

Improving Quality through Clinical Governance in Primary Health Care

Report of a systematic review
addressing drivers for quality in primary
health care

APHCRI Stream 13

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CHAPTER 1

INTRODUCTION

The review outlined in this report is part of Stream 13 of the work plan of the Australian Primary Health Care Research Institute (APHCRI), examining what is known about drivers of successful primary health care. This review examines a potentially important driver of successful primary health care quality in Australia: **clinical governance** as a strategy for simplifying, consolidating and improving the efficiency of activities to improve primary health care.

CLINICAL GOVERNANCE

In Australia in recent years there have been highly publicised failures of the health care system. While these have been largely confined to the hospital sector, failures in quality and safety are an unfortunate reality in Australian primary care as they are in the wider health sector. Makeham et al¹ found that when an anonymous, voluntary reporting system is used, one error is reported for every 1000 Medicare items billed by GPs. In a study of 805 adverse events in general practice reported by 324 GPs, 76% of the incidents were considered preventable, with major contributing factors being poor communication, the actions of others, lack of continuity and errors in judgement².

The term 'clinical governance' was initially used to describe a system through which National Health Service (NHS) organisations in the UK are held accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care can flourish³. Clinical governance was introduced to "consolidate, codify and universalize often fragmented policies and approaches" to clinical care⁴, partly in response to high profile health system failures such as Bristol Royal Infirmary and the Shipman cases⁵. It emphasises accountability and responsibility at specified levels of the health organisation. Most importantly, the introduction of clinical governance gives extra credence to the ideal of clinical excellence commonly sought by clinicians⁴. In the UK clinical governance is a statutory responsibility of NHS organisations, equalizing emphasis on clinical outcomes alongside fiscal and organisational ones. With respect to primary care services, clinical governance likewise became a statutory responsibility when general practices were incorporated into local primary care groups as part of NHS reform in 1999⁶.

Clinical governance has been defined as

"a systematic and integrated approach to assurance and review of clinical responsibility and accountability that improves quality and safety resulting in optimal patient outcomes"⁷.

There is a multitude of evidence that clinicians and health care organisations actively pursue professional development, evidence-based practice, quality improvement initiatives and risk management strategies. Unfortunately, these have often grown in a disjointed and sketchy fashion to resemble a 'quality jigsaw'⁷. Clinical governance foregrounds an approach to leadership, which seeks to tackle barriers by bringing apparently disparate quality activities together under a single umbrella and adopting an overtly strategic approach⁸.

CLINICAL GOVERNANCE IN AUSTRALIA

Interest in clinical governance as an approach to streamlining, standardizing and organising quality improvement initiatives began to spread beyond Britain in the early 2000's. This coincided with an increasing interest in quality processes demonstrated in the USA by health care organisations such as Kaiser Permanente in California⁸. At this time countries such as Australia and New Zealand began exploring clinical governance as a mechanism for health system change.

The term came to denote various mechanisms of quality review or enhancement, as it moved beyond its specific statutory meaning. Occasionally, the term was interpreted as denoting “governance *by* clinicians or governance *of* clinicians”⁹, generating tensions around its use and implementation.

In Australia, most work on clinical governance has occurred within the acute public health sector¹⁰, and numerous States have adopted approaches to clinical governance within hospitals. Much of the published international literature addressing clinical governance has focused on larger institutions, or on primary care sectors with structural links between general practice and various jurisdictional aspects of the health system. Clinical governance within Australian primary care sector is undeveloped, and rarely described, despite widespread discourse about quality and safety in the health system¹¹, and specific initiatives targeting general practice quality^{12 13 14 15}. Localised efforts have been documented in community based primary care services¹⁶, but these remain distinct from general practice based primary care delivery.

There are as yet no published reviews on the relevance of clinical governance initiatives from other countries for the Australian primary care sector.

CHALLENGES IN PRIMARY CARE

In Australia, the general practice sector is changing rapidly - with changes in practice size, changing staffing configurations, an increase in part-time workers and female doctors, and evolving business structures and funding models. At the same time there is a growing emphasis on the development of multidisciplinary primary care teams and collaborative models of care - factors which reinforce the need for an organisational focus. This need to develop an organisational identity is often challenging and may be perceived as threatening by those general practices that have historically functioned as a series of owner operated small businesses (the majority).

Unlike other countries, Australian general practices are generally connected to one another only through voluntary, collegiate relationships. There are no hierarchical relationships between general practice and fundholders or reporting bodies. Participation in quality activities, including compliance with professional standards, is also voluntary. Few general practices have experience in variable funding arrangements or financing structures which entail governance mechanisms. While there are examples of financial incentives directed at quality measures¹⁷, these are fragmented and limited by structural requirements. As a result, lines of accountability are limited, with many GPs perceiving they are accountable only to patients – a view reinforced by a single fee-for-service funding model, underpinned by a universal patient insurance scheme. While general practice is federally and privately funded, there are discrepancies between States in the relationships with state-funded public primary care services, meaning that integration and collaboration arrangements are highly variable, often ad hoc, and difficult to describe or measure.

SAFETY & QUALITY & THE REFORM AGENDA

Quality and safety have become an increasing focus of funders and the community, evidenced by the creation of bodies such as the Australian Commission on Safety & Quality in Healthcare (ACQSHC), which has an evolving interest in primary care settings¹⁸. A series of key reform documents has recently been released in Australia^{19 20}, most notably the Report of the National Health & Hospitals Reform Commission²¹ (NHHRC), which called for the establishment of Comprehensive Primary Care Centres and recommended that Divisions of General Practice evolve into Primary Health Care Organisations with more formalised structures and responsibilities. These strategies both create and imply the need for more comprehensive clinical governance. The NHHRC has also recommended that the ACQSHC become a national independent body, which would provide a clearer structure for setting and monitoring clinical standards.

As interest in health care quality and safety strengthens and the health care reform agenda in this country takes shape, pressure will mount on general practice and primary care organisations to demonstrate their commitment to achieving and sustaining high quality in care delivery, and

substantiate this with outcomes. At the same time, growing team size will necessitate structures and systems to articulate and coordinate standards of care delivery, and the expansion of different funding models may create greater demands for accountability.

There is a body of literature on organisational development as a means of changing the culture of (usually large) health institutions. However, in Australia general practices tend to be small businesses staffed by independent contractors, with flat, entrepreneurial staffing structures²². In addition they are highly influenced by health care policy initiatives enacted through the Medicare Benefits Schedule, and are usually very responsive to local contextual stimuli. We characterize general practices as micro-cultures that operate in a changing environment. Quality initiatives are often formulated in response to regulatory and funding drivers that arise from outside the practices' micro-culture. For example, the Australian General Practice Nursing Study²³ found that practice accreditation and occupational health and safety are the most frequently cited quality and safety initiatives undertaken by practice teams, despite strong valorised notions of quality care arising from patient / clinician relationship.

System fragmentation is one of the challenges of the primary care sector internationally, and has led some to worry that good clinical governance, especially in primary care, may not be measurable, and that clinical governance policies are developed a priori, rather than from evidence²⁴. This review seeks to inform this debate by determining what clinical governance structures are most suited to, and likely to be successful in, Australia.

IMPLICATIONS AND OPPORTUNITIES

Clinical governance is essentially an organisational concept^{6 12 25}. It provides an opportunity for general practice and other primary care organisations to develop and channel their capacity to promote, maintain and improve quality. A defining feature of clinical governance is the notion of **reciprocal accountability**¹⁰: managers and funders for clinical outcomes affected by their administrative and resource allocation decisions, and clinicians for the fiscal outcomes of the clinical decisions they make.

Data systems to support clinical governance have the potential to generate new understandings of disease and redefine 'quality' through their capacity to collect, organize and manipulate routinely collected data. An example of this is the reframing of chronic kidney disease as a primary care priority in the UK²⁶. Chronic kidney disease had previously been conceptualized as a condition identified, monitored and treated in tertiary care settings. With the aid of routine primary care information systems, the extent of chronic kidney disease was identified, redefined and developed as an area predominantly managed in primary care.

Electronic technologies are likely to be a key feature of any feasible model, due to the dependence on monitoring and reporting capabilities, and the requirement in many systems for sharing of information between institutions and health care settings.

