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EXPLANATORY NOTES

Patient Safety Management Systems

Australian Council for Safety and Quality in Health Care



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Preface

Improving patient safety is not the sole domain of patient safety experts. In the acute hospital setting, patient safety experts have a small role to play in the process of safety improvement, because the business of improving safety is the responsibility of all staff that work with and around patients. In the health sector, the single most important person in the system is the patient, and so the patient must also play a part in ensuring that the care they receive is safe.

While all members of a health organisation play a part in safety improvement, the part they play will differ markedly depending on where members fit into the organisation. It is important to recognise that no one group can change the system, because although members' roles are necessarily diverse, they are all linked by a shared responsibility for patient safety. A safe and effective health care system cannot be achieved without commitment at the highest levels. This requires good leadership, supported by adequate resources and team effort. At all times, the focus must be on continually improving the system so as to ensure that patients receive safe health care.

These Explanatory Notes have been developed to support the Patient Safety Management System (PSMS) Checklist, a self-assessment tool designed to assist Chief Executive Officers (CEOs) and their executive colleagues, managers and clinician managers, health professionals, and patients to assess the organisation's safety management system/s. The PSMS Checklist is intended as an internal management tool only, and has not been designed for external benchmarking. It does, however, allow managers and health care professionals at all levels of an organisation to assess their PSMS, and may be used to gauge the attitudes of health professionals and patients about the systems that are in place in an organisation.

It needs to be emphasised that organisations may have some or all of the appropriate policies, protocols, and systems in place, but do not refer to the sum of these things as a PSMS. In addition, the materials should complement framework arrangements in jurisdictions, where they exist (eg. the ACT's *Clinical Risk Management Framework*, and Victoria's [Better Quality, Better Health Care: A Safety and Quality Improvement Framework for Victorian Health Services](#)).

These Explanatory Notes include a detailed introduction that considers *why things might go wrong*. The notes are then laid out in chapters that conform to the seven characteristics of a PSMS:

1. Demonstrated senior managerial commitment to patient safety;
2. Agreed policies and procedures concerning patient safety;
3. Clearly defined accountability arrangements for patient safety;
4. Systematic approach taken to the identification and investigation of patient safety risks;
5. Systematic approach taken to manage all sources of patient safety risks;
6. Process of review and evaluation; and
7. Systematic approach to training and education for staff.

Chapters 1-7 deal with the sub-elements of the seven PSMS characteristics. Each of these chapters provides further information about one characteristic, and what activities might be undertaken to realise these objectives.

To maintain a uniform language relating to patient safety, the Australian Council for Safety and Quality in Health Care (hereafter referred to as the Safety and Quality Council) has developed a glossary of commonly used terms (pp. 27-29).

Two terms commonly referred to include:

Safe

While safe may be defined as “free from accidental injury”, it also means achieving an acceptable level of risk (ACSQHC, 2001). In the health care system, the use of this term refers to making health care safer for patients by reducing the risk that a patient will be unintentionally harmed in the course of their treatment.

Adverse Event

An adverse event may be defined as “an incident in which harm results to a person receiving health care”. Problems commonly associated with adverse events include things such as infections, falls and other injuries, and medication errors.

Introduction

Why do things go wrong?

"The common initial reaction when an error occurs is to find and blame someone. However, even apparently single events or errors are due most often to the convergence of multiple contributing factors. Blaming an individual does not change these factors and the same error is likely to recur. Preventing errors and improving safety for patients requires a systems approach in order to modify the conditions that contribute to errors. People working in health care are among the most educated and dedicated workforce in any industry. The problem is not bad people; the problem is that the system needs to be made safer."

Institute of Medicine (2000)

Health care is a complex business that involves a multitude of interlocking processes and systems. These systems are often large and complicated, and involve many staff using very sophisticated equipment. Like all complex businesses, things sometimes go wrong, and unfortunately, the errors that occur in the health care system often put patient safety at risk. Although it would be impossible to prevent all errors from occurring in such a complex system, every effort must be made to minimise the error rate, and to ensure that protective barriers are erected within health care settings to minimise the consequences of these errors. In the literature, the available data suggests that the error rate in the Australian health care system can be reduced, and that further work can be done to create protective barriers to minimise the consequence of the errors that do occur.

A systems approach to patient safety seeks to both minimise the error rate, and to build protective barriers. This can be achieved by identifying where mishaps occur within the system, and learning from these so they do not occur again. The answer to error prevention does not lie in blaming an individual when things go wrong. Instead, we should look at how the system works, and what needs to be undertaken to make it safer as well as better.

In the health care setting, there are specific factors that have the potential to contribute to an adverse event and, therefore, have the potential to cause harm. Three primary factors should be considered: human, operational, and patient factors.

! Human Factors

In high-risk industries, human factors are considered the most significant contributor to adverse events. This is therefore true of the health sector. The first question to be posed is:

"Might human actions contribute to an adverse incident that has occurred, or has the potential to occur in the future?"

If the answer to the above question is yes, then the following are the sort of human factors that might be considered as contributors to the adverse event:

Culture

The culture of an organisation underpins the way it performs. Safe work practices are a good guide to a “healthy” culture within an organisation. A PSMS supports a healthy culture in the workplace by encouraging teamwork to foster partnerships in safety, and to improve communication between staff and patients. It may also promote safer staffing and workload practices that might result in less stress for staff, and increased motivation in the workplace, thereby creating a safer environment in which to treat patients.

