



Royal Australasian College of Surgeons

Research & Evaluation, incorporating ASERNIP-S

Clinical Governance Frameworks - Report

Acknowledgments

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¹ Australian Safety and Efficacy Register of New Interventional Procedures - Surgical

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Introduction

The Royal Australasian College of Surgeons (RACS) is responsible for training surgeons and maintaining surgical standards in Australia and New Zealand. As part of the RACS role in maintaining high surgical standards in Australia and New Zealand, RACS recognises the important role of clinical governance as a continuous improvement process which is clearly aligned with values of the College and its Fellows. The purpose of this report is to examine various aspects of clinical governance and to understand how they relate to the surgeon and the surgical team. The report details the interconnectedness of professionalism and clinical governance and the challenges for clinical governance in complex modern healthcare systems. It also provides a checklist for surgeons and teams to reflect on, and engage with, the principles of clinical governance.

Executive summary

Clinical governance

Most individuals who interact with healthcare systems receive high quality and safe care; however, as recognised in the seminal *To Err is Human* report (Institute of Medicine Committee on Quality of Health Care in 2000), as in all complex systems that involve human beings, errors occur. As a result of several highly publicised breaches of patient safety and key inquiries within Australia, Canada, the United States and the United Kingdom, it became apparent that some adverse events that occur within hospitals can be considered preventable. A recent example is 'The Review of Hospital Safety and Quality Assurance in Victoria' (Department of Health & Human Services, 2016) which found substantial failings of clinical governance. Over time, the literature has documented problems that extend to a variety of care settings and provides many compelling arguments for a focus on patient safety. Furthermore, there has been recognition that improving patient safety requires a multi-dimensional approach and that responsibility lies not just with individuals, but also with organisations and systems.

At the most basic level clinical governance is about a culture in which healthcare professionals routinely question: 'Am I doing it right? How can I do better?'

For the purpose of this report, clinical governance is considered in a holistic manner as the strategies and thinking that encourage health professionals and organisations to reflect on current practice and act to improve it.

Methods

This report was conducted in several phases and was designed to incorporate input and direction from the working group. The phases included a literature review, presentation of three case studies and the development of a checklist for surgical team assessment. The intention behind the varied methodology was to bring together a diverse body of literature and individual narratives to provide insight into a complex issue in contemporary medicine.

Findings

Measuring clinical governance

Overall, there is a paucity of evidence demonstrating the impact of clinical governance at the level of patient outcomes. Evidence is varied in nature and interventions to improve clinical governance are

varied in and of themselves. Interventions can include the introduction of specific audit-style measures, report card generation, checklists for care providers, new styles of meetings and other tools. In determining the value or importance of these interventions there is confusion regarding what is the best method of measuring success – is it best measured by rates of uptake and utilisation or should it be measured by clinical outcomes? Furthermore, there are potential confounders of whether measures not meeting the criteria for ‘success’ are a reflection of the value of clinical governance itself, or the utility of the tool or instrument used to deliver it. However, the fragmented nature of the evidence on clinical governance is not evidence of a lack of impact. Rather, it reflects challenges with the measurement of impact in terms of:

- What outcomes can or should demonstrate impact?
- How can these outcomes be measured?
- What constitutes a significant change?

Features of organisations with good clinical governance

From the literature review it was identified that organisations with functioning and thriving clinical governance are also likely to be organisations in which professionalism is high. Key features of organisations with good clinical governance include:

- positive relationships between managers and staff with shared values and goals at the clinical unit level
- clear lines of responsibility and accountability
- staff with a sense of engagement and commitment who are supported by measures to mitigate fatigue and burn out
- active systems in place to measure outcomes of care that are patient centred with participation in internal and external audits
- processes in place to measure and act on performance indicators, and a culture which encourages excellence and does not tolerate complacency
- open disclosure policies that foster trust between patients and staff as well as encourage learning and development
- continual pursuit of ways to benchmark performance and improve.

Lessons from the case studies

In considering how to build successful quality improvement into hospital activities it is clear that this cannot be achieved without significant commitment and dedication from staff at all levels over a long period of time. These activities flourish when the organisation has a shared understanding of the direction in which it is going. Three key points emerging from the case studies are outlined below.

- Effective clinical governance requires capacity building amongst staff, particularly at the leadership level. Training courses and education provide a strong foundation for effective leadership and quality improvement interventions.
- Effective clinical governance across an organisation requires shared goals with regards to performance and these need to be reinforced by clear understanding of norms and expectations.

- Achieving commitment and engagement from the workforce requires facilitating clinical ownership of performance improvement activities and data collection.

The successful implementation of the above three points within an organisation can lead to positive cultural shifts which support standards of excellence.

Checklist items for the surgical team

In consideration of the broad literature on clinical governance, and in response to questions arising throughout the drafting of the report, a list of items for a team assessment checklist has been drafted. The checklist items are not presented as a finalised checklist, but rather draft items. This is in recognition of the fact that a well-functioning checklist should be user and context driven. Any checklist generated based on draft items would need to be piloted before it is used and validated. These activities were beyond the scope of this report.

Reflection on the role of a surgical director

As a result of engagement with working group members and RACS Fellows, the following question arose ‘What material/thought process should a surgical director have to know that clinical governance is working at their hospital?’

There is no universal consensus on the issue. However, some important points arising from this report do address this question. These are discussed below and are elaborated more fully on pages 28–31.

Surgical directors are leaders and therefore set the tone and expectations for their team. Surgical directors need to take an active interest in clinical governance and should recognise that the central aim of good clinical governance is to provide consistent care and performance at the highest possible standard. The mechanisms used to affect this will vary according to institutional conditions. In looking at the role of surgical directors this report identified that:

- Those in leadership positions should be supported by access to training courses and mentors.
- Surgical directors should adopt a system for measuring and monitoring processes and outcomes in their unit. Administrative data sets are unlikely to be sufficient to truly drive performance improvement and thus context relevant, clinician-owned outcome and process data is an important part of driving improvement.
- Surgical directors should use this data should form part of a team approach to improvement practices, using a method and framework most applicable to the specific setting.

In evaluating whether clinical governance is working there is no one measure that can inform this assessment. However, Surgical Directors and teams who actively engage in clinical governance; are supported by appropriate training and knowledge; have shared goals and values; monitor and respond to performance data; and, who acknowledge and respond to staff feedback and concerns, are unlikely to experience failures of clinical governance.

Methods of review

Phase one – Literature review

This phase was a literature review aimed at understanding the nature of the peer-reviewed literature on the topic of clinical governance and its relationship with surgery. This included looking for literature regarding clinical governance activities such as surgical checklists or audit, and the relationship between these activities and performance indicators. The body of work on clinical governance is vast therefore this report draws on specific and relevant examples to illustrate particular points.

The databases searched include PubMed, the Cochrane Library, The trip database and Google scholar and the terms used included: clinical gov*, surg*, Health Facility Administration*, General Surgery/organization & administration*, Medical Audit, Risk Management, Health Care Rationing, Clinical Governance/standards, Clinical Governance/organization & administration*, Quality Assurance, Health Care/organization & administration*, Quality of Health Care*. Articles were selected for inclusion on the basis of relevance and timeliness. These searches were supplemented by targeted Google searches to look for high level reports on the topic. This phase was also supplemented by searches in the grey literature on clinical governance to describe the Australian and New Zealand approaches to clinical governance, and to map the different frameworks used in different states or territories within Australia. The aim of this was to provide context for the report as well as reference documents for those interested. An important aspect of this section is to illustrate the variation in approaches across jurisdictions.

Phase two – Presentation of selected case studies

The second phase of this report was guided by the results of the literature searching which highlighted the importance of learning from successes. This phase included engagement with examples identified in the literature and through engagement with key clinicians who provided local, relevant examples of clinical governance interventions that they thought were successful. These examples were reviewed by the researchers and selected for presentation as case studies if it was possible to identify the intervention, how its success had been shown and measured, and the drivers of that success. Narratives about patients, the experience of caring for them, and their recovery from illness, as well as pitfalls in treatments or outcomes, are shared among physicians as well as among patients and their relatives (Kalitzkus and Matthiessen 2009). Narratives can provide powerful context and insight into complex situations, and are an intuitive part of our learning process. The aim of presenting case studies in this report is to provide tangible examples of clinical governance in action and to identify important factors associated with successful intervention, with the aim of facilitating engagement and learning. Some research shows that clinicians are frequently disillusioned with clinical governance, feeling it is used as a cost-saving mechanism rather than a driver of quality care. In order to address this, case studies are presented to understand the drivers of successful implementation of clinical governance.

Phase three – Developing a team-assessment tool for surgeons

The third phase was undertaken with the aim of providing a tool for surgeons and surgical teams to facilitate reflection and engagement with clinical governance. The aim was to create a tool:

- that covers the principles of clinical governance;

- is relevant to surgeons and the surgical team irrespective of setting, team size and structure;
- is not onerous in its undertaking or consideration;
- facilitates action and thinking but is not prescriptive.

Inspired by the approach of Flynn and colleagues in Ireland (Flynn et al 2015) who developed a series of clinical governance prompts for multidisciplinary teams, this approach took a similar approach by developing checklist items for team assessment of clinical governance. The items on the checklist were informed through identifying other relevant checklists in the grey literature and from important learnings identified in the peer reviewed literature. Before being finalised it is envisioned that the checklist will go through an iterative cycle of feedback from surgeons.

The working group

The working group included the following fellows:

- Dr Lawrie Malisano
- Mr Richard Lander
- Professor Michael Grigg
- Professor Guy Maddern
- Dr John Quinn
- Associate Professor Stephen Tobin

Clinical governance, emergence and definitions

A focus on patient safety – redressing system failures

Most individuals who interact with health systems receive high quality and safe care; however, as recognised in the seminal *To Err is Human* report (Institute of Medicine 2000), as in all complex systems that involve human beings, errors occur. As a result of several highly publicised breaches of patient safety and several key inquiries within Australia, Canada, the United States and the United Kingdom, it became apparent that many adverse events that occur within hospitals can be considered preventable. Key inquiries often cited in literature on clinical governance include the following.

- Scally G, Donaldson LJ. *Clinical governance and the drive for quality improvement in the new NHS in England*. BMJ 1998; 317: 61-5.
- National Health Service. *An organisation with a memory: a report of an expert group on learning from adverse events in the NHS*. London: The Stationery Office, 2000.
- Institute of Medicine. *To err is human: building a safer health system*. Washington: National Academy Press, 2000.
- Douglas N, Robinson J, Fahy K. *Inquiry into obstetric and gynaecological services at King Edward Memorial Hospital 1990-2000*. Perth: Health Department of Western Australia, 2001.
- Department of Health. *The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995: learning from Bristol*. London: Stationery Office, 2001.
- Davis P, Lay-Yee R, Briant R, et al. *Adverse events in New Zealand public hospitals I: occurrence and impact*. NZ Med J 2002; 115: 271.
- Baker GR, Norton P. *Patient safety and healthcare error in the Canadian healthcare system: a systematic review and analysis of leading practices in Canada with reference to key initiatives elsewhere*. Winnipeg: Health Canada, 2003.
- Walker B. *Final report of the Special Commission of Inquiry into Campbelltown and Camden Hospitals*. Sydney: New South Wales Attorney General's Department, 2004.
- Davies G. *Queensland Public Hospitals Commission of Inquiry*. Brisbane: Queensland Government, 2005.

A recent example is 'The Review of Hospital Safety and Quality Assurance in Victoria' (Department of Health & Human Services 2016) which found substantial failings of clinical governance. Over time, the literature has documented problems in a variety of care settings and provides compelling arguments for a focus on patient safety. Furthermore, there has been recognition that improving patient safety requires a multi-dimensional approach and that responsibility lies not just with individuals but with organisations and systems. Clinical governance has emerged as a vehicle through which to improve patient safety and the quality of health care in a setting of rising demand, increasing consumer participation and burgeoning cost pressures (Balding 2008; Braithwaite and Travaglia 2008; Brandao et al 2013; Department of Health 2012).

Modern understandings of clinical governance

Literature reviews on the subject have identified substantial variation in definitions and confusion around the use and application of the term (Flynn et al 2015). However, at the most basic level clinical governance is about a culture in which healthcare professionals routinely question: 'Am I

doing it right? How can I do better?’ In 2001, the Office of Safety and Quality in Health Care in Western Australia published a background paper on clinical governance that defined it as –

“A systematic and integrated approach to assurance and review of clinical responsibility and accountability that improves quality and safety resulting in optimal patient outcomes”.

This is grounded in the often cited Scally and Donaldson definition in which –

*“Clinical governance is a system through which [health] 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.”*p62 Scally and Donaldson (1998).

For the purpose of this report, clinical governance is considered in a holistic manner as the strategies and thinking that encourage health professionals and organisations to reflect on current practice and act to improve it.

Clinical governance and its many faces

Within the international literature on clinical governance it is apparent that the term is indistinct, variably defined and with different meanings to different stakeholders (Braithwaite and Travaglia 2008; Brandao et al 2013; Brault et al 2015; Cowie et al 2013; Department of Health 2012; Flynn et al 2015). However, there are two important elements to recognise that drive top down and bottom up approaches to the operationalisation of clinical governance.