STUDY RATIONALE & AIMS

This is a realistic review exploring the applicability of clinical governance as a driver for successful quality initiatives in Australian primary care, the types of clinical governance models that are most suited to Australia, and the barriers to uptake. In particular, it focuses on policy levers at the levels of general practice, educational and professional regulation and health funding

Clinical governance would be impossible to study using traditional evidence-gathering designs such as randomised controlled trials. There is more research into the effectiveness of tools used for assessing clinical effectiveness, such as audit, mortality review, Continuing Medical Education, and Accreditation than there is into the drivers that lead practitioners to engage in clinical governance.

Specific research questions for the review are:

1. What clinical governance models are most suited to the Australian primary health care context?
2. How do different clinical governance models in primary care impact upon different dimensions of quality of care?
3. What clinical governance models are most appropriate for rural/remote or indigenous settings?
4. What policies will drive the uptake of clinical governance in Australia?

STRUCTURE OF THIS REPORT

Chapter Two outlines the review methods, including the conceptual development of synoptic models of clinical governance to guide sourcing, screening and interrogation of the literature. Chapter Three provides an overview of the literature, study types and quality. Chapter Four describes the orientation of different clinical governance literature, analyses and summarises various models. Chapter Five explores the potential of information technologies in clinical governance, including the potential for soft governance approaches, and Chapter Six proposes a series of policy options for introducing clinical governance to Australian primary care.

CHAPTER 2

METHODS

This review was undertaken in three phases. In the first phase, a conceptual model of clinical governance was developed to guide the systematic search process. In the second data collection phase, published and grey literature was interrogated and then evaluated within a framework articulated through the conceptual model; interviews with Australian and international key informants were conducted to determine points of relevance and contextual drivers and barriers; and an online survey of Australian stakeholders was conducted to identify perceptions and expectations. In the third analytical phase we developed a range of models from our data which we feel are plausible mechanisms for engaging with and ultimately embedding clinical governance into the Australian primary care context²⁷.

PHASE 1: A CONCEPTUAL MODEL OF CLINICAL GOVERNANCE

Earp and Ennett²⁸ argue that the development of conceptual models is critical for clarifying research questions, forming hypotheses, and ensuring that the right targets for intervention are available for policy makers. This study commenced by clarifying terminology through the development of a conceptual model.

To develop the conceptual model of clinical governance, we undertook a review of health policy in Australia, the UK and New Zealand on clinical governance. These three countries were chosen because each has operationalised clinical governance in ways that were intended to highlight its purpose and constitutive elements. We also reviewed the scene-setting papers on clinical governance referred to in those policy documents^{3 4 5 29 30}, and in the position documents on systematised quality approaches in health care in the USA.³¹

The conceptual model is presented in Figure 2.1. The apex of the model represents its dual purpose: accountability and the delivery of high quality health care. The literature describes clinical governance from both the structural (macro-level) perspective and the operational (micro, organisational or practice-level) perspective. The structural elements describe the context or operating environment, and are represented in blue as the canopy of the parachute. These include: workforce policy, financing mechanisms, regulation, cultural expectations (of health care professionals, and of the use of evidence in health care), and the medico-legal environment. The abstracted ideals of clinical governance are represented as an intermediary between the structural and operational elements – or strategies - for clinical governance. This range of operational strategies for delivering clinical governance is represented as strands of the parachute holding the cone. Not all of these strategies will necessarily be used in any one clinical governance model, but will be used in various configurations according to specific contextual drivers and objectives.

PHASE 2: USING THE CONCEPTUAL MODEL TO INTERROGATE THE LITERATURE.

Two search strategies were used:

- (a) a search for overt coverage of clinical governance models, using a set of terms around keywords and the MeSH term Clinical Governance; and
- (b) a search for covert coverage of clinical governance models, exploring the literature for concepts and elements signified in our conceptual model but not termed by the authors or MeSH coders as 'Clinical Governance'.

We operationally defined a 'model' as a 'set of replicable strategies and approaches which are used together to produce an intended outcome'. Because clinical governance is a heterogeneous

topic, we interrogated the literature using multiple filters focusing on context and function. The filtering process is described in detail in Appendix A. Except for a few occasions where a highly relevant article was located, usually in the snowballing component of the search, we limited our search to publications in the last 10 years – from 1999 onwards.

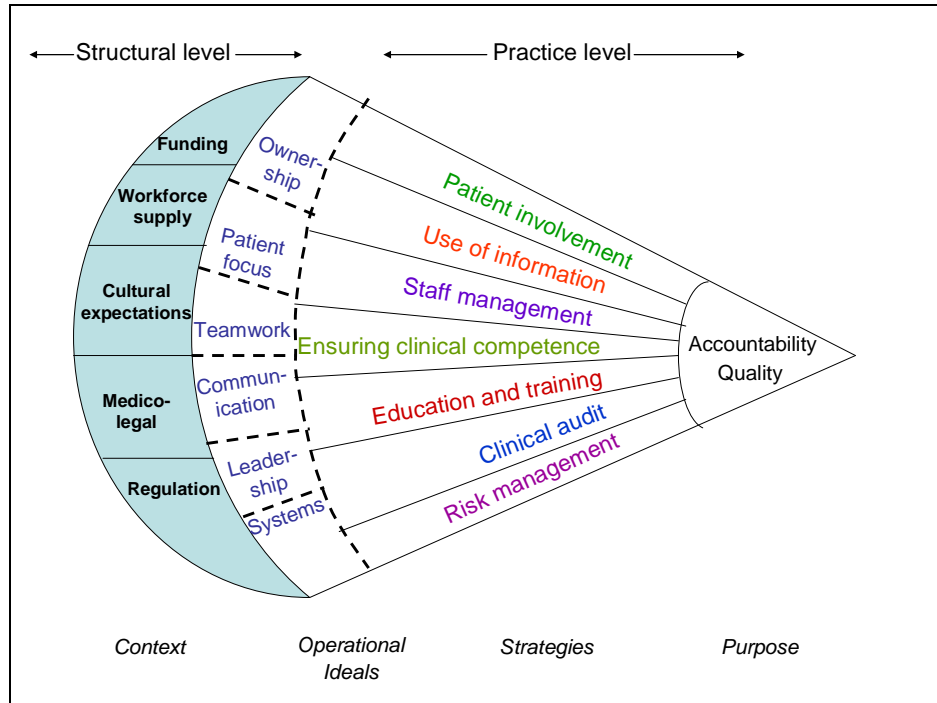


Figure 2.1. Conceptual model of clinical governance.

PHASE 3: DEVELOPING AND ANALYSING THE MODELS.

Literature Review

Using the large volume of informed commentary in the published literature as well as the papers on theory and experience, we developed an emergent concept about the foci of different clinical governance models, classifying them according to their accountability focus as managerial, community or professional models. The operational ideals of the models were used to determine the accountability focus. Models which included ownership and leadership tended to be models where the focus of accountability was towards the profession. Models which focused on systems and teamwork tended to be models where the focus was more managerial (though teamwork was also articulated in some of the professional models). Models with a patient focus tended to be those where the accountability focus was towards the community. Leximancer, a qualitative text analysis package, was used to produce a set of concept maps which independently confirmed the major themes and concepts in the literature identified by the researchers.

We re-examined the literature for studies of good quality, which were likely to be relevant to the context of our study (Australian primary care). The quality thresholds required were: $\geq 7/10$ for a case study; $\geq 10/14$ for an observation study; and $\geq 9/12$ for an intervention study rating and correlated quality focus and strategies with the types of models (managerial, community, professional). We excluded commentaries. To address applicability to the Australian primary health care context, we extracted the same high quality studies and filtered those deemed to be of high relevance (rated 2) to (a) Australian primary health care overall, (b) indigenous health

services, and (c) rural health settings. Assessment and data extraction forms are included at Appendix B. A data dictionary clarifying terms used in these forms is included at Appendix C.

