5 Clinical Governance and Risk Management for Medical Administrators

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Learning Objectives

By the end of this chapter, the learner should be able to understand:

- Fundamental elements of Clinical Governance in Health Services, including the structures, processes and frameworks that articulate the key roles, responsibilities and accountabilities at all staff levels from Board, management and clinicians, and enabled by robust data, culture, education and training and a continuous learning environment.
- Current literature relating to Clinical Governance and Risk Management.
- Elements of clinical governance which significantly impact medical staff.
- The value of medical engagement in clinical governance and techniques to improve engagement.
- The role of the Medical Administrator within a Clinical Governance system, as patient advocate on the Executive and translator between clinicians and management.

Introduction

One of the fundamental roles that Medical Administrators can lead in health care is that of Clinical Governance.

There are a number of books, journal articles and position papers outlining best-practice clinical governance, which will be briefly discussed in Sect. 5.1. However, this chapter will also focus on the role of the Medical Administrator in these systems, particularly if you are the senior executive in the health care organisation with ultimate Clinical Governance responsibility—Sect. 5.2. This chapter will also tailor the discussion to focus on medical staff issues—Sect. 5.3, framed around which of the National Safety and Quality Health Service Standards (NSQHSS) are particularly relevant for medical staff, how to you engage medical staff, in Sect. 5.4, and where there needs to be a different approach to senior medical staff and junior medical staff.

This chapter will also have an Australian focus and use state-based examples from Victoria. However, the core principles should be translatable to other states and countries. Please refer to your own state-country-based documents for subtle differences.

Please also note that Clinical Governance is a very broad concept, and inter-relates with Performance Development and review, supervision of junior staff, credentialing and scope of clinical practice—Sect. 5.5. In addition, clinical governance is part of a continuum of improving

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patient care, as a down-stream component to experimental and translational research for improving patient care. These areas are covered in other chapters, so they will be referred to as they relate to the overall framework.

5.1 Structures, Systems and Processes for Clinical Governance

Clinical Governance arose in the late 1990s from the United Kingdom to ensure high-quality care is integrated with the same level of importance as financial control and service performance [1], defined Clinical Governance as "a system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment tin which excellence in clinical care will flourish" [1].

The purpose of a Clinical Governance Framework is 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 … [to] maintain and improve the reliability, safety and quality of patient care, and improve health outcomes for patients'.

From a practical perspective, this means the systems to ensure that clinical care provided to patients is as safe, effective and appropriate as possible.

The science of quality improvement and Clinical Governance has emerged over the last few decades, ignited by the publication of *To Err is Human* by the Institute of Medicine in 1999, highlighting medical errors and the impact on patient safety [2] in the United States. The *Quality in Australian Health Care Study* in 1995, demonstrated that 16.6% of admissions studied were associated with an adverse event that resulted in disability or a longer hospital stay for the patient and was caused by healthcare management. In addition, 51% of those adverse events were considered preventable [3].

There are countless examples of poor Clinical Governance leading to poor patient outcomes, with a number of high-profile failures including Paediatric Cardiac Surgery at Bristol Royal Infirmary Public Inquiry in 2001 (Final report, 2001), chaired by Professor Ian Kennedy, and the Mid Staffordshire NHS Foundation Trust Public Inquiry, chaired by Robert Francis (Final Report, 2013). Russell and Dawda summarise the key recommendations identified of national and international inquires is that what goes on in hospitals is about patients, and the quality and safety of patient care must be placed by all parties – governments, bureaucrats, clinicians, and administrators – above all other aims. Patient care is their fundamental, core duty. That does not preclude efforts to reduce costs, increase efficiencies, and restructure and reform systems, but these efforts cannot be at the expense of providing best quality safe care [4].

The importance of Clinical Governance is as relevant in 2022 as over the couple of decades, with the *Targeting Zero: Report of the Review of Hospital Safety and Quality Assurance in Victoria* in 2016, commissioned by the Minister of Health following the discovery of a cluster of tragically avoidable perinatal deaths at Djerriwarrh Health Services [5]. The recommendations from the review include:

- Clear expectations for boards of all hospitals to have safety and quality as a core focus,
- Increased Board skill mix in "substantive clinical governance and consumer representation,
- All hospitals should be held to account for improving safety and quality of care, regardless of their size or sector,
- The flow of information in the health system must ensure deficiencies in care are identified and focus attention on opportunities for improvement,
- All hospitals should have access to independent clinical expertise to help identify deficiencies in care and focus attention on opportunities for improvement,
- Increased performance assessment framework from state department,

- Clinical leaders must be engaged to strengthen, direct, and lead efforts to improve safety and quality of care,
- Stronger focus on improving patients experience of care.

There are also a growing body of literature of specific initiatives to improve patient outcomes, such as antibiotic stewardship and hand hygiene to reduce rates of Methicillin Resistant *staphylococcus aureus* [6], or reduction in hospital-wide mortality and out-of-ICU cardiac arrest as a result of introduction Rapid Response Teams [7].

In addition, a landmark study, titled Deepening Our Understanding of Quality Improvement in Europe (DUQuE), involved a multi-methods study across eight European countries studying the effectiveness of quality improvement systems in hospitals. The DUQuE study demonstrated strong associations between quality management and clinical effectiveness of care, and to a less extent for patient safety culture [8]. The *Deepening Our Understanding of Quality Improvement in Australia (DUQuA) study* is in the final stages of implementation, with 32 hospitals, 4000 sets of data and feedback from almost 1900 participants across all states within Australia, mirroring the methodology of the European study, available at the DUQuA internet site 2017. At the time of publication, the DUQUA results were yet to be released.

Leggat and Balding [9], in their qualitative study on the implementation of quality systems in Australian hospitals, conducted interviews and focus groups with 270 board members, manages and staff. Leggat and Balding found that quality was consistently described as an extra set of tasks to do, rather than a means to creating sustained, safe, quality care, and that there was a lack of understanding of how to effect change in the complexity of hospitals that has led to boards and senior managers to execute a technical, top-down approach based on compliance and reactive risk.

Health care organisations are increasingly analysing the most appropriate mechanisms for reducing unwarranted variation in care, as highlighted via mechanisms such as the Australian Atlas of Healthcare Variation (Australian Atlas of Healthcare Variation Fourth edition 2021). Further, some Australian health services are exploring the concepts of high-reliability organisations, as lead by John Hopkins Medicine in the United States, of fractal-based quality management [10], and actively organising for a culture of high reliability where the organisation is constantly adapting, tweaking and solving smaller problems as they emerge, preventing more widespread failures and improving safety [11]. High reliability has been termed the third wave of innovation in patient safety, following from that of technical advances and standardising procedures [12].

The first section of this chapter briefly outlines the fundamental principles for exemplary Clinical Governance structure, systems and processes that Medical Administrators should ensure are implemented effectively in their organisations.

5.1.1 Principles of Implementing Clinical Governance at a Health Service Level

At health services, patient safety and quality improvement are an integral part of our culture. Organisations should facilitate the provision of the highest standard of patient safety, quality and risk management through a robust and effective Clinical Governance Framework that includes monitoring clinical outcomes, clear lines of accountability for clinical care, an effective process for identifying and managing risk and monitoring and addressing problems in performance.

The Clinical Governance Framework should be underpinned by the domains outlined in the National Model for Clinical Governance [13].

The five components of the Clinical Governance Framework are as follows:

1. **Governance, leadership and culture—**Integrated corporate and clinical governance systems are established and used to improve the safety and quality of health care for patients.
2. **Patient safety and quality improvement systems—**Safety and quality systems are

integrated with governance processes to actively manage and improve the safety and quality of health care for patients.
3. **Clinical effectiveness—**The workforce has the right qualifications, skills and supervision to provide safe, high-quality health care to patients.
4. **Safe environment for the delivery of care—** The environment promotes safe and high-quality health care for patients.
5. **Partnering with consumers**—Systems are designed and used to support patients, carers, families and consumers to be partners in healthcare planning, design, measurement and evaluation; elements of this component include:
   (a) Clinical governance and quality improvement systems to support partnering with consumers.
   (b) Partnering with patients in their own health literacy.
   (c) Partnering with consumers in organisational design and governance.

State health departments have established governing bodies to provide oversight of Clinical Governance within individual jurisdictions. These include but are not limited to the Clinical Excellence Commission in NSW and Safer Care Victoria.

The components of the frameworks across these jurisdictions are relatively similar and should be adapted by the health services within the relevant jurisdiction.

A Clinical Governance Framework should also be supported by:

- Role accountabilities within the Executive and management hierarchy – this will depend on the size and nature of the organisation. Often the Executive responsibility for Clinical Governance aligns with the Chief Medical Officer/Medical Administration portfolio.
- A committee and reporting structure that encompasses all clinical units and which reports ultimately to the Executive and the Board. This may have separate structures for unit-based or Division-based Clinical Governance but might also have specific committees established for specialised purposes, such as Medication Safety, Preventing harm from Falls. The size and complexity of the committee structures will be dependent on the organisational size and speciality.

5.1.2 Roles and Responsibilities

Clinical Governance is a shared responsibility that functions at all levels of the organisation and includes a programme of review and improvement at every point from the Board, to the Executive, the management team, clinicians and non-clinical staff.

The Board is responsible for oversight of the Clinical Governance Framework. Their role includes demonstrating a commitment to good governance and supporting an open and transparent management culture.