1. Healthcare is a complex system and errors are often the result of interconnected human interactions and actions. Therefore, improving safety and quality requires an abstraction from individual error or ‘blame’ culture to a systems and process view.
2. In order to achieve the goals of clinical governance there is an expectation that medical professionals will be given, and will willingly take on, responsibility for change and improvement.

This understanding of patient safety and quality issues recognises that governance and leadership on any issue begins at the highest level, but its success is contingent upon leadership at all levels and a willingness to build partnerships between those delivering and those managing healthcare. Literature has shown that health professionals are well placed to encourage and lead improvements in performance (Goodall 2011; Paulus et al 2008; Prenestini et al 2015).

Flynn et al (2015) undertook a review of clinical governance to inform initiatives in Ireland which looked at the different ways that clinical governance is operationalised across a number of countries. They found a high degree of inconsistency, even across different states within Australia. Processes for risk management, patient engagement, learning and clinical audit were commonly highlighted as important in operationalising clinical governance. Despite differences, what should be acknowledged is that **good clinical governance is achieved when multiple processes are working together to deliver safety and quality – i.e. it is more than the sum of its parts** (Flynn et al 2015; Lewis et al 2002).

‘Good’ clinical governance

Measuring clinical governance

Historically clinical governance has emerged as a vehicle to redress failures in the health system and the impetus for its implementation has been driven by documentation of adverse event rates and analysis of their preventability. However, these measures may not necessarily serve as good indicators of the impact of clinical governance. In fact, rates of error or adverse events do not necessarily correlate with performance (Westbrook et al 2015). Westbrook et al (2015) investigated prescribing errors in a hospital setting and found that incident reporting is an inaccurate reflection of the nature and severity of prescribing errors. The recommendations were that, for a range of reasons, the frequency of reported incidents should not be used as a measure to compare hospitals, measure safety or measure the effectiveness of interventions.

In Australia, important inquiries into health services that occurred from 2000–2005 highlighted problems with the monitoring and reporting of adverse events, a lack of support for patients or staff, concerns about safety and quality and failures of medical credentialing or performance review systems (Gluyas et al 2011). Similar concerns have been highlighted internationally. Gluyas et al (2011) examined the changes at King Edward Memorial Hospital following an inquiry established to review the quality of obstetric and gynaecological services and found significant evidence of improvements in the areas of credentialing and performance management since the inquiry. However, they did not find evidence of improvement in the provision of training and education to improve communication skills for clinicians. It was concluded that changes had occurred at the administrative function level but not at the point of care or with communication.

Phillips et al (2010) undertook a literature review to identify governance models that could deliver quality care relevant to Australian primary health care. Of the models they identified the most commonly employed strategies for implementation were audit, performance against indicators, and peer-led reflection on evidence or performance. The authors described the literature as fragmented and noted that most evidence is concentrated on prescribing practices with less data on areas where outcomes are harder to measure such as mental health care, chronic disease and age-related health problems.

One study (Sarchielli et al 2016a) attempted to measure the relationship between knowledge and application, as well as perceived utility of clinical governance (by doctors) and performance measures and efficiency indicators. This Italian study looked at six public hospitals and included a sample of 1250 doctors (249 heads of units and 1001 physicians). A checklist and questionnaire were used to gauge doctors’ knowledge and application of clinical governance as well as the perceived utility of such tools. The performance indicators were patient mortality and efficiency indicators.² The study used a cross-sectional design with a deterministic record-linkage approach.

The authors used multiple linear regression analyses to explore the relationship between medical perspectives on clinical governance practice and performance. It was found that safety perception was the most considered aspect by the entire sample, followed by clinical audit, quality, and guidelines. It was also found that the application of clinical governance tools in clinical units is

² Efficiency indicators were extra-region mobility rate, average hospital stay, bed occupancy, rotation and turnover rates, and comparative performance index.

associated with the mortality rate and certain efficiency indicators. Where doctors perceived their units to be unsafe there were higher mortality rates, showing that perceptions were representative of the real situation. However, the same doctors did not necessarily feel that clinical governance tools were useful. In units where doctors claimed knowledge and application of these tools as higher, there was an observed reduction in the mortality rates of those units.

Overall, there is a paucity of evidence demonstrating the impact of clinical governance at the level of patient outcomes. Evidence is varied in nature and interventions to improve clinical governance are varied in and of themselves. The interventions can include things such as the introduction of specific audit-style measures, report card generation, checklists for care providers, new styles of meetings and other tools. It is difficult to know whether the appropriate measure of success is the successful uptake and usage of interventions or whether it is the outcomes of care. Furthermore, there are potential confounders of whether a measure not meeting the criteria for 'success' is a reflection of the value of clinical governance itself or the utility of the tool or instrument used to deliver it. However, the fragmented nature of the evidence on clinical governance is not evidence of a lack of impact. Nor should it be interpreted as evidence to support clinician scepticism around clinical governance. Many reports into the failures of the health system to safeguard patients in their care highlight that we need robust clinical governance initiatives. Rather, the literature reflects challenges with the measurement of impact in terms of, what outcomes can or should demonstrate impact? How can these outcomes be measured? And, what constitutes a significant change? These are questions that both researchers and clinicians need to resolve in order to progress the evidence base on this issue.

Connecting clinical governance and medical professionalism

Medical professionalism refers to the values and skills that the profession and society expects of doctors. This includes both the individual doctor-patient relationship and the wider social 'contract' between the profession and society. The underlying principles of clinical governance are intrinsically linked to medical professionalism. Good clinical governance should promote medical professionalism and foster an environment in which there are shared objectives and mutual respect amongst managers, clinicians and patients.

However, the literature has documented a spectrum of clinician views, which show that whilst some see it as increasingly important and essential, a large proportion are disillusioned and sceptical of its benefits. A New Zealand study, which had a total of 10,303 responses across a broad spectrum of professionals, recorded overwhelmingly negative responses – in particular, a strong theme prevalent in this study was the perceived or actual misalignment between management and clinicians.

“This DHB [district health board] has a management culture which is dismissive of clinicians’ perspectives and focused on corporate perspectives rather than truly appropriate care...critical thinking is strongly discouraged, feedback systems do not allow true reflection on real situations. Obedience is valued, conformity is rewarded. Clinicians neither trust or respect managers. Decisions are often arbitrary and made without consultation”^{p3} Gauld and Horsburgh (2015b)

Similar findings are reported in a study of 3064 medical staff in England, Wales, Australia, and New Zealand (Degeling et al 2003). This is a major barrier to successful clinical governance because clinicians are at the core of clinical work and hence are essential to the success of clinical governance. This discord between the actual or perceived goals of management and the pursuit of

professionalism by medical staff is something that must be resolved in order for clinical governance to function as it is intended, as a culture in which excellence in clinical care will flourish.

It is clear that efforts to create thriving systems in which clinical governance is a success require active partnerships between managers and clinical staff in which goals are shared and not perceived as oppositional. For example, the Mayo Clinic has demonstrated that both clinical excellence and financial control can be achieved through the shared central tenet that the needs of the patient come first. Within the structure of the Mayo Clinic, managers and physicians both have a stake in providing excellence in clinical care using a unique *“physician/administrative partnership in which they jointly lead an effort, initiative or committee. The physician brings the perspective of the patient to the decision-making process, and the administrator leverages business acumen”*. p24 Peters et al (2014) The Mayo Clinic is considered a world leader in value-based care and innovation as well as having achieved good cost savings.

According to the Mayo Clinic, a key component of success is their physician led approach and their recognition that for both the wellbeing of patients and organisations, physicians need to be at the centre of organisational practices and leadership. The Mayo Clinic recognises that *“To flourish, physicians need some degree of choice (control over their lives), camaraderie (social connectedness), and an opportunity for excellence (being part of something meaningful). Organizations can provide these opportunities by establishing constructive organization-physician relationships and developing physician leaders.”* p105 Swensen et al (2016). This model of incorporating physicians into leadership and governance is an important step in bringing professionalism and clinical governance together.

Furthermore, the literature also tells a story of success with organisational approaches that encourage a physician-led model lead to improvements in performance (Goodall 2011; Paulus et al 2008; Prenestini et al 2015). A review of the literature on the effect of clinical leadership and hospital performance by Sarto and Veronesi (2016) found a largely positive impact of greater clinical involvement in governance and management. The authors note that clinical leadership has been found to enhance efficiency and effectiveness of hospitals in terms of quality of care and hospital resource management. Good clinical governance is not measurable through one outcome – it has a number of indicators. To measure ‘good’ clinical governance it is important to have a wide lens and consider that it is an organisation-wide value rather than a single intervention that can be quantified. Organisations with functioning and thriving clinical governance are likely to be organisations in which professionalism is high. Organisations with good clinical governance are likely to share many important features, such as:

- positive relationships between managers and staff with shared values and goals at the clinical unit;
- clear lines of responsibility and accountability;
- engaged and committed staff who are supported by measures to mitigate fatigue and burn out;
- active systems in place to measure outcomes of care that are patient centred with participation in internal and external audits;
- processes in place to measure and act on performance indicators, and a culture which encourages excellence and does not tolerate complacency;

- open disclosure policies which foster trust between patients and staff as well as encourage learning and development;
- a desire to continually pursue ways to benchmark and improve performance.

Moving towards excellence

A KPMG (2013) report on global perspectives on clinical governance notes the difficulty in benchmarking and a need for hospitals to be able to use data to find out whether the cost of implementing improvement measures translates into saving lives. The report also notes that for stakeholders to act on and invest in measurement and outcomes, these outcomes should be *available, reliable* and *valid*. When outcome measures are not seen as valid by hospitals and clinicians, or when professions question their relevance their continued emphasis can lead to ‘gaming’ the system. Hence, to have useful measurement and evaluation of quality and safety changes associated with good clinical governance, the measures need to be appropriate and have buy-in from all levels. The report notes the following.

“Strong purpose, enduring values, great leadership and a restless curiosity to improve truly distinguish excellence” p2 KPMG (2013)

High performing hospitals are those which consistently demonstrate excellence across multiple performance measures and across multiple departments or services (Taylor et al 2015). Whilst there is still a long way to go in terms of identifying appropriate measures of excellence, data has become increasingly robust over time and it has been possible to identify substantial variation in performance between hospitals (Taylor et al 2015). A consistent finding is that hospital practice frequently does not align with well-established evidence on care (Morris et al 2011) and that hospitals often perform well on some indicators but do not perform consistently well across the spectrum of indicators (Bradley et al 2006; Braithwaite et al 2005; Morris et al 2011; Rosenthal et al 2007).

Taylor et al (2015) undertook a qualitative systematic review of literature that identified factors associated with high performing hospitals and practical strategies for improvement. The review included 19 studies of high performing hospitals in the United States (15 studies), the United Kingdom (3 studies) and South Africa (1 study). The review noted that definitions of high performance were frequently based on single outcomes rather than on multiple domains which can confound the issue of how to assess and attain excellence across an organisation. However, despite shortcomings in the literature the authors, using qualitative analysis and data triangulation with individuals from large tertiary hospitals, identified seven high level themes associated with high performance. These were:

- positive organisational culture;
- senior management support;
- effective performance monitoring;
- building and maintaining a proficient workforce;
- effective leaders across the organisation;
- expertise-driven practice;

- Interdisciplinary teamwork.

No Australian or New Zealand hospitals were studied in literature included in this review. The relationship between these main themes and other sub-themes are illustrated in a model shown in Figure 1. For a detailed explanation of the seven themes and their relationship with other sub-themes refer to the comprehensive review article. Supplementary files to the review also provide further details on strategies for improvement.