For each paper, the key questions of relevance to Australian primary health care, indigenous health services and rural health settings were then articulated and explored

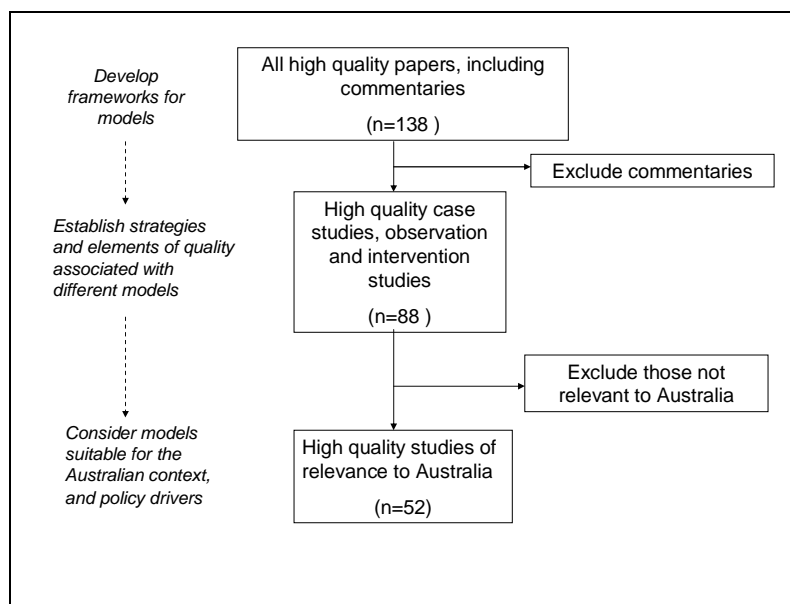


Figure 2.2. Summary of data analysis processes to answer research questions.

Narrative Review

Sixteen interviews were held with key informants and stakeholders. Interviewees were purposively selected to throw light on the microsystem of clinical governance (what happens at the service level), the mesosystem (the level of organisation above the local health service, generally a regional health body) and the macrosystem (the structural drivers of clinical governance).

Microsystems. Four key services were identified through knowledge of their work or through the literature review which had particular experiences with clinical governance in a small service. Clinicians or administrators working within these institutions discussed their experiences with establishing clinical governance.

Mesosystems. Three representatives of the organisations located at the meso-level were the Victorian Healthcare Association, a state level Aboriginal Medical Organisation, which oversees the community-controlled Aboriginal medical service sector in that region, and the National Aboriginal Community Controlled Health Organisations. A description of the sets of clinical focus of the micro- and meso-level services, their structure and funding is presented in Table 2.1.

Macrosystems. To examine the structural drivers of clinical governance, stakeholder interviews were held with representatives of the Australian Primary Care Collaboratives (APCC), General Practice Education and Training (GPET), Australian General Practice Accreditation Limited (AGPAL), and a medico-legal expert. We also interviewed representatives of the British Medical Council, Kaiser Permanente, the UK National Centre for Primary Care Research and Evaluation, Pegasus Health New Zealand, and the Australian National Registration and Accreditation Board. These five informants made up the International Reference Group for the study.

The mean length of interviews (n=16) was 57 minutes. All were transcribed and coded using an emergent coding framework in NVivo 8.0 (QSR International).

Representatives of the following organisations were part of the National Reference Group, and also participated in an online survey exploring the purpose of and strategies underpinning clinical governance in Australian primary health care:

- The Royal Australian College of General Practitioners (RACGP);
- Australian Government Department of Health and Ageing (DoHA);
- Australian Medical Association (AMA)*
- Australian College of Remote and Rural Medicine (ACRRM);
- Centre for General Practice Integration Studies – UNSW (CGPIS);
- Australian General Practice Network (AGPN);
- Royal College of Nursing Australia (RCNA);
- National Institute for Clinical Studies (NICS);
- Australian Commission for Safety & Quality in Health Care (ACSQHC).

Software analysis

Software is emerging as a potential tool of clinical governance which can provide decision-support and GPs, and promote continuity of quality care for patients. An analytical framework for software elements which support governance was developed by two researchers (CP and SdeL) and applied to existing Australian software.

Testing of models

Emerging analyses were tested for conceptual robustness and practicality with the national and international reference groups. The RACGP Clinical Governance standards committee was formed towards the end of this study, and drew upon this research, also enabling the emerging analyses to be tested for relevance and acceptability in this forum.

Table 1. Key informants representing services with expertise in clinical governance at the practice level.

NAME OF SERVICE	SERVICE DESCRIPTION	CORPORATE GOVERNANCE	SETTING
WA AMS	State based organisation supporting community-controlled Aboriginal Medical Services in that state. Supported by Public Health Medical Officer	WA Board with community-elected board. Not-for-profit structure.	State, covers urban and rural
NACCHO	National organisation supporting community-controlled Aboriginal Medical Services across Australia	National Board, community-elected. Not for profit structure	National, covers urban and rural
Cessnock Uni Clinic	General practice service, focus on health care with nurses and allied health in GP-led teams	Independent practice, for profit.	Rural
Newtown Union Health Service	Community health service with general practice and nursing services. Serves poorer and diverse population	Community-owned, not for profit, capitated structure	Inner city
Inala Primary Care	General practice service. Serves poor and culturally diverse population	Not-for-profit structure with University and Department of Health as shareholders	Inner city
Hatzolah	Community-staffed first responder service for Jewish patients. Staff are volunteer with no clinical background	Not for profit. Community elected board.	City
Victorian Healthcare Association	Peak body for Victorian community health sector	State Department of Health	State urban and rural community health centres

CHAPTER 3

MODELS OF CLINICAL GOVERNANCE AND QUALITY

In the policy and theoretical literature on clinical governance, quality and accountability – both outcomes of clinical governance - operate in slightly different ways. *Quality* is driven and constructed through the various strategies prioritised in the model. *Accountability*, on the other hand, is both an emergent, property (signifying the transparency and openness of the service), and a prior-order determinant of the type and focus of clinical governance which is undertaken within the service. In the first sense, accountability signals *what* account is made; the second sense signals *to whom* an account should be made³² The frequent comments in the literature about whether clinical governance is conceived as a “bottom-up” or “top-down” process encapsulate this uncertainty how and to whom a service should account for its performance.

CLASSIFICATION OF CLINICAL GOVERNANCE MODELS

We classified the clinical governance models in the literature according to their accountability focus, using the operational ideals of the governance approaches as a framing device. We identified three notions of accountability focus, in which the models were accountable for quality to the profession, to management or to the community served by the practice.

Professional accountability

In this accountability orientation, the workers in the service see themselves as accountable for providing a good service according to the norms and values of their profession. These norms and values are both codified by bodies such as professional colleges, and exist as tacit, practice norms. The codified norms are created for doctors through medical training and ongoing education, and through maintenance of standards set by professional bodies. In general practice, this is instantiated through practice accreditation against standards set by the RACGP, and for GPs, through the undertaking of continuing medical education which ensures ongoing vocational registration. There is extensive literature on autonomy as a key element of the professional identity for GPs, and to a lesser extent for other allied health professions, such as physiotherapy^{33 34 35}. Nursing, the profession most represented alongside doctors in primary health care, seems not to privilege individualist approaches to clinical work to the same degree. A combined analysis of studies³⁶ undertaken in Wales³⁷, England³⁸, Australia³⁹ and New Zealand⁴⁰, all confirmed the tendency for nurse clinicians to have more systematised conceptions of their clinical work, while medical clinicians viewed their clinical work in a more individualist manner. Although all these studies were undertaken in hospitals, the emerging evidence is that these professional sub-cultural differences are reflected in primary care in Australia²⁵.

These differences in professional subculture mean that professional accountability may have particular valence for GPs when contrasted with managerial accountability, often articulated through concerns about leadership over and ownership of quality initiatives. As a result professional accountability may be accorded more weight in sectors of primary health care that are dominated by doctors, although this accountability orientation would also be evidenced in the community health sector for doctors. Professional accountability orientations tend to privilege clinical care over other broader aspects of primary health care.

Managerial accountability

In this model of accountability, the orientation is towards the organisation. Typically, accountability is defined through measurement, and some effort is expended in ensuring that there is a framework against which the quality of the service can be measured and compared with other services. Managerial accountability for good services is different to corporate

accountability for prudent use of resources, although the managerial accountability model recognises and incorporates priority-setting in the real world of constrained resources. Key operational ideals of this model are leadership, a focus on systems and communication.

Community accountability

In this model, the service is held to be accountable to the community it serves for its health care. We noted two subtypes of community accountability models: transparency to community, and direction by community. In the former, a service might set out to ensure that the community being served was exposed to the kinds of decision-making processes that underpinned resource allocation or priority setting.⁴¹ In the latter, the community are directly engaged in the direction setting of the service, for example through participating on the Board overseeing the health service. An example of the latter are the Aboriginal community controlled health services. In both community accountability models there are often strong notions of shared purpose which assist in the development of teamwork⁴². Teamwork and a patient focus are key operational ideals of community accountability.

