7 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

7.1 Introduction

One of the fundamental roles that Medical Administrators can lead in healthcare 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. 7.2. 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 healthcare organisation with ultimate Clinical Governance responsibility—Sect. 7.3. This chapter will also tailor the discussion to focus on medical staff issues—Sect. 7.4, framed around which of the National Safety and Quality Health Service Standards (NSQHSS) are particularly relevant for medical staff, how to engage medical staff, in Sect. 7.5, 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. 7.6. In addition, Clinical

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governance is part of a continuum of improving patient care, as a downstream component to experimental and translational research for improving patient care. These areas are covered in other chapters, so will be referred to as they relate to the overall framework.

7.2 Structures, Systems and Processes for Clinical Governance

Clinical Governance arose in the late 1990s from the United Kingdom, to ensure high quality care are considered with the same level of importance as financial control and service performance. Scally and Donaldson, 1998, 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 in 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 and quality of patient care, as well as improve patient outcomes' (National Safety and Quality Health Service Standards (NSQHSS) [2].

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 [3] 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 [4].

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 [5], chaired by Professor Ian Kennedy, and the Mid Staffordshire NHS Foundation Trust Public Inquiry, chaired by Robert Francis [6]. Russell and Dawda summarise the key recommendations identified of national and international inquires, and states 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" [7].

The importance of Clinical Governance is as relevant in 2017 as over the last decade, 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 [8]. 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* [9], or reduction in hospital-wide mortality and out-of-ICU cardiac arrest as a result of the introduction of Rapid Response Teams [10].

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 [11]. 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 [12], in their qualitative study on the implementation of quality systems in Australian hospitals, conducted interviews and focus groups with 270 board members, managers 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.

Healthcare organisations are increasingly analysing the most appropriate mechanisms for reducing unwarranted variation in care, as highlighted through mechanisms such as the Australian Atlas of Healthcare Variation [13]. 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 [14], 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 [15]. High reliability has been termed the third wave of innovation in patient safety, following from that of technical advances and standardising procedures [16].

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.

7.2.1 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 of quality as outlined in the relevant jurisdictional health department. The Victorian Clinical Governance Policy Framework, which was refreshed in June 2017 in light of the Targeting Zero report includes: [17].

1. Leadership and culture—visible, accountable and purposeful leadership at all levels of the health service is required to cultivate an inclusive and 'just' culture and facilitate the delivery of high quality healthcare
2. Consumer partnerships—effective consumer partnerships are crucial for improving healthcare outcomes, organisational design and the patient experience

3. Workforce—all health service staff must have the appropriate skills and knowledge required to fulfil their roles and responsibilities within the organisation
4. Risk management—all health services must have in place a broad-based risk management system that integrates organisational, financial, occupational health and safety and clinical risk
5. Clinical practice—staff must be effectively supported to continuously improve the safety and appropriateness of clinical care through evidence-based best practice

New South Wales Health has established a Clinical Excellence Commission to provide oversight of Clinical Governance within New South Wales Health [18].

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

Figure 7.1 outlines an example of the high-level components within a Clinical Governance Framework for a health service.

The 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 specialty.

7.2.2 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.

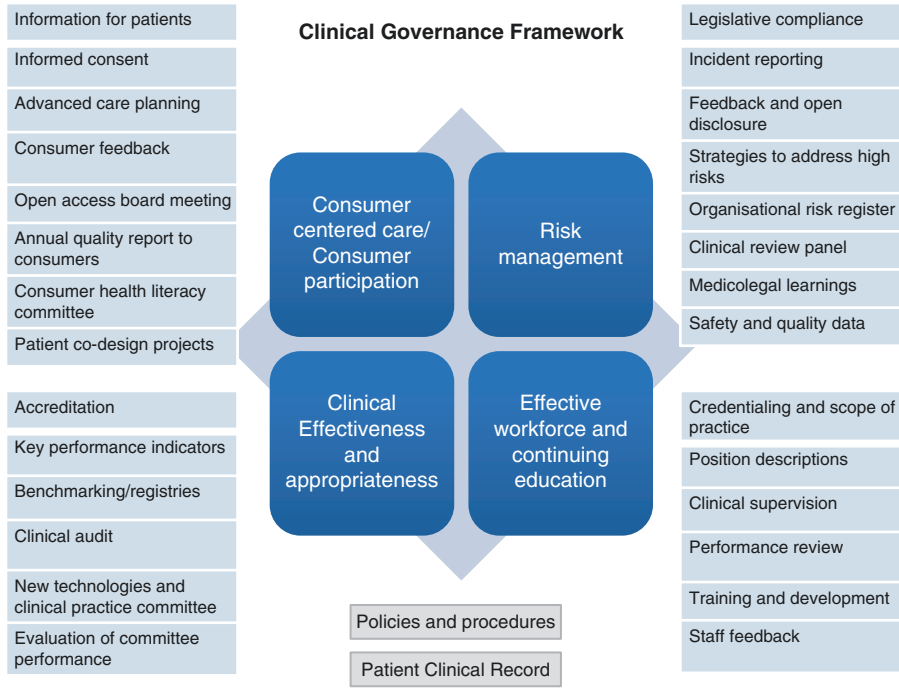

Fig. 7.1 Example domains and components of Clinical Governance Framework for a health service

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 transparent 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 review 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 healthcare through the provision of appropriate information on the clinical care provided, 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 the 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%), and 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 indicated that additional training in quality and safety would be advantageous [19].

7.2.3 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 for 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.

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, specialty breadth, need for cross-campus and acute, subacute and community representation.