Skill Mix

Skill mix refers to the mix of skills within a team at any given time. In contrast, role mix refers to the combination of roles that are required to complete a whole piece of work. The delivery of health care requires an interchangeable mix of staff with appropriate skills and skill levels, and defined roles to deliver safe and effective care (ACSQHC, 2003).

Fatigue

Fatigue has traditionally been underplayed as a causal component of adverse events. More recently, however, there is a growing recognition of its role in adverse events in the health sector. Knowledge of the factors that cause fatigue (eg. roster principles and their application, etc.), and an awareness of the critical functions that may be impaired lay the foundation for good fatigue management strategies. Fatigue, regardless of the cause, should routinely be considered as a causal component of adverse events that occur in hospitals. “Tolerance levels, and reward, for people who are fatigued and continue to work needs to significantly change” (ACSQHC, 2003).

Competence

The Safety and Quality Council (2002) defines competence as “the application of knowledge and skills in interpersonal relations, decision making, and performance consistent with the professional’s practice role”. It has established guidelines to manage issues associated with the competence of medical specialists, to ensure that they have the appropriate credentials and privileges. In the health sector, the notion of competence should not just be restricted to medical specialists. It should encompass all clinical staff; that is, all health professionals assigned to a clinical setting.

Professional Development and Training

It is now recognised that continuing professional development (CPD) and life-long learning are pivotal to ensuring the competency of clinicians. From an organisational perspective, CPD and life-long learning activities should be supported by mechanisms for further training, retraining, and reassessment where necessary.

Performance Management

While the majority of clinical staff clearly do a good job, there is now widespread acceptance that poor performance needs to be identified and addressed in a prompt and consistent manner. A performance management framework that includes regular appraisal and re-validation processes will achieve this objective. It should be noted that, in this context, poor performance is not limited to technical performance, but also considers the full range of behaviours required to work effectively within an organisation.

Peer Review

Peer review is a process of evaluating the quality of health care being provided by an individual. It is undertaken by fellow health professionals of similar training and experience. The process of peer review may occur in a structured or unstructured manner. It can involve a group (or individual) exchange of information, and may occur spontaneously or in a planned setting. Regardless of the approach adopted, the aim of peer review is to analyse the successes, failures, and/or complications of care provision, and to make subsequent changes for improvement where indicated. The ultimate objective is to provide a non-threatening mechanism for reviewing clinical performance.

Code of Conduct

A clearly defined Code of Practice should underpin the notion of clinical competence for clinical staff. A Code of Practice articulates the standard of professional conduct required, and acts as a measure against which an individual member's conduct can be assessed. It is only effective when there is an explicit commitment on the part of senior managers to ensuring ethical conduct, and a clear commitment to ethical conduct by those involved in the provision of health care.

! Operational Factors

Operational factors relate to the non-human element of service delivery. It should be noted, however, that this division is arbitrary in some senses because even when operational factors appear paramount, there is a human contributory factor in most circumstances. For example, the lighting might be poor because of a blown light globe that was not reported to a maintenance person, or was reported and not replaced. The question to be posed is:

“Might operational factors have contributed to the adverse event?”

If the answer is yes, then the following should be considered:

Standard operational protocols, procedures, and guidelines should be in place to minimise the risks posed by operational factors. At the same time, clinical standards, clinical guidelines, clinical pathways, and local practice protocols should also be in place to highlight safety issues as they arise, and to act to prevent further lapses in safety. Functions that support the patient safety system include activities associated with equipment and its repair and maintenance, drugs and their safety, as well as the physical working environment, including noise, heat, light, exposure to infectious agents, and toxic releases.

! Patient Factors

Factors associated with the patient are, at times, a contributor to adverse events that occur in the health sector. The question to be posed is:

“Might patient factors have contributed to the adverse event?”

If the answer is yes, then the following factors should be considered:

Failure to Disclose

Whether intentionally or inadvertently, patients may fail to disclose or report ambiguous or inaccurate information that increases the possibility of their exposure to unsafe treatment.

Clinical Risks

There may be significant clinical risk factors that increase safety risk. Within the course of treatment, for example, patients may have an atypical response that increases risk.

Cultural and Linguistic Diversity

Cultural and linguistic diversity may contribute to a breakdown in communication between patients and health care professionals. This can compromise patient safety in a health care facility.

Chapter 1

Is senior managerial commitment to patient safety important?

The management of patient safety requires the involvement of staff at all levels of the organisation. The actions and attitudes of senior managers (ie. CEOs and their executive colleagues), however, are pivotal because these will influence the actions and attitudes of all staff. Senior managers should articulate and exemplify the safety culture of an organisation, and set the standard. If senior managers do not care about patient safety, or are perceived not to care, then it is unlikely that safety will be a priority for staff within the organisation.

A successful PSMS requires visible support from CEOs and executive. Patient safety will be at risk without the complete support of senior managers.

