From quality assurance to clinical governance

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Abstract

Clinical governance is seen as a relatively new concept; but a long history of health care quality improvement sits behind it. Over the last 20 years, a number of approaches have been tried and discarded, with some inadequately implemented and others poorly adapted from other industries. Quality programs have evolved slowly, hampered by a conservative and complex health care culture and a lack of focus, data and resources. Despite the advent of clinical governance, driven by a patient safety crisis, many of these issues remain unresolved, and are impacting current clinical governance implementation. Reflecting on the quality journey clearly demonstrates that the potential of clinical governance cannot be realised without the leadership, commitment and support of governing bodies and executives.

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What is known about the topic?

Clinical governance has evolved from a long history of quality programs in health care and is now the dominant approach to health care quality improvement. Despite widespread support for this model, implementation is slow and problematic for many health services.

What does this paper add?

This paper builds on the clinical governance overview provided by Braithwaite and Travaglia[1] to explore some of the reasons behind the difficulties associated with clinical governance implementation. The paper provides one perspective on the evolution of health care quality in Australia over the last 20 years to illustrate some of the background to the transition from quality assurance to clinical governance, with a view to learning some lessons to better shape the future.

What are the implications for practitioners?

An understanding of some of the barriers and drivers involved in the Australian quality journey may prove useful for governing bodies and executives charged with clinical governance, especially those who are meeting resistance or experiencing slow progress.

THROUGHOUT AUSTRALIA health service governing bodies and executives are looking for practical ways to meet their clinical governance responsibilities. In their article "An overview of clinical governance policies, practices and initiatives"[1] Braithwaite and Travaglia described the components of effective clinical governance. Their purpose was to examine clinical governance policies and practices in Australia and internationally with an emphasis on the need for active participation of executives and boards if the goals of clinical governance are to be achieved. They noted that there is much work to be done before all health services have successfully implemented the detailed clinical governance model.

Why is this? Members of governing bodies and executives will be familiar with aspects of organisational resistance to enacting their clinical governance responsibilities, but may not understand the genesis or context of these problems. This makes it difficult to develop effective solutions to implementation issues. While Braithwaite and Travaglia[1] describe clinical governance as a relatively recent phenomenon, a long history sits behind it, involving cultures, complexity, champions, blind alleys and roadblocks. A greater understanding of this journey on the part of governing bodies and executives may be useful in formulating responses to the implementation struggles likely to be encountered.

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Where we've been shapes where we're going

Every year, millions of people interact safely with the Australian health care system and receive good quality care. But the increasingly diverse and complex nature of the system means that the delivery of health care will always involve some risk. Things can, and do, go wrong. Health care is a complex and high-risk industry, with many steps and people involved in the simplest care episode.[2] Add to this the explosion of new technologies, medications and medical devices, and the constant growth in knowledge through research, and it is not surprising that we struggle to contain the potential for error. It is also difficult to implement a systems approach within a highly individualised health professional environment encompassing countless sub-cultures, each with its own priorities, traditions, territories, rules and languages. Combine these issues with state–federal funding, a bureaucratic system that can sometimes appear to be more about politics than patients, a bottomless demand fed by growing populations and rising community expectations fanned by public inquiries into sub-standard care, and we have a recipe for an unpredictable health care "cake".

Clinicians and managers have long recognised the difficulties of assuring a consistently high level of health care. Various improvement frameworks and programs have been trialled, adopted and discarded with clinicians and managers struggling to agree on the best approach. Clinicians have traditionally engaged in various forms of clinical audit and case review to monitor the effectiveness and appropriateness of their care as part of their professional commitment to their patients. These activities have not always been recognised by managers as effectively contributing to overall safety and quality, however, and have at times been criticised as insular and professionally dominated, with benefits not always readily apparent to the health service or to patients.[3]

