hospitals. The influence of these specialised hospitals on overall risk adjustment profiles was studied by conducting analyses with and without the data from the specialised women's and children's hospitals. Their inclusion did not appear to have a material impact on the results of the risk-adjustment process, so the patients treated within them were retained in the overall analysis. Their outcomes are, however, presented separately in the report.²

Both public and private hospitals contribute to NHMD, but specific private hospitals were not identified within the database provided for analysis. Although the model-building process used to calculate the expected number of deaths for a public hospital's particular population was based on all eligible patients treated in Australian hospitals, the report contains an extended analysis of public hospital outcomes only because that is what the available data allows.

Results of the cross-sectional analysis

The patient-level variables tested for inclusion followed those identified in the Canadian and other studies. They were age, gender, length of stay, admission category (emergency or elective) and diagnosis group. Table 8.2 presents the effects of the selected patient variables on the odds of in-hospital mortality. That is, the table shows the extent to which patient variables, such as age, principle diagnosis, and secondary diagnoses, increase or decrease the likelihood of death in hospital. The results are provided as odds ratios. The odds ratios can be interpreted as the effect each variable exerts on changing the likelihood of a particular patient dying while in hospital. For instance, elective admissions were associated with a little over one-quarter (0.28) of the likelihood of an in-hospital death compared with an emergency admission. The presence of two or more Charlson comorbidity categories were associated with a six-fold increase in the likelihood of death during a hospital stay.

There are a number of ways that the discriminatory and explanatory power of the modelling process can be tested. The relevant mathematical indices (the c statistic, the pseudo R-squared and the change in pseudo R-squared) were provided in the report, which demonstrated that the mathematical model used provides appropriate levels of discrimination and explanatory power, closely resembling those generated by similar processes in other settings.

The report contains detailed discussion of technical issues related to the statistical 'fit' of the mathematical model involved. A well-fitting model is a model whose outcomes

closely resemble the distribution of the outcomes in the data itself. That is, the outcomes of the mathematical model closely 'fit' the reality that is being modelled.

Taking the outcomes overall, it is possible to say that the NHMD is an acceptable source of information on which to base an analysis of HSMRs.

The coefficients generated from the modelling process were then applied to the relevant patients treated in each hospital in Australia, generating an observed and expected mortality rate for each Australian hospital studied. Those rates were then used to generate an HSMR for every hospital studied. The report also gives HSMR outcomes by hospital peer groups using a variety of different approaches (as seen in figures 8.1 and 8.2).

Longitudinal analysis

Having confirmed the robustness of the underlying data systems, a longitudinal analysis was performed on data covering the years 2004–2005, 2005–2006 and 2006–2007 to confirm that stable results were being generated. An extensive data-matching process was undertaken to ensure that hospitals were correctly identified in each of the three years, and only those hospitals whose identity could be confirmed in all years were included in this analysis.

A longitudinal analysis of this nature depends on tracking individual hospitals over time. Unfortunately, this is not as simple as it sounds. Hospitals merge, change ownership, change their names, and change from public to private and vice versa. Private hospitals were generally

Table 8.2 Odds ratios for the effect of each of the included covariates on 80% in-hospital mortality

	Odds ratio	95% CI	P-value
Age (years)	1.045	(1.044–1.046)	<0.001
Sex (male=1, female=2)	1.007	(0.984–1.031)	0.556
Urgency admission (emergency=1, elective=2)			
1	1.000	—	—
2	0.281	(0.271–0.291)	<0.001
Canadian Charlson category			
0	1.000	—	—
1	2.756	(2.637–2.880)	<0.001
2	6.048	(5.780–6.330)	<0.001
Transferred patient	1.578	(1.519–1.639)	<0.001

not identified separately in the NHMD and were not in the tables, and could not be included in this part of the analysis. Of the 856 hospitals identified in the three data years, 736 were matched across all three years and retained for the longitudinal analysis.

The aim of the longitudinal analysis was to look at the stability of the HSMR values over the three-year period, to determine the extent to which random variation in measured HSMR outcomes might make it problematic to interpret Australian HSMRs.

A two-stage analytic process was used, the first a logistic regression modelling on a year-by-year basis, the second a two-stage multi-level logistic regression. Detailed results are provided in the report, but the results were clear.²

Although the Australian hospitals differed from each other, within-hospital variation over time was small in comparison to differences between hospitals, and generally accounted for no more than 15% of overall variability. Mortality rates in Australian hospitals were generally stable over time, and random variation can be discounted as a source of difference between Australian hospitals.

Possible limitations of the analysis

The analysis presented in the *Measuring and reporting mortality in hospital patients* report is an initial step in the development of Australian HSMRs.² There are a number of limitations that should be acknowledged. Although the NHMD is generally a robust resource, the analysis is only as good as the underlying data within it, and any problems with data collection and data transmission could not be accounted for in this study. Hospitals and jurisdictions have not yet had an opportunity to review their own results in detail, and to point out any problems that they think might relate to variations in coding or other administrative issues.

The analysis was confined to deaths occurring in hospitals, as this is the only source of relevant information that is currently available Australia wide. It has been argued that including deaths that occur shortly (ie within 30 days) after leaving hospital would provide a more complete representation of the impact of hospital care on mortality. When Australia-wide linked datasets become available, it may be possible to examine this issue further.

The analysis was also confined to those patients whose care was defined as 'acute'. The potential impact of certain other care types, including Geriatric Evaluation and Management, and maintenance care, would need to be the subject of further study, as would the extent to which the excluded palliative care type is used across Australian hospitals.

Also, certain secondary diagnoses are included in the NHMD that could be seen as the consequence of care in hospital, rather than a description of the clinical condition of the patient at the point of arrival. From the beginning of the financial year 2008–2009, hospital coders are designating secondary diagnoses as to whether they were or were not present on admission, allowing the importance of separating out those secondary diagnoses that were not present on admission to be tested out in future years.

Future use of HSMRs in Australia

The Commission convened a national forum on Use of Mortality Measures to Monitor and Improve Health Care on 19 March 2009. Public and private hospital representatives from across Australia were present, and particular attention was paid to whether and how Australia should use HSMRs to monitor for significant variations in healthcare outcomes between peer hospitals and over time.¹³ General agreement was reached on the appropriateness of using HSMRs as one of a range of tools to monitor and improve quality and safety in hospitals.

Subsequently, an HSMR Technical Working Group was established to support the development of HSMR use. Composed of jurisdictional health statistics experts and academics this group has been established to:

- identify and resolve technical and statistical issues
- oversee reporting and analysis of HSMRs
- log and analyse methodological and reporting issues, and
- review the model against these issues and learnings.

The Commission has arranged for the AIHW to provide individual jurisdictions with their own HSMR data, by hospital, for the three-year reference period. Although the study dataset did not include private hospitals, ongoing representation and participation from that important sector is anticipated.

