Standard 1

Governance for Safety and Quality in Health Service Organisations

Safety and Quality Improvement Guide

October 2012

Australian Commission on Safety and Quality in Health Care

Acknowledgements

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The National Safety and Quality Health Service Standards

The *National Safety and Quality Health Service (NSQHS) Standards*[1] were developed by the Australian Commission on Safety and Quality in Health Care (the Commission) in consultation and collaboration with jurisdictions, technical experts and a wide range of other organisations and individuals, including health professionals and patients.

The primary aims of the *NSQHS Standards* are to protect the public from harm and to improve the quality of care provided by health service organisations. These Standards provide:

- a **quality assurance** mechanism that tests whether relevant systems are in place to ensure minimum standards of safety and quality are met

- a **quality improvement** mechanism that allows health service organisations to realise developmental goals.

Safety and Quality Improvement Guides

The Commission has developed Safety and Quality Improvement Guides (the Guides) for each of the 10 *NSQHS Standards*. These Guides are designed to assist health service organisations to align their quality improvement programs using the framework of the *NSQHS Standards*.

The Guides are primarily intended for use by people who are responsible for a part or whole of a health service organisation. The structure of the Guides includes:

- introductory information about what is required to achieve each criterion of the Standard

- tables describing each action required and listing:
  - key tasks
  - implementation strategies
  - examples of the outputs of improvement processes

- additional supporting resources (with links to Australian and international resources and tools, where relevant).

Direct links to these and other useful resources are available on the Commission's web site:

www.safetyandquality.gov.au

The Guides present **suggestions** for meeting the criteria of the Standards, which should not be interpreted as being mandatory. The examples of suggested strategies and outputs of improvement processes are **examples only**. In other words, health service organisations can choose improvement actions that are specific to their local context in order to achieve the criteria. The extent to which improvement is required in your organisation will heavily influence the actions, processes and projects you undertake.

You may choose to demonstrate how you meet the criteria in the Standards using the example outputs of improvement processes, or alternative examples that are more relevant to your own quality improvement processes.

Additional resources

The Commission has developed a range of resources to assist health service organisations to implement the *NSQHS Standards*. These include:

- a list of available resources for each of the *NSQHS Standards*

- an *Accreditation Workbook for Hospitals* and an *Accreditation Workbook for Day Procedure Services*

- *A Guide for Dental Practices* (relevant only to Standards 1–6)

- a series of fact sheets on the *NSQHS Standards*

- frequently asked questions

- a list of approved accrediting agencies

- slide presentations on the *NSQHS Standards*.

Overarching NSQHS Standards

Standard 1: Governance for Safety and Quality in Health Service Organisations, and *Standard 2: Partnering with Consumers* set the overarching requirements for the effective application of the other eight *NSQHS Standards* which address specific clinical areas of patient care.

Standard 1 outlines the broad criteria to achieve the creation of an integrated governance system to maintain and improve the reliability and quality of patient care, and improve patient outcomes.

Standard 2 requires leaders of a health service organisation to implement systems to support partnering with patients, carers and other consumers to improve the safety and quality of care. Patients, carers, consumers, clinicians and other members of the workforce should use the systems for partnering with consumers.

Core and developmental actions

The *NSQHS Standards* apply to a wide variety of health service organisations. Due to the variable size, structure and complexity of health service delivery models, a degree of flexibility is required in the application of the standards.

To achieve this flexibility, each action within a Standard is designated as either:

CORE
– considered fundamental to safe practice

OR

DEVELOPMENTAL
– areas where health service organisations can focus activities or investments that improve patient safety and quality.

Information about which actions have been designated as core or developmental is available on the Commission's web site.

Quality improvement approaches in health care

Approaches to improving healthcare quality and safety are well documented and firmly established. Examples of common approaches include Clinical Practice Improvement or Continuous Quality Improvement. The Guides are designed for use in the context of an overall organisational approach to quality improvement, but are not aligned to any particular approach.

Further information on adopting an appropriate quality improvement methodology can be found in the:

NSW Health Easy Guide to Clinical Practice Improvement[2]

CEC Enhancing Project Spread and Sustainability[3]

Institute for Healthcare Improvement (US)[4]

The National Safety and Quality Health Service Standards (continued)

Roles for safety and quality in health care

A range of participants are involved in ensuring the safe and effective delivery of healthcare services. These include the following:

- **Patients and carers**, in partnership with health service organisations and their healthcare providers, are involved in:
  - making decisions for service planning
  - developing models of care
  - measuring service and evaluating systems of care.

  They should participate in making decisions about their own health care. They need to know and exercise their healthcare rights, be engaged in their healthcare, and participate in treatment decisions.

  Patients and carers need to have access to information about options and agreed treatment plans. Health care can be improved when patients and carers share (with their healthcare provider) issues that may have an impact on their ability to comply with treatment plans.

- The role of **clinicians** is essential. Improvements to the system can be achieved when clinicians actively participate in organisational processes, safety systems, and improvement initiatives. Clinicians should be trained in the roles and services for which they are accountable. Clinicians make health systems safer and more effective if they:
  - have a broad understanding of their responsibility for safety and quality in healthcare
  - follow safety and quality procedures
  - supervise and educate other members of the workforce
  - participate in the review of performance procedures individually, or as part of a team.

  When clinicians form partnerships with patients and carers, not only can a patient's experience of care be improved, but the design and planning of organisational processes, safety systems, quality initiatives and training can also be more effective.

- The role of the **non-clinical workforce** is important to the delivery of quality health care. This group may include administrative, clerical, cleaning, catering and other critical clinical support staff or volunteers. By actively participating in organisational processes – including the development and implementation of safety systems, improvement initiatives and related training – this group can help to identify and address the limitations of safety systems. A key role for the non-clinical workforce is to notify clinicians when they have concerns about a patient's condition.

- The role of **managers in health service organisations** is to implement and maintain systems, resources, education and training to ensure that clinicians deliver safe, effective and reliable health care. They should support the establishment of partnerships with patients and carers when designing, implementing and maintaining systems. Managing performance and facilitating compliance across the organisation is a key role. This includes oversight of individual areas with responsibility for the governance of safety and quality systems. Managers should be leaders who can model behaviours that optimise safe and high quality care. Safer systems can be achieved when managers in health service organisations consider safety and quality implications in their decision making processes.

- The role of **health service senior executives and owners** is to plan and review integrated governance systems that promote patient safety and quality, and to clearly articulate organisational and individual safety and quality roles and responsibilities throughout the organisation. Explicit support for the principles of consumer centred care is key to ensuring the establishment of effective partnerships between consumer, managers, and clinicians. As organisational leaders, health service executives and owners should model the behaviours that are necessary to implement safe and high quality healthcare systems.

Terms and definitions

Accreditation: A status that is conferred on an organisation or an individual when they have been assessed as having met particular standards.

Advance care directive: A set of documents containing instructions that consent to, or refuse, specified medical treatments and that articulate care and lifestyle preferences in anticipating future events or scenarios. They become effective in situations where the person is no longer able to make decisions. For this reason, advance care directives are also referred to as living wills. An advance care directive has legal status and is part of the separate legislative arrangements in each State and Territory in Australia.[15]

Advance care plan: Instructions that communicate the wishes and goals of patients for their care at the end of life.[7] This may include their preferences for the future use of specified medical treatments such as cardiopulmonary resuscitation but the document does not carry legal status.

Advance care planning: The process of preparing for likely scenarios near the end of life. This includes discussion of a person's understanding of their medical condition and prognosis, values, preferences and personal and family resources.[5] It may or may not include the development of documents such as advance care directives.

Adverse event: An incident in which harm resulted to a person receiving care.

Clinical governance: A system through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care. This is achieved by creating an environment in which there is transparent responsibility and accountability for maintaining standards and by allowing excellence in clinical care to flourish.[6]

Clinical indicators: Measures or benchmarks that enable health service organisations to compare themselves against similar health services.

Clinical audit: A systematic process of improving the quality of patient care by looking at current practice and modifying it where necessary.[7]

Consumers: Patients and potential patients, carers and organisations representing consumers' interests.

Continuous improvement: A systematic, ongoing effort to raise an organisation's performance as measured against a set of standards or indicators.

Credentialing: The formal process used to verity the qualifications, experience, professional standing and other relevant professional attributes of medical practitioners for the purpose of forming a view about their competence, performance and professional suitability to provide safe, high quality healthcare services within specific organisational environments.

Terms and definitions (continued)

Flexible standardisation: Flexible standardisation recognises the importance of standardisation of processes to improve patient safety. However, the standardisation of any process, and related data sets and participants, must be designed and integrated to fit the health service organisations' context, and patient and staffing profiles. These will vary widely as health service organisations will have differing functions, size and organisation with respect to service delivery mode, location and staffing. Tools, processes and protocols should be based on best available evidence and the requirements of jurisdictions, external policy and legislation.

Governance: The set of relationships and responsibilities established by a health service organisation between its executive, workforce and stakeholders (including consumers). Governance incorporates the set of processes, customs, policy directives, laws and conventions affecting the way an organisation is directed, administered or controlled. Governance arrangements provide the structure through which the corporate objectives (social, fiscal, legal, human resources) of the organisation are set and the means by which the objectives are to be achieved. They also specify the mechanisms for monitoring performance. Effective governance provides a clear statement of individual accountabilities within the organisation to help in aligning the roles, interests and actions of different participants in the organisation to achieve the organisation's objectives. Governance includes both corporate and clinical governance.

Incident: An event or circumstance that resulted, or could have resulted, in unintended and/or unnecessary harm to a person and/or a complaint, loss or damage.

Outputs: The results of your safety and quality improvement actions and processes. Examples of outputs are provided in this guide. They are examples only and should not be read as being checklists of evidence required to demonstrate achievement of the criterion. Outputs will be specific to the actions, processes and projects undertaken in your context which will be influenced by your existing level of attainment against the criterion and extent to which improvement has been required.

Risk management: The design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the institution.

Scope of clinical practice: The extent of an individual medical practitioner's approved clinical practice within a particular organisation based on the individual's credentials, competence, performance and professional suitability and the needs and capability of the organisation.

Standard 1:
Governance for Safety and Quality in Health Service Organisations

Health service organisation leaders implement governance systems to set, monitor and improve the performance of the organisation and communicate the importance of the patient experience and quality management to all members of the workforce. Clinicians and other members of the workforce use the governance systems.

The intention of this Standard is to:

Create integrated governance systems that maintain and improve the reliability and quality of patient care, as well as improve patient outcomes.

Context:

This Standard provides the safety and quality governance framework for health service organisations. It is expected that this Standard will apply to the implementation of all other Standards in conjunction with *Standard 2: Partnering with Consumers.*

Introduction

Standard 1 provides the safety and quality governance framework for health service organisations. The Standard seeks to support development of integrated governance systems that maintain and improve the reliability and quality of patient care, as well as improve patient outcomes.

This Standard requires health service organisations to establish and maintain systems for ensuring accountability and responsibility for delivery of safe, high quality care. The Standard does not specify how a health service organisation should develop or implement its governance systems. Rather, the Standard provides a framework to enable the organisation to develop and implement its own comprehensive governance systems, taking into account local needs and values.

Implementing systems to ensure effective governance for safety and quality

Actions required to achieve each criterion are detailed in the Standard. This Guide has been developed to assist those responsible for the implementation of this standard to complete each action and achieve the criteria in the Standard.

The governing body of a health service organisation is responsible for governing all organisational domains of activity including business performance, human resources management, information technology, work health and safety and the safety and quality of the product or service the organisation produces or delivers. Ultimately, responsibility for ensuring the integrity and effectiveness of the governance system rests with the governing body.

In the private sector, the governing body is usually a corporate board. Many health service organisations are small businesses that are owned, operated and governed by clinicians who also provide the organisation's services. In the public sector, governance structures are often complex. Responsibility for ensuring the integrity of governance systems may be shared between senior executives, boards, government departments, individuals and various statutory authorities.

Good governance has eight major characteristics. It is participatory, consensus oriented, accountable, transparent, responsive, effective and efficient, equitable and inclusive, and follows the rule of law.[8-9]

Standard 1:
Governance for Safety and Quality
in Health Service Organisations (continued)

Good clinical governance requires:

- strong strategic and cultural leadership of clinical services, focusing on:
  – effective planning to enable development and improvement opportunities to be captured
  – cultural leadership which requires and prioritises safety and quality and supports continuous improvement
  – allocating resources appropriately, to support the delivery of quality care
- clarity of responsibility for managing the safety and quality of clinical care and delegation of the necessary management authority through the health service organisation's senior officer
- reliable processes for ensuring systems for the delivery of clinical care that are designed and performing well and clinicians who are fully engaged in the design, monitoring and development of service delivery systems
- effective use of data and information to monitor and report on performance, throughout the health service organisation to the governing body
- well-designed systems for identifying and managing risk.

The engagement of clinicians in the design of clinical and organisational systems and the monitoring, assurance and improvement of quality is critical for sustainable governance. Ultimately, responsibility for ensuring the integrity and effectiveness of the governance system rests with the governing body.

