

Part B - Background Information and Resources

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About this section

The 'Background information and resources' section of the 'Measurement for improvement toolkit' provides the theoretical background and resources to assist health professionals and organisations to understand the application and interpretation of patient safety measurement. It summarises current knowledge and research relating to the measurement of patient safety, and recommends resources to further guide professionals in this important area.

The background material and literature review focuses on the three key influences on patient safety:

- Organisational capacity.
- Patient safety incidents.
- Clinical performance.

Many publications describe the importance of implementing patient safety initiatives, however few have examined the direct impact of measurement on patient safety outcomes. The review therefore describes research findings where available and is supplemented by corresponding theoretical knowledge aimed at raising awareness and understanding of patient safety issues.

See Appendix 1 for further details of the literature and website search.

The resources section contains a comprehensive list of patient safety resources and references. These include national and state-based health department publications on patient safety; links to professional bodies; Australian and international patient safety agencies; consumer resources; accreditation agencies; and general practice resources. Website addresses and links, postal addresses and phone contact numbers are provided where available.

Background information

Introduction

The primary aim of all health care facilities is to provide high-quality and safe care. Measurement of patient safety is an important process that supports achievement of this aim. Measurement of patient safety informs health care organisations and health care professionals about:

- gaps in current provision of safe health care services
- the impact of changes implemented to achieve improvement
- performance relative to national and international standards, or comparable peer groups.

The health care safety system is comprised of many facets, one of which is patient safety measurement (see Figure 6 below). It is important that the measurement of patient safety is integrated within this broader safety system.

Figure 6: Health care safety system



Measurement for improvement

Organisational capacity to provide safe care, measures to detect patient safety incidents, and the evaluation of clinical performance are the three key influences on patient safety in health care. Each will be discussed in further detail below.

1. Organisational capacity

Definition

Organisational capacity refers to the capacity of a health care organisation to provide safe health care. Organisational capacity incorporates the structures, resources and commitment of an organisation to patient safety, and as such is a key to the achievement of safe health care. Organisational capacity can be divided into six elements, which impact directly on patient safety (Victorian Quality Council 2003, National Patient Safety Agency 2004). These include:

1. Clinical governance and leadership.
2. Safety culture.
3. Communication and teamwork.
4. Consumer and community involvement.
5. Professional competence and ongoing education.
6. Information management.

Accreditation and the safety framework are the management processes health care organisations and practices use to drive the delivery of safe health care, while the six elements of organisational capacity to provide safe care listed above are the key areas in which organisational capacity can be measured. These six elements will now be discussed in further detail.

1.1 Clinical governance and leadership

What is clinical governance and leadership?

Clinical governance refers to the system by which the governing body, managers and clinicians share responsibility and are held accountable for patient care, for minimising risks to consumers, and for continuously monitoring and improving the quality of clinical care (ACHS 2004).

Leadership, for the purposes of this Toolkit, is the capacity to drive the vision of delivering safe health care. Leadership in patient safety encompasses (Mohr, Batalden & Barach 2004):

- establishing a safety vision in the organisation
- providing the tools and knowledge necessary to accomplish that vision
- identifying existing constraints within the organisation
- allocating resources for planning, development, implementation, ongoing monitoring and evaluation of patient safety
- ensuring participation of frontline staff in planning and development
- aligning organisational quality and safety goals

- engaging the organisational board or governing body in ongoing discussion regarding progress towards achieving safety goals
- recognising honesty in reporting patient safety incidents.

Measuring clinical governance and leadership

Measuring organisational capacity creates an opportunity to identify trends or changes in governance and leadership patterns. It also enables managers and leaders to assess the impact of new rules and regulations on safety and quality. To achieve this, however, measurement of clinical governance and leadership must engage executive or board level staff as well as clinical leaders, and must integrate with ongoing quality improvement processes (Freeman 2003).

The Toolkit offers a number of tools to assess clinical governance and leadership in the context of patient safety. These are described in **Part C ‘Measurement tools and processes’** of the Toolkit. The diversity of tools allows a choice of measurement options based on specific needs.

Research into clinical governance and leadership

Clinical governance and leadership can positively impact on patient safety by driving the quality improvement cycle and by promoting a non-punitive culture of trust and honesty (Victorian Quality Council 2004).

Studies have found that where clinical governance and leadership encourage collaboration between health care managers and clinical leaders, change is more likely to be achieved than in environments of unilateral governance (Ham 2003). Team coordination and leadership have also been found to be important in achieving safe, high-quality performance in the aviation industry and warrants further investigation in the health industry (Schaefer, Helmreich & Scheidegger 1995). Consultation among staff at various levels is important for successfully implementing improvements in patient safety. More specific research is needed to determine the nature of effective safety governance and leadership.

1.2 Safety culture

What is safety culture?

The safety culture of an organisation is determined by individual and group values, attitudes, perceptions and competencies, as well as behaviour towards health and safety management (Sexton, Thomas & Helmreich 2000, Sorra & Nieva 2004).

Research describes the characteristics of organisations with a positive safety culture as being:

- constructive communication
- mutual trust
- shared perceptions of the importance of safety
- confidence in the efficacy of safety measures (Nieva & Sorra 2003).

To achieve improvements in patient safety, health care organisations need to move from a culture of blaming individuals for errors, to a non-punitive culture in which errors are seen as opportunities to explore and learn from system failures (Nieva & Sorra 2003, Firth-Cozens 2004).

Measuring safety culture

The measurement of safety culture enables the identification of strengths and weaknesses and the development of appropriate interventions to tackle arising issues (Sexton, Thomas & Helmreich 2000). Safety culture measurement may also enable the evaluation of new safety initiatives through a comparison of safety culture before and after implementation. The 'Safety culture section' of **Part C 'Measurement tools and processes'** describes the tools available to assess the culture of safety among health care professionals. The vast majority of these measurement tools are based on extensive research and are accompanied by information regarding the reliability and validity of their use.

Research into safety culture

Research into safety culture originated from the aviation and engineering industries. In health care, numerous studies have investigated the impact of safety culture on day-to-day health care practice.

Shortell et al conducted a cross sectional study of 61 US hospitals to examine the relationship between organisational culture, quality improvement and various implementation approaches. Results revealed that hospital cultures that emphasised flexibility, teamwork, group affiliation and risk taking, experienced more effective quality improvement compared to hospitals that adopted more bureaucratic and hierarchical cultures. Quality improvement was in turn associated with improved patient outcomes and staff development (Shortell et al 1995).

Another study by Shortell et al (1994) also found that care-giver interaction consisting of culture, leadership, coordination, communication and conflict management abilities was significantly associated with a lower risk-adjusted length of stay, lower nurse turnover, higher evaluated technical quality of care and a greater evaluated ability to meet family needs (Shortell et al 1994). Similarly Vincent, Taylor-Adams & Stanhope (1998) found that safety climate was one of several factors that influenced clinical practice and quality of care. Other factors included staff morale, work environment, managerial support, teamwork, supervision and staff confidence.

These findings highlight two importance issues. Firstly, they emphasise the importance of safety culture in achieving a positive working environment and ultimately quality and safe health care. Secondly, they draw attention to the close interaction between safety culture, clinical governance and leadership.

Lack of appropriate leadership has been linked to failed culture change (Schien 1995). Accordingly, safety culture, leadership and governance should be integrated in any system of quality and safety improvement.

1.3 Communication and teamwork

Communication in health care is relevant at all levels. The exchange of information among health care staff and between staff and patients is an ongoing process with the potential to impact on numerous management, clinical and consumer outcomes.

Characteristics of good communication

Communication between health care professionals often takes the form of teamwork and information sharing. According to research, good communication ensures that:

- each member of the team knows where responsibility lies for clinical and managerial issues and who is leading the team
- systems are in place to facilitate collaboration and communication between team members
- systems are in place to monitor, review and, if appropriate, improve the quality of the team work

- teams are appropriately supported and developed, and are clear about their objectives (National Patient Safety Agency 2004, Kaissi, Johnson & Kirschbaum 2003).

Good communication between health care professionals and patients is characterised by:

- the provision of needed information to patients
- shared decision making
- facilitation of self-care management (collaborative planning for behaviour change, routine follow-up and support)
- listening
- enquiring about patient concerns and preferences
- encouraging and answering questions (Bethell, Myers & Smith 2000).

Measuring communication

The measurement of communication between health care professionals and patients provides an opportunity to identify barriers in the flow of information within a health care organisation and instigates strategies for improving communication styles. The measurement of communication is also closely related to the achievement of effective leadership and a positive safety culture, as the flow of information between health care professionals often influences and reflects leadership style and the opinions and attitudes of staff towards safety. This interrelationship should be carefully considered in assessing communication.

The measurement tools available for assessing communication between health care staff are often quite distinct from those designed to assess communication between health care professionals and patients. Choice of the most appropriate tool will depend on the nature of the assessment to take place. Only one measure was identified that primarily measured communication among health care professionals, and has been described in **Part C ‘Measurement tools and processes’** of the Toolkit. In addition, many of the tools that assess the safety culture of an organisation and the consumer participation incorporate the assessment of communication and teamwork.

Research into communication and teamwork

Recent research has documented that ineffective and insufficient communication is a significant contributor to medical error in inpatient care. The Joint Commission on Accreditation of Healthcare Organizations documented that the root cause of more than 60% of sentinel events was communication failures between doctors and nurses. A study by Lingard et al revealed that 36.4% of communication failures in the operating room resulted in visible effects on system processes (Lingard 2005).

Improving communication is documented to enhance the capacity of health care professionals to provide safe care. Numerous studies have demonstrated that improved teamwork resulted in enhanced effectiveness, fewer and shorter patient delays, improved staff morale and job satisfaction, increased efficiency, and reduced staff stress. These organisational outcomes have been attributed to improved communication and teamwork as the information sharing between staff is believed to allow proper integration and execution of clinical activities, which in turn provides health care professionals with greater control over their work environment, making them less likely to err.

Studies have also documented a direct link between good communication and improved patient outcomes. Strasser et al (2005) found that improved team functioning among rehabilitation staff of a stroke unit was associated with patient functional improvement and reduced length of rehabilitation stay. Studies have also reported increased patient adherence to medical advice, improved satisfaction, and improved self-reported health status. Other positive outcomes of good communication and improved teamwork include a reduction in

unhealthy behaviours, reduced emotional health distress as well as reduced presentation of clinical indicators and use of acute care services (Bethell, Myers & Smith 2000). These findings highlight the significance of communication to achieving quality and safe health care as well as the importance of ongoing measurement of this key element of organisational capacity.

1.4 Consumer and community involvement

What is consumer and community involvement?

Consumers (patients), their carers and community members are important participants in quality and safety improvement activities, including the planning, development, implementation and evaluation of such activities. The National Resource Centre for Consumer Participation in Health Participation (2004) describes consumer participation as

...the process of involving consumers (and community members) in decision-making about their health care, health service planning, policy development, setting priorities and addressing quality issues in delivery of health services.

Consumer and community involvement provides feedback to health care professionals regarding perceived quality of care, which can help guide quality improvement activities. Such involvement also empowers consumers with knowledge to actively contribute to patient safety. For example, through their understanding of medication prescribing, consumers can serve as a powerful resource in the prevention of adverse drug events.

Consumers and the community may be involved in health care in a number of ways, including participating in:

- consumer satisfaction surveys
- consumer complaints and incident reporting
- health care committees
- consumer or public health education programs.

Measuring consumer and community involvement

A number of tools are available to measure the level of consumer or community engagement in planning, development, implementation and evaluation of health care. These tools are listed in **Part C 'Measurement tools and processes'** of the Toolkit. Also included in the **Resources** of this section is consumer educational material, which may be used to inform consumers of issues related to safety of care. While these resources are not measurement tools per se, they are an important part of empowering consumers to engage with their health service to minimise risks to safety.

In considering which tools to employ in an organisation or clinical practice, it is important to differentiate between tools to be completed by health care staff, and those to be completed by consumers or members of the general public. This distinction is important as the perceptions of each of these groups about the extent of consumer and community involvement and their satisfaction with this level of engagement may differ.

Research into consumer and community involvement

The past 20 years have seen a growing recognition of the importance of consumer and community involvement in health care. This has been demonstrated by the World Health Organization's establishment of the Patients for Patient Safety Program as part of the World Alliance for Patient Safety. Patients for Patient Safety is designed to ensure that the perspectives of patients and families, consumers and citizens are considered in shaping health service delivery.

At a local level, many consumer and community programs have been developed to educate, encourage and empower consumers and the public to become involved in health. Examples of these programs include consumer health seminars, consumer educational materials (such as pamphlets, patient fact sheets) and consumer satisfaction surveys. In Australia, these initiatives have been largely led by the Australian Council for Safety and Quality in Health Care.

Despite this growing activity and recognition of the consumer's role, there is an absence of research into the direct impact of this involvement on patient safety outcomes. One recent British study set out to assess the extent to which general practitioners involve their patients in the decision-making process. They developed and tested a measurement tool called the OPTION scale and found that general practitioners did not usually list options, often did not explain the pros and cons of options, and did not explore patients' expectations about how their health problems were to be managed (Elwyn et al 2003, 2005).

One area of research that highlights the importance of consumer engagement in health care is the evaluation of self-management programs. Such programs are an important aspect of quality of care (Lorig & Holman 1993, Bodenheimer et al 2002), and aim to educate consumers about preventative and therapeutic activities relevant to their disease. Self-management has been particularly successful for the management of chronic diseases, such as diabetes and arthritis. A systematic review of self-management education programs for chronic diseases revealed that programs produced small to moderate effects on patient outcomes depending on the chronic disease studied (Asra Warsi et al 2004). The positive effect of self-management on health outcomes was attributed to the education of patients about monitoring and medication regimens. These findings suggest that involving consumers in their care is an effective strategy for improving health outcomes, and in turn their own health safety.

1.5 Professional competence and ongoing education

What is professional competence and ongoing education?

Professional competence is defined as a range of abilities including clinical skills, knowledge and judgement, together with communication skills, personal behaviour and professional ethics (Royal Australasian College of Surgeons 2005). Ensuring staff have the skills and knowledge necessary to maintain high levels of competence is the responsibility of all health care executives and clinical leaders, particularly as competence is often regarded as a precursor to strong clinical performance and professional development.

Ongoing education and professional competence are often discussed in tandem as participation in professional development activities is an important contributor to competence levels. Ongoing education should aim to address quality improvement, professional and technical knowledge of best-practice, change in health care, consumer involvement, health care systems, human factors, and teamwork.

Professional development programs may take the form of:

- mentorship
- short course or workshops
- experiential learning opportunities
- didactic information presented by respected peers
- literature from peer-reviewed journals
- supervision of junior staff.