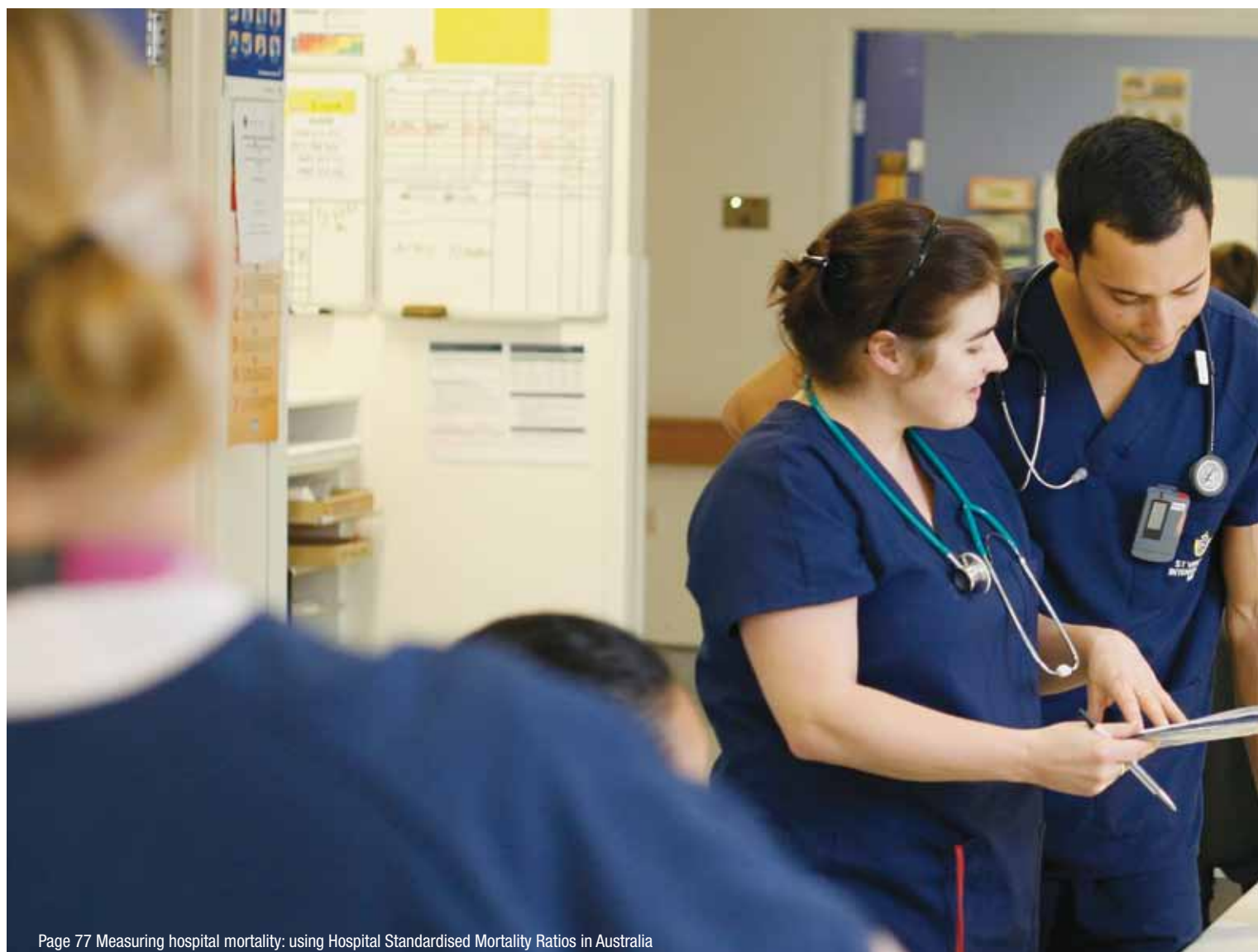
In October 2009, the Commission recommended to Health Ministers that the jurisdictions routinely generate and review their HSMRs, and that HSMRs be included as one of a core set of hospital-based outcome indicators for safety and quality.

Conclusions

The key reason for measuring hospital mortality is to use that information to improve the safety and quality of the care that hospitals provide. Before measures of hospital mortality can be calculated, they need to demonstrate some validity and reliability. The Commission-sponsored *Measuring and reporting mortality in hospital patients* report provides the basis for reaching conclusions about the reliability and validity of measuring hospital mortality using national hospital data. The report allows two conclusions to be drawn.

Firstly, many of the earlier anxieties about the robustness of HSMRs have been laid to rest by the accumulation of studies on their development. The appropriate interpretation of variations in HSMRs remains contentious. They are best regarded as screening tools that should prompt further analyses, rather than as tools to diagnose poor (or superior) quality of care.

The NHMD is a suitable resource for calculating HSMRs for Australian hospitals, and a longitudinal study of Australian HSMRs confirms that they are not subject to any substantial degree of random variation. There is considerable variation across Australia in mortality rates of hospitals of similar kinds, but this has been found to be the case in all other studies of hospital mortality. This reinforced the view that understanding the origins of variations in hospital mortality may provide a powerful opportunity to improve the safety and quality of the care provided in Australian hospitals.



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9

Measuring and reporting on safety and quality in hospitals

'Quality indicators...can be used as a basis for self-improvement in quality-improvement cycles, to inform policy and strategy making, to monitor performance of services and of funding bodies, to empower consumers to help make decisions about their choice of healthcare services, and to identify poor performance'.¹

The availability of timely, useful information is an essential component of high-performing healthcare systems.²

The National Health and Hospitals Reform Commission (NHHRC) stressed the importance of analysing and reporting on safety and quality as a key component of healthcare reform.³ The NHHRC final report states that 'a nationally consistent approach is essential to the collection and comparative reporting of indicators which monitor the safety and quality of care delivery across all sectors'. Such an approach would incorporate 'local systems of supportive feedback, including to clinicians, teams and organisations in primary health services and private and public hospitals'. Further, the NHHRC report states that 'data on quality and safety should be collated, compared and provided back to hospitals...in a timely fashion', and that 'public and private hospitals [should] be required to report publicly on performance against a national set of indicators which measure access, efficiency and quality of care'.³

The Australian Commission on Safety and Quality in Health Care (the Commission) has a responsibility to recommend national datasets for safety and quality. Datasets provide the definitions, elements and standards for data collections. The purpose of health data collection is to generate indicators and measures to describe and monitor the volume, access, cost and provision of healthcare services, and the quality of health care. Quality improvement in health care should be driven by information. This chapter looks at the use of indicators to support improvement in hospital care.

Current initiatives for monitoring and reporting on safety and quality

In Australia, data on clinical-quality measures of effectiveness (compliance with guidelines, or measures of actual healthcare outcomes) are found in patterns of care studies, clinical quality registries and hospital-level projects. Other clinical and safety-indicator programs operate at the levels of private or public hospital networks, jurisdictions, or private hospital ownership groups. These include Queensland Health's clinical indicators (QCI) and Variable Life Adjusted Display (VLAD) reporting methodology (Box 9.1) and Victoria's Australian Patient Safety Indicators (AusPSIs) (Box 9.2). Some members of the Australian Private Hospitals Association (APHA) are also trialling reporting against a common set of hospital indicators.

Box 9.1 Queensland's Variable Life Adjusted Displays (VLADs)

Queensland Health monitors clinical indicators (QCI) spanning four main services — obstetric, medical, mental health and surgery — according to outcomes of mortality, complications of surgery, length of stay, re-admission, caesarean section, episiotomy, and induction. Reports are presented to hospitals using VLADs.

VLAD is a statistical methodology based on an 'expected' minus 'observed' plot to monitor clinical outcomes over the course of a selected time period within an individual hospital. The majority of the time, individual patients are risk-adjusted based on their co-morbidities to create a 'level playing field' for all hospitals to compare themselves to the state average.

This technique enables rapid identification of trends in patient outcomes at the individual healthcare service level. That is, every separation influences the graphical display.⁵

A flagging mechanism can be applied that indicates the degree of variation between the hospital and state to indicate if a hospital has a higher or lower rate of outcomes than the state overall. The degree of variation can be adjusted to differing levels and can form the basis of clinical governance policies, implemented where greater levels of variation prompt more intensive review.

(Courtesy of Queensland Health)

The longer standing Australian Council on Healthcare Standards (ACHS) collects and reports on a range of clinical indicators.⁴ ACHS collects clinical indicators from 341 public and 348 private (including not-for-profit) healthcare organisations with the stated intention to 'shed light on quality issues such as whether the care given is accessible, safe, appropriate and responsive'.⁴ These indicators are collected voluntarily from hospitals across Australia and hospitals decide which indicator sets to submit to ACHS. In return, hospitals receive reports on their performance with respect to other hospitals.

Box 9.2 Victoria's Patient Safety Indicators Program – AusPSIs^{6 7 8}

The AusPSIs are a set of patient safety indicators providing information on potential in-hospital complications and adverse events following surgery, procedures and childbirth. They were developed from the United State's Agency for Healthcare Research and Quality (AHRQ) PSI project.⁹

The Victorian Department of Health's approach uses indicators chosen to address large portions of the sector, in sufficient numbers for areas of known concern and that are amenable to change.