Figure 7.2 provides an example Committee structure for Clinical Governance.

The specific roles of the committee hierarchies are outlined below:

7.2.3.1 Board-Level Clinical Safety and Quality Committee

Usually a subcommittee of the Board, the Committee is a forum for in-depth review of quality issues as 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.

7.2.3.2 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 the representatives from other key directorates such as Pharmacy, Allied Health and Radiology. Often Executive-level committees also have community or consumer representation.

7.2.3.3 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

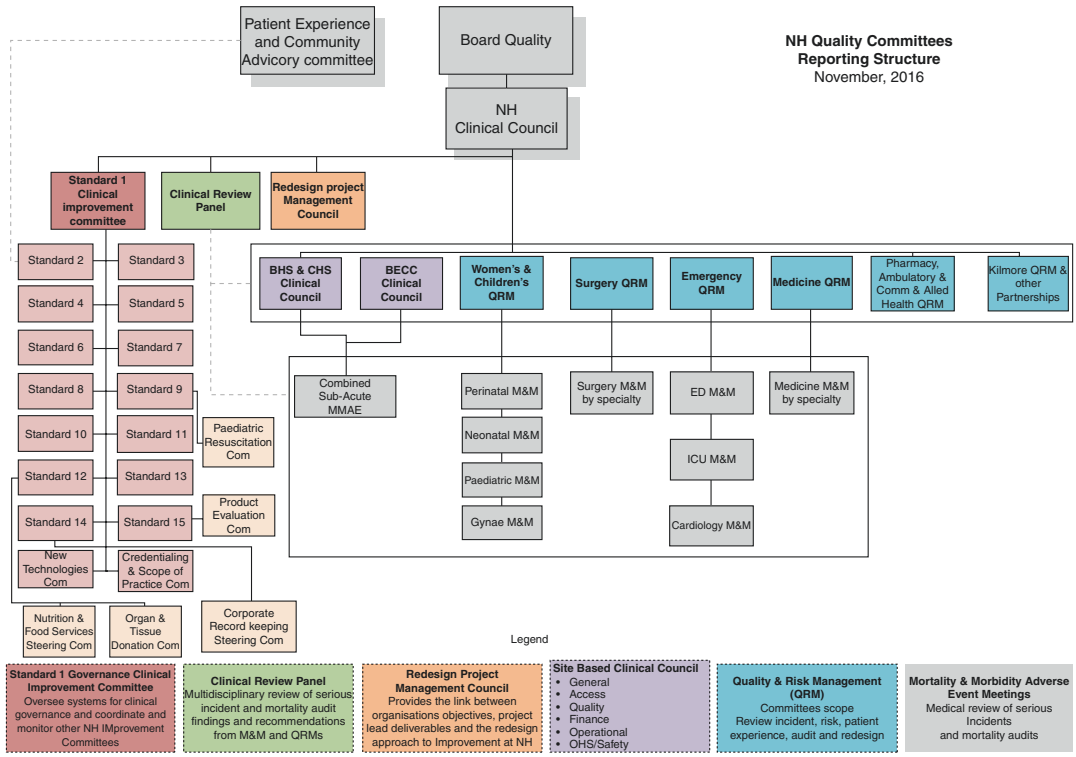

Fig. 7.2 Committee structure for Clinical Governance. Northern Health's committee structure incorporates (1) Standards Governance, in alignment with the ACSQHC Standards and Australian Council for Healthcare Standards EquipNational, (2) Multi-disciplinary peak clinical review panel, to review serious incidents in a transparent an open culture, (3) Project management, to provide organisational oversight of redesign projects, (4) Site-Based Clinical Councils for the various sites within the health service, which incorporate quality, access, finance operations, occupational health and safety, (5) Division-Level Quality and Risk Management Committees with similar specialty groupings, (6) Unit-based mortality and morbidity committees. All committees report via a single Executive-level committee (Clinical Council), ultimately to Board Quality and Safety subcommittee, and to the Health Service Board. The Committees are evaluated on an annual basis, and may change over time as the organisation's structure and function change

- Medication Safety
- Comprehensive Care (including Falls Prevention, Pressure Injury, Nutrition)
- Communicating for Safety
- Blood Management
- Recognising and Responding to Acute Deterioration
- Clinical Policies and Procedures Committee
- New Technology and Clinical Practice Committee

7.2.3.4 Division-Level or Unit-Level Quality and Safety Committees

There are a range of specialty committees that may be appropriate, depending on the size and complexity of the organisation. These committees have often arisen from mortality and morbidity committees at specialty level.

7.2.4 Enablers of Exemplary Clinical Governance

The following enablers of good clinical governance are essential to support clinicians and managers determine 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.

7.2.5 Data Management to Support Clinical Governance

7.2.5.1 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, completion of incident reviews within timeframes, and implementation of recommendations arising from incidents within timeframes
- Medication Safety key performance indicator suite
- Statement of Priority indicators such as hand hygiene rates, infection surveillance rates, aged care quality indicators
- Benchmarked mortality data such as Hospital Standardised Mortality Ratios
- Patient satisfaction measures, for example, Victorian Hospital Experience Survey results

7.2.6 Benchmarking

Health services should participate in a range of benchmarking activities including infection control monitoring such as Victorian Healthcare Associated Infections Surveillance System (VICNISS), 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 7.3 outlines principles for data management at the various committee levels.