MAPPING QUALITY AND ACCOUNTABILITY ORIENTATION IN CLINICAL GOVERNANCE

Figure 3.1 maps the operational ideals of the examples of clinical governance discussed in the literature (including commentaries and reports about experience) against different components of quality. The operational ideals of the model in turn are associated with different accountability orientations.

All models of clinical governance prioritise capability. The managerialist model, defined through such ideals as a systems focus and communication, also emphasises effectiveness and safety. Accessibility and continuity were the qualities least likely to be associated with this model, indicating possibly the difficulty in finding ways of measuring these two attributes of a system.

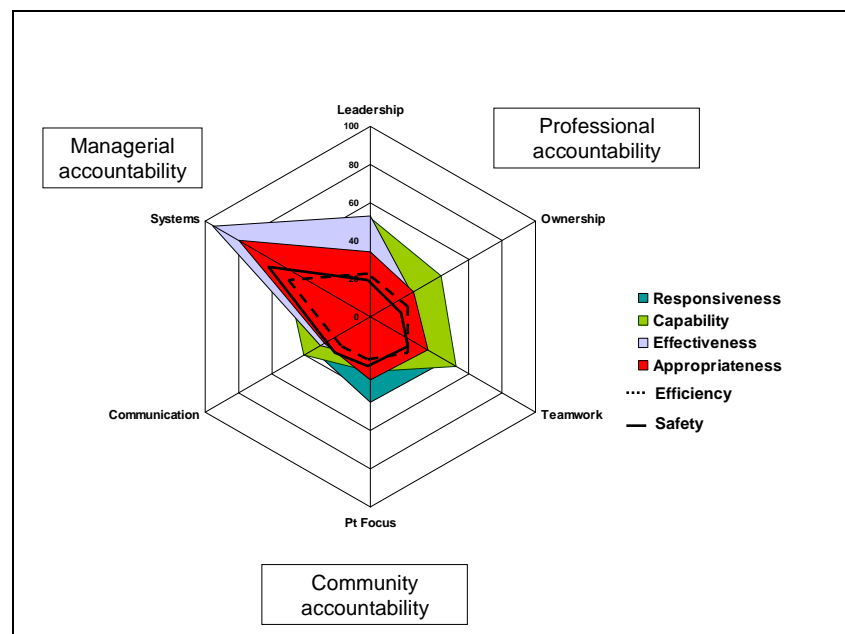


Figure 3.1: Map of elements of quality associated with different abstracted ideals and accountability orientation in extracted papers on governance

The professional model, characterised by the ideals of leadership and ownership, prioritises capability and responsiveness. Safety featured less prominently in the professional model than in the managerial model.

The community model, signified by the ideals of patient focus, and to a lesser degree, teamwork, emphasises responsiveness and capability. Sustainability and continuity – both attributes of the organisation rather than the individual, and relatively hard to measure - were the qualities least likely to be discussed in relation the community model.

We identified 52 papers which were of high quality and relevant to the Australian context, and extracted from them the strategies, models and quality value that might be added for each. There were 33 high quality, high relevance studies addressing the processes of clinical governance, and 19 addressing the outcomes of clinical governance. The elements of quality associated with these papers are presented in Table 3.1.

Table 3.1: Quality domains in high quality, high relevance studies on clinical governance

	NO. OF STUDIES	
	<i>Process (n=33)</i>	<i>Outcome (n=19)</i>
Capability	<i>21</i>	<i>16</i>
Effectiveness	<i>11</i>	<i>10</i>
Safety	<i>2</i>	<i>4</i>
Efficiency	<i>3</i>	<i>4</i>
Continuity	<i>-</i>	<i>-</i>
Accessibility	<i>-</i>	<i>6</i>
Responsiveness	<i>16</i>	<i>5</i>
Sustainability	<i>5</i>	<i>1</i>
Appropriateness	<i>5</i>	<i>1</i>

The majority of studies addressed capability. There were no studies addressing continuity of care, and few addressing appropriateness, accessibility and sustainability. This is despite appropriateness and responsiveness being among the most common ideals of governance cited in our review of the literature. The predominance of capability as a study focus may be because capability is often defined as adherence to clinical guidelines and is more amenable to measurement, than interpersonal aspects of care such as appropriateness or continuity. "Responsiveness" often indicated the responsiveness to other services, and rarely responsiveness to the patient. There were surprisingly few studies that addressed safety in primary care, possibly because this may be more difficult to measure, but also reflecting the delay in some clinical governance systems in setting up systems to identify poor performance and critical incident reporting.⁴³ Although there are many studies exploring incentive systems and their relation to quality outcomes, very few of them described a clinical governance process, but rather posited a kind of black box between the incentive and the outcome. As a result, there are few studies exploring the relationship between clinical governance and efficiency.

MAPPING STRATEGIES USED IN DIFFERENT ACCOUNTABILITY ORIENTATIONS IN CLINICAL GOVERNANCE.

Figure 3.2 sets out the strategies mapped against operational ideals, and accountability orientation.

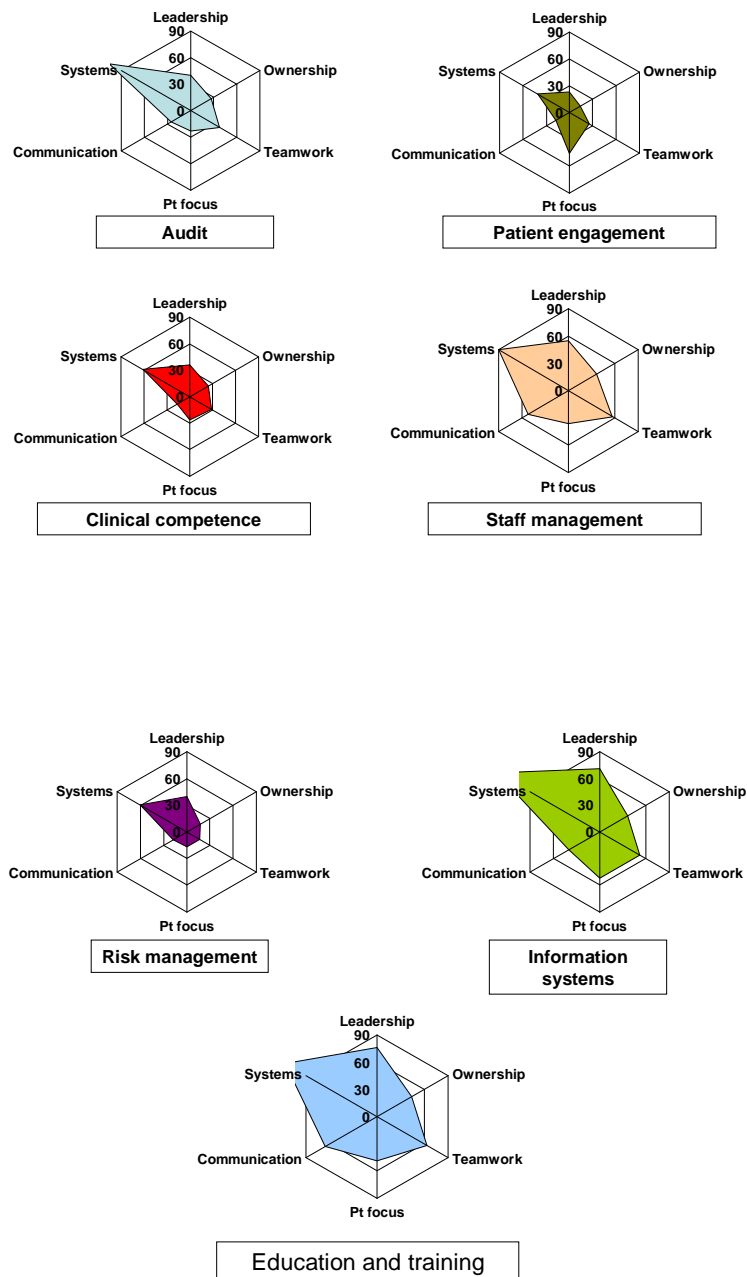


Figure 3.2: Maps of strategies associated with the operational ideals of clinical governance

The strategies used most frequently were staff management, information systems and education/training. Assessment of clinical competence was described relatively infrequently in the literature as a governance strategy, possibly reflecting the fact that in this early stage of implementation of clinical governance, there are more papers describing the “enticement” of practitioners into clinical governance than the use of “hard governance” measures like assessment of professional competence.