Criteria to achieve the Governance for Safety and Quality in Health Service Organisations Standard:

Governance and quality improvement systems

There are integrated systems of governance to actively manage patient safety and quality risks.

Clinical practice

Care provided by the clinical workforce is guided by current best practice.

Performance and skills management

Managers and the clinical workforce have the right qualifications, skills and approach to provide, safe, high-quality health care.

Incident and complaints management

Patient safety and quality incidents are recognised, reported and analysed and this information is used to improve safety systems.

Patient rights and engagement

Patient rights are respected and their engagement in their care is supported.

For the purposes of accreditation, please check the Commission's web site regarding actions within these criteria that have been designated as core or developmental.

Criterion: Governance and quality improvement system

There are integrated systems of governance to actively manage patient safety and quality risks

A health service organisation's governance system is an important element to safeguard and improve safety and quality of care. Evidence suggests a significant correlation between the effective governance system of a health service organisation and the level of performance achieved within that organisation.[10]

Effective governance involves setting direction, making policy and strategy decisions, overseeing and monitoring organisational performance and ensuring overall accountability for a service. Effective governance is also about making informed organisational policy choices, such as defining the mission and goals, determining how to achieve these objectives, defining what resources are necessary and how best to secure them, and determining how to measure the organisation's overall impact.[11]

Systems for delegating and exercising authority, accountability and responsibility are essential elements of good governance. 'Authority' refers to the scope given to members of the workforce at each level of the health service organisation to carry out their responsibilities, the individual's authority to act, the resources available and the boundaries of their role. 'Accountability' requires clear definition of the responsibilities of individuals, functions and committees for safe, high quality services. Effective governance also requires personal assumption of responsibility, with members of the workforce accepting personal ownership of their actions and their role in the safety and quality of services provided by their health service organisation.

'Risk management' is the identification, assessment and prioritisation of risks followed by the systematic application of resources to minimise, monitor and control the probability and/or impact of adverse events or to maximise the realisation of opportunities.[12] Risk management is an essential component of governance as provision of care carries an element of risk to patients, providers and the health service organisation within which care is delivered. Clinical risk management is an approach to improving the quality and safe delivery of health care by placing special emphasis on identifying circumstances that put patients at risk of harm and by acting to prevent or control those risks. The objectives of clinical risk management are to maintain a safe environment for patients, the workforce and visitors.

Measurement is an effective tool for driving change. Measuring clinical performance should be used to determine if short-term priorities and long-term strategic goals are being achieved. Measures should include compliance with legislative, regulatory and policy requirements, process indicators that have supporting evidence to link them to outcomes and indicators of the outcomes of care.[13]

All members of the workforce should be able to access information that identifies areas for improvement. This information needs to be reliable, timely, useful and not a burden to collect.

Actions required	Implementation strategies

1.1 Implementing a governance system that sets out the policies, procedures and/or protocols for:
- **establishing and maintaining a clinical governance framework**
- **identifying safety and quality risks**
- **collecting and reviewing performance data**
- **implementing prevention strategies based on data analysis**
- **analysing reported incidents**
- **implementing performance management procedures**
- **ensuring compliance with legislative requirements and relevant industry standards**
- **communicating with and informing the clinical and non-clinical workforce**
- **undertaking regular clinical audits**

1.1.1 An organisation-wide management system is in place for the development, implementation and regular review of policies, procedures and/or protocols	**Key tasks:** • Develop or adopt a comprehensive suite of policies and associated procedures and protocols addressing safety and quality; establish mechanisms to keep them current; and communicate them effectively to the workforce • Develop or adopt a legislative compliance system that incorporates a compliance register or log and policies, procedures and protocols to ensure the organisation is kept regularly and reliably updated and responds to relevant regulatory changes, compliance issues and case law • Review the organisation's committee structure to ensure it supports the governing body and senior executive and clinicians to implement and maintain the governance system • Maintain organisational accreditation through an approved accrediting agency **Suggested strategies:** The governing body, through the chief executive, is responsible for ensuring the development, regular review and maintenance of a comprehensive suite of organisational policies and associated procedures and protocols. These need to address clinical safety and quality and are consistent with the regulatory obligations of the organisation, governing body and senior executive. Adoption by the governing body of a high level clinical governance policy, which may specify the governing body's role, responsibilities, and accountabilities; delegations to senior executives; and approach to leading and monitoring organisational performance, will establish the foundations for the health service organisation's clinical governance system. While the governing body may authorise some high level clinical governance policies itself, clear delegation of responsibility for developing and maintaining the policies, procedures and protocols is also consistent with good governance. You should nominate an appropriate 'custodian' for each policy to ensure processes for developing, reviewing and maintaining policies, procedures and protocols (and monitoring compliance with them) are documented and implemented. You are required to provide clear documentation of authority to amend or endorse each policy and associated procedure or protocol, together with clarity of the roles and responsibilities of individuals and organisational committees in that process. You may develop and adapt clinical policies, procedures and protocols at different levels within the organisation according to delegated authorities, but you need to integrate all policies, procedures and protocols into a single coherently-designed system in order to ensure their utility.

Actions required	Implementation strategies
1.1	(continued)

(continued)

1.1.1 An organisation-wide management system is in place for the development, implementation and regular review of policies, procedures and/or protocols

The organisation's approach to and expectations for delivery and/or support of clinical care systems should be described in organisational policies, procedures and protocols. These will need to be endorsed at a high level of governance or management in the organisation. These clinical care systems need to cover the areas of:

- monitoring and reporting of clinical system performance
- clinical risk management
- adverse event reporting and management, including reporting on sentinel events and other events of significance
- management of complaints and compliments
- escalation of quality concerns to senior management and the governing body
- open disclosure
- qualified privilege and/or statutory immunity
- credentialing and defining scope of clinical practice, including for locums, clinicians from an agency and other short-term employees
- clinician engagement in documented peer review in accordance with accepted guidelines and standards
- clinician engagement in planned, systematic audit of clinical services in accordance with agreed protocols and schedules
- performance development of all members of the organisation's workforce, including the clinical workforce, in accordance with accepted standards and guidelines
- engagement of consumers in strategic planning, service reviews, provision of feedback and monitoring of organisational performance.

Drafting of policies, procedures and protocols provides you with an opportunity to clearly convey the organisation's cultural approach to:

- learning from experience
- supporting all members of the workforce to participate in the organisation's safety and quality system
- providing professional support to individuals who are involved in incidents, adverse events and near misses, including patients and members of the workforce.

You can support effective implementation of the organisational safety and quality policy system by:

- ensuring all members of the workforce have ready access to the relevant policies, procedures and protocols
- ensuring that position descriptions and performance development policies require all members of the workforce to comply with their roles, responsibilities, and accountabilities, as well as organisational policies and associated procedures and protocols.

To meet its legal obligations, your organisation should have a well-designed and documented legislative compliance system. This should incorporate a compliance register or log, and procedures or protocols to ensure the organisation is regularly and reliably updated and can respond to:

- relevant regulatory changes
- compliance issues and
- case law.

Actions required	Implementation strategies
1.1	**(continued)**

(continued)

1.1.1 An organisation-wide management system is in place for the development, implementation and regular review of policies, procedures and/or protocols

The industry standards that apply will vary between health service organisations. You should identify those standards that apply to your organisation and build the necessary implementation and monitoring of compliance in to the processes. Industry standards may include:

- service specific standards such as mental health, pathology or medical imaging where these services are applied
- Standards Australia standards for items such as user identification labels for use of fluid bags, syringes and drug administration lines (AS 4940:2002)
- guidance developed by peak bodies, such as the *Australian Medicines Handbook*.

Responsibility for maintenance and control of the compliance system should be allocated to a defined individual or organisational position to facilitate its effective implementation and maintenance.

Committees can assist the governing body and senior executive to maintain the organisation's policies, procedures and protocols. You should periodically review the organisational committee structure to ensure its continued relevance and utility. Committee charters that clearly define the role of each committee, its terms of reference, and whether it is advisory or has delegated authority to assist to maintain the organisation's safety and quality policies and associated procedures and protocols, will assist committees and managers to work together efficiently and effectively. It is good practice to review the composition and performance of committees regularly.

Accreditation by an approved accrediting agency will provide assurance to the governing entity, senior executive, clinicians and other stakeholders about the design and integrity of your organisation's system of governance.

Outputs of improvement processes may include:

- a documented governance system that sets out the policies, procedures and/or protocols for:
  - establishing and maintaining a clinical governance framework
  - identifying safety and quality risks
  - collecting and reviewing performance data
  - implementing prevention strategies based on data analysis
  - analysing reported incidents
  - implementing performance development procedures
  - ensuring compliance with legislative requirements and relevant industry standards
  - communicating with the clinical and non-clinical workforce
  - undertaking regular clinical audits
- a committee structure detailing terms of reference and linkages.

1.1.2 The impact on patient safety and quality of care is considered in business decision making

Key tasks:

- **Review the organisation's strategic and business planning processes to ensure they explicitly capture safety and quality strategies and initiatives**
- **Review the organisation's clinical safety and quality plan to ensure it is effectively integrated into business and strategic planning processes**
- **Review templates for submitting business proposals to the governing body and senior executive and ensure they facilitate appropriate consideration of the impact of the proposal on safety and quality**

Suggested strategies:

You are required to include safety and quality strategies, objectives and goals prominently in the organisation's strategic plan. This should establish a clear direction and accountability for assurance of and improvement in safety and quality over the strategic period.

Actions required	Implementation strategies
1.1	(continued)

Actions required	Implementation strategies
(continued) **1.1.2** The impact on patient safety and quality of care is considered in business decision making	You should re-assess current clinical risks and opportunities annually. Defining achievable and measurable safety and quality outcomes, and defining relevant actions in an annual safety and quality plan, will assist the organisation to address safety and quality risks and opportunities. You should explicitly identify safety and quality risks and opportunities and allocate resources to address them through the organisational business/operational planning processes. This will enable the safety and quality plan to be implemented. You should adopt policies, procedures or protocols where all proposals for service development or change explicitly identify the implications for patient safety and quality. This should also include any clinical risks associated with the proposal and how they will be managed. The clinical workforce should be trained and supported to take into consideration safety and quality in the development of business cases and influencing business decisions. **Outputs of improvement processes may include:** • strategic, business and quality plans detailing clinical risk and safety objectives • business proposal templates • minutes of strategic and decision making committees.

1.2 The board, chief executive officer and/or other higher level of governance within a health service organisation taking responsibility for patient safety and quality of care	
1.2.1 Regular reports on safety and quality indicators and other safety and quality performance data are monitored by the executive level of governance	**Key tasks:** • Review the template or calendar for reporting to the governing entity and senior executive on safety and quality indicators and data, and consider whether over time it covers all services, locations, major risks, all dimensions of quality and all key elements of the quality management system • Review the suite of safety and quality indicators and data regularly reported to the governing entity and senior management team and consider whether they are relevant and comprehensive • Review the agenda template for meetings of the governing body and senior executive team and consider whether sufficient time and prominence is allocated to safety and quality • Review the organisation's audit program for the adequacy of its safety and quality content **Suggested strategies:** Governing bodies and senior executive should prioritise and allocate an appropriate amount of time to reviewing clinical governance issues (as a guide, high performing governing entities may spend equivalent time at meetings on clinical governance as they spend on non-clinical business governance). Members of the governing body have an independent obligation to satisfy themselves of the integrity and performance of the clinical governance systems.

Actions required	Implementation strategies

1.2 The board, chief executive officer and/or other higher level of governance within a health service organisation taking responsibility for patient safety and quality of care

(continued)

(continued)

1.2.1 Regular reports on safety and quality indicators and other safety and quality performance data are monitored by the executive level of governance

The governing body and senior managers should review a 'dashboard' of the organisation's most important quality metrics. This can assist the governing body to fulfil some of its clinical governance responsibilities.

Relevant indicators may include:

- key national priority indicators and regulatory requirements
- a selection of other metrics covering safety, clinical effectiveness, patient experience, access, efficiency and appropriateness
- trends in adverse event, incident and near miss reporting
- risk ratings
- compliance with best practice pathways.

In addition to monitoring indicators of the type listed above, high performing governing bodies and senior executive teams should devote significant time to receiving structured and in-depth reports and audits about the design and performance of relevant clinical and organisational systems. You should develop a calendar of reports for the governing body and senior management teams over a defined period, such as 1–3 years. Reports may be organised in different ways – for example, they may address quality systems in high risk areas (such as infection control, medication management), specific clinical services (such as cardiac services) or specific locations (such as services provided from a particular campus or home-based services).

The governing body and senior executive should have access to appropriate clinical advice at meetings to assist them to interpret audits and performance reports. This may be achieved by including clinicians as members of the governing body or executive team, seeking advice from clinicians or accessing independent advice.

The governing body and senior management team should carry out regular self-assessment of their skills and capabilities in clinical governance, to assist them to maintain and develop those skills. In undertaking succession planning, governing bodies and senior management teams should also consider whether the necessary skills and expertise are available to them.