Fig. 7.3 Principles of levels of Data at various committees

Standard 6: Clinical Handover						
	Target	Q3	N=	D=	Q2	Tracking
% of nursing handovers documented in the care plan by staff on the previous shift	100%	87.8%	203	231	89.8%	
% of patients who stated that nursing staff include them when they are giving handover	80%	83.6%	154	187	71.2%	
% of patients who stated that medical staff include them when they are doing ward rounds	80%	85.0%	159	187	80.9%	
% patients who felt that they could ask questions during medical ward rounds	80%	69.3%	160	231	NA	

- Additional question relating to the patients opinion on whether they feel they can ask questions of medical staff during ward rounds. There is no comparative data at this stage.

Fig. 7.4 Example traffic light data system to support Clinical Governance

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 who have flagged beyond their limits (Fig. 7.4).

7.2.7 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
- 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 [20]
- Improvement Science, with Testing and Learning Cycles - Plan, Do, Study, Act (PDSA) Cycles [21]
- Patient safety measurement tools [22]
- Root cause analysis methodology. Most state health departments provide Root Cause Analysis training and tools for clinicians, such as the Victorian Department of Health and Human Services. It is recommended that the jurisdictional frameworks are utilised for specific methodology relevant for the state [23]

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 [24], 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 [25].

Most quality improvement projects arise due to a perceived gap in performance and patient outcomes. By necessity, there will need to be change to address the gap. However, all quality improvement projects need to consider the workload impacts on the clinicians and front-line staff. Hayes, Batalden and Goldmann [26], 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.

7.2.8 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. Figure 7.5 outlines a conceptual diagram of ensuring consistency of Clinical Governance at a health service level.

7.2.9 A Specific Comment on Accreditation for Medical Administrators

All Australian Health Services are required to comply with an accreditation process. From January 1st 2013, the NSQHSS are mandatory across all Australian Health Services. These standards are designed to assist health services to deliver safe and high quality care through the

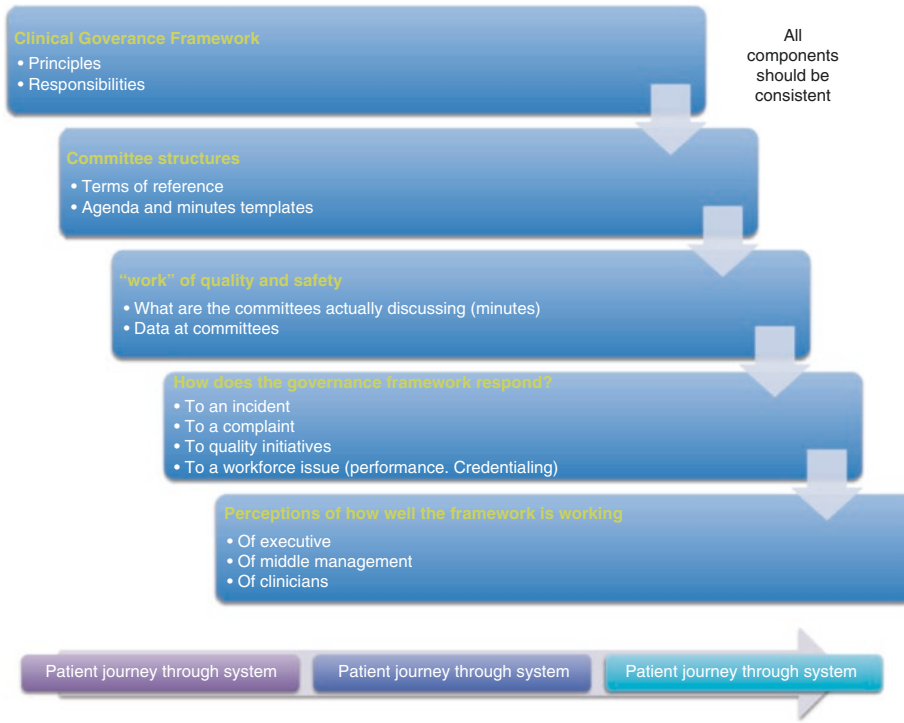

Fig. 7.5 Considerations to ensure consistency throughout organisation's Clinical Governance

implementation of evidence-based improvement strategies in key areas:

1. 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 a clinical deterioration in acute healthcare

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 risk rated, any high risk identified, and management plans put in place.
- Compliance based: organisations need evidence to demonstrate compliance with policies and guidelines.
- Consumer Focussed: based on the concept that consumers are a partner in the planning and delivery of healthcare.

Overall there are 256 actions pertaining to the Standards which must be met to obtain accreditation, conducted by an independent accrediting body. If an organisation excels on an item then it can be Met with Merit. If any items are Not Met then the organisation will be given a high priority recommendation and provided with 120 days to rectify the concerns.

The state jurisdiction will then respond through a regulatory framework setting out their concerns. The hospital Board would also become actively involved.

If the organisation does not satisfactorily address the regulator's concerns it will no longer be able to continue as a training hospital for medical and nursing staff or able to bill Medicare Benefits Scheme in Australia. Many research projects are conditional on being undertaken in an accredited organisation.

Version 2 of NSQHSS is in development and due for release late 2017.

There are also Accreditation Standards in Australia for Mental Health National Standards, Community Standards, and Aged Care Standards. The detail of these is beyond the scope of this chapter.

7.3 Clinical Risk Management for Medical Administrators

Clinical Risk Management (CRM) is an approach to improving the quality and safe delivery of healthcare 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:

7.3.1 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.

7.3.2 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.