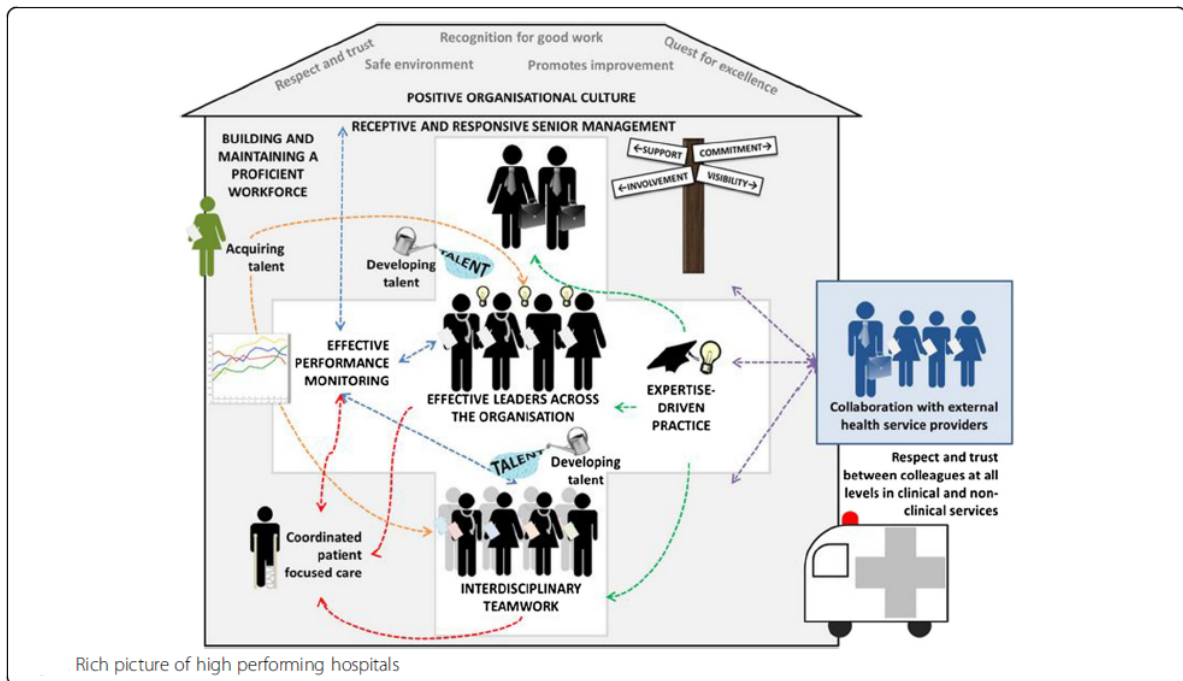


Figure 1 Model of factors associated with high performing hospitals reproduced from Taylor et al (2015)

Understanding that healthcare is provided in complex and varied settings and that there is no one-size fits all approach to delivering good clinical governance, this report recognises that there is much to learn from success. As pointed out by Taylor et al (2015) there is value in studying examples of high performance. Healthcare is in a state of constant change and evolution, often led by the innovation of individuals or teams. Understanding what has led others to success may translate to success at the local level. However, rather than describing high level themes as has been done by others on the topic, this report will focus on providing illustrative vignettes, predominantly from the local setting.

To understand what 'good' clinical governance looks like it is important to focus on examples of excellence and success to understand the underlying drivers behind those achievements. In doing this three case studies were examined. The first is a case study about a large audit-type intervention from the USA. The second, from Australia, considers the experience of the Division of Surgery at the Flinders Medical Centre over 15 years of practice improvement. The third is an example from Eastern Health, Box Hill that illustrates the importance of bringing together medical and administrative staff. The case studies are structured around three main questions.

1. In what way was success realised and measured? Was it by improving quality of care, reducing errors, boosting morale or patient trust etc?
2. From the perspective of the individual/organisation/author, what was key to that success?
3. What was the instrument for success? Were frameworks, data sets or other tools employed?

Case study 1 – Improving the safety of surgical care through rich clinical data

This case study draws upon the work of Melinda Maggard-Gibbons (2014) who undertook both a literature review and qualitative research to examine the benefits, harms and costs associated with the American College of Surgeons National Surgical Quality Improvement Project (ACS NSQIP). The ACS NSQIP was launched in 1994 with the aim of collecting and reporting clinical variables and outcomes across all Veterans Affairs (VA) hospitals; this came in response to concerns about high complication rates in VA hospitals. From there it grew from VA hospitals to non-VA hospitals becoming the formal ACS NSQIP program in 2014. According to the author, the literature (which predominantly consists of pre-post design) indicates that participation in the ACS NSQIP results in measurable and significant reductions in 30-day mortality and morbidity rates following surgery. In general, reports show that improvements in complication rates have been relatively large, improvements in mortality have ranged from modest to no change and that reductions in postoperative complications and mortality can result in large cost-savings (Hollenbeak et al 2011; Khuri et al 1998).

A key component of the program is that the improvements are developed as direct responses to outcomes shown to be in need of improvement. Changes and improvements were site-specific. To achieve this, the ACS NSQIP employs a report card system which contains the key elements listed below (Maggard-Gibbons 2014).

- 1) A surgeon champion - an individual staff member at the participating site who assumes a significant role in establishing and overseeing the participation of each site.
- 2) A surgical clinical reviewer who is trained to collect data on preoperative clinical variables and on 30-day outcomes.
- 3) Risk-adjusted models of expected mortality and morbidity by procedure type.
- 4) The presentation of analysed data back to the individual sites alongside masked data for the other sites.

Data are provided for each morbidity, such as unplanned readmission, urinary tract infection and pulmonary embolism and mortality. Sites are displayed as being high (worse than expected) or low (better than expected) outliers for each category of morbidity and for mortality. The participating sites are encouraged to address and correct problem areas of clinical care. For example reporting see Figure 2. The ACS NSQIP values identifying good and bad aspects of surgical care; however, it does not provide insight into how or why they occur. The program relies upon the organisations own insight and knowledge to correct issues.

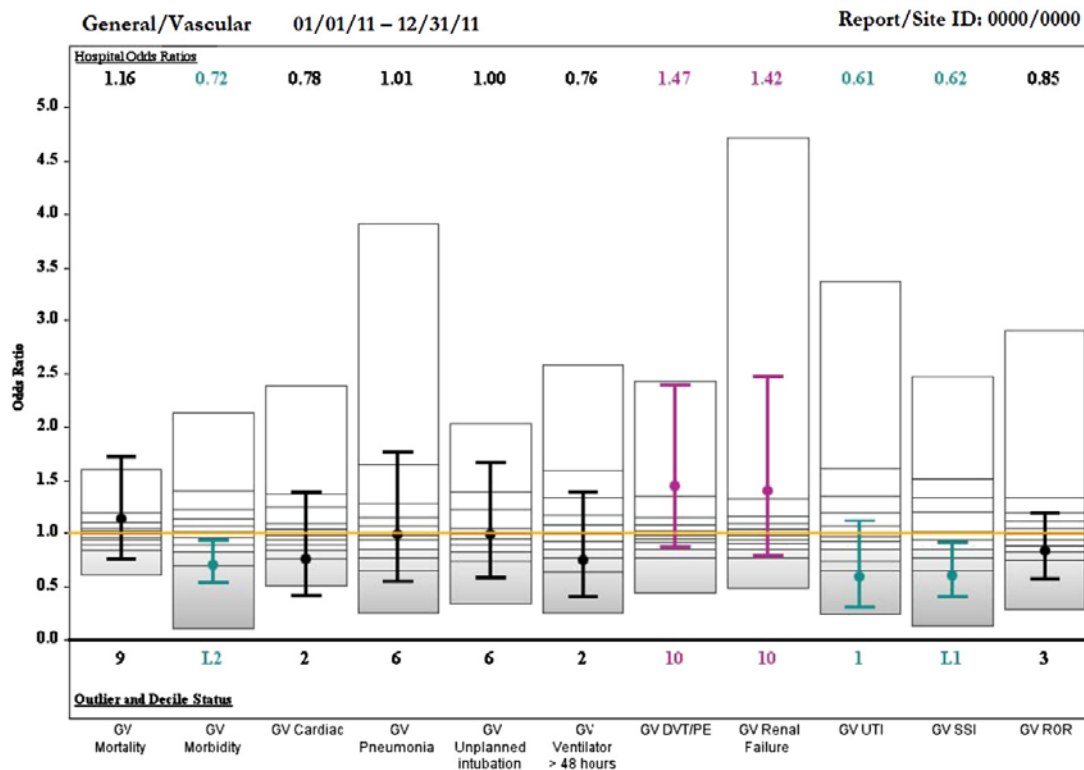


Figure 2 Example of reporting of events by odds ratio with hospital specific odds ratios³ taken from Cohen et al (2013)

ACS NSQIP is a program that has been developed with a specific focus on surgery. Maggard-Gibbons note that it works best in situations **where outcomes are measurable within a short time frame** after the relevant care has been delivered, and there are **reasonable means to adjust for case-mix differences**. The advantage offered by the ACS NSQIP is that it provides data beyond the hospitals administrative data which lacks clinical information and is inadequate for highlighting areas that need improvement when assessing quality. The ACS NSQIP provides hospitals and providers with **usable clinical data that are otherwise not available** with most sites, before participation, being unaware of their adverse event rates or how they compare to other sites. The greatest benefit has been seen with procedures with higher complication rates in the larger hospitals. . Change has been facilitated by **highlighting problems and then relying on the unit to know itself and to work to identify and rectify the underlying causes**. For it to be successful the program also requires **leadership at the local level** in order to drive change.

³ All general/vascular surgery (GV) outcomes models are reported. DVT, deep vein thrombosis; PE, pulmonary embolism; ROR, return to operating room; SSI, surgical site infection; UTI, urinary tract infection. Each box shows the distribution of odds ratios for hospitals in the model. The point and vertical line within each box give the individual hospital's odds ratio and 99% confidence intervals. Green bars represent outcomes for which the hospital is in the low outliers category and purple represents the high outliers.

Case study 2 – the Flinders Medical Centre experience of shared values and capacity building

The Flinders Medical Centre (FMC) in South Australia has undergone a number of changes in the past two decades through programs to redesign care, such as those reported by Ben-Tovim et al (2008), which have been successful in improving quality and assuring safety. This case study draws on the perspectives of Prof. Robert Padbury (Divisional Director of Surgery at the FMC) and Ms Margaret Walker (Project Manager, Surgery and Perioperative Medicine Division at the FMC) both of whom are highly involved in activities of clinical governance at the FMC. In discussions with Prof. Robert Padbury it became clear that, as Director of Surgery, he is a strong proponent of continuous quality improvement and clinical governance, and has been successful in creating teams within the FMC that share those ideas and values. When he started at the FMC his staff report that there were limited systems or processes in place to allow them to know how good a job they were doing, or how to improve.. However, over the past 14 to 15 years, major transformations have taken place. In talking about clinical governance it is clear that the FMC approach focuses on care which is consistent, but more than that, **it is consistent at the highest possible standard**. In taking on the responsibilities of his position Prof. Padbury made it clear that his primary focus was, and still is, on clinical outcomes rather than fiscal processes. In turn, this focus on improving and maintaining high standards of clinical care has reduced wastage and kept finances under control.

What you know and what you don't know

In order to establish systems and processes for continuous improvement Ms Margaret Walker describes their approach to information as two parallel processes.

- 1) To identify what data was available to them from the hospital data and how useful it was.
- 2) To identify what extra data was needed that was not currently available.

In the beginning, the main data source was the hospital inpatient data-set which funnels data into the state-wide database that has a standardised coding system (ICD-10). This database contains information on patient demographics, length of hospital stay, diagnoses and procedures etc. From this database there is also information about deaths and re-admissions. This dataset is collected by all Australian hospitals (although there are some local and state variations) and is often called an administrative dataset. The FMC team took that data to the clinical units to canvass their views on how useful the data was, and they indicated that whilst they were certainly interested in deaths, and re-admissions and length of stay, there was a whole range of information that was desired but not captured. A range of outcomes and also additional background information that would be useful were identified to supplement what was available centrally, and this differed substantially according to specialty – a key feature of the FMC model. For example, the plastic surgery department, which has a very low expected mortality rate, were particularly interested in outcomes such as incomplete excision rates, flap failure, tendon repair or bleeding. In comparison, the colorectal unit was particularly interested in whether deaths were reported to the coroner or not. So a key part of the FMC process was to have clinical units define the data that would be most useful to them in understanding the performance of their units.

Once the clinical units had decided on the data they were interested in collecting, they began collecting this information into an 'integrated spreadsheet'. Each clinical unit had their own

customised version and had complete control over the data they collected. This data was collected as part of routine daily activities by Interns and Resident Medical Officers in each unit, collected largely from the discharge summary. Over time, they developed the spreadsheet into a web-based database that is integrated with the overall hospital database, making it a robust and stable platform. This database outputs into spreadsheets which provide units with month-by-month charts of complication rates and other outcomes of interest. This data set now contains many years' worth of information.

Moving from information gathering to continuous practice improvement

In line with this data collection, Prof. Padbury and his team recognised that they did not have a scientific or consistent approach to practice improvement. Rather, it was a more *ad hoc* approach that was largely led by one or two individuals and was rarely if ever evaluated. In order to develop systems and processes to facilitate robust and sustained practice improvement Prof. Padbury embarked on a process of training and capacity building within his team. The FMC approach to this involved training of the senior doctors and nurses in healthcare improvement and then developing and reviewing standardised protocols. In speaking to these actions Prof. Padbury says they ***“got people trained in the process to go through to identify problems, identify the key contributing factors and identify solutions specific to these, implement the solutions – the PDSA⁴ cycle material– and then try and sustain it. And we still use that methodology, so that became part of how we do business. And, the second part of it was the clinical protocols and clinical standardisation and I have employed people specifically within the division to do that sort of work”***. So the first and key step has been capacity building; this means educating and upskilling the workforce to be able to identify and implement performance improvement interventions. In this area the FMC has undertaken substantial efforts in the training and capacity building of the workforce. In the article by Ben-Tovim (2013) they describe receiving support from the staff of the School of Management at the University of South Australia, where a specified team, plus senior managers, participated in a Diploma in Lean Manufacturing⁵ to equip them with the skills needed to redesign care. Similarly, Prof. Padbury describes the process of sending senior clinicians and senior nurses on health practice improvement training at regular intervals; a course he attended in 2002. The surgical division went on to establish the South Australian Centre for Healthcare Improvement in 2007 with money provided by SA Health and ran courses for clinicians from across South Australia as well as interstate and overseas for a number of years. Individuals would often attend courses with a specific clinical problem that they wanted to improve and the course, along with the mentorship that followed, gave them the skills to achieve the change. Typically two people from different clinical perspectives attended the course to work on the problem together; a surgeon with a nurse, an allied health professional with an anaesthetist. The value of this was three-fold.