Outputs of improvement processes may include:

- governing committee agendas and minutes
- reporting templates and calendars
- performance and reporting frameworks that address system design as well as system performance
- reports to the governing body and senior management team on clinical safety and quality issues.

Actions required	Implementation strategies
1.2 The board, chief executive officer and/or other higher level of governance within a health service organisation taking responsibility for patient safety and quality of care (continued)	

1.2.2 Action is taken to improve the safety and quality of patient care	**Key tasks:** • Review the organisational structures and delegation policies and ensure responsibility for taking action on safety and quality issues is clearly delegated • Review procedures of all committees with a clinical governance role and ensure minutes are comprehensive and there is a reliable method in place to follow up actions • Establish registries to systematically record the outcomes of internal and external clinical audits and reviews, allocate responsibility for implementation of recommended actions and regularly review progress **Suggested strategies:** The governing body and senior executive need to be confident that the organisational culture and management system support action at the appropriate level in the organisation to address safety and quality risks and opportunities. This will be achieved if: • responsibility and accountability for clinical safety and quality and risk management are delegated clearly and appropriately • resources are made available to address safety and quality risks and opportunities • the organisational culture is demonstrably founded in concepts of support, justice and accountability. You should record what was discussed and what action was proposed at each meeting of the governing body and other committees to ensure appropriate accountability. You should complete actions sheets at the conclusion of all meetings, defining what is to be done, by whom and by when, enabling progress to be reviewed and appropriate accountability to be demonstrated. Training the workforce and providing systems that support the standardisation of data entry will enable accurate auditing and comparison of information and help to resolve variation and support practice. You should ensure the outcomes of audits (internal and external) and reviews of clinical and organisational systems are collated in centralised registries, delegate responsibility to maintain those registries, and monitor and report implementation. **Outputs of improvement processes may include:** • registries that collate the outcomes of audits and reviews and demonstrate that they are acted on • agendas, meeting minutes or reports of relevant committees demonstrating action and follow through on safety and quality issues.

Actions required	Implementation strategies

1.3 Assigning workforce roles, responsibilities and accountabilities to individuals for:
- **patient safety and quality in their delivery of health care**
- **the management of safety and quality specified in each of these Standards**

1.3.1 Workforce are aware of their delegated safety and quality roles and responsibilities	**Key tasks:** • Review the governing body's charter and ensure it appropriately describes responsibility for governance • Review the organisational structure, position descriptions and contract templates of the senior executive, managers, clinicians other members of the workforce to ensure responsibility for safety and quality is clearly defined at all levels in the organisation • Review the organisation's performance development policy and ensure it appropriately incorporates leadership in safety and quality management and governance for all managers and clinicians **Suggested strategies:** The governing body is required to adopt a charter which describes the role and accountability of the governing body and its members for the safety and quality of care and will provide a foundation for a strong governance system. The governance system should be supported by: • clear definition and delegation of reporting lines and responsibilities for safety and quality • inclusion within the position descriptions and contractual responsibilities of the chief executive, managers and clinicians of clearly documented accountabilities for safety and quality of clinical care • inclusion within the position descriptions and contractual responsibilities of senior clinicians of descriptions of their roles, responsibilities and accountabilities for supervising the performance of the junior clinical workforce • consistency of safety and quality policies, procedures or protocols with the allocation of responsibilities through the organisational management system • implementation of a structured performance development system for all clinicians and managers, incorporating regular review of their engagement in safety and quality and in specific activities including peer review and audit; supervision of the junior workforce; and goal setting for future activities. **Outputs of improvement processes may include:** • position descriptions • induction and ongoing training programs • employment contracts • performance review criteria and evidence of discussions regarding clinical governance responsibilities in reviews • organisational chart and delegations policy demonstrating clinical governance reporting lines and relationships.

Actions required	Implementation strategies
	1.3 Assigning workforce roles, responsibilities and accountabilities to individuals for: • **patient safety and quality in their delivery of health care** • **the management of safety and quality specified in each of these Standards** (continued)

1.3.2 Individuals with delegated responsibilities are supported to understand and perform their roles and responsibilities, in particular to meet the requirements of these Standards	**Key tasks:** • Review the induction and training program for Board members and senior executive, to ensure they are provided the appropriate assistance to undertake their role • Review the organisation's training and performance development policies and programs for managers and senior clinicians and ensure they incorporate an appropriate emphasis on safety, quality and clinical governance • Review the clinical governance expertise of the governing entity and senior executives and ensure appropriate succession planning **Suggested strategies:** Members of the governing body and senior executive should undertake education and training in their governance role, responsibilities and accountabilities. You should ensure that the membership of the governing body includes individuals with specific clinical governance skills and competence to assist it to fulfil its responsibilities. Training in clinical governance concepts and practices, including managing for safety and quality, for managers at all levels of the organisation and senior clinicians will also support them to fulfil their responsibilities effectively. Managers with responsibility for implementing the performance development system will benefit from training to assist them to integrate safety and quality concepts into their performance development role. When developing their own performance development plans and goals, managers and senior clinicians should be encouraged to incorporate appropriate development opportunities in clinical safety, quality, leadership and risk. Incorporating specific clinical governance elements in performance review processes for managers and senior clinicians will assist to reinforce their key responsibilities for safety and quality leadership. **Outputs of improvement processes may include:** • Board induction training and evidence of attendance • training programs for the workforce in governance, clinical safety and quality, with records of attendance • succession plans for key clinical governance positions.
1.3.3 Agency or locum workforce are aware of their designated roles and responsibilities	**Key tasks:** • Review the organisation's contract templates for the purchase of clinical services. Ensure they incorporate appropriate safety, quality and clinical governance requirements of the agencies that supply a contract workforce and of the individuals who work on a contracted basis in the health service organisation. • Review policies, procedures and protocols for engaging locums and agency clinicians and ensure they incorporate clear specification of their responsibility to comply with safety, quality and clinical governance systems. • Ensure organisational policies, procedures and protocols provide for effective orientation of clinicians engaged via locum and agency arrangements to the organisation's safety, quality and clinical governance systems.

Actions required	Implementation strategies

1.3 Assigning workforce roles, responsibilities and accountabilities to individuals for:
- **patient safety and quality in their delivery of health care**
- **the management of safety and quality specified in each of these Standards**

(continued)

(continued) **1.3.3** Agency or locum workforce are aware of their designated roles and responsibilities	**Suggested strategies:** Governing bodies and senior managers should ensure contracts with suppliers of locum and short-term professionals: • clearly identify who is responsible for credentialing and defining scope of clinical practice of the workforce that is supplied through the contract, and incorporate standards, compliance and reporting requirements • clearly specify requirements for the supplied workforce to comply with the organisation's clinical governance and safety and quality policies and procedures and ensure that the locum workforce is advised of how to locate the organisation's safety and quality policies and procedures • require reporting to the organisation of designated safety and quality events • incorporate robust requirements for validating the credentials of the contracted workforce and defining scope of clinical practice. **Outputs of improvement processes may include:** • contracts with suppliers of agency and locum workforces • credentialing policies and examples of processes • position descriptions • induction checklists

1.4 Implementing training in the assigned safety and quality roles and responsibilities

1.4.1 Orientation and ongoing training programs provide the workforce with the skill and information needed to fulfil their safety and quality roles and responsibilities **1.4.2** Annual mandatory training programs to meet the requirements of these Standards **1.4.3** Locum and agency workforce have the necessary information, training and orientation to the workplace to fulfil their safety and quality roles and responsibilities **1.4.4** Competency-based training is provided to the clinical workforce to improve safety and quality	**Key task:** • **Review the organisation's orientation, education and training policies and programs and consider their adequacy with respect to ensuring members of the workforce are exposed to appropriate and effective orientation, education and training in safety, quality and clinical governance** **Suggested strategies:** Maintaining a competent and capable workforce requires education and training. Providing access to this education and training is a core responsibility of health service organisations. A health service organisation's education and training program will be most effective if: • there is a demonstrable link between the organisation's orientation, education and training program and its safety and quality systems • a demonstrable and substantial element of the organisation's orientation, education and training program for all managers and clinical professions and disciplines addresses clinical safety, quality, leadership and risk. The governing body and senior managers overseeing the effectiveness of clinical governance systems should seek to satisfy themselves that organisational policies: • define mandatory orientation, education and training requirements in relevant aspects of safety, quality, leadership and clinical risk for all members of the workforce • support provision of planned and integrated education and training to all members of the workforce, based on comprehensive and regularly-updated assessment of need

Actions required	Implementation strategies
1.4 Implementing training in the assigned safety and quality roles and responsibilities (continued)	

(continued) **1.4.1** Orientation and ongoing training programs provide the workforce with the skill and information needed to fulfil their safety and quality roles and responsibilities **1.4.2** Annual mandatory training programs to meet the requirements of these Standards **1.4.3** Locum and agency workforce have the necessary information, training and orientation to the workplace to fulfil their safety and quality roles and responsibilities **1.4.4** Competency-based training is provided to the clinical workforce to improve safety and quality	• require evaluation of the outcomes of education and training in safety, quality, leadership and risk provided to all members of the workforce • ensure appropriate records are maintained of the education and training in safety, quality, leadership and risk undertaken by each member of the workforce • provide each member of the workforce with the opportunity, through performance review and development programs, to define their education and training goals in safety, quality, leadership and risk and agree with their manager on opportunities to achieve those goals. Governing entities and senior managers should also consider whether induction and regular training in safety, quality, leadership and risk that includes orientation to relevant organisational policies, procedures and protocols are reliably provided to all members of the workforce. Provision of orientation and training covering the core elements of clinical governance and quality management systems will assist members of governing bodies and senior managers to maintain their competence and expertise in clinical governance. Training can include: • face-to-face programs • short sessions • peer review, mentoring and supervised practice • self-directed programs • online learning • external programs • formal learning programs • conferences and seminars • secondments and placements. **Outputs of improvement processes may include:** • evidence of the assessment of training need through review of incidents, near misses, adverse events, performance data, feedback from the workforce, performance reviews, system audits and policy • evidence of training opportunities and attendance • training evaluation reports.

Actions required	Implementation strategies
1.5 Establishing an organisation-wide risk management system that incorporates identification, assessment, rating, controls and monitoring for patient safety and quality	

1.5.1 An organisation-wide risk register is used and regularly monitored

1.5.2 Actions are taken to minimise risks to patient safety and quality of care

Key tasks:

- Review the organisation's risk management system and consider whether it is appropriately designed, resourced, maintained and monitored
- Consider existing sources of information about the patient safety climate, and whether additional information is needed to assess the climate reliably
- Consider whether risk management orientation, education and training is appropriately included within the organisation's education and training program
- Ensure clear allocation of roles, responsibility and accountabilities for maintaining the risk register
- Periodically review the effectiveness of the organisation's risk management system

Suggested strategies:

Ultimate responsibility for ensuring the integrity of the organisational risk management system rests with the governing body.

Commitment and leadership

Commitment and leadership can be demonstrated by:

- ensuring the organisation's risk management system is clearly documented in a suite of policies, procedures and protocols which define a vision, principles, objectives, practices, responsibilities, resources, outcomes and how outcomes will be measured
- ensuring adequate resources are allocated to the organisation's risk management system
- fostering an organisational culture that supports an unwavering focus on clinical safety and continuous improvement in identifying and managing risk
- ensuring appropriate integration of clinical and non-clinical risk in all risk systems.

Risk management

The risk management system should be regularly audited, with submission of results to senior managers and the governing body, to help assure the adequacy of its design and the integrity of its operations.

The governing body needs to provide feedback to the workforce about the planned, systematic monitoring and evaluation of patient safety performance at all levels of the organisation. This should cover all organisational services and service sites and promote continuous improvement.

Culture and engagement

The workforce (including but not limited to the clinicians) should participate in the organisational risk management system if risk management is to be effective. The clinical workforce has the best knowledge of and ability to identify risks. Effective risk management systems are open and clinicians are both encouraged and required to participate.