From QA to TQM

In the 1980s and 90s, health service managers began to move from quality assurance (QA), which was largely audit and checklist based, to organisational industry-based approaches, such as total quality management, with varied success. They were seldom well adapted for health care, and tended to position quality programs as having a management, rather than clinical, pre-occupation. This perception was reinforced by the corresponding use of management jargon in quality improvement programs, shifting the ownership of these programs to those who could speak the language, and seemingly away from patient outcomes towards organisational processes.[4] It was difficult for clinicians, who felt they used both art and science to do the best for their individual patients, to see the point of the paperwork and compliance demanded by quality programs largely derived from manufacturing. Somewhere along the way we began to confuse a commitment to the quality of patient care with involvement in quality programs, and over time, the word "quality" itself took on such a negative connotation that many health services dropped it in favour of other terms and acronyms. Some of that confusion — and negative connotation — is still seen today.

Early approaches to accreditation tended to reinforce the management perspective, and did little to persuade sceptical clinicians that quality programs, which for many became a pseudonym for preparing for and achieving accreditation, were anything more than a paper-based exercise designed to assist managers to tick their boxes. In the mid 1980s, the Australian Council on Healthcare Standards (ACHS) changed the quality program paradigm, requiring an organisational quality program, involving all staff, both clinical and non-clinical, as a prerequisite for hospitals to achieve accreditation. While not necessarily welcomed by either managers or clinicians, this initiative reinforced the need for an organisation-wide approach, and helped to drive the spread of quality programs. The introduction of clinical indicators into ACHS accreditation in 1993 was intended to re-focus clinician and management attention on clinical process and outcomes measurement, in an effort to combat the belief that accreditation had little relevance to clinicians and patient care.[5]

Personality-driven quality

New South Wales was the first jurisdiction to attempt a statewide approach to quality improvement through a project to implement common quality assurance structures and processes across all hospitals in the mid 1980s. This may have been Australia's first foray into systematised clinical governance. Other state and territory health departments gradually developed their quality programs and agendas, but there was little consistency between them, nor agreement on the fundamentals of high quality care. Up until this time improvement tools and approaches tended to be implemented by individual health services, often driven by passionate individuals, both clinical and non-clinical, who were tolerated more because their activities assisted hospitals to achieve accreditation than because they impacted on patient care. Many of these quality champions appeared to advance the quality cause from the high moral ground, endearing themselves to neither clinicians nor managers in the process. Health service quality managers, or quality assurance co-coordinators as they were more commonly known, were often placed in a position of being responsible for quality, rather than for the quality program — an impossible position for those with no line management authority or positional power.

The personality-driven approach to quality improvement dominated in the absence of consistent and agreed quality direction, definitions, measures and expectations. In an era when it was likely that a vocal group of health professionals, managers or board members believed there was no need for review or improvement of the care delivered, these quality champions were indeed pioneers, and probably still have the scars to prove it. Some of their approaches may have led us down blind alleys, but others were sowing the seeds of the more systematic approaches we have today. Despite the difficulties, the range and type of quality activities undertaken slowly grew into a large quality jigsaw, but with little agreement on what the overall picture should look like. There was still no common understanding or definition of quality and how it should be measured, and little attention paid to consumer perspectives. The patients in some health care facilities were probably better off for the commitment of these quality champions, but we have little way of knowing, as there was no universal system for measuring, learning from or building on their endeavours. Similarly, governing bodies and executives found it hard to justify funding and supporting improvement programs that were unable to demonstrate improved patient outcomes or efficiency. We lacked the tools and the will to measure cost savings as a by-product of improvement activities, and this may have further delayed high-level organisational commitment to quality programs.

