RACMA
ROYAL AUSTRALASIAN COLLEGE
of Medical Administrators

CLINICAL GOVERNANCE TRAINING FRAMEWORK

ADAPTED FROM A REPORT PREPARED FOR
THE ROYAL AUSTRALASIAN COLLEGE OF MEDICAL ADMINISTRATORS

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Contents

1 Introduction

1.1 Background

While clinicians have always had a role in leading health care organisations, concerted involvement of clinicians in governance processes began in the 1990s in response to a series of safety incidents in the United States[B1],[1] United Kingdom (UK),[2][B2] Australia and Canada.[3] Over the last two decades, clinical governance has evolved to encompass accountability, performance, and appropriate culture and workplace behaviour.[4] More recently, with recognition of healthcare as a complex adaptive system,[5] clinical governance is beginning to embrace the need for resilient thinking and understanding the differences between work-as-imagined by managers and work-as-done at the frontline of patient care.[6] A robust clinical governance approach is critical for quality and safety, which in turn is important for high performing hospitals.[7]

The Royal Australasian College of Medical Administrators (RACMA) Fellows and Candidates occupy an important variety of medical management roles within the Australian healthcare system. RACMA trains Fellows to be experts in organisations, systems, leadership and management and in meeting the goals of the organisation and the boards that are responsible for governing them. RACMA is therefore well placed to be responsible, through its Fellows, for clinical governance and quality and safety across the Australian Health System.

1.2 Objective

This Clinical Governance Training Framework is adapted from a report developed for RACMA. That report provided advice on what clinical governance looks like from a medical administration perspective, and how the College [B3]could take the leadership role of clinical governance in healthcare. To meet this aim, the authors analysed the evidence base for clinical governance, incorporating peer-reviewed and grey literature and expert opinion; developed a clinical governance framework; discussed what needs to be done to improve the way health organisations manage clinical governance operations; and developed a case where RACMA assumes a level of responsibility for it in the Australian Health System. A full copy of the original report is available from the RACMA web site; this paper contains extracts from that paper and for your reading convenience figures and tables have been re-sequenced.

A clinical governance framework that articulates RACMA Candidates' requirements in terms of capabilities, skills and knowledge in clinical governance is outlined. Outcomes of this project and incorporation into the ongoing education and training framework for RACMA trainees will strongly contribute to RACMA's vision that it will be recognised internationally, as the Australasian medical college providing professional education, leadership, advice and expertise in medical management that promotes safe and effective healthcare.

1.3 Methods

A multi-method approach was employed in this project. Each method is described in more detail in the relevant chapters, however these are summarised below[B4]:

- Literature Review: an update of the literature reviews related to clinical governance carried out previously by Braithwaite and Travaglia [4] was undertaken.
- Consultation Framework reviews: in association with the literature review, we reviewed clinical governance frameworks that have been developed in Australia and internationally.
- Consultation with the sector (1): Australian and New Zealand experts in clinical governance were identified and interviewed. A semi-structured approach was used to elicit the views of 13 experts.
- Consultation with the sector (2): A facilitated half-day workshop with 21 RACMA Fellows in association with the RACMA Winter Forum.

The findings from these data sources were synthesised and developed a clinical governance framework and an associated training framework.

2 Literature Review

2.1 Introduction

Clinical governance is an unusual concept in that its origins are largely unambiguous. The U K's Department of Health issued a white paper 20 years ago called *The new NHS: modern and dependable* which noted that *"… a new system of clinical governance in NHS Trusts and primary care to ensure that clinical standards are met, and that processes are in place to ensure continuous improvement, backed by a new statutory duty for quality in NHS Trusts"* Secretary of State for Health [8].

Sir Liam Donaldson, the then Chief Medical Officer of the English National Health Service (NHS), had searched for a new way of conceptualising the role of clinicians in the preventions of errors. Corporate governance, he reasoned, provided a framework for fiduciary and legal responsibilities and accountabilities. Clinical governance could do the same for quality and safety. Donaldson's 1998 article put the case succinctly "*Clinical governance: a statutory duty for quality improvement*" [9].

As an organising framework, clinical governance developed largely in unison with the worldwide movement for patient safety, which emerged around the same time[1]. This movement in turn was based on studies of errors conducted up to a decade previously [10 11], but was given impetus by a number of large scale patient safety inquiries in the U K and internationally, including Australia [12].

In the UK, the original aim of clinical governance was to shift the focus of the NHS away from managerialism and financial targets to one of quality, and more specifically quality improvement, as the responsibility of *"… organisations and of each of their staff as individual professionals*" [8]. The key elements of clinical governance as outlined in 1997 remain largely unchanged. As conceptualised in that early paper, a 'quality' organisation ensured that:

- *quality improvement processes (e.g. clinical audit) are in place and integrated with the quality programme for the organisation as a whole*
- *leadership skills are developed at clinical team level*
- *evidence-based practice is in day-to-day use with the infrastructure to support it*
- *good practice, ideas and innovations (which have been evaluated) are systematically disseminated within and outside the organisation*
- *clinical risk reduction programmes of a high standard are in place*
- *adverse events are detected, and openly investigated; and the lessons learned promptly applied*
- *lessons for clinical practice are systematically learned from complaints made by patients*
- *problems of poor clinical performance are recognised at an early stage and dealt with to prevent harm to patients*

- *all professional development programmes reflect the principles of clinical governance.*

In Australia, Braithwaite and Travaglia [13] conducted a literature review and bibliometric analysis of the clinical governance literature. They identified four components required for effective clinical governance. These included: using clinical governance as a focal point for quality assurance and continuous improvement as a way of promoting quality and safety; the creation of relevant structures to manage risk and performance and improve quality and safety; the creation of and effective use of data, knowledge and expertise exchange strategies; and the promotion and sponsoring of a patient centred approach to service delivery. These elements were used to ensure a link between corporate and clinical governance. These findings were supported by a second review conducted three years later [14].

Although recognised internationally, clinical governance remains a largely "Westminster" concept, spreading and sustaining most vigorously in the UK [15], Australia [16], New Zealand [17] and Canada [18] as an organising principle for the quality and safety of care. The same basic approaches and drivers are applied internationally but have been more frequently subsumed under the broader patient safety agenda [19 20]. Recent critiques of that agenda speak primarily to the lack of systemic reductions in patient safety [21-23], but there is also a growing reflection on the distance between approaches to improving safety compared to approaches to improving quality. This is pertinent to clinical governance because, as noted, its origins lie in quality improvement and clinical effectiveness rather than patient safety *per se* [24].

As several Australian reviews of clinical governance have already been undertaken, this report will focus on the literature from 2011 and research addressing the specific role of doctors. As a consequence, this review needs to be read in conjunction with Braithwaite and Travaglia [13] and Travaglia, et al. [14].

2.2 Method

2.2.1 Literature search

In methodology similar to our prior reviews [13 14] we identified and interrogated the literature that focused directly on clinical governance as a cohesive approach, rather than those which dealt with its component elements (e.g. risk and or data management). Because of the specificity of concept, a single term "clinical governance" was used to search all of the databases. The term was employed according to the conventions and internal logic of the databases, so for example clinical governance is a MESH term in the Medline database, whereas in the EMBASE database it was used as a keyword.

The databases searched included: Medline and Medline In process (1946 to 10 Feb 2017); Embase (from 1947 to 10 Feb 2017); CINAHL including in press (from 1981 to 10 Feb 2017); Scopus (from 1966 to 10 Feb 2017); ProQuest health management data base (1993 to 10 Feb 2017); all other Proquest (1993 to 10 Feb 2017); Web of Science (from 1945 to 10 Feb 2017). The specifics for each search are listed in Table 1 on page 6. Although a complete search of databases was conducted, the first related reference to clinical governance appears in 1995, and the earliest published references to directly mention clinical governance were published in 1998, as noted in the introduction.

The initial search conducted was for all references to clinical governance available from the inception of the database. The results were then downloaded to Endnote X7, a reference management system. Duplicates were then removed. A hand search of the International Journal

of Health Governance[1] was conducted. As the search was comprehensive, crosstab analyses were conducted within the final database.

We analysed the results using Leximancer, a data mining package. Leximancer produces a ranked list of concepts emerging from the data (in this case the article abstracts) as well as maps indicating the relationship between concepts [25]. The absence of concepts or words from the ranked list does not indicate their absence for[B5] the literature, but rather their relative significance.

We present the data for all the search results, and then focus on core concepts since 2012. Our primary analysis and discussion is of the literature pertaining to doctors/physicians. This was irrespective of the date of publication.

2.3 Results

2.3.1 Search findings

Table 1 below, presents the findings from the search of clinical governance as a coordinating concept for quality and safety activities. The results indicate the two focus areas for the review: articles from 2012-2017 (n = 2282[B6], 44% of the total references) and results including direct references to doctors (1018, 20% of total references from 1998).

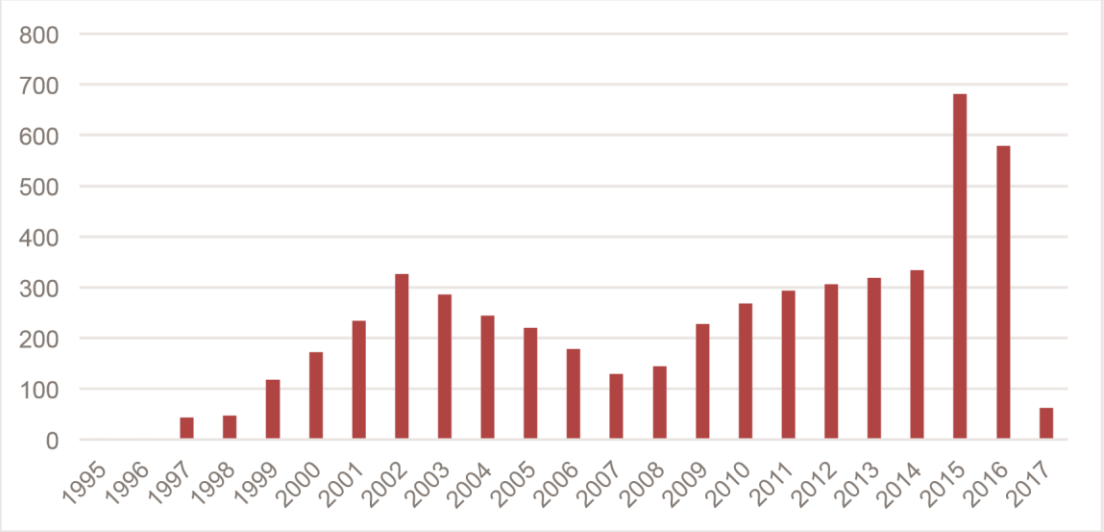
Table 1: Search findings for "clinical governance" as a key search term

Database	Medline and Medline	EMBASE	CINAHL Clinical	Scopus	Proquest Health Management database	All other Proquest	Web of Science
Delineator	MeSH (exp)	Key word [B7]	Major term (exp)	Keyword	Keyword peer reviewed	Keyword peer reviewed	Keyword
Results	416	2,454	912	8,634	1,020	1,743	971
Total							16,150
Total minus duplicates							5,218
Results from 2012-2017							2,282
Results referencing doctor(s)/physicians/general practitioner(s)							1,018

[1] The title of this journal provides a potted history of clinical governance. The journal started as the *Journal of Clinical Effectiveness* (1996-1998) and then became the *British Journal of Clinical Governance* (1999-2002) incorporating *Clinical Performance and Quality Healthcare* (1999-2000). The title was then changed to *Clinical Governance: An International Journal* (2003-2015) and most recently it was re-launched as *The International Journal of Health Governance* in 2016.