Measuring professional competence and on going education

The measurement of clinical competence must involve an evaluation of knowledge, skills, and abilities. Competence around skills versus abilities and knowledge is often distinguished by the terms technical and non-technical competence, respectively. The most common form of competence measurement is credentialling. Credentialling is the formal process of assessing a professional health care provider's credentials in relation to the relevant professional's role. The Australian Council for Quality and Safety in Health Care (2004) describes that credentialling should take into account the clinician's:

- professional registration
- qualifications and training both undergraduate and postgraduate
- clinical experience and integrity in their field
- commitment to continuing professional development
- professional referees
- acceptable and safe practice
- communication skills
- collaboration skills
- management skills
- advocacy skills
- academic and research skills.

Measurement tools available to assess professional competence and education have been incorporated with the recently developed NSW Health's '**The clinician's toolkit for improving patient care**' (2001) and The Victorian Quality Council's '**Checklist for reviewing your safety and quality program against the framework elements**' (2003). The Australian Council for Quality and Safety in Health Care is also currently in the process of developing a support package to enable clinicians to take up the practice of credentialling. Further details regarding these tools and references are available in the **Part C 'Measurement tools and processes'** and '**Resources**'.

Regarding ongoing education, these tools also examine the extent to which educational initiatives are encouraged and accessible in health care organisations. Readers are also referred to the clinical governance and leadership tools, some of which briefly address approaches to professional education.

Research into professional competence and on going education

Professional competence is a complex area. The literature describes many ways in which competence may be assessed, however the focus is often on the competence of medical students and trainees rather than established clinicians. This review found no studies that linked clinical competence with health outcomes or patient safety.

In contrast, the impact of ongoing professional education on clinical practice has been subject to some research. In a systematic review assessing the effectiveness of clinician educational and implementation techniques on patient outcomes, academic detailing and the use of local opinion leaders were found to be the most effective. Use of physician reminder systems were also effective and the technique of audit and feedback was only of marginal effectiveness (Trowbridge & Weingarten 2001).

1.6 Information management

What is information management?

Information management refers to the process of collecting, analysing and using patient safety data within a health care environment aimed at informing and improving safety. Information management enables an organisation to monitor and evaluate areas of safety concern. It also facilitates improved efficiency in health service delivery by enhancing the flow of information regarding the detection and monitoring of patient safety incidents through incident reports, patient or consumer complaints, audits, coroner's reports and many other sources. In doing so, data management also supports effective clinician decision-making and maximises quality of care (Victorian Quality Council 2003).

Functional data management systems around patient safety incidents involve a single point data collection, aggregation of data for multiple uses, and privacy and confidentiality protocols (James 2003). An effective information management system:

- includes supportive resources that effectively collect, collate and analyse data
- is accessible and available within the health care facility
- generates timely, valid and reliable data
- generates useful and relevant data (for example linking clinical and administrative data sets)
- displays and feeds back data to those who can implement the changes required.

The availability of resources is a key reflection of organisational capacity. Thus, an organisations' capacity to provide data management systems requires ongoing review and improvement in and of itself.

Research into information management

While there has been no direct evaluation of overall information management models with better health outcomes, an indirect relationship has been found between specific types of integrated data management systems and health outcomes in case studies. The introduction of computerised physician order entry or clinician decision-making tools have been shown to be associated with improved patient outcomes (Bates et al 1998, Evans et al 1994, Hunt et al 1998, Shea, DuMouchel & Bahamonde 1996, Kawamoto et al 2005, Monane et al 1998). Collectively, these studies support the need for and use of data management systems across health care organisations and clinical practices as a key strategy in maintaining safety and quality of care. The ongoing evaluation of these systems is also necessary to ensure their implementation is as required and needed.

1.7 Accreditation – a process to assess organisational performance

Accreditation is the most common form of assessing organisational performance and as such focuses on an organisation's capacity to provide safe and high quality health care. Many of the themes assessed during the accreditation process, are also the key elements of an organisation's safety framework.

It is a formal process to ensure delivery of safe, high quality care based on standards and processes devised and developed by health care professionals for health care services (ACSQHC 2005). The aim of accreditation is to assist an organisation to improve their performance, raise the level of patient care and demonstrate accountability (Joint Commission on Accreditation of Healthcare Organizations 2000). For further information of the accreditation process please refer to the '**Clinical performance**' section of this document and to **Part C 'Measurement tools and processes'**.

2. Patient safety incidents

Definitions

A **patient safety** incident is defined as an event or circumstance, which could have or did lead to unintended and/or unnecessary harm to a person and/or complaint, loss or damage (ACSQHC 2005). Patient safety incidents include **adverse events** and **near misses**.

An **adverse event** is a type of patient safety incident in which unintended harm occurs as a result of a patient receiving health care (ACSQHC 2005). A type of adverse event is an adverse drug reaction, which is a noxious and unintended response to a drug, and occurs at doses used in man for prophylaxis, diagnosis or therapy of disease or modification of physiologic functions (WHO 1984). Adverse drug events are the single greatest risk factor for harm to patients in health care (IHI 2004).

Another important type of incident is a **near miss**. This is an incident that did not cause actual harm, but had the potential to. The identification and management of a near miss is considered as important as that of an adverse event, as the system failures associated with a near miss may be similar to those that result in adverse events (Bates et al 1995). Different studies have estimated that near misses occur 3 to 300 times more often than an adverse event (Wald Shojania 2001). Bates et al (1995) found that for each preventable adverse drug event, there were nearly three times as many potential adverse drug events or near misses.

International attention to patient safety incidents increased dramatically in 2000 following the publication of the US report 'To err is human' which highlighted the threats to medical practice and patient safety present in hospitals.

In Australia, the 'Quality in Australian health care study' estimated that 16.6% of all hospital admissions were associated with an adverse event which resulted in disability or a longer hospital stay. Of these, 51% were judged to have been highly preventable. In 77.1% of the adverse events identified, the disability was resolved within 12 months, while for 13.7% the disability was permanent and 4.9% resulted in death (Wilson et al 1995). In another Australian study analysing general practice patients, it was estimated that 76% of the adverse events reported were preventable (Bhasale et al 1998).

The financial cost of adverse events is also enormous. Medication errors have been estimated to cost Australia \$350 million per year (Roughead 1999), while the total cost of adverse events has been estimated to be \$2 billion per year (ACSQHC 2003). These statistics highlight the importance of incorporating the management of patient safety incidents into every health care program. It is only through measurement and understanding of the underlying causes of these events that such threats to patient safety can be prevented and minimised.

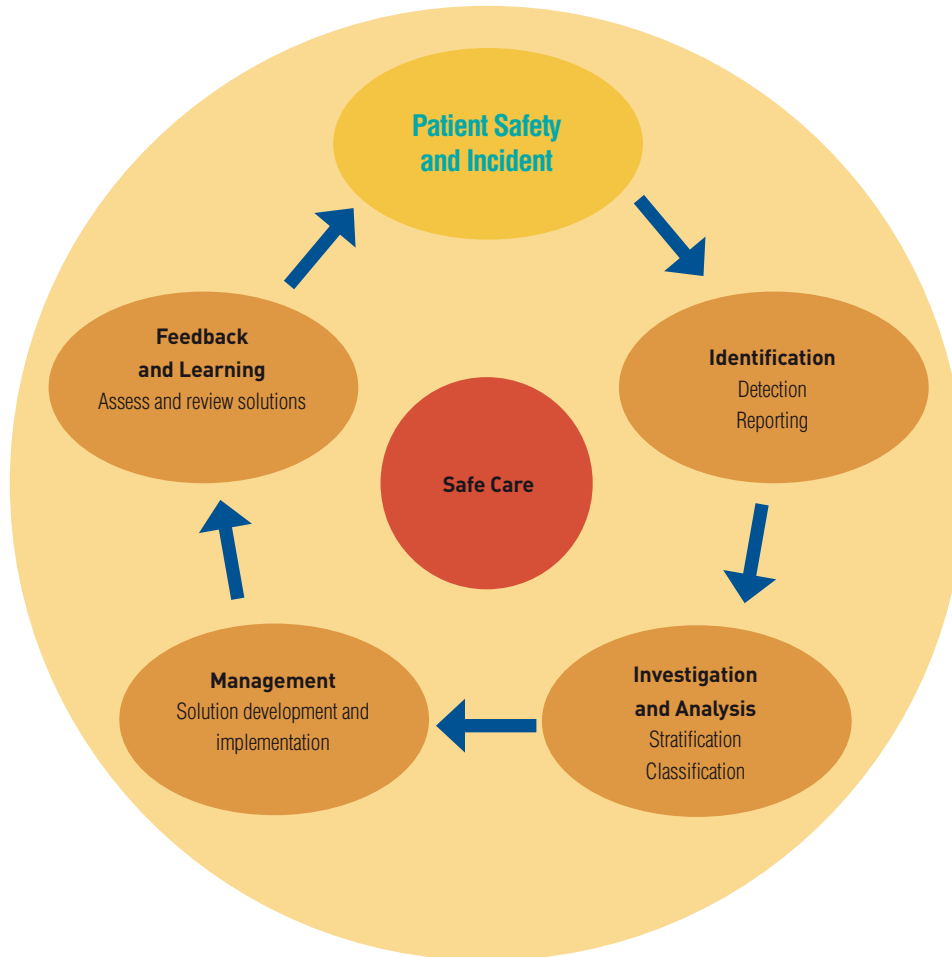
2.1 Risk management and patient safety incidents

Risk management is the systematic application of management policies, procedures and practices to the task of identifying, analysing, assessing, managing and monitoring risk (Auditor General of Victoria 2005). Measurement of patient safety incidents is considered an important part of a comprehensive risk management program in the health sector, and may involve measuring elements of the risk assessment and/or the incident management strategies that are in place. Approaches to reducing and managing patient safety incidents involve a complex series of steps including:

- identification
- investigation and analysis
- management of the incident(s)
- feedback and learning.

Health care organisations can measure the above elements to review their patient safety incident management.

Figure 7: Patient safety incident cycle



A number of risk management programs are available and currently in use in the public and private health sectors that provide a system for the multiple components described above. In the hospital and larger organisational settings, commercially available and computerised incident management systems are generally used, and overseen by the quality and safety or clinical risk department. In private practice, risk management assessment can be provided by medical indemnity insurers or accreditation agencies.

2.2 Identification of patient safety incidents

Identification of patient safety incidents refers to the process by which the health care organisation becomes aware that a patient safety incident has occurred. These detection processes underpin the effectiveness of a clinical risk management program, as programs aimed at the reduction of patient safety incidents cannot be put in place without knowledge of their potential or actual occurrence.

Methodologies currently used to identify patient safety incidents include:

- medical record review/clinical audit and other surveillance methods such as limited adverse occurrence screening and trigger tools
- incident reporting, including clinical incident reporting, sentinel event reporting, and facilitated incident reporting

- consumer reporting via verbal or documented reports and complaints, consumer satisfaction surveys, medicolegal claims
- morbidity and mortality meetings.

The most widely used methods of identifying patient safety incidents are medical record reviews and/or the use of incident reporting systems. These are described in more detail in the following pages.

It is important to note that each of the methods used to identify patient safety incidents is a measure of the prevalence (frequency or count) of patient safety incidents, and on their own do not give a measure of patient safety or risk.

The rates of patient safety incidents detected by methods such as medical record review or incident reporting require careful interpretation. When using the data as a measurement over time or as a measure against other data, there is a need to ensure comparisons are made with like-populations. The rates may not provide a true measure of patient safety or risk within the organisation if there has been no adjustment for risk factors that may have contributed to the adverse events.

2.2.1 Medical record review, clinical audits and other surveillance tools

What is medical record review?

A medical record review or clinical audit is a retrospective method of identifying patient safety incidents by reviewing patient medical records.

The methodology was developed in the early 1970s for the California Insurance Feasibility Study and involves a two-stage review process. The initial review is undertaken by a trained nurse or medical staff member to identify the presence of an adverse event(s) using well defined screening criteria. The positively screened medical record is then reviewed by trained medical staff to further determine whether an adverse event has occurred, and if so to classify the event, rate its preventability and its level of severity (Wilson et al 1995, Brennan et al 1991). More information on the methodology and tools that can assist in conducting a medical record review can be found in **Part C 'Measurement tools and processes'**.

Specific audit or medical record review tools have also been developed based on the California Insurance Feasibility Study, the Harvard Medical Practice Study (Brennan et al 1991a&b), and the Quality in Australian Health Care Study (Wilson et al 1995).

Research into medical record reviews

Most of the research into medical record review has assessed the inter-rater reliability of detection between the clinicians reviewing the medical records, and/or has focused on the rate of adverse events this method detects compared to other mechanisms of identification.

In the Quality in Australian Health Care Study, physicians reviewing the positively screened records for confirmation that an adverse event had taken place, had moderate to poor inter-rater reliability. Whereas, during the initial screening process agreement was found to be good among nurses and moderate among medical officers (Wilson et al 1995). Similar results were found in the Utah and Colorado Medical Practice Study. For agreements in judgements among the three sets of reviewers, moderate ($k: 0.40$ to 0.41) inter-rater reliability for the presence of adverse events and poor inter-rater reliability ($k: 0.19$ to 0.23) for negligent adverse events resulted. These findings suggest that organisations using medical record review to detect patient safety incidents may need to use more reliable methods of measurement to detect and evaluate patient safety interventions (Thomas, Studdert & Brennan 2002).

Research comparing medical record review to other methods of patient safety incident detection is discussed below.

The pros and cons of medical record review

There is much debate regarding the effective use of medical record review and the potential of this method to detect adverse events (Neale & Woloshynowych 2003, Wilson 2003).

Major studies in patient safety such as the Harvard Study and the Quality in Australian Health Care Study, used medical record review to measure the incidence of adverse events in hospitals. Their findings lead to an increased awareness of patient safety incidents, further research and investigation into how health care delivery can be safer, and efforts aiming to reduce the incidence of these adverse events (Neale & Woloshynowych 2003).

However, results obtained from conducting medical record review should be used and interpreted with caution (Thomas, Studdert & Brennan 2002), as crude rates of adverse events may give a false picture of the true risk and clinical reality. There are several disadvantages to using this method including the fact that:

- it does not provide information on how or why things went wrong
- it only detects those adverse events that are documented in the medical record, and has been estimated to miss up to 20% of adverse events
- it identifies adverse events only and does not focus on near misses
- it is the most costly and labour intensive of the detection methods currently used in health care organisations.

Other issues that need to be considered when using medical record review include:

- access to the medical records in a timely manner
- accuracy and completeness of the documentation
- the legibility of notes within the medical record
- the need to train staff to screen and review records.

All of these factors can influence the time and resources required to perform a successful and unbiased medical record review. In favour of medical record review, a number of studies comparing it to other forms of patient safety incident identification have shown that it detects the greatest number of adverse events (Wilson 2003, Beckmann et al 2003, Wolff, Taylor, McCabe 2004, Rozich, Haraden & Resar 2003).

Recommendations from the research

Several studies advise on how best to conduct a medical record review. Wilson (2000) recommends:

For effective use of the medical record review to improve health care, two elements are (therefore) needed – an alerting system to indicate records worthy of detailed examination and a systematic approach to that examination.