The indicators for participating hospitals are provided back as VLAD reports, with flags of significant variation. Healthcare services consider flags on a case-by-case basis depending on the level of flagging. Investigation of identified trends would expose potential areas for quality and safety improvement. To improve the usability and applicability of the PSI reports, the initiative actively seeks and welcomes feedback from health services.

The 11 indicators chosen to address large portions of the sector are:¹⁰

- death in low mortality diagnosis-related groups
- complications of anaesthesia
- in-hospital fracture
- post-operative haemorrhage or haematoma
- post-operative deep vein thrombosis or pulmonary embolus
- obstetric trauma — vaginal or caesarean delivery
- stroke in-hospital mortality
- heart failure in-hospital mortality
- acute myocardial infarction (heart attack) in-hospital mortality
- pneumonia in-hospital mortality, and
- fractured neck of femur in-hospital mortality.

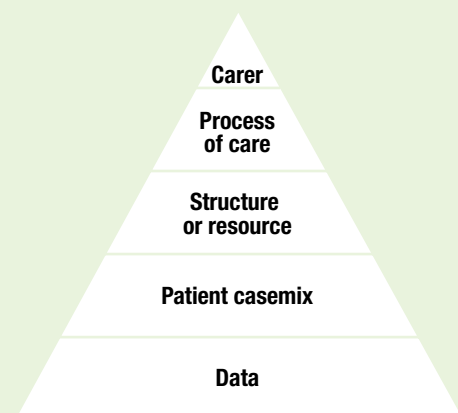
Using indicators to monitor hospital quality of care

The identification and development of these safety and quality indicators are important first steps in the process of measuring and reporting on safety and quality in hospitals. However, simply 'switching on' a suite of indicators, or using them to publicly rank hospitals or clinicians, is neither possible or advisable. It has been claimed that: 'What is critical in the new approach is not that an indicator is flagged for further investigation, but that robust investigation takes place'.¹¹

The difficulty of making comparisons between hospitals that provide different types of care and in which patients have different ages, health profiles and procedures (this is known as casemix) have been noted. The Productivity Commission, in its review of public and private hospitals, has commented on 'a paucity of reliable published data with which to compare the hospital sectors'.¹²

Queensland Health has developed an approach to investigating variance in hospital performance for those with a significantly better or worse performance than the state average. Using the 'pyramid model of investigation'¹³ (Box 9.3), data issues are reviewed as the first potential cause of reported variance. Local investigation then ascends through the pyramid looking at issues of the relative patient health and procedure profiles, structure and resources, care processes, and eventually clinicians, as possible explanations.

Box 9.3 The pyramid model of investigation¹³



Ideally, the processes for responding to 'outlier' reports would be transparent, fair and have high visibility at the hospital executive level. There are a number of issues to consider when measuring and reporting on the safety and quality of health care; some of these are discussed below.

Data quality and the relative merits of administrative and other data sources

One way of measuring safety and quality in hospitals is to use coded data gathered for each hospital patient's admitted care episode (see Box 9.4). The data gathered about every patient are used for the broad purposes of managing a healthcare system. Such datasets are commonly described as administrative or morbidity datasets. Administrative data are relatively inexpensive, readily available, tends to be universally collected and applied, and are usually available in a single database within jurisdictions, and even within private hospital ownership groups. Such datasets usually contain quite detailed information, but lack the accuracy and rigour of the measurements taken in clinical trials and clinical studies. The cost and burden of manual, rigorous, point-of-care data collection by dedicated data managers and clinical trials nurses, however, are beyond the capacity of the healthcare system.

Although broad outcome data such as death and re-admission is collected accurately within administrative datasets, information regarding specific clinical practices at the level of compliance with guidelines is generally not recorded. For this reason, HSMRs (see Chapter 8), the VLAD and the AusPSI programs focus on the significant outcomes that can be reliably obtained from administrative data, including in-hospital mortality, readmission, and fractures.

Comparability and risk adjustment

Meaningful comparison or benchmarking of performance among hospitals is not straightforward. Hospitals differ in the types of patients that they see, and the types of treatment they provide: one hospital may have a healthier or younger cohort of patients undergoing less complex procedures than another. Clinical and statistical techniques enhance the comparability of different patients by accounting for differences in the patient's age, general health, risk factors and medical history (co-morbidities), and the complexity and intensity of therapy.

As can be seen in the chapter on HSMRs (Chapter 8), variables collected and reported as part of the National Hospital Morbidity Database (NHMD) can be used for risk adjustment. In many specialties, more specific assessments

have been developed and validated to establish individual patient's risk. For example, the anaesthetists use the American Society of Anesthesiologists patient status classification in pre-operative assessment as an indicator of risk. The scale starts at P1, a healthy patient, and progresses through increasingly unwell patient status to a P5 score where a patient is classified as 'moribund', and P6 for brain-dead patients where organ harvest is planned.

More commonly, a simple and common form of risk adjustment for hospitals is to compare 'like' facilities for a common measure or set of measures for a common reference period. A peer hospital classification allocates all Australian public hospitals by size and locality characteristics into 'like' or 'peer' groups. The assumption underlying this approach is that peer hospitals tend to treat broadly similar types of patients. The main peer groups used by the Australian Institute of Health and Welfare (AIHW) are:¹⁴

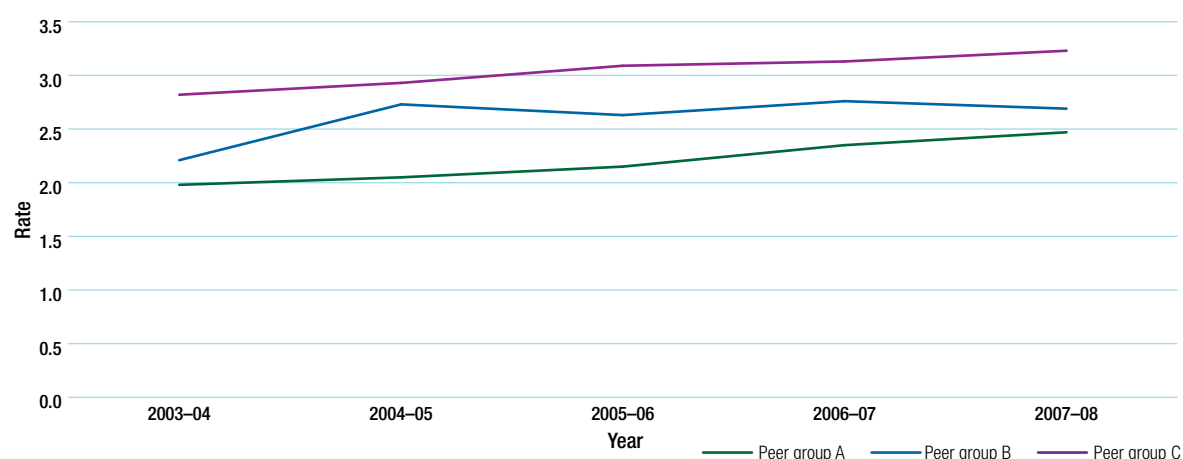
- principal referral, and specialist women's and children's hospitals (peer group A)
- large-sized hospitals (peer group B)
- medium-sized hospitals (peer group C)
- small-sized acute hospitals
- subacute and non-acute hospitals
- unpeered and other hospitals, and
- psychiatric hospitals.

Box 9.4 Coded or administrative data

In Australian hospitals, the medical notes, laboratory reports and other relevant information are integrated into an individual patient's ongoing medical record and 'coded' after the patient is discharged, transferred or dies. Trained medical coders assign codes for principal and other diagnoses, procedures, and other events to a coded electronic summary of that admission. This coded record then goes into a hospital database which eventually populates, via state, territory or private hospital ownership chain aggregation, a national data collection called the NHMD.