Figure 1 shows the distribution of articles emerging from our search, from 1995-1998. The graph indicates periods of steady growth from 1995[B8]-1998 to 2002, a decline to 2007, a slow reemergence in the following seven years, followed by a spike in 2015. While it is not possible through this process to identify a single cause of the 2015 spike, the impact of the Francis Inquiry into the Mid Staffordshire Hospital cannot be discounted [26].

Figure 1: The distribution of articles from 1995 - (February) 2017

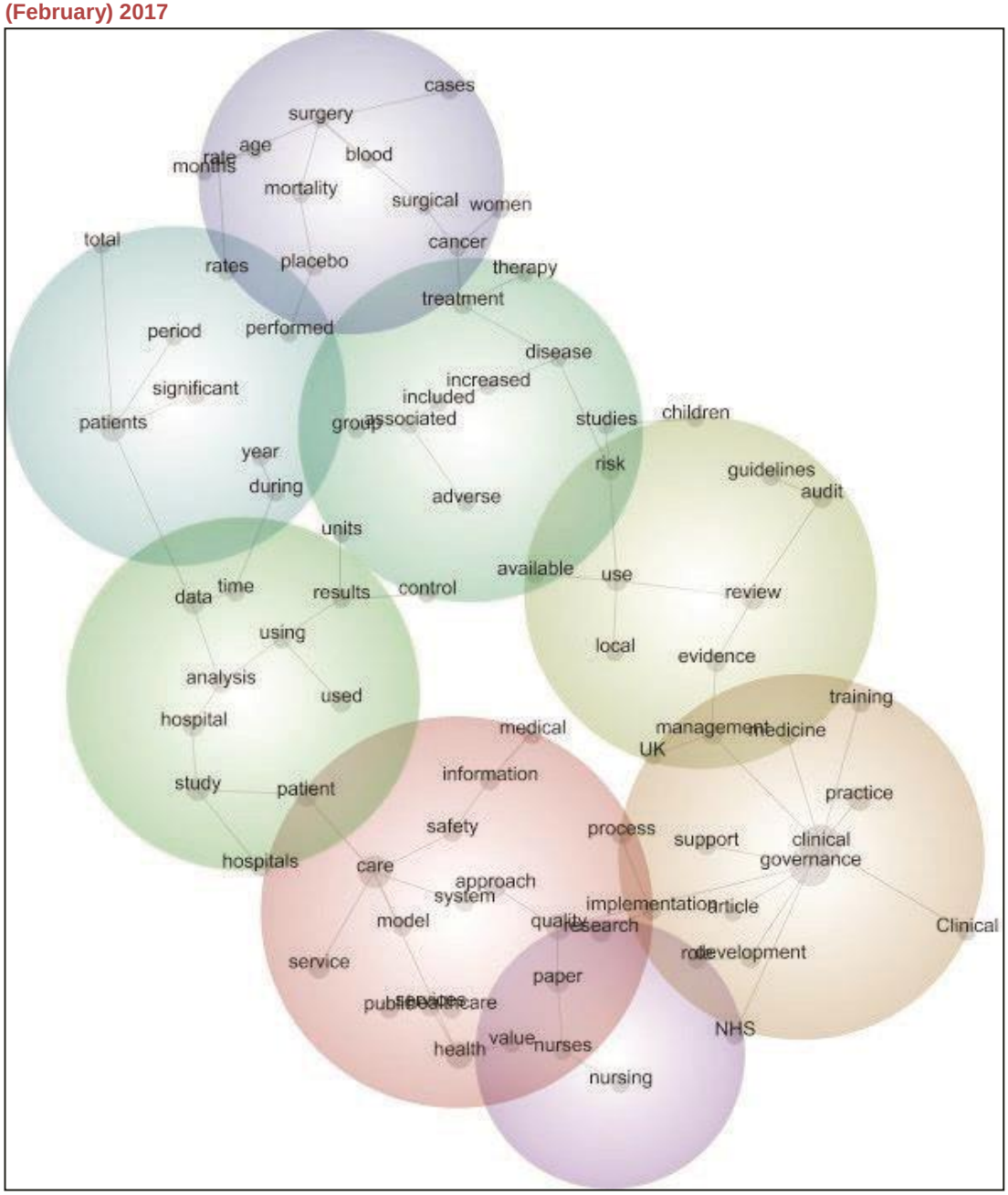


2.3.2 Clinical governance literature from 1995 – 2017

Figure 2 on page 8 is the automated data mining map of all key concepts with the clinical governance literature from 1995 to February 2017. The map was generated via the use of the Leximancer package. A series of tables was also generated, and are provided in Appendix A. The map should be read in conjunction with Appendix A, Table 1 (key themes or groupings) and Table 2 (key concepts). Themes are indicated in **bold** in the analysis and concepts in *italics*.

The map, themes and concepts reflect the centrality of ***clinical*** *governance* and **care** as organising principles in this body of work. The dominance of **review** and **treatment** align to the literature on *evidence, guidelines* and *audit*. **Care** is associated with *systems approach* to *safety* and *quality,* including *medical information* and to *patient* on the other. The only country to emerge as a key concept is the *UK* and its *NHS*. The only professional group to emerge is *nurses* and *nursing*.

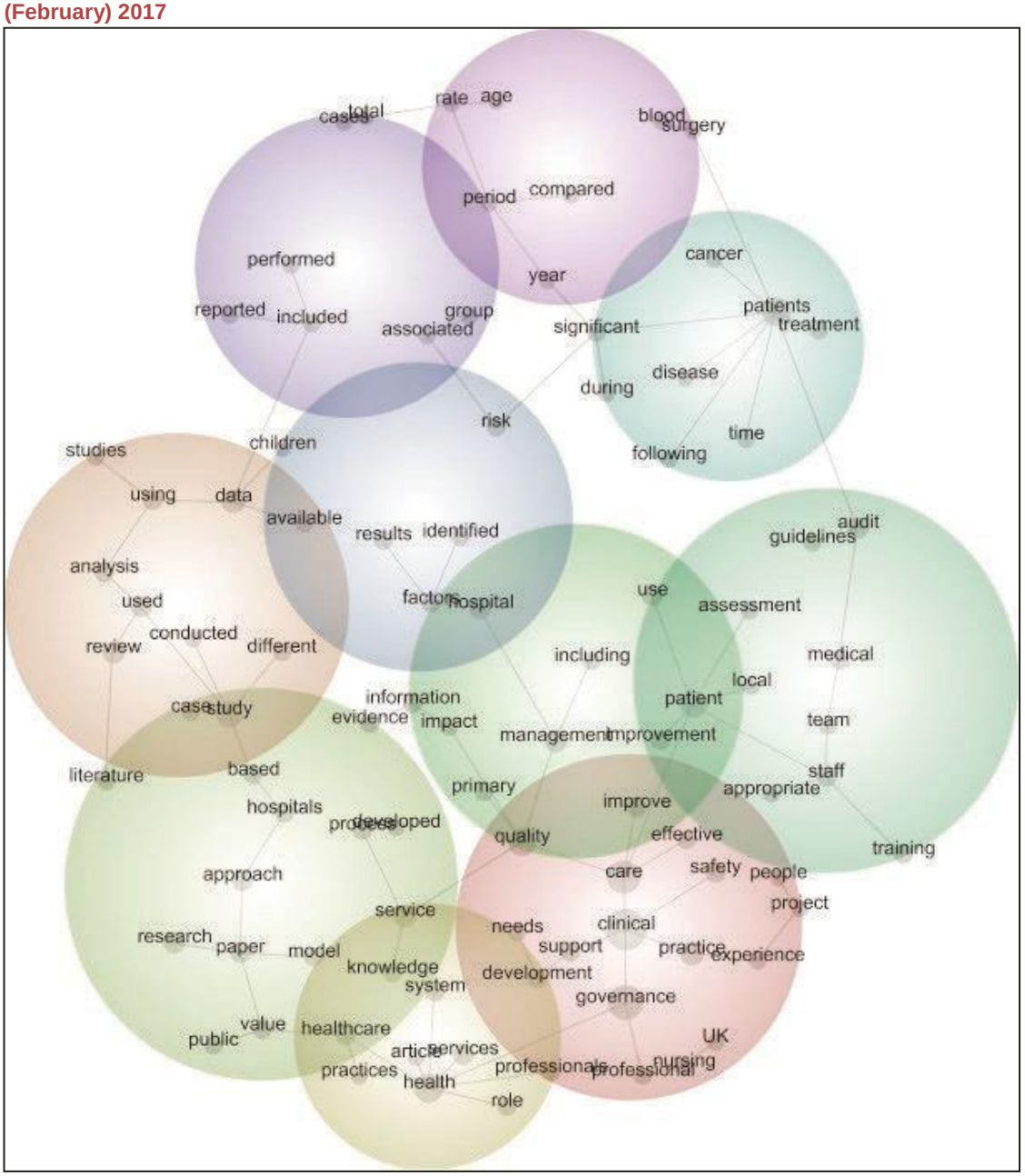
Figure 2[B9]: Leximancer map of key concepts within the clinical governance literature from 1995 - (February) 2017



2.3.3 Clinical governance literature from 2012-2017

Figure 3 on page 9 is the automated Leximancer map of all key concepts with the clinical governance literature from 2012 to February 2017. Appendix A, Table 3 presents the key themes, and Table 4 the key concepts.