! CEOs and their executive must take an active lead with the PSMS

Senior managers must take an active lead in the establishment and maintenance of the PSMS. Without their commitment, the PSMS will be less effective, or worse, ineffective. Senior managers are able to visibly demonstrate their commitment to patient safety by:

- publicly acknowledging their commitment;
- encouraging the commitment of others;
- promoting and fostering a team approach to patient safety;
- allocating sufficient resources to support the PSMS;
- involvement in induction/orientation training; and
- ensuring that there is a clear and continuing flow of information concerning issues of patient safety.

! Familiarise all people in the organisation with the PSMS and how it applies to them

The responsibility for staff involvement in the operation of a PSMS can not be delegated to a quality manager, or other associated personnel. The quality manager can, and should, assist with encouraging staff involvement as a technical expert (eg. ensuring staff are trained and equipped to participate in the PSMS, setting up appropriate monitoring and reporting systems, providing guidance with planning, executing and evaluating activities, etc). Rather, senior managers need to encourage staff participation and involvement in the operation of a PSMS by nurturing and supporting leaders and champions at all levels of the organisation. Tangible forms of support that should be considered to assist staff include the following:

- dedicated staff support for the PSMS, and expertise that can be shared with all relevant areas of the organisation;
- training and development that ensures all staff understand the purpose of the PSMS, and their role in its operation and effectiveness;
- adequate information technology (IT) systems, especially for tracking adverse events and managing identified risks; and

- the Executive's capacity to respond quickly and appropriately to an unforeseen and significant adverse event.

! Promote and foster a team approach to patient safety throughout the organisation

The CEO and senior managers should promote and foster a team approach to patient safety throughout their organisation. CEOs and their executive managers are able to visibly demonstrate their commitment to a team approach to patient safety by:

- including interdisciplinary and consumer representation in the Terms of Reference of committees that administer the organisation's patient safety system;
- incorporating teamwork selection criteria into the organisation's appointments process; and
- incorporating the assessment of teamwork into the organisation's formal and informal performance management processes.

! Use objective criteria to determine the amount of resources provided to support the PSMS, including its evaluation

Iatrogenic injury is costly. In Australia, at least 10% of admissions to acute care hospitals are associated with a preventable adverse event. It has been estimated that the direct medical cost of these events exceeds \$2 billion per year and that the total life-time cost of such preventable injury may be twice that amount. There is also a heavy toll in terms of human costs, including for those who are harmed and for those who care for them. Furthermore, medical misadventure accounts for over half the amount spent on compensation and insurance by State Treasury Departments (Runciman & Moller, 2001).

The resources required to establish and maintain a PSMS are comparatively small. Indeed, it has been suggested that "good safety management is a state of mind, not an expensive add-on; it's about the mindset of everyone" (Civil Aviation Safety Authority, 2002). In the health sector, acute hospitals need to determine what resources are necessary to sustain their PSMS in the longer term in order to effectively improve patient safety. This might include approving staff back-fills at the ward level to enable staff to deal with issues of safety, and to attend committee meetings and training sessions. The allocation of resources to support the PSMS should include provision for its evaluation.

! Give and receive regular and meaningful reports on issues related to patient safety

Those accountable for patient safety should ensure that they are aware of the ongoing risks to patient safety that exist in their organisation. An effective PSMS needs to be supported by a reporting system, so that relevant data is available at all levels of the organisation. Data might include analysis of indicators collected from:

- incident monitoring systems;
- limited adverse event screening;
- other clinical indicators;

- written complaints and compliments;
- Freedom of Information (FOI) requests;
- claims; and
- investigations, including internally conducted root cause analyses (RCAs), coronial inquiries, and inquiries conducted by other statutory bodies.

Regular reporting is essential to identifying safety issues, detailing the activities to mitigate or address these issues, and highlighting the savings (real and perceived) that can be/have been realised.

! Provide timely and meaningful feedback about actions arising from reports on issues related to patient safety

CEOs and their executive managers should establish processes in the organisation for feedback to be provided to those who have identified and reported a safety hazard. Information about what actions have been taken in relation to staff safety reports may be circulated in numerous ways, including:

- formal reporting and/or discussion at the individual level;
- formal reporting in a “What’s New in Safety” section of the organisation’s staff bulletin;
- formal reporting through the organisation’s safety committee; and
- formal reporting (including in written reports) to consumer representatives on what safety improvements have been effected within the organisation.

CEOs and Executive Managers must recognise that hazards will be identified in their organisation as the PSMS begins to operate effectively. They must therefore be prepared to commit resources to address these hazards. If hazards are not addressed, then the enthusiasm for the PSMS will quickly dissolve.

Chapter 2

Is there a guide to patient safety management policies and operating procedures?

The AS/NZS 4360:99 Risk Management Standard (RMS) provides a logical and systematic method for managing risk. This industry framework is equally applicable to the management of risks associated with patient safety, and to the management of corporate risks. The AS/NZS RMS provides a framework within which the policies and operating procedures in support of a PSMS can be constructed. The advantage of this approach is that the PSMS will complement the organisation's other risk management policies and operating procedures, and can be fully integrated into the organisation's risk management framework.

! Have agreed policies and operating procedures concerning patient safety

Safety-specific policies should be incorporated into the standard operating policies and procedures of all acute hospitals. Agreed procedures on how to deal with reported safety issues should be open and transparent to enable anyone reporting to see:

- that they are reporting appropriately;
- that they are reporting to the right person, committee, and/or manager; and
- what will likely occur as a result of the report being submitted.