The Chief Executive Officer and the Executive are responsible for leading the organisation in a manner that is fair, open and challenging and demonstrates a commitment to good Clinical Governance. They must ensure that the appropriate systems and processes, including policies and procedures, are in place to support excellence in clinical care and patient safety, to report and manage incidents and facilitate consumer feedback. In addition, they are responsible for establishing a risk management framework that facilities the identification, monitoring and management of risks to the organisation, patients, staff and visitors. They must ensure a positive and timely organisational response to change.

Directors and Medical Directors of Clinical Service Units and Business Units are responsible for ensuring that the Clinical Governance Framework is appropriately applied within their areas. This includes that policies and procedures are maintained, that work practices are compliant with organisational standards and that risks are reviewed and remedial action completed. They need to ensure that staff are appropriately trained and qualified to meet the requirements of their role in clinical practice. Directors must ensure that systems for reviewing clinical outcomes are maintained, and performance issues are addressed.

Unit/Department Heads and Managers are responsible for applying the Governance Framework within their areas of accountability. This means establishing clear lines of accountability within their unit or department for the quality and safety of the services provided. Organisational policies and procedures must be maintained and embedded into local practice, and quality business plans should include work plans for continuous improvement in systems and content of care. Managers at this level are required to ensure that incident management systems are appropriately applied, and a systematic response to local issues and performance improvement occurs. Managers should also ensure that appropriate opportunities for training, education and performance review are provided. All staff should embrace the responsibility for risk management at a local level.

Clinical Staff are expected to comply with policies and procedures that apply to their area of practice, report incidents that have or could impact on patient safety and be mindful of legislative requirements in undertaking their role. They should have a clear scope of practice expressed in their position description, supported by an appropriate credentialing process. Staff should participate in regular performance reviews with their manager, have regular review of their scope of practice, and seek access to appropriate ongoing education and training. Clinical staff must engage in the organisation's systems and processes for monitoring service delivery and initiatives to improve care delivery.

Consumers should be encouraged and supported to be active participants in decisions regarding their health care through the provision of appropriate information on the clinical care provided, the informed consent process and opportunity to provide feedback on the care they receive.

These roles and responsibilities should also be explicit in Position Descriptions, and the staff should be performance managed against their accountabilities.

Bismark et al. explored the role of board in Clinical Governance in 2013, which surveyed the Board Chair, Quality Committee Chair and two members of the board in all 85 Victorian Health Services. Most boards reviewed medication errors and hospital-acquired infections at least quarterly (77%), externally benchmarked performance (50%) with other health services. As such, the Board members need to understand quality and safety frameworks, with 90% of those surveyed in Bismark's study indicating that additional training in quality and safety would be advantageous [14].

5.1.3 Clinical Governance Committee Structures

The Clinical Governance Framework should be supported by Committee Governance structures, that facilitates an integrated model of decision-making, consumer participation, clinical effectiveness and risk management across all areas of the organisation by bringing together different areas of responsibility to achieve shared plans.

The Committee structure seeks to ensure that safety, quality and risk management should be embedded into the organisation's daily business by building quality structures that operate across the organisation and address key issues such as medication safety, mortality and morbidity review and the monitoring of new technologies through various standing committees.

These committees enact the domains of Clinical Governance in a practical sense. The structure should also ensure that there is appropriate governance for each of the NSQHSS.

The terms of reference for each committee should reflect the specific nature of their work and their delegated role for clinical safety and quality. Committee documentation should also include:

- Minutes and Agendas for all meetings.
- Risk Assessment of key Risks relevant to the committee.
- Action plan developed against the key risks.
- Actions register, to ensure actions are documented with person responsible and timeframes for completion of actions.

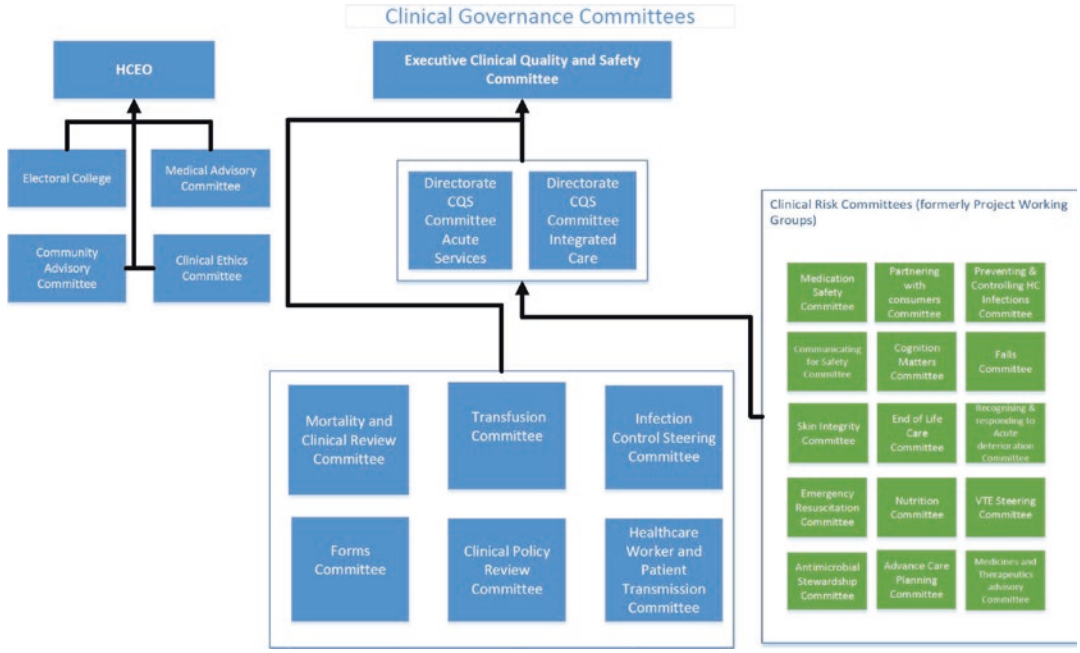

Fig. 5.1 Example of Committee structure for Clinical Governance. Source: author

As part of the terms of reference of all key Governance Committees, Committees should be reviewed annually or biannually. This ensures that the terms of reference and membership of the committee remain relevant and that the committees consider their effectiveness against their roles and responsibilities.

The structure and size of the committees will depend on the organisation size, speciality breadth, and need for cross-campus and acute, sub-acute and community representation.

Figure 5.1 provides an example Committee structure for Clinical Governance.

The specific roles of the committee hierarchies are outlined below:

5.1.3.1 Board-level Clinical Safety and Quality Committee

Usually a sub-committee of the Board, the Committee is a forum for in-depth review of quality issues at a governance level. This committee should include representatives from the Board, including members with clinical experience, Board members as consumer representatives, executive staff, senior medical and nursing staff. The Subcommittee may also include non-Board consumer and community representatives, who represent the diverse cultural and community backgrounds of the health service catchment.

The committee:

- Provides the strategy and direction for quality and safety within the health service.
- Monitors compliance with key quality and safety projects, organisation-wide clinical indicators, complaints and incident data, patient satisfaction results and other key quality indicator data.
- May receive updates on quality assurance activities such as accreditation, credentialing, clinical registry results, clinical audit, and legislative compliance activity.

5.1.3.2 Executive Level Quality and Safety Committee

The Executive level Quality and Safety Committee takes an organisation-wide oversight

of Clinical Governance. Specific accountabilities usually include accreditation compliance, organisation-wide quality and safety, enterprise risk management, credentialing and organisation-wide indicators to ensure quality, safety and appropriate clinical risk management. The membership usually includes the Executive, Clinical Service Unit Directors, Medical Directors and representatives from other key directorates such as Pharmacy, Allied Health and Radiology. Often Executive level committees also have community or consumer representation.

5.1.3.3 Cross Organisation Quality and Safety Committees

There are a number of committees that have a specific role in the Governance of a particular clinical risk/quality issue. Some of these committees are time limited. Most organisations have aligned such committees to the NSQHSS. Examples of these committees include:

- Clinical Governance.
- Partnering with Consumers.
- Preventing and Controlling Healthcare Associated Infections.
- Medication Safety.
- Comprehensive Care (including Falls Prevention, Pressure Injury, and Nutrition).
- Communicating for Safety.
- Blood Management.
- Recognising and Responding to Acute Deterioration.
- Clinical Policies and Procedures Committee.
- New Technology and Clinical Practice Committee.

5.1.3.4 Division Level or Unit Level Quality and Safety Committees

A range of speciality committees may be appropriate, depending on the size and complexity of the organisation. These committees have often arisen from mortality and morbidity committees at speciality level.

5.1.4 Enablers of Exemplary Clinical Governance

The following enablers of good clinical governance are essential to support clinicians and managers in determining the priorities for the organisation.

- Capability framework.
- Education strategy.
- Project support/administrative support.
- Data management.

For brevity reasons, this chapter will not cover in-depth the capability framework, education, or project support enablers but will comment on data management.

5.1.5 Data Management to Support Clinical Governance

5.1.5.1 Key Performance Indicators

Hospital-wide clinical performance indicators should be reported at key clinical governance committees. Indicators are measured against past performance and linked to strategies to reduce rates of adverse events.

Example indicators include:

- Clinical indicator suite.
- Complaints data such as the number and type of complaints, completion of review within timeframes, implementation of recommendations arising from complaints within timeframes.
- Incident data such as the number of incidents, number of incidents with harm ISR1/2 or SAC1/2, HS1/2 completion of incident reviews within timeframes, and implementation of recommendations arising from incidents within timeframes.
- Medication Safety key performance indicator suite.
- Jurisdictional performance indicators such as hand hygiene rates, infection surveillance rates, aged care quality indicators.