Actions required	Implementation strategies
1.5 Establishing an organisation-wide risk management system that incorporates identification, assessment, rating, controls and monitoring for patient safety and quality (continued)	

Actions required	Implementation strategies
(continued) **1.5.1** An organisation-wide risk register is used and regularly monitored **1.5.2** Actions are taken to minimise risks to patient safety and quality of care	You should foster engagement and participation of the workforce by: • regular provision of appropriate information about the organisation's risk management system, through system-specific orientation, education and training • regular reinforcement of information about the roles, responsibilities and accountabilities of managers, clinicians and other members of the workforce (for example, using screen savers and the Intranet) • implementation of an appropriate organisational meeting and committee structure that involves clinicians, other members of the workforce and managers at all levels of the organisation in systematic risk identification and assessment, and review of risks and their management • provision at all operational meetings of planned opportunities for members of the workforce to identify and discuss clinical safety concerns • inclusion of patient safety as a standing item on agendas for meetings of the governing body and senior executive • routine inclusion of questions about the patient safety climate in employee culture surveys • the provision of feedback regarding actions taken to mitigate risks • regular assessment of the organisational 'climate' in areas of risk, safety and quality through the use of validated survey tools. The governing body has a unique responsibility and opportunity to lead an organisational culture that is demonstrably 'just' and encourages involvement of the workforce. *A systems focus* You can achieve a systems focus through: • maintaining risk management policies, procedures and protocols in accordance with best practice and ensuring all clinical leaders, managers and other members of the workforce are familiar with them • establishing a reliable and systematic process of hazard identification across all clinical areas. This requires proactive analysis of the way systems of care are designed, to identify inherent risks. There should be opportunities for the workforce and other stakeholders to report potential or actual risks (for example, through risk reporting systems) • maintaining a comprehensive and accurate risk register or log which is used as a practical tool for risk management • assigning all risks to a 'risk owner' (who is responsible for their management and monitoring) and ensuring appropriate accountability arrangements • ensuring the organisation has a reliable system to identify and respond to hazards and risks reported by other organisations (for example, in the scientific literature and by insurers, coroners, safety and quality commissions) • conducting a planned, systematic program of in-house and external audits or reviews of the design and performance of clinical and organisational systems, with appropriate clinician engagement. The risk audit program should be incorporated into the organisation's formal audit program • ensuring the risk management system includes strategies, resources and clear accountability for remedying risks

Actions required	Implementation strategies
1.5 Establishing an organisation-wide risk management system that incorporates identification, assessment, rating, controls and monitoring for patient safety and quality (continued)	
(continued) **1.5.1** An organisation-wide risk register is used and regularly monitored **1.5.2** Actions are taken to minimise risks to patient safety and quality of care	• systematically providing appropriate information, orientation, education and training to employees, at induction and periodically thereafter • systematically monitoring and assessing performance in relation to risk, in accordance with a defined performance monitoring framework, at all levels of the organisation including at the governing body and senior executive levels. Outputs of improvement processes may include: • risk management policy, procedure, protocols, registers and assessment forms • agendas, meeting minutes or reports of relevant committees demonstrating discussion and management of risk • completed risk assessments • risk assessment training attendance and evaluation • feedback from the workforce • climate survey outcomes.
1.6 Establishing an organisation-wide quality management system that monitors and reports on the safety and quality of patient care and informs changes in practice	
1.6.1 An organisation-wide quality management system is used and regularly monitored **1.6.2** Actions are taken to maximise patient quality of care	**Key tasks:** • **Consider whether there is an organisation-wide definition of the elements of quality for clinical services (for example, effectiveness, safety and consumer experience) and if not, undertake a process to define and adopt a shared definition of quality** • **Review the structure of the organisation's quality management system – are the vision, mission, values and objectives for the organisation clearly aligned with clinical quality objectives?** • **Consider whether there is a coherent, planned and systematic schedule of audits of clinical and organisational systems, and reliable processes to capture findings and implement necessary improvements** • **Develop a calendar of presentations or reports to the governing body and senior executive on the design and performance of key clinical systems** • **Review the schedule of data and reports provided to the governing body and senior managers, to ensure it is comprehensive and relevant** **Suggested strategies:** You should have a quality management system in place which comprises the infrastructure and activities undertaken to direct and control an organisation for the purpose of improving the efficiency and effectiveness of its performance. ISO 9001 specifies the requirements for a quality management system that may be used by organisations for internal application, certification or contractual purposes. Elements of a quality management system include:[14] • management responsibility • resource management • product realisation • management, analysis and improvement.

Actions required	Implementation strategies
1.6 Establishing an organisation-wide quality management system that monitors and reports on the safety and quality of patient care and informs changes in practice (continued)	

(continued)
 	
1.6.1 An organisation-wide quality management system is used and regularly monitored
 	
1.6.2 Actions are taken to maximise patient quality of care
	To successfully implement a quality management system you should:
	
	• engage the governing body and senior management, by
	   – establishing a vision, mission and values
	   – defining stakeholders
	   – documenting a quality policy
	   – defining and aligning organisational objectives and clinical service quality objectives
	• identify key processes and the interactions needed to meet quality objectives
	• train the organisation's workforce
	• verify effective operation of the quality management system
	• manage the system by monitoring consumer satisfaction, measuring quality, and striving for continuous improvement.
	
	You should adopt an agreed organisational definition of the elements of quality for services (for example safety, effectiveness, consumer experience) to provide a common language and understanding for the design and monitoring of performance of an organisation's quality management system. The workforce and patients and carers can assist in identifying the elements of organisational services that define their quality.
	
	Measuring and monitoring consumer experience will require you to agree on consumer experience standards, review external benchmarks, review the results of both rapid feedback surveys and detailed surveys, and set indicators for measuring.
	
	An agreed definition will support the workforce and managers to design systems to deliver safe, high quality care and will enable systematic and comprehensive review of systems design, data collection and monitoring of all elements of performance.
	
	Engagement of the clinical workforce and managers in the annual quality planning process is critical to its effectiveness.
	
	Development of a planned, transparent and systematic schedule of reviews and audits of clinical and organisational systems will assist you to ensure systematic rather than opportunistic oversight of the adequacy of clinical and organisational systems.
	
	The introduction of an individual healthcare identifier in electronic health records and/or electronic medical records system will ensure correct patient identification and support clinical audit.
	
	You should conduct audits at different levels in the organisation (clinical, department, division, whole-of-organisation) which actively engage clinicians and focus on the design and performance of clinical and organisational systems. Audits will be most effective if their outcomes are applied for improvement and assurance purposes. Outcomes should therefore be reported through the performance development framework, including high level reporting to the governing body. Independent auditors or reviewers can assist to ensure a high level of assurance for the governing body. Over time, you can schedule audits to cover the range of services and locations used for the delivery of care.

Actions required	Implementation strategies

1.6 Establishing an organisation-wide quality management system that monitors and reports on the safety and quality of patient care and informs changes in practice

(continued)

Actions required	Implementation strategies
(continued) **1.6.1** An organisation-wide quality management system is used and regularly monitored **1.6.2** Actions are taken to maximise patient quality of care	It is good practice to record outcomes of clinical system audits on a register, together with proposed actions, responsibilities and evidence of implementation and follow up. This can be used to demonstrate how risks and opportunities identified through the quality management system are addressed to improve safety and continuously improve performance. The governing body and senior executive will benefit from regularly receiving comprehensive safety and quality presentations and reports from senior managers and clinicians. You should schedule these presentations in accordance with agreed selection criteria (for example, significance of risk, patient volume). Presentations that comprehensively address the adequacy of systems design, service safety and risk management, compliance with evidence-based practice, system outcomes including consumer experience, and plans to improve safety and quality and reduce risk will be most effective. Routine collection of process and outcome data and active monitoring for trends can alert clinicians, managers and the governing body of deviations from expected performance. Performance monitoring that systematically covers all clinical service areas and all locations of service delivery will be most effective. Clearly documented, robust controls to assure the ongoing accuracy, validity and comprehensiveness of information will increase confidence in data. Providing the workforce and the governing body with access to an up-to-date 'dashboard' of the organisation's most important safety and quality metrics will enable regular review and response. Suitable metrics may include: • key relevant national priority indicators and regulatory requirements • other metrics covering safety, clinical effectiveness, patient experience, access and efficiency across the organisation's range of services and service locations • trends in adverse event, incident and near miss reporting • compliance with best practice pathways. Training the workforce in the design and performance of the organisation's quality management system will be important for its success, as will periodic audit of the design and performance of the quality management system itself. You should provide support for agreed methods to act on variance and poor performance. Methods such as clinical practice improvement, 'lean thinking' and 'six sigma' have all demonstrated their effectiveness. Clinical practice improvement tools are widely available from a number of health bodies and encourage multi-disciplinary input using Plan, Do, Study, Act cycles. **Outputs of improvement processes may include:** • a quality framework • a quality plan • quality reports and presentations • policy, processes, tools and training opportunities in the use of improvement methods.

Criterion: Clinical practice

Care provided by the clinical workforce is guided by current best practice

Good clinical governance promotes clinical practice that is effective and based on evidence.[15] The progressive introduction, use, monitoring and evaluation of evidence-based clinical pathways supports the provision of effective care. This promotes an organisational culture in which evaluation of organisational and clinical performance, including clinical audit, is expected in every clinical service.[16]

Clinical effectiveness can be promoted through the development of guidelines and protocols for particular diseases and clinical interventions. The National Health and Medical Research Council's Clinical Practice Guidelines Portal provides one of the key links to clinical practice guidelines developed for use in Australian healthcare settings.[17]

Considering clinical effectiveness on its own is useful, but is enhanced by considering whether the intervention is appropriate and whether it represents value for money. In the modern health service organisation, clinical practice needs to be continually refined in the light of emerging evidence of effectiveness, but also has to consider aspects of efficiency and safety from the perspective of the individual patient and carers in the wider community.[15]

Mechanisms are also required to promote accountability of clinicians for their practice. This includes compliance with accepted clinical guidelines or pathways. Oversight of clinical practice should enable the early identification and management of practices that place patients at risk of harm.[18]

Actions required	Implementation strategies
1.7 Developing and/or applying clinical guidelines or pathways that are supported by the best available evidence	

Actions required	Implementation strategies
1.7.1 Agreed and documented clinical guidelines and/or pathways are available to the clinical workforce **1.7.2** The use of agreed clinical guidelines by the clinical workforce is monitored	**Key tasks:** • Evaluate the extent to which documented clinical guidelines or pathways have been formally adopted by the clinical workforce; the proportion of patient episodes potentially covered by clinical guidelines or pathways; and whether additional opportunities exist to adopt clinical guidelines or pathways as a quality improvement initiative • Review how compliance with and variations from evidence-based clinical guidelines or pathways are monitored, especially for high volume or high risk conditions **Suggested strategies:** You should ensure effective design and periodic review of systems for the delivery of patient care to facilitate delivery of evidence-based care. You should ensure explicit support by the governing body and senior managers for the adoption of clinical guidelines or pathways where they are available and appropriate, to assist in the provision of care that is evidence based, and unwarranted variations in care are limited. You should make resources available through organisational budget processes for implementation of clinical guidelines or pathways to provide information for clinicians to provide evidence-based care and monitor variations from recommended practice. Organisational systems that enable peer-based feedback to be provided to the clinical workforce about compliance with evidence and management of variation will support the workforce to implement evidence-based care. Effective quality management systems will produce information about the extent of variation from agreed clinical guidelines or pathways, and how such variation is managed. The workforce, senior managers and the governing body will benefit from receiving information generated through audits and other sources that enable them to monitor the proportion of care that is provided in accordance with clinical guidelines or pathways. Periodic review by the governing body and senior managers of the extent of and variations from evidence-based practice will provide assurance of appropriate care and enable quality improvement opportunities to be identified. **Outputs of improvement processes may include:** • policy to support the development, adoption and implementation of clinical guidelines and pathways • guidelines and information on clinical pathways that are accessed at the point of care • audits and performance reports which track variance against guidelines and protocols • evidence of increasing rates of compliance with clinical guidelines or pathways.

Actions required	Implementation strategies
1.8 Adopting processes to support the early identification, early intervention and appropriate management of patients at increased risk of harm	

1.8.1 Mechanisms are in place to identify patients at increased risk of harm **1.8.2** Early action is taken to reduce the risks for at-risk patients	**Key task:** • **Incorporate into the organisation's audit program a systematic review of the adequacy of systems to identify and protect patients at high risk of harm** **Suggested strategies:** You should use patient-level screening tools to identify factors that contribute to adverse events in health care. Evidence is available that details the risk factors that are condition- or procedure- specific, as well as factors that have been identified that generally increase the risk of adverse events. Other national standards deal specifically with reducing the risk of adverse events such as falls, pressure injuries and medication errors. You should identify and adopt evidence based or best practice screening tools where they are available for specific risks (for example, patient falls, pressure injuries) and for risks associated with different types of treatment (for example, anaesthetic risks associated with surgery). Using practice guidelines that weigh factors contributing to postoperative complications in older patients, including patient characteristics such as age and co-morbidities, and surgical factors, such as type of anaesthesia and length of surgery may also be useful.[19] You should incorporate patient risk assessment processes in the organisation's quality management system where there are specific risks associated with particular types of patients or locations of treatment. Clinical guidelines and pathways for particular conditions or interventions will also incorporate risk management strategies (for example, pre-operative anaesthetic assessment) relevant to known patient risk groups. Monitoring of clinical outcomes for at risk patient groups and actions taken that risks are not being appropriately controlled, will ensure management strategies are effective. You should use the risk management system and relevant external sources of information (for example, coroners' reports, the literature) to enable continuous monitoring and analysis to identify emergent risks affecting particular groups of patients. See also specific strategies addressed in Standards 4, 5, 6, 7, 8, 9 and 10. **Outputs of improvement processes may include:** • risk assessment policies and protocols • audits of identification of patients at risk and actions taken.