The NHMD is managed by the AIHW, and provides a great depth and breadth of information on admitted patient hospital activity. Examples of the outputs from the NHMD include the *Australian hospital statistics* series.¹⁴

Figure 9.1 Falls in public hospitals, by hospital peer group, 2003–2004 to 2007–2008 (per 1,000 separations)



Source: AIHW

Notes

1. The specification for the indicator defines a fall in hospital as being one for which the place of occurrence is coded as 'health service area'. The health service area as a place of occurrence is broader in scope than hospitals — it includes other healthcare settings such as day surgery centres or hospices. It may include separations resulting from a fall that occurred in a healthcare setting other than a hospital.
2. The numbers of falls occurring in hospital that were treated may be underestimated, as the records for some 25 per cent of all separations involving a fall had the place of occurrence as 'unspecified'. The degree to which the rate is underestimated due to this factor is not known.
3. In calculating this indicator, separations where a person was admitted to hospital with a principal diagnosis of an injury were excluded on the basis that if the injury was the principal diagnosis, it was associated with an external cause relating to an event occurring prior to admission. These exclusions may result in an underestimation of the indicator. It does not count separations where a person is injured and admitted to hospital and then subsequently experiences a fall in hospital.
4. The rates of falls presented for this indicator have not been standardised for age and consequently the results do not take into account the known association between the rate of falls and increasing age.

Figure 9.2 Falls in public hospitals, hospital peer group A, 2007–2008 (per 1,000 separations)

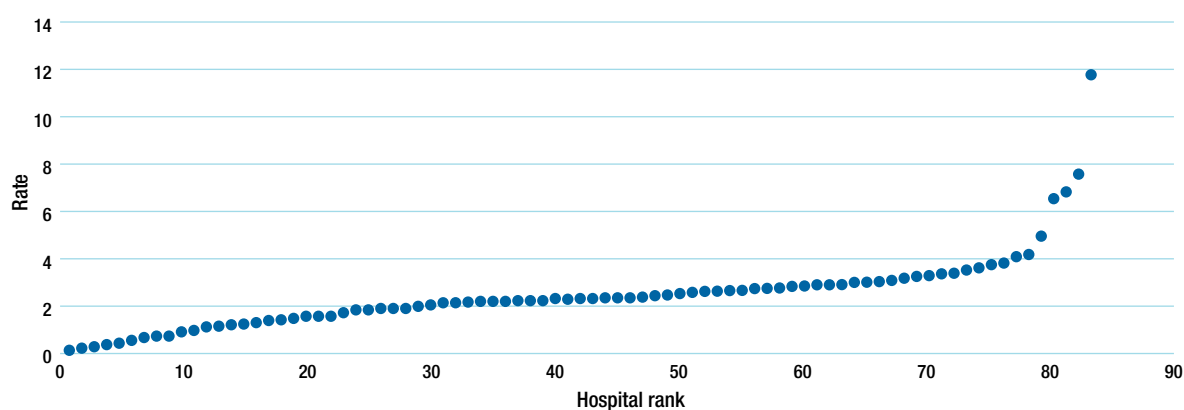
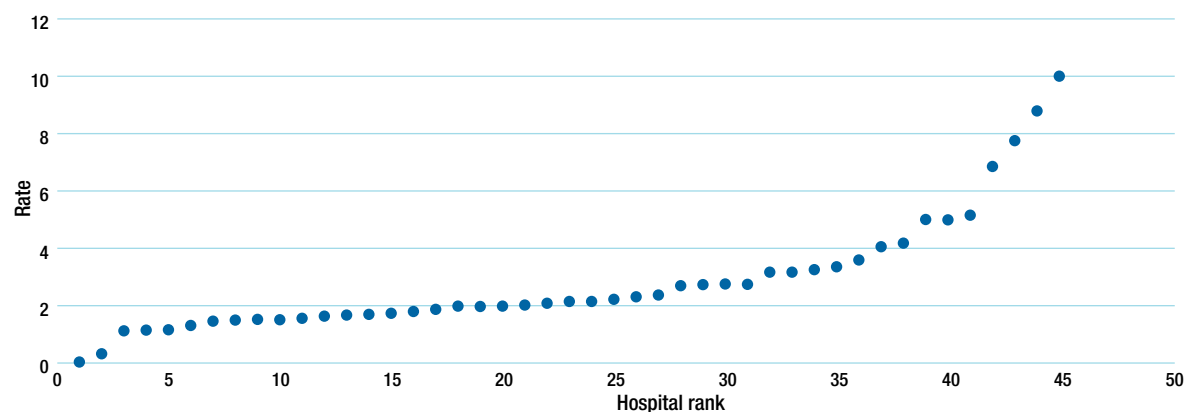


Figure 9.3 Falls in public hospitals, hospital peer group B, 2007–2008 (per 1,000 separations)



A limitation of this model is that currently there is no national peer grouping taxonomy for private hospitals. In addition, some facilities provide subspecialty services for specific clinical areas. These hospitals can accrue a higher risk, as more complex patients may not be distributed equally across hospitals of that peer group.

Level of reporting

Caution is required when making inferences about hospitals or healthcare services from indicators such as ‘unplanned return to operating theatre’, when different teams and specialties — as well as different procedures, patients, and degrees of surgical urgency — are combined into a single measure. However, a focus on jurisdiction-level compliance with national benchmarks, for example, with rates of *Staphylococcus aureus* bacteraemias, would mask the significance of a small number of ‘outlier’ hospitals where rates merit serious review. For example, the rate of falls in public

hospitals shows generally unremarkable trends over time for peer groups A, B and C (Figure 9.1).

However, breaking the report down into hospital-by-hospital rates shows there are a small number of facilities with rates that appear to be significantly higher than their peers, as seen at the right-hand ends of figures 9.2 and 9.3.

This pattern of hospital variation can be demonstrated to differ slightly from year to year. Each year, however, there is usually a small group of hospitals where a significantly higher rate of patient self-harm occurs. It is not possible to state whether such hospital-level variance is due to random fluctuations, coding practices (data), a different patient population casemix, or other factors more closely related to resources and quality of care. Using a structured investigation method, such as the ‘pyramid model of investigation’, will allow for a clearer understanding of this inter-hospital variation and

Box 9.5. Australian Institute of Health and Welfare recommended indicators of safety and quality

The AIHW report *Towards national indicators of safety and quality in health care* recommends a total of 55 indicators.¹⁶ The indicators address six service categories including *Hospitals — admitted patient care, emergency department, and out-patient and other non-admitted patient care*.

The hospital indicators are:

- assessment for risk of venous thromboembolism in hospitals
- pain assessment in the emergency department
- reperfusion for acute myocardial infarction in hospitals
- stroke patients treated in a stroke unit
- complications of transfusion
- healthcare associated infections acquired in hospital
- *Staphylococcus aureus* (including methicillin-resistant *Staphylococcus aureus* or MRSA) bacteraemia in hospitals
- adverse drug events in hospitals
- intentional self-harm in hospitals
- malnutrition in hospitals and residential aged care facilities
- pressure ulcers in hospitals and residential aged care facilities
- falls resulting in patient harm in hospitals and residential aged care facilities
- complications of anaesthesia
- accidental puncture or laceration in hospitals
- obstetric trauma — third and fourth degree tears
- birth trauma — injury to neonate
- post-operative haemorrhage
- post-operative venous thromboembolism
- unplanned return to operating theatre
- unplanned re-admission to an intensive care unit
- Hospital Standardised Mortality Ratio (HSMR)
- death in low mortality diagnosis-related group (DRGs)
- independent peer review of surgical deaths
- discharge medication management for acute myocardial infarction
- timely transmission of discharge summaries
- mental health admitted patients having seclusion
- post-discharge community care for mental health patients
- unplanned hospital re-admissions
- failure to diagnose
- post-discharge community care for mental health.

the development of an effective approach to minimising this patent risk. Clearly, there are risks in simply attributing significant variation either too broadly — at a national or jurisdictional level — or too specifically to teams, wards or even individual clinicians. Effective safety and quality indicators should provide ‘signals’ for local investigation of significant variation.

Box 9.6 Principles of a National Reporting Strategy for Safety and Quality

Principle 1 — safety and quality indicators at the provider level will be designed for reporting within a structured and timely cycle of feedback to and response from providers.

Principle 2 — appropriate levels of disaggregation will be used to present indicators of safety and quality of care, including peer hospitals, indices of remoteness, and risk adjusted by patient casemix where appropriate.

Principle 3 — indicator development will be prioritised by clinical relevance and feasibility. A phased approach to reporting is proposed, leveraging existing data collections as much as possible. The benefits of using available data will be balanced against the lag and burden of new data collection and the need for new information focused on quality of care.