⁴ The PDSA cycle is shorthand for testing a change by developing a plan to test the change (Plan), carrying out the test (Do), observing and learning from the consequences (Study), and determining what modifications should be made to the test (Act) – see the [Institute for Healthcare Improvement](#)

⁵ Lean thinking is an approach to the redesign of complex processes derived from methods developed in the manufacturing sector. Ben-Tovim, DI, Bassham, JE, Bennett, DM, Dougherty, ML, Martin, MA, O'Neill, SJ, Sincock, JL & Szwarcbord, MG 2008, 'Redesigning care at the Flinders Medical Centre: clinical process redesign using "lean thinking"', *Med J Aust*, vol.188(6 Suppl), pp. S27-31.

- 1) Individuals and teams came to understand and appreciate the potential of performance improvement activities.
- 2) Individuals and teams became equipped with the necessary skills to identify and analyse problems as well as implement solutions.
- 3) Shared understandings and values were built within the teams, enabling them to work cooperatively and proactively.

The second part of the improvement methodology was to create the clinical protocols that would become the drivers of improvement in care. In doing this, personnel were employed specifically to support this process and the clinical units were responsible for the development of the protocols. The design of the protocols was also important. After trying several formats they evolved to be short (typically 2 pages back to back), often use flow chart type formats and cover key decision points rather than time points. The interventions that were introduced at the FMC have come from a range of ways of thinking that borrow from the manufacturing industry as well as prominent thinkers in the healthcare sector. A key observation that has been made by Prof. Padbury throughout this process is that, although not anticipated, the changes have had significant impacts on the culture within the division. He says of the model *“it’s fantastic, not only in terms of clinical outcome but it’s culture changing. What you find is that because all the protocols have been developed by the clinicians within the unit, and they have ownership of them, it actually removes some of the competitiveness between the consultants and develops a better clinical relationship and more respect between the consultants. Thus, it completely changes the environment...I hadn’t appreciated the power that it would have, and it has been enormous”*.

The FMC model is based on the Intermountain Healthcare approach⁶ (James and Savitz 2011) which focuses on creating an events based approach to standardising care pathways and then using trained individuals and audits to, at repeated intervals, assess compliance with those pathways. They currently have more than 200 protocols within the Division of Surgery which were all developed in-house by the clinical workforce. One example provided was that in the early stages of this transformation, compliance with appropriate deep vein thrombosis prophylaxis was approximately 60 per cent; following improvement initiatives this was increased substantially to 90 per cent. Repeated audit has consistently demonstrated that appropriate DVT prophylaxis is routinely applied. In terms of the protocols that have been generated, Prof. Padbury emphasised that they are living and dynamic and can be modified following internal audit or based on new evidence. This process is undertaken and owned by the teams and personnel that will apply them. In this way the clinical workforce has taken ownership over the way care is provided and holds themselves to account on its consistent delivery. This approach maintains staff engagement and reduces confusion because they have explicit and relevant information about what they should be doing. In this model clinical governance is embedded in the workforce and *“it’s something you do continuously, dynamically and have ownership of it within the clinical units, it’s not something that is done to you from*

⁶ Intermountain Healthcare is an integrated delivery system based in Utah and Idaho and has been identified as a low-cost, high-quality care provider. In order to achieve this, Intermountain has a concerted focus on improving clinical quality that has consequently lowered the cost of care. They attribute success to a) “an ability to measure, understand, and feed back to clinicians and clinical leadership detailed clinical variation and outcome data” and b) “an administrative structure that uses its robust clinical information to oversee the performance of care delivery and to drive positive change.” p 1185 James and Savitz (2011)

outside” – Prof. Padbury. This approach is supported by the easy availability of the protocols, in hard copy at ward level and electronically on the Intranet. They are not buried in a manual that no one looks at. A hard copy of the relevant protocol is kept in the bedside notes of each patient so it can be referred to easily during ward rounds, etc. Junior staff have reported that this makes it much easier for them to consistently choose the best treatment options as needless variation has been reduced.

Sustaining and monitoring improvement efforts

In terms of developing these protocols, as well as other practice improvement initiatives, Ms Walker talked about several key features of the FMC approach that are important when deciding whether certain things are worth working on and in embedding continuous improvement. This process is highly structured and the project team:

- looks at problems that have been identified, and determines whether they are indeed problems based on data;
- identifies what contributing factors can be identified;
- votes and decides on what problems need to be addressed;
- votes and decides on the intervention to be trailed, what outcomes to measure and how to know if it’s working.

When things are identified that result in improvement – i.e. represent tangible and measurable **improvement, then the team looks at how to embed those changes** and then moves on to a new target. Another key feature of the sustained improvement methodology is being able to abandon actions that don’t work or that are not appropriate for the FMC, and supporting these processes with resources in the form of Project Managers, such as Ms Margaret Walker. In her capacity as a Project Manager she has oversight of the data and programs that are being implemented across units. Through her many years at the FMC strong and robust relationships with units have been built that enable them to reflect on their performance and processes. The importance of this is that changes or trends can be reviewed at the project management level that clinical units might dismiss and then support is available to assist units in developing interventions to mitigate issues or improve.

In talking to Ms Walker, it was also apparent that an important part of the sustained performance of the FMC is the respect garnered by Rob Padbury and his team, as well as a robust induction process for new staff that ensures there are clear responsibilities and expectations of staff working at FMC. For example, with respect to the protocols that have been developed, new staff are always clear that the expectation at the FMC is that those protocols will be followed, unless they are inappropriate for a particular patient. When deviations do need to be made there is a clear and explicit decision process about why and how deviations should be made. This ensures both consistency and transparency and allows the FMC to identify when adaptations to protocols can and should be made. Staff are also expected to be open and honest about decisions at internal mortality and morbidity meetings as well as audits. Ms Walker describes how this means that senior staff model appropriate behaviour to junior staff which promotes a culture of honesty and respect. In her words *“Anyone can make a mistake and everyone at some stage will do so. There is a shared understanding that human factors contribute to errors and mistakes and robust systems and processes help to mitigate these human factors.”*

In considering how to build successful quality improvement into hospital activities the experience of the FMC provides a real-world example of how clinical governance can function within the workforce. However, what is also clear is that this approach has required significant commitment and dedication from staff at all levels over a long period. Prof. Padbury is adamant that this is not a short-term project; it takes years of work to achieve sustained success, but it is worth it. Another salient point that is apparent when discussing this experience is that health practice improvement requires more than goodwill, it also requires skills and knowledge obtained from education and training. This is an important issue as training in clinical governance activities does not appear to be routinely offered to the clinical workforce within Australia – there is some empty space where education and awareness activities could be situated/placed. Furthermore, the positive cultural changes that have occurred within the FMC demonstrate the tangible benefits to the workforce of clinical governance when it is applied by and owned by them. In this sense there are real parallels between the observations of Prof. Padbury and those made by the Mayo Clinic (Swensen et al 2016) – that physicians flourish when they have the opportunity for excellence and the camaraderie of peers working towards shared goals.

Case study 3 – Organisational structures for strong administrative and clinical partnerships

The Eastern Health is one of Victoria's largest metropolitan public health services and its main sites include:

- Angliss Hospital in Upper Ferntree Gully;
- Box Hill Hospital in Box Hill;
- Healesville & District Hospital in Healesville;
- Maroondah Hospital in Ringwood East;
- Peter James Centre in Burwood East;
- Spectrum - which provides treatment for people with personality disorders;
- Turning Point - which provides treatment, research and education in the fields of alcohol, other drugs and gambling;
- Wantirna Health in Wantirna;
- Yarra Ranges Health in Lilydale;
- Yarra Valley Community Health Service.

Being such a large service provider Eastern Health faces the challenge of establishing robust systems to effectively manage a vast contingent of clinicians with a broad scope of services and facilities. In addressing this, the Eastern Health team, with respect to surgery, has taken a discipline based rather than locality based approach to structure, organisation and communication streams. A key feature of the Eastern Health Service model is the hierarchical, vertical reporting system for communication between clinical directors and health teams.

When considering clinical governance Prof. Michael Grigg points out that there are differences in the management versus clinician perspective of clinical governance, and that interpretation of the concept is highly variable. In general, it could be characterised from a clinical perspective as governance *by* clinicians whilst the managerial view might tend to be governance *of* clinicians. In the Eastern Health context the structures and processes they have developed contain a mixture of those

two clinical governance approaches with the focus of their efforts being on clear, timely and engaged communication across the system.

Hierarchical reporting structures and clarity of responsibilities and roles

When considering the Eastern Health approach this case study focuses on the surgical and anaesthetic services provided across the numerous hospitals which is Prof. Grigg's area of management. Because Eastern Health administers surgical services across multiple sites with numerous employees there were real challenges in communication both from the leadership downwards and also from the point of care upwards in the form of potential delays in communication and opportunities for miscommunication. In approaching this challenge Prof. Grigg describes the introduction of a hierarchical organisational structure that was able to solve both logistical and practical obstacles and also to achieve buy-in and commitment from staff at all levels. The structure is based on clear lines of responsibility and an understanding of how surgeons best function and perform. Prof. Grigg describes two key principles of his model.

- 1) Everyone in the structure knows who they are responsible for and who they are responsible to.
- 2) Peer groups units of between four and six surgeons in size work best and can lead to organisational and teaching benefits.

The model consists of directors of various streams (e.g. orthopaedics, urology, upper gastrointestinal etc.) and depending on the nature of the stream, there were site-based heads or multiple units (as in general surgery) that would report to that divisional director. This structure is stream specific and is determined based on the size of the stream. For example, the vascular stream is located at one site and consists of eight people and hence it is logical that they form one unit. Whereas, for general surgery the scope of the stream and number of individuals in it necessitates multiple units and site-based heads reporting to a divisional director of surgery. Other streams such as anaesthesia, being slightly different, were divided into sections based on interest such as teaching and pain management with each of those having a head. This key first step ensured that members of the clinical team understood what unit and structure they sat within, and therefore had clarity about their roles and responsibilities.

Empowering the model through adherence and consensus based decision-making

Once the model had been established Prof. Grigg describes the next stage of delivery as empowering the structures created. A key component of this was the selection process and training process for directors and heads within the structure as well as ensuring that chains of communication and command are adhered to by thorough instruction and induction of staff. By ensuring adherence to the structures in place the model is empowered by a shared understanding of processes and decision making. Those applying for directorship positions underwent rigorous selection processes and following appointment were sent on training courses in leadership. The end goal being that ***“any request or recommendation that came from a unit about the way things were done or the way equipment was purchased had to go up the line and they had to report to the head, and then up to the divisional director of surgery”***.

The system ensures timely communication and decision making through their schedule of group meetings with directors and divisional leaders meeting at least fortnightly. Whilst meeting

attendance is voluntary there is a cultural expectation of attendance. This ensures that both requests up the chain of command and decisions down from the directors and divisional directors are communicated swiftly and regularly. Furthermore, a representative from the non-clinical team also attends the divisional meetings, which provides for communication and integration between clinical and administrative services. Fortnightly meetings serve as a central forum for discussion and consensus based decision-making and Prof. Grigg makes the observation that this multi-stream approach has not resulted in conflict but rather in engagement, discussion and eventual consensus. This is evidenced by a decade of experience in which he has never observed the need for a vote and in which meeting attendance is consistently high.

Ensuring buy-in, good relationships and learning from experience

Another important feature of the system is that its surgical head, Prof. Grigg, recognises the importance of, and actively encourages, clinical ownership of decisions. What this means is that the meetings and communication strategies serve as an opportunity for problems to be presented to the surgical community and for them to have a forum for proposing solutions. Prof. Grigg recognises the value of individuals at all levels of the structure and although the structure is hierarchical it is not a one way street. As the divisional director of surgery, Prof. Grigg is not dismissive of a solution or idea that comes from the bottom up. Rather, **the hierarchical structure means that there are clear lines of accountable communication through which those at the point of care and those in the management team can engage in dialogue about issues and their resolution.** By utilising those in the chain of command anyone within the unit can pass on thoughts to the heads and divisional directors within a fortnight; a degree of access and rapidity that is often unavailable in large busy hospitals. This means that when decisions are made and communicated clinicians accept, adhere to and respect them.

In describing the evolution and implementation of the model it is clear that its design and features have been given substantial thought and have grown and changed with director attitudes in response to learnings. One example provided by Prof. Grigg is the change in attitude regarding budgetary control from one of feeling that without responsibility for budgets the directors had limited control to one of feeling that ***“if you’ve got budget control then you have to forfeit a degree of patient advocacy”*** – what this means is that in the current structure directors are aware of budgets but they are free to advocate for whatever they like without having fiscal responsibility. This budget knowledge without control means that directors can have, as a main focus, improving care rather than saving money in recognition that improving care can alleviate financial pressures but constantly attending to financial pressures can distract from quality service provision.