At the same time, there are now a number of policies around which there will be a mandatory compliance requirement, for example:

- the implementation of the Open Disclosure Standard (ACSQHC, 2003);
- the reporting of any occurrence from an agreed list of sentinel events;
- the distribution of "Ten tips for safer health care" (ACSQHC, 2004) to all patients admitted to a health facility; and
- the implementation of "Correct Patient, Correct Site, Correct Procedure" (ACSQHC, 2004).

! Integrate patient safety into other management activities

Although patient safety is of paramount importance, no PSMS should be constructed in isolation from other management systems. In the health sector, a comprehensive risk management framework considers both the organisation's corporate risks, as well as patient safety related risks. For example, tracking occupational health and safety (OH&S) incidents provides a mechanism for capturing details of the organisation's exposure to occupational illness and injury. This may have implications for patient safety and could be considered to be part of the PSMS. While it is conventional to consider OH&S as a corporate rather than a clinical risk, a conscious decision must be made about where it is managed within the organisation.

Other areas where overlaps might occur, and may require management role delineation, include:

- performance management;
- incident reporting;
- claims; and
- Coronial and other enquiries.

! Support activities to heighten staff understanding of the patient safety policies and supporting procedures in your organisation

There are a number of simple ways to support activities that allow all staff to understand the patient safety policies and supporting procedures in your organisation. These include:

- encouraging staff learning activities relating to the PSMS;
- allowing for the back-filling of staff to encourage attendance at dedicated education sessions on the PSMS;
- including a dedicated PSMS session during staff orientation; and
- encouraging participation at every level of the organisation through senior managerial recognition of contributions to the PSMS. This may include publishing the achievements of safety committees in staff bulletins, and distributing certificates of attendance at safety education sessions.

! Support activities to heighten patient awareness of the relevant patient safety policies and supporting procedures

There are a number of initiatives that might be implemented to heighten patient awareness of the relevant patient safety policies and supporting procedures in your organisation, including by:

- ensuring that all patients are provided with a copy of "Ten tips for safer health care" (ACSQHC, 2004);
- making patients and their carers aware of the local implementation of the Open Disclosure Standard (ACSQHC, 2003) that requires health professionals to communicate openly and honestly with patients and their families following an adverse event;
- ensuring that patients are provided with access to information on how they can participate in patient safety as a patient; and
- providing patients and their carers with information about the various avenues available to them to address any concerns they may have about their safety (eg. access to a person who undertakes a specific patient liaison function in the organisation, safety reports, direct discussions with staff or area managers, and patient satisfaction surveys, etc).

An effective PSMS will be totally integrated with the organisation's overarching risk management framework and will conform to the arrangements of that framework.

Chapter 3

Who is accountable for patient safety?

There are various layers of accountability and responsibility in relation to the operation of patient safety management systems. The Commonwealth, State, and Territory Ministers are ultimately accountable to the community for patient safety. This is enshrined in the legislative and regulatory framework within which our health services operate. In an operational sense, the layers of accountability may be summarised as follows:

CEOs and Executive

CEOs and their Executives are responsible for an area or network that is usually based on more than one facility and/or service. CEOs and their Executives are accountable for patient safety in their designated area of responsibility.

Managers/Clinician Managers

Managers and clinician managers are responsible for a work area. They are accountable for the outcomes in their work area.

Health Care Professionals

Health care professionals are responsible for day-to-day practice in their sphere of work, and are accountable for their own actions.

Patients

Insofar as their condition allows, patients and their carers assume a degree of responsibility for reducing their exposure to safety risks. This includes seeking information and assistance from their health care professionals.

Many organisations support these different layers of responsibility and accountability by establishing a quality and safety committee structure, and often have dedicated staff to support these processes. Staff and committees administer the patient safety system and, although their responsibilities may include the identification, reporting, and analysis of adverse events, they do not include operational accountability. These structures, and the appointment of support staff with designated roles in relation to patient safety, do not diminish the level of accountability that line managers have for the outcomes in their areas.

! Maintain a clearly defined structure to manage patient safety that includes everyone in the organisation

The overarching structure for managing patient safety should be clearly defined and publicised in every organisation. At each level of the organisation, an individual should have easy access to information explaining what their role is in relation to the PSMS, including their responsibilities and accountabilities. Because all staff and consumers have some responsibility for patient safety, every effort must be made to ensure that everybody has access to information about the PSMS, and are involved in its effective operation.

! Maintain open and transparent accountability arrangements

It is important to ensure that the accountability arrangements for the PSMS are open and transparent. At any level of the organisation, a person should be able to access information about the role of other people to identify and clarify those things for which they are responsible and accountable. This should translate across all levels of the system: from the patient to the CEO.

! Maintain processes for relevant staff to understand their individual accountabilities and responsibilities

At orientation, staff should be offered information on the organisation's PSMS and how it works. This information should be readily accessible to all staff. The availability of this information should also be reiterated and reinforced periodically at education sessions, and by any other means deemed appropriate by the organisation.

Everyone is responsible for patient safety. Accountability for patient safety cannot be delegated to designated quality and safety staff, or supporting committee structures.

Chapter 4

How do you know if patient safety is at risk?