This is not to say that clinicians have not always wished to offer anything but the best care. Health professionals have traditionally pursued high standards through their own audit, professional associations and education. The extent to which these translated to a systematic approach to improved patient care varied considerably, depending on the commitment of the managers and clinicians in each organisation. And what happened when things went wrong? There were few mechanisms in the 1970s and 80s for identifying and discussing care that did not meet clinicians' high personal expectations. Traditionally, clinicians are trained to act as autonomous experts responsible for the care of individual patients, making it difficult to acknowledge anything less than the highest standard of care. Fear of legal confrontation, and a hospital culture that blamed error on human failing, ensured organisations were slow to acknowledge and learn from mistakes, and to share those lessons with outsiders.[6] For a high risk industry, acute care did — and generally still does — tolerate a high level of ambiguity and risk in the way things were done and measured. This culture, and the lack of valid data, masked many individual and systems inadequacies.[6]

In the 1980s and early 1990s patient safety was a specialised term yet to be introduced into everyday use. The content of the early national quality conferences organised by the newly formed Australian Association for Quality in

Health Care covered topics such as the transition from quality assurance to total quality management to continuous improvement, quality program planning, audit and other QA activities. The introduction of more outcome-based approaches to improvement was a feature of these conferences, with casemix data, concurrent record screening and clinical indicators promoted as new quality tools. These innovations were not targeted at specific quality problems, however, as these had not yet been quantified, and conference participants often returned to their health services as lone voices, with few organisational systems or supports for implementing what they had learned. Despite the fact that a 1989 Australian Institute of Health and Welfare study reported that 50% of Australian hospitals had implemented a formal quality program,[7] many hospitals still operated on an implicit belief that well trained staff with good intentions, grateful patients and modern facilities and equipment, were synonymous with high quality care.[3] Despite the early attempts to capture useful clinical data to improve processes, the level of care delivered was still largely dependent on the personal capabilities of clinicians, who often managed to provide good care despite organisational systems, rather than because of them.[8]

The turning point

As we now know, the release of the first nationally representative study of adverse events in hospital patients in 1995 was a turning point. The Quality in Australian Health Care Study revealed that 16.6 percent of reviewed admissions were associated with an adverse event with fifty one percent of these considered preventable.[9] The study results were presented in federal parliament, and for the first time health care safety joined access and efficiency as public and political issues, with the spotlight firmly on acute care in hospital settings. Australia responded by setting up the Australian Safety and Quality Council in 1999, charged with developing Australia's first national approach to system-wide quality issues.[10]

Just as we were coming to terms with the problems identified by the Australian data, and other studies from around the world showing similar results, the statistics were given a startling human face by a series of public inquiries into safety and quality of care in hospitals, firstly in the United Kingdom, with the Bristol Royal Infirmary case[11] and then in a number of Australian hospitals.[12] These inquiries deepened our understanding of the systems causes of poor care, and added the frightening dimension that substandard care was not always the result of a lack of awareness or knowledge, but a lack of action. They also tipped hospitals from their pedestals in the eyes of the public, who began to demand answers and justice from a health care system that was more fallible than previously thought. The term "patient safety" entered the lexicon of health professionals, governments and consumers, and finally our quality programs had a universal focus.

A clearer focus

A synthesis of the public inquiries around the world found a number of common themes:

- the problems were longstanding and known about locally for years or even decades but were not acted upon
- they often happened in organisations that lacked appropriate management systems and clinical leadership
- the problems were frequently repeated, because lessons were not learned
- there were major barriers to disclosure and investigation
- lines of accountability for patient care were unclear
- there was a culture of blame and shame
- there was a lack of systematic performance monitoring and reporting; and
- poor systems for staff training and credentialling, or none at all.[13]

There would be few health service executives who did not recognise some or all of these characteristics in their own health services. Suddenly quality programs had more executive support, purpose, urgency — and in some cases —

resources. Clinicians and managers discussed definitions of quality and the dimensions of high quality care, such as safety, effectiveness, appropriateness, person-centredness, efficiency, continuity and accessibility.[14] Key safety drivers that had never been addressed on a large scale, such as open disclosure, credentialling, adverse event data, patient flow and human factors engineering became national projects.[15] We began to learn tools and techniques for safety and quality measurement and improvement from other countries and industries — but this time we understood the importance of adapting them to the health care environment. In the United States and UK, money was poured into safety and improvement research from which Australia benefited.