The Quality in Australian Health Care Study indicates that for successful conduct of a medical record review, the medical discharge summary and all volumes of the patients' medical record should be available and accessible (Wilson et al 1999).

In the UK, Woloshynowych et al (2003) designed a modular review form (MRF2) to facilitate conduct of the medical record review. It comprises five stages:

1. Patient information and background to the adverse event.

2. Disability caused by the adverse event.
3. Period of hospitalisation during which the adverse event occurred.
4. Principal problems in the process of care.
5. Causative/contributory factors and preventability of the adverse event.

This review form was evaluated in a pilot study, which was conducted by several teams around the world, two of which were in Australia. From this evaluation, mostly positive feedback was received and further modifications were made to the form. Further information on the MRF2 form has been provided in **Part C 'Measurement tools and processes'**.

Medical record review is a valuable tool and the most effective way of detecting adverse events, however it is also the most resource intensive method. Health care organisations using medical record review will need to weigh up the benefits to the costs of using this tool.

Other methods of detecting patient safety incidents

Limited adverse occurrence screening

Limited adverse occurrence screening is a tool developed in Australia based on the methods of medical record review used in the California Insurance Feasibility Study. Compared with medical record review it is a less resource intensive method of identification. It has been defined as 'a continuous process of retrospective screening and review of inpatient medical records to detect adverse patient occurrences' (Wolff 1996).

Limited adverse occurrence screening involves a two-stage review process – an initial screening of an adverse patient occurrence based on nine criteria, followed by a medical review of the positively screened records. The screening process takes place after the patient has been discharged, at the time health information service staff are finalising the patient's medical record. See **Part C 'Measurement tools and processes'** for further details.

Research on limited adverse occurrence screening

There have been several studies evaluating the use of limited adverse occurrence screening. One study compared its use to the more comprehensive medical record review method used in the Harvard study (18 criteria and more resources). It found that the limited adverse occurrence screening method was able to detect approximately half of the adverse events detected using medical record review, and almost two thirds of adverse events with major severity (Wolff 1995). This was considered a positive finding as the majority of adverse events were detected using limited adverse occurrence screening, and a greater proportion of the severe and sentinel events were detected.

Another study assessing the use of limited adverse occurrence screening over an eight-year period, found the annual rate of adverse events significantly reduced between the first and eighth year of the study. However there are limitations to these studies, including the lack of risk adjustment to the adverse events, and lack of a control group to compare the findings to (Wolff et al 2001).

These findings demonstrate the potential benefits of using limited adverse occurrence screening to detect adverse events, however further research that takes into account other patient risk factors would provide a stronger evidence base to using the tool.

Unlike a medical record review, limited adverse occurrence screening provides a health care organisation with a continuous stream of detected adverse events. This knowledge then allows analysis of the event and consequent action(s) to be implemented. Users of limited adverse occurrence screening report the challenge is not during the detection phase, but in the steps of event management that follow. Limited adverse occurrence screening also provides a strategy that allows the detection of most adverse events at a much lower cost to a health care organisation compared to medical record review. Further information on this tool is provided in the **Part C 'Measurement tools and processes'**.

Trigger tools

The trigger tool for measuring adverse drug events provides instructions for conducting a medical record review using triggers to identify possible adverse drug events (IHI 2004). It is a paper-based adaptation of Classen's computerised hospital information system (Classen et al 1992). In a study evaluating its use in 86 hospitals in the USA, 274 adverse drug events were identified using the trigger tool, of which only 1.8% (five adverse drug events) had an incident report filed. Through the use of this tool, participants in the study were able to quantify the occurrence of adverse drug events, and take action to reduce the preventable events. Further information on this tool is provided in the **Part C 'Measurement tools and processes'**.

A number of tools that assist in conducting a medical record review are described in more detail in **Part C 'Measurement tools and processes'** of the Toolkit.

Prospective screening

In contrast to the retrospective approach offered by medical record review, identification of patient safety incidents may also occur prospectively. Prospective detection of patient safety incidents involves identifying adverse events at the time of health care delivery. Studies comparing retrospective medical record review to prospective screening revealed that the latter method was more effective in identifying preventable adverse events (Michel 2004). Preventable adverse events are defined as 'those events which result from an error in management due to a failure to follow accepted practice at an individual or system level' (Wilson et al 1995).

Another study used prospective detection of adverse drug events by having a nurse investigator visiting each hospital unit at least twice daily (weekdays only) to solicit information from nursing, pharmacy and clerical staff; and a nurse investigator to review all charts at least daily (weekdays only). Staff were also asked to report incidents to the nurse investigator. Using all three strategies, they detected 6.5 adverse drug events per 100 admissions (adjusted rate) of which 28% were preventable, and 5.5 potential adverse drug events per 100 admissions (adjusted rate). Although multiple strategies were used in this study, it demonstrates that using prospective methods enables the detection of adverse drug events, and in particular this study emphasised both preventable and potential adverse drug events (Wald & Shojanja 2001).

2.2.2 Patient safety incident reporting

Incident reporting refers to the activity of documenting the occurrence of a patient safety incident. A person directly involved in the event usually completes incident reporting, and this reporting tends to take place at the time the event is discovered. The reporting of patient safety incidents is critical to any patient safety management program. It raises staff awareness of an incident and, as with all adverse event identification methods, triggers the formal processes necessary to investigate and analyse its cause, and ultimately institute the appropriate management and learning processes to prevent further patient safety incidents from occurring (Karson & Bates 1999).

There are three main types of incident reporting currently used in the health care sector including:

- Clinical incident reporting – involving internal reporting of patient safety incidents by clinical staff.
- Sentinel event reporting – involving reporting of unexpected occurrences involving death or serious physical or psychological injury, or the risk thereof, to an external statutory body.
- Consumer incident reporting – involving reporting of incidents by consumers via complaints mechanisms, surveys or other mechanisms.

Each of these types of reporting processes are discussed in detail below.

Clinical incident reporting

Clinical incident reporting refers to a process used by clinical staff to document the occurrences of patient safety incidents within an organisation or clinical practice (Cullen, Bates & Leape 2000). This form of incident reporting is in widespread use in health care facilities in Australia. It is voluntary, and clinicians typically complete their account on a reporting template. These templates are either paper- or electronic-based. The reports generally contain information about when and where the event occurred, the role of the person reporting, patient details, characterisation of the event (severity, type, preventability), and identification of systems that failed (Boxwala et al 2004). The aim is to collect qualitative data from frontline providers including information about the contributing factors, faulty processes or undesired outcomes (Shojania et al 2002, Webb et al 1993).

In the hospital setting or in larger health care organisations, incident reporting is generally overseen by the clinical risk management department. It can be carried out by any health care professional, however in the hospital setting, studies have shown that most are completed by nursing staff (Kingston 2004). Examples of a clinical incident report may include the reporting of an error in drug administration, a patient fall or a surgical complication.

Research into clinical incident reporting

Most of the research into clinical incident reporting has focused on the number of patient safety incidents this method can identify. Several studies have compared the rates of patient safety incidents reported via incident reporting systems to the rates detected using other methods such as medical record review. It has generally been found that incident reporting systems significantly underestimate the number of actual patient safety incidents due to an under-reporting of incidents by health care professionals. As a result, further studies have attempted to assess the magnitude of this problem.

Underestimates and under-reporting

Incident reporting is one of the main mechanisms by which health care organisations identify patient safety incidents. However, only a small proportion of patient safety incidents are detected using this method due to clinicians not reporting all incidents that occur. Under-reporting by clinicians is a significant problem in the health care sector, with one article from the US estimating between 50% and 96% of incidents are not reported (Barach & Small 2000). In a study assessing the reporting of adverse drug events by nurses, it was found that only 6% of adverse drug events identified by research investigators, had a corresponding incident report submitted (Cullen 1995). Antonow, Smith & Silver (2000) estimated the extent of medication error under-reporting by comparing results from a survey to those that were submitted as written incident reports by nursing staff over a six-month period in a paediatric hospital. The surveys were completed during mandatory skills sessions and an excellent survey response rate resulted (93.5%). The surveys identified 177 medication errors, with most (62.1%) being prevented from reaching the patient. When these figures were compared with those found in the incident reports, only 51 incident reports (30.5%) were completed for all medication errors observed. Incident reports tended to be written for those errors that reached the patient, with only 10% of near misses being documented on incident reports. This finding is consistent with another study that found health care professionals tended to report incidents that cause actual harm to patients, and were less likely to report near misses (Lawton & Parker 2002). In an American study conducted to estimate the extent of perceived medication administration errors under-reported, a consistent perception among the nurses surveyed revealed that approximately 40% of these errors are not being reported (Wakefield 1999). A number of studies have then sought to identify why this under-reporting occurs.

Barriers to clinical incident reporting

Research has documented a strong reluctance of health care professionals to report patient safety incidents (Cullen et al 1995, Antonow, Smith & Silver 2000, Lawton & Parker 2002), attributed to the traditional culture of blame that has dominated the health care sector. One Australian study examined the attitudes of doctors and nurses in the public hospital sector, towards incident reporting and also identified process disincentives to reporting. Their main findings were that there are cultural differences between doctors and nurses, and the barriers to incident reporting included:

- a lack of awareness and knowledge regarding the process of incident reporting – unclear what to report
- an uncertainty of the different types of incidents, for example adverse events or near misses
- the fact that nurses tended to complete incident reports more habitually than doctors, leading to the form being thought of as a 'nursing form'
- the time consuming nature and complexity of completing reports
- a lack of incentive to report and lack of feedback once report is generated, and therefore little value being associated to reporting
- a lack of legal privilege – doctors concerned with potential medico legal implications associated with reporting
- a culture of blame – insecurity, distrust and anxiety regarding the use of the data generated from reports (Kingston et al 2004). (The reporting systems used in the public hospitals at the time of this study were not anonymous ones.)

An American study that surveyed nurses in the acute hospital setting found that the four factors that best explained why nurses may not report medication errors were fear, disagreement over whether an error occurred, administrative responses to medication errors, and the effort required to report medication adverse events (Wakefield 1996).

These studies suggest that the main barriers to incident reporting are attributed to the safety culture and leadership of a health care organisation, and therefore, shifting the culture of safety within a health care organisation from one of assigning blame to a non-punitive systems approach is seen as the key to overcoming these under-reporting issues. Safety culture and organisational leadership has been discussed in detail in the '**Organisational capacity**' section of this document.

Benefits of clinical incident reporting

Clinical incident reporting is in widespread use across many Australian health care organisations. Compared to medical record review, it offers a mechanism to identify patient safety issues from the clinicians themselves at, or close to, the time they occur. It is also a much more cost-effective means of identifying patient safety incidents. The benefits of incident reporting have been discussed in much of the literature and include the following:

- Knowledge gained from individual and aggregated incident reports can contribute to positive change and influence work practice (Kingston et al 2004, Firth-Cozens 2002).
- Incident reporting is an effective means of making governing bodies aware of problems (Kingston et al 2004).
- It leads to review and investigation of the reported event, and ultimately to analyses of multiple causation at the system level (Barach & Small 2000).
- It is relatively inexpensive to implement (Wald & Shojania 2001).

To our knowledge, studies of clinical incident reporting have not specifically sought to establish the benefit of this practice to patient safety outcomes. However, we can draw on the experiences and research of other industries that use incident reporting mechanisms.

The direct impact of incident reporting systems on safety has been more intensively studied within the aviation industry. One such study found that as the reporting of incidents increased (more than fivefold since it was first introduced), the number of high-risk incidents filed dramatically declined. The authors interpreted these findings as support for their incident reporting systems as a means of raising staff awareness of the relevant safety issues and in turn success in reducing the frequency of high risk events (O'Leary, Macrae & Pidgeon 2002). Such findings also highlight the importance of applying caution in interpreting reporting rates as correlates of safety. The initial implementation of reporting systems, or of a strategy to encourage reporting, is likely to be associated with a perceived rise in incidents. However, such results typically reflect the change in practice rather than increased threats to safety. Conversely, a reduction in incident reports might signal complacency in reporting rather than a reduction in the number of high-risk incidents.

Battles et al (1998) assessed the implementation of a new confidential and no-fault reporting system for use in transfusion medicine departments (three hospitals and three blood centres in the USA). This system was made up of seven components – detection, selection, description, classification, computation, interpretation and local evaluation. They found that the number of reports increased, with one institution reporting a 10-fold increase in the number of reports received, and attributed this to the confidential and no-fault culture and the immediate feedback the system provided to those individuals reporting incidents (Battles et al 1998). Although these are only the preliminary findings of the implementation of this system, we can assume that like the aviation system, an increase in reporting rates may lead to a reduction in the number of high-risk events and improvements in patient safety outcomes.

Successful incident reporting systems

In a study analysing the incident reporting systems for near misses in four non-medical industries, results showed that most of the systems were mandated and implemented by the federal government. Participation was voluntary and most systems were confidential, those not confidential were anonymous. They concluded that in order for an incident reporting system to be successful they required the following factors:

- immunity for the persons reporting
- confidentiality or data de-identification
- independent outsourcing of report collection and data analysis by peer experts
- rapid meaningful feedback to all parties involved in the incident
- ease of reporting
- sustained leadership support (Barach & Small 2000).

Many of the hospital-based studies have also made similar suggestions of ways to facilitate reporting including:

- render it less time consuming
- simplify and clarify near misses, adverse events and others
- increase awareness and knowledge of the process
- protect from liability and disclosure
- ensure anonymity
- ensure provisions for analysis and feedback of the information
- provide incentives to encourage reporting (Kingston et al 2004, Cooper 1996).

Facilitated incident reporting

To improve reporting rates, a number of studies used methods that facilitated or prompted the use of incident reporting systems.

In an Australian study, incident monitoring was facilitated by senior clinicians reminding and encouraging all staff to identify incidents, by further discussing incident monitoring at ward rounds and clinical sessions. When it was identified that an incident had occurred, the senior clinician invited a staff member involved in the incident to report it. Reporting was voluntary and anonymous. The results of this method showed that 211 incidents were identified using this method of facilitated incident monitoring (FIM). They also found that FIM yielded contextual information about the incidents (Beckmann et al 2003).

The provision of prompts aimed at physicians to report incidents has been assessed in a number of studies. Two of the studies (Field et al 2004, O'Neil et al 1993) compared the facilitated incident reporting mechanisms to other methods of detection, and so have been discussed in greater detail below in '**Comparisons of identification methods**'.

Sentinel event reporting

A sentinel event is 'an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof' (ACSQHC 2005). Serious injury specifically includes loss of limb or function. The phrase, 'or the risk thereof' includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called sentinel because they signal the need for immediate investigation and response (Joint Commission on Accreditation of Healthcare Organizations 2005).

Sentinel event reporting refers to reporting that is external to the health care organisation, such as to a statutory body. All Australian states and territories have mandatory reporting of sentinel events, however the sentinel events required to be reported in each state or territory differ.