In the first instance, there are judicial and regulatory bodies that investigate and report matters associated with risks to patient safety. Coronial findings are an important source of information about adverse events because of the comprehensive investigation of the causes and circumstances surrounding a death. The dissemination and use of coronial findings should be used to inform organisational clinical risk management. Like the findings of coronial inquiries, the findings from other independent statutory authorities (eg. Professional Registration Boards, Ombudsmen, Health Complaints Commissioners, etc), might be made available to an organisation and alert managers and staff to the possible risks associated with particular processes and procedures. Consultancy reports provide another useful basis for risk identification.

From an internal management perspective, there is good evidence to suggest that action with an emphasis on prospective measures better enables an organisation to intervene and minimise the level of risk. Prospective processes seek to identify potential adverse events before they occur. Irrespective of circumstance, the same risk management principles apply, and the risk to the patient is at the centre of the query. For example, with the introduction of any new therapy or procedure comes the inherent risk of the unknown. Health care organisations need to be aware that a potential risk exists, and then utilise the safety systems they have in place to assess and obviate or reduce the risk to their patients. At the same time, activities of a retrospective nature can provide useful insights into what is happening within an organisation.

! Maintain a staff-instigated reporting system that addresses patient safety

Incident monitoring systems allow staff to voluntarily notify the occurrence of an adverse event, or a near miss. They provide a standardised mechanism for capturing details and trend analysis. Staff-instigated reporting must be encouraged in order for managers to be made aware of issues relating to patient safety. Staff must be encouraged to report without fear of reproach. In addition, appropriate and timely reporting must be promoted because it is essential in order for a PSMS to function effectively.

While incident monitoring systems are voluntary, there will soon be a mandatory requirement to report all sentinel events. Sentinel event reporting allows the review of clear-cut, relatively infrequent events that have resulted in an unanticipated death, or major permanent loss of function unrelated to the natural course of a consumer's illness/underlying condition (ACSQHC, 2004). Sentinel events commonly reflect health system and process deficiencies. The nationally agreed sentinel event list is:

1. Procedures involving the wrong patient or body part.
2. Suicide of a patient in an in-patient unit.
3. Retained instruments or other material after surgery requiring re-operation or further surgical procedure.
4. Intravascular gas embolism resulting in death or neurological damage.
5. Haemolytic blood transfusion reaction resulting from ABO incompatibility.

6. Medication error leading to the death of a patient reasonably believed to be due to incorrect administration (wrong drug, route, and/or dose) of drugs.
7. Maternal death or serious morbidity associated with labour or delivery.
8. Infant discharged to wrong family.

! Use consumer feedback processes to identify sources of risk to patient safety

Health facilities have traditionally used patient satisfaction surveys to assess the acceptability of service delivery. Often, these tend to place more emphasis on the “personality” aspects of the hospital, with an assumption by respondents that the “technical” skills of medical staff were high. It should be noted, however, that patient satisfaction surveys can and should be used to assess technical aspects of health care delivery that relate to patient safety.

Consumer feedback is often managed as part of a consumer “complaints” process. While one goal for both the service provider and consumer should be the prompt resolution of the complaint, another should be improvement in service delivery by addressing the basis of the complaint. In Australia, the Safety and Quality Council has been working to address the resolution of complaints, and has developed complaints management guidelines and a handbook for health care organisations. At the same time, the complaint should also be used as another means of identifying an issue that may need to be addressed in the delivery of clinical care. Appropriate internal management processes for health care related complaints should therefore be used to effectively recognise safety issues, and to improve the quality of health care.

It is essential for every organisation to have a variety of means by which consumers are able to provide feedback. While some consumers may feel comfortable talking directly with their immediate caregiver or health care professional to provide feedback, it may be that others prefer to speak with a supervisor, or a person who undertakes a specific patient liaison function in the organisation. Some consumers may prefer to remain anonymous in their reporting and can complete a patient satisfaction survey, or similar form.

Claims provide an indirect source of information on an incident from a consumer perspective. While the claims process is often linked to a complaint, this is not always the case. The incident giving rise to the claim should not only be investigated because of the medico-legal implications, but also from a systems perspective as part of a clinical risk management process.

A request by a patient to view clinical records under Freedom of Information (FOI) legislation also offers the organisation the opportunity to identify an issue or incident from a consumer perspective. FOI requests can be used as another trigger for incident assessment and investigation.

! Encourage staff and consumers to report when patient safety is at risk

The reporting of risk prior to an actual safety breach (including near misses) or worse, an adverse event, should be strongly encouraged at all levels of an organisation. All staff and

patients should be confident that reports are managed without the possibility of reproach and/or sanction. This will empower everyone in the organisation. It will also promote and reinforce the principle that patient and staff safety are the ultimate goals of the reporting system. With an effective PSMS, senior managers should expect to become aware of any safety failings in their areas of responsibility and accountability. They should also acknowledge that without reporting, risk will remain unnoticed and unaddressed.

! Have processes to maintain confidentiality of reports

Every acute care hospital should have stringent processes in place to ensure the confidentiality of reports and the reporters. Only then will patients and staff be confident that they can report without fear of reproach or sanction. The principle of confidentiality should be strongly emphasised in every organisation's PSMS.

