AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Please note that the following document was created by the former Australian Council for Safety and Quality in Health Care. The former Council ceased its activities on 31 December 2005 and the Australian Commission for Safety and Quality in Health Care assumed responsibility for many of the former Council's documents and initiatives. Therefore contact details for the former Council listed within the attached document are no longer valid.

The Australian Commission on Safety and Quality in Health Care can be contacted through its website at http://www.safetyandquality.gov.au/ or by email mail@safetyandquality.gov.au

Note that the following document is copyright, details of which are provided on the next page.

AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

The Australian Commission for Safety and Quality in Health Care was established in January 2006. It does not print, nor make available printed copies of, former Council publications. It does, however, encourage not for profit reproduction of former Council documents available on its website.

DRAFT FOR COMMENT

PATIENT SAFETY MANAGEMENT SYSTEMS
A CHECKLIST

Health care is one of the most complex activities that humans engage in, and there are inherent risks of harm associated with being a patient. In the Quality in Australian Health Care Study (QAHCS) published in 1995, the study found that 16.6% of admissions were associated with an adverse event. Approximately half (51.2%) of the adverse events were assessed as having a high preventability. Extrapolating the data to all hospitals, the study estimated that about 470,000 admissions in 1992 were associated with an adverse event and that 3% of all admissions resulted in permanent disability or death. This means that, according to this study, 50,000 patients may have suffered permanent disability and 18,000 may have died in 1992 as a result of their health care. These figures are those most often quoted by the media and represent the highest estimates of the rate of adverse events.

The Quality in Australian Health Care Study data were re-analysed to take into account differences in method compared with the Utah/Colorado Medical Practice Study (UTCOS). Following this re-analysis, it was estimated that, based on the Utah/Colorado Medical Practice Study method, 10.6% of admissions in Australia would have been associated with an adverse event. (Thomas et al. 2000[i])

The report went on to state that the overall number of adverse events is less important than doing something to prevent them. Patient safety management systems are now available to achieve that end. They have evolved from the lessons learned from other high-risk industries such as the commercial aviation and the oil and gas industry. These industries have achieved exemplary safety records through positive attitudes to safety and the operation of effective safety management systems. (Hudson P. 2003[ii]).

What is a Patient Safety Management System?

A Safety Management System is a series of cross-organisational processes designed to protect against risks. The processes are used to identify, classify and manage risks to the safety of an organisation's operation. They are an integral part of an organisations risk management framework. They are generally used to:

- Minimise the direct and indirect costs of incidents and accidents;
- Meet legal responsibilities to manage safety;
- Improve productivity; and
- Market the standards of an organisation. (CASA 2002[iii])

The basic premise of a safety management system is that errors can occur at all levels of an organisation and that seemingly minor errors in one area combine with errors that occur in other areas and result in the occurrence of an adverse event. Professor James Reason describes this as the "Swiss cheese effect" where breaches of safety defences have occurred at all levels and cause a hazard that results in losses. (Reason, J 1995[iv])

A Patient Safety Management System is based on the same principles that apply to a Safety Management System. However it differs in that where the main concern of most industries is about staff and production, in health the risks are mainly to patients. The goal of a patient safety management system is to actively seek to minimise harm to patients as they journey through the health care system. It is a system based on a set of shared values and beliefs. It is an integrated set of policies, procedures and work practices that are used to monitor and improve patient safety. It recognises the potential for errors to occur and the need to establish robust defences to ensure that these errors do not result in adverse events.

What are the key attributes of a successful Patient Safety Management System?

A successful Patient Safety Management System provides a systematic, explicit and comprehensive process for managing the risks that patients face in a health care setting. It must be embedded in the organisation's culture of work and be reflected by commitment from top-level management down. All successful Patient Safety Management Systems have the following elements:

- Discovery and assessment of the hazards of particular operations;
- Specifying how these hazards are to be managed; and
- What is to be done if things, despite their best endeavours, go wrong.

The most common taxonomy used to delineate system risks recognises human, operational and environmental contributing factors. However decades of research have demonstrated that of these three elements the vast majority of errors can be attributed to some form of human error, usually slips and lapses. Patient safety management systems are designed to anticipate and manage those risks.

Is patient safety management the same as quality management?

Quality and patient safety management system are based on the same principles, they are both planned and managed and depend on measurement, monitoring and improvement. However there are also differences of emphasis, in particular, patient safety management focuses on potential risks rather than whether outcomes of care have been maximised. A Patient Safety Management System recognises that human and organisational errors will never by eliminated and works to ensure that actions are taken to minimise the safety risks associated with patient care.

Who is responsible for the Patient Safety Management System?