Australia developed state and national policy drivers and incentives, and government-funded organisations were set up to assist health services to better monitor and manage risk and improve the safety of their care. Professional bodies, such as medical colleges, strengthened activities and requirements for maintenance of their members' professional standards, and hospitals and other health care facilities developed and reinforced infrastructure such as committees and departments to oversee patient safety activities. Adverse event reporting was encouraged and supported. Patient safety and accreditation reports were introduced into the public domain. These advances involved significant effort and resources not previously allocated to health care quality programs, and resulted in widespread changes in practice.[10]

At last we understood that intelligence and good intentions, while important, were not enough to guarantee safe and high quality care. Both clinicians and managers reluctantly accepted that a lack of safety systems resulted in significant harm to our patients in many areas, with the internationally recognised list of key risks seemingly lengthening with each new piece of research: medications, falls, pressure ulcers, blood, infections, wrong side/site procedures, poor communication of test results, patient identification and ineffective handover practices. We learned from other high risk industries about the inevitability of human fallibility — a concept that is yet to be universally accepted in a health care system founded on professional expert knowledge and skill.[16]

The introduction of clinical governance

The introduction of clinical governance was part of these changes. The UK National Health Service (NHS) introduced clinical governance in response to the Bristol Royal Infirmary inquiry in 1998 and subsequently built a whole reform program on clinical governance: "A framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish".[3]

In Australia, a number of definitions have evolved with each state and territory defining its own purpose and approach. The concept of management responsibility for supporting high quality clinical care was not new in Australia, as this had been a requirement for ACHS accreditation since the mid 1980s. This was strengthened by positioning clinical governance as a key area of health service corporate governance, with all the attendant accountabilities, legal ramifications and requirements for a systematic approach. The initial approach focused on the management of clinical risk, and this continues to be a central component of any clinical governance framework. As noted by Braithwaite and Travaglia,[1] there was scepticism regarding its introduction, but a consistent message, supported by government directives and incentives, is slowly cementing corporate accountability for clinical care. Gradually managers and clinicians have realised the value, and necessity, of addressing clinical care with the same rigour as financial and business issues are addressed by corporate governance: "The resonance of the two terms is important, for if clinical governance is to be successful it must be underpinned by the same strengths as corporate governance: it must be rigorous in its application, organisation-wide in its emphasis, accountable in its delivery, developmental in its thrust, and positive in its connota-

tions".[17] The corresponding transition of the quality manager role, from being seen as responsible for quality, to a technical resource and support for line managers to fulfil their clinical governance role, is also underway.

The principles and components of clinical governance as described by Braithwaite and Travaglia[1] have translated into a wide variety of policies, frameworks and approaches throughout Australia across the care continuum. Reflecting the differences in our federal, state and territory governance arrangements, some jurisdictions take a centralised, compliance and policy-based approach to clinical governance requirements in the public sector, while others have adopted more of a guiding role with suggested clinical governance frameworks. Some are wading into the area of standards setting and monitoring. We see some clinical governance approaches focusing primarily on safety, while others support improvement across all dimensions of quality.[18]

There has been a recent resurgence of interest in effectiveness and appropriateness as governing bodies, executives and clinicians demand a comprehensive picture of quality in their organisations that focuses on, but is not confined to, patient safety. Innovative state and national clinical audit programs are evolving.[19] We are reminded, via research and organisations such as the National Institute of Clinical Studies,[20] that as much harm can be caused through ineffective and inappropriate care as through unsafe care. We have learned that managers, consumers and clinicians may all define quality differently, but that this is often just semantics — most people agree that quality care is basically the right care, the best possible care, available when needed, that achieves the desired result in a safe, supportive environment. Various stakeholders will place emphasis on different dimensions of quality, requiring health service managers to employ a framework that addresses each dimension, to ensure a balanced approach. The importance of staff ownership is better understood, with effective improvement programs delegating responsibility and empowering managers and clinicians to play their part.[21] Clinical governance makes it easier to identify the impact of a quality program on the safety and quality of patient care, and positions clinicians in a central role.