Existing national processes for developing clinical quality datasets and standards will be actively promoted. Clear data definitions will form information standards to underpin clinical and administrative computer system development, strengthening the ‘harvest’ of existing clinical and administrative data flows for secondary analyses.

Principle 4 — where effective models of reporting and feedback have been developed and implemented by specific jurisdictions, sectors or specialist clinical groups, the national approach will build on these ‘best of breed’ systems.

Principle 5 — reporting should lead to review and action.

The relative merits of measuring process and outcomes

Clinical guidelines for the management of a given condition are based on the higher levels of evidence from trials and studies around the world.¹⁵ In such cases, measuring the level of compliance with best practice — a *process* of care measure — is a marker of care that will give the best outcomes.

Outcome measurements give a more accurate picture of treatment effectiveness. Outcomes include 30-day mortality for heart attacks, one and five-year survival rates for cancers, or levels of mobility and independence three and six months after a stroke. Such outcomes, however, are harder to monitor, requiring dedicated follow-up or ethically approved data linkage.

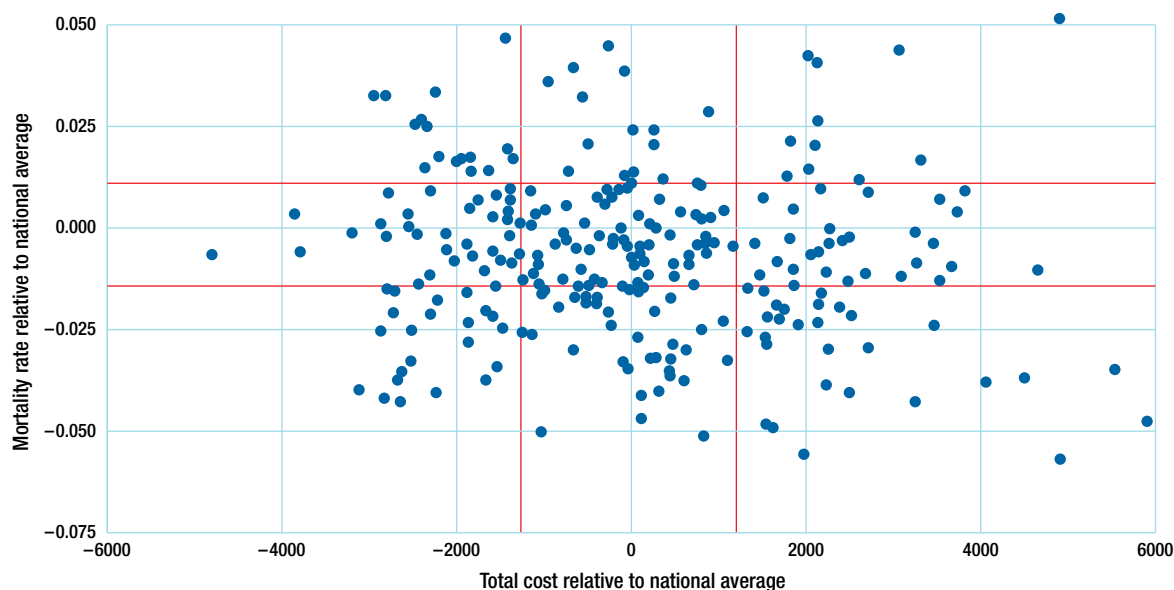
Ideally, a suite of safety and quality indicators for hospitals would include measures of process — (was the indicated care given?) — and short-term outcome measures — (was the patient re-admitted?) Longer-term outcomes, such as recurrence of angina at 12 months, for example, will provide feedback on the effectiveness of therapies at the system level and once generated should also be made available to individual hospitals.

National indicators of safety and quality

There are significant gaps in national healthcare data collections in that they lack a consistent focus on safety and quality in health care. In recent years, there have been a number of initiatives that have aimed to address this gap:

- In 2007, the Commission engaged the AIHW to develop a set of indicators of safety and quality. This year, the AIHW recommended a set of 55 indicators of safety and quality in health care for national reporting, of which at least 30 specifically relate to hospitals (Box 9.5).¹⁶ Not all of these indicators can be reported from current data. Some can be reported for parts of Australia, whereas others need data and conceptual development before they can be measured and reported. However, there are a number of recommended safety and quality indicators for which national data are currently available.
- In 2008, the Council of Australian Governments (COAG) Reform Group announced the development of a suite of healthcare performance indicators, which will be included in the National Healthcare Agreements (NHA), the health funding arrangements between the Australian Government and the states and territories.¹⁷

Figure 9.4 Hospital variation in one-year mortality and costs



Source: Unpublished analysis of Medicare claims data by investigators at the Dartmouth Institute for Health Policy and Clinical Practice.

A major role of the Commission is to report nationally on the safety and quality of hospitals. The Commission will work with jurisdictions and the private hospital sector to develop a national approach to reporting on a core set of indicators of safety and quality.

The Commission has recommended a core set of hospital-based outcome indicators for safety and quality to Health Ministers. These would be used across public and private hospitals to identify areas of significant variation in outcomes, and to identify priority areas for safety improvement action. Most of these indicators are drawn from the set recommended by the AIHW, and complement the National Healthcare Agreement Performance Indicator approach by focusing on hospital-level monitoring and comparison. The indicators are:

1. Hospital Standardised Mortality Ratio (HSMR).
2. Death in low-mortality diagnosis-related groups (DRGs)
3. In-hospital mortality rates for:
 - a. acute myocardial infarction (AMI)
 - b. heart failure
 - c. stroke
 - d. fractured neck of femur, and
 - e. pneumonia.
4. Unplanned hospital re-admissions of patients discharged following management of:
 - a. AMI
 - b. heart failure
 - c. knee and hip replacements
 - d. depression
 - e. schizophrenia, and
 - f. paediatric tonsillectomy and adenoidectomy.

5. Healthcare associated *Staphylococcus aureus* (including MRSA) bacteraemia
6. *Clostridium difficile* infections
7. Obstetric trauma — third and fourth degree tears.

The Commission proposes that these indicators be generated by the jurisdictions, or private hospital ownership groups, and reported back to facilities for routine comparison of performance of a hospital over time, and against peer hospitals. They are outcome measures which can, with the exception of *Clostridium difficile* rates, be derived from existing data flows. The safety and quality value lies in establishing the report–review–act cycle based on the routine supply of timely and targeted data back to hospitals.

A national approach to reporting of safety and quality in hospitals

The important question for safety and quality in health care is how to move from reporting against a group of indicators to an active process of improvement in patient outcomes. There has not been a consistent national approach to the development of clinical indicators, and some duplication of process is also apparent. Principles for development and use of indicators were developed by the Commission (Box 9.6), to support reporting and response models to drive improvement in safety and quality. Reporting needs to be linked with review and action.

For quality improvement to take place, it is essential that data be routinely and objectively generated and fed back to hospitals within a timely reporting –and–response cycle. Hospitals could then routinely examine their own indicators, in comparison with their peers and with any existing benchmarks. This is the approach that both the Queensland VLAD and Victorian AusPSI models have adopted.

In 2010, the Commission will work with jurisdictions and the private hospital sector to develop best practice models for generating, presenting and responding to variation in these core, hospital-based outcome indicators.

An example of the value of presenting hospital-level variation can be seen in Figure 9.4. In the United States, the Dartmouth Institute mapped United States' Medicare expenditure and mortality rates for a basket of three complex interventions (AMI, hip fracture and colon cancer) by hospital. What is remarkable is that a number of the low-cost hospitals also had low mortality rates, and a small group of high-cost hospitals also had high-mortality rates. Without the generation of such graphs, the hospitals with the worst mortality would not know that better outcomes were possible, and need not be costlier.

Conclusion

The recent inclusion of a group of indicators for 'selected adverse events' in the National Healthcare Agreement Performance Indicators highlights the increasing

importance given to patient safety in national reporting. It is instructive to note, however, that there are no routine and accurate data currently available to report on adverse drug events, falls, and pressure ulcers acquired in hospitals. It is very important to have good indicators to drive improvement in preventing these incidents, but there needs to be care in how these are implemented to avoid having the effect of reducing reporting of events rather than reducing the incidence of events.