- Benchmarked data such as Hospital-Acquired Complications (HACs).
- Patient experience and outcome measures (PREMS and PROMS).

5.1.6 Benchmarking

Health services should participate in a range of benchmarking activities including infection control monitoring such as MyHospitals website, various national clinical benchmarking databases and clinical registries such as the Australian and New Zealand Society of Cardiac and Thoracic Surgeons database and the Health Roundtable. In addition, health services should consider approaching other similar health services to compare practices, processes, and outcomes to ensure that their practice is consistently reviewed against current industry standards and opportunities for improvement are identified.

The key is to determine what depth and breadth of data should be reviewed at the various levels of the organisation. Figure 5.2 outlines principles for data management at the various committee levels.

It is also important to consider the nature and format of data presentation, to assist decision-makers and clinicians. High-level trends can be tracked over time with Statistical Process Charts/Run charts, with control limits to highlight those varying from controls.

Alternatively, heat maps or traffic light systems can be used to identify indicators that have flagged beyond their limits.

5.1.7 Implementing a Clinical Governance System

Implementing a clinical governance system which involves all the aforementioned components requires using appropriate change management principles including:

- Establish the right Clinical Governance system and processes for the organisation.

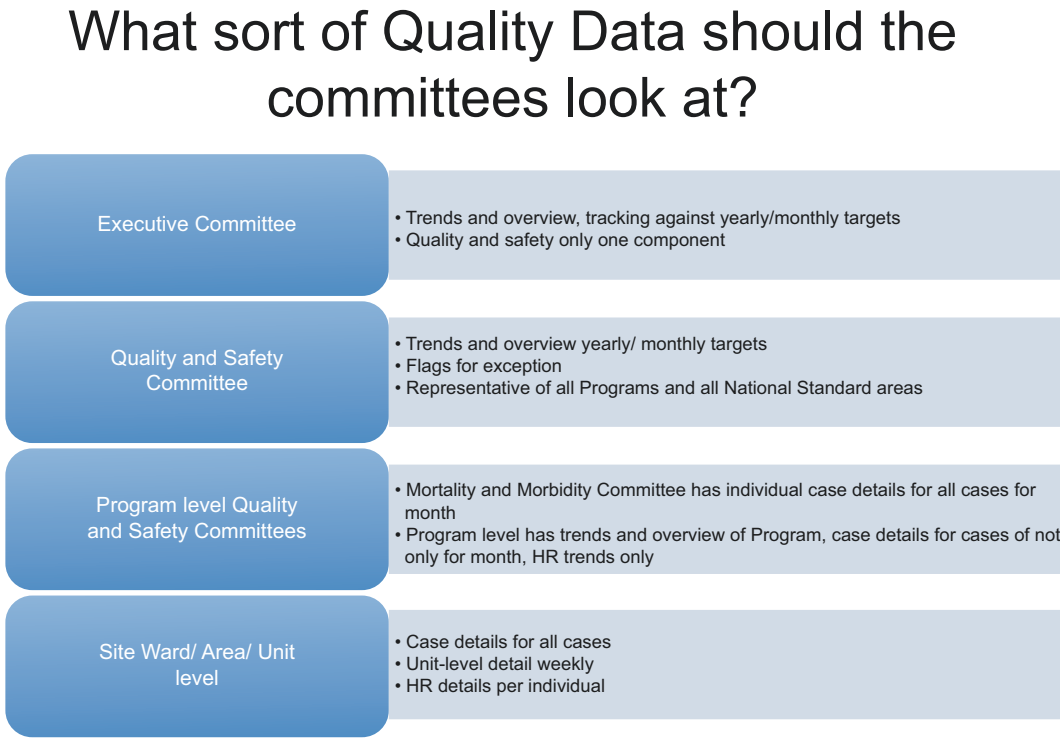

Fig. 5.2 Principles of levels of Data at various committees

- Develop a change management and a communication strategy.
- Implement the system.
- Evaluate the system.

There are an extraordinary large number of diagnostic, mapping and measurement methodologies available to support the implementation of a clinical governance system. Examples include:

- Systems thinking [15].
- Improvement Science, with Testing and Learning Cycles – Plan, Do, Study, Act (PDSA) Cycles [16].
- Patient safety measurement tools [17].

Incident Investigation tools. Most state health departments provide training and tools for clinicians on incident investigation tools including but not limited to Root Cause Analysis, London Protocol, Cluster analysis and AcciMap. The choice of tools and methodologies used by the organisation will be guided by the state department guidelines, organisation's culture and existing systems, and the context of the specific clinical situation being reviewed.

From practical experience, it is important to be aware of the types of recommendations generated from case review and improvement science, and the cultural context of the organisation that requires the change. Recommendations should be Specific, Measurable, Assignable, Realistic, and Time-related (S.M.A.R.T.) where possible [18], and of as few as possible to address the root cause of the incident. Raj Behal in his Safety Steps framework outlines a 100-point Treatment Plan, which classifies recommendations according to a hierarchy of effectiveness for removing or controlling the hazard. Removing the hazard, or addressing the human factors contributing to the incident is rated more effective than management controls or managing culture [19].

Most quality improvement projects arise due to a perceived gap in performance and patient outcomes. By necessity, there will need to be changes to address the gap. However, all quality improvement projects need to consider the workload impacts on the clinicians and frontline staff. As Hayes, Batalden and Goldmann (2015), state that years of study of innovation diffusion, change management and behaviour change have demonstrated that increasing workload demands, especially when not understood, perceived to be unneeded, or felt unlikely to lead to improvement, leads to change fatigue and resistance cynicism, burnout and turnover. In addition, if true and sustainable improvement in outcomes is to be realised, we must, at all levels of the system, understand and aim to embed a work smarter, not harder approach and limit the workload – including improvement-related workload – on those charged with delivering care.

5.1.8 An Integrated and Consistent Approach to Clinical Governance

Once all of the elements, roles, committees, policies and frameworks are implemented, it is essential to reflect on whether all of the elements are integrated, and consistent.

5.1.9 A Specific Comment on Accreditation for Medical Administrators

1. All Australian Health Services are required to comply with an accreditation process. The National Safety and Quality Health Service Standards were first introduced in 2013, and are mandatory for all public and private, acute, sub-acute, day procedure and multipurpose health services. The Standards were updated in 2017. The National Standards are designed to protect the public from harm and to improve the quality of health service provision. The eight NSQHS Standards provide a nationally consistent statement about the level of care consumers can expect from health services and include: Clinical Governance.

2. Partnering with consumers.
3. Preventing and controlling healthcare-associated infections.
4. Medication safety.
5. Comprehensive Care.
6. Communicating for Safety.
7. Blood management.
8. Recognising and responding to clinical deterioration in acute health care.

In addition, most health services participate in a range of specialist accreditation programmes, including Aged Care Standards, National Association of Testing Authorities Accreditation Review (NATA), Professional Medical College Accredited programmes (e.g. Royal Australasian College of Physicians for Physician Training) and the Department of Health/Commonwealth Health and Ageing programmes.

The new national standards are clinically based and are relevant and tangible for clinicians on the front line. It is also:

- Risk-based approach: the organisation will need to be able to demonstrate that key services have been, identified the highest risk risks and put in place plans to manage.
- Compliance-based: organisations need evidence to demonstrate compliance with policies and guidelines state.
- Consumer Focussed: based on the concept that consumers are a partner in the planning and delivery of health care.

There are also Accreditation Standards in Australia for Mental Health National Standards, Community Standards, and Aged Care Standards and Clinical Trials Standards.. The principles for compliance/accreditation remain the same; however, the details of these are beyond the scope of this chapter.

The Governing Body (usually the organisation's Board) is required to submit an annual Attestation to their accrediting agency. The Attestation process is outlined in Fact sheet 7 from the ACSQHC, defining attestation as "a formal process that involves authorised officers of a health service organisation confirming compliance, in this case to the NSQHS Standards. This is in the form of a written affirmation".

Each Health Service is required to undergo an Accreditation every 3 years by an independent body to assess compliance with the safety and quality standards.

When a health service organisation has shown it meets all of the NSQHS Standards, it is awarded accreditation. If an action is not met at the first assessment by the accrediting agency, the health service organisation has 60 business days to make improvements. If at the final assessment, the action is still not met, the health service organisation will not be awarded accreditation. All actions must be met to achieve accreditation.

If a health service organisation is not awarded accreditation, various sanctions may apply depending on the extent and the type of actions that were not met. These sanctions may include administrative oversight by the regulator, loss of licences and/or loss of funding. Any health service organisation that does not achieve accreditation must undergo a reassessment of all eight NSQHS Standards within 12 months to continue to be able to operate.

5.1.10 Clinical Risk Management for Medical Administrators

Clinical Risk Management (CRM) 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 acting to prevent or control those risks. Clinical Risk Management should be part of a broader organisational risk management system, which integrates the management of organisational, financial, occupational health and safety, plant, equipment and patient safety risks. The organisation should have in place a systematic approach to minimising risk and improving the quality of clinical care. This should include compliance with relevant legislation, the reporting and investigation of incidents and risks and the implementation of strategies to reduce the occurrence of adverse events and improve patient safety.

The clinical risk management system at a health service should utilise a range of strategies to mitigate and manage risk and improve the quality of clinical care. These include:

5.1.11 Risk Register

A Risk Register is a comprehensive repository for the documentation of identified risks arising out of the operations of the organisation. The primary purpose of a risk register is to act as a decision-making tool in managing risks. In this regard, it helps inform strategic planning processes and prioritisation of resources.