Figure 3[B10]: Leximancer map of key concepts within the clinical governance literature from 2012 - (February) 2017

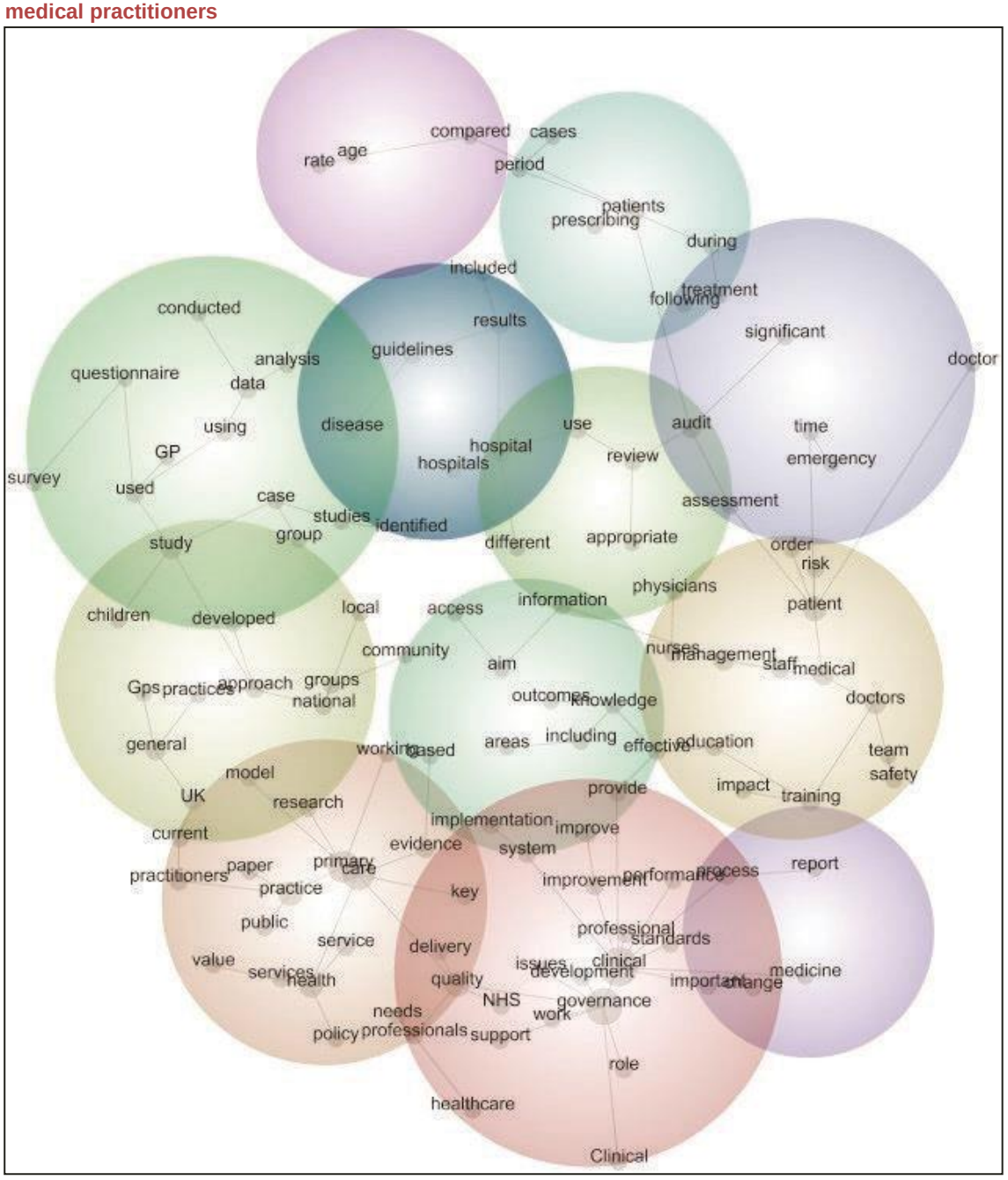


The themes and key concepts of the clinical governance literature from 2012 to 2017 show some differences, although major themes such as **clinical** and concepts including *care,* remain highly ranked. What has emerged over the last five years, is a greater emphasis on *clinical experience*, increased use of *research* and *knowledge system*, and increased focus on *improvement* and *improved* [ed] *safety* and *project*. One significant change is the shift of *care* from the third to the second ranked concept. *Nursing* remains the only professional group to emerge from literature and the *UK* remains the only country.

2.3.4 Clinical governance and medical practitioners

Figure 4 provides an automated Leximancer map of all key concepts with the clinical governance literature which includes references to medical practitioners including doctors, physicians or general practitioners. Appendix A, Table 5 presents the key themes, and Table 6 the key concepts.

Figure 4: Leximancer[B11] map of key concepts within the clinical governance literature relating to medical practitioners



The Leximancer analysis of the literature relating to medical practitioner provides a rich picture of the issues addressed in this body of work. Major themes including **clinical, care** and **patient** continue to dominate. New themes, such as **guidelines** and **time** increase in importance. *Clinical governance* is strongly associated with *professional standards* and *role,* as well as *performance, process report, improvement,* and *implementation* on one branch and *issues* and *development* on the other. Governance is also linked to a specific *role. Professional needs* are

aligned with organising concepts such as *quality delivery, policy* and *health service. Primary care* as a major cluster is associated with *practice, public and health services*, but also *national, community* and *local groups*, speaking to the situated nature of primary care. *Appropriate review* and *audit* are central to the map. *GP* is associated with *using data analysis, surveys* and *questionnaire*. *Doctors* are associated with *team safety, medical staff, management, nurses* and *patient risk. Time* is linked to *emergency* and *risk*.

2.3.5 Summary of the themes from the literature

One of the earliest reports on clinical governance in the British Medical Journal reports on a speech given by Dr Ian Bogle, the then chairman of the British Medical Association council[B12] who *"... believes that clinical governance and self-regulation are compatible and should reinforce each other"* [27]. The article describes the parameters of this new approach in a normative fashion, repeating the requirements established by the NHS through its white paper [8] and reflecting some of the concerns associated with the introduction of the approach.

The article commences with: "*... doctors must take part in clinical audit; leadership skills must be developed within clinical teams; evidence based medicine must be practised; good practice must be disseminated; procedures must be in place for reducing risk; adverse events must be detected and investigated; lessons learnt must be applied to clinical practice; and poor clinical performance must be recognised early and tackled promptly.*" Its conclusion is somewhat more tentative "*Many doctors, Dr Bogle believes, see the proposed Commission for Health Improvement as a threat to self regulation because it can impose solutions on clinical problems on behalf of the government, health authorities, or trusts—"this poses the danger of managers guiding surgeons' scalpels." But the chairman maintains that robust self regulation will ensure that the commission never has to intervene on clinical matters in this way."* [27].

Tension between the potential of clinical governance and its actual or intended impact are reflected in a number of articles throughout out the literature. Articles titles such as *Clinical governance: fine words or action?* [28], also in the BMJ, and *"Clinical governance-watchword or buzzword?"* [29] reflect some of earliest scepticism about the approach. Its description as *"... essentially bureaucratic strategy in that it places great emphasis on controlling the behavior of National Health Service clinical professionals via a web of rules"* [30] speaks to this concern.

This tension is emerged noticeably in the aftermath of reports of large scale patient safety inquiries which raised (and continue to raise) questions about the governance of medical practitioners, and the role of medical practitioners in the process of governance. Soon after the announcement of the Bristol Royal Infirmary Inquiry the then Editor of the BMJ, Richard Smith, reported that *"... secretary of state announced a public inquiry and claimed that all three doctors should have been struck off. The profession went into overdrive to produce overdue reform, particularly in local self regulation. The GMC came up with the idea of revalidation. Meanwhile, media stories have appeared almost daily on "rogue doctors" and "butcher surgeons."* [31]. The *"emotive and largely hostile"* media reporting, loss of trust and the "*... scathing criticism"* received by profession. Self regulation and revalidation [32-36] were recurring themes in the BMJ [37] and other medical journals [38] post Bristol, and the between professional autonomy and governance has continued over the last two decades [39 40].
A similar and associated tension arose between the demands the health service, patients and the public, and the medical practitioners themselves. Allen [41] sums up this tension as *"... the aims and desires of the groups to whom professionals are accountable may not be compatible at all times*-[B13]*in particular, the views of the public at local level may not coincide with the goals of the centrally managed NHS ... professionals will need to concentrate on a mixture of centrally*

identified clinical and organisational issues, particularly those set out in the national service frameworks, and issues identified in local health improvement programmes."

Early arguments against clinical governance included the claim, for example that *"… clinical governance is actually a means to promote excellent practice of a particular kind and that noncompliance does not necessarily equate to bad practice"* [42] and that "*Clinical freedom is under threat from the state & peer group pressure in the form of clinical governance"* [43]. One author even argued that individuals such as Harold Shipman could not be stopped by a focus on procedures and accountability, but rather by focusing on quality [44].

Reports of medical practitioners' attitudes towards clinical governance show some change, although the types of studies and reports vary greatly so there is a need to proceed with caution in interpreting results as trends. By 2004, the argument forwarded was that *"Clinicians have always been accountable for maintaining high quality care; clinical governance merely imposes structure in this and makes it explicit"* [45]. A study in the follow year however, found that *"… doctors are not enthusiastic about clinical governance and it is not receiving wholehearted support from doctors because they feel that clinical governance is a management-led initiative imposed without adequate consultations"* [46]. Ironically a recent study found that *" … doctor managers having more formal decision making responsibilities in strategic hospital management areas is positively associated with the level of implementation of quality management systems."* [47].

A focus on clinical governance produced greater scrutiny of organisational factors that impede quality and safety. The lack of effective clinical audit processes was identified as a potential contributor to risk early on [48], although a national sentinel audit for stroke (in the UK) was announced soon after [49]. In turn, as the field matured the effectiveness of specific audits were analysed and an improvement cycle instigated [50]. Early work in clinical governance also alluded to the process by which the scope and nature of errors were determined [51].