Sustainability and engagement

When asked about the level of engagement with the system across directorship and units Prof. Grigg explained that one key way that they keep track of how engaged everyone is, is through meeting attendance. Although directors are not paid to attend meetings attendance has consistently been almost 100 per cent. This is a testament to the fact that directors find them constructive and useful. When surveyed, surgeons report that meetings are the number one reason they choose to work in public hospitals. The peer interaction and camaraderie provided by these meetings and unit organisation has proven to be a strong motivator for clinicians. In addition to meetings, Eastern

Health also holds an annual review to see what directors think has and hasn't worked and this has contributed to learning and growth within the system.

In considering how to build successful communication and governance pathways in a large health service provider setting the experience of Eastern Health provides an illustrative example of how **structure can support robust communication and quality**. What is also clear from this example is the dual efforts of both creating a structure which meets the communication and governance needs of such a large organisation as well as the commitment in sustaining and empowering that model through adherence and growth. The system is organised **around clarity of role and purpose and is empowered by the benefits of staff feeling that they are part of a team that is supported and listened to by clinical and administrative managers**. An interesting aspect of this example is that Eastern Health has recognised that leadership is a skill set and has devoted time to recruitment and capacity building in this area and it speaks to an acknowledgement of the importance of building governance and leadership capacity within the clinical workforce.

Questions arising from the report and reflections on them

As a result of engagement with working group members and RACS Fellows the following question arose , ‘What material/ thought process should a Surgical Director have to know that clinical governance is working at their hospital?’

This question is complex in that it speaks to three issues.

1. What knowledge and theoretical understanding of clinical governance should a surgical director have?
2. What methods and materials should a surgical director have in place to enable clinical governance?
3. How does a surgical director know whether clinical governance is working?

It is crucial to note that there is no universal consensus on these issues. Hence, what follows is a series of salient points drawn from the literature and from the experience of individuals who shared their experience with the report authors. The authors have attempted to draw together broad pieces of information to pose some thoughts in response to these questions. The authors encourage readers to use their judgement in determining which points might be useful in their specific context and in line with their position and responsibilities.

1. What knowledge and theoretical understanding of clinical governance should a surgical director have?

To understand this, it is important to recognise that **Surgical Directors are leaders**. Their position affords them respect, authority and influence and therefore, their attitudes and understandings regarding clinical governance set the tone and expectations for their team. Clinician scepticism about clinical governance is a pervasive issue and in order to overcome the negative implications of this scepticism, leaders must themselves have both a personal and professional commitment to clinical governance.

For clinical governance to flourish, the specific framework adopted appears less important than a genuine commitment to reflecting on ‘Am I doing it right? How can I do better?’ In such reflections it is important to recognise that the ultimate goal is a combination of both consistent care and performance at the highest possible standard. Ultimately, good clinical governance enables delivery of care that is consistently excellent. It is a global measure of excellence that extends to more than one procedure, surgeon or team. Consistent excellency in its best form should pervade the organisation and all aspects of care, including that of its staff.

With this understanding of clinical governance it is also apparent that this is a continuous and ongoing process that does not have a clear threshold of attainment. Rather, this conceptualisation of clinical governance moves beyond the achievement of minimal or mandated standards and towards a process of continual evolution and drive for excellence of the surgical unit.

Furthermore, Surgical Directors have an important role in establishing this as a cultural norm within their division and leading the conversation about what shared goals and norms their unit should have. It is suggested that as a framework or guide, Surgical Directors and their teams should adopt

those principles which most resonate with their culture and their circumstances as this will increase the relevance and therefore utility..

2. What methods and materials should a surgical director have for substantiating the effects of clinical governance?

From both the literature and the case studies it is clear that capacity building is a key part of establishing robust clinical governance. Those in leadership positions should be supported by access to training courses and mentors. The skills necessary for establishing effective clinical governance need to be distributed within the team such that everyone in the team is working with shared understandings and knowledge. Specifically, this report identified that in places where there is a robust clinical governance process the staff at those institutions had been through a capacity building phase.

Another key method or material Surgical Directors could adopt is a system for measuring and monitoring processes and outcomes in their unit. One point that emerged strongly from the literature and experience is that the information collected from a hospital administration standpoint or for overall health service oversight is not always sufficient for individual units to use in driving practice improvement. One activity Surgical Directors might consider is reviewing the administrative data sets and then identifying the additional information that units and clinicians think would be relevant to their practice. For example, although rates of re-admission are globally relevant to health outcomes, specific units might have more granular information needs such as looking at incomplete excision rates. Once identified, units can come up with processes to facilitate collection of this information.

This is key because this data forms the bedrock of practice improvement initiatives. Good data facilitates the implementation of specific practice improvement models such as the PDSA cycle, which is shorthand for testing a change by developing a plan to test the change (Plan), carrying out the test (Do), observing and learning from the consequences (Study), and determining what modifications should be made to the test (Act). It is these cyclical processes that drive continuous improvement.

3. How does a surgical director know whether clinical governance is working?

This is perhaps the most challenging question as it speaks to the generalised and unspecific nature of clinical governance that has made its study fraught with uncertainties. In speculating on this question, it is relevant to consider reports on failures in clinical governance, of which *The Review of Hospital Safety and Quality Assurance in Victoria* (Department of Health & Human Services, 2016) is the most recent.

Reviews of notable failures of clinical governance to safeguard patient safety have highlighted key issues associated with adverse events. In most cases, the adverse event(s) in question were not specifically predicted. However, there were features of the organisational culture, staff knowledge and competency as well as systems issues that were already known to those in that system. In retrospect, **some eventual failure or harm to patients was predictable**. It is, for example, a common finding that the voiced concerns of staff were not followed up or acted upon (Faunce, et al. 2004).

The Department of Health and Human Services review (2016) in particular notes that a commitment to clinical governance is often lacking at the most senior levels of responsibility, something that is at odds with our societal expectations about quality healthcare institutions. The review states *“We also heard in our consultations that many boards did not see their responsibilities for clinical governance as being on a par with their financial responsibility. No board member today would think that oversight of budget performance is something that can be delegated to a finance committee or left up to board members with financial qualifications. However, some board members apparently believe that they do not have to apply the same diligence to clinical governance, as if clinical quality was not the core business of the hospital.”* (The Review of Hospital Safety and Quality Assurance in Victoria, p27)

In particular, the report emphasises three keys to creating conditions for excellence:

- clinical leadership of quality improvement;
- clinical data to drive and guide quality improvement;
- a more ambitious and accountable health system.

This finding is in line with overall messages from the literature and is echoed by those championing clinical governance in their own units. Illustrating that although the literature on indicators of clinical governance is fragmented it does not necessarily follow that it is hard to identify when clinical governance is not functioning well.

When staff are concerned about patient safety this should be seen as a strong indicator of problems requiring attention. Furthermore, if continuous improvement practice is not an explicit organisation goal and/or if this value is not supported by individuals in leadership and active monitoring of current outcomes is lacking, then clinical governance cannot be said to be functioning well. By being aware of these organisation characteristics and preferences, Surgical Directors can be alerted to potential problems.

It is with this in mind the example checklist items were compiled. These checklist questions are intended to facilitate reflection within surgical teams and organisations on areas in which a lack of cognisance about clinical governance can result in safety and quality issues. At this stage the items have not been through an iterative process of refinement; however, they should be considered an aid to discussion around the norms and practices of the surgical team and potentially identify areas requiring focus.

Based on the literature, and case studies, surgical units with good clinical governance exhibit the following:

- managers and staff have positive relationships with shared values and goals at the clinical unit level;
- lines of responsibility and accountability are clear;
- staff have a sense of engagement and commitment that is supported by measures to mitigate fatigue and burn out;
- active systems are in place to measure outcomes of care that are patient centred with participation in internal and external audits;

- processes are in place to measure and act on performance indicators, and there is a culture which encourages excellence and does not tolerate complacency;
- open disclosure policies which foster trust between patients and staff as well as encourage learning and development;
- continual pursuit of ways to benchmark performance and improve.

Although lacking comprehensive externally validated tools to characterise and measure good clinical governance, Surgical Directors can be alerted to potential problems through listening to these and other signals. In addition, they can be re-assured by positive attitudes and behaviours in their units. A KPMG (2013) report on this issue is aptly entitled *The more I know the less I sleep: global perspectives on clinical governance*. This captures the essence of 'good' clinical governance in that it is an ongoing, cyclical process defined more by commitment to continuous improvement processes than attainment of a specific standard or measure.

Resources regarding clinical governance and/or practice improvement gathered

Note: This section of the report is not intended to be comprehensive; it has been compiled as a list of resources drawn upon in the writing of this report. However, specific searches for resources were not conducted. Many colleges, societies, universities and other professional organisations have a wealth of resources available on a whole host of issues. Readers are encouraged to check with organisations relevant to their specialty and setting for further information if required.

Capacity building

Training courses aim to build capacity within the workforce and, as evidenced by the case studies included in this report, can be an invaluable tool in delivering clinical governance change in institutions.

The NSW Clinical excellence commission offers a two day clinical practice improvement course which guides clinicians to understand a framework for continuous improvement that can be applied within their relevant institutions. See: http://www.cec.health.nsw.gov.au/quality-improvement/improvement-academy/qi-academy-curriculum/clinical_practice_improvement

Similarly, The Australian Healthcare and Hospitals Association (AHHA), in collaboration with Peloton Health Care Improvement Consulting, is delivering a two day clinical practice improvement course and in addition a one-day Root Cause Analysis Training Workshop. See <http://ahha.asn.au/clinical-practice-improvement-short-course> and <http://justhealthconsultants.com/root-cause-analysis-workshop>

The AHHA also offer courses in lean training (which is a philosophy that requires the continuous elimination of waste or non-value-added elements from processes so that customers or patients are given ever greater value), health economics, and palliative care.

See <http://justhealthconsultants.com/lean-training>, <http://justhealthconsultants.com/health-economics-online-training>, <http://justhealthconsultants.com/pallcareonline>

The Australian Council on Healthcare Standards (ACHS) Improvement Academy offers a range of training opportunities in the areas of quality improvement training and patient safety. In particular, it offers The Evaluation and Quality Improvement Program (EQiP) which is the core accreditation program, guiding organisations through a four year cycle of self-Assessment, organisation-wide survey and periodic review to meet ACHS standards. See [http://www.achs.org.au/achs-international/products-and-services/evaluation-and-quality-improvement-program-\(equip\)/](http://www.achs.org.au/achs-international/products-and-services/evaluation-and-quality-improvement-program-(equip)/)

Mortality and Morbidity (M&M) meetings

Although currently in the development stage, RACS has been in the process of developing an evidence-based guidance document to assist teams in undertaking M&M meetings. M&M meetings involve the peer review of errors which occurred during the care of patients and resulted in a complication or death. They facilitate learning and improvement through discussion and analysis which has important flow on effects in terms of avoidance of future errors. They are also an opportunity for units to build connections with peers and develop strong working relationships. The

guidance document aims to bring together the diverse literature on this topic to assist in the development of good M&M formats. When publicly available the reference to this document will be included here.

Effective care

The Choosing Wisely Australia campaign is an initiative which aims to help healthcare providers and consumers start important conversations about improving the quality of healthcare by eliminating unnecessary and sometimes harmful tests, treatments, and procedures. Their website provides resources for both clinicians and patients to help initiate dialogue about the care that is best for each patient. They provide a range of resources on topics such as antibiotic resources, sexual health recommendations, radiation oncology and more. See: <http://www.choosingwisely.org.au/home>

The Australian Research Council funded a research project entitled “*On the cutting edge: promoting best practice in surgical innovation*” (LP110200217). 2011-14 Rogers W, Johnson J, Sheridan S, Ballantyne A, Lotz M, Meyerson D, Tomossy F, Evers T, Maddern G, Thomson C. This research recognises the difficulty in balancing innovation and risk within surgery and through the project the authors have developed the Macquarie surgical innovation identification tool (MSIIT) to support responsible innovation. Relevant publications include: Hutchison, K, Rogers, W, Evers, A & Lotz, M 2015, 'Getting Clearer About Surgical Innovation: A New Definition and a New Tool to Support Responsible Practice', *Ann Surg*, vol.262(6), pp. 949-54. And Rogers, WA, Lotz, M, Hutchison, K, Pourmoslemi, A & Evers, A 2014, 'Identifying surgical innovation: a qualitative study of surgeons' views', *Ann Surg*, vol.259(2), pp. 273-8.

HealthPACT is a sub-committee of the Australian Health Ministers' Advisory Council (AHMAC), reporting directly to the Hospitals Principal Committee (HPC). It provides advance notice of significant new and emerging technologies to health departments in Australia and New Zealand. The HealthPACT website contains links to evaluations of numerous new and emerging technologies that may be of use to the clinical workforce at large. See <https://www.health.qld.gov.au/healthpact/>

The Australian Centre for Evidence Based Aged Care provides training packages and workshops regarding the quality delivery of care in the older population. They attempt to translate evidence into the real world in a way that positively impacts on the care of older people in Australia. See <http://www.latrobe.edu.au/aipca/australian-centre-for-evidence-based-aged-care>

Web-resources/Centres of improvement

The Institute for Healthcare Improvement is an independent not-for-profit organisation based in Cambridge, Massachusetts. Their website contains many useful links and educational materials, particularly with respect to the PDSA cycle mode. See: <http://www.ihl.org/about/Pages/default.aspx>

The Centre for Healthcare Resilience and Implementation Science at Macquarie University is a leading health services and systems research centre. They have published many informative papers around clinical governance and practice improvement in Australia.