Ideally, hospitals would receive regular reports on a range of indicators of their safety and quality. Reports would be generated in a timely manner, risk adjusted, and plotted against peer hospitals. Data collection would be timely and succinct. Data specialists, clinicians and managers would focus more energy on analysis and planning improvement strategies, rather than on collecting and reporting.

A core set of indicators would be common across Australian hospitals, and the risk adjustment and calculation of 'expected' rates and benchmarks would be robust, rigorously calculated, and frequently updated using recent data. Public and private hospitals would be able to 'compare notes' on their respective practices and outcomes.

This vision of hospitals receiving regular, timely feedback on their performance, and plotted against markers of peer performance, is not new. The challenge is how to develop a shared approach in which states,



territories and the private hospital sector can easily implement low-burden, accurate data collection to support such reporting.

The Commission will continue to work with AIHW, the jurisdictions and the private hospital sector to develop indicators of safety and quality, and agile reporting models to help optimise the potential for healthcare improvement.

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10

Impact of clinical registries

To improve the safety and quality of health care, it is necessary to know from where one is starting. It is necessary to establish the baseline or existing standard to be able to proceed and identify changes, and the impact of changes to practice. One approach to monitoring care has been the development of clinical registries or medical data registries.¹

Clinical registers are databases that systematically record healthcare-related information on individuals who are treated with a particular surgical procedure, device or drug; diagnosed with a particular illness; or managed via a specific healthcare resource. The system or organisation governing the register is known as the registry. Information in clinical registers is captured on an ongoing basis from the defined population.² Registries collect data about real-world clinical populations, not the somewhat artificial populations of clinical trials. Ideally, they encompass the entire relevant clinical population, thereby allowing monitoring of all patients regardless of provider and removing selection bias.

Registers, registries and Australian Clinical Quality Registries

The terms register and registry are often used synonymously. Strictly speaking, a 'register' is the actual list or database, and a 'registry' is the system or organisation managing the register. Information is provided to a 'registry', for inclusion in a 'register'.

Clinical registers are lists or databases of clinical information. Clinical registries hold this information.

Australian Clinical Quality Registries hold and analyse clinical information to improve the safety or quality of health care. It is the use and feedback of clinical information to inform the care that patients receive that is one of the most important distinguishing features of an Australian Clinical Quality Registry.

Clinical registries

Clinical registries have been established for the purpose of improving patient care and outcomes through greater understanding of events, treatments and outcomes. The data collected by a registry are analysed and used to identify trends, and these analyses are used to lead to improvements in practice. Clinical registries can be used to identify and investigate variation in processes and clinical outcomes. They can drive quality improvement in various ways, including indirectly through the fostering of competition, more directly through evaluating compliance with guidelines, and through informing policy areas such as regulation and pricing policy. Registries can also play a role in post-market surveillance and notification. Where

they have been introduced at a state or national level, registries have become one of the most clinically valued tools for quality improvement.³ In some countries, this has been an area of significant development. For example, Sweden has developed more than 70 clinical quality registries in a wide range of domains.⁴

Clinical quality registries

Clinical quality registry are a particular form of clinical registry. The primary purpose of a clinical quality registry is to improve the safety or quality of health care provided to patients by collecting key clinical information from individual healthcare encounters. These data can be analysed and the risk-adjusted outcomes used to drive quality improvement. Clinical quality registries are one of the most appropriate and accurate methods of providing monitoring. They can benchmark data and have the potential to have a significant impact on healthcare performance across institutions and providers. Clinical quality registries tend to be focused on conditions and procedures where outcomes are thought to vary and where improvements in quality have the greatest capacity to improve quality of life or reduce costs.

Many clinical registries have been developed as research activities, often by committed and innovative clinicians. However, the real value of registries is perhaps unappreciated and the full potential yet to be realised. More recently, there has been recognition that these efforts have the potential to provide significant information and feedback into the quality and safety of clinical practices.^{3,5,6}

International experiences

Clinical quality registries and clinical trials can form complementary alliances. Registry analyses can identify areas for focused clinical trials, or they can provide real-world validation and understanding of how trial results can be applied. One recent example of this saw registry data used to compare coronary artery bypass graft (CABG) surgery with percutaneous coronary intervention (PCI). Clinical trial evidence did not reflect the complexities of real-world patients, but had suggested that myocardial infarction and mortality were comparable for patients treated with CABG or PCI. Registry data revealed that 'comparative survival after PCI or CABG varied significantly according to the extent of coronary disease'.⁷ The use of registry data and analyses to examine and alter clinical practice was also evident in the United Kingdom, where the Society for Cardiothoracic

Australian Cardiac Procedures Registry

www.ccretherapeutics.org.au/research/acpr.html

The benefits and impact envisaged for the Australian Cardiac Procedures Registry (ACPR) will be significant. Cardiac surgeons and cardiologists will benefit from having a disease-based registry with shared common definitions. The provision of such a database represents a crucial step towards developing national strategies for treating heart disease. A cardiac procedures registry may become an invaluable tool for clinicians, allowing them to review practice, compare outcomes to a standard and make changes to improve practice. The registry will be able to play a pivotal role in ensuring that all patients are getting the best possible treatment and achieving the best outcomes. Patients will be able to know the likely outcome of various treatments, with appropriate risk adjustments, in order to make informed choices. Policy makers will be able to know how well clinical cardiac services are provided to the community in order to make better choices, identify centres of excellence and develop strategies for quality improvement. The ACPR will make this information available while ensuring the privacy of individual patients and clinicians is protected.

Surgery of Great Britain and Ireland examined more than 400,000 operations and found that mortality rates had been reduced by 21% for coronary artery surgery and by a higher rate for isolated valve surgery since 2001 (which was when the publication of cardiac surgery mortality rates had started).⁸ This is not to say that the reduction in mortality was a direct causal consequence of the registry activity; however, the use and analysis of data about clinical practices can be a vital step in identifying and refining best practice.

A recent article in the *Journal of the American Medical Association* noted some of the impacts clinical registries are having in the United States and the United Kingdom.⁵ From the United Kingdom, the National Institute for Health and Clinical Excellence (NICE) uses registries for decision support. Examples included the use of British Society for Rheumatology Biologics Register information in the evaluation of anti-tumour necrosis factor drugs,⁹ and

the use of registry data to assess novel interventional procedures.¹⁰ In the United States, registry data have been used to inform decisions by regulatory agencies about safety. For example, information from the Antiretrovirals in Pregnancy Registry led to a Food and Drug Administration (FDA) change in labelling of the drug acyclovir from category C (risk cannot be ruled out) to category B (no evidence of risk in humans).¹¹ The FDA has also used registry information to refine other labelling indications, including the expanding of age groups for intra-ocular lenses,¹² and an additional indication (suicide prevention) for an anti-psychotic agent.¹³ Also in the United States, the Centers for Medicare & Medicaid Services expanded coverage for positron emission tomography (PET) scans in managing certain cancers based on registry data.¹⁴

Australian experience

In Australia, the more prominent examples of clinical registries are the Australia and New Zealand Dialysis and Transplant Registry (ANZDATA), Australian and New Zealand Intensive Care Society (ANZICS) Centre for Outcome and Resource Evaluation (CORE) and the Australian Orthopaedic Association (AOA) National Joint Replacement Registry (NJRR). The success of these and other registries here and abroad has led to the development of further registries, advocacy for more registries and the increased application of analyses of the data held.^{15–18}

Australia and New Zealand Dialysis and Transplant Registry

ANZDATA records the incidence, prevalence and outcome of dialysis and transplant treatment for patients with end-stage renal failure. It collects information for the purpose of monitoring treatments and performing analyses to improve the quality of care for people with kidney failure. It collects data from renal units in Australia and New Zealand, covering all patients who have received dialysis and transplantation services. ANZDATA releases reports on a variety of topics, including an annual report examining the rates and treatment of kidney failure in Australia and New Zealand. ANZDATA claims that it plays a major role in ensuring the quality of patient care and that it does this by sending each kidney unit the annual report, outlining its activity. These reports also compare the outcome of the treatment provided with that of other units throughout the two countries. Reports are also produced at a state and national level, and analyses may also be produced for renal units, government health departments and industry concentrating on particular aspects of renal failure management.¹⁹