Other issues addressed in the implementation of clinical governance focused on legal [52-54], management [55] and systems perspectives [56]. Guidelines were to be introduced to manage *"unjustifiable variations"* in the cost and quality of care and care pathways were to be develop to "*enhance clinical governance"* [57]. Learning from patient complaints in a systematic manner was raised early within the context of primary care groups [58] as was the need for lead clinical governance clinicians in the same sector [59]. Recognition of the benefits of engaging with carers as well as patients emerged a little later [60].

Factors impeding engagement with clinical governance included: time [61]; clinicians' attitudes towards specific components of clinical governance, for example audits [62]; lack of effective indicators in key skills such as communication [63]; lack of standardised information and communication technology [64]; the complexity of clinical governance processes including audits [65]; the usefulness of clinical governance reports [66]; the fragmentation of services [67]; the lack of clear role boundaries for medical practitioners engaged in supervising or assisting in clinical governance strategies, such as clinical leads [68]; lack of clinical and organisational leadership [69]; a focus on sanctions rather than norms to change the behaviour of individuals [70]; and a lack of board expertise in clinical governance [71 72].
The need for education is a recurrent theme from the concept's inception [73-80]. Heard[B14] (1998) argues for the need for more education on the topic for both doctors and managers who need to become *"… part of this new culture"*, while for Hill [81] [B15]"*Clinical governance is a novel concept with potentially profound implications for the practice of medicine in the next millennium"*.
Later authors noted the limitation of information as a way of effective change in clinicians' behaviour, arguing instead for multifacted strategies including the use of guidelines and audits [82].

Methods of learning and development include a range of techniques, including the use of learning

sets [83], the development of practice based evidence [84] and the development of continuous quality improvement approaches [85].

Both the development of specific competencies and associated training was said to be required if evidence based healthcare was to be implemented [86][B16] [87]. Change management was identified early on as one of the specific skills required by doctors engaged in clinical governance [88][B17], as was the ability to cope with change [89]. A series of papers on clinical governance in New Zealand argued that its implementation required *"clinicians to accept transparent accountability, teamwork rather than individualism, a systems view and the need to share power with others in the clinical domain"* [90].

Other factors contributing to the effective implementation of clinical governance and its component elements include: an ongoing commitment to quality [91]; culture and cultural change [92-94]; understanding variation within and across practices and services [95]; implementation of research findings (evidence based medicine) [96]; patient engagement in the process both[B18] of care [97]; the direct involvement of clinicians in the design of technology, including clinical information systems [98][B19]; and bottom-up approach to clinical governance, ownership, teamwork, learning from mistakes and feedback [99][B20]. A lack of clinical governance was attributed, early on, to the abuse of elderly patients [100][B21], prescient of the findings of the Francis Inquiry into Mid-Staffordshire Hospital.

Many of the articles identified addressed clinical governance in relation to the management of specific conditions or services. These included: smoking cessation [101][B22]; chronic pain [102]; orthopaedic screening [103]; acute asthma [104]; congenital heart disease [105]; diabetes [106] [107] and the delivery of nuclear medicine [108]. Discussion, if not primary research, has been ongoing for the role of clinical governance in every level of care from primary [109] [110]; through to community care including mental health services [111] [112] and rehabilitation services [113]; pre-hospital [114]; military [115]; and tertiary care [116].

Some authors saw clinical governance as a way of effecting wider change in health services (albeit largely the NHS). Leadbeatter and James [117] and Cowan [118], for example, discussed expanding the involvement of coroners in the clinical governance process as a way of increasing accountability and transparency in the review of patient deaths. Clinical governance was seen as one way of influencing everything from the training and hours of work of 'senior house officers' [119], including in the use of hospital equipment [120] and obtaining patient consent [121] to improving patient outcomes at a primary care level [122].

2.4 Conclusion

Medical practice and medical practitioners have a long and complicated relationship with clinical governance as an approach to improving the quality and safety of care. This is to be expected: clinical governance in essence emerged as a result of responses to public inquiries into patient safety within which medical practitioners were key players.

While many world experts in clinical governance and its component parts are medical practitioners themselves, and notwithstanding the engagement of medical practitioners in all forms of clinical governance – including its management – the tensions which marked its emergence remain. Analysis of the body of literature relating to clinical governance reflects a strong consistency in the arguments around the approach.

Most of the major concepts which emerge relate to the way in which clinical governance is implemented. Much less remains known, however, about how it is enacted. In examining the

literature on clinical governance in relation to medical practitioners, a more granular image emerges. Four broad categories of engagement emerge:

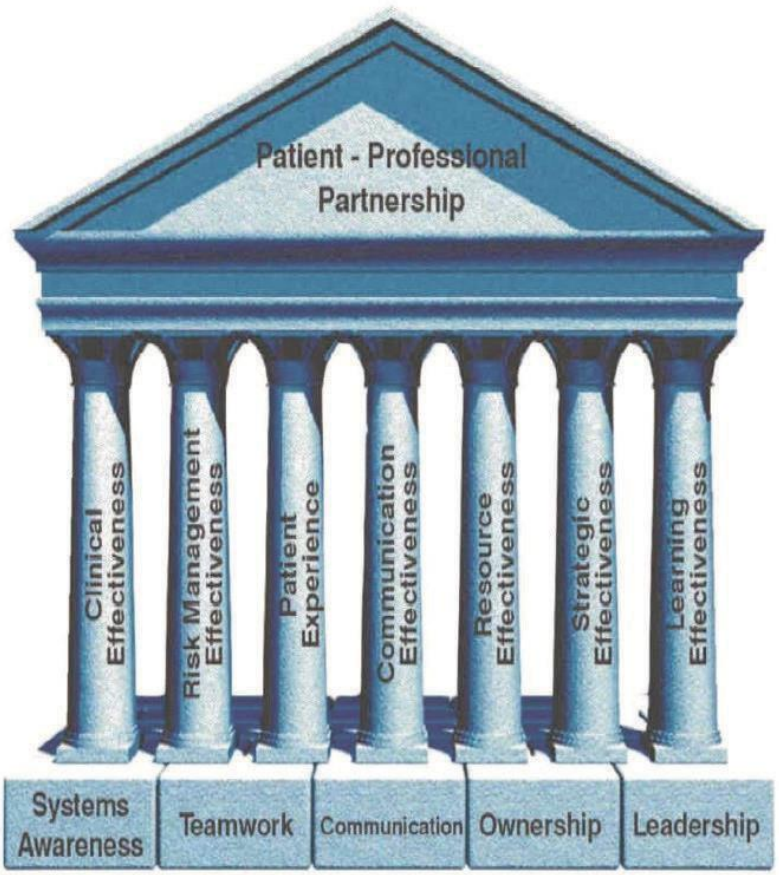
- antipathy (clinical governance is about the control of medical practitioners against their better professional judgement);
- disengagement (clinical governance is nothing more than a label on a set of activities in which medical practitioners engage in any case);
- engagement (medical practitioners as active members of clinical governance and quality improvement programs and teams); and
- ownership (medical practitioners are and should not only be fully engaged in, but leading, clinical governance).

Of these four categories, the least research evidence available is for the fourth category of ownership. This in itself raises questions for RACMA.

3 Clinical Governance Frameworks

Having reviewed the literature, we turn to an examination of extant clinical governance frameworks. The first widely used clinical governance framework was developed within the NHS in the late 1990's [9]. The framework (Figure 5) used the concept of Seven Pillars comprising patient experience, and effectiveness in the clinical area, risk management, communication, resources, strategy, and learning. The pillars rely on the foundations of systems awareness, teamwork, communication, ownership and leadership.

Figure 5: The original NHS clinical governance [9]



Many adaptations of this original model have been developed (see Figures 6-8 for three examples) which introduce concepts such as openness, research and development, clinical audit, education and training, practice standards, clinical measurement, economics, and informatics. Clinical effectiveness and risk management are common features of most of the models that we have reviewed and as noted in the literature review, a greater emphasis on improvement methods and science in the most contemporary models.

Figure 6: Modified version of NHS clinical governance model [123][B23] commonly used in dictionary and Wikipedia descriptions

Figure 7: Clinical governance model from British Association for Applied Nutrition and Nutritional Therapy (BANT) (see: https://bantonline.wordpress.com/category/bant/bant-clinical-governance/)