5.1.12 Policies and Procedures

Health Services should have a range of policies and procedures, which set out expectations in relation to staff behaviours/actions and specific clinical intervention. Policies should be developed through a rigorous Governance process and have a strong evidence base. Each policy should have an identified owner and a clearly defined review date.

5.1.13 Incident Management System

Any occurrence that is not consistent with the routine care of the patient or functioning of the health service is reported. This includes any event or circumstance that could have or did result in unintended harm, suffering, damage or loss to an individual, patient, or staff, the organisation, facilities or property. There are multiple Incident/Risk Management systems in use across Australia including RiskMan, RL Datix, VHIMS, IMMS and many others. These are primarily web-based incident reporting system, which enable incidents to be entered on-line. Incidents are risk-rated and high-level incidents are then escalated to ensure appropriate notification and action to reduce the likelihood of reoccurrence.

The severity of the incident will guide the level of review. High-level incidents (ISR/SAC/HS 1 or 2), which result in significant patient harm or death, are reviewed through structured case review or incident investigation methodology (like RCA) to identify critical points, and root causes of the incident. Recommendations are developed to address the identified vulnerabilities and contributing factors.

Trends of incidents can also be monitored over time, including analysis of groups/clusters of incidents for patterns in patient cohorts, to assist with identifying risk reduction strategies to reduce the occurrence of incidents, or to reduce the level of harm from incidents. Appropriate sampling [20] of incidents can allow meaningful analysis of contributory factors to incidents, whilst ensuring high yield from quick, efficient, manageable analysis.

Medical staff reporting of incidents is historically low compared to other health professional groups in the literature. Studies have identified that doctors are reticent to embrace incident reporting systems, with United States and Australian experience of physicians reported only 1.9–2.9% [21, 22] and 5% [23] of incidents, respectively. Key barriers to reporting incidents by medical staff have been shown to be a lack of feedback on outcomes and too long to complete incident reports [24].

Benn et al. [25] identified a number of key factors for successful feedback from incident reporting systems: the role of leadership, the credibility and content of information, effective dissemination channels, the capacity for rapid action and the need for feedback at all levels of the organisation. Pham et al. [26] also recommend several strategies to maximise the value of incident reporting systems, including:

1. Making reporting easier,
2. Making reporting meaningful to the reporter,
3. Make the measure of success system changes, rather than events reported,
4. Prioritise which events to report and investigate, do it well,
5. Convene with diverse stakeholders to enhance their value.

Throughout incident/adverse event review, Medical Administrators should also be cognisant of the staff distress and concern that can arise from being involved with an incident resulting in patient harm. Most health professionals do not undertake their work to harm patients. Harrison, Lawton and Steward [27] survey of doctors' experience of adverse events identified a significant impact personally and professionally, with 76% of respondents believing this had affected them personally, 74% reporting stress, 68% reporting anxiety, and 63% lower professional confidence. The ACSQHC Open Disclosure Standard 2013, note that Clinicians (and the non-clinical workforce) may be affected by being involved in an adverse event, and may require emotional support and advice in the aftermath of the incident. The organisation should ensure that these staff have formal and informal support processes and provide facilities for debriefing for those involved in an adverse event. In addition, information on the support systems for clinicians who are distressed by an adverse event include Doctors' Health.

Advisory Service, medical defence organisations, professional and collegiate associations and employee assistance schemes.

Medical Administrators should ensure there are targeted strategies within their organisations to ensure medical staff are aware of incident reporting systems, encouraged to report appropriate incidents, supported through the process, following best practice processes for respectful management of adverse events, and are provided timely feedback of the outcomes of reviews on patient care.

5.1.14 Sentinel Event Reporting

All Australian States are required to establish Sentinel Event Reporting system from health services to the local jurisdiction. The ACSQHC Sentinel Event List (Version 2) 2020, defines a Sentinel Event as "a particular type of serious incident that is wholly preventable and has caused serious harm to, or the death of, a patient". These events are considered "wholly preventable" in the context of preventative barriers being available to stop the event from occurring.

To be classified a sentinel event, a strict set of criteria need to be met:

- The event should not have occurred where preventive barriers are available
- The event is easily recognised and clearly defined
- There is evidence the event has occurred in the past.

The ACSQHC defines "serious harm" when, as a result of the incident, the patient:

- Requires life-saving surgical or medical intervention, or
- Has shortened life expectancy, or
- Has experienced permanent or long-term physical harm, or
- Has experienced permanent or long-term loss of function.

The 10 revised National Sentinel Events defined in 2020 include:

1. Surgery or other invasive procedure performed on the wrong site resulting in serious harm or death.
2. Surgery or other invasive procedure performed on the wrong patient resulting in serious harm or death.
3. Wrong surgical or other invasive procedure performed on a patient resulting in serious harm or death.
4. Unintended retention of a foreign object in a patient after surgery or other invasive procedure resulting in serious harm or death.
5. Haemolytic blood transfusion reaction resulting from ABO incompatibility resulting in serious harm or death.
6. Suspected suicide of a patient within an acute psychiatric unit or acute psychiatric ward.
7. Medication error results in serious harm or death.
8. Use of physical or mechanical restraint resulting in serious harm or death.

9. Discharge or release of a child to an unauthorised person.
10. Use of an incorrectly positioned oro- or nasogastric tube resulting in serious harm or death.

Each state health jurisdiction will have reporting guidelines, templates for health services to complete for any sentinel events reported.

5.1.15 Clinical Review Panels

Medical staff have an important role to play in promoting a culture of safety by championing incident reporting initiatives and participating in multidisciplinary teams that analyse adverse events and promote change [28]. To facilitate this engagement, many larger health services have established clinical panels, alternately called Mortality and Incident Review Committees, with broad representation to review such incidents and develop recommendations. The panels should usually review significant clinical events that

1. Undergo a formal incident investigation and or,
2. Involve multiple units or departments.

The role of the panel is to facilitate the identification of deficiencies in the system that contributed to the occurrence of these events in an open and transparent manner, and to develop recommendations for improvements in the systems of care. The panels should complement existing unit-level case review mechanisms.

5.1.16 Legislative Compliance

Most health services have a legislative compliance responsibilities register that clearly articulates executive and management responsibility for ensuring compliance with relevant health-related legislation to support risk reduction across the organisation. Tools to audit policy and practice on a regular basis to assess compliance and identify areas requiring remedial action should support the register. In addition, updates to legislation should be reviewed regularly to ensure appropriate amendments are made if required.

Health services should also be familiar with other reporting requirements including but not limited to special committees investigating deaths following surgery and anaesthesia, maternal and perinatal committees etc.

5.1.17 Medico-Legal

Through the management of medico-legal cases, potential clinical risk issues, such as the occurrence of a clinical incident, may be identified. As appropriate, these should be referred by medico-legal services or relevant clinical governance/risk Management team for investigation and follow-up. Additionally, all inpatient deaths reported to the coroner and outpatient deaths where Coronial review of the organisation's provision of care is undertaken should be similarly referred. On completion of cases, all Coronial findings and, in the case of litigation any recommendations provided by the appointed legal team arising from the case should be routinely distributed to the Risk Management team, the Chief Medical Officer and relevant Clinical Units. Monitoring of the compliance with Coronial reporting is valuable to ensure appropriate cases by junior doctors are being referred for review [29].

5.1.18 Complaints or Concerns About Clinicians

Health services should ensure there are processes to raise concerns or complaints about clinician performance, which included a clear process for reporting concerns, appropriate investigation and response pathways and an avenue for anonymous reporting. Australian Health Practitioners Regulation Agency (AHPRA) also has mandatory reporting requirements for any clinicians undertaking notifiablte conduct (see AHPRA intranet site for details of Mandatory reporting criteria).

5.1.19 External Reviews

Most health services engage external providers to conduct auditing of health service clinical and corporate governance frameworks. The importance of independent clinical reviewers on significant case reviews has been a key recommendation arising from the Review into Djerewarra Health Service [5].

5.2 The Medical Administrator as the Executive Oversight for Clinical Governance

Medical Administrators, are in a unique role to significantly influence and improve patient care via overseeing clinical governance in the organisation [30, 31]. In a survey of Directors of Medical Services in Victorian metropolitan health services, 12 of the 14 (85.7%) Medical Administrators were responsible for Clinical Governance as part of their role [30, 31].

Medical Administrators on the Executive of Health Services (usually in Chief Medical Officer or Executive Director Medical Services roles [30, 31], advocate on behalf of the patient and for clinical governance on the Executive. By virtue of their position on the Executive team, Medical administrators can ensure that all decisions, financial, strategic, operational, occupational health and safety, have consideration for the impacts on patient safety.

In her 2011 study of the association between physician leaders and hospital performance Goodall concluded that there is a strong positive association between the ranked quality of a hospital and whether the CEO is a physician or not ($p < 0.001$), reinforcing the importance of medical leadership in quality outcomes for patients. A study in Iran also found a similar association existed ([32]).

It is however difficult to oversee all of the clinical governance elements by one individual. Appropriate delegation of roles and responsibilities across the clinical governance spectrum to other Executives and senior leaders within the organisation will assist with an integrated matrix of accountabilities for clinical governance. Other members of an executive leadership team who may share responsibilities include leads of clinical governance, nursing, allied health, operations and human resources/people and culture.

It is the role of the medical administrator to ensure the framework, policies and procedures are developed, implemented, monitored and evaluated. In addition, the medical administrator should ensure that they have enough knowledge depth of the subject matter to validate clinical assumptions presented by the clinicians, whilst providing a broader guidance on the orgnaistaional position, risks and drivers.