See: <http://www.mq.edu.au/research/research-centres-groups-and-facilities/healthy-people/centres/australian-institute-of-health-innovation/centre-for-healthcare-resilience-and-implementation-science>

The NSW Agency for Clinical Innovation has an innovation exchange website on which there are a range of programs and interventions that have been implemented are reported on. Examples are real-world, local interventions. Their website also has a range of other useful information.

See: <https://www.aci.health.nsw.gov.au/ie>

Intermountain Healthcare is a provider of health services in the United States that has received awards for the transformation of its services and is recognised as a provider of high quality, low-cost care. They run training courses and have a range of useful information on their website. Their website provides a useful resource for those interested in understanding more about the Intermountain approach: <https://intermountainhealthcare.org/about/transforming-healthcare/>

The Australian Healthcare and Hospitals Association is the independent peak membership body and advocate for the Australian healthcare system and it offers a range of online resources regarding health policy as well as training resources: <http://justhealthconsultants.com/about-ahha>

Clinical governance in Australia and New Zealand

Clinical governance in Australia

Within Australia there have been several high-profile inquiries into patient safety including the inquiry into obstetric and gynaecological services at King Edward Memorial Hospital (1990-2000), the final report of the Special Commission of Inquiry into Campbelltown and Camden Hospitals Sydney (2004) and the Queensland Public Hospitals Commission of inquiry (2005). Further to these reports the 1995 Quality in Australian Health care study identified that the proportion of inpatient episodes leading to harmful adverse events was 16.6 per cent, of which, three per cent resulted in permanent disability or death. This report estimates that about 50 per cent of adverse events occurring in hospitals could be considered preventable.

In response to these issues, the Australian Safety and Quality Council was established (1999) to develop Australia's national approach to patient safety and quality. Subsequently the Australian Commission on Safety and Quality in Health Care was established in 2006 by state and territory governments to lead and coordinate national improvements in safety and quality in health care. Following the passing of the National Health Reform Act in 2011 the commission became a corporate Commonwealth entity that is jointly funded by state and territory governments. The Commission ***“develops and supports national safety and clinical standards; formulates and implements national accreditation schemes; and develops national health-related data sets. The Commission is also working to reduce unwarranted variations in practice and outcomes for individuals and populations, and coordinating national action to address healthcare-associated infections and antimicrobial resistance.”*** (Australian Commission on Safety and Quality in Health Care 2015)

The Australian Commission on Safety and Quality in Health Care developed the National Safety and Quality Health Service (NSQHS) Standards to improve the quality of health service provision in Australia. The NSQHS Standards provide a nationally consistent statement of the level of care consumers can expect from health service organisations. Standard 1 is Governance for Safety and Quality in Health Service Organisations. This is described in Appendix A. The Commission is currently undertaking a review of the NSQHS Standards. In addition, the Commission is responsible for the accreditation of health services to these standards; all Australian hospitals and day procedure services must be accredited and accrediting agencies approved by the Commission assess services with respect to the standards. However, states and territories also have individual initiatives designed to address issues of clinical governance.

Clinical governance in New Zealand

In New Zealand clinical governance emerged as a term in 1999. In the early 2000s studies into the occurrence, impact and preventability of adverse events in public hospitals within New Zealand found that the proportion of hospital admissions associated with an adverse event was 12.9 per cent and approximately half of all events were preventable (Davis et al 2002; Davis et al 2003). Within New Zealand the key clinical governance initiatives of recent times have come from a government report about clinical leadership. The report *In Good Hands: Transforming Clinical Governance in New Zealand* (Ministerial Task Group on Clinical Leadership 2009) sought to provide insight and guidance to efforts in New Zealand to develop corporate governance structures and systems for outcome

reporting. The report highlighted a need for national reporting on outcomes and effectiveness and for well-functioning distributed leadership of health services with clinicians at the centre.

The New Zealand (NZ) government has also invested in an assessment of clinical governance changes within NZ through qualitative research that seeks to track progress on its implementation. As a result, researchers involved developed a Clinical Governance Development Index (CGDI) which is designed to measure the extent to which a healthcare organisation is working to develop clinical governance. It has been the subject of a number of peer reviewed publications (Gauld and Horsburgh 2014a; Gauld and Horsburgh 2014b; Gauld and Horsburgh 2015a; Gauld et al 2011).

Mapping high-level state and territory clinical governance frameworks

Nine relevant documents were identified via web searches and high level components of the frameworks were extracted and tabulated (Appendix B). Documents differed substantially in their purpose, format and approach to the issue of clinical governance and not all documents make reference to the National standards. Only South Australian documents explicitly dealt with each item of the national standards, and this document was intended to guide services in terms of accreditation. Some documents referenced the Scally and Donaldson (1998) definition of clinical governance whilst others used the NHSQS definition, or had their own definition. One referenced seven standards whilst another states that there are four domains of quality and safety. It is clear that although national standards exist, the concept of clinical governance has not been harmonised. However, this may well be appropriate as the national standards are already enforced through accreditation. Individual state-level policies may be aimed at driving performance above national accreditation levels.

Ongoing initiatives

Prof. Jeffrey Braithwaite is a professor at the Centre for Healthcare Resilience and Implementation Science at Macquarie University and is a leading health services and systems researcher. He and his team are highly regarded in the field of systems improvement and are currently in receipt of an NHMRC research grant of \$AUD 11,293,644.22 for *creating safe, effective systems of care: the translational challenge* [2014-2018](Research Data Australia 2016). In addition, the Centre for Healthcare Resilience and Implementation Science have many ongoing projects aimed at helping to improve safety and quality in Australian hospitals. The objectives of the centre are listed below (Macquarie University 2016).

- ***“To undertake internationally recognised inter-disciplinary research and development projects on clinician led approaches to organising and managing clinical work across the full spectrum of care.***
- ***To provide a focal point for initiating and managing collaborative research and development projects on clinician led approaches to the organisation and management of clinical work involving partners drawn from other groups within the Faculty of Medicine, other departments within the University, Federal, State and Area health authorities and potential collaborators in other universities both within and external to Australia.***
- ***To provide a supportive environment for developing research skills of young health researchers from both clinical and social science disciplines.***
- ***To develop an international research reputation not simply in health but also in the base disciplines from which Centre members are drawn viz., policy studies, discourse analysis,***

sociology, organisational behaviour, social theory, anthropology, health informatics and clinical studies.

- *To be an internationally recognised reservoir of knowledge and expertise on clinical work management issues with a capacity to respond to requests for advice and consultation.*
- *To facilitate the development of education and training activities both within and outside the University in support of clinical governance.”*

The centre has areas of inquiry related to systems and culture, clinician behaviour, systematisation of work, comparative health care systems, consumer participation, and health policy development and implementation. For detailed information see the centres' [website](#).⁷

⁷ <http://www.mq.edu.au/research/research-centres-groups-and-facilities/healthy-people/centres/australian-institute-of-health-innovation/centre-for-healthcare-resilience-and-implementation-science>

Developing clinical governance checklist items

In the book *The Checklist Manifesto* Atul Gawande (2010) highlights how checklists can prove to be an effective tool in complex situations and help physicians navigate and plan for difficulties. Studies of the Safe Surgery Saves Lives program which implemented the World Health Organization (WHO) safe-surgery checklist in eight hospitals around the world found that implementation was associated with reductions in rates of death and complications among patients at least 16 years of age who were undergoing non-cardiac surgery in a diverse group of hospitals (Haynes et al 2009). This finding is not unique; many studies have documented the success of surgical safety checklists including the WHO checklist on both patient outcomes such as mortality and more subjective outcomes such as teamwork or communication (Braham et al 2014; Cadman 2016; Christian et al 2014; Jammer et al 2015; Lyons and Popejoy 2014; Mayer et al 2016; Oak et al 2015; Pugel et al 2015; Reames et al 2015a; Reames et al 2015b; Robert et al 2015). Successful checklists can:

- formalise knowledge of the situation and patient reducing the risk of errors such as wrong-side surgery;
- flag potential risks that may have gone unnoticed due to time pressures or missed steps;
- allow for planned management of risks;
- reduce the likelihood of misunderstandings;
- improve communication and teamwork;
- reduce operating time and theatre costs.

There may be the perception that standardisation could stifle innovation or necessary variation, this perception is unfounded (KPMG 2013). In fact, with higher levels of scrutiny and the opportunity for 'double-checks', processes become more resilient and successful. This is because as variation and complexity are reduced, surgeons are better able to focus on the necessary and innovative deviations (KPMG 2013). This results in better outcomes for patients, lower costs associated with care and reductions in avoidable errors.

In considering clinical governance, the difficulty in both applying it and measuring it resides in its nature. However, there are fundamental principles that apply irrespective of its definition. By translating these principles into directed and answerable questions it is reasoned that a carefully considered checklist could prove a useful tool for surgical teams by facilitating engagement with clinical governance on a day-to-day level. The aim is not to standardise processes for clinical governance but rather to provide a common scaffold for surgeons and their teams to consider the right processes for clinical governance in their context. This is in recognition that the instruments of clinical governance are best driven by those with the most insight into their own environment. The purpose of these checklist items is to stimulate discussion and action amongst surgical teams. The items are not presented as a finalised checklist, but rather draft items. This is in recognition of the fact that a well-functioning checklist should be user driven and piloted before it is used and validated. These activities were beyond the scope of this report and therefore these are presented as draft items that may be used by others in considering an appropriate checklist.

A table summarising other checklists regarding clinical governance as identified in the grey literature can be found in appendix D.

Draft Clinical governance checklist items for the surgical team

Introduction

These checklist items have been developed with the understanding that patient safety and quality care requires leadership and vigilance across all levels of clinical services from the workforce to the Chief Executive Officer. There is no one tool or method that can be applied to improve clinical governance, but rather, clinical governance functions best when the organisation and team work together to reflect on their performance. These checklist items recognise the knowledge and experience that the surgical team has and encourages the team to engage in discussions about quality and safety, and to be leaders of continuous improvement at the local level.

“Clinical governance is a system through which organisations are accountable to the community for continually improving the quality of their service and safe guarding high standards of care, ensuring they are patient-centred, safe and effective.” – The Australian Commission on Safety and Quality in Health Care (2012).

The Standards

At the national level there are standards of clinical governance that are provided for within the hospital system through the processes of accreditation. These standards provide guidance for the organisation on what actions to engage in in order to improve the quality, safety and reliability of health care. The standard requires the following.

- An integrated system of governance that actively manages patient safety and quality risks.
- A governance system that sets out safety and quality policies, procedures and/or protocols and assigns roles, responsibilities and accountabilities for patient safety and quality.
- A clinical workforce that is guided by current best practice and uses clinical guidelines that are supported by the best available evidence.
- Managers and the clinical workforce to have the right qualifications, skills and approach to provide safe, high-quality health care.
- patient safety and quality incidents to be recognised, reported and analysed, and this information is used to improve safety systems.
- Patient rights to be respected and their engagement in their care supported.

How to use this list of checklist items

These checklist items are intended to facilitate the development of a facility and team relevant checklist. Items in this list provide prompts for the consideration of, and action on, clinical governance at the level of the surgeon and the surgical team. The intent is that both heads of units and individual staff can easily obtain and review the checklist items and come up with a checklist that could be integrated into staff or team meetings to gauge how the team feels they are performing against the items, and how measures could be taken to remediate any issues. The checklist can be used in many different ways; however, it is primarily a tool for reflection and engagement. The items contained have been adapted from existing checklists and take on salient points from the literature and pertinent case studies.

Clinical governance and the surgical team – checklist items	
Leadership and teamwork	Team-assessment responses
Are we aware of who leads our team and do we understand each other's roles and responsibilities?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we have shared goals, as a team, in terms of patient safety and quality of care?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we know the consultant responsible for a patient's care at all times?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we know what national, state and hospital policies and procedures around clinical governance and audit apply to us and do we have access to them?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Can any member of the team raise concerns about the safety and quality of services we provide?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we have procedures in place to make changes based on those concerns?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we support each other and ensure that we protect our own health and wellbeing?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we discuss and resolve issues in our team?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Patient centred care	Team -assessment responses
Do we know what the main priorities for our patients are in terms of reduced symptoms or increased functionality?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Have we considered how the care we are providing aligns with these priorities (see previous question) and has this been explained to the patient?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we provide patients with information on the care they receive and its risks and benefits and do we ensure they understand it?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we seek, record and respond to feedback from our patients?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Evidence-based care	Team -assessment responses
Are we compliant with best practice in our respective specialties?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we record or measure this?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Clinical governance and the surgical team – checklist items

	To some degree <input type="checkbox"/> Other response:
Do we have access to information about the latest guidelines and evidence-based information?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we have tools or definitions that help us recognise novel therapies and practice responsibly? ⁸	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
If we wish to use new techniques, devices, medications or other technologies do we gain approval from department heads or relevant committees and are we aware of hospital, state or national policy on the use of novel technologies?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we document care and undertake patient handovers and does this usually go smoothly?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Safe care	Team -assessment responses
Are we all practicing within the scope of our credentialing and training? If we needed training in a particular area could we access that?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we document adverse events and near misses and do we have enough information to understand how they occur?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we as individuals disclose, and as a team openly discuss adverse events and near misses?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we take actions to learn from these discussions, and, do we action our learnings?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we have a standard method to identify potential risks associated with care and do we plan to mitigate any risks?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
De we as a team have shared goals and priorities in terms of patient safety outcomes?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:
Do we benchmark our outcomes and measure improvement on them?	Yes <input type="checkbox"/> No <input type="checkbox"/> To some degree <input type="checkbox"/> Other response:

* Recording a 'no' against an item does not equate with poor clinical governance or poor performance, rather you should evaluate whether the item is applicable to your individual or team situation and act accordingly.