Where to from here?

Braithwaite and Travaglia[1] have constructed a useful and comprehensive description of clinical governance context and components. However the best clinical governance program at jurisdictional or health service level is of little use unless it supports clinicians to consistently deliver safe, effective, appropriate care based on best available evidence, in partnership with the patient. Where attention focuses less on clinical priorities than on activity targets, waiting list initiatives and financial issues, clinicians are likely to become frustrated and demoralised. Effective clinical governance strives to balance both clinical and management imperatives with a focus on the patient. The safety, effectiveness and appropriateness of care are where clinicians' hearts lie, and the implementation of clinical governance should reinforce that improvement of health care performance relies on supporting clinical staff to make and execute good decisions.[22]

Slow progress

Since 2000 we have seen an explosion in knowledge to meet these challenges, in areas such as: consumer participation; human error and risk management and reduction; evidence-based care; credentialling, education and training for safety and quality; organisational culture and a systems approach to improvement.[15] It can be difficult for health services to keep up. Despite this growing awareness and activity, it seems we have a long way to go before we adopt a consistent approach across all health services, and are willing — and able — to quantify the effect on patient care, safety and quality at state or national levels.[1,10] Many believe that safety issues are still the health care faultlines.[23] It is not just the patient safety area that requires our continued focus and determination. We are not able to say that we deliver consistently appropriate and effective care for every patient, and the uptake of evidence into

practice is slow. Access to care and patient centredness are addressed differently, with diverse results, across health services and jurisdictions. We still have a high tolerance for ambiguity in process, outcomes and roles compared with other high risk industries.[6] Accreditation, in its various forms, although now more focused on the quality of clinical care, is still seen as an administrative burden, with most health services subject to a rolling schedule of requirements and visits from a range of accreditation providers. Continuous improvement as a science is still underdeveloped, with many health services unaware of or underutilising useful improvement tools and methods.

Progress is slow.[1,10,15] What are the barriers? We know that our need for valid and reliable data remains unmet. What else? Are we trying to do too much at once in this complex environment? Are we unclear about our focus in terms of goals and roles? Do our quality initiatives lack the teeth to overcome the significant hurdles in their path? Do we lack concentrated national and local leadership? Do we still not really understand the critical role of consumers in improving the quality of care? Are we distracted by funding demands and budget issues?

It may be all of these — and more. Health care organisations are complex environments.[2] Health care professionals tend to be linear thinkers. Health services may not yet have the expert knowledge and capacity to undertake the significant culture and systems change required. Is it also possible that we have swung the pendulum too far to a systems focus? While sound systems are integral to achieving consistently high quality and safe care, other high-risk industries recognise the benefits of balancing them with the considerable skills and experience of senior professionals.[24] Are we sophisticated enough to enable both systems and people to play their part in safety?

It is also argued that there is a need to position clear clinical governance goals, structures and implementation at local, jurisdictional and national levels within a more rigorous framework of regulation. In a complex environment, self-regulation by health professions is unlikely to guarantee the safety and quality of care, and increased regulation is viewed by some as an appropriate model. In reality, we already engage in a mix of responsive regulation at jurisdictional level. Some jurisdictions rely mostly on volunteerism, self-regulation and minimum metaregulation to guide health services' safety and quality efforts. Others are moving towards a stronger emphasis on metaregulation via centralised policy frameworks.[25]

What is clear is that we do not have a nationally agreed approach to addressing safety and quality regulation, nor do we have systematic measures or levers to escalate or de-escalate when required. A more uniform application of responsive regulation around the country would assist jurisdictions to drive a more consistent approach to achieving safety and quality goals, and make this a less negotiable proposition for managers and clinicians. Whatever the model, it appears that the pendulum is slowly swinging towards compliance, an area with which the aged care sector is all too familiar, as multiple accreditation systems demand health services' time and resources, funders and bureaucrats look for ways to eliminate poor practice and the community demands safe care without compromise. These system-wide barriers and drivers are currently being considered by state and territory governments and the Australian Commission on Safety and Quality in Health Care,[26] charged by Australian Health Ministers with leading and coordinating safety and quality improvements in the Australian health sector.