Medical administrators also have a role to coach and mentor Heads of Units, Clinical Service directors and medical leaders within their organisations in clinical governance structures. By the nature of the professional hierarchy [30, 31], the Medical Administrator is trusted by the clinician, and can act as the interlocutor between the clinicians and the executive to prevent any potential disconnect between management and clinicians within the clinical governance framework.

Monitoring of the frameworks can be challenging, as there is a need to balance the patient safety aspects with the operational and corporate imperatives. The Institute for Healthcare Improvement (2013) outlines the principles of High-impact Leadership that can assist Medical Administrators to form the balance between corporate and clinical governance needs including:

1. High-impact leadership requires the adoption of new mental models. That is how leaders think about challenges and solutions.
   (a) Individuals and families are partners in their care.
   (b) Compete on value, with continuous reduction in operating costs.
   (c) Reorganise services to align with new payment systems.
   (d) Everyone is an improver.

2. High-Impact Leadership Behaviours or what leaders do to make a difference.
   (a) Person-centredness: Be consistently person-centred in word and deed.
   (b) Frontline engagement: be a regular, authentic presence at the front line and a visible champion of improvement.
   (c) Relentless focus: remain focussed on the vision and strategy.
   (d) Transparency: require transparency about results, progress, aims and defects.
   (e) Encourage and practice systems thinking and collaboration across boundaries.
3. High-Impact Leadership Framework where leaders need to focus their efforts.
   (a) Driven by persons and community.
   (b) Create vision and build will.
   (c) Develop capability.
   (d) Deliver results.
   (e) Shape culture.
   (f) Engage across boundaries.

5.3 Areas of Clinical Governance with Relevance for Medical Staff

The following areas are particularly relevant for medical staff

- National Standards.
- Credentialing and Scope of Practice – how to describe the clinical scope undertaken by our medical staff, how to document and formally recognise the qualifications and experience of our medical staff.
- Introduction of New Clinical Services, Procedures and Other Interventions – how to ensure that these are linked to credentialing and scope of clinical practice assessments, evaluation of new products, and research ethics.
- Peer review and clinical audit – how to monitor our patient outcomes within the scope of practice for the health service.
- Performance management – how to ensure we have opportunities to optimise the ability to provide the best patient care.

As Credentialing and Scope of Practice, and Performance management of medical staff is addressed in other chapters of this book, the detail is beyond the scope of this chapter. Of note however is the credentialing and scope of practice implications for introducing new technologies or clinical practice. The proactive participation of senior medical staff at all stages of the introduction of new technologies is paramount, and can ensure safe, appropriate and effective patient care as a result. However, as illustrated by Dwyer et al. [33] doctors are not necessarily aware of the importance of their participation in these processes, and the organisation and such committees need to be promoted to all medical staff.

This conclusion of this chapter will therefore focus on the elements of Accreditation, Peer Review and Clinical Audit/Mortality and morbidity review, Hospital Standardised Mortality Ratio, and Clinical Registries.

5.3.1 National Standards

The NSQHS Standards aim to protect the public from harm and to improve the quality of health service provision. They provide a quality assurance mechanism that test whether relevant systems are in place to ensure that expected standards of safety and quality are met. Medical administrators, should be familiar with the entire suite of standards, however Table 5.1 below outlines the elements particularly relevant for medical staff.

Table 5.1 NSQHSS elements relevant for medical staff

Standard	Element
Standard 1—Clinical Governance	Leaders at all levels in the organisation set up and use clinical governance systems to improve the safety quality of health care for patients
Governance, leadership and culture	1. The governing body: (a) Provides leadership to develop a culture of safety and quality improvement, and satisfies itself that this culture exists within the organisation (b) Provides leadership to ensure partnering with patients, carers and consumers (c) Sets priorities and strategic directions for safe and high-quality clinical care, and ensures that these are communicated effectively to the workforce and the community (d) Endorses the organisation's clinical governance framework (e) Ensures that roles and responsibilities are clearly defined for the governing body, management, clinicians and the workforce (f) Monitors the action taken as a result of analyses of clinical incidents (g) Reviews reports and monitors the organisation's progress on safety and quality performance
Organisational leadership	2. The health service organisation establishes and maintains a clinical governance framework, and uses the processes within the framework to drive improvements in safety and quality
	3. The health service organisation considers the safety and quality of health care for patients in its business decision-making
Clinical leadership	4. Clinical leaders support clinicians to: (a) Understand and perform their delegated safety and quality roles and responsibilities (b) Operate within the clinical governance framework to improve the safety and quality of health care for patient
Measurement and quality improvement	5. The health service organisation uses organisation-wide quality improvement systems that: (a) Identify safety and quality measures, and monitor and report performance and outcomes (b) Identify areas for improvement in safety and quality (c) Implement and monitor safety and quality improvement strategies (d) Involve consumers and the workforce in the review of safety and quality performance and system
Risk management	6. The health service organisation: (a) Identifies and documents organisational risks (b) Uses clinical and other data collections to support risk assessments (c) Acts to reduce risks (d) Regularly reviews and acts to improve the effectiveness of the risk management system (e) Reports on risks to the workforce and consumers (f) Plans for, and manages, internal and external emergencies and disasters

Table 5.1 (continued)

Standard	Element
Incident management systems and open disclosure	7. The health service organisation has organisation-wide incident management and investigation systems, and: (a) Supports the workforce to recognise and report incidents (b) Supports patients, carers and families to communicate concerns or incidents (c) Involves the workforce and consumers in the review of incidents (d) Provides timely feedback on the analysis of incidents to the governing body, the workforce and consumers (e) Uses the information from the analysis of incidents to improve safety and quality (f) Incorporates risks identified in the analysis of incidents into the risk management system (g) Regularly reviews and acts to improve the effectiveness of the incident management and investigation systems
Performance management	8. The health service organisation has valid and reliable performance review processes that: (a) Require members of the workforce to regularly take part in a review of their performance (b) Identify needs for training and development in safety and quality (c) Incorporate information on training requirements into the organisation's training system
Credentialing and scope of clinical practice	9. The health service organisation has processes to: (a) Define the scope of clinical practice for clinicians, considering the clinical service capacity of the organisation and clinical services plan (b) Monitor clinicians' practices to ensure that they are operating within their designated scope of clinical practice (c) Review the scope of clinical practice of clinicians periodically and whenever a new clinical service, procedure or technology is introduced or substantially altered
	10. The health service organisation: (a) Conducts processes to ensure that clinicians are credentialed, where relevant (b) Monitors and improves the effectiveness of the credentialing process
Evidence-based care	11. The health service organisation has processes that: (a) Provide clinicians with ready access to best-practice guidelines, integrated care pathways, clinical pathways and decision-support tools relevant to their clinical practice (b) Support clinicians to use the best available evidence, including relevant clinical care standards developed by the Australian Commission on Safety and Quality in Health Care
Variation in clinical practice and health outcomes	12. The health service organisation has systems to: (a) Monitor variation in practice against expected health outcomes (b) Provide feedback to clinicians on variation in practice and health outcomes (c) Review performance against external measures (d) Support clinicians to take part in clinical review of their practice (e) Use information on unwarranted clinical variation to inform improvements in safety and quality systems (f) Record the risks identified from unwarranted clinical variation in the risk management system

Medical Administrators should ensure they are familiar with the remaining seven standards and the aligned governance requirements for each criteria.

Standard 2—Partnering with consumers	Ensure systems are designed and used to support patients, carers, families and consumers to be partners in healthcare planning, design, measurement and evaluation • Healthcare rights and informed consent
Standard 3—Preventing and controlling healthcare-associated infections	Describe, implement and monitor systems to prevent, manage or control healthcare-associated infections and antimicrobial resistance, to reduce harm and achieve good health outcomes for patients • Surveillance • Standard and transmission based precautions • Hand hygiene • Aseptic technique • Invasive medical devices • Workforce immunisation • Reprocessing reusable devices • Antimicrobial stewardship
Standard 4—Medication safety	Describe, implement and monitor systems to reduce the occurrence of medication incidents and improve the safety and quality of medication use • Medicines scope of practice • Medication reconciliation • Adverse drug reactions • Medication review
Standard 5—Comprehensive care	Set up and maintain systems and processes to support clinicians in delivering comprehensive care, including systems to prevent and manage specific risks • Designing systems to deliver comprehensive care • Collaboration and teamwork • Clinical assessment
Standard 6—Communicating for safety	Set up and maintain systems and processes to support effective communication with patients, carers and families, between multidisciplinary teams and clinicians and across health services • Correct identification and procedure matching • Clinical handover • Communicating critical information • Documentation of information
Standard 7—Blood management	Describe, implement and monitor systems to ensure the safe, appropriate, efficient and effective care of patients' own blood, as well as other blood and blood products • Optimising and conserving patients' own blood • Prescribing and administering blood and blood products • Reporting adverse events
Standard 8—Recognising and responding to acute deterioration	Set up and maintain systems for recognising and responding to acute deterioration • Recognising acute deterioration • Escalating care • Responding to deterioration

Although there is clearly a strong role for nursing leadership in the successful implementation of the NSQHSS [34], there are a number of NSQHSS that benefit from specific medical staff involvement:

1. Clinical Guidelines and pathways.
   (a) Ensure medical staff provide leadership for the development of evidence-based guidelines and pathways relevant to the organisation.
   (b) Ensure medical staff provide oversight of regular review and update of the guidelines and pathways.