The strategy least used across all the models is patient engagement. This points to the difficulty of operationalising this concept in a clinical governance model. While 21% of the papers were rated as incorporating the patient focus as an abstracted ideal, only half of the papers that did actually discussed patient involvement as a strategy. When patient engagement was raised in papers associated with the professional accountability model⁴⁴, GPs discussed it in terms that suggested patient co-option to their world view.

Information systems were identified as being associated with all accountability models, but particularly with the managerial accountability model.

CLINICAL GOVERNANCE MODELS: WHAT IS THE EVIDENCE THAT THEY ADD QUALITY?

The models which emerge from the literature can be summarised as:

- System level: system level external benchmarking with or without development and support at the meso level. These systems typically have established performance indicators which are frequently associated with some sort of financial incentive. Accreditation and the UK Quality Outcomes Framework are examples of system-level external benchmarking for quality. Important components for these models are: audit, information technology and staff management. These models almost always encapsulate a managerial accountability focus.
- Meso level: networking between clinicians, or other services to undertake activities (generally education and guided reflection) to improve clinical care. Structures at the meso level, such as Primary Care Trusts or Divisions of General Practice, help to support meso level collaboration. The Collaboratives program, NSW's Area Health Services and the state Aboriginal Medical Service boards are all examples of meso-level support for individual practices. National bodies such as the National Aboriginal Community Controlled Health Organisations and the Australian General Practice Network assist this meso-level work through activities such as supporting accreditation or NACCHO's Quality Use of Medicines support program. Education and training, as well as information technology are important components of these models. These models can encompass all three accountability foci.
- Practice level: organisational development measures that enable practices to reflect on their processes and develop new ways of delivering health care that improves their quality. These models usually use staff management, education and training, audit, and information technology. These models usually encompass professional accountability focus, but also can be part of a multilevel managerial or accountability focus.

Table 3.2 outlines the potential impacts of the various models on different elements of quality. Full details of the studies are presented in Appendix D.

As the table indicates, interventions at different levels can improve capability of care, but this improvement appears to be related to the type of care and possibly how easy it is to systematise care processes, or how low the baseline is. Improvements in capability of care are more easily achieved in prescribing practice than in chronic disease management, where the evidence for improvement is varied and context-dependent. There is less data on effectiveness (i.e. whether the intervention results in a measurable health improvement) than in capability (i.e. whether the intervention results in an improvement in recorded management), but in two uncontrolled studies, an improvement occurred in the outcomes of chronic disease (angina, asthma [Campbell et al 2003] and diabetes [Bailie et al 2007]) without an improvement occurring in capability. Both these studies suggest that secular trends and/or unmeasured contextual impacts lead to changes in outcomes irrespective of clinical governance measures.

System level interventions down to the service level appear to need some meso-level support (and meso level services need national support); this may improve the flow and acceptance of managerial accountability. Without this, there is some suggestion that sustainability may deteriorate under this model, something also noted at interview by workers within the Aboriginal health sector.

Table 3.2: Impact of clinical governance model on elements of quality in publications on outcomes of clinical governance (n=19)

	TYPE OF MODEL	EVIDENCE FOR IMPACT ON QUALITY			
		May improve	Conflicting evidence of impact	Further research needed – no evidence of impact	May worsen
System level	System-level external bench-marking with meso-level development support	Accessibility ⁵ ;	Capability ^{5*}	Responsiveness ⁵	
	System level external bench-marking with no meso-level support			Responsiveness ^{6,10} ; Capability ^{10β}	Sustainability ⁶ ; Accessibility ¹⁰
Meso level	Collaboration across services to review care			No outcome studies	
	Collaboration with other GPs, with targeted feedback to improve practice	Capability ^{7§} ; Safety ^{7§}	Effectiveness ¹⁵ *	Accessibility ¹⁵ Capability ^{15*}	
	Collaboration with other GPs to improve practice, without targeted feedback	Efficiency ¹⁸ Capability ^{18*}		Capability ^{8§} ; Effectiveness ^{8§,18*}	Accessibility ¹⁸
	Community-oriented priority-setting and/or management	Accessibility ⁹		Efficiency ⁹	
Practice level	Practice-determined organization of interventions and capacity, using targeted feedback to GPs and practice with supported reflection	Effectiveness ^{11,13,14*} ; Safety ^{3,4 §} ; Efficiency ^{4 §} ; Capability ^{4 §,17} ; Responsiveness ^{3,4 §}	Capability ^{1,2,11,13,14*} ; Effectiveness ^{1,11,17*}		
Multi-level	System-level benchmarking and incentive-setting, meso-level network support, support for practice-determined organisation of interventions and capacity using targeted feedback for practices	Efficiency ^{12§,19§} ; Effectiveness ^{16*} ; Responsiveness ¹⁶ ; Capability ^{12§,19§,16§+*}		Effectiveness ^{12§} ; Safety ^{12§}	

*Chronic disease management §Prescribing practice ¶ Complex care (e.g. elder care, mental health) β Curative services in developing countries

¹Cranney et al 1999; ²Cheater et al 2006; ³Fraser et al 2002; ⁴McKinnon 2001; ⁵Campbell et al 2003*[¶]; ⁶Gene-Badia et al 2007; ⁷Wensing et al 2004; ⁸Van Driel 2007; ⁹Crampton et al 2005; ¹⁰Catacutan 2006, ¹¹Baker 2003; ¹²Beilby et al 2006; ¹³Bailie et al 2007; ¹⁴Valk et al 2004; ¹⁵Landon et al 2004; ¹⁶Tausch et al 2001; ¹⁷Si et al 2007; ¹⁸Ornstein et al 2008; ¹⁹Malcolm et al 2001

A large number of the high quality, high relevance studies were located at the practice level, and although the evidence about improvement in capability through clinical governance strategies at this level is unclear, intervention at this level has been associated with improvements in efficiency, responsiveness and safety (in relation to medication use).

"SOFT BOUNDARIES" BETWEEN THE CLINICAL GOVERNANCE MODELS

The most effective interventions in the published studies were located at multiple levels. A good example is Beilby's evaluation of the Australian National Prescribing Service program to improve safety, effectiveness and capability in medication prescription and use. This model effectively combines managerial, community and professional accountability foci. Strong rhetorical distinctions were made in both the literature and the interviews between the types of models. In practice, however, the models often develop soft boundaries after they have been in place for some time.

GPs at interview and in the literature often mounted a case that professional accountability was diametrically opposed to managerial accountability. This is particularly the case in the literature discussing the introduction of clinical governance and the Quality and Outcomes Framework in the National Health Service in England and Wales^{45 46}. If these models are oppositional, policy makers would have to make a choice about which to introduce. However, the perception that these models are opposites may reflect professional dissatisfaction with the implementation of the model, or the novelty of the implementation, rather than genuine firm distinctions.

The distinction between professional and managerial models is a commonplace in the commentary on clinical governance in the UK and, to a degree, in Europe. In the US, however, managerial and professional models are much less distinct. The aligning of managerial and professional accountability foci in relation to clinical governance may reflect the greater sophistication and training of medical managers, who can act as boundary riders, introducing professionalism as an ethic into the bureaucratic notions of transparency and objective measurement. The healthcare marketplace in the USA, in which management, professionalism and competition are intertwined is very different to the healthcare marketplace of the NHS or Europe where universal access to health insurance is the norm. The best example of this is Kaiser Permanente, whose hospital usage rates were controversially found to be much lower than those of the NHS by Feacham⁴⁷. Feacham's study was critiqued on methodological grounds, but a subsequent study by Ham did confirm that overall hospitalisation rates were lower in the hospitals run by Kaiser Permanente⁴⁸.

Key components of the Kaiser Permanente model appear to be the engagement of doctors and managers in contracting services, the alignment of primary care doctors with specialists, incentives for performance paid to individual doctors, and patient education. While managerialist and professional accountability models can be aligned in the USA, some commentators have argued that this may be at the expense of equity and patient engagement⁴⁹. This may not, however, be a criticism that is fairly levelled at the health services themselves, reflecting instead the lack of external structures that support health cover for the uninsured. *Within* Kaiser Permanente, the engagement with patients in delivering can be essayed in ways that have provided a model for the NHS's approach to clinical governance.⁵⁰

"On a statistically validated basis with a selection of every visit to every doctor, a member is mailed a form, a survey, within 24 to 48 hours of the visit, and they are asked to complete a series...of very important questions about that visit. The courtesy and respect with which the doctor treated you, the primary doctor's intellectual and medical capabilities...There are about ten validated questions, and so for every physician that survey is completed every quarter. And then those results are aggregated and reported to them." [*Interview, Physician leader, Kaiser Permanente*].