! Provide timely feedback to all staff and consumers who report an adverse event

Every acute care hospital should have processes in place to provide all staff and consumers who report an adverse event with timely feedback. It is important to recognise that the assurance of anonymity does not mean that feedback cannot be provided. Reporting can be designed to address this issue (eg. organisations could incorporate a "Request for Feedback" section on staff and consumer incident report forms). Timely feedback on the outcomes of actions taken as a result of reported adverse events may be provided to staff and consumers in staff bulletins and consumer newsletters. In addition, organisations can provide feedback on the number of incident reports received. Where a change is implemented as a result of the PSMS, the organisation can highlight how the PSMS is working effectively for staff and patients to provide a safer system.

! Have a process of incident management that ensures all identified adverse events in the organisation are investigated

Broadly speaking, the nature of an investigation into an adverse event will be determined by the seriousness of the event, often characterised by undertaking a severity assessment. There are a number of analytical tools available to consider the causes of specific incidents, including:

- aggregated review analysis;
- ad-hoc audits;
- clinical audit;
- clinical record review;
- limited internal investigation;
- Root Cause Analysis (RCA); and
- external review.

As the above hierarchy of investigative tools suggests, more significant events are investigated by limited internal investigation, RCA, and external review. A limited internal investigation is warranted for high-risk events, and is the minimum requirement for events

characterised as an extreme risk. RCA is the appropriate investigative tool for sentinel events. In exceptional circumstances, it may be appropriate to conduct an external review into an adverse event. Policies and procedures for these incident investigations must be open and transparent. In addition, they should be linked with the organisation's policy of open disclosure and other supporting policies, so that anyone is able to access information that outlines what will take place when a patient safety issue is reported.

No identified adverse event should be ignored.

Chapter 5

If you know patient safety is at risk, what can you do to fix it?

In the United States of America, the Institute of Medicine (1999) suggests that health care is a decade or more behind other high-risk industries insofar as its attention to ensuring basic safety through systematic risk management approaches is concerned. Today, there is an increasing acceptance that the management of clinical risk at an organisational level is an important aspect of good governance. A clinical risk management framework recognises that risk might arise at many points in a patient's journey, and that aspects of how organisations are managed can systematically influence the degree of risk.

A number of industries have led the way in risk management. The AS/NZS 4360:99 Risk Management Standard provides a logical and systematic method for managing risk (ACSQHC, 2002). The concept of risk has three elements: the perception that something could happen; the likelihood of something happening; and, the consequences if it happens. The level of risk is the combination of the likelihood of a risk occurring, and the consequences if it does occur. Action taken to manage the risk, and to therefore change the level of risk, must address the likelihood of the event occurring, or the consequences if it does occur, or both. Risk treatment involves identifying the range of options for treating the risk, assessing the options, preparing risk treatment plans, and implementing them. As mentioned previously, this generic industry risk management framework is applicable in a clinical setting. It provides a logical method to consider all the issues, and takes into account the perceptions of patients and health professionals regarding a particular intervention.

A database should be used to monitor all reported incidents. The database can then be used to monitor trends in incidents, as well as to identify risky areas within the organisation. It should include the following standard fields:

- incident identifier;
- nature of incident;
- location;
- instigator of report;
- severity assessment score; and
- probable causes.

! Use objective criteria to measure and evaluate risks associated with patient safety

Organisations should use objective criteria to measure and evaluate all risks associated with patient safety. The principal aim of risk analysis is to establish the level of risk associated with a particular incident. The magnitude of the consequences of the event, and the likelihood of the event, are assessed in the context of existing controls. Likelihood and consequences are combined to produce a level of risk.

! Have processes in place to ensure identified risks are ranked in accordance with their risk rating

A Risk Rating Matrix should be used to determine the level of risk and its acceptability by pairing a severity category with a probability category for an event. This will identify a ranked matrix rating. The Risk Rating can then be used for:

- determining risk potential;
- comparative analysis;
- deciding who needs to be notified about the event;
- determining which events require urgent remedial action; and
- prioritising safety projects.

! Use risk management plans to eliminate, avoid, and/or reduce risks

The first step in developing a risk management plan is to consider the options available to manage the risk. One of the following options should be selected to decide the preferred course of treatment:

- risk avoidance;
- risk reduction;
- risk acceptance; or
- risk transfer.

The identification and assessment of management options informs the development of a Risk Reduction Action Plan (RRAP), which identifies the strategies to be implemented to reduce the risk of similar events occurring in the future. A RRAP should address:

- responsibility for implementation of each action item identified;
- pilot testing as appropriate;
- time lines;
- text and/or journal references considered in the development of the action items; and
- strategies for measuring the effectiveness of the action items.

! Take a systematic approach to monitoring the status of each identified risk to patient safety

A register of risks that aggregates all identified risks, action plans, and consequent outcomes should be established and maintained. The Risk Register will support the timely evaluation of outcomes achieved, and highlight the issues yet to be addressed.

! Demonstrate that PSMS initiatives have led to positive and timely change

It is important to monitor the progress of all change initiatives implemented as a result of an identified risk. This will allow an organisation to demonstrate to staff and patients that initiatives have resulted in positive organisational change (eg. to policies and/or operating procedures, etc). If change initiatives are implemented in a timely manner, staff and patient confidence in the value of reporting to the system is likely to be increased.