Australian and New Zealand Intensive Care Society Centre for Outcome and Resource Evaluation

ANZICS CORE is a bi-national peer-review and quality-assurance program that has provided audit and analysis of the performance of Australian and New Zealand intensive care since 1992. The main adult patient database now contains data on over 800,000 patient episodes, and it is one of the largest single datasets on intensive care in the world. The associated Australian and New Zealand Paediatric Intensive Care Registry, ANZPICR, contains over 10 years of paediatric admission data. As well as benchmarking performance in intensive care, these datasets provide an invaluable resource for the intensive care community and other healthcare sectors. The data have led to publications on treatment of intensive care unit (ICU) patients, including analyses of factors such as blood glucose control,²⁰ kidney injury and sepsis,²¹ inter-hospital transfer of patients,²² after-hours discharge,²³ and length of stay.²⁴ It enables resource planning to assist in daily activities, research and service delivery. Examples include local hospital staffing and resource planning, state-wide infrastructure planning, influenza pandemic planning, and biosecurity and terrorism planning.²⁵

Australian Orthopaedic Association National Joint Replacement Registry

In 1993, the AOA recognised a need for a national joint replacement registry. Outcomes of this type of surgery in Australia were unknown and it was not clear who was receiving joint replacement, or the types of prostheses and techniques being used. From the start of operations in 1999, the purpose of the NJRR has been to define, improve and maintain the quality of care of individuals receiving joint replacement surgery. This is done by collecting a defined minimum dataset that enables outcomes to be determined on the basis of patient characteristics, prosthesis type and features, method of prosthesis fixation and surgical technique used. The registry measures revision surgery and mortality.

Analysis of revisions, combined with a careful analysis of the timing and reasons for revision, ensures this can be used as an accurate measure of the degree of success of a procedure. The analyses are used to inform surgeons, other healthcare professionals, governments, orthopaedic companies and the wider community. The AOA NJRR has contributed directly to the quality of care, particularly to changes in clinical practice, including changes in the use (or non-use) of particular prostheses and techniques.²⁶

The stated aims of the NJRR include providing accurate information on the use of different types of prostheses in both primary and revision joint replacements, evaluating the effectiveness of different types of joint replacement prostheses and surgical techniques at a national level, the provision of confidential data to individual surgeons and hospitals to audit their joint replacement surgery, and educating Australian orthopaedic surgeons in the most effective prostheses and surgical techniques to achieve successful outcomes.²⁷

National Breast Cancer Audit

www.surgeons.org/nbca

The National Breast Cancer Audit (NBCA) has been developed with the aim of improving quality of care by surgeons for patients with early breast cancer in Australia and New Zealand. The Royal Australasian College of Surgeons notes that although the audit was originally initiated as a pilot study in 1998, it has grown to be possibly the largest collection of breast cancer clinical information of its kind, comprising over 70,000 breast cancer episodes from over 270 surgeons from Australia and New Zealand (as of 2008). The NBCA provides surgeons with a self-audit tool to monitor their own surgical practice in relation to evidence-based standards, as well as participating in a quality-improvement cycle.

Cost effectiveness

A criticism that has been levelled at clinical registries is that they can be expensive activities. Certainly, registries may require considerable investment to develop and maintain. However, this cost needs to be judged against the cost savings and healthcare quality improvements gained from the information and analyses. For example, the AOA NJRR has apparently influenced changes in clinical practice, and captures information on revision (where a prosthesis is replaced) rates following hip and knee surgery. Over the past four years, the proportion of hip and knee procedure revisions has declined from 14.8% to 11.1% and from 10.4% to 7.9% respectively. These declines are in part largely attributable to monitoring systems incorporated into the registry design that detect poorly performing prostheses. The annual cost

saving has been estimated at \$44.6 million. Given that the cost of running the registry is approximately \$1.5 million per year, this represents a significant value.²⁸

Limitations and potentials

Notwithstanding some excellent examples, the value and impact of some clinical registers have been limited by factors such as unnecessarily extensive collection of data, poor quality control, inadequate governance procedures, lack of standardisation of definitions and processes, lack of adequate funding, and lack of an effective and timely operator arm for gaining quality improvement in clinical practice. These limitations have curtailed their contribution to clinical quality improvement to date.

The potential value of clinical registries has led the Australian Commission on Safety and Quality in Health Care (the Commission) to develop a project aimed at enhancing the understanding, utility and application of clinical registries. The Commission, the National Health and Medical Research Council (NHMRC), Centre of Research Excellence in Patient Safety at Monash

University, and the National E-Health Transition Authority (NEHTA) have collaborated to develop operating principles and technical standards for Australian Clinical Quality Registries.²

Australian Clinical Quality Registries

Australian Clinical Quality Registries are registers that are (potentially) national in coverage and are primarily focused on supporting improvement in clinical practice, particularly clinical safety and quality. An Australian Clinical Quality Registry is a registry whose purpose is to improve the safety or quality of health care provided to patients and thus must demonstrate potential for significant impact and relevance on quality and safety. The improvement should be commensurate to cost and effort. The data collected, and the subject matter or 'content' of a registry, should be clearly relevant to clinical practice

For registries to meet their full potential in informing the state of health care in Australia, confidence is needed in the quality and relevance of the data. The purpose of the

Neck of Femur Fracture Registry of Australia

www.dmac.adelaide.edu.au/NOffRA/

The establishment of a national hip fracture registry would help determine the demographics of hip fracture and improve the outcome of hip fracture management. It would also compare and improve the effectiveness of acute healthcare delivery by all hospitals involved in managing hip fractures. The optimum management of hip fracture patients involves a coordinated and seamless cooperative approach between many different departments and service areas within a hospital, making the outcome of hip fracture management an excellent measure of hospital performance.

The Neck of Femur Fracture Registry of Australia (NOffRA) pilot project aims to determine the effectiveness and efficiency of establishing a national neck of femur fracture registry. The reasons for a registry in this area include:

- hip fracture is a major clinical issue that is becoming increasingly important as the population ages

- there are a number of international examples where considerable benefit has been obtained from hip fracture registries
- hip fracture is a sentinel diagnosis *par excellence* that enables effective assessment and comparison of hospital specific outcomes, and
- a registry in this area will establish and monitor the implementation of best practice, and will be important in assisting the development of preventative strategies.

It is anticipated the NOffRA will report to all stakeholders by means of an annual report. This will report hospital-specific data, as well as the outcomes of hip surgery using a similar approach to the AOA's NJRR annual report. The annual report will be sent to all orthopaedic surgeons and will also be made publicly available on the internet. Hospitals will have web-based password-protected access to their individual data, with comparison to all other participating hospitals combined. Similarly, medical device companies could have web-based access to a report specific to their products in relation to a report of all other products.

proposed operating principles and technical standards is to:

- provide a means of improving existing clinical registers and enhancing the value of the information they provide
- provide guidance for the establishment and maintenance of Australian Clinical Quality Registries aiming to measure quality of care, and
- suggest a best-practice model to which Australian Clinical Quality Registries should adhere.

The draft Operating Principles contain 42 principles covering key areas, including:

- key attributes
- organisation and governance
- data collection
- data elements
- data security
- data quality
- risk adjustment
- custodianship
- ethics and privacy, and
- outputs and reporting.

The Operating Principles have been undergoing testing and validation by six clinical quality registries. These registries cover a range of medical domains, are at varying stages of development and provide testing from various perspectives. The six testing registries are:

- Australasian Rehabilitation Outcomes Centre (AROC)
- Australian Cardiac Procedures Registry (ACPR)
- Australian Stroke Clinical Registry (AuSCR)
- Bi-National Burns Registry
- National Breast Cancer Audit (NBCA)
- Neck of Femur Fracture Registry of Australia (NOFFRA).