7.3.3 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. Victorian Health Services uses VHIMS, a web-based incident reporting system, which enables incidents to be entered online. 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 (ISR1 or 2), which result in patient harm, are reviewed through structured case review or Root Cause Analysis methodology to identify critical points, and root causes of the incident. Recommendations are developed to address the contributing factors.

Trends of incidents can also be monitored over time, including analysis of groups 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 [27] of incidents can allow meaningful analysis of contributory factors to incidents, while 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% [28, 29] and 5% [30] of incidents, respectively. Key barriers to reporting incidents by medical staff have been shown to be lack of feedback on outcomes and too long to complete incident reports [31].

Benn et al. [32] 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. [33] 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 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 [34] survey of doctors' experience of adverse events identified a significant impact personally and professionally, with 76% of respondents believed this had affected them personally, with 74% reporting stress, 68% reporting anxiety, and 63% lower professional confidence.

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 [35], and are provided timely feedback of the outcomes of reviews on patient care.

7.3.4 Sentinel Event Reporting

All Australian States are required to establish Sentinel Event Reporting system from health services to the local jurisdiction. The Joint Commission in the United States originally defined a sentinel event as a 'Patient Safety Event that reaches a patient and results in any of the following:

Death, permanent harm or severe temporary harm and intervention required to sustain life'. [36]

The term 'Sentinel' signals the need for immediate investigation and response [36]. An agreed list of eight national sentinel events from the Department of Health Australia [37] are:

1. Procedures involving the wrong patient or body part resulting in death or major permanent loss of function
2. Suicide of a patient in an inpatient unit
3. Retained instruments or other material after surgery requiring re-operation or further surgical procedure
4. Intravascular gas embolism resulting in death or neurological damage
5. Haemolytic blood transfusion reaction resulting from ABO incompatibility
6. Medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs
7. Maternal death or serious morbidity associated with labour or delivery
8. Infant discharged to the wrong family

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

7.3.5 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 multi-disciplinary teams that analyse adverse events and promote change [38]. 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 root cause analysis 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.

7.3.6 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.

7.3.7 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 to the 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 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 [39].

7.3.8 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 notifiable conduct (see AHPRA intranet site for details of Mandatory reporting criteria).

7.3.9 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 [8].

7.4 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 [40]. 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 [41].

Medical Administrators on the Executive of Health Services (usually in Chief Medical Officer or Executive Director Medical Services roles) [41] 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 [42].

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. In practice, the following elements are usually delegated effectively to:

- Chief Nursing Officer: Falls Prevention, Pressure Injuries Prevention
- Executive Director Human Resources: Performance management, organisational development, education and training.

Medical Administrators in practice tend to hold onto the portfolios of:

- Credentialing and Scope of Practice, especially for medical staff, and sometimes other disciplines
- Infection Prevention
- Medication Safety
- Clinical Deterioration

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, while providing a broader guidance on the organisational 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 [41], the Medical Administrator is trusted by the clinician, and can act as the translator 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 [43] 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) Front-line engagement: be a regular, authentic presence at the front line and a visible champion of improvement
   (c) Relentless focus: remain focused 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.

7.5 Areas of Clinical Governance with Relevance for Medical Staff

The following areas are particularly relevant for medical staff

- 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
- 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

Table 7.1 outlines the NSQHSS elements particularly relevant for medical staff.

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. In Victoria Health Services are expected to have established New Technologies and Clinical Practice Committees that oversee the introduction of any new technology in to the organisation. 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. [44] doctors are not necessarily aware of the importance of their participation in these processes, and the organisation and such

Table 7.1 NSQHSS elements relevant for Medical Staff

Standard	Element
Governance	1.10.1 A system is in place to define and regularly review the scope of practice for the clinical workforce
	1.10.2 Mechanisms are in place to monitor that the clinical workforce are working within their agreed scope of practice
	1.10.3 Organisational clinical service capability, planning, and scope of practice is directly linked to the clinical service roles of the organisation
	1.10.4 The system for defining the scope of practice is used whenever a new clinical service, procedure or other technology is introduced
	1.10.5 Supervision of the clinical workforce is provided whenever it is necessary for individuals to fulfil their designated role
	1.11.1 A valid and reliable performance review process is in place for the Clinical workforce
	1.11.2 The clinical workforce participates in regular performance reviews that support individual development and improvement
Standard 1 Governance	1.3.1 Workforce are aware of their delegated safety and quality roles and responsibilities
	1.3.3 Agency or locum workforce are aware of their designated roles and responsibilities
	1.4.1 Orientation and ongoing training programmes provide the workforce with the skill and information needed to fulfil their safety and quality roles and responsibilities
	1.4.2 Annual Mandatory training programmes to meet the requirements of these standards
	1.4.3 Locum and agency workforce have the necessary information, training and orientation to the workplace to fulfil their safety and quality roles and responsibilities
	1.7.1 Agreed and documented clinical guidelines and/or pathways are available to the clinical workforce
	1.7.2 The use of agreed clinical guidelines by the clinical workforce is monitored
	9.2.2 Deaths or cardiac arrests for a patient without an agreed treatment-limiting order (such as not for resuscitation or do not resuscitate) are reviewed to identify the use of the recognition and response systems, and any failures in these systems
Standard 2 Consumers	Principles of patient-centred care, how to engage patients in their management plans
Standard 3 Infections	Hand hygiene, aseptic technique, Antibiotic stewardship
Standard 4 Medication	Many elements, Adverse drug reactions, discharge summary medications
Standard 6 Clinical Communication	Three patient identifiers, correct patient matching, consent, Handover tools and processes, discharge summary completion
Standard 7 Blood	Documenting reasons for blood transfusion, follow-up post transfusion
Standard 8 Deterioration	Urgent review criteria, response, escalation processes

committees need to be promoted to all medical staff.