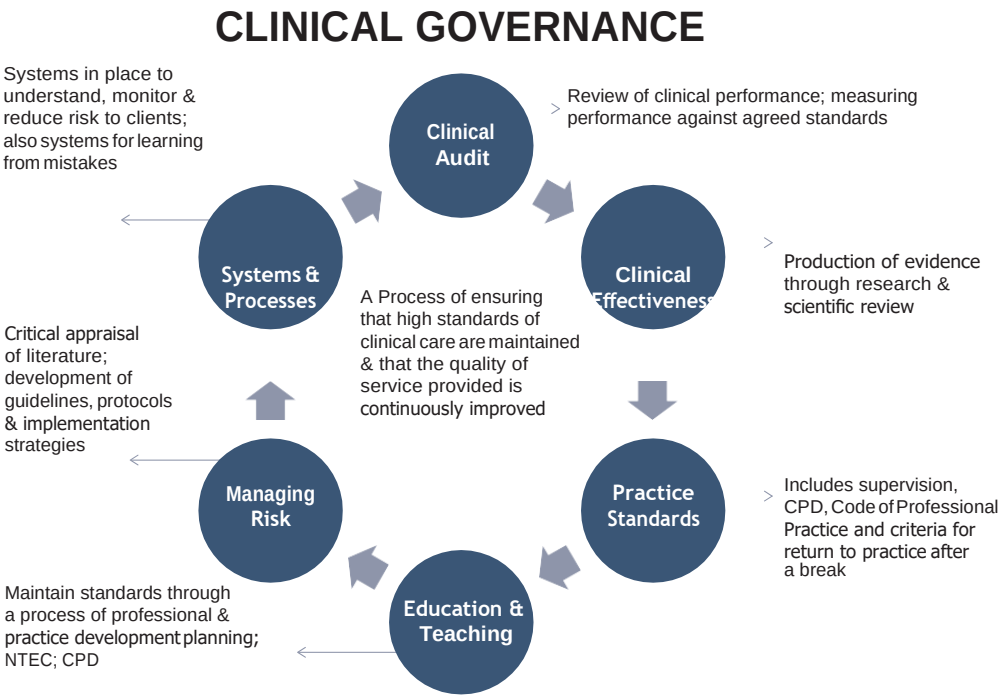
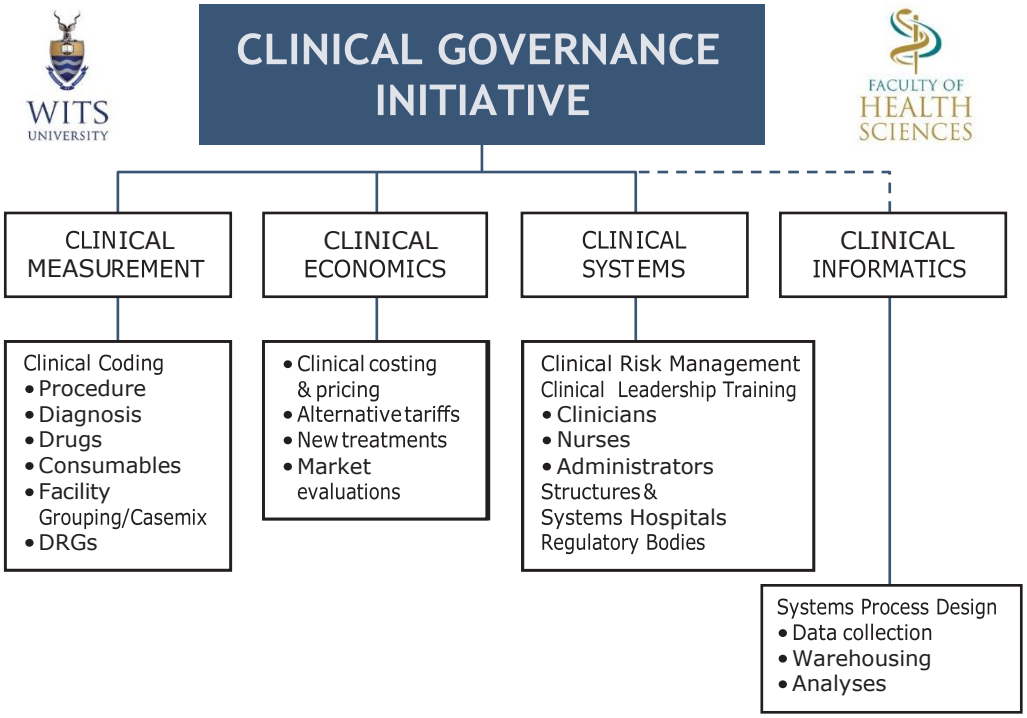


Figure 8: Clinical governance model from University of Witwatersrand (see: https://www.wits.ac.za/health/academic-programmes/short-courses/clinical-governance-initiative/)



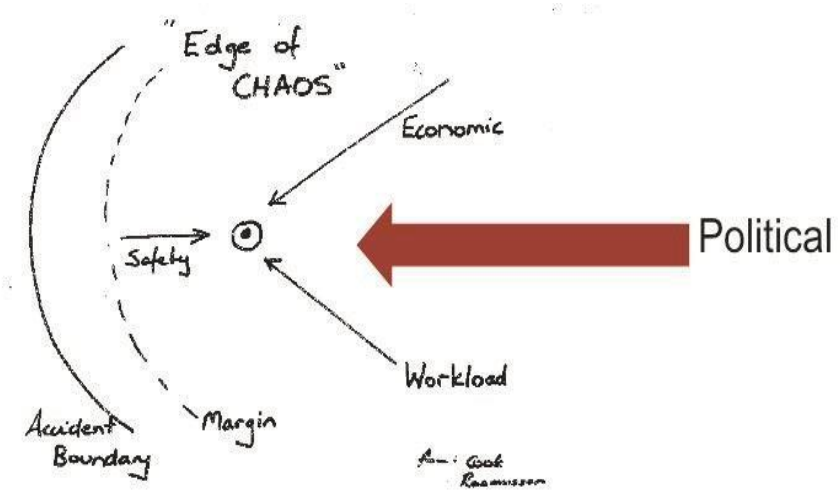
Most frameworks have a similar flavour, and all are derived to one degree or another from the original NHS concept. They take elements of clinical governance, such as risk, effectiveness, patient involvement, and leadership, and map them to the core construct.

4 System thinking underpinning the Framework

As discussed in previous chapters of this report, the concept of clinical governance has evolved to include multiple features [4]. More recently, with recognition of healthcare as a complex adaptive system,[5] clinical governance is beginning to embrace the need for resilient thinking and understanding the differences between work-as-imagined by managers and work-as-done at the frontline of patient care [6]. We believe that this area offers the greatest opportunity for innovation in clinical governance frameworks. The purpose of this chapter is summarise some of the underlying concepts behind complex adaptive systems.

Clinical governance is enacted within a context in which work is constrained by boundaries (see Figure 9). Healthcare professionals must operate within the bounds of safety; regulation, standards and guidelines function to assist clinicians in keeping within this space. On the other side, however, there are opposing pressures (economic, workload, political), demanding that clinicians treat more patients, with fewer resources, and meet government mandated targets. While healthcare professionals are likely to feel most comfortable acting well within these defined boundaries, complex systems [5 124] function most efficiently along the "edge of chaos", thereby allowing hospitals and health organisations to provide cheap, busy, and efficient -- yet safe -- care.

Figure 9: Edge of Chaos (from Cook and Rasmussen [B24][123])



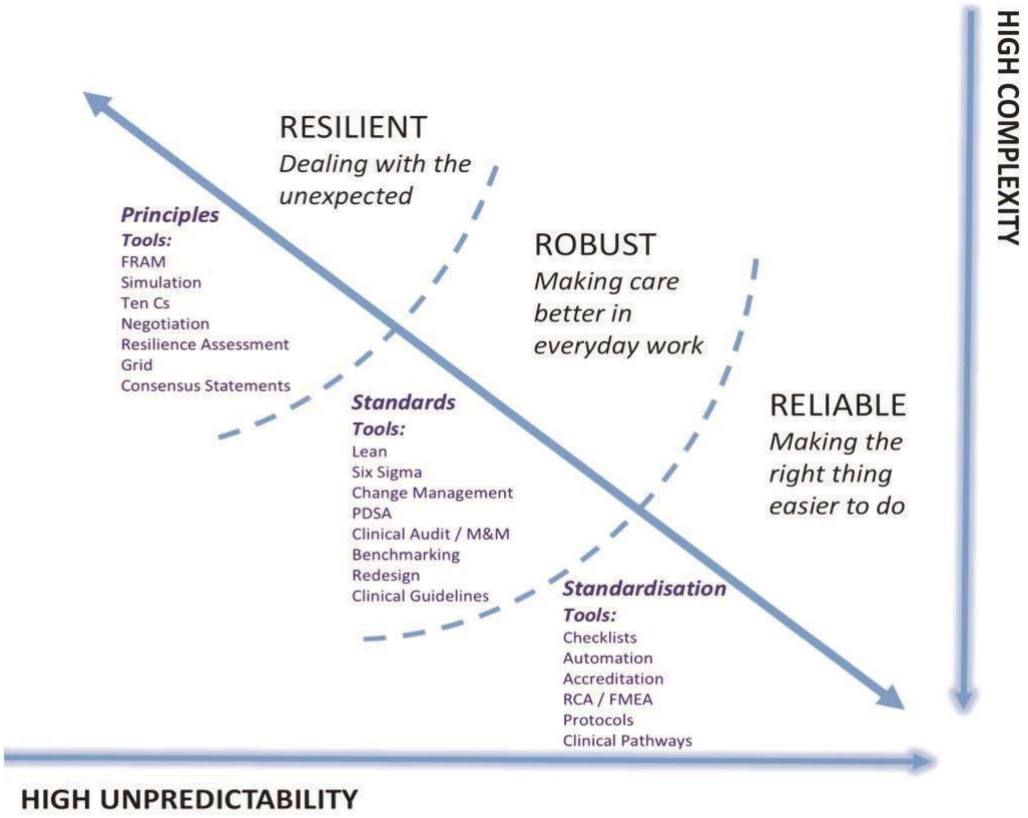
Care delivery also operates within an environment of variability and complexity (see Figure 10). Ideally, we would like to reduce the complexity and variability that we encounter in the workplace as much as possible (illustrated by the direction of the arrows on the axes). In this *reliable* space, where actions result in predictable outcomes, clinicians can employ tools (e.g. Root Cause Analysis, RCA[B25]; Failure Mode Effects Analysis, FMEA[B26]) that constrain variability to great effect.

The *reliable* space forms the structure of clinical work, and underpins safety. Compliance with the National Safety and Quality Health Service (NSQHS[B27]) Standards, strategic planning, credentialing, and other management activities, and preparing for elective surgery, for example, fit within this area. Frequently, however, some variability is essential for clinicians to do their work. In a *robust* space, they must vary their actions where necessary to meet the variable needs of the patient. Here, some reliability tools (e.g. guidelines, checklists) may be less effective, and in

some cases may add unnecessary workload with little discernible benefit. Tools that might be