⁸ For examples of such tools see:

Hutchison, K, Rogers, W, Eyers, A & Lotz, M 2015, 'Getting Clearer About Surgical Innovation: A New Definition and a New Tool to Support Responsible Practice', *Ann Surg*, vol. 262(6), pp. 949-54.

Rogers, WA, Lotz, M, Hutchison, K, Pourmoslemi, A & Eyers, A 2014, 'Identifying surgical innovation: a qualitative study of surgeons' views', *Ann Surg*, vol.259(2), pp. 273-8.

Resources:

Braithwaite et al. 'A four-year, systems-wide intervention promoting interprofessional collaboration.' BMC Health Services Research 2012 12:99.

Hutchison, K, Rogers, W, Evers, A & Lotz, M 2015, 'Getting Clearer About Surgical Innovation: A New Definition and a New Tool to Support Responsible Practice', Ann Surg, vol. 262(6), pp. 949-54.

Rogers, WA, Lotz, M, Hutchison, K, Pourmoslemi, A & Evers, A 2014, 'Identifying surgical innovation: a qualitative study of surgeons' views', Ann Surg, vol.259(2), pp. 273-8.

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Appendix A: National Safety and Quality Health Service (NSQHS) Standards

The Australian Commission on Safety and Quality in Health Care developed the National Safety and Quality Health Service (NSQHS) Standards to improve the quality of health service provision in Australia. The NSQHS Standards provide a nationally consistent statement of the level of care consumers can expect from health service organisations. Standard 1 is Governance for Safety and Quality in Health Service Organisations. This standard requires the following.

- An integrated system of governance that actively manages patient safety and quality risks.
- The governance system sets out safety and quality policy, procedures and/or protocols and assigns roles, responsibilities and accountabilities for patient safety and quality.
- The clinical workforce is guided by current best practice uses clinical guidelines that are supported by the best available evidence.
- Managers and the clinical workforce have the right qualifications, skills and approach to provide safe, high-quality health care.
- Patient safety and quality incidents are recognised, reported and analysed, and this information is used to improve safety systems.
- Patient rights are respected and their engagement in their care is supported.

The standard is broken down into criteria and actions across these points, as shown in the table below.

Table 1 Standard 1 – Governance for Safety and Quality in Health Service Organisations.

Standard 1	
Governance and quality Improvement systems	
There are integrated systems of governance to actively manage patient safety and quality risks	
Criterion	Actions
1.1 Implementing a governance system that sets out the policies, procedures and/or protocols for: <ul style="list-style-type: none"> • establishing and maintaining a clinical governance framework • identifying safety and quality risks • collecting and reviewing performance data • implementing prevention strategies based on data analysis • analysing reported incidents • implementing performance management procedures • ensuring compliance with legislative requirements and relevant industry standards • communicating with and informing the clinical and non-clinical workforce • undertaking regular clinical audits 	1.1.1 An organisation-wide management system is in place for the development, implementation and regular review of policies, procedures and/or protocols 1.1.2 The impact on patient safety and quality of care is considered in business decision making
1.2 The board, chief executive officer and/or other higher level of governance within a health service organisation taking responsibility for patient safety and quality of care	1.2.1 Regular reports on safety and quality indicators and other safety and quality performance data are monitored by the executive level of governance

	1.2.2 Action is taken to improve the safety and quality of patient care
1.3 Assigning workforce roles, responsibilities and accountabilities to individuals for: <ul style="list-style-type: none"> patient safety and quality in their delivery of health care the management of safety and quality specified in each of these Standards 	1.3.1 Workforce are aware of their delegated safety and quality roles and responsibilities 1.3.2 Individuals with delegated responsibilities are supported to understand and perform their roles and responsibilities, in particular to meet the requirements of these Standards 1.3.3 Agency or locum workforce are aware of their designated roles and responsibilities
1.4 Implementing training in the assigned safety and quality roles and responsibilities	1.4.1 Orientation and ongoing training programs provide the workforce with the skill and information needed to fulfil their safety and quality roles and responsibilities 1.4.2 Annual mandatory training programs to meet the requirements of these Standards 1.4.3 Locum and agency workforce have the necessary information, training and orientation to the workplace to fulfil their safety and quality roles and responsibilities 1.4.4 Competency-based training is provided to the clinical workforce to improve safety and quality
1.5 Establishing an organisation-wide risk management system that incorporates identification, assessment, rating, controls and monitoring for patient safety and quality	1.5.1 An organisation-wide risk register is used and regularly monitored 1.5.2 Actions are taken to minimise risks to patient safety and quality of care
1.6 Establishing an organisation wide quality management system that monitors and reports on the safety and quality of patient care and informs changes in practice	1.6.1 An organisation-wide quality management system is used and regularly monitored 1.6.2 Actions are taken to maximise patient quality of care
Clinical practice Care provided by the clinical workforce is guided by current best practice	
1.7 Developing and/or applying clinical guidelines or pathways that are supported by the best available evidence	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
1.8 Adopting processes to support the early identification, early intervention and appropriate management of patients at increased risk of harm	1.8.1 Mechanisms are in place to identify patients at increased risk of harm 1.8.2 Early action is taken to reduce the risks for at-risk patients 1.8.3 Systems exist to escalate the level of care when there is an unexpected deterioration in health status
1.9 Using an integrated patient clinical record that identifies all aspects of the patient's care	1.9.1 Accurate, integrated and readily accessible patient clinical records are available to the clinical workforce at the point of care 1.9.2 The design of the patient clinical record allows for systematic audit of the contents against the requirements of these Standards
Performance and skills management Managers and the clinical workforce have the right qualifications, skills and approach to provide safe, high	

quality health care.	
1.10 Implementing a system that determines and regularly reviews the roles, responsibilities, accountabilities and scope of practice for the clinical workforce	<p>1.10.1 A system is in place to define and regularly review the scope of practice for the clinical workforce</p> <p>1.10.2 Mechanisms are in place to monitor that the clinical workforce are working within their agreed scope of practice</p> <p>1.10.3 Organisational clinical service capability, planning and scope of practice is directly linked to the clinical service roles of the organisation</p> <p>1.10.4 The system for defining the scope of practice is used whenever a new clinical service, procedure or other technology is introduced</p> <p>1.10.5 Supervision of the clinical workforce is provided whenever it is necessary for individuals to fulfil their designated role</p>
1.11 Implementing a performance development system for the clinical workforce that supports performance improvement within their scope of practice	<p>1.11.1 A valid and reliable performance review process is in place for the clinical workforce</p> <p>1.11.2 The clinical workforce participates in regular performance reviews that support individual development and improvement</p>
1.12 Ensuring that systems are in place for ongoing safety and quality education and training	1.12.1 The clinical and relevant non-clinical workforce have access to ongoing safety and quality education and training for identified professional and personal development
1.13 Seeking regular feedback from the workforce to assess their level of engagement with, and understanding of, the safety and quality system of the organisation	<p>1.13.1 Analyse feedback from the workforce on their understanding and use of safety and quality systems</p> <p>1.13.2 Action is taken to increase workforce understanding and use of safety and quality systems</p>
<p>Incident and complaints management Patient safety and quality incidents are recognised, reported and analysed, and this information is used to improve safety systems</p>	
1.14 Implementing an incident management and investigation system that includes reporting, investigating and analysing incidents (including near misses), which all result in corrective actions	<p>1.14.1 Processes are in place to support the workforce recognition and reporting of incidents and near misses</p> <p>1.14.2 Systems are in place to analyse and report on incidents</p> <p>1.14.3 Feedback on the analysis of reported incidents is provided to the workforce</p> <p>1.14.4 Action is taken to reduce risks to patients identified through the incident management system</p> <p>1.14.5 Incidents and analysis of incidents are reviewed at the highest level of governance in the organisation</p>
1.15 Implementing a complaints management system that includes partnership with patients and carers	<p>1.15.1 Processes are in place to support the workforce to recognise and report complaints</p> <p>1.15.2 Systems are in place to analyse and implement improvements in response to complaints</p> <p>1.15.3 Feedback is provided to the workforce on the analysis of reported complaints</p> <p>1.15.4 Patient feedback and complaints are reviewed at the highest level of governance in the organisation</p>

1.16 Implementing an open disclosure process based on the national open disclosure standard	<p>1.16.1 An open disclosure program is in place and is consistent with the national open disclosure standard</p> <p>1.16.2 The clinical workforce are trained in open disclosure processes</p>
<p>Patient rights and engagement Patient rights are respected and their engagement in their care is supported</p>	
1.17 Implementing through organisational policies and practices a patient charter of rights that is consistent with the current national charter of healthcare rights	<p>1.17.1 The organisation has a charter of patient rights that is consistent with the current national charter of healthcare rights</p> <p>1.17.2 Information on patient rights is provided and explained to patients and carers</p> <p>1.17.3 Systems are in place to support patients who are at risk of not understanding their healthcare rights</p>
1.18 Implementing processes to enable partnership with patients in decisions about their care, including informed consent to treatment	<p>1.18.1 Patients and carers are partners in the planning for their treatment</p> <p>1.18.2 Mechanisms are in place to monitor and improve documentation of informed consent</p> <p>1.18.3 Mechanisms are in place to align the information provided to patients with their capacity to understand</p> <p>1.18.4 Patients and carers are supported to document clear advance care directives and/or treatment-limiting orders</p>
1.19 Implementing procedures that protect the confidentiality of patient clinical records without compromising appropriate clinical workforce access to patient clinical information	<p>1.19.1 Patient clinical records are available at the point of care</p> <p>1.19.2 Systems are in place to restrict inappropriate access to and dissemination of patient clinical information</p>
1.20 Implementing well designed, valid and reliable patient experience feedback mechanisms and using these to evaluate the health service performance	1.20.1 Data collected from patient feedback systems are used to measure and improve health services in the organisation

Appendix B: Clinical governance policies and documents according to Australian state or territory

	Title	Year	Health professional/service area	Definition of clinical governance	Contains checklist	References the national standards
ACT	<i>ACT Health Quality and Clinical Governance Framework 2015–2018</i>	?	All Health services	Uses the NSQHS definition “a system through which organisations are accountable to the community for continually improving the quality of their service and safe guarding high standards of care, ensuring they are patient-centres, safe and effective”	No	Yes, the definition from the standards is provided.
New South Wales	<i>Section two: Governance framework</i>	2012	The NSW health system	The governance framework recognises the organisation’s purpose, its legislative, policy and ethical obligations, as well as its workforce and employment responsibilities. The framework is supported by the organisation’s CORE values and structures and is underpinned by the seven governance standards *contains seven standards	No	No – this is a higher level/corporate framework document
South Australia	<i>SA Health Accreditation Resource to support Health Services</i>	?	Health services	Refers explicitly to the NSQHS standards on clinical governance. Directs individuals to the relevant policy	No	Yes, very explicitly – the document outlines the standards and provides guidance about relevant SA Health documentation that is relevant.
Tasmania	<i>The Tasmanian Health Services Accreditation Framework, implementing the Australian Health Services Safety and Quality Accreditation Scheme in Tasmania</i>	2012	Tasmanian health care services	Not articulated – the document is a guide for how accreditation might be undertaken rather than a clinical governance policy per se	No	Yes
Victoria	<i>Victorian clinical governance policy framework</i>	2015	Health services	The policy framework states that ‘Good clinical governance ensures the governing body, managers, clinicians and their staff are responsible and accountable for the safety and quality of care they provide’ *the policy states that there are four domains	No	No

	Title	Year	Health professional/service area	Definition of clinical governance	Contains checklist	References the national standards
				of quality and safety		
Western Australia	<i>Clinical Governance, Safety and Quality Policy Framework</i>	2016	All Health Service Providers (HSPs)	The glossary states 'clinical governance is a system through which organisations are accountable for continuously improving the quality of their services and safe guarding high standards of care by creating an environment in which excellence in clinical care will flourish' *However, the key principles that underpin this policy framework are: care is consumer and carer centred – consumer partnership is evident at all levels of the organisation, care is driven by information, led for high performance, and organised for safety	No	No
Queensland	<i>Allied Health Clinical Governance Framework in Queensland Health</i>	2015	Allied Health workforce, intended for registered professions, self-regulated professions and unregulated professions	The system by which health organisations, managers, clinicians and staff share responsibility and accountability for quality of care, continuous improvement, minimisation of risks and fostering of an environment of excellence in care for consumers	No	Yes – the Australian Health Service Safety and Quality Accreditation scheme and the NSQHS standards, in particular standard 1.
Queensland, greater metro south Brisbane	<i>Section four: Clinical Governance Framework February 2014</i>	2014	Medicare local workforce	The system by which health organisations, managers, clinicians and staff share responsibility and accountability for quality of care, continuous improvement, minimisation of risks and fostering of an environment of excellence in care for consumers. *Subscribes to the seven pillars of clinical governance	No	No – references the WA department of Health clinical governance standards 2005 and the Victorian Clinical Governance Policy Framework 2009.
Queensland, Toowoomba	<i>Clinical governance framework 2014</i>	2014	Darling Downs Hospital and Health Service	A framework through which health organisations are accountable for continuously improving the quality of their services and safe guarding high standards of care by creating an environment in which excellence in clinical care will flourish *describes six internationally accepted domains (IOM 2001 Crossing the Quality Chasm)	No	Yes – references the standards but not explicitly. Does not directly reference them.