   (c) Ensure medical staff participate in auditing compliance against the guidelines at the front line.
2. Infection Prevention.
   (a) Particularly lead by Infectious Diseases consultants across the full suite of areas.
3. Medication Safety.
   (a) Particularly lead by Clinical Pharmacology and Physicians across the full suite of areas.
4. Blood Transfusion.
   (a) Particularly lead by Haematology across the full suite of areas.
5. Clinical Deterioration.
   (a) Requires a broad representation of medical staff across the organisation, particularly from Emergency Department, Intensive Care Unit, medical physicians on the ward, surgeons on the ward and in theatre, sub-acute and community physicians.
   (b) Require senior leadership for policy development and development of strategies, requires junior medical staff involvement to explore and clarify the frontline medical staff issues for managing deteriorating patients, particularly those at end-of-life.
6. Falls prevention –.
   (a) Reduction of number of falls – how to rationalie medications that can contribute to falls, early identification and management of delirium as a risk factor for falls,
   (b) Reduction of the harm caused by falls – appropriate anticoagulation, minimise duration and dosing for the clinical scenario, identification and management of osteoporosis.
7. Pressure Injuries.
   (a) Optimise skin integrity and nutrition, with early identification and management of conditions leading to poor skin integrity such as diabetes and vascular disease.
   (b) Pressure care intra-operatively or during procedures.
8. Clinical Handover.
   (a) Structures and processes for shift to shift junior doctor handover.
   (b) Structures and processes for medical handover at transitions throughout the patient journey from Emergency Department to ward, ICU to ward, acute to sub-acute services, on discharge to community.

5.3.2 Clinical Audit

Clinical audit aims to improve patient care and outcomes and the effectiveness and efficiency of processes by evaluating the services provided and patient outcomes against previous and identified best practice. Clinical audit forms part of a suite of tools within the clinical governance framework that ensure a systematic process to monitor clinical effectiveness and manage clinical risk.

Clinical units and specialities should undertake a range of audit activities as part of their quality improvement and review activities.

All clinical units and departments that undertake clinical activity should be required to have regular, structured clinical audit of patient outcomes. The clinical audit should:

- Be supported by available patient data,
- Provide opportunity for all staff within the unit or area to contribute,
- Provide opportunity for multidisciplinary review of patient outcomes as appropriate,
- Provide an opportunity for all units or areas to contribute and report their clinical audit activity to their relevant Division or Specialty Quality Committee, within the organisation's Clinical Governance framework,
- Contribute to external agencies for the relevant speciality, including clinical registries and Department of Health registries.

Maureen Bisognano, previous Chief Executive of the Institute for Healthcare Improvement, has four questions she always asks when visiting a hospital:

1. Do you know how good you are?
2. Do you know where you stand relative to the best?
3. Do you know where the variation exists?
4. Do you know the rate of improvement over time [35]?

These four questions can be adapted quickly by clinical leaders to form the basis of clinical audit processes within their units.

Clinical audit should be an integral part of any Quality Improvement project.

Clinical audit should include areas of:

- Known areas of patient safety risks, in alignment with the NSQHSS.
- Areas of risk for the organisation are identified through incident reporting systems.
- Compliance with ACSQHC clinical care standards.
- Areas of variation identified by Clinical Registries or external peer-reviewed reports.

In addition, a number of organisation-wide audits should be conducted regularly, with the results being reported through the clinical governance committee structure. The information from audit activity is used to identify areas where improvement is required to increase compliance with required standards.

5.3.3 Clinical Unit-Based Morbidity and Mortality

All clinical units and departments that undertake clinical activity should be required to have regular, structured clinical audit of patient outcomes.

This may include review of the following cases:

- Deaths.
- Significant complications of care.
- Serious adverse events and sentinel events.
- Triaging clinical deterioration cases and reviewing a proportion to investigate causes.

This clinical audit may also include the following concepts:

- High volume or high-risk procedures or conditions,
- Patient outcomes, for example, effectiveness of treatment,
- Appropriateness of treatment, e.g. in alignment with Choosing Wisely recommendations from Professional Colleges (e.g. Australian College of Emergency Medicine Choosing Wisely recommendations 2015),
- Conditions where the evidence is unclear and multiple treatment options are possible,
- New or emerging technologies within their patient groups,
- Right diagnosis [36], right treatment, and timeliness of treatment.

For specific specialties, the following may be relevant:

- Waiting list rates, day or surgery admission rates, unplanned returned to theatre rate for surgical or procedural units.
- Results of procedures in alignment with reporting requirements for the New Technologies and Clinical Practice Committees.
- Results of procedures and outcomes for areas with identified Extended Scope of Practice under the Credentialing and Scope of Practice Framework.
- Administrative data set indicators such as unplanned readmissions to hospital within 28 days, unplanned return to Intensive Care Unit rate, median length of stay, seclusion rates in mental health.
- Mental Health follow-up post-discharge.

For morbidity review, units who participate in Clinical Registries should include morbidity data as part of their registry. Complications can also be analysed using hospital-acquired diagnoses from routine hospital data (CHADx), as outlined by [37].

Table 5.2 Categories of deaths (expected occurrence and care management issues)

Categories	Description
Category 1	Expected death with no care management issues
Category 2	Expected death with care management issues
Category 3	Unexpected death occurred despite taking all necessary preventative measures
Category 4	Preventable death where steps may not have been taken to prevent it
Category 5	Unexpected death resulting from a medical intervention

Category 1 deaths do not require any further review
Category 2 deaths with care management issues can be managed within the local unit
Category 3,4,5 deaths require review beyond unit level

For Mortality reviews, all deaths should be classified according to a consistent classification system to facilitate those deaths requiring further review beyond unit level. An example classification system used in Brigham and Women's Hospital, Boston [38], are outlined in Table 5.2.

The treating clinicians and peers within the speciality should review all deaths, with external peer review for certain categories of deaths (such as Surgical Mortality via jurisdictional frameworks such as Victorian Audit of Surgical Mortality). Further organisational review will be required if there are any of the above issues identified. Conceptually the levels of review of deaths to provide robust and transparent review beyond the individual speciality, including external registries or external reviews if required.

Reporting of Medical Audit Activities should occur via Division or Specialty Quality Committee or relevant Division of Medicine or Division of Surgery relevant for the organisation.

All clinical units should provide an annual summary report of their audit activities to the management team outlining:

- A description of the process for clinical audit within their unit.
- Results of any Clinical Registry reports, including any areas of variation, and improvements in care as a result.
- Patient outcomes including:
- Evidence of results of patient outcomes in the areas audited, including performance against benchmarked best practice.
- Identification of areas of variation.
- Improvements in care and learning opportunities as a result of the audit, including innovations in practice and improvement strategies.

5.3.4 Clinical Registries

The establishment of Clinical Registries has accelerated during the past decade. Registries provide a clinically credible means for monitoring and benchmarking healthcare processes and outcomes, identifying areas for improvement, and driving strategies for improving patient care [39]. In addition, clinical registries are used to assess changes in clinical practice, appropriateness of care and health outcomes over time [40]. The American Heart Association Policy Statement in April 2011 called for expanding the application for existing and future clinical registries, with well-designed clinical registry programmes providing important mechanisms to monitor patterns of care, evaluate healthcare effectiveness and safety, and improve clinical outcomes [41].

Clinical registries are databases that systematically collect health-related information on individuals who are:

- Treated with a particular surgical procedure, device or drug, for example, joint replacement.
- Diagnosed with a particular illness, for example, stroke; or.
- Managed via a specific healthcare resource, for example, being treated in an intensive care unit.

Clinical Registries usually encompass patients treated by a single medical specialty group, for example, the Melbourne Interventional Cardiology Group involves patients treated by credentialed Cardiologists only, and hence collation of information for the registry is direct from the treating clinicians to the Registry.

Information in clinical registries is captured on an ongoing basis from a defined population. Clinical registries provide the most suitable and accurate method of providing monitoring and benchmark data and provide the greatest potential to improve healthcare performance across institutions and providers [42]. The focus of clinical registries is to capture data that reflects real-world clinical practice in large patient populations [43]. The data from clinical registries do not replace the need for traditional randomised controlled trials. Instead, registries and trials are complementary approaches [43].

Clinical Registries have high participation rates from clinicians, as outlined by Retegan and colleagues of the Victorian Audit of Surgical Mortality (VASM), with a survey of 257 individual stakeholders demonstrating a 95% agreed participation rate amongst Victorian Fellows of the Royal Australasian College of Surgeons [44]. The analysis of VASM-reported cases has also led to further understanding of cross-speciality differences with clinical management issues [45]. High participation rates were also identified in the Australian and New Zealand Intensive Care Society Centre for Outcomes and Resource Evaluation Registries, with 197 adult ICUs (75%) of Australian ICUs contributing to the registry [46].

It is expected that units that contribute to an external peer-reviewed Clinical Registry will:

- Review the results in a timely manner.
- Identify and analyse and variations for clinical relevance and impact.
- Integrate improvements in care or learning opportunities into the unit's quality improvement process.
- Report and feedback to relevant CSU Quality Committee for the organisation of the results, variations and actions required annually.

A study of Clinical Registry use in a major tertiary teaching hospital identified a very high level of medical staff participation, but a lack of systematic reporting of registry data into quality committees beyond unit level, and utilisation of such data to reflect upon practice and drive quality improvement [47].

Other National Standards that benefit from medical staff involvement.

5.4 Medical Engagement in Clinical Governance

Twigg et al. have highlighted the importance of nursing leadership for successful quality and safety; however, Medical Staff engagement in patient safety is essential for high-quality patient's outcomes. The Institute for Healthcare Improvement [48] outlines the principles for engaging medical staff in the quality agenda and includes the following aspects outlined below in Table 5.3.