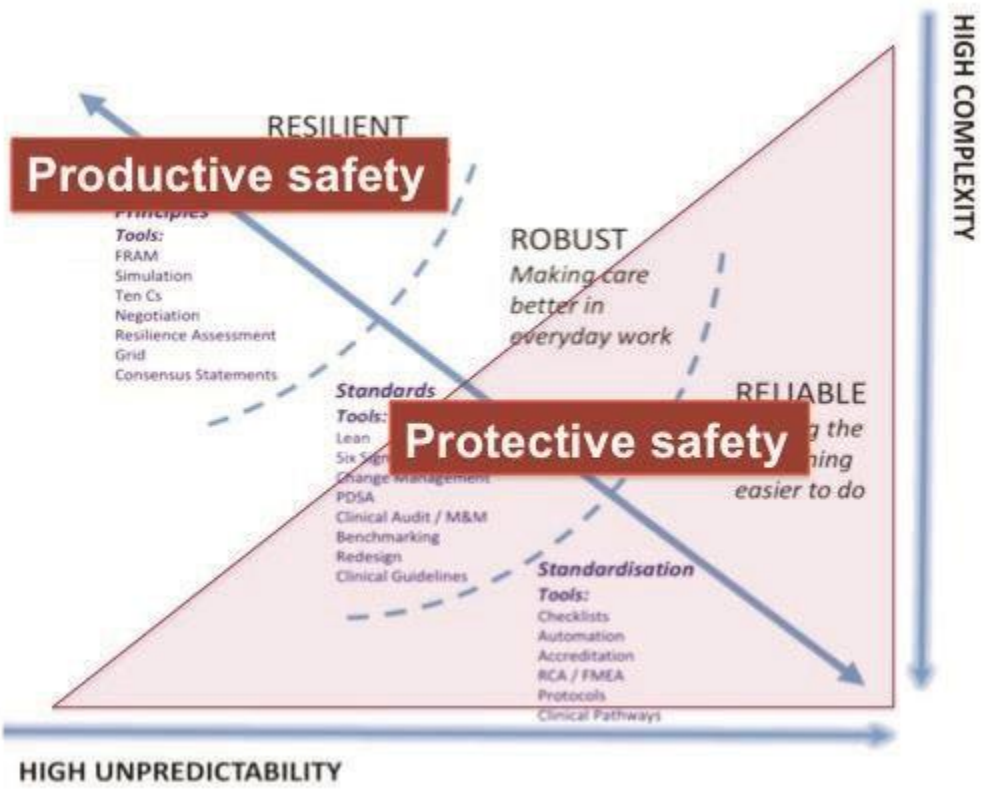
effective in this area include Lean, Plan-Do-Study-Act (PDSA), process improvement tools, and benchmarking. Most everyday clinical work, whether in hospitals or in primary care, fits within this space. As the work situations encountered become more complex and less predictable, standard procedures will not work, and clinicians need to be flexible and *resilient* to cope. Researchers have developed tools that show promise for working in the resilient space, such as Functional Resonance Analysis Method (FRAM) [125] [126], the Resilient Assessment Grid [128], and the TenCs Resilient Behaviour Model [127]. Work in dynamic contexts, such as in Emergency Departments, non-elective surgery, caring for the deteriorating patient, and any time that the patient, the environment, or the work requirements are complex or have multiple players, all fit within this space.

Figure 10: Better[B28] Care Framework (adapted from Johnson, Clay-Williams and Lane)[128]



The context where the most effective methods involve *constraining* variability is termed 'Protective Safety', and that where the most effective methods involve *leveraging* variability is termed 'Productive Safety' (see Figure 11). The characteristics of the Protective Safety space, and the tools required to function successfully here, are sometimes referred to as Safety-I. Similarly, Productive Safety is analogous to Safety-II. The reality of clinical work is dynamic and multifaceted and there are always trade-offs and overlaps. A clinical governance framework needs to afford the opportunity to move between these different spaces and modes of working, as the situation encountered by the clinician demands. The framework must also take into account the multidisciplinary nature of healthcare, and the need for clinicians (doctors, nurses and allied health professionals) and non-clinicians (administrative and other staff) to work in teams to safely care for patients.

Figure 11[B29]: Better Care Framework and Protective/Productive safety (adapted from Johnson, Clay-Williams and Lane)[128]



5 Proposed RACMA Clinical Governance Framework

From the foregoing literature review, assessment of frameworks, interviews and systematic review, we developed a framework for RACMA. The proposed framework (see Figure 12) is situated within the scientific literature, and underpinned by the expert opinion of medical and academic leaders. In contrast to other clinical governance frameworks, many of which are hamstrung by detail and peppered with buzzwords, the RACMA Clinical Governance Framework has three key characteristics:

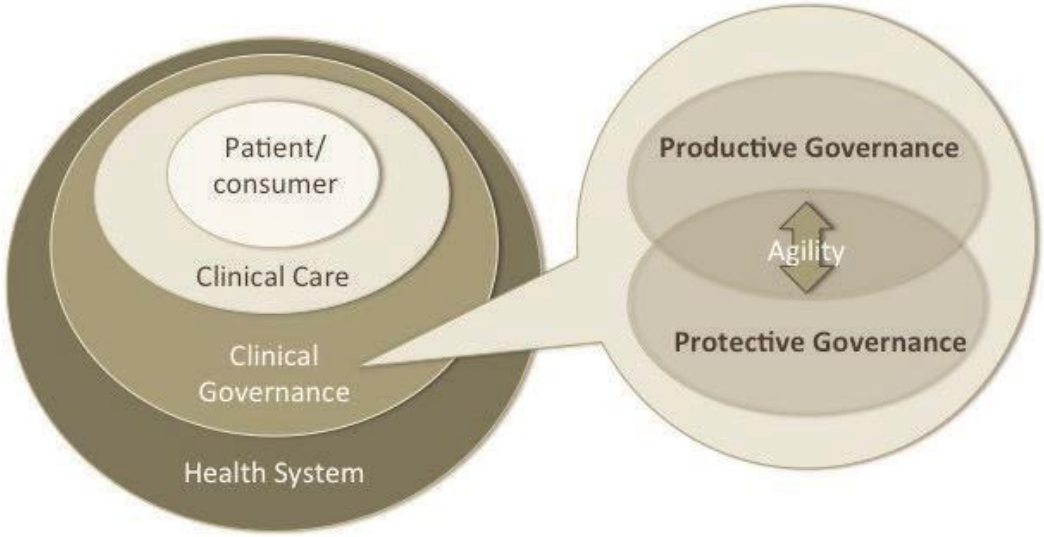
1. The framework is simple and memorable. To align thinking within RACMA, and to enable RACMA Fellows to succinctly explain the principles to others, the framework needs to be simple enough to easily remember, and able to be described in a few sentences (a key goal was to develop a framework that could be sketched 'on the back of an envelope').
2. The framework is flexible. The framework needs to be applicable across a wide variety of healthcare organisations, and able to be easily adapted to meet the needs of medical administrators in a diverse range of roles. Healthcare is dynamic and variable, and the framework needs to allow for growth and change within both RACMA and the Australasian health environment without requiring constant update.
3. The framework is pragmatic. Medical administration has an intensely practical focus, and the framework needs to provide practical guidance that is relevant in day to day healthcare.

At the centre of the framework is the patient or health consumer. Clinical care is wrapped around the patient, illustrating the direct day to day interface between clinician and consumer. Clinical governance supports the clinician and patient, providing quality assurance and quality improvement underpinning effective and efficient care. Clinical governance also sits within the broader healthcare system.

Within clinical governance, there are three main components:

1. 'Protective (accountability) governance[B30]', which consists of the management and administrative processes to reduce variation and assure safety and quality of care.
2. 'Productive (or better care) governance', which consists of the leadership processes to leverage variation and improve safety and quality in a dynamic environment.
3. Agility, which consists of the knowledge to understand whether protective or productive principles are applicable to a context or problem, and the skill to be able to move between the two as the situation demands.

Figure 12[B31]: RACMA Clinical Governance Framework



Clinical Governance: Process to ensure safety and quality of healthcare

Protective Governance: implementing *management or administrative* processes to stop bad things happening

Productive Governance: implementing *leadership* processes to increase the number of things that go right

Within each of the three components, there are a number of domains which are outlined below and in more detail in Tables 2-4.

Protective 'Accountability' Governance: compliance (Refer Table 2)

- Management/administration activities
- Identify/analyse/respond
- Formal mechanisms to reduce variation e.g. lean, six-sigma, wanted and unwanted[B32]
- Regulation, standardisation, quality assurance, risk management
- Data: measurement, metrics, validated tools
- E.g. accreditation, audit, credentialing, dealing with complaints, disclosure
- Managing change

Productive 'Better Care' Governance: (Refer Table 3)

- Leadership activities
- Mechanisms to embrace/leverage variation
- Promotion, advocating, inspire, inform, transformation
- Communication, negotiation, conflict resolution
- Leading change
- Learning

Agility: (Refer Table 4)

- Understanding healthcare as a complex adaptive system
- Ability to move between, or incorporate elements of, protective and productive governance depending on the needs of the emerging situation
- Ability to develop and apply strategic and tactical methods

The competencies in each table are divided into Knowledge (K), Skills (S) and Attitudes (A). These were identified through the literature search and interviews. As such, the are currently indicative only, and need validation.

Table 2: Protective 'Accountability' Governance

Protective governance: is the implementation of management or administrative processes to reduce variations and errors. This requires the ability to:	
Undertake management or administrative activities in relation to clinical governance	Develop expert knowledge of the managerial, legal and systems requirements of clinical governance (K) Identify and utilise best available evidence the management of clinical governance processes and procedures (S) Ensure appropriate structures to enable the active engagement of the community, clients/patients, carers and families in the process of care (S) Identify and respond to the factors which impede clinician and staff engagement with clinical governance strategies, approaches and mechanisms (K) Manage resources (financial and human) and assist in the alignment of financial incentives with quality and safety and Patient Reported Outcome Measures (PROMS) (K) Build relationships with other strategic systems and organisational partners (S)
Identify, analyse and respond to risks and threats to the quality and safety of care	Identify latent and emerging organisational factors which contribute to the risk of harm (S) Undertake investigations into the quality and safety of care (S) Utilise clinical audit and related processes as a way of identifying risks (S) Continually critically assess activities in terms of patient benefit (A) Engage clinicians and staff in the design and development of technology to identify and respond to risks (S) Communicate and escalate risks in a timely and appropriate manner (S) Support research to identify and respond to threats, and to improve care (A)
Utilise formal mechanisms	Develop expert knowledge of tools and mechanisms to reduce

Protective governance: is the implementation of management or administrative processes to reduce variations and errors. This requires the ability to:

[B33]

to reduce variation	variation (eg lean, six sigma, wanted and unwanted[B34]) (K) Develop expert knowledge of guidelines to manage unjustifiable variations in the cost and quality of care (K) Engage clinicians and staff in the implementation and use of guidelines (S) Choose appropriate tools to identify and address specific variations within and within and across practices and services (including early warnings) (K) Contribute to the development and implementation of continuous quality improvement approaches (K) Undertake performance reviews (S)
Support regulation, standardisation, quality assurance and risk management strategies and mechanisms	Create and or support the relevant structures to manage risk and performance and improve quality and safety (S) Ensure that self, clinician and staff performance is monitored in relation quality and safety of care and that any issues are addressed as early as possible (S) Support transparency and accountability in line with regulatory and professional requirements (A) Ensure that accountability for clinical governance is acknowledged by clinicians and staff (S)
Utilise data including measurement, metrics, validated tools	Develop expert knowledge of quality and safety data tools including accreditation, audit and credentialing (K) Address individual patient and community complaints utilizing the principles transparency and full disclosure (S) Identify patterns and early warnings of systematic issues through analysis of patient and community complaints (S) Actively lead accreditation and auditing processes (S) Communicate indicators (including clinical governance reports) and their implications and evaluate the impact of this communication (S) Create and or support the effective use of data, knowledge and expertise exchange strategies (S)
Managing change	Analyse and address the specific cultural context within which change is to occur (S)
Protective governance: is the implementation of management or administrative processes to reduce variations and errors. This requires the ability to:[B35]	