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

7.5.1 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 specialties 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 multi-disciplinary 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 specialty, including clinical registries, Department of Health registries.

Maureen Bisognano, previous Chief Executive of 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? [45]

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 identified through incident reporting systems
- 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.

7.5.2 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 [46]).
- Conditions where the evidence is unclear and multiple treatment options are possible.
- New or emerging technologies within their patient groups.
- Right diagnosis [47], right treatment, and timeliness of treatment.

For specific specialties, the following may be relevant:

- Waiting list rates, day or surgery admission rates, unplanned returns to theatre rate for surgical of 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 Jackson et al. [48].

For Mortality reviews, all deaths should be classified according to a consistent classification system to facilitate those deaths requiring further review beyond unit level. The treating clinicians and peers within the Specialty 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. Levels of review of deaths provide robust and transparent review beyond the individual specialty, including external registries or external reviews if required (Fig. 7.6) [49].

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:

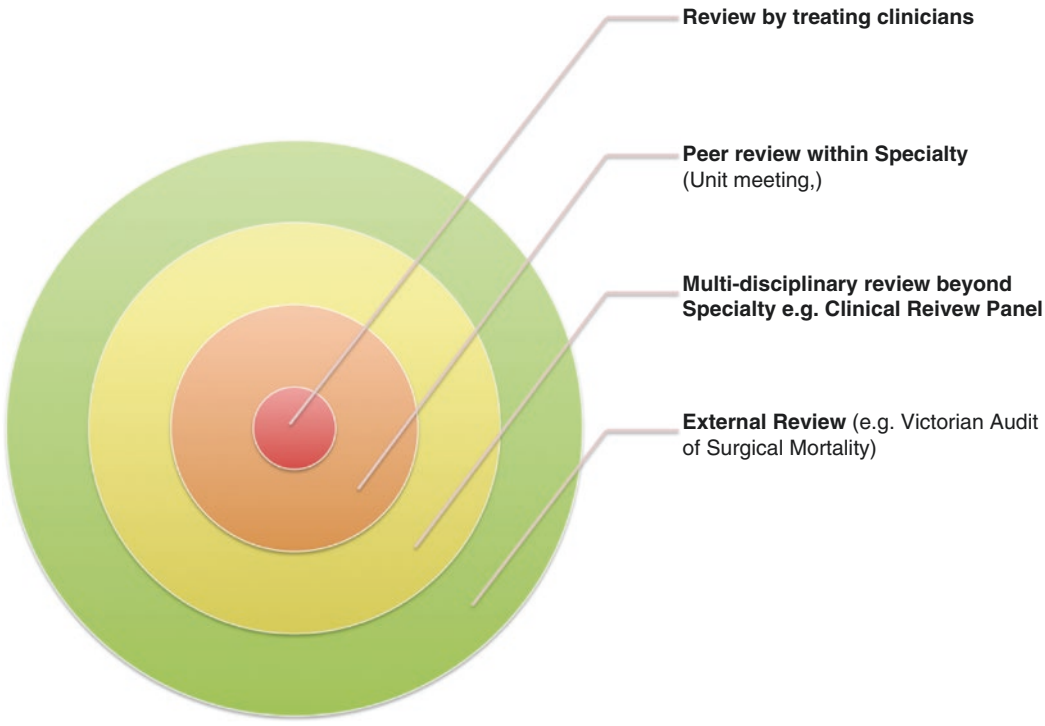

Fig. 7.6 Levels of review of deaths relating to distance from clinical care of patient

- 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

7.5.3 Hospital Standardised Mortality Ratio (HSMR)

Systematic review of patients' deaths has been identified as an effective tool for identifying systems issues to improve patient care. Historically, Surgical-Based Mortality and Morbidity committees discussed individual cases for education and learning, without necessarily focusing on the broader health service or systems issues that may have impacted care.

The emergence of accountable care has driven the need for governments, health departments and health funders to develop measures for comparing health service outcomes. The developments of Hospital Standardised Mortality Ratios (HSMR) have arisen out of the need for such measures. HSMR is defined as the ratio of the observed to expected deaths for a hospital, multiplied by 100, with expected deaths derived from statistical models that adjust for available case mix factors such as age and comorbidity [50].

Medical Administrators need to be familiar with the advantages and disadvantages of HSMR, how they are developed, what they mean and what are the implications for the patients within their health service. There are varying opinions on the value of HSMR; however, within various jurisdictions, these measures may be used to benchmark hospital performance. Mackenzie et al. [51] contends hospital-wide mortality is a relatively imprecise, crude measure of quality, but disaggregation into condition and service-line specific mortality can facilitate targeted improvements efforts. If tracked over time, both observed and expected mortality rates should be monitored to ensure that apparent improvement is not due to increasing expected mortality, which could reflect changes in case mix or coding. Risk adjusted mortality can be used as an initial signal that a hospital's mortality rate is significantly higher than statistically expected, prompting further inquiry [51].

The key point of contention is that HSMR data is based on administrative datasets that were primarily established to code patient's admissions for funding purposes, and not primarily established for measuring patient outcomes of care.

The role of the medical administrator is to determine:

- How will HSMR be used in my organisation's clinical governance framework?
- How do we exclude or remove data and coding artefact?
- At what point do we engage medical staff to review the data?
- How do we effectively determine whether there are clinical care issues?
- How does this relate to unit-level mortality and morbidity review?