The degree to which you involve doctors in quality initiatives involves striking a balance between ensuring there is the right amount of engagement and medical input while being cognisant that clinicians are very busy. It is critical to think about determining what is required from medical staff, and best to arrange time with the right medical staff.

There are excellent examples in the literature on how to best engage doctors in quality and safety. The following are some reflections from practice:

5.4.1 Senior Medical Staff

- Senior medical staff are required for leadership of quality projects, advice and guidance on policy or guideline development, advice on strategic priorities for the organisation or

Table 5.3 Institute for Healthcare Improvement principles for engaging medical staff in the quality agenda [48]

1. Discover common purpose
2. Reframe values and beliefs
3. Segment the engagement plan
4. Use "engaging" improvement methods
5. Show courage
6. Adopt an engaging style

linkages with community partners, such as research institutes. Collaboration across units for certain patient cohorts also required Heads of Units or senior medical leadership.
- Senior medical staff are also essential for any outpatient processes, as the predominance of outpatient clinics is delivered by senior doctors. Any quality improvement initiatives involving theatre, surgical procedures operations also require Surgical or Anaesthetic senior medical staff involvement.
- Introduction of any new electronic clinical information technology systems requires both senior and junior medical staff, for varying views on the practicalities of the system and how this will affect the workflows of patient care.

5.4.2 Junior Medical Staff

- The approach to engaging junior medical staff needs to be tailored differently than that of senior medical staff because of their differing understandings and confidence regarding patient safety. However, engaging with the junior staff is essential for understanding the practicalities of day-to-day patient care.

5.4.3 Committee Involvement

Medical Administrators should strongly consider including some representation of the Senior Medical Staff on their peak Clinical Governance or equivalent Committee. Where local Boards exist, inclusion of senior medical staff is highly recommended. Veronesi et al. in [49], in their study of NHS hospital trusts performance measures from the Healthcare Commission and Dr. Foster, and comparing the proportion of physicians on hospital Boards, there was a significant and positive association between a higher percentage of clinicians on boards and the quality ratings of service providers, with lower morbidity rates.

From practical experience, the following observations have assisted with successful relationships with medical staff:

- Medical staff do not respond well to being told to comply with regulations without explanation of the reasons, as they value autonomy and independence.
- Checklists are challenging for medical staff, as they are aware that although a majority of patients follow routine care, often there are exceptions based on patient needs or clinical conditions, and require treatment regimes to be adapted for the individual's needs.
- Even if the medical staff must comply with something from a patient safety perspective, they respond better if they are able to be provided with an opportunity to provide advice on how they will comply.
- If the medical staff do not agree with action that will be implemented, they appreciate knowing that the change will be evaluated robustly, and their views are recorded and used as part of the evaluation.
- Meet the medical staff on their terms, in their office. They are the experts with years of experience in their field, and treat them with the respect that their experience deserves.
- Avoid asking doctors to criticise or comment on areas beyond their scope.
- As most clinicians have full schedules throughout the day, meetings often have to be scheduled before hours, after hours, or at lunchtimes. If you are inviting medical staff at lunchtime, consider feeding them, as you will more likely engender higher levels of support and engagement.
- Consider multiple avenues for seeking feedback. Examples include:
  - One-on-one interviews for guided leadership advice from particular specialties, such as Head of Infectious Diseases for Antibiotic Stewardship strategies, or Head of General Surgery to define extended scope of practice and credentialing requirements for General Surgery.

- Workshops on specific quality issues with a variety of different clinicians seeking multidisciplinary advice or endorsement.
- Trial or simulation environments when introducing a new change that may impact practice, for example the introduction of an electronic medication prescribing platform.
- Organisation-wide electronic surveys for views on topics such as patient safety climate survey, junior medical staff feedback on rostering and safe hours.

5.5 The Inter-Relationship of Clinical Service, Scope of Practice and Patient Outcomes

As highlighted earlier, medical staff often appreciate an explanation of the drivers for certain quality improvement initiatives, and how the concepts relate in the global view. Credentialing and scope of practice frameworks require evaluation and monitoring of compliance. Clinical audit is a mechanism to undertake this monitoring.

The steps required to determine what the medical workforce profile should be within an organisation are:

Step 1: Clinical Service requirements

Determine the emergency patient mix such as the types of patients, demographics, patient conditions, and specialities required.

Step 2: Scope of Practice

Define what scope of the various clinical services are required to appropriately treat the emergency patients mix. If the health service is in a young community population with families and children, the health service will require a higher proportion of paediatric specialists.

Step 3: Credentials

Determine the type, seniority, and number of doctors that are needed to deliver the scope of clinical practice, and clinical service requirements. This will then define the credentials such as qualifications, fellowship specialities and seniority experience level of the medical staff.

Step 4: Senior and Junior Medical Workforce profile

Employ the number, proportion and mix of senior medical staff to match your scope of practice noting that workforce availability will affect recruitment

Step 5: Junior Medical Workforce profile

Employ the junior medical staff that matches the senior medical staff to ensure appropriate levels of training and supervision. Noting that workforce availability will affect recruitment

Step 6: Clinical Audit

How do we know we are providing high-quality patient care? Via clinical audit mechanisms outlined previously, and ensuring that the patient care provided by individual clinicians complies with their scope of practice.

Step 7: Performance development

How can we strengthen the skills and experience of our medical staff? Via education and training, performance management and development programmes

Step 8: Delineation of scope of clinical service

Are there any restrictions to our clinical service based on our availability of medical staff or delineation of the size and scope of our service, for example, elective surgery patient mix depends on the speciality of the senior medical staff available within the health service. What types of patients do we need to transfer to other health services?

5.5.1 Links Between Evidence-Based Measurement and Quality Improvement

Evidence-based medicine has become a cornerstone of good clinical practice and drives the principles of research, teaching and clinical practice. However, there is often a considerable gap between what we know from research and what is done in clinical practice. Propose that there are benefits for the patient by integrating the complementary disciplines of Evidence-Based Medicine (EBM) or doing the right things, and Clinical Quality Improvement (CQI) or doing things right; Glasziou and colleagues propose a clear

connection between EBM and CQI, in the form of:

- Those working in CQI teams should routinely check the validity, applicability and value of the proposed change before taking on a change.
- Those working in EBM should recognise that it is not sufficient to simply appraise the evidence but ask what can be done to address the gap between the evidence and practice.
- Those working in CQI should recognise the complementary value of experiential learning in a cyclical process by exploring concepts and models, learning from them, and then doing it again better.
- Those teaching the next generation of clinicians should value both disciplines, which should be taught, integrated and modelled in clinical training.

Of note, the governance processes for introducing established technologies or clinical practice into the organisation are at the boundary of EBM and CQI, and use both elements and concepts for improving patient care.

5.5.2 Ready Reckoner

- Clinical Governance at a health service level requires structures, processes and frameworks that articulate the key roles, responsibilities and accountabilities at all staff levels from Board, management and clinicians, enabled by robust data, culture, education and training and a continuous learning environment.
- Successful clinical governance encompasses the domains of clinical effectiveness, risk management, patient safety and consumer engagement, and should address the priority areas and accreditation requirements of any national regulatory bodies.
- Successful clinical governance requires strong authentic medical engagement, at a leadership, senior and junior medical staff level, that allows the advice, guidance and leadership from medical staff across a suite of patient safety areas, whilst utilising their time in an efficient and effective manner.
- The Medical Administrator role is an essential element within the clinical governance system as the patient safety advocate on the Executive. The Medical Administrator also provides an interface to translate management concepts to medical staff, and medical concepts to the broader management.
- This chapter outlines the literature and practical examples of implementing Clinical Governance within a health service, and particularly focuses on the strategies to effectively engage medical staff, and addresses the essential role of the Medical administrator within the clinical governance system.

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References

1. Scally F, Donaldson LJ. Clinical governance and the drive for quality improvement tin the new NHS in England. BMJ. 1998;317:61.
2. Institute of Medicine. To err is human; November 1999.
3. Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. The quality in Australian health care study. Med J Aust. 1995;163(9):458–71.
4. Russell L, Dawda P. Lessons for the Australian healthcare system from the Berwick report. Aust Health Rev. 2013;38(1):106–8.
5. Duckett S, Cuddihy M, Newnham H. Executive summary targeting zero: supporting the Victorian hospital system to eliminate avoidable harm an strengthen quality of care, report of the review of hospital Safety and quality assurance in Victoria, Victorian Government; 2016. https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/hospital-safety-and-quality-review. Accessed 25 Sept. 2022.
6. Kim YC, Kim MH, Song JE, Anh JY, Oh DH, et al. Trend of methicillin-resistant staphylococcus aureas (MRSA) bacteremia in an institution with a high rate of MRSA after the reinforcement of antibiotic stewardship and hand hygiene. Am J Infect Control. 2013;41:e39–43.
7. Beitler JR, Link N, Bails DB, Hurdle K, Chong DH. Reduction in hospital-wide mortality after