There are various levels of responsibility for a Patient Safety Management System. At the highest level, the Commonwealth, States and Territories are ultimately responsible for patient safety and this is achieved through the legislative and regulatory framework within which our health services operate. In an operational sense the levels of responsibility may be summarised as follows:

- **Governing bodies/CEOs a**re responsible for an area or network that is usually based on more than one facility and or service. They are responsible for policy that relates to patient safety (*see draft checklist on page 4*);

- **Managers/clinician managers a**re responsible for a facility or department in a facility. There focus is on procedures in support of organisational policy (*see draft checklist on page 6)*;

- **Clinicians** are responsible for day to day practice within their sphere of work (*see draft checklist on page 8)*; and

- **Consumers** also have responsibilities to be active participants in the Patient Safety Management System (*see draft checklist on page 10).*

How do you know if your Patient Safety Management System is successful?

A successful Patient Safety Management System will have the following characteristics:

- Demonstrated senior management commitment to patient safety;
- Agreed policy regarding patient safety and an effective set of operating procedures;
- Single point of accountability for patient safety;
- Systematic approach is taken to the identification and investigation of patient safety risks;
- Systematic approach is taken to manage all sources of patient safety risks;
- Process of review and evaluation exists; and
- Training and education programme for the staff that addresses patient safety.

The attached checklists have been provided to assist members of governing bodies and their CEOs, managers/clinician managers, clinicians and patients in their understanding of the part they play in a patient management safety system.

A CHECK LIST FOR MEMBERS OF GOVERNING BODIES AND CEOs

- You demonstrate commitment to patient safety. You:
  - Are actively involved in the PSMS;
  - Have processes in place to demonstrate that all staff and patients are familiar with your PSMS and how it applies to them;
  - Actively encourage all staff to participate in the PSMS;
  - Have allocated appropriate resources to the PSMS;
  - Receive regular reports on patient safety issues; and
  - Provide timely feedback on the reports you receive.

- Your organisation has an agreed policy regarding patient safety and a set of operating procedures. You:
  - Have approved the policy that covers patient safety;
  - Ensure the patient safety policy aligns with other risk management policies;
  - Have a process in place that ensures all staff understand the patient safety policy and supporting procedures; and
  - Have a process in place that ensures all patients are aware of the patient safety policy and supporting procedures.

- Your organisation has a single point of accountability for patient safety. You:
  - Have a clearly defined accountability hierarchy for patient safety that extends to the CEO;
  - Have processes in place to ensure all staff understand how the accountability structure works; and
  - Ensure that if a patient safety committee is established to support the accountability hierarchy it includes representatives from across the organisation and should also include a consumer representative.

- Your organisation takes a systematic approach to the identification of patient safety risks. Your organisation:
  - Has a staff instigated reporting system;
  - Uses all available patient feedback processes to identify safety risks;
  - Ensures staff and patients are encouraged to report;
  - Has a policy that ensures confidentiality of reports is maintained; and
  - Ensures timely feedback is provided to staff and patients who report risks.

- Your organisation takes a systematic approach to manage all sources of patient safety risks. Your organisation:
  - Uses objective criteria to evaluate risks associated with patient safety;
  - Has processes in place to ensure identified risks are analysed, investigated and ranked;
  - Uses treatment plans to eliminate, avoid or reduce risks;
  - Has a system in place to monitor the status of each identified patient safety hazard; and
  - Ensures that staff are aware of the treatment plans.

- Your organisation has a process to evaluate how the patient safety management system is working. Your organisation:
  - Has a plan to review the patient safety management systems policy and procedures;
  - Ensures that treatment plans are evaluated to confirm that they are working;

- Allocates adequate resources to the evaluation process; and
- Involves staff at all levels in the evaluation process.

- Your organisation takes a systematic approach to training and education for all staff. Your organisation:
  - Has an effective patient safety related induction-training programme for all staff (including the governing body and CEO); and
  - Provides on-going training and education for all staff on topics relevant to patient safety.

A CHECKLIST FOR MANAGERS/CLINICIAN MANAGERS

- There is demonstrated senior management commitment to patient safety. You:
  - Are aware of senior management active involvement in patient safety;
  - Receive adequate resources to provide your part of an effective patient safety management system; and
  - Report regularly and receive timely feedback from senior management on patient safety issues.

- Your organisation has an agreed policy regarding patient safety and a set of operating procedures. You:
  - Have an approved set of operating procedures that covers patient safety and these conform to your organisations policy on patient safety;
  - Have aligned your patient safety procedures with other risk management procedures;
  - Ensure that your staff understand the PSMS and how it applies to them;
  - Ensure that your patients are aware of the PSMS and how it applies to them; and
  - Encourage your staff and patients to participate in the PSMS.

- There is a single point of accountability for patient safety. You:
  - Have a clearly defined and accountable person for patient safety in your area of responsibility;
  - Ensure that if you establish a patient safety committee it includes relevant representatives from across the organisation and should also include a consumer representative;
  - Ensure all your staff understands how the accountability structure works; and
  - Ensure your patients are aware of the accountability structure.

- A systematic approach is taken to the identification of patient safety risks. You:
  - Use a staff instigated reporting system;
  - Use patient feedback processes to identify safety risks;
  - Encourage staff and patients to report;
  - Have procedures in place to maintain confidentiality of reports; and
  - Provide timely feedback to staff and patients who report risks.