	Identify and appropriately respond to cultural factors influencing resistance or acceptance of systems, service or professional change (S) Model and support a workplace culture and workplace behaviour that values, enacts supports and sustains the principles of clinical governance (A)

Table 3: Productive 'Better Care' Governance

Productive governance: is the implementation of leadership processes to improve quality and safety of care. This requires the ability to:	
Display leadership capabilities and capacity	Demonstrate leadership in clinical governance across the profession, health systems, services and the community (S) Support and develop Board and managerial expertise in clinical governance issues (S) Communicate the expectations and implications of clinical governance strategies, approaches and activities (S) Actively engage the community, clients/patients, carers and families in the process of care (S) Develop self and clinician awareness of the role of medical practitioners in clinical governance strategies, approaches and mechanisms as individuals and as supervisors (A) Demonstrate the vision and capacity to champion clinical governance (S) Display informed ethical influence (S) Build clinical governance leadership governance capacity in other clinicians and staff (S)
Utilise mechanisms to embrace and leverage variation	Develop an understanding of health care as a dynamic system (K) Describe how complexity and variation can be leveraged to improve system performance and safety (K) Actively link corporate and clinical governance communication and improvement processes (S) Identify and address issues and solve problems relating to clinical governance (S)

Productive governance: is the implementation of leadership processes to improve quality and safety of care. This requires the ability to:

[B36]

	Describe the importance of encouraging diversity in teams to deal complexity (A) Describe importance of slack and redundancy, and how they may be applied to assure safety in a dynamic system (K) Utilise 'positive deviants' to improve system performance (S) Implement dynamic methods to detect when variation exceeds productive levels (S)
Promote, advocate, inspire, inform, transform health systems and services in accordance with clinical governance principles	Create relationships and the sharing of power across professionals in accordance with best practice approaches to clinical governance and clinical care (S) Promote patient centred care (S) Promote and coordinate efforts to ensure that goals of clinical governance to reduce risk to patients, improve clinical outcomes and improve patient experience are achieved (S) Actively advocate for and champion clinical governance and quality improvement (A) Participate in local, national and international quality and safety committees and organisations (A) Coach, support and nurture the clinical governance capabilities of clinicians and staff (S) Act as clinical governance experts for other Colleges, systems and services (S) Provide expert input into patient safety inquiries (K)
Communicate, negotiate and manage conflict resolution	Analyse how power works within the healthcare system (K) Utilise power judiciously and ethically to improve the quality and safety of care and to reduce harm (S) Promote and support teamwork (S) Describe negotiation styles of self and others (K) Demonstrate skill in negotiation at multiple levels (S) Describe a range of conflict resolution methods and their appropriate utilisation (S) Demonstrate skill in conflict resolution between staff, and between staff and patients/carers (S)
Productive governance: is the implementation of leadership processes to improve quality and safety of care. This requires the ability to:[B37]	

Lead change	Model and support positive attitudes to change and change management (A) Acknowledge and address difficulties associated with multiple and long-term change strategies (S) Recognise and respond to the challenges of an ongoing commitment to quality and safety (A) Present clinical governance activities in terms of patient benefits (S)
Undertake and support lifelong learning	Develop expert knowledge and utilisation of multifaceted strategies to support learning about clinical governance and its associated issues (K) Develop expertise in innovative educational and training techniques related to clinical governance (K) Contribute to research in evidence based practice in clinical governance (K) Engage clinicians and staff in the bottom-up clinical governance, ownership, teamwork, learning from mistakes and feedback (S) Undertake a Safety 2/[B38]appreciative inquiry approach to learning from positive as well as negative outcomes (S)

Table 4: Agility

Agility: is the decision making process by which RACMA Fellows choose to action elements of productive and or proactive governance. This requires the ability to:	
Comprehend the implications of healthcare as a complex adaptive System	Explain how clinical governance is located within the complex adaptive system that is healthcare (K) Identify and explain the implications of a systems perspective of healthcare for clinical governance (K) Apply complexity and systems thinking (S) Address the argument for resilient thinking in clinical governance (K) Describe and address the differences between work-as-imagined by managers and work-as-done on frontline Patient care (K)

Agility: is the decision making process by which RACMA Fellows choose to action elements of productive and or proactive governance. This requires the ability to:[B39]	

Move between, or incorporate elements of, protective and productive governance depending on the needs of the emerging situation	Acknowledge and address the tension between the potential of clinical governance and its actual or intended impact on individuals and services (S) Acknowledge and address scepticism about and resistance to clinical governance and its elements (S) Manage tensions relating to the strategies, approaches and mechanisms associated with clinical governance (S) Describe protective governance methods and when to apply productive governance methods to a problem (K) Demonstrate appropriate application of protective and productive governance (S)
Develop and apply strategic and tactical methods	Support approaches that demonstrate clinical governance and self-regulation are compatible and reinforce each other (A) Work across systems, services and boundaries to promote and ensure the quality and safety of individuals throughout their patient journey (S) Demonstrate personal agility, flexibility and adaptability and support the development of these skills in others (S) Implement methods to monitor and feedback system performance at multiple levels (S)

6 Clinical Governance Training Framework

When considering the RACMA clinical governance training framework, four factors come into play these are:

1) what[B40] specifically does RACMA propose that Fellows are to be experts in?

2) what are the tensions inherent in the way in which clinical governance is understood and enacted and how might that affect the training of RACMA Fellows?

3) what is the most effective way for Fellows to gain clinical governance expertise? And

4) what are the critical core clinical governance competencies where RACMA Candidates must demonstrate competence to be awarded a Fellowship?

What is required of RACMA Fellows?

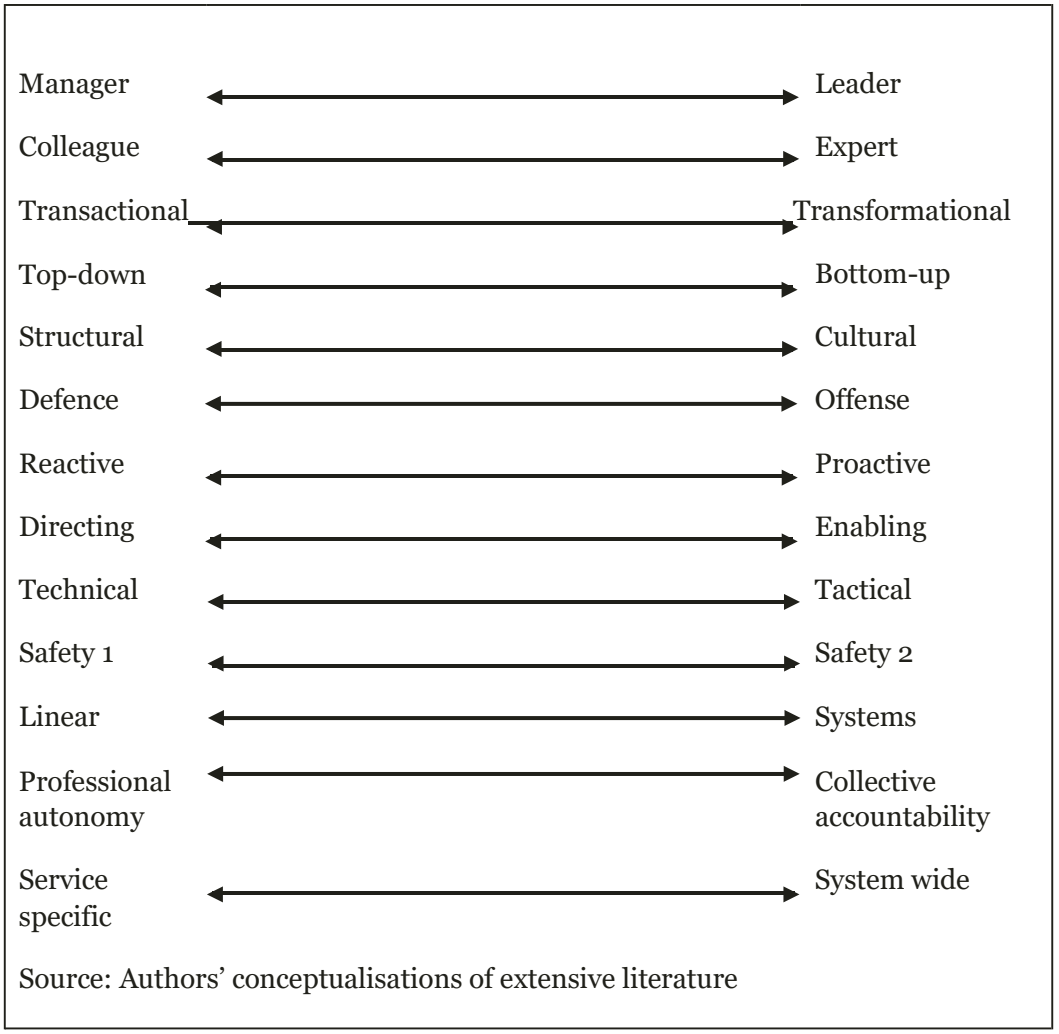
The tables presented in chapter 5 form a proposed list, subject to refinement, of the capabilities required by RACMA Fellows in relation to clinical governance as a whole. The literature review and interviews with Fellows indicated that expertise in the field of clinical governance essentially requires four building blocks of knowledge, skills and attributes/attitudes (KSAs): (1) theories, evidence and tools associated with clinical governance and each of its component elements; (2) an understanding of the complex adaptive nature of healthcare systems and the implications of these for clinical governance strategies, approaches and mechanisms; (3) the ability to engage others in the vision and processes of clinical governance, that is the ability to act as a leader; and (4) the ability to manage change, including the cost of change, for individuals and organisations.