This strategy functions as a way of making the health system accountable to community, but also provides the management with a way to monitor performance, and for professionals to respond to the feedback to better meet the norms of their profession.

Another example of soft boundaries between the governance models is the community model of clinical governance espoused by the Aboriginal community-controlled sector in Australia and the managerial accountability focus of their funders.

Box 3.1: Managerial accountability meets community accountability: the case of the Aboriginal community-controlled sector.

The Aboriginal community-controlled sector includes over 150 ACCHS which provide comprehensive primary health care for their communities. All are members of state affiliates and NACCHO. NACCHO and state affiliates employ a range of professionals (including Public Health Medical Officers, accreditation officers, workforce policy officers, QIC and IT officers) who work towards QI and clinical governance within a framework of Aboriginal leadership. The services receive most of their funding through the government sector and through multiple small project funding. Of the services sampled in the recent Overburden report⁵¹ there were an average of 22 funders per service (range, 6 to 51).

Clinical governance in Aboriginal medical services: A tension exists between the philosophical orientation of the sector towards community accountability, and the administrative orientation of the services towards managerial accountability. While the services articulate a need to be accountable to community for their care, in practice financial and clinical accountability have been bundled into a conjoined managerial accountability model, in which the services find themselves reporting “up” not “down” against sets of clinical and financial indicators. The development of clinical indicators in some services (eg Kimberley Aboriginal Medical Services) preceded mainstream work in this area⁵². While clinical indicators developed by ACCHSs are of local relevance, this is not necessarily the case for those which are externally imposed upon them. While the services recognize the need to contribute to data collection on Aboriginal health, they often struggle to see the relevance between externally-directed monitoring and clinical quality on the ground. This is brought into relief when resource-poor services have to redirect personnel to data collection rather than data translation into service.

Nevertheless, the ACCHS sector is at the vanguard of clinical governance in Australia. There has been a concerted and long-term development of the capacity and personnel to drive QI/clinical governance activities across all levels of the sector. The services are already practised in the extraction and reporting of data, if often a little jaded about the utility of the data. The commitment to community accountability offers a counter to the managerial accountability model of the service. These services demonstrate the importance of responsible autonomy – a more useful term in this context than clinical leadership, with its overtones of external control – supported through enabling structures (the peak bodies and the Boards) and widespread capacity enhancement.

CHAPTER 4

WHICH CLINICAL GOVERNANCE MODELS ARE SUITED TO THE AUSTRALIAN CONTEXT?

Australian primary health care is delivered through a patchwork of services and sectors. There are several key factors which influence this individuated, poorly networked structure:

- A state / federal divide in funding and accountability, where state governments are generally responsible for care delivery in publicly funded acute care services, and the federal government responsible for Medicare, the national health insurance program. Primary care is essentially delivered by GPs and therefore most (but not all) of their funding is federally supported fee-for-service. . Cohesion and continuity between the two systems is often poor.
- A historical lack of structures for organisation, cohesion or governance in general practice, and little continuity between general practice and other (especially public) primary health care services. This is changing somewhat with the Divisions of General Practice network now providing a framework for inter-practice linkage and cohesion with system level structures, but participation for GPs and practices is voluntary. A recent quantitative study on the clinical impact of Divisions found they had some impact on improvement of infrastructure, but no impact on the uptake of clinical items for cervical screening, asthma and diabetes⁵³
- General practices are usually small businesses owned and operated by GPs, although these dynamics are changing and there is an increasing corporate presence in general practice with growing numbers of employed GPs. In the main, nurses and other staff are employed by GPs or business owners, so there are hierarchical employment relationships affecting interdisciplinary interactions.
- Community health services funded by the states and territories provide suites of ambulatory services by nurses and allied health workers. In contrast to general practice, doctors are in the minority in community health services and tend not to have leadership roles.

An additional and very important player in primary health care is the Aboriginal Medical Service sector, which provides accessible health care services to Aboriginal and Torres Strait Islander people. These operate as NGOs funded through direct government grants and a melange of other special-purpose grants. A considerable amount of time in these services is devoted to reporting against the various grants a service may hold.

CLINICAL GOVERNANCE MODELS SUITED TO AUSTRALIA OVERALL

The diversity of service models, structural drivers and corporate governance arrangements means that proposing one model of clinical governance suited for Australian primary health care is challenging, and probably not desirable. This is in contrast to the acute care sector, where the clinical governance models are relatively similar in different hospitals and states, and draw on experience in hospitals in the UK, Europe and USA. The recent National Health and Hospital Reform Commission report²² proposed that policymakers consider combining general practitioners and state-funded community health systems under the one regional structure. This would be analogous in some ways to the Primary Care Trusts in the UK, and the District Health Boards of New Zealand. However, the UK experience is that no one geographical configuration of locality management has proved sustainable. Whilst practices and hospitals largely remained constant, although they have slowly rationalized into smaller numbers of larger units; there has been wave after wave of reorganization based on different populations, one or two tiers,

separate or combined family practice and health authorities.

When interrogating the literature for governance models which would be most suited to the Australian primary health care scene, the following determinants of the health sector were prioritized:

- Heterogeneous services with different systems of funding and governance
- Medical profession with a strong view of itself as independent
- Loose nodal network of general practices with little hierarchical structures
- Poor collaboration between state-funded sectors and general practice

Appendix D presents a summary of the high quality studies that were felt to be of high relevance to Australian primary health care overall, classified according to their clinical governance models. This analysis suggests that all three clinical governance models had relevance for Australia. Although they have been classified as models in which the orientation may have been upwards (managerial), horizontal (professional), or downwards (to community), many of the same themes emerge in the literature.

For general practice, as in other countries, professional accountability models are likely to act as bedrock for other models. The profession itself in Australia is used to acting autonomously but within an environment in which professional norms and technical evidence are inculcated into professional practice – the former through accreditation and continuing medical education, both of which are subject to financial incentives, and the latter through the provision of guidelines and personalized feedback (for example from the National Prescribing Service). It should be noted, however, that these activities have only been in existence for less than 20 years.

Clinical governance strategies that are part of a professional accountability model may be effective when that profession has a clear and salient position on the issue at hand. Thus, the translation of evidence into practice is part of a professional model, and is readily accepted when the evidence addresses a recognized clinical entity (hypertension or diabetes). It is likely to be less effective when the medical enterprise is engaged with a health issue which is a national priority – mental health care, or obesity - but for which the evidence base is less clear, and the indicators are largely process ones. A three year follow-up of quality indicators in British general practices tends to confirm these findings. Between 1998 and 2001, when the NHS was undergoing a series of reforms supporting systematized improvement, improvement occurred in management of chronic diseases across the practices, but not in elder care or in mental health care.⁵⁴ Practice-based education to find local solutions is key to translating evidence into changes in clinical practice.

Managerial models that focus on reporting against performance indicators need to ensure that the indicators have local relevance and if they are financially incentivized, that the burden of reporting against them is not too heavy. The UK reforms incorporate the automated extract from routine data of pay-for-performance data.

In both models, networking at the meso- and micro-level is critical to success. The networks described in these studies included formal ones at the meso-level (Local Health Care Collaboratives in Scotland, the Primary Care Trusts in the UK, the Primary Health Organisations in New Zealand) and informal (the collaborative networks that develop around Sweden's local commissioning of services, the networks within academic medical centres in USA). Networks at the micro-level (within the practice) are probably at the heart of successful teamwork within the practice and are driven by a focus on staff management, intra-practice communication and education within the practice. Australia has networks at the meso-level to drive clinical governance in general practice: the Australian General Practice Network. Because the network's relationship with general practice, and indeed with itself, is based more on non-coercive change management, with no capacity to compel participation, it functions as a professional resource. It is, however, effective in promoting change⁵⁵ and is likely to be a key player in the dissemination of clinical governance models. In the community health sector, a model for networking is offered by the Victorian Healthcare Association.

In comparison to the other two models, community accountability models are less theorized, and

less explored in the literature, despite the existence of a number of service types for indigenous persons in Australia, Canada and New Zealand which were set up to provide clinical services which were poorly provided (or not provided at all) by mainstream primary and hospital services, and are community controlled. These services have not been the subject of a good deal of theorized organizational research, which potentially would have value for all of primary care. Insights into community accountability may be sought from practices outside the mainstream medical ones. One such example is the Hatzolah emergency response team (Box 4.1). Secular first responder services built along the same principles have been set up in rural Victoria, indicating the relevance of a community accountability model in rural settings⁵⁶.