- A systematic approach is taken to manage all sources of patient safety risks. You:
  - Use objective criteria to evaluate risks associated with patient safety;
  - Have processes in place to analyse, investigate and rank identified risks;
  - Use treatment plans to eliminate, avoid or reduce risks;
  - Have processes in place to monitor the status of each identified patient safety hazard; and
  - Ensure staff and patients are aware of these treatment plans.

- Your organisation has a process to evaluate how the patient safety management system is working. You:
  - Have a plan to review the patient safety management systems procedures;
  - Ensures that treatment plans are evaluated to confirm that they are working;
  - Use allocated resources to support the evaluation process; and

- Involve your staff at all levels in the evaluation process.

- Your organisation has a training and education programme for all staff. You
  - Ensure that your staff attends induction patient safety related training;
  - Provide on-going training and education for all your staff on topics relevant to patient safety in your area.

A CHECKLIST FOR CLINICIANS

- There is demonstrated senior management commitment to patient safety. You are:
  - Aware of senior management involvement in the PSMS;
  - Familiar with the PSMS and how it applies to you;
  - Actively encouraged to participate in the PSMS; and
  - Aware that the PSMS is appropriately resourced.

- Your organisation has an agreed policy regarding patient safety and an effective set of operating procedures. You are:
  - Familiar with the senior management approved policy and operating procedures that covers patient safety;
  - Aware that the patient safety policy and procedures aligns with other risk management policies and procedures; and
  - Involved in the process of policy and operating procedure review.

- There is a single point of accountability for patient safety. You:
  - Know who the single point of accountability for patient safety is in your area;
  - Understand how the accountability structure works; and
  - Know that if a patient safety committee is established it includes relevant representatives from across the organisation and should include a consumer representative.

- A systematic approach is taken to the identification of patient safety risks. You
  - Actively participate in a staff instigated reporting system;
  - Understand that patient feedback processes are also used to identify safety risks;
  - Are encouraged to report;
  - Encourage your patients to report;
  - Know that confidentiality of reports is maintained; and
  - Receive timely feedback when you report risks.

- A systematic approach is taken to manage all sources of patient safety risks. You:
  - Know the criteria that are used to evaluate risks associated with patient safety;
  - Participate in the analysis, investigation and ranking of identified risks;
  - Participate in the development of treatment plans to eliminate, avoid or reduce risks;
  - Are aware of the status of each patient safety hazard that has an effect on your area; and
  - Participate in the evaluation of treatment plans to confirm that they are working.

- Your organisation has a process to evaluate how the patient safety management system is working. You:
  - Participate in the review of patient safety management systems procedures; and
  - Participate in the evaluation of treatment plans to confirm that they are working.

- Your organisation has a training and education programme for the staff that deals with patient safety. You:
    - Attended induction patient safety related training; and
    - Receive on-going training and education on topics relevant to patient safety in your area.

A CHECKLIST FOR PATIENTS

- There is demonstrated senior management commitment to patient safety. You are:
  - Aware that senior management is actively involved in the PSMS;
  - Aware of the PSMS and how it applies to you; and
  - Actively encouraged to participate in the PSMS.

- The acute care facility in which you are being treated has an agreed policy regarding patient safety and an effective set of operating procedures. You are:
  - Aware of the senior management approved policy and procedures that covers patient safety;
  - Aware that the patient safety policy and procedures aligns with other risk management policies and procedures; and
  - Encouraged to be involved in the process of policy and operating procedure review.

- There is a single point of accountability for patient safety. You:
  - Know who is accountable for patient safety in your area;
  - Understand who that person reports to; and
  - Are aware that if a patient safety committee is established in your area it should include a consumer representative.

- A systematic approach is taken to the identification of patient safety risks. You
  - Are aware that patient feedback processes are used to identify safety risks;
  - Are encouraged to report;
  - Understand that confidentiality of reports is maintained; and
  - Receive feedback when you report risks.

- A systematic approach is taken to manage all sources of patient safety risks. You:
  - Are aware of the criteria that are used to evaluate risks associated with patient safety;
  - Might be invited to participate in the investigation of an identified risk;
  - Might be invited to participate in the development of a treatment plan to eliminate, avoid or reduce risks; and
  - Are aware of the status of each patient safety hazard that has an effect on your area.

- Your organisation has a process to evaluate how the patient safety management system is working. You:
  - Are aware that there is an evaluation process.

- The acute care facility in which you are being treated has a training and education programme for the staff. You:
  - Are aware that all staff attend induction training and receive ongoing patient safety related training.

References

[i] Thomas EJ, Studdert DM, Runciman WB et al. 2000. A comparison of iatrogenic injury studies in Australia and the United States 1: context, methods, casemix, population, patient and hospital characteristics. *Int J Qual Health Care 12: 371-8.*

[ii] Hudson P, Applying the lessons of high risk industries to health care. Qual Saf Health Care 2003; 12 (Suppl 1):i7- i12

[iii] CASA, Safety Management Systems What's in it for you? July 2002. www.casa.gov.au

[iv] Reason, J. "A systems approach to organisational error". Ergonomics 38:1708-1721