Examples of coding artefact may include:

- Wrong diagnosis code allocated to the case.
- Missing, incorrect or lack of detail of the clinical case notes to adequately represent the severity of illness or complications arising, therefore coding personnel can only code what is documented.

7.5.4 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, identify areas for improvement, and drive strategies for improving patient care [52]. In addition, clinical registries are used to assess

changes in clinical practice, appropriateness of care and health outcomes over time [53]. 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 [54].

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 [55]. The focus of clinical registries is to capture data that reflects real-world clinical practice in large patient populations [56]. The data from clinical registries do not replace the need for traditional randomised controlled trials, rather registries and trials are complementary approaches [56].

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 [57]. The analysis of VASM reported cases has also lead to further understanding of cross-specialty differences with clinical management issues [58]. 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 [59].

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

- Review the results in a timely manner
- Identify and analyse any 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 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 up on practice and drive quality improvement [60].

7.5.5 Other National Standards that Benefit from Medical Staff Involvement

Although there is clearly a strong role for nursing leadership for successful implementation of the NSQHSS [61], 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 for 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, subacute and community physicians
   (b) Require senior leadership for policy development and development of strategies, requires junior medical staff involvement to explore and clarify the front-line medical staff issues for managing deteriorating patients, particularly those at end-of-life
6. Falls prevention
   (a) Reduction of number of falls—how to rationalise 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 subacute services, on discharge to community.

7.6 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 [35] outlines the principles for engaging medical staff in the quality agenda.

The degree in 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 determine 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:

7.6.1 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 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 are 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

7.6.2 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.

7.6.3 Committee Involvement

Medical Administrators should strongly consider including some representation of the Senior Medical Staff on the Board Quality and Safety Committee. Veronesi et al. in 2013 in their study of NHS hospital trusts performance measures from the Healthcare Commission [62] 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 multi-disciplinary 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

7.7 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.

Figure 7.7 outlines a conceptual diagram of the relationship between clinical service requirements, medical staff scope of practice, credentialing and clinical audit. The figure should be read in conjunction with details from other chapters.

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, specialties 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 specialties 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 match the senior medical staff to ensure appropriate levels of training and supervision. Noting that workforce availability will affect recruitment.

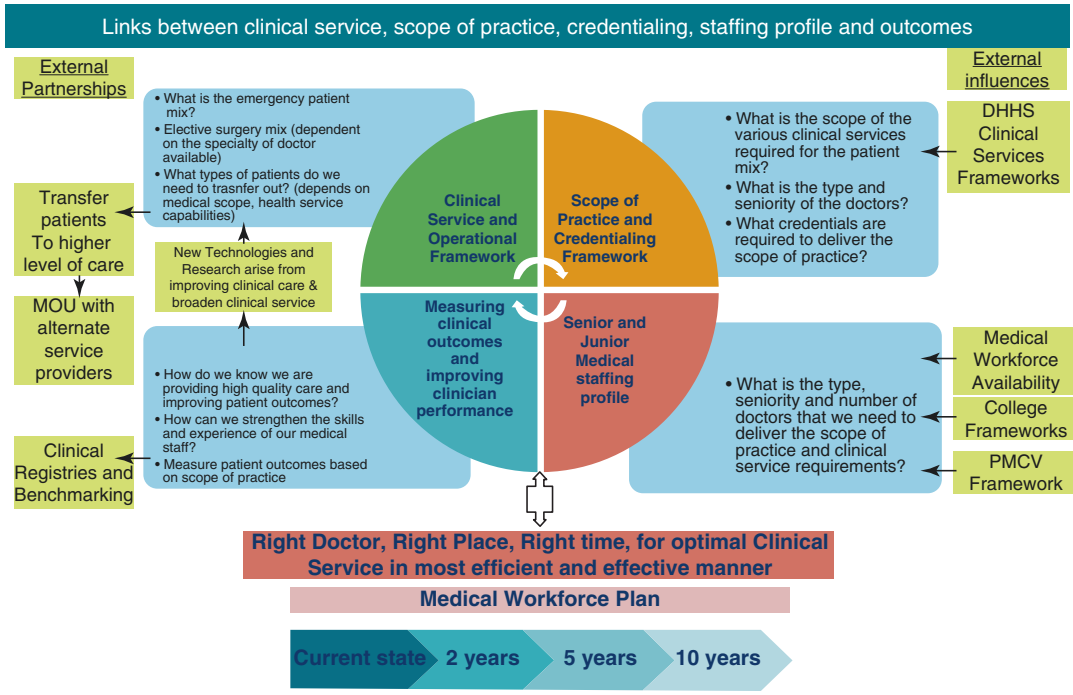

Fig. 7.7 Links between clinical service, scope of practice, credentialing, staffing profile and patient outcomes

- *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, e.g. elective surgery patient mix depends on the specialty of the senior medical staff available within the health service. What types of patients do we need to transfer to other health services?

7.7.1 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. Glasziou et al. [63] proposes that there is 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.
- In addition to formal evaluation recognising 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.