Actions required	Implementation strategies

1.8 Adopting processes to support the early identification, early intervention and appropriate management of patients at increased risk of harm   (continued)

1.8.3 Systems exist to escalate the level of care when there is an unexpected deterioration in health status	**Key task:** • **Incorporate into the quality management system a systematic review of the organisation's policies and associated procedures and protocols for recognising and responding to clinical deterioration, with the objective of ascertaining whether the system is well designed and performing well** **Suggested strategies:** Organisations that comply with NSQHS *Standard 9: Recognising and Responding to Clinical Deterioration in Acute Health Care* will meet this action. You can undertake monitoring of compliance with Standard 9, and associated clinical outcomes, via the quality management system and report to the governing body, enabling it to ascertain that the Standard has been achieved and a cycle of continuous improvement has been implemented. Organisations that are not required to comply with Standard 9 will still need to implement reliable systems including policies, procedures and protocols to: • measure and document appropriate physiological observations in accordance with evidence-based practice • establish a documented protocol for responding to abnormal physiological observations including access to emergency assistance • ensure appropriate communication with patients and carers about the risks of possible deterioration. **Outputs of improvement processes may include:** • policies, procedures, protocols and tools to recognise and respond to clinical deterioration • evidence of evaluation of the effectiveness of procedures and protocols for recognising and responding to clinical deterioration.

Actions required	Implementation strategies
1.9 Using an integrated patient clinical record that identifies all aspects of the patient's care	

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1.9.1 Accurate, integrated and readily accessible patient clinical records are available to the clinical workforce at the point of care

1.9.2 The design of the patient clinical record allows for systematic audit of the contents against the requirements of these Standards

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Key tasks:

- Incorporate a systematic review of the organisation's policies, procedures and protocols for management of patient clinical records into the organisation's audit program, with the objective of ascertaining whether the system is well-designed and performing well
- Review the design of the clinical record to ensure it facilitates documentation of the relevant clinical elements of these Standards

Suggested strategies:

A clinical record is a documented account of a person's health, illness or treatment in hard copy or electronic format.[20] It is a tool for planning provision of health care and for contemporaneous tracking of the patient's condition, care, services and interventions performed by the care team. The clinical record allows for the transfer of important clinical information between healthcare professionals. Further, it creates an historical record of the care provided to the patient for later use for a variety of clinical, quality, audit and research purposes. It is also a potentially rich source of information about safety and quality of care that can be used to improve clinical and organisational systems, and for research.

The role of the governing body and senior managers is to ensure an effective system is in place for recording, communicating, using and securely storing patient clinical information, for the purpose of providing safe, high quality care to individual patients and enabling later extraction of relevant information for quality assurance, teaching and research purposes.

A number of standards, guidelines and policies apply to clinical record documentation. For example, the Medical Board of Australia defines medical record keeping requirements for good medical practice.[21] State health departments have published clinical record documentation and data capture standards.[20,22]

You should ensure patient clinical record systems are effective and incorporate:

- a workforce which is appropriately qualified and experienced in the management of clinical records systems, with appropriate leadership skills and authority
- policies, procedures and protocols addressing:
    - standards and processes for management of clinical records (including retention, access at the point of care, emergency access to electronic records when a patient is unable to consent, and disposal requirements)
    - standards of documentation, with a focus on the information that should be recorded to enable monitoring of quality of care
    - how changes to the clinical record are authorised
    - standards and processes for establishing stand-alone clinical registries for quality or research purposes
    - the conduct of compliance audits
    - legislative requirements and relevant standards.
- structures (for example, medical record committees) and processes to enable clinical record risks and opportunities to be evaluated and changes made to improve standards of documentation
- orientation and training of the clinical workforce in the organisation's requirements for clinical record documentation, including the safety and quality rationale for those requirements

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Actions required	Implementation strategies
1.9 Using an integrated patient clinical record that identifies all aspects of the patient's care (continued)	

(continued) **1.9.1** Accurate, integrated and readily accessible patient clinical records are available to the clinical workforce at the point of care **1.9.2** The design of the patient clinical record allows for systematic audit of the contents against the requirements of these Standards	• accountability for clinical record documentation in performance development processes for the clinical workforce • physical or electronic facilities for the reliable and secure management of patient clinical records. Clearly document the accountabilities and terms of reference for the individual or committee responsible for governance of the patient clinical records system. Periodic audit of the design and performance of the patient clinical records system will assist to ensure system effectiveness. You should structure the clinical record to guide members of the clinical workforce to record important information relevant to the safety and quality of care. This will also assist organisations to audit compliance with relevant standards. **Outputs of improvement processes may include:** • policies, procedures, protocols and forms for clinical record keeping • policies for the creation, retention, archiving and destruction of clinical records • policies detailing the governance arrangements for transition to electronic health records and the maintenance of hybrid records where relevant • audits of clinical records to determine compliance with policy • clinical records committee terms of reference, agendas, meeting minutes and/or reports of relevant committees • policies and process for the creation of forms or electronic templates.

Standard 1

Criterion: Performance and skills management

Managers and the clinical workforce have the right qualifications, skills and approach to provide safe, high quality health care

Clinical safety and quality depends on both systems and individuals. Safety and quality of care will be at risk if the workforce does not have the appropriate level of skill or experience, or is not managed effectively, even if systems of care are well designed. Organisations have a responsibility to ensure the care they provide meets minimum standards, to support continuous improvement and to identify and manage clinicians whose performance does not meet appropriate standards. Credentialing, clinical audit, performance review and education can all assist individuals to provide safe, high quality services.[23]

'Credentialing' is the formal process used to verify the qualifications, experience, professional standing and other relevant professional attributes of clinicians. This is to help confirm their competence, performance and professional suitability to provide safe, high quality services. Clinicians' scope of practice is defined following credentialing. This involves delineating the extent of an individual clinician's practice within the organisation based on their credentials, competence, performance and professional suitability, and the needs and capability of the organisation.

Credentialing and defining clinicians' scope of practice, together with participation by all members of the clinical workforce in robust performance development systems, will assist organisations to ensure healthcare professionals possess the knowledge, skills and experience necessary for safe practice.

Performance development is an important and constructive activity that enables an organisation to ensure all members of the clinical workforce meet professional registration and continuing professional development requirements. Issues affecting the individual's performance are identified and addressed as part of the performance development process. Goals for quality improvement and further education

and training are also agreed and implemented. In organisations with effective governance systems, performance is managed in a supportive way, using continuous processes that take account of clinical professionalism and reasonable needs for autonomy.[24]

In order to be effective, performance development needs to be undertaken in a manner that does not disengage clinicians. The values of fairness, accountability and support underpin effective systems of performance development. Where significant under-performance is identified, an initial response should be triggered which includes increased support and facilitates access to relevant tools, education and expertise. However, patient safety is paramount and remedial strategies need to protect patient safety at all times.

Health service organisations are also accountable for ensuring adequate supervision of the clinical workforce. In particular, junior healthcare professionals who have limited clinical experience require oversight and regular review of their clinical practice. The purpose of supervision is to ensure that the less experienced clinician's professional practice is of an acceptable standard and to identify opportunities for learning and development.

Induction of new members of the workforce is an important organisational quality activity that should provide the workforce with the necessary knowledge and skills to work safely within the health service organisation. Comprehensive orientation includes but is not limited to orientation to the organisation's model of care; policies, procedures and protocols; risk reporting and management processes; quality assurance, improvement and monitoring systems; performance development and human resources systems; and information systems.

Actions required	Implementation strategies

1.10 Implementing a system that determines and regularly reviews the roles, responsibilities, accountabilities and scope of practice for the clinical workforce

1.10.1 A system is in place to define and regularly review the scope of practice for the clinical workforce

1.10.2 Mechanisms are in place to monitor that the clinical workforce are working within their agreed scope of practice

1.10.3 Organisational clinical service capability, planning and scope of practice is directly linked to the clinical service roles of the organisation

1.10.4 The system for defining the scope of practice is used whenever a new clinical service, procedure or other technology is introduced

1.10.5 Supervision of the clinical workforce is provided whenever it is necessary for individuals to fulfil their designated role

Key tasks:

• Verify that the organisation has adopted and implemented an evidence-based process as the basis for its system of credentialing and defining scope of clinical practice for all clinicians (medical, nursing and midwives, allied health), including clinicians with independent decision making authority and clinicians who work under supervision

• Consider whether the system for credentialing and defining scope of clinical practice is appropriately designed, resourced, maintained and monitored

• Incorporate periodic review of the organisation's system for credentialing and defining scope of clinical practice into audit programs, with a focus on consistency with adopted standards, performance measures and outcomes

Suggested strategies:

Credentialing and defining the scope of clinical practice are essential processes, which should be applied to all health service professionals (medical, nursing and allied health). They reflect mutual commitments between the organisation and each member of the clinical workforce to the provision of safe, high quality care.

The governing body needs to be assured that processes are in place for monitoring and maintaining effective systems for credentialing and defining scope of practice.

While the purpose of these processes is to ensure the delivery of safe, high quality care, approaches may differ for senior clinicians (that is, those with independent clinical decision making authority) and junior clinicians (that is, those who routinely practice under supervision). Regardless of the approach, the governing body is responsible for ensuring policies, procedures and protocols are implemented, compliance is monitored and reported, and any variations are investigated.

Senior clinicians

In 2004, Australian Health Ministers endorsed the Australian Council for Safety and Quality in Health Care publication: *Standard for credentialing and defining the scope of clinical practice of medical practitioners, for use in public and private hospitals* (the Standard). Implementation of the Standard is underway in all jurisdictions, across the public and private sectors. The structures and processes used vary between states and different healthcare settings. A number of states have developed policies and procedures to support implementation of the Standard.

While the Standard focuses on medical practitioners with independent clinical decision making rights, its principles are universal and it has the potential for wider application to other clinicians who have independent clinical decision making authority within organisations.

The Standard comprehensively describes structures and processes which, if implemented, will ensure:

• verification of each clinician's credentials, and periodic re-verification, in accordance with defined organisational policy

• clear definition of scope of clinical practice of clinicians in the context of the organisation's needs and capability

• the safe and appropriate introduction of new clinical services, procedures and other technologies

• appropriate supervision of clinicians, when such supervision is necessary

Actions required	Implementation strategies
1.10 Implementing a system that determines and regularly reviews the roles, responsibilities, accountabilities and scope of practice for the clinical workforce (continued)	

(continued)

1.10.1 A system is in place to define and regularly review the scope of practice for the clinical workforce

1.10.2 Mechanisms are in place to monitor that the clinical workforce are working within their agreed scope of practice

1.10.3 Organisational clinical service capability, planning and scope of practice is directly linked to the clinical service roles of the organisation

1.10.4 The system for defining the scope of practice is used whenever a new clinical service, procedure or other technology is introduced

1.10.5 Supervision of the clinical workforce is provided whenever it is necessary for individuals to fulfil their designated role

- effective processes for reviewing clinicians' competence and performance, if concerns are raised
- regular review of clinicians' credentials and scope of clinical practice
- reasonable steps are taken if a concern arises about the capability of a clinician or appropriateness of a service in the context of an organisation's needs and capability.

The governing body should adopt the principles in the Standard as the basis for the development of effective policies, procedures and protocols for credentialing senior medical practitioners with independent practising rights. The organisation may also use the Standard as a basis for ensuring appropriate processes are in place for other non-medical, senior clinicians. As with all elements of the clinical governance system, clear allocation of responsibility for ensuring appropriate processes are in place establishes a foundation for reliable implementation.

Junior clinicians

Junior clinicians (medical, nursing and allied health) routinely provide services under supervision. Their numbers are large, their skills develop rapidly and their employment or engagement may be transient as they move through training programs. Individualised approaches to defining their scope of clinical practice may therefore be impracticable. While some organisations may choose to include junior clinicians in their general credentialing and scope of clinical practice systems, the usual approach is to adopt policies that establish clear limits on the scope of clinical practice of junior clinicians of varying levels. These define scope of practice for varying levels of seniority, together with definition of the requirements for effective supervision and support for each level.

You should verify and periodically re-verify the credentials of all junior clinicians in accordance with defined organisational policy.

Supervision of all junior clinicians in accordance with their assessed capabilities and consistent with organisational policies, procedures and/or protocols is a key safeguard of the safety and quality of care. The organisation's orientation, education and training program, together with effective clinical supervision and participation in the organisation's performance development system, will support all members of the junior clinical workforce to develop their capabilities safely.

You should provide clear definition of clinical supervision responsibilities in the contracts of employment or engagement of all senior clinicians, and in relevant organisational policies, including those that apply to the performance development system. This will help to ensure junior clinicians develop their skills while protecting the safety and quality of patient care.

The role of the governing body and senior managers is to ensure policies, procedures and protocols that address credentialing, scope of clinical practice, supervision and monitoring of performance of all members of the junior clinical workforce are in place and implemented. In a robust clinical governance system, the governing body and senior managers will ensure that responsibility for implementing these policies, procedures and/or protocols is clearly allocated, compliance is monitored and reported and any variances are investigated and explained or addressed.