Most sentinel events rarely occur at a local level, and the purpose of collecting their occurrences collectively (for example from all public hospitals) is to give a greater wealth of information about the events. Aggregating this data allows a more comprehensive assessment, and may provide significant information about their common underlying contributory factors. No research was found regarding the impact of sentinel event reporting on the incidence of these events.

Consumer incident reporting

The consumer is a valuable source of information for the detection and reporting of adverse events. Consumers can report incidents through a number of mechanisms including through patient complaints services, via consumer satisfaction surveys, through legal action or via consumer reporting phone services. The availability of these options for consumer incident reporting may vary depending on the health service.

Research into consumer incident reporting

The impact of consumer incident reporting on patient safety is yet to be fully investigated. The majority of research has focused on the reporting of medication errors given their status as the greatest risk factor for patient harm. A study of the primary care sector revealed that 18% of patients discussed incidents involving medications with their medical professional but only 3% documented the occurrence of the adverse drug events in the patients' medical records (Gandhi et al 2003).

Comparisons of the effectiveness of consumer telephone surveys and medical record review in identifying patient safety incidents revealed that 92% of adverse drug events were identified through consumer telephone surveys as compared to 28% by medical record review. This same study also reported that patients discussed 69% of their medication symptoms with their physician, and this reporting led to the physicians changing their drug treatment in 76% of cases. These findings suggest consumers are also aware of patient safety issues that need to be identified to improve the safety of health care. This reporting rate, however, falls well short of 100% suggesting that many safety incidents go unidentified. Reluctance to report safety incidents may be due to feelings of embarrassment on the part of patients and language barriers between the consumer and health care provider (Weingart et al 2005).

Egberts et al (1996) compared the time differences taken by patients to report adverse drug events to the time taken to report adverse drug events by health professionals. They found the reporting by patients may contribute to earlier detection of known and unknown adverse drug reactions. However this study lacks a statistical analysis of the data. They also found the telephone reporting service could not be relied upon as an independent reporting system, as information received by consumers was often incomplete.

Further research is needed to identify more effective consumer reporting programs, including the use of consumer telephone reporting services. At the time of writing this report the Australian Adverse Medicine Events Line was in the preliminary stages of undergoing an evaluation, which will no doubt provide valuable information and could improve the safety of medication use. To date, however, little information of the impact of these services is available.

2.2.3 Comparisons of identification methods

Several studies have compared the number and types of incidents identified using the different methods. These will now be discussed in greater detail.

O'Neil et al (1993) compared the use of prompted physician incident reporting to the method of medical record review to detect adverse events in a hospital setting. To conduct the medical record review, similar screening criteria to those used in the Harvard Medical Practice Study were used. Physician reporting used a daily reminder to report events via the electronic mail system. These reminders were sent out to the heads of medical teams, while a reminder of the importance of reporting was given at weekly meetings. This method was not strictly incident reporting as described above, but was a facilitated approach. The medical record review detected 2.7% of all admissions had an adverse event secondary to medical management and the physician incident reporting strategy detected 2.8% of all admissions. These figures demonstrate that very similar numbers of adverse events were detected using these two methods. However, less than half of these adverse events were identified by both strategies ($k=0.52$). A cost comparison found that medical record review is much more resource intensive – more than double that of the facilitated physician reporting method used in this study. Further investigation into the method of physician reporting used could be of great benefit as it has the potential to improve the quality of health care delivery in a more economical way. These findings highlight the need for health services to consider a multifaceted approach to patient safety incident identification using both detection and reporting methods so as to ensure a comprehensive awareness of the pertinent safety issues.

Field et al (2004) compared four sources of identification to detect adverse drug events among older people in the ambulatory care setting: the use of computer generated signals, automated review of electronic notes, clinical incident reporting, and medical record review of hospital discharge summaries and emergency department visits. They found that computer generated signals detected 31% of the adverse drug events and 37% of preventable adverse drug events, that automated reviews of electronic notes were the source of 39% of adverse drug events and 29% of preventable adverse drug events, that clinical incident reporting identified only 11% of the adverse drug events and 6% of preventable adverse drug events, and that medical record review identified only 24% of the adverse drug events and 21% of preventable adverse drug events. There was little overlap in the adverse drug events identified across all the sources.

Beckman et al (2003) compared the use of facilitated incident reporting to medical record review in detecting adverse events in an intensive care unit setting. A total of 221 incidents, 66 of which were adverse events, were detected using the facilitated incident reporting method, compared to 256 incidents, 132 of which were adverse events, identified by medical record review. Although more patient safety incidents were detected using medical record review, the authors found that facilitated incident reporting yielded more contextual information about incidents, and identified a higher proportion of preventable problems than medical record review. They also reported that medical record review was more resource intensive than facilitated incident reporting, but that, in contrast to other studies, there was good agreement among the medical record review reviewers.

Use of multiple methods to identify patient safety incidents

Several of the above-mentioned studies found that using more than one method to identify patient safety incidents increases the total number of incidents detected, and that there is little overlap of the incidents detected using the varying methods (Beckmann et al 2003, Field et al 2004, O'Neil et al 1993, Wolff & Bourke 2002)

Summary

Ultimately, the type of reporting system implemented within a health care organisation or governing body depends on the aims of the system and its context. For example, a statutory body may introduce a mandatory reporting system to increase accountability, while a hospital may opt for a voluntary confidential reporting system to encourage reporting of incidents by the clinicians delivering the care.

The focus of strategies to identify patient safety incidents are on those that detect, and these tools have been further described in the **Part C 'Measurement tools and processes'**. Established incident reporting tools tend to be computer-based with the Australian Incident Monitoring System (AIMS) being the most widely used and researched incident reporting system in Australia. Incident reporting has been discussed in further detail in the **Part C 'Measurement tools and processes'**. There is also information on the Australian consumer reporting telephone service, Adverse Medicine Events Line, in the **'Resources'** section.

2.3 Analysis and investigation

What is analysis and investigation?

Following the identification of a patient safety incident, some form of analysis and investigation should be conducted. This serves two purposes:

- To identify or reveal what happened, how it happened and why the incident happened.
- To put actions into place to prevent future incidents.

An analysis of an incident or incidents aims to develop a broader understanding of the cause of the incident. Understanding the what, how and why an incident occurred is critical to leading focused change in specific processes of health care identified as having failed. Often it is these outcomes of an analysis and investigation into an incident or incidents that drives policy change and development in health care.

System versus individual approach

Reason (2000) describes two ways of approaching the problem of human error:

- The individual approach.
- The system approach.

The individual or person approach is one that focuses on the error of the health care professional, blaming them for inattention, forgetfulness, or others. The system approach focuses on the conditions and factors under which the individual works, with errors seen as consequences rather than causes. This approach accepts that humans are fallible and errors are to be expected in the health care setting.

Other industries, such as aviation, have successfully implemented the system approach to analyse an incident with a reduced focus on individuals. Health care organisations are beginning to shift their focus to the organisational factors that influence or contribute to the incident, with the Institute of Medicine reporting that the majority of medical errors are attributable to faulty systems, processes and conditions (Institute of Medicine 2000).

A system approach has the potential to recognise flaws in the system that can then be rectified and have a greater impact in the prevention of future occurrences. This less individualistic and more systemic approach has been called the 'human factors' approach (Vincent, Taylor-Adams & Stanhope 1998).

A general framework

Vincent et al (1998) developed a framework of factors that influence clinical practice and contribute to adverse events. Components of the framework include the following factors and their possible contributory factors (an example of one contributory factor has been given for each domain):

- institutional factors – medicolegal environment
- organisation and management factors – safety culture
- work environment – staffing levels
- team factors – verbal communication
- individual staff member factors – knowledge and skills
- task factors – availability of protocols
- patient characteristics – complexity of the condition.

The main aim of analysing and investigating an event using the above framework is to be able to identify gaps and inadequacies in the system that contributed to the incident.

Types of analysis and investigation

There are several ways of analysing and investigating errors. In general, analysis begins with an adverse event, and works to identify and assess all combinations of process failures that may have led to the event. This process will now be described further.

Investigation and analysis in response to an event

The literature describes the process of analysis and investigation of an event as involving the following steps:

1. Identify that an event has occurred. Classify according to severity.
2. Outline a timeline of events and identify any obvious care management problems – for example wrong treatment given, delay in diagnosis.
3. Establish clinical context and patient factors associated with the event.
4. Gather information about the incident from all available sources – case records and interviews.
5. Assemble a composite analysis, identifying both specific and general contributory factors (see those described in the framework above).
6. List causes of care management problems and recommendations to prevent their recurrence (Vincent, Taylor-Adams & Stanhope 1998, Vincent et al 2000, Denison & Pierce 2003).

This type of investigation and analysis is considered a reactive process, and includes the following commonly used tools:

- **Root cause analysis (RCA)**

Root cause analysis was developed by the aviation industry and has been adapted to be used in the health care setting. A root cause analysis is conducted after the occurrence of an adverse event and is a comprehensive analysis, which involves multiple stages. It is a tool currently used by many in the hospital setting to analyse serious and sentinel events, including near misses of a serious event.

The benefits of conducting a root cause analysis has included building collaborative relationships among staff (team) members, and providing a valuable learning opportunity for those involved in the root cause analysis. The sequential steps involved in conducting a root cause analysis for sentinel events and case examples has also been discussed in the literature (Boyer 2001, Carroll, Rudolph & Hatakenaka 2002). However, we were unable to identify any conclusive studies that assessed the impact of implementing root cause analysis on patient safety outcomes.

- **Morbidity and mortality meetings**

This is the traditional format in which clinicians review deaths and adverse events that lead to serious morbidity. The main objectives of the meetings are to analyse the circumstances that surrounded the outcomes, to make recommendations for improving the processes of care given, and to initiate and review actions based on these recommendations (NSW Health Department 2001).

- **Risk rating matrix**

This tool is used to map risks against the likelihood of occurrence and severity of impact, combining judgements with numerical analysis (National Patient Safety Agency). The matrix is used to assess each incident in terms of the actual or potential consequence of the risk to patients. Once the level of risk has been assessed, the prioritisation of response or action efforts should be established.

A number of risk rating tools have been developed for use in the health care setting, including the 'Severity assessment code' (NSW Health), the 'Safety assessment code matrix' (Veterans Administration, USA), and the 'Risk assessment matrix – likelihood and consequences categories tables' (WA Department of Health). These tools are discussed further in **Part C 'Measurement tools and processes'**.

As discussed above an analysis and investigation can be conducted into a single incident. For single sentinel events and near misses of serious events, a comprehensive analysis such as root cause analysis is usually conducted. Data obtained from more than one incident can also be analysed. The aggregated data can then be assessed for any trends. Aggregated data also enables individual organisations to learn from the experience of others (Boxwala et al 2004).

Investigation and analysis before an event

Analysis and investigation can also be conducted before an event occurring. A number of tools currently used in other industries are now being used in health care to identify potential failures (National Patient Safety Agency 2004). The most commonly used tools include the following:

- **Failure modes effects analysis (FMEA)**

This technique has been described in the literature as a form of proactive evaluation of weaknesses in a system or a process before a patient safety incident occurs, and is currently used in the US health care sector (Boxwala et al 2004, National Patient Safety Agency 2004). It is known as a 'bottom up' process, as it begins by asking the question 'what if?' and not with the occurrence of an adverse outcome (Marx & Slonim 2003). This tool is discussed in further detail in **Part C 'measurement tools and processes'**.

DeRosier et al (2002) describe a specific version of the failure mode and effects analysis they developed for the health care setting. A comprehensive description of the five steps in the health care failure mode and effects analysis (HFMEA) process, and information on the worksheets that can be used to assist in these stages are discussed. This study, however, does not discuss the impact of implementing this analysis on patient safety outcomes.

- **Probabilistic risk assessment (PRA)**

Probabilistic risk assessment is an integration of failure modes and effects analysis, fault tree analysis, and other techniques to assess the potential for failure and to help find ways to reduce risk (NASA 2000), and involves a mixture of quantifying risk and using judgement (National Patient Safety Agency 2004). Like failure mode and effects analysis, it is also a proactive approach in which the undesirable outcome to be modelled is identified first, followed by an investigation of all combinations of process failures that may lead up to this event (Wreathall & Nemeth 2004). The probabilistic aspect of this tool is a way of quantifying the potential risk (National Patient Safety Agency 2004).

Probabilistic risk assessment has been used in high-risk industries such as the aeronautical and nuclear power industries, and has recently been studied for its potential use in the health care sector. One such article describes the probabilistic risk assessment and examines its strengths and limitations and relevance to patient safety. Probabilistic risk assessment focuses on a potential adverse event, and uses an event tree analysis to map out the different pathways by which the event could come about. A fault tree analysis is an extension of this, and can be used to build a model to predict the likelihood of each branch of the tree (Wreathall & Nemeth 2004). Marx and Slonim (2003) also describe the use of probabilistic risk assessment in the health setting, and compare it to using the failure mode and effects analysis. The advantages of probabilistic risk assessment compared to failure mode and effects analysis, is that it calculates the conditional probabilities associated with health outcomes in a complex system.

Each of these methods is described in detail in **Part C 'Measurement tools and processes'** to enable health care professionals the choice of the most appropriate investigation and analysis tool.

Investigation and analysis research

As with incident reporting, no research was found evaluating the direct impact of investigation and analysis methods on patient safety outcomes. Most of the literature available on this topic describes how a method of investigation and analysis could be applied and implemented in the health care setting.

All these methods include an evaluation of the effectiveness of the final outcome – the action plan and recommendations. Once the investigation team has identified the contributory factors, recommendations are made and an action plan developed to address each contributory factor. Then, those who will be responsible for the implementation of each action need to be identified, and a timeline with an expected completion date of each action should be recorded. Follow up measurement strategies and outcomes are also developed by the team, enabling the team to evaluate the effectiveness of their action plan. This is how health care organisations can measure the effectiveness of using these tools. Although evidence is not available in the literature, these tools are valuable mechanisms to improve patient safety outcomes.

2.4 Management – solution development and implementation

Management of a patient safety incident involves the development of strategies to prevent or minimise the recurrence of a patient safety incident. These strategies may take the form of an action plan developed by key management staff and clinical leaders (as discussed above). This action plan may entail initiatives to modify medical processes (identified as having failed), amend hierarchical consultation between medical staff, or introduce staff training. While no specific management tools are available in the area of patient safety, the particular management strategies formulated should be developed based on the nature of the patient safety incident and the outcome of the issues identified by the investigation and analysis method chosen.

2.5 Feedback and learning

Feedback and learning is imperative to benefiting from patient safety incidents. Feedback and learning aims to provide staff with insight into the failures leading up to a patient safety incident and to stimulate discussion and

action for the prevention of further threats to patient safety. Engaging frontline staff in feedback processes is particularly important given their key role in quality improvement and the detection and reporting of incidents. In the absence of any specific tools for feedback and learning, the most common way to achieve this process is through staff meetings and forums.