SA = South Australia, NSW= New South Wales, ACT=Australian Capital Territory, NSQHS= the National Safety and Quality Health Service, WA = Western Australia, IOM= Institute of Medicine, WHO=World Health Organisation

Appendix C: Studies of clinical governance interventions in the literature

Study author, year, country	Clinical governance intervention	Outcomes measured	Key result	Direction of effect
Checklists				
Braham et al (2014)	Modified WHO surgical safety checklist in a cardiac catheterisation laboratory	Audit of performed versus documented: sign in, time out, sign out.	Improvement in all sections with no patient safety incidents during the post-intervention audit period	Positive
Cadman et al (2016)	WHO Safe Surgery Checklist	Critical literature review of studies reporting outcomes following implementation of the checklist.	The introduction of surgical safety checklists has had many impacts, predominantly positive, on theatre departments. Staff however, do not appear to be fully aware of all of this evidence and have many negative perceptions surrounding the checklist which are demonstrably false.	Mixed
Christian et al (2014)	Customised checklist for endoscopic endonasal transsphenoidal surgery	Prospective evaluation in 25 endoscopic endonasal operations for a variety of sellar and skull base pathological entities.	The checklist was readily adopted by nursing and anaesthesia colleagues without any barriers to implementation. It was valuable in identifying missing key components of the operation in 9 cases (36% of operations). It was viewed as being especially helpful for new operating room personnel or in institutions that are just beginning to use endoscopy.	Positive
Haynes et al (2009)	19-item surgical safety checklist	Clinical processes and outcomes from 3,733 consecutively enrolled patients undergoing noncardiac surgery in eight hospitals in eight cities	Significant reduction in the rate of death and inpatient complications ($p<0.05$)	Positive
Jammer et al (2015)	WHO surgical checklist	Retrospective analysis of checklist use and surgical outcomes in 28 European nations. Multivariate logistic regression and mixed models were used to explore the relationship between surgical checklist use and hospital mortality	Surgical checklist exposure was associated with lower crude hospital mortality ($p<0.05$)	Positive
Kim et al (2015)	WHO surgical safety checklist	Long-term reduction in perioperative harm following the introduction of the checklist-based surgical quality improvement program in a resource-limited country in Eastern Europe		
Lilaonitkul et al (2015)	WHO surgical safety checklist	Checklist and surgical count compliance rates	Use of the checklist was associated with performance of surgical counts ($p<0.05$)	Positive

Study author, year, country	Clinical governance intervention	Outcomes measured	Key result	Direction of effect
Lyons et al (2014)	Surgical safety checklists	Meta-analysis of 19 studies on the effects of checklists on teamwork, communication, morbidity and mortality	Results showed that surgical safety checklists improve teamwork and communication, reduce morbidity and mortality and improve compliance with safety measures	Positive
Mayer et al (2016)	WHO surgical checklist	Complications before hospital discharge at 5 academic and community hospitals	Checklist completion did not affect mortality reduction but significantly lowered risk of postoperative complications (16.9% vs 11.2%) and was most significant when all 3 components of the checklist had been completed. Calculated population-attributable fractions showed that 14% of the complications could be prevented if full completion of the checklist was implemented.	Positive
Reames et al (2015b)	Implementation of a checklist (Keystone Surgery)	Surgical outcomes (superficial site infection, wound complications, any complications and 30-day mortality) in 64,891 patients in 29 hospitals in Michigan, USA from 2006 to 2010	Implementation of a checklist-based quality improvement intervention did not affect rates of adverse surgical outcomes amount patients undergoing general surgery	None
Reames et al (2015a)	Statewide implementation of an evidence based checklist and comprehensive unit-based safety program (Keystone Surgery)	Surgical outcomes and health care costs in patients undergoing general and vascular surgery from 2006 to 2011 (n=1,002,241)	Keystone Surgery implementation in participating centres was not associated with improved outcomes. No differences were found in 30-day mortality, any complication, reoperations or readmissions. Medicare payments for the index admission increased following implementation as did readmission payments	No change in surgical outcomes. Negative effect on health care costs
Robert et al 2015	Implementation of a detailed presurgical safety checklist	The prevention of serious medical errors on 2,951 consecutive patients who had primary or enhancement laser vision correction between July 2009 and February 2014	There were 2 serious errors in the prechecklist cohort and none following implantation of the safety checklist protocol (p=0.23)	Positive change observed but it was not significant
Audit type intervention or data management systems				
Bowermaster et al (2015)	New recording processes for tracking failures in a paediatric cardiac operating room	Event rates	Recognition of major system-wide issues	Positive
Dindo et al (2010)	Prospective quality database administered by surgical residents	An audit was done to evaluate the validity of the recorded data	Residents failed to report most complications (80% and 79% of negative postoperative events were not recorded during the 1 st and 2 nd period, respectively). Comorbidities were incorrectly assessed in 20% of the patients in the first period and in 14% thereafter.	None
Hollenbeak et al (2011)	National Surgical Quality improvement Program (NSQIP)	Cost-effectiveness of NSQIP was evaluated at an academic medical centre between the first 6 months and through the first and second years of implementation	NSQIP appeared to be cost-effective. Its cost-effectiveness improved with greater duration of participation in the program, resulting in a decline to	Positive

Study author, year, country	Clinical governance intervention	Outcomes measured	Key result	Direction of effect
James et al (2011)	Data systems and management structures developed to increase accountability, improvement and savings in Intermountain Healthcare (a not-for-profit health system in Utah, USA). Example provided is of a new delivery protocol designed to reduce rates of elective induced labour, unplanned caesarean sections and admissions to newborn intensive care units	using an estimated cost-effectiveness ratio comparing costs before and after its adoption Cost savings	28.7% of the initial cost It is estimated the delivery protocol saves an estimated US \$50 million in Utah each year and if applied nationally would save about US \$3.5 billion	Positive
John et al (2010)	Regional audits by the West Midlands Rheumatology Service and Training Committee	Survey of rheumatology healthcare professionals about the audits	There was consensus that the regional audits were valid and reliable, benefited patients and units and provided education opportunities for specialist registrars.	Positive
Taboli et al (2014)	Novel surgical tool for auditing surgical notes (STAR)	Audit of surgical notes using STAR was performed	A significant improvement in surgical documentation was noted ($p < 0.05$). All participants involved in an education exercise said the tool would change their practice with 25% implementing major changes.	Positive
Outcome measure Boyce et al (2014)	Patient-reported outcomes measures (PROM) feedback given to surgeons	Surgeons attitudes to PROM and whether it would influence their behaviour	Surgeons had mixed opinions on the value of PROM. PROM information alone was considered insufficient to help identify opportunities for quality improvements	None
Laronga et al (2014)	Breast cancer quality of care indicators (QCI)	Performance with respect to medical oncology QCI and surgical QCI	Performance on medical oncology QCI improved over time for documentation of clinical trial participation discussion, documentation of consent for chemotherapy, definitive surgery done after neoadjuvant chemotherapy and planned dose of chemotherapy consistent with published regimens ($p < 0.05$). Improvements in surgical quality of care indicators were seen for: documentation of specimen orientation, inking of margins and performance	Positive

Study author, year, country	Clinical governance intervention	Outcomes measured	Key result	Direction of effect
of sentinel lymph node biopsy (p<0.05)				
New technologies				
Dwyer et al (2012)	Framework for introducing new technologies and clinical practices in tertiary teaching hospitals	Survey of medical Heads of Units for framework's effectiveness and comparison of level of medical staff engagement against a best-practice model	Successful external funding achieved. Most elements of the best-practice model for engaging medical staff were achieved	Positive
Standardized protocols				
Kneflin et al (2016)	Use of clinical governance to make a practice change involving standardised bathing across a paediatric hospital	Central-line associated blood stream infection	Patients with central-lines have a decreased risk of infection	Positive
Loftus et al (2015)	Implementation of a standardised safe surgery program across a large health care system	Comparison of serious reportable events (SRE) before and after implementation of program	There was a 52% reduction in the SRE event rate (p<0.05). The mean time between SREs increased from 27.4 days to 60.6 days (p<0.05)	Positive
Clinical governance and its relationships				
Hastings et al (2014)	Systematic review examining the relationship between health system governance and workforce outcomes	Workforce outcomes	Six types of governance mechanisms were identified. Shared governance, magnet accreditation and professional development initiatives were all associated with improved outcomes for the health workforce (decreased turnover, increased job satisfaction, increased empowerment etc.) Implementation of <i>'quality-focused initiatives'</i> increased quality and improved work attitudes. Research on <i>'reorganization of healthcare delivery'</i> suggested that changing to team-based care is accompanied by stress and concerns about role clarity, that outcomes vary for providers in private versus public organizations, and that co-operative clinics are beneficial for physicians	Mostly positive
Nasiripour et al (2014)	Clinical governance	Used correlation analysis to determine if there was a relationship between clinical governance performance and hospital performance indicator scores in 16 hospitals	There was no statistically meaningful relationship between clinical governance and its seven pillars and performance indicators (bed occupancy rate, mean hospital stay, bed turnover rate, bed turnover interval rate, net mortality, gross mortality) in the hospitals studied (p>0.05). Of the seven pillars of clinical governance performance, only risk management and	None

Study author, year, country	Clinical governance intervention	Outcomes measured	Key result	Direction of effect
National Audit Office (2003)	Clinical governance program – components include clinical risk management, adverse incident reporting, better information for patients and use of information technology.	Progress report on implementation of clinical governance by NHS trusts	patient's safety, use of information, management and leadership and clinical audit were positively and significantly related to clinical governance performance The report shows that as a result of the implementation of clinical governance strategies, boards have become more involved in clinical concerns; clinicians have begun to see those concerns as corporate rather than professional and personal; and attitudes of staff within trusts have become less defensive and more open. Three quarters of trusts can identify specific improvements to patient care as a result of the effective use of clinical governance strategies. However, progress in implementing clinical governance has been patchy, varying between and within NHS trusts and between the components of the initiative.	Mostly positive
Sarchielli et al (2016b)	Clinical governance tools	Knowledge, application and perceived utility by doctors of clinical governance tools and how they impact on clinical units performance as measured through mortality rates and efficiency indicators (bed occupancy rate, bed turnover interval, and extra-region mobility)	Multiple linear regression showed that clinical governance knowledge and application was correlated with clinical units mortality rates and some efficiency indicators	Positive
Speechia et al (2015)	Clinical governance tools	The relationship between clinical governance implementation levels and the appropriateness of hospital stay in 47 units in an Italian Teaching Hospital	The percentage of inappropriate days of hospital stay showed an inverse correlation with almost all the main clinical governance implementation levels ($p < 0.01$). Evidence based management and clinical audit represented the clinical governance dimensions which had the strongest association with organisational appropriateness	Positive

SA = South Australia, NSW= New South Wales, ACT=Australian Capital Territory, NSQHS= the National Safety and Quality Health Service, WA = Western Australia, IOM= Institute of Medicine, WHO=World Health Organisation

Appendix C: Summary of checklists regarding clinical governance

Country	Document Name	Contents of checklist
Ireland	Clinical Governance Checklist (National) 2011	Clinical governance checklist with 24 questions with yes/no response divided into the following sections. <ul style="list-style-type: none"> • Accountability and governance • Quality and performance indicators • Risk management • Clinical effectiveness and audit • Managing performance
Australia	Medicare Locals Corporate Governance Self-Assessment 2013	Clinical governance self-assessment check list with 15 questions with yes/no response divided into the following sections. <ul style="list-style-type: none"> • Risk management • Clinical effectiveness • Education, training and continuing professional development • Use of information • Employees and employees management • Quality improvement • Clinical audit • Patient/consumer engagement • Research
Australia	Victorian Organisational Readiness Checklist	Organisational readiness checklist for achieving effective clinical governance with 17 questions with yes/no response divided into the following sections. <ul style="list-style-type: none"> • Senior management commitment • Clinical governance – policy • Clinical governance – operational management • Safety and quality committee • Clinical governance monitoring • Legal considerations
Wales	Clinical Governance Practice Self-Assessment Tool (CGPSAT) 2015/17 Checklist	The document is aimed at general medical practices completing the Clinical Governance Practice Self-Assessment Tool. It provides a checklist to enable readers to keep a note of which matrices they have completed.