Outputs of improvement processes may include:

- policies, procedures and/or protocols for credentialing and defining scope of practice including adoption of an explicit standard
- position descriptions for junior clinicians
- register of Health Provider Identifiers and Prescriber Provider Numbers
- audits of compliance with policy, that may include cross checking the identification of clinicians using healthcare provider identifiers.

Actions required	Implementation strategies
1.11 Implementing a performance development system for the clinical workforce that supports performance improvement within their scope of practice	

1.11.1 A valid and reliable performance review process is in place for the clinical workforce

1.11.2 The clinical workforce participates in regular performance reviews that support individual development and improvement

Key tasks:

- Verify that the organisation has adopted and implemented an appropriate standard as the basis for a robust system of performance development for all clinicians (medical, nursing, allied health)
- Consider whether the performance development system is appropriately designed, resourced, maintained and monitored
- Incorporate into the organisation's audit program periodic review of the performance development system, with a focus on consistency with adopted standards, clinician engagement and outcomes

Suggested strategies:

'Performance management' and 'performance development' are terms used to describe systematic processes of goal setting and periodic review of performance. Well-designed systems are constructive and are based on mutual commitment by the organisation and each member of the clinical workforce to safety and quality of care.

The governing body needs to be assured that effective systems are in place and are monitored to assess if they are working well.

The organisation is responsible for establishing an environment in which safe, high quality care can be delivered, supporting its workforce to work safely and effectively in that environment and assisting members of the clinical workforce to develop their competence and performance by supporting their achievement of mutually agreed goals.

Members of the clinical workforce are responsible for understanding organisational objectives, setting professional goals that are consistent with those objectives and working collaboratively with the organisation to achieve professional and organisational goals.

Effective performance development systems rely on continuous constructive interaction between members of the clinical workforce and their managers. They are flexible and responsive and include but are not limited to periodic (for example, annual) review of performance.

You should identify a designated senior manager with responsibility for ensuring compliance with the organisation's performance development policy. This includes monitoring and reporting on performance to support effective implementation of the performance development system.

The performance development system should include systematic monitoring of each clinician's participation in formalised audit and peer review and participation in continuing professional development in accordance with the requirements of their professional organisation and registration body.

Outputs of improvement processes may include:

- clear accountability for performance review and development processes
- policies, protocols and tools to support performance review and development
- tracking systems for performance review
- evidence that outcomes from performance review are fed into appropriate areas such as training and development
- satisfaction of the workforce with performance review processes.

Actions required	Implementation strategies
	1.12 Ensuring that systems are in place for ongoing safety and quality education and training

1.12.1 The clinical and relevant non-clinical workforce have access to ongoing safety and quality education and training for identified professional and personal development	**Key tasks:**
	
	 • Review the organisation's orientation, education and training needs
	 • Provide or facilitate access to training that incorporates appropriate modules in the theory and practice of safety and quality
	 • Implement policies that require members of the workforce to participate in orientation, education and training on safety and quality
	 • Consider adoption of performance indicators to monitor participation in and outcomes of the safety and quality elements of the education and training system
	
	 Suggested strategies:
	
	 Effective systems for education and training in safety and quality incorporate:
	
	 • adequate investment
	 • evidence-based content about the organisation's approach and commitment to safety and quality
	 • participation by relevant members of the workforce
	 • monitoring of knowledge gaps and program effectiveness leading to continuous program improvements.
	
	 To achieve an appropriate system, the governing body should:
	
	 • adopt an organisational orientation, education and training policy that clearly defines the organisation's commitment to education and training in safety and quality. The policies, procedures and protocols by which that commitment will be fulfilled should include:
	   – a commitment to incorporating consideration of safety and quality education and training needs in organisational resource allocation decisions
	   – a requirement that participation in safety and quality education and training is a described duty in each clinician's position description and is routinely reviewed as part of their performance development plan
	   – incorporation of reporting on the organisation's safety and quality education and training activity and performance into the governance reporting framework
	   – identification of a senior manager with responsibility for overseeing policy implementation, compliance and performance
	 • receive regular reports on the implementation and outcomes of the policy.
	
	 Outputs of improvement processes may include:
	
	 • training policy
	 • evidence of the provision of opportunities and participation in training
	 • evaluation of the effectiveness of education and training activities.

Actions required	Implementation strategies

1.13 Seeking regular feedback from the workforce to assess their level of engagement with, and understanding of, the safety and quality system of the organisation

Actions required	Implementation strategies

1.13.1 Analyse feedback from the workforce on their understanding and use of safety and quality systems
 	
1.13.2 Action is taken to increase workforce understanding and use of safety and quality systems
	Key tasks:
	
	• **Identify the multiple sources of information that provide an insight into the level of workforce engagement with, and understanding of, the organisation's safety and quality system**
	• **Periodically aggregate and analyse relevant information and use it to develop and improve the effectiveness of the organisation's education and training system**
	
	Suggested strategies:
	
	Multiple strategies should be used to gain feedback from the workforce. These may include:
	
	• informal feedback via usual collegiate and management communication processes
	• formal feedback via:
	   – structured analysis of de-identified information gained from performance reviews
	   – audits and surveys targeting specific elements of the safety and quality system
	   – organisational climate and cultural surveys.
	
	Monitoring the adequacy of workforce engagement with, and understanding of, the safety and quality system provides useful information for the governing body and senior managers. This can be achieved by receiving regular reports on this topic, incorporating systematically-collected data and information. The governing body may include an opportunity in its annual reporting calendar to receive and consider relevant reports.
	
	Having identified the strengths and weaknesses of the safety and quality system, take steps to improve it using a Plan, Do, Study, Act approach.
	
	Outputs of improvement processes may include:
	
	• reports on analyses of workforce engagement with, and understanding of, the safety and quality system
	• results of workforce climate surveys
	• quality improvement reports.

Criterion: Incident and complaints management

Patient safety and quality incidents are recognised, reported and analysed, and this information is used to improve safety systems

Incidents can occur while providing health care, and some of these can have serious consequences for patients, health service providers, family members, volunteers and the public. It is therefore essential that health service organisations establish a structured incident and complaints management process that is consistent with best practice and is supported by the organisation's clinical governance system.

Complaints and suggestions are an important source of information about the safety and quality of health services. The purpose of a complaints process is to provide a mechanism for identifying and responding to issues that affect the safety and quality of the organisation's services. Complaints should trigger a response by the relevant manager that is consistent with a clearly defined process outlined in the organisation's policies and procedures.

Effective clinical governance creates a learning environment and a comprehensive program of continuous quality improvement. A culture of trust, openness, respect and caring where achievements are recognised is an important element of good clinical governance. Open discussion of error should be embedded in everyday practice and relevant information should be communicated openly to patients. Members of the workforce should feel supported to willingly report adverse events and near misses, so there can be a focus on learning, research and improvement. Appropriate action should be taken where there are opportunities to improve the delivery of care.

Actions required	Implementation strategies
1.14 Implementing an incident management and investigation system that includes reporting, investigating and analysing incidents (including near misses) which all result in corrective actions	

1.14.1 Processes are in place to support the workforce recognition and reporting of incidents and near misses

1.14.2 Systems are in place to analyse and report on incidents

1.14.3 Feedback on the analysis of reported incidents is provided to the workforce

1.14.4 Action is taken to reduce risks to patients identified through the incident management system

1.14.5 Incidents and analysis of incidents are reviewed at the highest level of governance in the organisation

Key tasks:

- **Verify that the organisation has adopted and implemented a comprehensive incident management and investigation system that complies with jurisdictional requirements. Consider whether:**
  - **the system is appropriately designed, resourced, maintained and monitored**
  - **responsibility for leading and maintaining the system is clearly designated**
- **Define a reporting and management framework that will ensure incident data are utilised to optimal effect**
- **Incorporate into the organisation's audit program periodic review of the incident management and investigation system, with a focus on its design, performance and adequacy of resourcing**

Suggested strategies:

A 'clinical incident' is an event or circumstance resulting from health care, which could have, or did, lead to unintended harm to a person, loss or damage, and/or a complaint. Clinical incidents include near misses and adverse events.

Most large organisations and state and territory health departments have overarching risk management and incident reporting policies in place. Local organisations need to establish systems that comply with these policies, taking into account the local resources, level of risk and context.

The governing body needs to be assured that an effective system is in place and working well.

A well-designed clinical incident management and investigation system should be in place, that complies with jurisdictional clinical incident management policies and supports the workforce to identify, report, manage and learn from clinical incidents. A well-structured system would generally incorporate the following:

- a clear policy framework defining the key elements of the system and the roles and responsibilities of individuals, positions and committees. This should include the responsibility of all clinicians to report all incidents they observe or are involved in, or that arise from the use of electronic health or patient clinical records
- a focus on managing each incident appropriately from a clinical perspective and the absolute imperative of providing safe, high quality care to the patient following the incident
- an identifiable senior individual with responsibility for maintaining the integrity of the system and receiving and coordinating the management of incidents
- adequate and appropriate systems including relevant equipment and technology to support incident reporting and analysis
- workforce responsibilities for managing reported incidents, including grading their severity and leading further investigations
- policies, procedures and protocols regarding confidentiality of information and the ability of the workforce to report anonymously
- responsibilities for analysing incident data and identifying trends and opportunities for improvement. Generally, responsibility for analysing incident data should be team-based. Usually, a committee will play a key role in overseeing the incident management system – their role, responsibilities and accountabilities must be clearly defined
- responsibilities for disseminating information about incidents and their quality improvement implications

Actions required	Implementation strategies
1.14 Implementing an incident management and investigation system that includes reporting, investigating and analysing incidents (including near misses) which all result in corrective actions	(continued)

(continued) **1.14.1** Processes are in place to support the workforce recognition and reporting of incidents and near misses **1.14.2** Systems are in place to analyse and report on incidents **1.14.3** Feedback on the analysis of reported incidents is provided to the workforce **1.14.4** Action is taken to reduce risks to patients identified through the incident management system **1.14.5** Incidents and analysis of incidents are reviewed at the highest level of governance in the organisation	• responsibilities for following up incidents to ensure improvements, where appropriate, have been made • responsibilities for reporting incidents to other parties (for example, health departments) in accordance with relevant organisational obligations • links to the organisation's open disclosure, risk management and credentialing and scope of clinical practice systems • a link to the jurisdictional clinical incident management system, where applicable • a link to the procedure for communicating with the organisation's professional indemnity insurers • support for patients, carers, providers and other individuals who are involved in clinical incidents • a requirement for education and training in clinical incident systems to be included in the organisation's safety and quality orientation and education programs. The system will facilitate timely and effective review of information about clinical incidents, and use of that information at all levels of the organisation to improve the safety and quality of care. Review of each reported incident by the clinicians involved and the manager responsible for the operational area in which the incident occurred will enable lessons to be learned and improvements to be implemented locally. A system to verify that managers follow up incidents appropriately will ensure integrity of the risk management system. Classification and escalation processes should be in place to ensure serious incidents and those associated with significant risks are managed appropriately. Definition of a reporting framework that clearly identifies the data that will be available and reported at each level in the organisation will enable the workforce and members of the governing body to monitor and respond to system performance. Provide information to the governing body and senior executive about all category 1 (most serious) incidents and summary performance information about all other incidents. Include information such as the actions taken as a result of a specific incident or category of incidents, and indicators such as time to complete actions stemming from incident reports. This will help to enable governance bodies and senior executives to fulfil their clinical governance responsibilities. The design and performance of the clinical incident management system should be periodically reviewed. The governing body should consider whether it complies with best practice design principles and whether adequate resources have been allocated to support effective clinical governance and risk management. **Outputs of improvement processes may include:** • incident management policy, procedure, protocols and tools • incident management reporting and escalation tools • incident severity assessment tools • committee structure responsible for assessing severe and trended incidents • patient feedback following the management of incidents.

Actions required	Implementation strategies
1.15 Implementing a complaints management system that includes partnership with patients and carers	

1.15.1 Processes are in place to support the workforce to recognise and report complaints

1.15.2 Systems are in place to analyse and implement improvements in response to complaints

1.15.3 Feedback is provided to the workforce on the analysis of reported complaints

1.15.4 Patient feedback and complaints are reviewed at the highest level of governance in the organisation

Key tasks:

- Verify that the organisation has adopted and implemented a comprehensive complaints management and investigation system. Consider whether:
  - the system is appropriately designed, resourced, maintained and monitored
  - responsibility for leading and maintaining the system is clearly designated
- Define a reporting and management framework that will ensure complaint data are utilised to optimal effect
- Incorporate into the organisation's audit program periodic review of the complaint management and investigation system, with a focus on its design, performance and adequacy of resourcing

Suggested strategies:

Effective management of complaints is consistent with the core values of health services. An effective complaints management system should be in place, to:

- improve patient satisfaction
- improve workforce satisfaction
- lower complaints management costs
- increase the potential to improve safety and quality of care over time
- improve risk management.