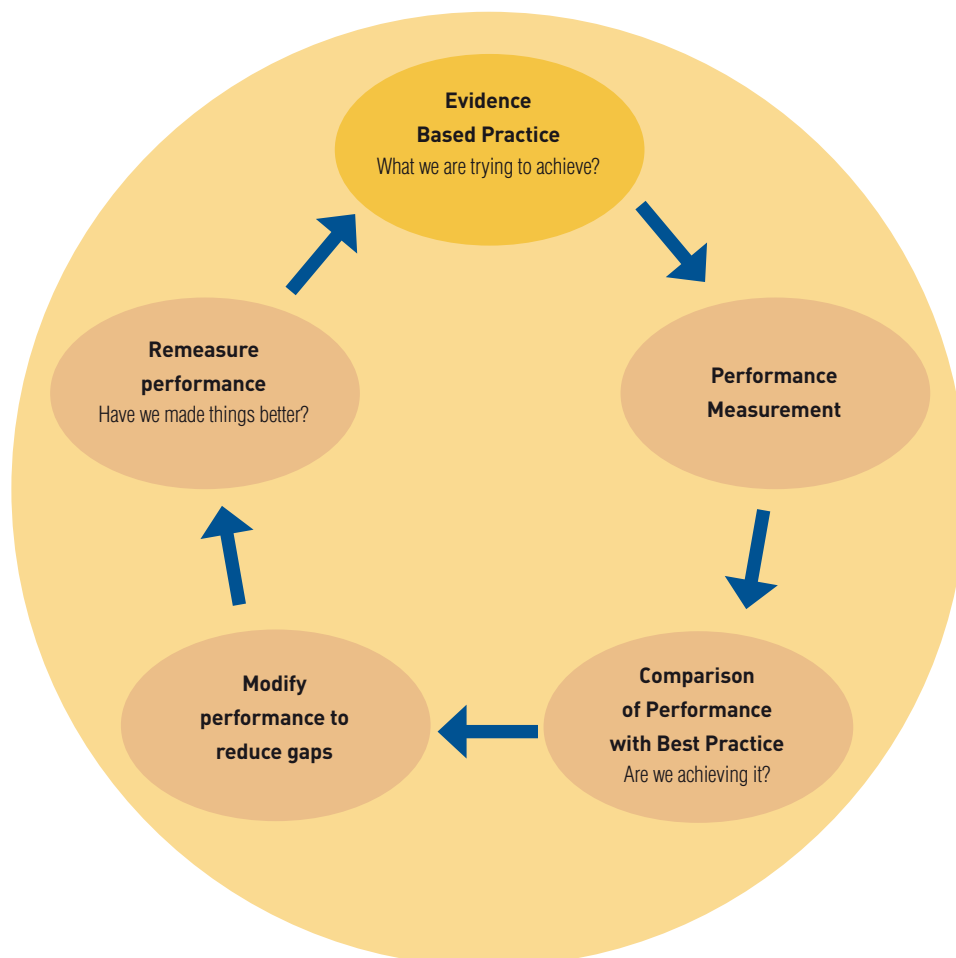
3. Clinical performance

3.1 What is performance measurement?

The measurement of clinical performance refers to the assessment of the extent to which an organisation or individual clinician provides care that is consistent with objective evidence-based best-practice (Daley et al 2002).

Clinical performance measurement can be implemented at any level of health care provider, from individual clinicians to departments, individual organisations and composite health care entities (Brook, McGlynn & Cleary 1996). Measuring clinical performance is only useful where measurement is integrated with continuous quality improvement methods that facilitate reporting, analysis, investigation, feedback, and appropriately linked actions. See Figure 8 below (Physician Consortium for Performance Improvement 2001, Berwick, James & Coye 2003).

Figure 8: Performance measurement quality improvement cycle



3.2 How is clinical performance measured?

The evaluation model most commonly applied in clinical performance measurement is that of Donabedian's 'structure, process, outcome' framework that consists of:

- structural measurement – such as accreditation, certification and credentialling
- process measurement – such as assessment of adherence to evidence-based health care practices
- outcome assessment – such as mortality, morbidity and disability [Donabedian 1988].

Structural measures for assessing clinical performance

Structure describes the physical features of health care, and includes the human, physical and financial resources of the organisation [Ram et al 1998, ACHS 2002]. It includes assessing many of the domains of organisational capacity described earlier in '**Organisational capacity**'.

Process measures for assessing clinical performance

Process data are the components of the encounter between a health care professional and a patient [Brook, McGlynn & Cleary 1996], and are the measures of interest to clinicians as they directly relate to an episode of care. However, for process measures to be valid indicators of quality, strong evidence of a causal relationship between process and outcome is required. Data collection is contingent upon access to clinical datasets and in most instances this information is not easily accessible from routine datasets unless electronic records have been implemented. Process measures are therefore usually extracted in retrospective medical record review where poor documentation limits data validity [Powell, Davies & Thomson 2003]. There may also be a long lag time between the process of care and subsequent poor outcomes, as exemplified by poor diabetic control and vascular complications such as limb amputation.

Outcome measures of safety for assessing clinical performance

Outcome data refer to the patient's subsequent health status such as an improvement in symptoms. There is a preference for outcome measures for assessing clinical performance on the basis that it is the health outcome that is of interest, and that process is often difficult to attribute to outcome. In addition, routine surveillance is likely to support that appropriate action be taken in response to documented deficiencies in care provision. Administrative outcome data are characterised by their ready availability and can be used retrospectively over large time periods. The resources required to use routine data for quality purposes are low in comparison to other data methods such as prospective dataset development and collection or medical record review, and there is a wide range of patient data relating to diverse conditions and demographic factors that can be easily accessed.

However outcome measurement alone may underestimate quality of care deficiencies, as deficiencies in process of care may not lead in every instance to adverse outcome. The availability of outcome data is also limited if the analysis relies on administrative datasets that have been developed for purposes other than measuring quality (usually administrative reasons such as health care utilisation). The attribution of health care utilisation data such as readmissions to quality of care has been debated, and interpretation of the literature is impaired by heterogenous study designs and data definitions [Brook, McGlynn & Cleary 1996].

Another useful way of thinking about clinical performance measurement has been suggested by Brook, McGlynn & Cleary [1996].

Implicit measurement

Implicit measurement is based on judgemental decisions regarding the adequacy of care. It includes assessing the adequacy of health care processes, assessing whether better outcomes would be associated with use of different processes, and appraising both process and outcome to reach an overall assessment of the acceptability of care activities. Implicit measurement usually involves medical record review or peer review processes. However, this form of measurement is limited by the validity of judgmental decisions and poor correlation between different evaluators.

Explicit measurement

Explicit measurement involves the measurement of process or outcomes of care in which there is comparison to known best-practice or agreed standards. It commonly involves application of statistical methods to assess clinical indicators from routine datasets or paper-based auditing tools to define adherence to best-practice processes of care. Use of explicit measurement can drive quality improvement planning for health care providers and also allows comparison between health care providers through benchmarking and roundtable activities and by public dissemination of health performance such as in publication of report cards, league tables, and star ratings (Marshall et al 2000a&c, Jacobson, Mindell & McKee 2003, Nutley & Smith 1998, Mannion, Davies & Marshall 2005).

3.3 Characteristics of performance measurement

Performance measurement, while applicable to all areas of health care, will differ in its implementation, depending on the **purpose of measurement**. It is essential that organisations, departments or individual health care professionals understand the purpose for which measurement is undertaken (consumers/professionals) in order to:

- choose the process or outcome measure(s) of interest
- allocate the necessary resources to measurement.

It is then necessary to consider which general outcomes (such as mortality) or specific outcomes (such as postoperative wound infection), and which general processes (such as hand hygiene compliance) or specific processes (such as use of ACE inhibitors for chronic heart failure) would be useful within the specific context.

Regardless of the context however, an effective performance measurement system should be characterised by:

- evidence-based measures of acceptable and unacceptable performance
- valid and reliable data collection processes which can be tracked over time
- a measurement that is appropriately customised to particular clinical specialities, organisation, or clinician
- the ability to capture performance that is attributable to the competence of the organisation and/or clinician
- feasible data collection processes which are readily available
- the ability to adjust for confounding patient factors
- provision of comprehensive feedback to staff (Daley et al 2002, Physician Consortium for Performance Improvement 2001).

3.4 The pros and cons of measuring clinical performance

There has been considerable debate about the most appropriate measures of clinical performance, as well as the most robust methods of measuring explicit clinical performance. The benefits and limitations of clinical performance measurement will now be discussed.

The benefits

Clinical performance measurement provides the opportunity to monitor, evaluate and review the practices of an organisation and/or clinician, ensuring continuous improvement in safety and quality of care. More specifically, the implementation of an effective performance measurement system has the potential to improve safety by:

- encouraging professional development
- promoting and maintaining minimum standards of care
- enhancing the coordination and management of care
- ensuring organisational and clinician accountability for health care
- providing a standard against which organisations and clinicians can compare their performance to that of their peers
- rewarding organisations and individual clinicians for excellence in quality and safety of care
- from the perspective of consumers and carers, creating confidence that they will receive the highest standards of evidence-based health care.

Some examples of how clinical performance measurement can be applied to drive change and improvement include the following.

- The Toward a Safer Culture (TASC) is a project in which clinical pathways for acute coronary syndrome and stroke were developed and implemented across 30 participating NSW hospitals. Clinical performance was measured using performance indicators and benchmarking against participating hospitals, and was shown to improve cardiac and stroke care (Institute for Clinical Excellence 2004).
- In Queensland, a quality improvement program designed for acute coronary syndromes and chronic heart failure patients was implemented. The program was assessed before and after implementation using process of care indicators for in-hospital and after-hospital care. The authors concluded that 'quality improvement programs that feature multifaceted interventions across the continuum of care can change clinical culture, optimise care and improve clinical outcomes' (Scott et al 2003, 2005).

The limitations

One general criticism of clinical performance measurement has been the focus on technical performance to the exclusion of other areas of quality of care, such as communication skills, and domains that are not easily measurable such as caring and patient compliance. Deficiencies in these areas may adversely impact on individuals' emotional wellbeing, and increase the risk of potential patient safety incidents (Feinstein 2002).

Although clinical performance is an essential component of safe health care provision, it is important to recognise a number of issues that limited the degree to which measurement takes place. Some of these limitations include:

- confidence in the strength of safety outcome indicators such as mortality
- limitation of data access, data quality and data management, and analysis skills
- lack of national safety standards for existing quality indicators
- inability to measure other factors that influence impact of clinical performance, such as patient compliance
- lack of confidence in organisational capacity to support a culture of safety
- lack of evidence-based robust tools to support clinical performance measurement (Feinstein 2002, Ben-Tovim & Elzinga 2002, Boyce 2002, Boyce et al 1997).

3.5 Performance measurement strategies and tools

A number of approaches are available to measure performance, however tools to put these approaches into action are scarce. These approaches include accreditation, benchmarking, clinical audits (including medical record review), peer review, and use of indicator sets. The nature and implementation of these approaches will vary depending on whether they are intended to assess organisational or clinician performance.

Accreditation – a process

Accreditation is a formal process to ensure delivery of safe, high quality care, based on standards and processes devised and developed by health care professionals for health care services (ACSQHC 2005). The aim of accreditation is to assist an organisation to improve their performance, raise the level of patient care and demonstrate accountability (Joint Commission on Accreditation of Healthcare Organizations 2000).

Accreditation systems are now being expanded to community health centres, general practice and residential care facilities (Majoor & Ibrahim 2001). It is the most common form of assessing organisational performance, and as such focuses on an organisation's capacity to provide safe and high quality health care.

The **Australian Council on Healthcare Standards** is the major accreditation organisation in Australia, and uses the following main accreditation themes:

- safe practice and environment
- leadership and management
- continuum of care
- human resources management
- information management
- improving performance.

Many of the themes outlined above are further discussed in '**Organisational capacity**' in this document as key elements of organisational capacity to provide safe care. Not all of the standards used in accreditation relate directly to patient safety in health care, however it is recognised that different standards within a system are interrelated, and all are intended to combine to improve the quality of health care being provided by a health care organisation (ACSQHC 2003). It is also important to note that management of a health care organisation, while relevant, does not wholly reflect clinical performance, and that further individual performance factors should be considered and assessed (Ram et al 1998).

Benchmarking – a process

Benchmarking is the process of measuring patient care and outcomes against other comparable health care organisations or practices. Although benchmarking is predominantly carried out by health care organisations, it may also be performed by individual clinicians using standards set by their relevant professional body.

Benchmarking involves five phases, which constitute an evaluation cycle:

1. Benchmark preparation – Identification by an organisation or clinician of what should be benchmarked and against whom to benchmark.
2. Comparison of results with benchmarking peers.
3. Investigation – The identification of practices and processes to reduce performance gaps identified through comparison with peers.

4. Implementation – The adaptation or modification of processes or practice identified through the investigation stage as needing improvement to achieve best-practice.
5. Evaluation – The monitoring of newly adopted best-practices and repeat of the benchmarking cycle.

Implementation of the benchmarking cycle is consistent with the processes needed to maintain ongoing quality improvement in the delivery of health services.

Clinical audit

Clinical audit has been defined by the National Institute for Clinical Excellence (2002) as:

...a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria.

Clinical audit can be undertaken by individual clinicians or by teams of health care workers. They can be conducted manually or electronically and data can be collected from a number of sources including from paper-based sources such as medical (clinical) records or reports, or from electronically-stored data such as administrative databases. A number of audit tools are available to abstract and collect the data, some of which have been listed with website links in **'Resources'** in this section.

Medical record review

As well as being a method used for detecting patient safety incidents (discussed in detail in 'Patient safety incidents'), medical record review may also be used to assess the clinical performance of an organisation or clinician. For example, medical record review may be used as a method to assess adherence to guidelines where the medical record is used as the source of the data.

Electronically stored information

Existing data sets and systems, such as administrative data, can also be used as the source of data to conduct a clinical audit. These data sets are generally stored electronically, and the audit tool used to conduct the audit tends to also be electronically-based.

Control charts

Processes can be subject to common causes (natural) or special causes (extraordinary or unusual) of variation. Statistical process control methodologies offer a recognised way to measure and track these causes in variation, to ensure more consistent outcomes of a process, and to understand when and where problems occur in a process (Montgomery 2001, Cleary 2005).

The 'magnificent seven' tools of statistical process control are:

- histogram or stem and leaf plots
- check sheets
- Pareto charts
- cause and effect diagrams
- defect concentration diagrams
- scatter diagrams
- control charts – including cumulative sum charts (CUSUMs).

Control charts are the most widely used of the statistical process control methodologies in the health care setting currently. They involve plotting the change in a measure (usually the outcome of a process) over time against predefined targets, and upper and lower control limits, to assess when the process is or isn't in control. Common or special causes of variation in the process can then be identified and remedied. They offer some promise in this area and have been used in both clinical (such as infection surveillance) and managerial (such as patient flow measurement) contexts.