7.8 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, while 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. Australian Commission on Safety and Quality in Health Care (ACSQHC). National safety and quality health service standards. Sydney: ACSQHC; 2011.
3. Institute of Medicine. To err is human, November 1999. Accessed 25 Sept 2017.
4. 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.
5. Kennedy I. The Report of the public inquiry into childrens's heart surgery at the Bristol Royal Infirmary 1984-1995: learning from Bristol, July 2001. Available at http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPOlicyandGuidance/DH_4005620. Accessed on 18 June 2015.
6. Francis R. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry Executive Summary. 2013. Available at www.midstaffpublicinquiry.com/sites/default/files/report/Executive%20summary.pdf. Accessed on 18 June 2015.
7. Russell DP. Lessons for the Australian healthcare system from the Berwick report. Aust Health Rev. 2013;38(1):106–8.
8. 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. Available at https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/hospital-safety-and-quality-review.
9. 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.
10. 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.
11. 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.
12. 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.
13. Australian Commission on Safety and Quality in Healthcare (ACSQHC). June 2017, Australian Atlas of Healthcare Variation. Available at https://www.safetyandquality.gov.au/atlas/, Accessed 28 Sept 2017
14. Pronovost PJ, Marsteller JA. Creating a fractal-based quality management infrastructure. J Health Organ Manag. 2014;28(4):576–86.
15. Sutcliffe KM, Paine L, Pronovost P. Re-examining high reliability: actively organizing for safety, BMJ Qual Saf published on line March 21 2016. Available at http://qualitysafety.bmj.com/content/early/2016/03/21/bmjqs-2015-004698. Accessed 17 Oct 2016.
16. Ghaferi AA, Myers CG, Sutcliffe KM, Pronovost P. The next wave of hospital innovation to make patients safer. Harvard Business Review; 2016.
17. Victorian Department of Health and Human Services. Victorian Health Incident Management System Internet site. 2017. Available at https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/clinical-risk-management/vhims. Accessed 28 Sept 2017.
18. Clinical Excellence Commission. About the CEC. 2017. Available at http://www.cec.health.nsw.gov.au/about/about-cec. Accessed 25 Sept 2017.
19. 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.
20. Dekker SWA, Levenson NG. The systems approach to medicine: controversy and misconceptions. BMJ Qual Saf. 2015;24:7–9.
21. Perla RJ, Provost LP, Parry GJ. Seven propositions of the science of improvement: exploring foundations. Q Manage Health Care. 2013;22(3):170–86.
22. 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.
23. Victorian Department of Health and Human Services Root Cause Analysis Training internet site, available at https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/clinical-risk-management/clinical-risk-education/root-cause-analysis. Accessed 28 Sept 2017.
24. Doran GT. There's a S.M.A.R.T way to write management's goals and objectives. Manage Rev. 1981;70(11):35.
25. Behal R. Safety Step 2.0 A systematic framework for case review and action plans for improving patient safety. 16 October 2016. Available at https://itunes.apple.com/au/book/safetysteps/id521567746?mt=11. Accessed 28 Sept 2017.
26. Hayes CW, Batalden PB, Goldmann D. A 'work smarter, not harder' approach to improving healthcare quality. BMJ Qual Saf. 2015;24(2):100–2.
27. Perla RJ, Provost LP, Murray SK. Sampling considerations for health care improvement. Q Manage Health Care. 2013;22(1):36–47.

28. Nuckols TK, Bell DS, Liu H, Paddock SM, Hilbourne LH. Rate and types of events reported to established incident reporting systems in two US hospitals. Qual Saf Health Care. 2007;16:164–8.
29. 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 Mar;5(1):9–15.
30. 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;2007(16):169–75.
31. Evans SM, Berry JG, Smith BJ, Esterman A, Slemin P, O'Shaughnessy J, De Wit M. Attitudes and barriers to incident reporting: a collaborative hospital study. Qual Saf Health Care. 2006;15:39–43.
32. Benn J, Koutantji M, Wallace L, Spurgeon P, Rejman M, Healey A, Vincent C. Feedback from incident reporting: information and action to improve patient safety. Qual Saf Health Care. 2009;18:11–21.
33. Pham JC, Girard T, Pronovost PJ. What to do with healthcare incident reporting systems. J Public Health Res. 2013;2:e27.
34. 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.
35. Reinertsen JL, Gosfield AG, Rupp W, Whittington JW. Engaging Physicians in a Shared Quality Agenda. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2007. Available on www.IHI.org.
36. Joint Commission Sentinel Event Policy and Procedures. 2017. Available at https://www.jointcommission.org/sentinel_event_policy_and_procedures/. Accessed 6 Dec 2017.
37. Victorian Department of Health and Human Services. Sentinel Event Program. 2017. Available at https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/clinical-risk-management/sentinel-event-program. Accessed 28 Sept 2017.
38. Shojania KG, Wald H, Gross R. Understanding medical error and improving patient safety in the inpatient setting. Med Clin North Am. 2002 Jul;86(4):847–67.
39. 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.
40. Dwyer AJ. Medical managers in contemporary healthcare organisations: a consideration of the literature. Aust Health Re. 2010;34(4):514–22.
41. Dwyer AJ. Roles, attributes and career paths of medical administrators in public hospitals: survey of Victorian metropolitan directors of medical services. Aust Health Rev. 2010;34(4):506–13.
42. Goodall AH. Physician-leaders and hospital performance: is there an association? Soc Sci Med. 2011;73(4):535–9.
43. Swensen S, Pugh M, McMullan C, Kabcenell A. High impact leadership: improve care, improve the health of populations, and reduce costs. IHI White Paper Cambridge, Massachusetts*:* Institute for Healthcare Improvement; 2013.
44. 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.
45. Bisognano M. Healthcare Improvement Guru Maureen Bisognano sees Hospitalists as Agents for Change. The Hospitalist, 2015 February; 2015 (2). Available at http://www.the-hospitalist.org/hospitalist/article/122592/healthcare-improvement-guru-maureen-bisognano-sees-hospitalists-agents. Accessed 28 Sept 2017.
46. Choosing Wisely Australia 2015. Australian College of Emergency Medicine: tests treatments and procedures that clinicians and consumers should question. Available at http://www.choosingwisely.org.au/recommendations/acem. Accessed 6 Dec 2017.
47. 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.
48. 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.
49. Provenzano A, Rohan S, Trevejo E, Burdick E, Lipsitz S, Kachalia A. Evaluating inpatient mortality: a new electronic review process that gathers information from front-line providers. BMJ Qual Saf. 2015;24:31–7.
50. Bottle A, Aylin P. Strengths and weaknesses of hospital standardised mortality ratios. BMJ. 2011;342:c7116.
51. Mackenzie SJ, Goldmann DA, Perla RJ, Parry GJ. Measuring hospital-wide mortality pitfalls and potential. J Healthc Qual. 2014;38(3):187–94.
52. Evans SM, Scott IA, Johnson NP, Cameron PA, McNeil JJ. Development of clinical-quality registries in Australia: the way forward. Med J Aust. 2011;194(7):360–3.
53. 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.
54. 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.
55. Clinical Registries, Centre of Research Excellence in Patient Safety. Available at http://www.crepatientsafety.org.au/registries/. Accessed on 18 Mar 2012, last updated 13 June 2011.
56. 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.
57. Retegan C, Russell C, Harris D, Andrianopoulos N, Beiles B. Evaluating the value and impact of the Victorian audit of surgical mortality. ANZ J Surg. 2013;83:724–8.
58. 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.
59. ANZICS Centre for Outcome and Resource Evaluation Annual Report 2012-2013, ANZICS Melbourne.
60. 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 Manage. 2016;11(1):56–64.
61. 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.
62. Veronesi G, Kirkpatrick I, Vallascas F (2013) Clinicians on the board: what difference does it make? Soc Sci Med, vol 77, 2013, p 147–155.
63. Glasziou P, Ogrinc G, Goodman S. Can evidence-based medicine and clinical quality improvement learn from each other? BMJ Qual Saf. 2011;20(Suppl1):i13–7.