The governing body must be assured that an effective system is in place and working well.

A well-designed complaints management system should generally incorporate the following:

- compliance with jurisdictional requirements
- a clear policy framework defining the key elements of the system and the roles, responsibilities and accountabilities of relevant individuals, positions and committees
- an identified senior individual with responsibility for maintaining the integrity of the system and receiving and coordinating the management of complaints
- a documented philosophy that acknowledges that complaints represent opportunities for improvement
- systems to encourage patients and their carers to report complaints
- adequate and appropriate equipment and technology to support the reporting and analysis process
- policies, procedure and protocols regarding confidentiality of information
- responsibilities for receiving, investigating and managing complaints
- responsibilities for grading the severity of complaints
- responsibilities for communicating effectively with complainants about the assessment and management of the complaint
- responsibilities for analysing complaints data and identifying trends and opportunities for improvement, including protocols for identifying which incidents require root cause analysis. Generally, responsibility for analysing complaints data should be team-based. Usually, a committee will play a key role in overseeing the complaints management system – the roles and responsibility of relevant committees must be clear
- responsibilities for following up complaints to ensure improvements, where appropriate, have been made
- responsibilities for disseminating information about complaints and their quality improvement implications
- responsibilities for reporting complaints to other parties (e.g. complaints commissioners, regulatory authorities) in accordance with relevant organisational obligations
- links to the organisation's open disclosure, risk management and credentialing and scope of clinical practice policies

Actions required	Implementation strategies
1.15 Implementing a complaints management system that includes partnership with patients and carers	(continued)

(continued) **1.15.1** Processes are in place to support the workforce to recognise and report complaints **1.15.2** Systems are in place to analyse and implement improvements in response to complaints **1.15.3** Feedback is provided to the workforce on the analysis of reported complaints **1.15.4** Patient feedback and complaints are reviewed at the highest level of governance in the organisation	• a link to the jurisdictional complaints management policy, where applicable • a link to the procedure for communicating with the organisation's professional indemnity insurer • support for patients, carers, providers and other individuals who are involved in incidents that lead to complaints • inclusion of effective education and training in complaints systems in the organisation's safety and quality orientation and education programs. The system will facilitate timely and effective review of information about complaints, and use of that information at all levels of the organisation to improve the safety and quality of care. Review of each complaint by the clinicians involved and the manager responsible for the operational area in which the complaint was generated will enable lessons to be learned and improvements to be implemented locally. A system to verify that managers follow up complaints appropriately at that level should be in place to ensure system integrity. Classification and escalation processes will ensure serious complaints and those associated with significant risks are managed appropriately. Definition of a reporting framework which clearly identifies the data that will be available and reported at each level in the organisation will enable the workforce and members of the governing body to monitor and respond to system performance. Provide information to the governing body and senior executive about all serious complaints and summary performance information about all other complaints. Include information such as the actions taken as a result of a specific complaint or category of complaints, and indicators such as time to complete actions stemming from complaints. This will help to enable governance bodies and senior executives to fulfil their clinical governance responsibilities. The design and performance of the complaints management system should be periodically reviewed. The governing body should consider whether it complies with best practice design principles and whether adequate resources have been allocated will support effective clinical governance and risk management. **Outputs of improvement processes may include:** • complaints policy, procedures, protocols and tools • information provided to patients and carers about making a complaint • evidence of effective complaint management • complaints reports and actions taken as a result • agendas, meeting minutes and/or reports of relevant committees • engagement of the workforce in complaint management.
1.16 Implementing an open disclosure process based on the national open disclosure standard	
1.16.1 An open disclosure program is in place and is consistent with the national open disclosure standard	**Key tasks:** • **Verify that the organisation has adopted and implemented the national open disclosure standard, or a standard that is otherwise consistent** • **Incorporate into the organisation's audit program periodic review of the organisation's open disclosure system, with a focus on its consistency with the adopted standard, clinician participation and outcomes** **Suggested strategies:** Open disclosure is the open discussion of incidents that result in harm to a patient receiving health care. The national open disclosure standard was endorsed by all Health Ministers in 2003 and was reviewed in 2012. In April 2008, Australian Health Ministers agreed to work towards implementing the standard in all Australian healthcare services and facilities.

Actions required	Implementation strategies
1.16 Implementing an open disclosure process based on the national open disclosure standard (continued)	
(continued) **1.16.1** An open disclosure program is in place and is consistent with the national open disclosure standard	Governing bodies should lead implementation of effective open disclosure by: • leading a 'just culture' characterised by openness and constructive learning from mistakes • adopting, or requiring the organisation to adopt, the national open disclosure standard or a standard that achieves an equivalent outcome • ensuring adequate resources are allocated to support implementation of the adopted standard • ensuring responsibility for implementing the adopted standard is allocated to a senior individual • satisfying themselves that there is a system in place to monitor and maintain compliance with the adopted standard. All variations from the adopted standard should be investigated and explained or addressed • receiving and considering regular reports on performance in open disclosure. **Outputs of improvement processes may include:** • an open disclosure policy.
1.16.2 The clinical workforce are trained in open disclosure processes	**Key tasks:** • **Review inclusion of open disclosure modules in the organisation's orientation, education and training programs and confirm that all members of the clinical workforce have sufficient opportunity to gain appropriate knowledge and skills** • **Monitor and ensure participation by all members of the clinical workforce in open disclosure education and training** **Suggested strategies:** A review of the national open disclosure standard is currently under way by the Commission. The review has found that inadequate education and training is a barrier to conducting open disclosure. Governing bodies and senior managers should ensure the organisation's education and training policy adequately addresses open disclosure by: • explicitly defining whether participation in open disclosure education and training should be mandatory or optional • ensuring responsibility for the effectiveness of education and training in open disclosure is allocated to a senior individual(s) • ensuring all members of the workforce have access to training modules in open disclosure with content and learning methodologies developed in accordance with evidence of effectiveness • ensuring participation in open disclosure training is monitored and deficiencies and opportunities addressed • ensuring business plans and budget allocations incorporate adequate resources for open disclosure education and training. **Outputs of improvement processes may include:** • inclusion of training requirements for relevant sections of the workforce in the open disclosure policy • opportunities for training, and evidence of participation and evaluation • awareness of the workforce about open disclosure.

Criterion: Patient rights and engagement

Patient rights are respected and their engagement in their care is supported

Consumers have a right to safe, high quality health care and to the provision of the information they need to participate in decisions about their care. They also have the right to open and honest communication and to be cared for in an environment that fosters trust in those providing care.[25-26]

Consumer participation improves the way services are delivered by increasing awareness and understanding of the consumer perspective and needs. Identifying what matters most to consumers in their journey through the health system can enhance the design of systems and processes of care, and improve consumer participation, experience and health outcomes.[27]

Consumer participation should occur at multiple levels of the organisation and be evident in planning, policy development, health service management, clinical research, training programs and guideline development.

The organisation should use consumer complaints, compliments, surveys and freedom of information (FOI) requests to inform improvements. Consumer input should also be used in the development of information resources and communication strategies for consumers, patients, residents and carers.

Actions required	Implementation strategies

1.17 Implementing through organisational policies and practices a patient charter of rights that is consistent with the current national charter of healthcare rights

Actions required	Implementation strategies
1.17.1 The organisation has a charter of patient rights that is consistent with the current national charter of healthcare rights **1.17.2** Information on patient rights is provided and explained to patients and carers **1.17.3** Systems are in place to support patients who are at risk of not understanding their healthcare rights	**Key tasks:** • Formally adopt (with or without amendment) the *Australian Charter of Healthcare Rights* • Periodically review the effectiveness of the Charter's implementation in the organisation **Suggested strategies:** The *Australian Charter of Healthcare Rights* (the Charter) was developed by the Australian Commission on Safety and Quality in Health Care and adopted by all Health Ministers in 2008. The Charter defines rights to access, safety, respect, communication, participation, privacy and comment. Some jurisdictions have developed supporting information that expands on the Charter. Formal adoption of the Charter by the governing body and identification of a senior individual who is responsible for promulgating the Charter and ensuring it appropriately guides the delivery of services, will facilitate its implementation throughout the organisation. An effective system to implement and maintain the Charter should generally include the following elements: • allocation of responsibility for implementing the Charter to a senior individual(s) • prominent display of the Charter within the organisation • ready accessibility to copies of the Charter by all users of the organisation's services and their carers, including availability of the Charter in community languages and formats relevant to people unable to use the written Charter • inclusion of information about the Charter in corporate communications • orientation to the Charter for new members of the workforce (including contract and agency workforce), and inclusion of information about the Charter in regular education and training sessions • use of the Charter as a platform for discussions about health care rights between patients, consumers, families, carers and providers. Knowledge about the Charter can be evaluated from information collected during organisational culture and patient satisfaction/experience surveys. That knowledge can then be shared throughout the organisation and reported periodically to the governing body. The governing body should receive regular reports to enable it to monitor the effectiveness of the Charter in establishing a framework for patient rights. **Outputs of improvement processes may include:** • evidence of adoption of the Charter • evidence of information about the Charter given to patients • evidence of widespread awareness of the Charter amongst the workforce.

Actions required	Implementation strategies
1.18 Implementing processes to enable partnership with patients in decisions about their care, including informed consent to treatment	

Actions required	Implementation strategies
1.18.1 Patients and carers are partners in the planning for their treatment **1.18.2** Mechanisms are in place to monitor and improve documentation of informed consent **1.18.3** Mechanisms are in place to align the information provided to patients with their capacity to understand	**Key tasks:** • Formally adopt a comprehensive policy, and associated procedures on consent and engagement of patients and their carers in clinical decision making • Schedule periodic reviews of the effectiveness and outcomes of the policy **Suggested strategies:** Patients and (where applicable) their substitute decision-makers have the right to receive understandable information and to make informed decisions about their health care in a timely and culturally appropriate manner. The quality of clinical decision making benefits from engagement (with patient consent) of patients' carers, who can often contribute important information about patient preferences and concerns. Open communication between patients (and, where applicable, their substitute decision-makers), carers (with patient consent) and clinicians underpins the prevailing ethical framework for contemporary health care. It also reflects the legal right of patients to autonomous and supported decision making and facilitates good clinical decision making. Effective systems should be in place for informing patients (and, where applicable their substitute decision-makers) and their carers, determining patient treatment preferences and gaining and documenting their consent to treatment. Effective systems guide and support the clinical workforce towards good standards of practice which meet legal and ethical requirements. It is also likely that such systems will: • improve the safety and quality of care and minimise preventable harm to patients • reduce complaints and litigation. The governing body needs to ensure that an effective system is in place and working well. A well-designed patient information and consent system should generally incorporate: • an explicit foundation in principles of patient autonomy and respect for the individual's right to bodily integrity • recognition of the importance of continuous open communication, consultation and shared decision making about treatment options with patients (or, where applicable, their substitute decision-makers) and their carers (with patient consent) • recognition of the rights of patients (or, where applicable, their substitute decision-makers) and their carers (with patient consent) to receive all relevant information in an accessible format (taking into account language, sensory and cultural needs). Procedures and protocols should be in place to ensure this occurs appropriately, and is consistent with the law and good practice • common law and legislative requirements in the relevant jurisdiction relating to provision of information about and obtaining of consent to treatment, including the recognised requirement to disclose all material risks • an identifiable senior individual with responsibility for maintaining the integrity of the consent system and its continuous improvement

Actions required	Implementation strategies

(continued)

1.18.1 Patients and carers are partners in the planning for their treatment

1.18.2 Mechanisms are in place to monitor and improve documentation of informed consent

1.18.3 Mechanisms are in place to align the information provided to patients with their capacity to understand

- clarity about the circumstances in which consent must be documented, and clear procedures and protocols for documentation that are consistent with the law and good clinical practice
- the availability of comprehensive written information about a range of healthcare interventions, particularly those that are high prevalence and/or high risk
- clarity about the requirement for the consenting person to be competent to consent, and what to do if there are concerns about their competence to consent
- operational systems across all areas of the organisation that ensure:
  - no treatment is instituted without the informed consent of the patient or (where applicable) their substitute decision-maker
  - compliance with the specific consent requirements established by jurisdictional legislation including, for example, mental health acts, guardianship and administration acts and human tissue legislation
- protocols for receiving, investigating and managing complaints about consent processes
- a link to the organisation's open disclosure policy
- a link to the jurisdictional consent policy (where applicable)
- consistency with all legislation that establishes specific consent requirements (for example, mental health legislation, guardianship and administration legislation, human tissue legislation)
- education and training for all members of the clinical workforce in:
  - effective communication to underpin good clinical practice
  - the legal, ethical and practical foundations of requirements for patient consent and engagement in clinical decision making
  - the organisation's consent policy and procedures
  - understanding barriers for patients with a poor level of health literacy
- monitoring, including systematic audit, of the effectiveness of the organisation's consent policy and procedures.

The design and performance of the consent system should be periodically reviewed to evaluate whether it complies with best practice design principles and whether adequate resources have been allocated. This will support effective clinical governance including risk management.