Credentiailling

Credentiailling refers to the formal process used to verify the qualifications, experience, and professional standing of doctors for the purpose of evaluating their competence, performance and professional suitability to provide safe, high quality health care services for patients. The aim of credentiailling is to enable health care organisations to be confident that health care professionals' performance is maintained. All health care organisations (organisational governance responsibilities) and group private practice settings are subject to a credentiailling process. An external party, such as a medical board, may undertake the collection of evidence of credentials and confirmation of their validity on behalf of an organisation or professional college, society, or association, provided the organisation is satisfied that the external party's approach is rigorous and complete (ACSQHC 2004).

Peer review meetings – a process

Peer review meetings are a professional development initiative in which a clinician's professional performance is reviewed and evaluated by peers of the relevant profession. Peer review is an important part of the quality improvement cycle. The aim of these meetings is to improve the treatment of patients and maintain high standards of performance. A peer review meeting should be driven by guidelines regarding the form, content and documentation of discussions. According to *The NSW Clinician's Toolkit – For Improving Patient Care*, peer review meetings should be held at least four times a year with at least three participants in each meeting. The *NSW Clinician's Toolkit* (see '**Resources**' of this section) includes a template on which to base peer review meetings which includes the discussion of adverse events, audits, indicator sets and system issues (NSW Health Department November 2001).

Performance appraisal

Performance appraisal involves the ongoing review of the performance and development of an individual clinician. The key feature of the performance appraisal process is the exchange of regular verbal and written feedback about performance between the clinician and their supervisor or manager. This process allows the identification of professional development opportunities, unsatisfactory performance, and opportunities to improve performance through collaborative goal-setting. Performance appraisals can occur at regular intervals (for example, six-monthly, annually). There is no predetermined formula for how to conduct performance appraisals, however a number of instruments are available to conduct a performance appraisal (Evans, Elwyn & Edwards 2004, Archer, Norcini, Davies 2005). The performance priorities included in this review process will vary, depending on the performance priorities of the health care environment.

Performance indicators

Indicators are a metric or measure that screens for the occurrence of a particular medical event (ACHS 2002). Indicator sets are used as tools to assist in assessing whether a standard of performance in patient care is being met. As a rate-based measure, indicator sets do not provide definitive answers, but are designed to indicate

potential problems in organisational or clinical performance that may need to be addressed by highlighting statistical outliers or variations within data results (Campbell et al 2002). Indicator sets are used to assess, compare, and determine the potential to improve care (Howley & Gibberd 2003).

Numerous categories of performance indicators are available against which to assess organisational and clinician performance, including clinical indicators and patient safety indicators. Also available are an extensive number of specialist indicators specific to particular areas of health care (such as internal medicine indicators, obstetric indicators and surgical indicators among many others). Given the innumerable choice of indicators available to organisations, the ensuing section will focus on choosing the appropriate indicators to assess performance while some links to indicator sets are provided in **'Resources'** in this section.

Choosing indicators

As mentioned above, many indicator sets are available. However, they are highly variable, and the selection of the most appropriate clinical indicators against which to assess clinical performance requires careful consideration. The selection of indicator sets should be determined based on whether they possess the following characteristics:

- **Robust** – A robust indicator is one that is reliable, field-tested, and able to be stratified for risk and derived from an intervention known to be effective.
- **Useful** – A useful indicator is one that is clinically relevant, suggests system-wide performance, displays a high practical benefit to cost ratio, has the potential to be used in an intervention study to test its effectiveness as an indicator, and is applicable in the Australian health care context.
- **Understandable** – An understandable indicator is a clearly defined event or outcome to be tracked and is readily identified by its frequency, laboratory or clinical diagnosis.
- **Accessible** – An accessible indicator is readily available. It is representative; it was drawn from the population of interest.
- **Representative** – Sample population reflects the population of interest.
- **Ethical** – To be ethical, the collection of an indicator must guard the rights of the individual to confidentiality, freedom of choice in supplying data, and informed consent (Ben-Tovim & Elzinga 2002).

It is essential that the indicators used are meaningful, scientifically sound, interpretable, and can be generalised. To achieve this, indicators as with all quality measures, must be designed and implemented with scientific rigour. Before selecting indicators, consideration is also needed about how the information collected will be used, as not only is the collection process resource intensive, but the generation of actions and the review and implementation of these actions needs further resources.

The development and testing of indicators

An organisation, practice group or health care team intending to develop indicators should have a thorough understanding of their strengths and limitations. Careful consideration is required before deciding to use and develop indicators.

Rubin, Pronovost & Diette (2001) discuss the steps required in developing and implementing quality indicators. They describe this process in seven steps:

1. Define the audience and purpose of measurement.
2. Choose the clinical area to evaluate.
3. Organise the assessment team.

4. Select aspect of care or process criteria to be measured.
5. Write measure specifications.
6. Perform preliminary tests.
7. Write scoring, analytical specifications.

Step 4 includes determining if there are existing measures that are reliable and valid – if an organisation lacks the extensive resources required for the development and testing of the indicators, it may be worthwhile to choose existing measures and data collection methods that have been demonstrated to be valid and reliable.

3.6 Research into performance measurement

While no studies specifically assess the impact of an organisation or clinician's performance measurement on health outcomes, there is evidence that adherence to evidence-based recommendations has a positive impact on health outcomes (Weingarten et al 1998). Studies have also shown that the dissemination of clinical practice guidelines using a combination of peer review and management support have been effective in influencing clinician behaviour (Wensing, van der Weijden & Grol 1998, McKinlay et al 2004, Eccles & Grimshaw 2004), and the use of clinical practice guidelines has also been associated with an improved process of care (Grimshaw & Russell 1993, Shiffman et al 1999). These findings have supported the use of clinical practice guidelines as a standard against which to assess performance (Worrall, Chaulk, Freake 1997). Clinical audits and clinician feedback have also been found to produce small to moderate improvements in clinical practice (Del Mar 2004).

Individual clinician clinical performance measurement

Clinician clinical performance in health care is a complex concept influenced by numerous cognitive, social, professional, and system variables. Reflecting this complexity is the fact that there is no single definition of clinical performance agreed upon by health care professionals nationally or internationally. A number of cognitive attributes including communication skills, teamwork and problem-solving have been identified and supported by research as prerequisites for effective clinical performance (Fallowfield et al 2003, Yedidia et al 2003, Razavi et al 2003, Ong 1995). These attributes are identified as process measures. That is, they help the achievement of good clinical performance.

Conclusion

This section of the Toolkit provides the background information for health care organisations and professionals wanting to undertake measurement of key influences on patient safety.

The literature review revealed there is limited research and evidence available regarding the measurement of patient safety and the impact it has on patient safety outcomes. As with all literature reviews, the information available at the time of writing this document may change. For those seeking the most up to date knowledge in the field of patient safety, a further review of the literature may provide information on research that was not available at the time this review was conducted.

Resources

General patient safety resources

Australian patient safety resources

Australian Commission on Safety and Quality in Health Care

Website: <http://www.safetyandquality.gov.au>

Email: mail@safetyandquality.gov.au

Phone: (02) 9263 3633

10 tips for safer health care

<http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/10tips-languages>

National patient safety education framework

<http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/former-pubs-archive-annrept2005>

Charting the safety and quality of health care in Australia, July 2004

<http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/charting>

Setting the human factor standards for health care: Do lessons from aviation apply?

<http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/former-pubs-archive-annrept2004>

Explanatory notes on patient safety management systems

<http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/patient-safety-management>

Australian Patient Safety Foundation

Website: <http://www.apsf.net.au/>

Email: research@apsf.net.au

Address: GPO Box 400, Adelaide SA 5001

Phone: (08) 8222 5544

Australian Resource Centre for Healthcare Improvement (ARCHI)

Website: <http://www.archi.net.au/>

Email: admin@archi.net.au

Address: PO Box 896, The Junction NSW 2291

Phone: (02) 4924 0900

State health departments and resources

Department of Health and Ageing – Australian Government

Website: <http://www.health.gov.au>

Address: GPO Box 9848, Canberra ACT 2601

Phone: 1800 020 103

Australian Capital Territory – Quality and Safety

Website: <http://www.health.act.gov.au/c/health?a=da&did=10084733>

Email: HealthACT@act.gov.au

Address: GPO Box 825, Canberra City ACT 2601

Phone: 13 2281

NSW Health

Website: <http://www.health.nsw.gov.au>

Email: nswhealth@doh.health.nsw.gov.au

Address: Locked Mail Bag 961, North Sydney NSW 2059

Phone: (02) 9391 9000

Northern Territory Department of Health and Community Services

Website: <http://www.health.nt.gov.au/>

Address: PO Box 40596, Casuarina NT 0811

Phone: (08) 8999 2400

Queensland Health's Quality and Safety Program

Website: <http://www.health.qld.gov.au/quality/default.asp>

Address: GPO Box 48 Brisbane, Queensland 4001

Phone: (07) 3234 0186

South Australian Department of Health – Safety and Quality

Website: <http://www.safetyandquality.sa.gov.au>

Phone: (08) 8226 6304

Tasmanian Department of Health and Human Services

Website: <http://www.dhhs.tas.gov.au/index.php>

Phone: 1300 135 513

Victorian Department of Human Services – Quality and Safety Branch

Website: <http://www.dhs.vic.gov.au/rrhacs/qualitybranch.htm>

Phone: (03) 9616 7201

Victorian Quality Council

Victorian Quality Council Secretariat

Website: <http://www.health.vic.gov.au/qualitycouncil>

Email: vqc@dhs.vic.gov.au

Phone: 1300 135 427

Safety and quality framework evaluation report <http://www.health.vic.gov.au/qualitycouncil/secret.htm>

Western Australia Department of Health – Office of Safety and Quality in Health Care

Website: <http://www.health.wa.gov.au/safetyandquality/about/index.cfm>

Email: Safetyandquality@health.wa.gov.au

Phone: (08) 9222 4080

International patient safety resources

Agency for Health Care Research and Quality (USA)

Website: <http://www.ahrq.gov>
Address: 540 Gaither Road, Suite 2000, Rockville, MD 20850.
Phone: +1 301 427 1364

Health Research and Educational Research Trust (USA)

Pathways for medication safety

Website: www.medpathways.info
Email: medpathways@aaha.org
Address: One North Franklin, Suite 3000 Chicago, Illinois 60606
Phone: +1 312 422 2600

Institute of Medicine (USA) – Shaping the future for health

Website: <http://www.iom.edu/>
Email: iomwww@nas.edu
Address: 500 Fifth Street NW, Washington DC 20001
Phone: +1 202 334 2352

Report brief. Crossing the quality chasm: a new health system for the 21st Century

<http://www.iom.edu/Object.File/Master/27/184/0.pdf>

Report brief. To err is human: building a safer health system

<http://www.iom.edu/Object.File/Master/4/117/0.pdf>

Institute for Healthcare Improvement (USA)

Requires login/registration to access tools free of charge.
Website: <http://www.ihl.org/IHI>
Email: access via website
Address: 20 University Road, 7th Floor Cambridge, MA 02138 USA
Phone: +1 617 301 4800

NHS – National Patient Safety Agency (UK)

Website: <http://www.npsa.nhs.uk/>
Email: enquiries@npsa.nhs.uk
Address: 4-8 Maple Street, London W1T 5HD
Phone: +44 20 7927 9500

Seven steps to patient safety

<http://www.npsa.nhs.uk/health/resources/7steps>

NHS – National Institute for Clinical Excellence

Website: <http://www.nice.org.uk/>
Address: MidCity Place, 71 High Holborn, London WC1V 6NA
Phone: +44 20 7067 5800

Veterans Administration (USA) – National Center for Patient Safety

Website: <http://www.patientsafety.gov/index.html>

Email: NCPS@med.va.gov

Address: PO Box 486, Ann Arbor, MI 48106-0486

Phone: +1 734 930 5890

Medication safety resources

Australian resources

Australian Commission on Safety and Quality in Health Care – National Medication Breakthrough Collaborative

Website: <http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/former-pubs-archive-breakthrough>

NSW Therapeutic Advisory Group

Website: <http://www.clininfo.health.nsw.gov.au/nswtag/>

Queensland Pharmaceutical Advisory Services

Website: <http://www.health.qld.gov.au/phs/pas/>

Address: GPO Box 48, Brisbane Qld 4001

Phone: (07) 3234 1143

Victorian Medicines Advisory Committee

Website: <http://www.health.vic.gov.au/vmac/>

Address: Department of Human Services, GPO Box 4057, Melbourne VIC 3000.

Phone: (03) 9616 7786

International resources

Academy of Managed Care Pharmacy (USA)

Website: <http://www.amcp.org>

Address: 100 North Pitt Street, Suite 400, Alexandria, VA 22314

Phone: +1 800 827 2627

California Health Care Foundation (USA)

Website: <http://www.chcf.org>

Address: 476 Ninth Street Oakland, CA 94607

Phone: +1 510 238 1040

Health Research and Educational Research Trust (USA) – Pathways for Medication Safety

Website: www.medpathways.info

Address: One North Franklin, Suite 3000 Chicago, Illinois 60606

Email: medpathways@aaha.org

Phone: +1 312 422 2600

Institute for Safe Medication Practices (USA)

Website: <http://www.ismp.org/>

Email: ismpinfo@ismp.org

Address: 1800 Byberry Rd., Suite 810, Huntingdon Valley, Pa. 19006

Phone: +1 215 947 7797

Trigger tools – further references

Hartis CE, Gum MO & Lederer JW Jr. **Use of specific indicators to detect warfarin-related adverse events.** American Journal of Health-System Pharmacy 15 August 2005;62(16):1683–1688.

Morimoto, T K Gandhi, A C Seger, T C Hsieh & D W Bates. **Adverse drug events and medication errors: detection and classification methods.** Quality and Safety in Health Care 1 August 2004;13(4):306–314.

Resar RK, Rozich JD, Classen D. Methodology and rationale for the measurement of harm with trigger tools. Quality and Safety in Health Care 2003;12(90002):39ii–45.

Patient safety incident resources

Incident management

NSW Health

Incident management

<http://www.health.nsw.gov.au/quality/iims/eval.html>

Victorian DHS

Incident reporting departmental instruction

<https://fac.dhs.vic.gov.au/documents/repsys.pdf>

Clinical risk management – incident reporting

<https://www.fac.dhs.vic.gov.au/home.aspx?TabID=content&contentID=1030>

WA Health

Clinical risk management guidelines for the Western Australian health system

http://www.health.wa.gov.au/safetyandquality/publications/docs/50621_Risk%20Management%20Final.pdf

Incident reporting management policy

[http://www.health.wa.gov.au/safetyandquality/docs/Incident_Reporting-\(Final\).pdf](http://www.health.wa.gov.au/safetyandquality/docs/Incident_Reporting-(Final).pdf)

Sentinel event reporting

Australian Commission on Safety and Quality in Health Care

Sentinel events fact sheet:

<http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/former-pubs-archive-factsheets>

ACT <http://www.health.act.gov.au/c/health?a=da&did=1000000&pid=1141002432>

NSW http://www.health.nsw.gov.au/policies/pd/2005/pdf/PD2005_604.pdf

NT Contact the Quality Improvement Unit (08) 8999 2406.