Box 4.1 Hatzolah emergency first responder service: case study in community and managerial accountability

Hatzolah is a first responder service run and staffed by members of a Jewish community in a locality with the highest density of Holocaust survivors outside Israel. It arose out of a concern that many older members of the Jewish community were reluctant to seek emergency support from state services when in medical crisis, and is based on a concept originated to serve orthodox New York Jews in 1973. In 1995, a group of Jewish community members established Hatzolah (in Hebrew "to save") in collaboration with a metropolitan ambulance service. The service operates through a network of trained community members who can respond to a radio call for medical help within the community in a matter of minutes. The responders carry emergency equipment, including defibrillators, and provide support until the ambulance arrives. The service has 28 volunteers who are on call 24 hours a day, seven days a week. Hatzolah's median response time is 2 to 3 minutes compares favourably with the Metropolitan Ambulance Service's key performance indicator of 12 minutes for time-critical responses. The service is funded entirely from private donations.

Clinical governance is central for a service staffed by lay persons who are responding to medical and psychiatric crises. The Medical Standards Subcommittee supporting the service includes an emergency physician from the regional health service and specialists from referral hospital, ambulance staff and GPs. The subcommittee monitors clinical performance and advises on structures to improve service delivery. Rigorous monitoring is achieved through the establishment of performance standards and auditing of records. Service responders commitment to quality improvement is reinforced through networking with health services, especially the ambulance services, and ongoing training. The achievements of this service reflect over a decade of collaboration and increasing trust between formal health care and the community-run service. The Hatzolah first responders have had to develop a culture of rigorous quality assurance in an area which is not the main focus of their working lives.

"...they're sort of living this work life and they are taken out of that work life for half an hour to an hour and put in this medical field..., do what they do, and go back to their world and they they've got me trying to chase them up and go through case reviews and debrief and they they've got to fill out a patient care record which has to be reviewed which might mean more follow-ups. It's a bit of a challenge" [*Manager, Hatzolah*]

A culture of "lay professionalism" in Hatzolah has resulted from the openness of this service to adopting both community and managerial accountability governance models, both of which are incorporated into an ideal of service to community.

CLINICAL GOVERNANCE MODELS SUITED TO RURAL PRACTICES

Key features of rural practice that we examined to answer this question were

- isolation,
- small practices,
- working without the support of tertiary level services
- strong inter-relationships with the local community

- higher numbers of nurses in rural general practices than in urban general practices

Although there were a number of papers which presented their own experience in rural settings⁵⁷, these papers were excluded from this level of analysis as they did not present data on outcomes, processes or effectiveness of their models. In studies, rurality was occasionally included in the sampling frame, but the analysis was presented in aggregate. For this section of our review, we therefore operationalised key elements of rural practice in Australia, and extracted studies which were relevant. The studies relevant to rural settings are marked in Appendix D.

This analysis suggests that in rural areas networking as a communication approach is of particular importance in developing improved systems and overcoming professional isolation. The Australian Healthcare Collaboratives program represents one example of a strategy to engage groups of general practitioners in professional networks that translate evidence into practice, and it is not surprising that this has been taken up with great alacrity in rural areas. Beacon practices such as Cessnock Uni-Clinic also function as network centres for health care managers and clinicians seeking new models of providing general practice services in rural areas. Excessive requirements to report (i.e. rigid use of a managerial governance model) may overwhelm the fragile resources of some rural practices, and may also create a perverse incentive to focus on indicators that are not of immediate relevance to their community.

Community engagement and openness is relevant in rural settings in which the immediate community becomes the context of the network of health care providers, as in the rural first responder units which have developed from the Melbourne Hatzolah.

CLINICAL GOVERNANCE MODELS SUITED TO ABORIGINAL MEDICAL SERVICES

Key features that would make a study highly relevant for Aboriginal medical services were:

- not for profit practices,
- social service,
- multidisciplinary services,
- focus on equity and access and
- community ownership

The literature overall is very light on community models of clinical governance for marginalized or disadvantaged communities. The studies on the managerial model relevant for this sector have emphasized clarity around performance contracting with limited and locally-relevant reporting requirements⁵⁸, and the willingness of management to support local reorganization of work to meet performance standards. This sector is often characterized by a high level of trust in the service. In Australia Aboriginal community controlled health services have developed a range of ways to account for the mobility of populations including patient transport systems and record sharing between services. This is in contrast to mainstream general practice, where patient populations tend to be less mobile, and to state-funded community health services where doctors tend to be in the minority.

Clinical governance models suitable for Aboriginal medical services are community models of clinical governance, with a focus on teamwork. The professional model of accountability is of relevance in this sector, though the 'professional ideal' will be reframed to emphasise customised responses to local population needs in addition to individual needs. Although the professional ideal is often used to argue that GPs should be allowed clinical independence, in the Aboriginal community controlled health service sector this capacity to recognize and plan individualized personal and population-based solutions is reframed as a service-level resource. As services that are governed by the Aboriginal community, they offer a model of culturally appropriate care which is also applicable to mainstream services seeking to reframe themselves as "safe places" for Aboriginal places; at the very least, this would require mainstream services to reconfigure themselves as being responsive to and learning from Aboriginal communities.

The managerial approach which holds sway in indigenous health services runs the risk of ignoring professional models of accountability (i.e., marginalizes a clinical and service resource for quality) and limiting, through compliance and reporting burdens, the true possibilities of community oriented models of clinical governance. An informant commented that

"Aboriginal medical services are quite scrutinized externally, but they're often on issues that don't have immediate relevance to services trying to improve themselves."

Although there is an absence of robust academic literature on community models, there is now a wealth of case study material in the Aboriginal community controlled health service sector itself (eg the experience of Kimberley Aboriginal Medical Services Council, set up in the early 1980s to provide corporate and clinical governance support services to ACCHSs in the region), which should guide policy making. In addition to its relevance for service provision to Aboriginal patients, there is an urgent need to collate formal case studies outlining the ACCHS sector's experience with clinical governance as a resource for mainstream primary care.

MULTI-LEVEL APPROACHES TO CLINICAL GOVERNANCE IN AUSTRALIA

There is good evidence that quality improvement initiatives, such as clinical governance, need to be constructed as multi-level, systematised approaches^{59 60 61}. The large volume of studies from England were conducted at a time of policy change to introduce clinical governance at the structural (macro level), and used their intermediate structures (Primary Care Trusts/Organisations) to support the introduction of change to general practices (the micro level). In Australia, formalised networks, such as Divisions of General Practice or hierarchies such as Area Health Services constitute the meso-level for clinical governance.

The meso-level of governance, which appears to offer a critical support for clinical governance within practices provides both infrastructure and support for practices to review their own data, and networking among other GPs. Meso-level organizations (university departments, Area Health Services, Divisions of General Practice, IPAs) often take on the role of wrangling the practice's own data and feeding it back to them. This level would be more fruitfully employed in supporting networks and knowledge sharing, rather than playing a role that good data extraction software could do. Indeed, the work done by meso-level in processing practice data – necessitated by the cumbersome nature of practice IT systems – arguably represents a lost opportunity for the practice to undertake deep reflection on their work and come up with new insights into clinical care. The case study in Appendix G provides an example of the use of data generated from practices by practitioners to generate new insights into a relatively neglected disease area, chronic kidney disease. The case study exemplifies the roles of IT in supporting multilevel approaches to clinical governance which rest on the work done within the clinic.

SUMMARY

To be effective, clinical governance needs:

- Supported peer networks, within the practice, between services of similar types, and between different ambulatory care services, such as community health services, general practices, pharmacies, and state-funded mental health services.
- Clinical leadership within services, and clinical leadership at the regional level
- External support for clinical governance by the regional organisational level (Divisions or state-funded regional organisations).
- Acceptance of the use of locally produced data that are of local relevance but nationally and ideally internationally comparable to underpin reflectiveness and flexible solutions. Funders and insurers have a legitimate interest in performance and quality improvement and should engage with service representatives to develop performance indicators that are targeted to health priorities and do not overburden the services with monitoring requirements.

- The capacity to rapidly generate local data through software attuned to clinical governance.
- The ability to pool anonymised data extracted from ePR systems so that it is easy to make comparisons.
- Incentives to support the mechanics of clinical governance through financing mechanisms appropriate for different sectors. This should include incentivising IT systems standards which facilitate audit.