implementation of a rapid response team: a long term cohort study. Crit Care. 2011;15:R269.
8. Groene O, Sunol R. The investigators reflect: what we have learned from the Deepening our Understanding of Quality Improvement in Europe (DUQuE) study. Int J Qual Healthcare. 2014;26(S1):2–4.
9. Leggat S, Balding C. A qualitative study on the implementation of quality systems in Australian hospitals. Health Serv Manag Res. 2017;30(3):179–86.
10. Pronovost PJ, Marsteller JA. Creating a fractal-based quality management infrastructure. J Health Organ Manag. 2014;28(4):576–86.
11. Sutcliffe KM, Paine L, Pronovost P. Re-examining high reliability: actively organizing for safety. BMJ Qual Saf. 2017;26(3):248–51. http://qualitysafety.bmj.com/content/early/2016/03/21/bmjqs-2015-004698. Accessed 17 Oct 2022
12. Ghaferi AA, Myers CG, Sutcliffe KM, Pronovost P. The next wave of hospital innovation to make patients safer. Harv Bus Rev. 2016:94.
13. Australian Commission for Safety and Quality in Health Care, National Safety and Quality Health Service Standards Second Edition, 2017. https://www.safetyandquality.gov.au/sites/default/files/2019-04/National-Safety-and-Quality-Health-Service-Standards-second-edition.pdf.
14. Bismark MM, Walter SJ, Studdard DM. The role of boards in clinical governance: activities and attitudes among members of public health service boards in Victoria. Aust Health Rev. 2013;37(5):682–7.
15. Dekker SWA. Levenson NG (2015) the systems approach to medicine: controversy and misconceptions. BMJ Qual Saf. 2015;24:7–9.
16. Perla RJ, Provost LP, Parry GJ. Seven propositions of the science of improvement: exploring foundations. Q Manage Health Care. 2013a;22(3):170–86.
17. Brand C, Tropea J, Ibrahim J, Elkadi SO, Bain CA, et al. measurement for improvement: a survey of current practice in Australian public hospitals. MJA. 2008;189:35–40.
18. Doran GT. There's a S.M.a.R.T way to write management's goals and objectives. Manag Review. 1981;70(11):35.
19. Behal R. Safety Step 2.0 A systematic framework for case review and action plans for improving patient safety*;* 16 October 2016. https://itunes.apple.com/au/book/safetysteps/id521567746?mt=11. Accessed 28 Sept 2022.
20. Perla RJ, Provost LP, Murray SK. Sampling considerations for health care improvement. Q Manage Health Care. 2013b;22(1):36–47.
21. Levtzion-Korach O, Alcali H, Orav EJ, Graydon-Baker E, Keohane C, Bates DW, Frankel AS. Evaluation of the contributions of an electronic web-based reporting system: enabling action. J Patient Saf. 2009;5(1):9–15.
22. Nuckols TK, Bell DS, Liu H, Paddock SM, Hilbourne. Rate and types of events reported to established incident reporting systems in two US hospitals. Qual Saf Health Care. 2007;16:164–8.
23. Evans SM, Smith BJ, Esterman A, Runciman WB, Maddern G, et al. Evaluation of an intervention aimed at improving voluntary incident reporting in hospitals. Qual Saf Health Care. 2007;16:169–75.
24. Evans SM, Berry JG, Smith BJ, Esterman A, Slemin P, O'Shaughnessy J, DeWit M. Attitudes and barriers to incident reporting: a collaborative hospital study. Qual Saf Health Care. 2006;15:39–43.
25. Benn J, Koutantji M, Wallace L, Spurgeon P, Rejman M, Healey A. Vincent C (2009) feedback from incident reporting: information and action to improve patient safety. Qual Saf Health Care. 2009;18:11–21.
26. Pham JC, Girard T, Pronovost. What to do with healthcare incident reporting systems. J Public Health Res. 2013;2:e27.
27. Harrison R, Lawton R, Stewart K. Doctors experiences of adverse events in secondary care: the professional and personal impact. Clin Med. 2014;14(6):585–90.
28. Shojania KG, Wald H, Gross R. understanding medical error and improving patient safety in the inpatient setting. Med Clin North Am. 2002;86(4):847–67.
29. Dwyer AJ, Visser P, Russell L. Interpreting the coroners act at the bedside: how do junior doctors know they are doing it correctly? Med J Aust. 2013;199(1):25–6.
30. Dwyer AJ. Medical managers in contemporary healthcare organisations: a consideration of the literature. Aust Health Rev. 2010a;34(4):514–22.
31. Dwyer AJ. Roles, attributes and career paths of medical administrators in public hospitals: survey of Victorian metropolitan directors of medical services. Aust Health Rev. 2010b;34(4):506–13.
32. Kakemam E, Goodall AH. Hospital performance and clinical leadership: new evidence from Iran. BMJ Leader. 2019;3:leader-2019-000160.
33. Dwyer AJ, Becker G, Hawkins C, McKenzie L, Wells M. Engaging medical staff in clinical governance: introducing new technologies and clinical practice into public hospitals. Aust Health Rev. 2012;36(1):43–8.
34. Twigg DE, Duffield C, Evans G. The critical role of nurses to the successful implementation of the National Safety and quality healthcare standards. Aust Health Rev. 2013;37(4):5410546.
35. Bisognano M. Healthcare improvement guru Maureen Bisognano sees hospitalists as agents for change. Hospitalist. 2015, 2015;2015(2). http://www.the-hospitalist.org/hospitalist/article/122592/healthcare-improvement-guru-maureen-bisognano-sees-hospitalists-agents. Accessed 28 Sept 2022
36. Singh H, Sittig DF. Advancing the science of measurement of diagnostic errors in healthcare: the safer dx framework. BMJ Qual Saf. 2015;24(2):103–10.
37. Jackson TJ, Michel JL, Roberts RF, Jorm CM, Wakefield JG. A classification of hospital acquired diagnoses for use with routine hospital data. MJA. 2009;191:544–8.
38. Provenzano A, Rohan S, Trevejo E, Burdick E, Lipsitz S, Kachalia A. Evaluating inpatient mortality: a new electronic review process that gathers infor-

mation from front-line providers. BMJ Qual Saf. 2015;24:31–7.
39. Evans SM, Scott IA, Johnson NP, Cameron PA, McNeil J. Development of clinical-quality registries in Australia: the way forward. Med J Aust. 2011;194(7):360–3.
40. Grace BS, Clayton P, McDonald SP. Increases in renal replacement therapy in Australia and New Zealand: understanding trends in diabetic nephropathy. Nephrology (Carlton). 2012;17(1):76–84.
41. Bufalino VJ, Masoudi FA, Stranne SK, Horton K, Albert NM, Beam C, et al. The American Heart Association's recommendations for expanding and applications of existing and future clinical Registries, a policy statement from the American Heart Association. Circulation. 2011;123:2167–79.
42. Clinical Registries. Centre of Research Excellence in Patient Safety. Last updated 13 June 2011. http://www.crepatientsafety.org.au/registries/. Accessed 18 March 2012.
43. Moran JL, Solomon PJ, for the ANZICS Centre for Outcome and Resource Evaluation (CORE) of the Australian and New Zealand Intensive Care Society (ANZICS). Mortality and intensive care volume in ventilated patients from 1995 to 2009 in the Australian and New Zealand binational adult patient intensive care database*. Crit Care Med. 2012;40(3):800–12.
44. Retegan C, Russell C, Harris D, Andrianopoulos N, Beiles B. Evaluating the value and impact of the Victorian audit of surgical mortality. ANZJ Surg. 2013;83:724–8.
45. Vinluan J, Retegan C, Chen A, Beiles CB. Clinical management issues vary by specialty in the Victorian audit of surgical mortality: a retrospective observational study. BMJ Open. 2014;4:e005554.
46. ANZICS. Centre for Outcome and Resource Evaluation Annual Report 2012-2013. Melbourne: ANZICS; 2013.
47. Dwyer AJ, McNeil J. Are clinical registries actually used? The level of medical staff participation of clinical registries and reporting within a major tertiary teaching hospital. Asia Pac J Health Manag. 2016;11(1):56–64.
48. Reinertsen JL, Gosfield AG, Rupp W, Whittington JW. Engaging Physicians in a Shared Quality Agenda. IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement; 2007. www.IHI.org
49. Veronesi G, Kirkpatrick I, Vallascas F. Clinicians on the board: what difference does it make? Soc Sci Med. 2013;77:147–55.

Further Reading[1]

Australian Charter of Health Care Rights, Australian Commission on Safety and Quality in Health Care; 2008.
Delivering High Quality Healthcare - Victorian Clinical Governance Framework: Department of Health Victoria. 2017. https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/clinical-risk-management/clinical-governance-policy. Accessed 6 Dec 2017.
Doing it With Us Not for Us: Participation Policy, Department of Health; 2006.
Guide to Complaints handling in Health Care Services, Office of Health Commissioner; 2005.
National Safety and Quality Health Service Standards, Australian Commission on Safety and Quality in Health Care. 2011. https://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.pdf. Accessed 6 Dec 2017.
National Open Disclosure Standard, Australian Commission on Safety and Quality in Health Care; 2008.
National Standards in Credentialing and Defining the Scope of Clinical Practice, Australian Commission on Safety and Quality in Health Care; 2004.
Parliament of Victoria Charter of Human Rights and Responsibilities Act 2006, State Government of Victoria.
Safer Care Victoria: Clinicians as Partners—framework for clinician engagement. https://www2.health.vic.gov.au/hospitals-and-health-services/safer-care-victoria/safer-care-publications/clinicians-as-partners-framework-for-clinician-engagement. Accessed 6 Dec 2017.
Victorian Health Incident Management Policy, Department of Health; 2011
Victorian Health Policy and Funding Guidelines, Department of Health Victoria. https://www2.health.vic.gov.au/about/policy-and-funding-guidelines. Accessed 6 Dec 2017.

[1]A number of key frameworks should be considered when implementing Clinical Governance within health services