QLD http://www.health.qld.gov.au/health_sys_review/julyreport/app11.pdf

SA <http://www.safetyandquality.sa.gov.au/Default.aspx?tabid=66>

VIC <http://www.health.vic.gov.au/clinrisk/sentinel/ser.htm>

WA <http://www.health.wa.gov.au/safetyandquality/sentinel/index.cfm#reportable>

Failure modes effects analysis

Institute for Healthcare Improvement

<http://www.ihl.org/ihl/workspace/tools/fmea>

Reference

DeRosier J, Stalhandske E, Bagian JP & Nudell T. Using health care failure mode and effect analysis: the VA National Center for Patient Safety's prospective risk analysis system. *Joint Commission Journal on Quality Improvement* 2002;28(5):248-67.

Probabilistic risk assessment

References:

Marx DA & Stonim AD. Assessing patient safety risk before the injury occurs: an introduction to sociotechnical probabilistic risk modelling in health care. *Quality and Safety in Health Care* 2003;12 Suppl 2:ii33-8.

Wreathall J & Nemeth C. Assessing risk: the role of probabilistic risk assessment (PRA) in patient safety improvement. *Quality and Safety in Health Care* 2004;13(3):206-12.

Risk management

WA Department of Health

Risk assessment matrix

Clinical risk management guidelines for the Western Australian health system available by contacting **WA Department of Health** or :

http://www.health.wa.gov.au/safetyandquality/publications/docs/50621_Risk%20Management%20Final.pdf

Queensland Department of Industrial Relations

Workplace health and safety guide

<http://www.dir.qld.gov.au/workplace/law/codes/manualtasks/riskman/index.htm>

Address: PO Box 69, Brisbane Qld 4001

Phone: 1300 369 915

Root cause analysis

Veterans Administration, USA

Veterans Administration provides a guide on RCA available online:

<http://www.patientsafety.gov/rca.html>

National Health Service, UK

NHS has a number of tools available online to assist with RCA:

http://www.npsa.nhs.uk/health/resources/root_cause_analysis/conditions

Institute for Healthcare Improvement

<http://www.ihl.org/IHI/Topics/PatientSafety/>

Severity assessment code

NSW Health

http://www.health.nsw.gov.au/policies/pd/2005/pdf/PD2005_608.pdf

Systems analysis of clinical incidents: the London protocol

Clinical Safety Research Unit, Imperial College London

Website: <http://www.csru.org.uk/contact.htm>

Email: c.vincent@imperial.ac.uk

Address: Department of Surgical Oncology and Technology
10th Floor QEQM Building, St Mary's Hospital,
Praed Street, London W2 1NY

References:

Vincent C, Moorthy K, Sarker SK, Chang A & Darzi AW. Systems approaches to surgical quality and safety: from concept to measurement. *Annals of Surgery* 2004;239(4):475–82.

Vincent CA. Analysis of clinical incidents: a window on the system not a search for root causes. *Quality and Safety in Health Care* 2004;13(4):242–3.

Further reading

Clinical incident reporting

Beckmann U, Baldwin I, Hart GK & Runciman WB. The Australian incident monitoring study in intensive care: AIMS-ICU. An analysis of the first year of reporting. *Anaesthesia and Intensive Care* 1996;24(3):320–9.

Beckmann U & Runciman WB. The role of incident reporting in continuous quality improvement in the intensive care setting. *Anaesthesia and Intensive Care* 1996;24(3):311–3.

Beckmann U, Bohringer C, Carless R, et al. Evaluation of two methods for quality improvement in intensive care: facilitated incident monitoring and retrospective medical chart review. *Critical Care Medicine* 2003;31(4):1006–11.

Spigelman AD & Swan J. Review of the Australian incident monitoring system. *ANZ Journal of Surgery* 2005;75:657–61.

Webb RK, Currie M, Morgan CA, Williamson JA, Mackay P, Russell WJ, et al 1993. The Australian incident monitoring study: an analysis of 2000 incident reports. *Anaesthesia and intensive care* 21(5):520–8.

Clinical performance measurement resources

General information

NSW Health

The clinician's toolkit for improving patient care

http://www.health.nsw.gov.au/health-public-affairs/publications/quality/clinicians_toolkit.pdf

Accreditation

Australian Commission on Safety and Quality in Health Care

Standards setting and accreditation literature review and report

<http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/former-pubs-archive-standardssetting>

Public hospitals – Queensland Health

<http://www.health.qld.gov.au/quality/>

Public hospital accreditation in Victoria

<http://www.health.vic.gov.au/accreditation/>

Accreditation agencies

Australian Council on Healthcare Standards

Website: www.achs.org.au

Address: 5 Macarthur Street, Ultimo NSW 2007

Phone: (02) 92819955

Australian General Practitioner (AGPAL)

Website: <http://www.qip.com.au/>

Email: info@qip.com.au

Address: PO Box 2058, Milton Qld 4064

Phone: 1300 362 111

National Association of Testing Authorities (NATA)

Website: <http://www.nata.asn.au/>

Address: 7 Leeds Street, Rhodes NSW 2138

Phone: (02) 9736 8222

Quality Improvement Council (QIC)

Website: <http://www.qic.org.au/>

Email: qic@qic.org.au

Address: 5th Floor, Health Sciences 2, La Trobe University, VIC 3086

Phone: (03) 9479 5630

Standards Australia

<http://www.standards.com.au/>
Address: GPO Box 5420, Sydney NSW 2001
Phone: 1300 65 46 46
Australian Organisation for Quality Inc.
(QLD) <http://www.aoq.org.au/>
Phone: (07) 3849 6460
(NSW) <http://www.aoqns.com.au/>

Benchmarking

Australian Commission on Safety and Quality in Health Care

<http://www.safetyandquality.gov.au/>

The Australian Council on Health Care Standards (ACHS)

<http://www.achs.org.au/>

National Association of Testing Authorities (NATA)

<http://www.nata.asn.au/>

Quality Improvement Council (QIC)

<http://www.qic.org.au/>

Australian General Practice Accreditation Limited (AGPAL)

<http://www.qip.com.au/>

Royal Australasian College of Surgeons – Standards

<http://www.surgeons.org/Content/NavigationMenu/FellowshipandStandards/ProfessionalStandards/default.htm>
Address: Spring Street, Melbourne VIC 3000
Phone: (03) 9249 1200

Clinical audit resources

Auditmaker

Website: <http://www.acebcp.org.au/audit.htm>
Address: Room 6B320, Level 6 FMC, Flinders Drive, Bedford Park, SA 5042
Phone: (08) 8204 6061
RAND Health
Websites: <http://www.rand.org/health/ICICE/audit.html>
<http://www.rand.org/health/ICICE/tools.html>
Address: 1776 Main Street, Santa Monica, CA 90407-2138
Phone: +1 310 393-0411, x7239

Moving on Audits™

Website: http://www.movingonaudits.com.au/in_a_nutshell.htm
Phone: 1300 760 209

NHS – Principles for best-practice in clinical audit (NICE) (UK)

<http://www.nelh.nhs.uk/BestPracticeClinicalAudit.pdf>

Practical clinical audit handbook

http://www.cgsupport.nhs.uk/Resources/Clinical_Audit/1@Introduction_and_Contents.asp

Address: MidCity Place, 71 High Holborn, London WC1V 6NA

Phone: +44 20 7067 5800

Appraisal of guidelines for research and evaluation (AGREE) (UK)

<http://www.agreecollaboration.org/pdf/agreeinstrumentfinal.pdf>

<http://www.agreecollaboration.org>

Further reading

Ursprung R, Gray JE, Edwards WH, Horbar JD, Nickerson J, Plsek P, Shiono PH, Suresh GK & Goldmann DA. **Real time patient safety audits: improving safety every day.** *Quality and Safety in Health Care* 1 August 2005;14(4):284–9.

Control charts

Online references

<http://www.isixsigma.com/library/content/c030115a.asp>

<http://www.ganesh.org/spc/>

Further reading

Montgomery, D 2001. *Introduction to statistical quality control* (4th Ed). John Wiley and Sons.

Credentiailling

Australian Commission on Safety and Quality in Health Care

Standard for credentiailling and defining the scope of clinical practice <http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/former-pubs-archive-credentiailling>

Direct observation and performance assessment

Further reading

Beach MC, Roter D, Larson S, Levinson W, Ford DE & Frankel R. What do physicians tell patients about themselves? A qualitative analysis of physician self-disclosure.[see comment]. *Journal of General Internal Medicine* 2004;19(9):911–6.

Elwyn G, Edwards A, Wensing M, Hood K, Atwell C & Grol R 2003. Shared decision making: developing the OPTION scale for measuring patient involvement. *Quality and Safety in Health Care* 2003;12(2):93–9.

Elwyn G, Hutchings H, Edwards A, et al. The OPTION scale: measuring the extent that clinicians involve patients in decision-making tasks. *Health Expectations* 2005;8(1):34–42.

Ong LM, Visser MR, Kruijver IP, et al. The Roter interaction analysis system (RIAS) in oncological consultations: psychometric properties. *Psycho-Oncology* 1998;7(5):387–401.

Sugrue M, Seger M, Kerridge R, Sloane D & Deane S. A prospective study of the performance of the trauma team leader. *Journal of Trauma-Injury Infection and Critical Care* 1995;38(1):79–82.

Indicators

Australian Council on Healthcare Standards

www.achs.org.au

Quality and outcome indicators for acute health care services

National Hospital Outcomes Program

<http://www.archi.net.au/>

Publishing service address: GPO Box 84, Canberra ACT 2601

Phone: 132 447

National reports of performance indicators

<http://www.aihw.gov.au/publications/index.cfm/title/10085>

<http://www.health.gov.au/internet/wcms/publishing.nsf/Content/Home>

AIHW address: GPO Box 570, Canberra ACT 2601

Phone: 1300 889 873

Fax: (02) 6293 8333

National Stroke Foundation

Performance indicators for acute stroke

<http://www.strokesafe.com.au/pages/image.aspx?assetId=RDM38251.5060930556>

Address: Level 8, 99 Queen Street, Melbourne VIC 3000

Phone: (03) 9670 1000

AHRQ quality indicators (USA)

<http://www.qualityindicators.ahrq.gov/>

Assessing Care Of Vulnerable Elders (ACOVE)

<http://www.rand.org/publications/RB/RB4545-1/>

Contact RAND

Articles on using and developing performance indicators

McLoughlin V, Leatherman S, Fletcher M & Owen JW. Improving performance using indicators. Recent experiences in the United States, the United Kingdom, and Australia. *International Journal for Quality in Health Care* 2001;13(6):455–62.

Rubin HR, Pronovost P & Diette GB. The advantages and disadvantages of process-based measures of health care quality. *International Journal for Quality in Health Care* 2001;13(6):469–74.

Rubin HR, Pronovost P & Diette GB. From a process of care to a measure: the development and testing of a quality indicator. *International Journal for Quality in Health Care* 2001;13(6):489–96.

Resources for general practitioners

NSW Health

<http://www.health.nsw.gov.au/quality/crmgp/index.html>

HPSS guidance on analysis of risk/risk rating matrix (UK)

http://www.dhsspsni.gov.uk/guidance_on_analysis.pdf

Royal Australian College of General Practitioners

Website: <http://www.racgp.org.au/>

Email: racgp@racgp.org.au

Address: 1 Palmerston Crescent, South Melbourne VIC 3205

Phone: 1800 331 626

Consumer resources

General resources

Australian Commission on Safety and Quality in Health Care

10 tips for safer health care

<http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/10tips-languages>

Adverse Medicine Events Line

Website: <http://www.mater.org.au/ame/>

Phone: 1300 134 237

Institute for Safe Medication Practices (USA)

Recommendations and safety tips – how to prevent medication errors

http://www.ismp.org/PDF/Patient_Broc.pdf

Email: ismpinfo@ismp.org

Address: 1800 Byberry Road, Suite 810 Huntingdon Valley, Pa. 19006

Phone: +1 215 947 7797

Agency for Research Health care and Quality (USA)

Patient fact sheet – 20 tips to help prevent medical errors

<http://www.ahrq.gov/consumer/20tips.htm>

Five steps to safer health care

<http://www.ahrq.gov/consumer/5steps.htm>

Address: 540 Gaither Road, Suite 2000, Rockville, MD 20850.

Consumer satisfaction

ACT Health

ACT consumer feedback standards

<http://www.health.act.gov.au/c/health?a=da&did=10084733>

Victorian DHS

Victoria, ACT and Queensland patient satisfaction survey

Victorian Patient Satisfaction Monitor

<http://www.health.vic.gov.au/patsat/>

<http://www.health.vic.gov.au/patsat/patquest.pdf>

South Australia

<http://www.dh.sa.gov.au/pehs/>

Australian Institute for Primary Care

Primary health care consumer opinion survey

<http://www.latrobe.edu.au/aipc/projects.htm#CQHCS>

Phone: (03) 9479 3700

Royal Australian College of General Practitioners

The practice accreditation and improvement survey (PAIS)

<http://www.racgp.org.au/>

Consumer Complaints

Australian Commission on Safety and Quality in Health Care

Better practice guidelines on complaints management for health care services

<http://www.safetyandquality.gov.au/internet/safety/publishing.nsf/Content/complaints-management-handbook>

Department of Health and Ageing

Aged care services complaints handling kit

<http://www.health.gov.au/internet/wcms/publishing.nsf/Content/ageing-rescare-rescprov-compkit.htm>

Can be ordered from the **Aged Care Information Line 1800 500 853**.

ACT Health

Consumer feedback standards

<http://www.health.act.gov.au/c/health?a=dlpol&policy=1151122359&did=10107160&sid==>

Phone: 13 22 81

NSW Health

Complaints handling procedures and the quality agenda in the NSW Health system

http://www.health.nsw.gov.au/pubs/c/pdf/comps_handling.pdf

Queensland Health

Complaints coordinators handbook

<http://www.health.qld.gov.au/complaints/documents/CCHS2ComplaintsMgtProcess.pdf>

WA Department of Health, Office of Safety and Quality in Health Care

Complaint management resource toolkit (part of the Health complaint management policy)

Phone: (08) 9222 4080.