Think health system, act health service

While these issues are being considered at the system-wide level the question remains: how do we promulgate a sustained clinical governance program, as described by Braithwaite and Travaglia, underpinned by a culture of continuous improvement, at a local level in every health service? We know that one of the key determinants of success of a quality improvement initiative is the nature of the organisation in which it is used.[27] It is of little use to throw resources and projects at organisations in which they are unlikely to stick, even though we often persist

with this approach. A firm foundation of effective clinical governance is required in each health service to promulgate improvement activities that make a positive difference to patients.

To begin with, we must not make clinical governance so complicated and jargonistic that clinicians and staff cannot see the relevance of taking an active role in safety and quality initiatives for the wellbeing of their patients. It is important to understand the role of health care cultures and to recognise the inherent complexity and conservatism of health care organisations, requiring effective and empathic change management approaches to embed new ways of thinking and working. Quality programs work best where "top down" meets "bottom up" and staff involvement at all levels is vital.[21,22] Many health services still do not have an agreed definition of high quality care in their local context, and without this it is difficult to set goals and develop plans that motivate clinical and management participation and ownership.

A characteristic of other high-risk industries is the clarity with which staff understand and enact their responsibilities for safety and quality.[24] The diversity of professional staff and staffing arrangements in health care, coupled with current workforce issues, renders this a difficult area for managers, and in this respect health care faces challenges more akin to reducing the road toll than to stopping planes from crashing.

Governing bodies and senior managers are obliged, within a clinical governance framework, to provide transparent direction, knowledge, resources and support for line managers and clinicians regarding their roles in providing and assuring safe and high quality care.[21,28] We must continue to nurture the common ground between managers and clinicians provided by the focus on safety, effectiveness and appropriateness of care afforded by clinical governance, and balance this with the move towards greater compliance. There is also much work to be done to establish the vital role of consumers in driving safety and quality through changes to health care structures and processes to encourage and support consumers and clinicians to work together on individual episodes of care and systems issues.

These are not straightforward issues for governing bodies and executives to address within a funding environment primarily focused on efficiency, and perhaps our greatest ongoing challenge in this regard is to demonstrate that high quality care and efficient care are not mutually exclusive. Nor is it easy to acknowledge and learn from mistakes that harm patients, monitor and measure care with limited data, deal with substandard care and compromised clinicians, or to open health services to public scrutiny. While much progress had been made over the last 10 years, many board members still express discomfort with these clinical governance issues, and with their responsibility for the quality of clinical care overall, particularly in the absence of useful measures. The need for drive and commitment from the top to meet these challenges is self-evident.

In summary

This paper describes one perspective on the Australian acute health care safety and quality journey over the past two decades. It is a "median" view — there have of course been leaders and laggards that are not described. The history and issues also vary across health care sectors, with community health and aged care currently adapting clinical governance as "quality" and "care" governance as befits their roles beyond clinical care. Wherever we look, however, the journey has been one of ups and downs. High quality health care is about people — something that sometimes gets lost in the tangle of quality philosophies, methods and jargon. Our Australian approach to quality has evolved within a complex and rapidly growing health care environment populated with multiple stakeholders, many with polarised perspectives on what constitutes good care. Despite enormous amounts of effort at all levels of the system over the last 20 years, this has rendered high quality care a difficult concept to define, measure and achieve. We are moving from an environment in which indi-

vidual expertise, skills and goodwill largely determined the quality of care, towards a more robust approach in which the quality of care is determined by skilled and knowledgeable individuals working in teams, in partnership with consumers, underpinned by excellent systems and supported by robust governance. It is clear that this transition cannot be made without governing bodies, executives and clinical leaders demonstrating uncompromising commitment and leadership in each health service.

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Competing interests

The author declares that she has no competing interests.

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