Outputs of improvement processes may include:

- documented consent policies, procedures and protocols that demonstrably reflect good practice
- documentation in accessible formats addressing common or high risk clinical procedures
- inclusion of consent modules in mandatory education and training programs for members of the clinical workforce
- information from patient satisfaction surveys about their engagement in treatment decisions
- information from systematic audits including the availability of information in accessible formats and evidence of compliance with organisational policy.

Actions required	Implementation strategies
1.18 Implementing processes to enable partnership with patients in decisions about their care, including informed consent to treatment (continued)	

1.18.4 Patients and carers are supported to document clear advance care directives and/or treatment-limiting orders	**Key task:** • Review existing mechanisms or develop processes to inform and support patients and carers to put in place advance care directives and treatment limiting orders **Suggested strategies:** The governing body should ensure that an effective system for developing and applying advance care directives and treatment limiting orders is in place and working well. Advance care planning refers to the process of preparing for likely scenarios near the end of life and usually includes assessment of, and dialogue about, a person's understanding of their medical history and condition, values, preferences, and personal and family resources. An advance care directive, sometimes called a 'living will', is a document that describes a person's future preferences for medical treatment in anticipation of a time when they are unable to express those preferences because of illness or injury. Completion of an advance care directive ideally should be one component of the broader advance care planning process.[28] Advance care directives and/or treatment limiting orders can assist clinicians to provide appropriate treatment in accordance with the patient's wishes in circumstances where the patient is no longer able to express those wishes. They can be a particularly important aide to appropriate clinical decision making in emergency situations where decision making time is short. A working group of the Clinical, Technical and Ethical Principal Committee of the Australian Health Ministers' Advisory Council have developed *A National Framework for Advance Care Directives.*[29] The Framework recognises: • that under common law, the terms of an advance care directive must be respected whether or not the person was medically informed of the consequences when the directive was written • that a person or their substitute decision maker can consent to treatment options that are offered, and refuse such treatment, but cannot demand treatment that is not medically indicated • the need to protect health and aged care professionals from civil and criminal liability if they abide by the terms of an advance care directive that they believe, in good faith, to be valid • that voluntary euthanasia and assisted suicide are illegal in Australia. It is important that patients, when making advance care directives, are supported to consider a range of issues including: • the quality of life that would be acceptable to them • the importance of them being able to communicate with family and friends • how they will maintain the relevance and currency of their advance care directive in the context of improving technology and supports that may influence their future quality of life.

Actions required	Implementation strategies

(continued)

1.18.4 Patients and carers are supported to document clear advance care directives and/or treatment-limiting orders

Health service organisations can assist their patients to document clear advance care directives by:

- systematically inquiring, when patients enter their facility, whether they have an existing advance care directive and if so whether it requires review (noting that review is recommended periodically and when the patient's condition changes)
- considering whether patients that enter their facility have legal competence to complete an advanced care directive
- for patients who do not have an existing current advance care directive and wish to document and/or update one and are legally competent to do so, by providing:
  - an opportunity to discuss their preferences regarding future care in the event that they become incompetent to make decisions. This discussion should be held in an appropriate setting and with individuals who can assist the patient to understand the implications of relevant matters and can respond to their questions and concerns.
  - an opportunity to consider the benefits of appointing a person with authority to make medical decisions on behalf of the patient on an enduring basis, should the patient lose capacity
  - sufficient time to consider the implications of such important decisions
  - the relevant forms and supports necessary to enable them to document their advanced care directive, if they choose to do so
- for all patients who have a current directive on admission or who complete an advance care directive:
  - filing a copy of the directive in the patient's clinical record and ensuring that care planning and provision take account of the advance care directive
  - ensuring that a copy of the directive is provided to the patient and, with their consent, their enduring medical guardian (if applicable), their general practitioner and/or other health service providers, as relevant.

A well-designed advance care directive system should generally incorporate:

- effective promotion of advance care directives as an important tool to ensure the appropriate provision of care in accordance with peoples' wishes
- an explicit foundation in principles of patient autonomy and respect for the individual's right to decide the type and amount of health care they will receive, together with application of substituted judgement as the primary decision making standard
- consistency with legislative and common law requirements
- an identifiable senior individual with responsibility for maintaining the integrity of the system and its continuous improvement
- documentation that explains the roles and responsibilities of various stakeholders including the patient, carer, witnesses, substitute decision-makers and clinicians
- comprehensive but simple forms, guidelines and other easy-to-navigate tools for patients and carers, with content consistent with the law and good practice
- resources to assist patients to complete advance care directives in accordance with their wishes, including provision of information in appropriate languages and in a culturally sensitive context, and provision of sufficient time for patients to consider their circumstances and wishes

Actions required	Implementation strategies
1.18 Implementing processes to enable partnership with patients in decisions about their care, including informed consent to treatment	(continued)

Actions required	Implementation strategies
(continued) **1.18.4** Patients and carers are supported to document clear advance care directives and/or treatment-limiting orders	• promotion of the need for patients to discuss their preferences for their future health care with their substitute decision-maker, if one is appointed • methods for advance care directives to be reliably incorporated into clinical care planning • consideration of the special issues relating to involuntary treatment of people with mental illness who have expressed preferences about their treatment under such circumstances • mechanisms for periodic review of the advance care directive. **Outputs of improvement processes may include:** • advance care directive policies and procedures that comply with legislation and demonstrably accord with good practice • documentation in accessible formats including information about the legal status of advance care directives, simple forms and other well-designed tools to facilitate completion of advance care directives • clear instructions to the workforce about their role in assisting patients to consider and complete advance care directives • inclusion of advance care directive modules in mandatory education and training programs for members of the clinical workforce • information from audits of the effectiveness of the advance care directive system, including, for example, information about the proportion of patients offered the opportunity to complete an advance care directive, the proportion of patients with completed advance care directives and the proportion of patients with an advance care directive that has a material influence on treatment decisions.
1.19 Implementing procedures that protect the confidentiality of patient clinical records without compromising appropriate clinical workforce access to patient clinical information	
1.19.1 Patient clinical records are available at the point of care	**Key tasks:** • **Review systems for the availability of clinical records at the point of care, and ensure they are well-designed, well-resourced and working effectively** • **Develop policies, procedures and protocols for assessing Personally Controlled Electronic Health Records, including emergency access when a patient is unable to provide consent** **Suggested strategies:** A clinical record is a documented account of a person's health, illness or treatment in hard copy or electronic format.[22] Clinical records facilitate the provision of safe, high quality care and support quality improvement, audit and research. To be useful at the point of care, clinical records need to be • accurate • relevant • complete and comprehensive • legible. Ready access at the point of care facilitates contemporaneous recording of the patient's status as well as changes to treatment.

Actions required	Implementation strategies

1.19 Implementing procedures that protect the confidentiality of patient clinical records without compromising appropriate clinical workforce access to patient clinical information (continued)

Actions required	Implementation strategies
(continued) **1.19.1** Patient clinical records are available at the point of care	Action 1.9.1 of this standard addresses general requirements for clinical record systems. The governing body and senior managers should ensure that an effective system is in place and working well. To ensure access at the point of care, organisational systems may: • define an objective of prompt access at the point of care • incorporate infrastructure, policies, procedures and protocols designed to ensure access at the point of care, including electronic and manual storage and transport systems that facilitate prompt access • establish standards for contemporaneous recording of clinical information and the availability of formal reports on investigations, including imaging and pathology tests • provide orientation, education and training for the clinical workforce on the importance of contemporaneous clinical record-keeping and point-of-care access to clinical information • provide a continuous cycle of audit and improvement. **Outputs of improvement processes may include:** • documentation describing the clinical record system including standards, policies, procedures and protocols • relevant modules of education and training programs • audit outcomes.
1.19.2 Systems are in place to restrict inappropriate access to and dissemination of patient clinical information	**Key tasks:** • **Review the systems that support confidentiality and privacy of patient information, including infrastructure, personnel, policies, procedures and protocols for paper-based and electronic records, and ensure they are consistent with the law and good practice** • **Periodically audit system performance and institute improvements as necessary** **Suggested strategies:** Information about an individual's physical or mental health and wellbeing is recognised to be both personal and sensitive and there are many ethical, professional and legal restrictions on the way in which such information is used. Generally, people assume all communications between them and their health service providers are private, and the law generally reflects this expectation – the confidentiality and/or privacy of most health information is protected by statutory or common law requirements of confidentiality, in addition to statutory provisions relating to privacy. However, the precise requirements of the law vary between jurisdictions. Providing appropriate physical infrastructure (for example, private interview rooms, patient status boards that are screened from public view) is necessary but not sufficient to ensure privacy and confidentiality. The culture and practices of the workforce are key to the appropriate protection of patient clinical information.

Actions required	Implementation strategies
1.19 Implementing procedures that protect the confidentiality of patient clinical records without compromising appropriate clinical workforce access to patient clinical information	**(continued)**

(continued)
 	
1.19.2 Systems are in place to restrict inappropriate access to and dissemination of patient clinical information
	The role of the governing body and senior executive is to ensure systems are in place to protect the privacy and confidentiality of patient clinical information, in accordance with the law and good practice. Well-designed systems generally should:
	
	• explicitly recognise the sensitivity of patient clinical information and the need to protect its confidentiality and privacy
	
	• reflect and be designed to ensure strict compliance with all professional and legal requirements that apply in the relevant jurisdiction
	
	• be underpinned by infrastructure, procedures and protocols that support achievement of the policy objectives including:
	
	   – written documentation in appropriate formats, explaining to patients and their carers how patient information is collected, used and disclosed and the safeguards that apply
	
	   – specific policies and procedures addressing the use by the workforce and organisation of clinical information for clinical, educational, quality assurance and research purposes including robust authorising procedures for any uses or disclosures outside the usual provision of care (including the development of clinical registries)
	
	• recognise the role of patient consent in the use or disclosure of information for purposes other than direct provision of care
	
	• include position descriptions and statements of responsibility for all members of the workforce (clinical and non-clinical), which may explicitly define:
	
	   – the obligation of all members of the workforce to protect patient privacy and confidentiality
	
	   – the link to the organisation's performance management system
	
	   – the consequences of intentional breach of the obligation
	
	• be reliably incorporated into the organisation's orientation, education and training programs for all members of the workforce
	
	• allocate responsibility for maintaining the integrity of the system to a designated individual
	
	• be subject to periodic audit and continuous improvement.
	
	Outputs of improvement processes may include:
	
	• documentation of the standards, policies, procedures and protocols for protecting the confidentiality and privacy of patient clinical information
	
	• audit outcomes and reports
	
	• templates for the issuing of log on and password details for electronic patient record systems
	
	• polices, protocols and procedures to prohibit the sharing of log on and password details.

Actions required	Implementation strategies
1.20 Implementing well designed, valid and reliable patient experience feedback mechanisms and using these to evaluate the health service performance	

1.20.1 Data collected from patient feedback systems are used to measure and improve health services in the organisation	**Key tasks:** • Verify that the organisation has adopted and implemented a comprehensive patient feedback system. Consider whether the system is appropriately designed, resourced, maintained and monitored • Define a reporting framework that will ensure patient feedback is utilised to optimal effect • Incorporate into the organisation's audit program periodic review of the patient feedback system, with a focus on its design, performance and adequacy of resourcing **Suggested strategies:** The experience of patients in receiving health care is an important element of the quality of care. You should gather patient and carer experience feedback systematically, using well-designed and validated collection tools. Feedback gained using such tools should be applied to improve the quality of care provided by the organisation. The governing body should promote the organisation's awareness of and ability to respond to patient experience information in the following ways: • ensuring the organisation adopts a validated and reliable method of systematically seeking feedback from patients and carers • ensuring there is a designated individual who is responsible for maintaining the integrity of patient feedback systems • allocating sufficient resources to support the patient feedback system • ensuring patient feedback is systematically and regularly sought, and covers the range of services and patients necessary to provide reliable information about the patient experience. Feedback may be sought on a general (i.e. organisation-wide) or specific (i.e. individual service or unit) basis. A combination may be appropriate. Systematic analysis and testing of the type of feedback the organisation needs will enable an appropriate feedback system to be developed • clearly identifying the individuals and/or committees that are responsible for analysing and responding to patient feedback • ensuring the information gained from patient feedback is analysed for safety and quality improvement risks and opportunities and used to inform the health service's quality management system • receiving and considering aggregate information about the performance of the patient feedback system, the risks and opportunities it has identified and the actions taken as a result • ensuring patients and carers receive information about what has been learned from patient feedback, and how it has been used to generate improvements in the health service • benchmarking performance against like services and any nationally available benchmarks. The Commission is currently undertaking work to gain consensus on and facilitate coordinated approaches to patient experience measurement. **Outputs of improvement processes may include:** • patient feedback policy, protocols and tools • allocation of responsibility for patient feedback • patient feedback reports • action arising from patient feedback • analysis of performance against benchmarks.

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Appendix: Links to resources

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