Consumer complaint bodies:

ACT <http://www.healthcomplaints.act.gov.au/c/hcc>

Address: PO Box 977, Civic Square ACT 2608

Phone: (02) 6205 2222

NSW <http://www.hccc.nsw.gov.au/>

Address: Locked Mail Bag 18, Strawberry Hills NSW 2012

Phone: (02) 9219 7444

NT http://www.nt.gov.au/omb_hcsc/hcsc/index.htm

Address: GPO Box 1344, Darwin NT 0801

Phone: (08) 8999 1969

QLD <http://www.hrc.qld.gov.au/>

Address: GPO Box 3089, Brisbane, QLD 4001

Phone: (07) 3234 0272

SA <http://www.ombudsman.sa.gov.au/>

Address: Level 5 East Wing, 50 Grenfell St., Adelaide SA 5000

Phone: (08) 8226 8699

TAS www.healthcomplaints.tas.gov.au

Address: GPO Box 960, Hobart TAS 7001

Phone: 1300 766 725

VIC <http://www.health.vic.gov.au/hsc/>

Address: 30th Floor, 570 Bourke Street, Melbourne VIC 3000

Phone: (03) 8601 5200

WA <http://www.healthreview.wa.gov.au/>

Address: GPO Box B61, Perth WA 6838

Phone: (08) 9323 0600

Professional bodies

Medical

Australasian Faculty of Occupational Medicine

Website: <http://afom.racp.edu.au/>

Address: 145 Macquarie Street, Sydney NSW 2000

Phone: (02) 8247 6219

Australasian Faculty of Rehabilitation Medicine

Website: <http://afrm.racp.edu.au/>

Address: 145 Macquarie Street, Sydney NSW 2000

Phone: (02) 8247 6216

Australian College of Emergency Medicine

Website: <http://www.acem.org.au/>

Address: 34 Jeffcott Street, West Melbourne VIC 3003

Phone: (03) 9320 0444

Australian College of Rural and Remote Medicine

Website: <http://www.acrrm.org.au/>

Address: GPO Box 2507 Brisbane QLD 4001

Phone: (07) 3105 8200

Australasian College of Dermatologists

Website: <http://www.dermcoll.asn.au/>
Address: PO Box 2065, Boronia Park NSW 2111
Phone: (02) 9879 6177

Australian and New Zealand College of Anaesthetists

Website: <http://www.anzca.edu.au/>
Address: ANZCA House, 630 St Kilda Road, Melbourne VIC 3004
Phone: (03) 9510 6299

Royal Australasian College of Physicians

Website: <http://www.racp.edu.au/>
Address: 145 Macquarie Street, Sydney NSW 2000
Phone: (02) 9256 5444

Royal Australasian College of Radiologists

Website: <http://www.ranzcr.edu.au/index.cfm>
Address: Level 9, 51 Druitt Street Sydney NSW 2000
Phone: (02) 9268 9777

Royal Australian College of General Practitioners

Website: <http://www.racgp.org.au/>
Address: 1 Palmerston Cr, South Melbourne VIC 3205
Phone: (03) 8699 0414

Royal Australian College of Medical Administrators

Website: <http://www.racma.org.au/>
Address: 35 Drummond Street, Carlton VIC 3053
Phone: (03) 9663 5347

Royal Australian College of Ophthalmologists

Website: <http://www.ranzco.edu/>
Address: 94–98 Chalmers Street, Surry Hills NSW 2010
Phone: (02) 9690 1001

Royal Australian and New Zealand College of Obstetrics and Gynaecology

Website: <http://www.ranzcog.edu.au/>
Address: 254–260 Albert St, East Melbourne VIC 3002
Phone: (03) 9417 1699

Royal Australasian College of Surgeons

Website: <http://www.racs.edu.au/>
Address: Spring Street, Melbourne VIC 3000
Phone: (03) 9249 1200

Royal Australian and New Zealand College of Psychiatrists

Website : <http://www.ranzcp.org/>
Address : 309 La Trobe Street, Melbourne VIC 3000
Phone: (03) 9640 0646

Royal College of Pathologists of Australasia

Website: <http://www.rcpa.edu.au/>
Address: 207 Albion Street, Surry Hills NSW 2010
Phone: (02) 8356 5858

Nursing

Royal College of Nursing Australia

Website: <http://www.rcna.org.au/>
Address: PO Box 219, Deakin West ACT 2600
Phone: 1800 061 660

Australian Nursing Federation

Website: <http://www.anf.org.au/>
Address: Unit 3, 28 Eyre Street, Kingston ACT 2604 Australia
Phone: (02) 6232 6533

Joanna Briggs Institute for Evidence Based Nursing

Website: <http://www.joannabriggs.edu.au/about/home.php>
Address: Level 4, Margaret Graham Building, Royal Adelaide Hospital
North Terrace, Adelaide SA 5000
Phone: (08) 8303 4880

The College of Nursing

Website: <http://www.nursing.aust.edu.au/>
Address: Locked Bag 3030, Burwood NSW 1805
Phone: (02) 9745 7500

Australian Practice Nurses Association

Website: <http://www.apna.asn.au/>
Address: 1 Palmerston Cr, South Melbourne VIC 3205
Phone: (03) 6282 3820

Pharmacy

Pharmaceutical Management Agency (PHARMAC)

Website: <http://www.pharmac.govt.nz/>
Address: PO Box 10-254, Wellington, New Zealand
Phone: +64 4 460 4990

Pharmacy Guild of Australia

Website: <http://www.guild.org.au/>
Address: PO BOX 7036, Canberra BC ACT 2610
Phone: (02) 6270 1888

Society of Hospital Pharmacists of Australia (SHPA)

Website: <http://www.shpa.org.au/>
Address: PO Box 1774, Collingwood VIC 3066
Phone: (03) 9486 0177

Other

Australian Association of Practice Managers

Website: <http://www.aapm.org.au/>
Address: PO Box 2477, Fortitude Valley BC Qld 4006
Phone: 1800 196 000

Australian College of Health Service Executives (ACHSE)

Website: <http://www.gpatlas.org.au/subsector.php?id=108272>
Address: PO Box 341, North Ryde NSW 1670
Phone: (02) 9878 5088

Australian Physiotherapy Association

Website: <http://apa.advsol.com.au/>
Address: Level 3, 201 Fitzroy Street, St Kilda Victoria 3182
Phone: (03) 9534 9400

Australian Association of Social Workers

Website: <http://www.aasw.asn.au/>
Address: PO Box 4956, Kingston ACT 2604
Phone: (02) 6273 0199

Australian Association of Occupational Therapists

Website: <http://www.ausot.com.au/>
Address: 6/340 Gore St, Fitzroy, VIC 3065
Phone: (03) 9415 2900

Australian Institute of Radiography

Website: <http://www.a-i-r.com.au/>
Address: PO Box 1169, Collingwood VIC 3066
Phone: (03) 9419 3336

Australian Psychological Society

Website: <http://www.psychology.org.au/>
Address: PO Box 38, Flinders Lane Post Office, Melbourne VIC 8009
Phone: 1800 333 497

Appendix 1: Literature review

Literature search methodology

Search questions

A number of search questions were developed to direct the literature search around the measurement of patient safety. The questions were developed for each of organisational capacity, patient safety incidents and clinical performance. These questions are summarised below.

1. Organisational capacity

- a. What tools are available to measure organisational capacity in an acute, subacute, community, or residential health care facility aimed at improving patient safety?
- b. Does the use of this/these measurement tool(s) of organisational capacity improve patient safety outcomes?

2. Patient safety incidents

- a. What tools are available to measure patient safety incidents in an acute, subacute, community, or residential health care facility?
- b. Does the use of this/these measurement tool(s) of patient safety incidents improve patient safety outcomes?

3. Clinical performance

- a. What tools are available to measure clinical performance in an acute, subacute, community, or residential health care facility aimed at improving patient safety?
- b. Does the use of this/these measurement tool(s) of clinical performance improve patient safety outcomes?

Search strategy

A comprehensive search for patient safety tools, and better health outcomes associated with the use of these tools was conducted using Medline (1966-current) and CINAHL all years. Keywords and combinations of these keywords categories were combined for the search. A list of the keywords used is provided in the Table A. Article inclusion primarily focused on clinical studies. Literature was also located by searching the reference lists of the relevant articles, and by contacting authors of relevant studies, and enquiring as to the availability of further research or information.

Further to this, websites of all relevant national and international organisations specialising in patient safety in health care were searched for patient safety tools and further information on patient safety (see Table 2). A web search using the Google search engine was also conducted to search for tools referenced within the literature using the following terms:

- Patient safety tools.
- Patient safety toolkit.
- Measuring patient safety.
- Patient safety.

The literature and web-based searches were conducted in April to May 2005, and identified publications through to January 2005. The authors acknowledge that as comprehensive as the search strategy may have been, some publications may have been missed.

Table 1: Keywords used for literature search

Using Medline database and CINAHL database Limited to English language	
<p>Patient safety</p> <ul style="list-style-type: none"> • Patient safety • Patient care • Safety • Safety management • Risk management • Quality assurance of health care • Quality of health care • Total quality management <p>Measurement</p> <ul style="list-style-type: none"> • Outcome and process assessment (health care) • Patient outcome assessment • Task performance and analysis • Evaluation studies • Epidemiology research design <p>Patient safety incidents/adverse events</p> <ul style="list-style-type: none"> • Adverse event • Sentinel event • Medical audit • Medical errors • Adverse drug reaction reporting systems • Iatrogenic disease • Medication errors • Incident reporting/monitoring • Incident/sentinel surveillance • Adverse event/patient safety incident screening 	<p>Tools</p> <ul style="list-style-type: none"> • Tool • Tool (title) • Reminder systems • Questionnaire • Survey • Checklists • Medication systems • Self-evaluation program <p>Organisational capacity</p> <ul style="list-style-type: none"> • Organizational capacity • Organisational capacity • Organizational culture • Clinical governance <p>Clinical performance</p> <ul style="list-style-type: none"> • Clinical performance • Clinical competence • Professional competence • Benchmarking • Peer review • Audit • Communication • Teamwork • Best-practice adherence • Technical competence • Non-technical competence • Organisational skills <p>Health care facilities</p> <ul style="list-style-type: none"> • Hospitals • Hospital departments • General practice • Family practice • Primary health care

Table 2: Websites searched

Websites searched for additional information used in Part B	
<p>Australia</p> <ul style="list-style-type: none"> • Australian Resource Centre for Health Care Innovations • Australian Council for Safety and Quality in Health Care • Australian Patient Safety Foundation • Australian Government Department of Health and Ageing • State- and Territory-based department of health websites • Victorian Quality Council • Office of Safety and Quality in Health Care, Western Australia • National Resource Centre for Consumer Participation in Health 	<p>British</p> <ul style="list-style-type: none"> • National Health Service • National Patient Safety Agency • National Institute of Clinical Excellence <p>USA</p> <ul style="list-style-type: none"> • Institute for Healthcare Improvement • Agency for Health Care Research and Quality • American Health Research Centre • Institute of Medicine • Veterans Administration, National Centre for Patient Safety • Joint Commission of Accreditation in Health Care

References

ACHS (Australian Council on Health Care Standards) June 2002. ACHS EQUiP – The EQUiP Guide.

ACSQHC (Australian Council for Safety and Quality in Health Care) July 2003. Patient safety: towards sustainable improvement. Canberra: Commonwealth of Australia.

(ACSQHC) Australian Council for Safety and Quality in Health Care July 2003. Standards setting and accreditation in health: consultation paper.

ACSQHC (Australian Council for Safety and Quality in Health Care) July 2004. Standard for credentialling and defining the scope of clinical practice. In: Commonwealth of Australia 2004 (ed) A national standard for credentialling and defining the scope of clinical practice of medical practitioners, for use in public and private hospitals. Canberra: ACSQHC.

ACSQHC (Australian Council for Safety and Quality in Health Care). Definitions of safety and quality in health care. Consultation draft ed 2005.

Antonow JA, Smith AB & Silver MP. Medication error reporting: a survey of nursing staff. *Journal of Nursing Care Quality* 2000;15(1):42–8.

Archer JC, Norcini J, Davies HA. Use of SPRAT for peer review of paediatricians in training. *BMJ* 2005;330(7502):1251–3.

Asra Warsi BA, Wang PS, LaValley MP, Avorn J & Solomon DH. Self-management education programs in chronic disease. *Archives of Internal Medicine* 2004;164:1641–9.

Auditor General of Victoria 2005. Managing patient safety in public hospitals. Melbourne: Victorian Department of Human Services.

Australian Council on Health Care Standards. ACHS News issue 12. Sydney: ACHS 2004.

- Barach P & Small SD. Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. *BMJ* 2000;320(7237):759–63.
- Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. *JAMA* 1995;274(1):29–34.
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- Berwick DM, James B & Coye MJ. Connections between quality measurement and improvement. *Medical Care* 2003;41(1 Suppl):I30–8.
- Bethell DL, Myers WA & Smith DG. Does patient-centered care pay off? *Joint Commission Journal on Quality Improvement* 2000;26(7):400–9.
- Bhasale A, Miller G, Reid S & Britt H. Analysing potential harm in Australian general practice: an incident-monitoring study. *Medical Journal of Australia* 1998;169:73–6.
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- Boxwala AA, Dierks M, Keenan M, et al. Organization and representation of patient safety data: current status and issues around generalizability and scalability. *Journal of the American Medical Informatics Association* 2004;11(6):468–78.
- Boyce NW, McNeil JJ, Graves D & Dunt D 1997. Quality and outcome indicators for acute health care services. National Hospital Outcomes Program. Canberra: Commonwealth Department of Health and Family Services.
- Boyce NW. Potential pitfalls of healthcare performance indicators. *Medical Journal of Australia* 2002;177(5):229–30.
- Boyer MM. Root cause analysis in perinatal care: health care professionals creating safer health care systems. *Journal of Perinatal & Neonatal Nursing* 2001;15(1):40–54.
- Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study I. *New England Journal of Medicine* 1991a;324(6):370–6.
- Brennan TA, Leape LL. Adverse events, negligence in hospitalized patients: results from the Harvard Medical Practice Study. *Perspectives in Healthcare Risk Management* 1991b;11(2):2–8.
- Brook RH, McGlynn EA & Cleary PD. Quality of health care. Part 2: measuring quality of care. *New England Journal of Medicine* 1996;335(13):966–70.
- Campbell SM, Braspenning J, Hutchinson A & Marshall M. Research methods used in developing and applying quality indicators in primary care. *Quality and Safety in Health Care* 2002;11(4):358–64.
- Carroll JS, Rudolph JW & Hatakenaka S. Lessons learned from non-medical industries: root cause analysis as culture change at a chemical plant. *Quality and Safety in Health Care* 2002;11(3):266–9.

- Classen DC, Pestotnik SL, Evans RS & Burke JP. Computerized surveillance of adverse drug events in hospital patients. *JAMA* 8 April 1992;267(14):1922. *JAMA* 1991;266(20):2847–51.
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- Cullen DJ, Bates DW, Small SD, Cooper JB, Nemeskal AR & Leape LL. The incident reporting system does not detect adverse drug events: a problem for quality improvement. *Joint Commission Journal on Quality Improvement* 1995;21(10):541–8.
- Cullen DJ, Bates DW & Leape LL. Adverse Drug Event Prevention Study Group. Prevention of adverse drug events: a decade of progress in patient safety. *Journal of Clinical Anesthesia* 2000;12(8):600–14.
- Daley J, Vogeli C, Blumenthal D, Kaushal R, Landon B & Normand S 2002. Physician clinical performance assessment. The state of the art: issues, possibilities and challenges for the future. *The Institute for Health Policy: Massachusetts General Hospital*.
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