Next steps

We need to identify how data can be best used to drive change at the clinical interface, and how clinical quality registries can have the greatest beneficial impact. It may be that quality improvement is driven by the production of outputs, such as quality indicators from clinical registries and routine feedback to providers, teams within institutions, professional accreditation or auditing bodies, and the public. These outputs might include warning signals that trigger when performance falls below pre-determined levels. The use of these



Bi-National Burns Registry

<https://bi-nbr.org/Application/home.aspx>

The Bi-National Burns Registry is a data repository capturing information about adult and paediatric patients with new burn injuries admitted to all Australian and New Zealand burns units. The aims of the registry are to:

- describe the epidemiology of burn injuries and inform the development of burn injury prevention strategies in Australia and New Zealand
- monitor the type and quality of burn care management
- establish the clinical outcomes of burn patients
- improve service planning
- develop best practice clinical guidelines and initiatives, and
- benchmark performance indicators on a state, national and international level.

Australian Stroke Clinical Registry

www.auscr.com.au/

The Australian Stroke Clinical Registry (AuSCR) is a new collaborative national effort to monitor, promote and improve the quality of acute stroke care. The participants in AuSCR believe that by working together, patients, families, clinicians and researchers can make a difference in the lives of people affected by stroke.

Reliable data about the coverage of important interventions and their potential impact on health outcomes are not available in Australia for stroke. In other countries, the use of stroke clinical quality registries has been shown to be greatly effective for providing data to improve the quality of care and health outcomes. The data collected in AuSCR will be used to guide quality improvement interventions in hospitals to ensure best practice stroke care. The data can be used to reduce variations in care delivery and, ultimately, provide evidence of reduced deaths, disability and recurrent strokes from improvements in stroke care.

AuSCR is used by hospitals (public and private) that admit patients with acute stroke and transient ischaemic attack. A multi-disciplinary panel of experts agreed on a national minimum dataset through a scientifically rigorous, open and consensus-based process that was facilitated by an independent chairman. AuSCR is an online register that also has the facility for paper-based data capture.

Benefits of AuSCR include centralised patient follow-up at three to six months after admission, 'live' downloadable reports and data exports for clinicians, and conformity with the larger national acute services stroke audit program conducted by the National Stroke Foundation.

data by multi-disciplinary teams should facilitate quality improvement activities by identifying areas of need and assessing performance relative to efforts to improve care. Additionally, the operating principles for Australian Clinical Quality Registries require that a registry has a documented procedure for addressing significant and unexplained variances in the quality and safety of care. Such an 'outlier' procedure needs to be sophisticated and flexible enough to address the issues and appropriately involve the various stakeholders, such as healthcare professionals, facilities, peak bodies, consumers, funders and jurisdictions.

Conclusion

Clinical registries can have a key role in monitoring and improving the quality and safety of Australian health care. They have the potential to provide a strong evidence base for determining the efficacy, safety and quality of providers, interventions, medications, devices and treatments. Many of the gaps in knowledge we have identified will be addressed over the next few years as Australian Clinical Quality Registries are further developed in the context of the wider quality and safety agenda. The structures and governance of an Australian Clinical Quality Registry should form a nexus for clinicians, administrators, peak bodies, jurisdictions and consumers. These connections can be used to build confidence and transparency in Australian health care and help ensure that our activities are focused on the patient. In the upcoming electronic health-enabled environment, the utility and impact of registries should flourish as both a source and destination for information and analyses.

Australasian Rehabilitation Outcomes Centre

chsd.uow.edu.au/aroc/

Australasian Rehabilitation Outcomes Centre (AROC) is a clinical registry whose prime role is to provide a national benchmarking system to improve clinical rehabilitation outcomes. A rehabilitation medicine service aims to provide people with loss of function or ability due to injury or disease with the highest possible level of independence (physically, psychologically, socially and economically).

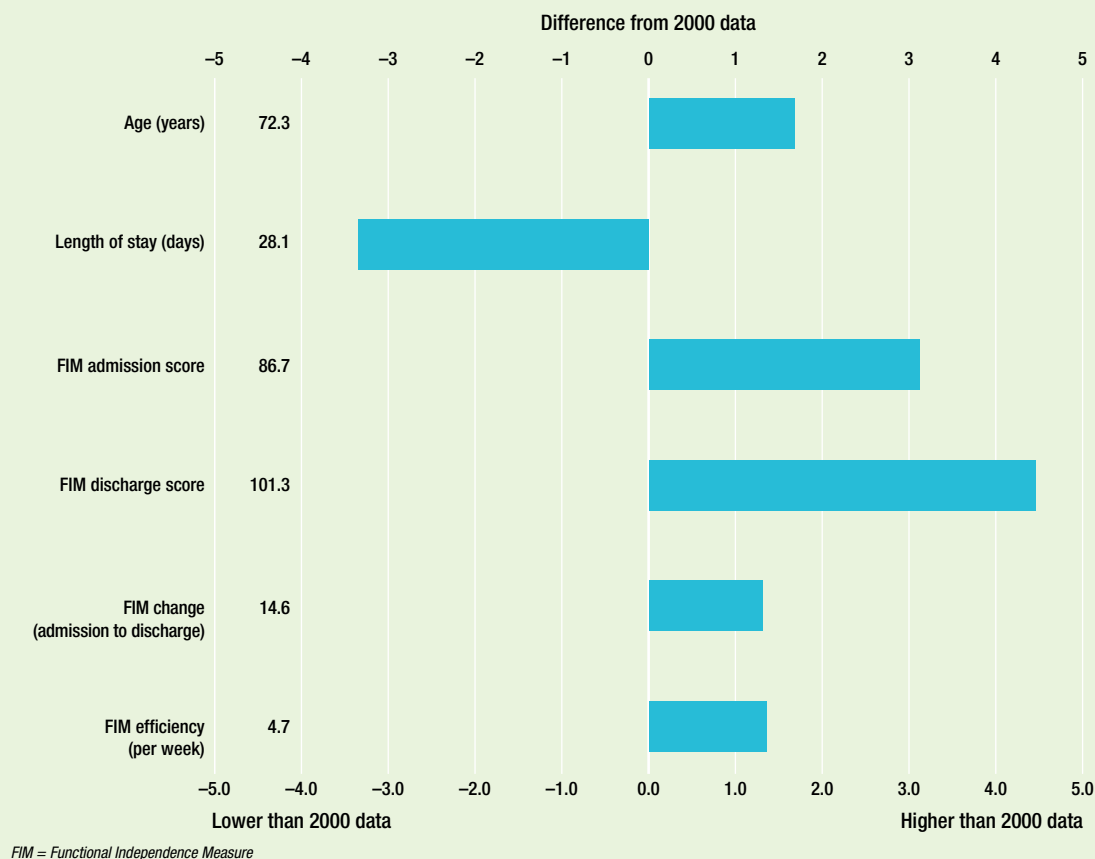
AROC aims to collect a standardised dataset against each and every rehabilitation episode of care. Collection of this data has enabled the provision of a national benchmarking system, which in turn has led to an improved understanding of factors that influence rehabilitation outcomes and costs, and therefore performance of the sector. AROC covers 95% of all rehabilitation beds (public and private) in Australia, with 155 of the estimated 165 rehabilitation units in Australia submitting data covering some 60,000 episodes each year. The AROC database now comprises data describing more

than 400,000 episodes of care and is thus a rich source of information.

Figure 10.1 indicates how key rehabilitation outcome measures, notably the Functional Independence Measure (FIM), have changed between 2000 and 2008. Although the average age of patients has increased, the average length of stay of a patient has decreased. However, average functional improvement has increased; that is, efficiency is higher.

Since 2007, AROC has been working on developing impairment-specific outcome targets. To date, outcome targets have been developed for fractured neck of femur, stroke, and brain injury rehabilitation. Outcome targets for spinal cord injury and reconditioning rehabilitation are in development. It is hoped that the process of setting outcome targets, and then measuring achievement against those targets, will encourage healthcare providers to strive for best practice and ultimately result in an increase in the quality of care provided to patients.

Figure 10.1 Changes in key rehabilitation outcome measures, 2000–2008



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