In addition to these four building blocks there remains a deeper issue. Interviewees spoke of the need for RACMA itself to define clinical governance (in the absence of consistent definitions or understandings). This then leads to questions about how RACMA will determine what elements it will choose to include or exclude as part of the clinical governance model it promotes and how (or if) the clinical governance framework will be integrated with the broader RACMA competencies required of Fellows.

What are the tensions inherent in clinical governance?

Our research identified a number of tensions in the discourse around clinical governance. These tensions or challenges provide insight into the complex work required by RACMA Fellows engaging as experts with the clinical governance agenda. The notion of agility within the competency training framework recognises that for RACMA Fellows wanting to take up this role, a position of ‘either or’ is not an option – rather, they need to be adept in both. These tensions, when fully explored, may provide a useful self- assessment tool for RACMA Fellows in identifying current strengths and areas for development. Figure 12 on page 22 outlines these tensions.

Figure 12: Challenges in clinical governance leadership



What is the most effective way for Fellows to gain clinical governance expertise?

As part of the interviews with RACMA Fellows participants were asked about the training of RACMA Fellows in clinical governance. The general consensus with regards to content is reflected in the framework and competencies in Tables 2, 3 and 4. In relation to training and development techniques, participants indicated a need for:

- A graduated approach to training, entering the training system at a point appropriate to level of KSAs demonstrated by the Candidate
- Standardisation of training content and approaches
- Development of skills and techniques toolboxes
- Joint multidisciplinary training including potentially opening up Associated Fellowships to other disciplines
- Joint training with postgraduate providers
- Experimental methods of discovery and learning
- Safe simulation environment for training
- The use of RACMA Forums as a conduit for skills and knowledge development
- Use of case studies
- Rigorous exam and log book assessments
- 360 degree assessments

- Use of clinical governance and quality improvement projects for assessment.

In addition to the findings of the interviews, the literature on assessment of competencies for medical practitioners provides insights into additional questions around skills development in this field. The first is the question of which competencies should be required of which individuals at what point in their progress as a RACMA Fellow and practitioner: in other words, are all clinical governance competencies to be required of all RACMA Fellows? Are they to demonstrate full competency at the end of their Fellowships or will there be a process of developmental milestones [131]? Novices, for example, may be able to understand the system in which clinical governance must function, including how the requirements might change depending on the complexity and predictability of the context or problem. They might have practical ability to apply one or two tools in each of protective and productive safety spaces. In contrast, an expert might not only have an in-depth knowledge of a number of appropriate tools, when to apply them, and also the ability to adapt quickly to changing circumstances and move with agility between the spaces. An expert would also be able to teach and mentor others in applying clinical governance in the workplace.

Second, what learning mechanisms and opportunities will best ensure Fellows have the opportunity to both develop the competencies associated with clinical governance and to demonstrate them [132]? Finally, what type(s) of assessment processes should be used over what time, this is particularly pertinent because clinical governance is a multifaceted construct, and as indicated by the challenges identified in Figure 12 on page 30, assessment processes need to be sensitive enough to address the intrinsic complexity in this field [133][B41].

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8 Appendix A: Leximancer Tables

Table 1: Key themes within the clinical governance literature from 1995 - (February) 2017

Theme	Connectivity
Care	100%
Clinical	79%
Review	43%
Study	41%
Treatment	29%
Patients	24%

Table 2: Key concepts within the clinical governance literature from 1995 - (February) 2017

Concept	Count	Relevance
Clinical	7041[B46]	100%
Governance	7019	100%
Care	4861	69%
Patients	3312	47%
Health	3028	43%
Quality	2666	38%
Practice	2383	34%
Study	2182	31%
Patient	2171	31%
Review	2146	30%
Data	1835	26%
Management	1782	25%
Service	1729	25%
Use	1688	24%
Audit	1681	24%
Hospital	1659	24%

Concept	Count	Relevance
paper	1595	23%

research	1533	22%
services	1492	21%
approach	1487	21%
used	1474	21%
medical	1411	20%
risk	1357	19%
process	1237	18%
healthcare	1223	17%
information	1208	17%
development	1175	17%
using	1159	16%
evidence	1148	16%
system	1140	16%
analysis	1099	16%
significant	1058	15%
training	1057	15%
treatment	1043	15%
support	1034	15%
guidelines	1029	15%
implementation	1005	14%
safety	986	14%
results	985	14%
role	961	14%
time	935	13%
studies	914	13%
nursing	899	13%
hospitals	893	13%

Concept [B47]	Count	Relevance
model	854	12%

NHS	829	12%
local	826	12%
nurses	809	11%
Clinical	807	11%
public	796	11%
group	741	11%
adverse	739	10%
included	737	10%
value	710	10%
surgery	708	10%
UK	780	11%
associated	683	10%
control	679	10%
during	670	10%
article	658	9%
disease	642	9%
available	640	9%
cases	631	9%
cancer	617	9%
rate	581	8%
surgical	570	8%
medicine	566	8%
increased	564	8%
rates	558	8%
period	536	8%
year	520	7%
mortality	495	7%
Concept [B48]	**Count**	**Relevance**
performed	489	7%
total	475	7%

placebo	461	7%
children	449	6%
women	437	6%
therapy	426	6%
blood	387	5%
months	384	5%
units	372	5%
age	286	4%

Table 3: Key themes within the clinical governance literature from 2012 - (February) 2017

Theme	Connectivity
clinical	100%
study	43%
health	43%
research	43%
patient	42%
audit	27%
patients	25%
risk	16%
included	13%
compared	10%

Table 4: Key concepts within the clinical governance literature from 2012 - (February) 2017

Concept	Count	Relevance
clinical	2462	100%

Concept [B49]	Count	Relevance
care	1790	73%
governance	1784	72%
patients	1645	67%

health	1353	55%
study	1189	48%
patient	1147	47%
quality	1126	46%
practice	899	37%
data	885	36%
review	753	31%
management	732	30%
service	730	30%
hospital	712	29%
use	702	29%
research	687	28%
used	636	26%
audit	620	25%
approach	618	25%
services	613	25%
healthcare	573	23%
medical	568	23%
paper	557	23%
using	535	22%
analysis	528	21%
process	504	20%
improve	496	20%
system	477	19%
results	476	19%

Concept [B50]	Count	Relevance
risk	468	19%
safety	467	19%
training	467	19%

information	466	19%
staff	465	19%
improvement	461	19%
hospitals	424	17%
support	421	17%
identified	419	17%
evidence	413	17%
significant	405	16%
treatment	404	16%
studies	392	16%
role	391	16%
time	388	16%
development	387	16%
model	370	15%
included	359	15%
factors	351	14%
guidelines	350	14%
effective	347	14%
value	340	14%
primary	339	14%
public	335	14%
based	331	13%
knowledge	325	13%
literature	324	13%
surgery	313	13%

Concept[B51]	Count	Relevance
experience	306	12%
cases	300	12%
professionals	295	12%

associated	294	12%
professional	293	12%
compared	291	12%
nursing	287	12%
different	287	12%
assessment	279	11%
including	278	11%
impact	278	11%
rate	275	11%
team	272	11%
UK	274	11%
reported	266	11%
during	264	11%
local	260	11%
case	259	11%
group	244	10%
total	244	10%
needs	243	10%
developed	236	10%
conducted	232	9%
performed	231	9%
appropriate	226	9%
article	224	9%
cancer	224	9%
following	215	9%
Concept [B52]	**Count**	**Relevance**
available	207	8%
project	206	8%
practices	197	8%
people	196	8%

period	195	8%
disease	184	7%
year	182	7%
blood	178	7%
children	164	7%
age	136	6%

Table 5: Key themes within the clinical governance literature relating to medical practitioners

Theme	Connectivity
clinical	100%
care	85%
patient	51%
study	32%
hospital	28%
data	23%
including	16%
patients	15%
guidelines	13%
time	8%
medicine	3%
rate	2%

Table 6: Key concepts within the clinical governance literature relating to medical practitioners

Concept [B53]	Count	Relevance

Concept	Count	Relevance
clinical	1537	100%
governance	1382	90%
care	1066	69%
primary	1035	67%
patients	758	49%

practice	630	41%
patient	603	39%
quality	584	38%
health	544	35%
doctors	473	31%
study	458	30%
medical	457	30%
management	426	28%
general	386	25%
audit	371	24%
hospital	343	22%
use	341	22%
data	330	21%
training	318	21%
service	276	18%
used	263	17%
information	259	17%
review	259	17%
guidelines	255	17%
approach	254	17%
services	252	16%
improvement	250	16%
practitioners	241	16%

Concept [B54]	Count	Relevance
staff	241	16%
using	235	15%
paper	232	15%
process	232	15%
research	222	14%

system	218	14%
development	217	14%
prescribing	215	14%
role	213	14%
healthcare	210	14%
improve	209	14%
time	207	13%
professional	202	13%
results	200	13%
nurses	199	13%
support	196	13%
hospitals	195	13%
UK	195	13%
important	188	12%
implementation	185	12%
evidence	181	12%
physicians	179	12%
safety	177	12%
NHS	175	11%
effective	174	11%
significant	173	11%
education	172	11%
Clinical	166	11%

Concept [B55]	Count	Relevance
analysis	165	11%
identified	162	11%
current	161	10%
work	161	10%
risk	160	10%

survey	159	10%
Gps	156	10%
standards	154	10%
professionals	151	10%
practices	151	10%
national	151	10%
assessment	151	10%
change	148	10%
outcomes	146	9%
issues	146	9%
medicine	145	9%
performance	144	9%
knowledge	144	9%
impact	143	9%
appropriate	140	9%
treatment	140	9%
including	139	9%
based	138	9%
local	135	9%
group	134	9%
team	134	9%
provide	129	8%
public	128	8%

Concept [B56]	Count	Relevance
model	126	8%
disease	124	8%
groups	123	8%
value	121	8%
included	120	8%

needs	119	8%
working	118	8%
during	117	8%
different	115	7%
emergency	115	7%
policy	114	7%
rate	114	7%
doctor	112	7%
aim	111	7%
key	110	7%
case	106	7%
compared	105	7%
delivery	103	7%
studies	103	7%
cases	103	7%
questionnaire	102	7%
GP	101	7%
developed	101	7%
report	101	7%
areas	100	7%
order	98	6%
following	90	6%
period	89	6%

Concept [B57]	Count	Relevance
access	85	6%
conducted	85	6%
community	81	5%
children	75	5%
age	54	4%

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