Further Reading[1]

Angood P, Birk S. The value of physician leadership. Phys Exec J. 2014;2014:p6–22.

Australian and New Zealand Society of Cardiac and Thoracic Surgeons. 2017. About the database. Available at https://anzcrs.org/database/about. Accessed on 25 Sept 2017.

Australian Government Department of Health, National Core Set of Sentinel Events. Available at http://www.health.gov.au/internet/publications/publishing.nsf/Content/mental-pubs-n-safety-toc~mental-pubs-n-safety-5~mental-pubs-n-safety-5-8. Accessed 6 Dec 2017.

Australian Health Practitioner Regulation Agency. Mandatory Reporting. Available at https://www.ahpra.gov.au/Notifications/Make-a-complaint/Mandatory-notifications.aspx. Accessed 6 Dec 2017.

Australian Institute of Health Innovation, Deepening our Understanding of Quality in Australia Project, Macquarie University. Available at https://duqua.org. Accessed 25 Sept 2017.

Clark J, Nath V. 2014. Medical engagement: A Journey not an event, The Kings' Fund, July 2014.

Conway J, Federico F, Stewart K, Campbell M. Respectful Management of Serious Clinical Adverse Events. 2nd ed. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2011. Available on www.IHI.org.

Department of Health Victoria. Victorian Clinical Governance Policy Framework: Enhancing Clinical Care, Department of Health; 2008.

Doyle P, VanDenKerkhof EG, Edge DS, Dinsburg L, Goldstein DH. Self-reported patient safety competence among Canadian medical student and postgraduate trainees: a cross sectional survey. BMJ Qual Saf. 2015;24:135–41.

Health Roundtable. 2017. Welcome. https://www.healthroundtable.org/. Accessed 25 Sept 2017.

Lee TH, Cosgrove T. Engaging doctors in the healthcare revolution. Harv Bus Rev 2014;92(6):104–11, 138.

Levinson W, Kallewaard M, Bhatia RS, Wolfson D, Shortt S, et al. Choosing Wisely: a growing international campaign. BMJ Qual Saf. 2015;24(2):167–74.

Victorian Healthcare Associated Infection surveillance System (VICNISS) 2017, What is VICNISS. Available at https://www.vicniss.org.au/aout/what-is-vicniss/. Accessed 25 Sept 2017.

Victorian Quality Council. Better quality better health care: a safety and better quality better health care: a safety and quality improvement framework for Victorian health services, Victorian quality council; 2005.

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

- Victorian Health Policy and Funding Guidelines, Department of Health Victoria, available at https://www2.health.vic.gov.au/about/policy-and-funding-guidelines , accessed 6 December 2017
- Delivering High Quality Healthcare - Victorian Clinical Governance Framework: Department of Health Victoria (2017), available at https://www2.health.vic.gov.au/hospitals-and-health-services/quality-safety-service/clinical-risk-management/clinical-governance-policy, accessed 6 December 2017
- National Safety and Quality Health Service Standards, Australian Commission on Safety and Quality in Health Care (2011), available at https://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.pdf, accessed 6 December 2017
- Safer Care Victoria: Clinicians as Partners – framework for clinician engagement, available at 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 December 2017
- Doing it With Us Not for Us: Participation Policy, Department of Health (2006)
- Victorian Health Incident Management Policy, Department of Health (2011)
- 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
- Australian Charter of Health Care Rights, Australian Commission on Safety and Quality in Health Care (2008)
- Guide to Complaints handling in Health Care Services, Office of Health Commissioner (2005)