! Inform all staff of actions taken to reduce sources of risk to patient safety

Organisations should ensure that all staff are aware of the actions taken to reduce sources of risk to patients. Organisational feedback can be provided to all staff using newsletters, bulletins, meetings, e-mail, and/or the intranet. Feedback should:

- acknowledge the contribution of staff;
- include all identified issues;
- demonstrate learning using the data;
- identify the actions taken and/or seek assistance to address the identified problem;
- coordinate with other quality processes; and
- separate learning from interventions.

Personal feedback should reassure individuals that they are making a valuable contribution to the enhancement of system safety. It can range from a simple acknowledgment that a response to the event is under consideration, to providing information about the corrective action that is planned, or has been taken. Timely feedback to reporters will promote an increased sense of staff commitment to the PSMS.

If risks to patient safety are identified, then positive actions should be taken in accordance with the risk rating.

Chapter 6

How do you review and evaluate your PSMS?

It is the responsibility of the CEO and executive managers to ensure that the PSMS is reviewed and evaluated at regular intervals. The purpose of a review process is not only to assure the ongoing sustainability of the system, but also to promote continuous improvement.

A key component of any PSMS is the incident reporting system. Sometimes, these systems are greeted with enthusiasm and, at other times, there is a reluctance to report. Any evaluation of the system should endeavour to understand the underlying causes of this reluctance/hesitation. It is important to recognise that although the PSMS system may be accepted with enthusiasm initially, the number of reports may reduce over time. This may signal that there is something wrong with the PSMS system, as opposed to an overall reduction in the number of patient safety hazards. Organisations may assist in maintaining overall enthusiasm for the reporting system by providing feedback to staff on identified risks, and the plans developed and implemented in order to reduce these.

! Routinely review the PSMS policies and procedures to confirm they are working

It is important to routinely review the PSMS policies and procedures to confirm that they are working. Traditionally, accreditation has been the primary mechanism for ensuring the quality of health care in a hospital setting. Notwithstanding the value of the accreditation process, major failings still exist in the quality and safety of health care delivery in Australia and, as such, accreditation should not be relied on as a sole evaluation mechanism.

! Periodically complete a self-evaluation assessment of the PSMS

A self-evaluation assessment of the PSMS should be completed periodically, and internal review processes should be considered. Part of the evaluation should include an assessment of the adequacy of resources, and the ongoing support of the PSMS by managers and clinician managers. Evaluation should also ensure that the system continues to effectively meet the patient safety objectives that have been set previously. Through the evaluation process, all staff should be provided with the opportunity to recommend changes to enhance the system. Staff feedback should be encouraged by senior managers.

! Encourage staff at all levels to be involved in the PSMS Evaluation process

All staff should be encouraged to be involved in the evaluation of the PSMS. It is only possible to obtain a broad cross-sectional view of the organisation's safety performance if staff are encouraged to complete the PSMS Checklist. This may highlight areas that need

to be addressed but have not yet become evident as a result of existing monitoring systems.

! Provide feedback to staff on the PSMS evaluation outcomes and actions taken

It is important to provide feedback to all staff on all PSMS evaluation outcomes, and any subsequent actions taken. The provision of such feedback is likely to serve as a positive reinforcement that staff participation is encouraged. It may heighten staff members' sense of value in terms of their individual and team contributions to the organisation.

Ensure your organisation has a robust plan to review the PSMS, and that adequate resources have been allocated to the evaluation process involving staff at all levels.

Chapter 7

Is staff learning and development important?

An essential element of any successful PSMS is a commitment to provide induction and ongoing refresher training for all staff. Induction training should be conducted by staff responsible for the PSMS, and should be customised to suit the requirements of individual staff members. It should include information about the PSMS, how it is supported, and the responsibilities of all employees to participate, especially with regards to the reporting of adverse events.

All staff should be encouraged to consider patient safety in all aspects of their work, and should be provided with access to information on what improvements to safety have been implemented as a result of the introduction of the PSMS. In addition, all staff should be encouraged to consider the implications of new technologies, equipment, and procedures on patient safety. Staff should also be informed and educated about current trends in patient safety, and should have access to relevant literature, as well as the opportunity to attend courses and seminars that will help them to enhance their approach to patient safety.

Evaluation of the staff training program should be undertaken. This might include a review of staff awareness of patient safety issues, knowledge about processes and practices, and any specific competencies that are critical to patient safety.

! Have an effective patient safety related orientation program for all staff, including the CEO and Executive Managers

Organisations should make effective patient safety related orientation programs available to all staff, including the CEO and Executive managers. All hospital orientation programs should have a period of time dedicated to the introduction, explanation, and reinforcement of the organisation's PSMS.

! The CEO is actively involved in the delivery of the orientation program

The CEO should be actively involved in the organisation's orientation program. This should include the CEO's attendance at each staff orientation program to emphasise the importance of the program, and it is useful if the CEO is visible and takes a lead role in the PSMS induction. Involvement of the CEO in the delivery of the orientation program will reinforce senior managerial commitment to the PSMS.

! Provide ongoing training and education for relevant staff on topics related to patient safety

Ongoing training and education should be provided to relevant staff on a variety of topics relating to patient safety, including the PSMS and other new initiatives as they are implemented. This is essential in maintaining a well functioning and effective PSMS. It is just as important for an organisation to offer accessible training to its staff as it is to ensure that there are sufficient resources allocated to the PSMS. If staff are unable to attend programs that are on offer, then the educational tool cannot be effective.

An essential element of any PSMS is a senior managerial commitment to staff induction, and ongoing refresher training for all staff.

Glossary

Definitions of words in *italics* can be found elsewhere in the glossary. The terms in this glossary have been developed as part of a broader Council process to achieve agreement on key safety and quality terms. At this stage, the definitions reflect broad agreement only and will be the subject of wider community consultation. People who wish to contribute to this process can do so through the Council's web site.

Adverse Event

An *incident* in which *harm* resulted to a person receiving *health care*.

Adverse reaction

A harmful *side effect*. For example, an adverse drug reaction or side effect will be said to have occurred when the right drug was used for the correct indication in the right given dose by the right route, but the patient suffered unexpected and unpreventable harm. Adverse reactions can also result from some diagnostic tests, therapeutic interventions, or devices.

Note: There is a continuum between *adverse reaction* and *side effect*. Whether an *adverse reaction* can be called a *side effect* depends on the *outcome* of the treatment and the degree of *harm* which may vary from minor to major. An *adverse reaction* is usually unexpected, unusual, and unpreventable, and can be major in nature. A *side effect* is usually known and minor in nature.

Agent

Someone or something that can produce a change.

Blame

Being held at fault (implies culpability).

Circumstance

All the factors connected with, or influencing, an *event*, *agent*, or person/s.

Complaint

An expression of dissatisfaction with something.

Complication

An adverse patient *event* related to medical *intervention*, and especially an *event* that has an expected consequence of, or that sometimes occurs in relation to, the patient's *disease* or its treatment.

Diagnosis

The determination of the nature of a case of disease.

The art or act of identifying a disease from its signs and symptoms.

An investigation or analysis of the cause or nature of a condition, situation, or problem.

Disability

Any type of impairment of body structure or function, activity limitation, and/or restriction of participation in society.

Disease

A physiological or psychological dysfunction.

Error

The failure to complete an action as intended, or the wrong use of a wrong plan to achieve an aim. Errors may occur by doing the wrong thing (commission), or by failing to do the right thing (omission).

Error (active)

An *error* which is the result of an act of omission or commission.

Error (latent)

An *error* that implies a predisposing condition or *circumstance*.

Event

Something that happens to or with a person (see also *incident*).

Harm

Death, *disease*, *injury*, *suffering*, and/or *disability* experienced by a person (see also *loss*).

Hazard

A *circumstance* or *agent* that can lead to *harm*, *damage*, or *loss*.

Health

A state of complete physical, mental, and social well-being, and not merely the absence of *disease* or *infirmity*.

Health Care

Services provided to individuals or communities to promote, maintain, *monitor*, or restore *health*. The term also includes self-care.

Incident

An *event* or *circumstance* which could have, or did lead to, unintended and/or unnecessary *harm* to a person, and/or a *complaint*, *loss*, or *damage*.

Health Care Incident

An *event* or *circumstance* resulting from *health care* which could have, or did lead to unintended and/or unnecessary *harm* to a person, and/or a *complaint*, *loss* or *damage*.

Injury

Damage to tissues caused by an external *event* or *circumstance*.

Intervention

An activity or set of activities aimed at modifying a process, course of action, or sequence of *events* in order to change one or several of their characteristics such as performance or expected *outcome*.

Loss

Any negative consequence, including financial, experienced by a person(s) or organisation(s).

Monitor

To check, supervise, observe critically, measure, or record the progress of an activity, action, or system on a regular basis in order to identify change.

Near miss

An *incident* that did not cause *harm* (see also *incident*).

Negligence

Lack of due diligence or care and/or omission of duty.

Outcome

Something that follows as a result or consequence.

Health care outcome

Something that follows as a result or consequence of *health care*.

Preventable

Potentially avoidable in the relevant *circumstances*.

Preventive (Preventative)

That which hinders, obstructs, or prevents *disease*.

A type of measure, step, or course of action taken in advance to keep something possible or probable from happening or existing.

Quality (degree of)

The extent to which the properties of a service or product produces a desired *outcome*.

Quality of Health Care

The extent to which a *health care* service or product produces a desired *outcome*.

Risk

The chance of something happening. It is measured in terms of consequences and likelihood.

Risk Management

The culture, processes, and structures that are directed towards effective management of *risk*.

Safety

A state in which risk has been reduced to an acceptable level.

Side Effect

An effect, other than that intended, produced by an *agent* in the absence of error (see also *adverse reaction*).

Standard

Sets out specifications and/or procedures designed to ensure that a material, product, method, or service is fit for its purpose and consistently performs the way in which it was intended.

Suffering

Experiencing anything subjectively unpleasant. This may include: pain, malaise, nausea and/or vomiting, *loss*, depression, agitation, alarm, fear, grief, or humiliation (see also *loss*).

Surveillance

Supervision, close watch.

Oversight; watch; inspection; supervision.

System

An interdependent group of items forming a unified whole.

A set of connected things or parts.

An organised body of material or immaterial things.

System failure

A fault, breakdown, or dysfunction within operational methods, processes, or infrastructure.

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