CHAPTER 5

INFORMATION TECHNOLOGY & CLINICAL GOVERNANCE

The computerization of clinical records allows clinical standards to be monitored with a speed and scale which was not possible with paper records. A sub-specialty of health informatics – primary care informatics – has developed a body of knowledge about how to harness the data held in routine records to improve health and the quality of medical care⁶². The dilemmas are that incorporation of IT into clinical workflow is challenging and the act of coding (creating machine processable labels for diseases) is particularly challenging in a specialty where diagnoses are often vague and emergent⁶³.

The use of computers is widespread in all aspects of the clinical interaction, from computers in the consulting room to large systems that manipulate centralized data stores. Across the globe the distribution of this computerisation is quite variable. In the Australia, the UK and Netherlands, primary care has computerised rapidly, with almost all primary care physicians having a computer in the clinical environment. In the US and Canada, primary care is less computerised, with the hospital sector leading the way⁶⁴. Using computers in clinical contexts is an evolving process and as they take an increasing role, so too will their influence on outcomes become more prominent⁶⁵. Eventually, as shared or personal health records become more prominent, a third issue - regarding the governance of these records - will open up⁶⁶.

Box 5.1: Kaiser Permanente - a case study of what can be

Kaiser Permanente is a large Health Maintenance Organization in the United States. Structurally, KP consists of an overarching insurance company that contracts with eight regional, independent doctor groups to provide services to the insured clients. These services are supplied through both primary care clinics and hospitals, and include the full gamut of medical services, from outreach primary care services to tertiary hospital sub-specialties. Through these eight groups KP supplies medical care to 12 million people, or to put it another way, manages a healthcare system roughly half the size of Australia's.

Key to managing this care is the structured and controlled use of information. Beginning ten years ago, all KP doctor groups implemented a uniform clinical system. All practices are paperless, all information generated within the system is available to be searched and used. Thus a primary care clinician can discuss a patient with a specialist, and the specialist has real time access to x-Ray, pathology etc in order to inform the clinical process. All data can be pooled and interrogated at local, national and regional levels and benchmarked according to best practice. Primary care units can prepare and measure themselves according to local needs, whilst the doctor group can monitor performance between primary care groups. During the recent Swine influenza outbreak, this enabled them to monitor the effects of the outbreak across the service and effectively redeploy services to meet need.

Concentrating on the clinical interaction, computers have many and varied roles. They influence the flow of the consultation⁶⁷, are used to implement decision support⁶⁸, a means of reducing errors⁶⁹, and improving quality through audit/feedback cycles^{70 71}. In effect, they now permeate all interactions between doctor and patient, and act as a third party to the interaction⁷². In terms of clinical governance, this raises two questions regarding the role information management plays. The first question is downstream: *to what uses are computers put to ensure clinical governance occurs and in what contexts?* This question relates mainly to computer involvement in audit and data processing. The second relates to the clinical governance of software itself: *if computers are to be used in the consultation, and insert information to influence the consultation, then by what methods and from what sources do these activities occur?*

THE AUSTRALIAN CONTEXT

Australian general practice and the Aboriginal community controlled sector is largely computerised. 98% of GPs have a computer on their desk and use them for clinical purposes, even if that is simply prescribing. Most GPs use a computer for recall systems and maintenance of immunization registers for the monitoring of population health, and over half use clinical notes and/or record diagnoses in a coded fashion⁷³. Over 40% of GPs are involved in some sort of audit or quality assurance cycle associated with using their computer data, usually mediated by the local Division of General Practice⁷⁴. Close to 20% of the clinical consultation can be spent interacting with the computer⁷⁵. There are some 22 or more clinical packages on the market, although 95% of the market is currently accounted for by just 6 packages⁶⁴. Although doctors use many sources of information in the consultation⁷⁶, it is the clinical software packages that can have the largest impact on clinical outcomes⁷⁷. Almost all Aboriginal community controlled services used prescribing software, and most have patient information recall systems.

MEASURING SOFTWARE QUALITY

In order to assess the currently available clinical software packages, we developed a tool (summarized below - see Appendix E for the complete tool) based on several principles of good clinical governance and information management. The tool is organized according to structure, processes and outcomes activities inherent in information technology applications. It includes some practical measures, some obvious ones and some that, in the Australian context, are aspirational, although may be more common in other countries.

Structures	
System Architecture	Elements such as user interface, clinical archetypes database type and access, coding systems, attribution
Information Support	Drug databases, interactions, clinical calculators
System Linkages	Patient registrations, laboratory links, Email
Search Function	Across populations, practices, Export functions
Patient access/Control	Access to information through web portals, etc.
Processes	
Quality Markers	Data quality, information quality, system accreditation
Billing/Pay for Performance	Routine data use for same.
Epidemiology	Epidemiology, sentinel networks
Outcomes	Surrogate markers of quality and outcomes.

Table 5.1: Summary of software assessment instrument

The six most commonly utilised packages (Medical Director (3); Best Practice; Genie; Practix; Medtech32; and ZedMed) were assessed against this tool, and one outlier package with a small installation base (Promed), was also tested for comparison.

Structures

All packages utilized a graphical user interface and all had standard clinical archetypes such as history, examination, past history, social history. All were able to represent a summary sheet that conformed to Royal Australian College of General Practitioner standards of same. All were able to code diagnosis and problem list data, although at least three different coding systems⁷⁸ are used: International Classification of Primary Care (ICPC), International Classification of Disease (ICD10) and DOCLE (Doctor Command Language - a locally developed non-numerical coding system). None used Systematized nomenclature of Medicine – Clinical Terms (SNOMED-CT), the Australian standard and none required data to be entered in a coded fashion; all allowed full free text entry of all data. All systems allowed attribution of data according to login, or according to source. Some incoming data (such as specialist letters) required manual attribution, whilst for data such as pathology the attribution was automatic.

All packages were able to accept pathology and radiology as atomized data. The Queensland pathology report (PIT) format has become the *de facto* standard for Australian pathology messages though this is a largely non-computable format. There are moves to introduce industry standard Health Level 7 (HL-7) led solutions. (HL-7 is highest, the application level integration set out in the ISO Communication model) However, none of the GP systems were able to generate electronic requests (i.e., paper forms were generated by the system). All programs allowed linking of requests with received reports. Four packages allowed both generation of electronic documents and receiving of same. All used proprietary systems to do this, with little ability to work cross platform.

Eleven programs (in keeping with the genesis of software systems as electronic prescribing packages) had comprehensive drug databases. All bar one used the database from Monthly Index of Medical Specialties (MIMS) Australia, the other using information from a variety of sources. Pharmaceutical Benefits Schedule (PBS) data came from the PBS itself. All had ability to generate drug interactions, although users were able to set the level of drug interaction alerts and in several packages turn them off altogether. Use and availability of drug calculators (weight/dose calculators or Warfarin calculators) was extremely variable. All packages had a variety of other external information sources available from within the system. All had immunization information, 5 of 7 had travel information, and one had an extensive library of text based resources within the program.

All systems generated a unique identifier for each patient, and all recorded the Medicare number. None had space for the upcoming Unique Health Identifier, the guidelines for which have recently been released, but the enabling legislation is yet to be passed. Only one package allowed patient access through a web portal, to which both the practice and the patient must have subscribed.

All programs have search functions built into the system. Most have some inbuilt searches (patients over 65, eligible patients without a PAP smear in the last five years) that relate to funding initiatives or chronic disease management. The ability to do other searches was quite variable and often required significant computer/database knowledge.

Processes

Only four of the packages were able to participate in regional or aggregated data quality activities. These activities generally revolve around the Australian Primary Care Collaboratives program, The Practice Health Atlas, and Divisions of General Practice's use of the PEN Clinical Audit tool; or in the ACCHS sector, the ABCD or Healthy For Life program. All these activities require the use of an external tool to interrogate the program's database and generate pooled data (taking into account differing coding systems). One other package had its own tool to perform similar functions. All programs were able to generate pay-for performance lists, according to the particular funding initiative. No system had inbuilt data quality checks (prescribing insulin without a diagnosis of diabetes, for example). One system had an 'in house' sentinel/research network ability, but no other program had such a designated function.

Outcomes

No package dealt effectively with health outcomes.

RAMIFICATIONS FOR CLINICAL GOVERNANCE

Data quality needs to improve

There are several implications from this study of Australian software. The most common and effective use of information in clinical governance has been in the use of data to generate information for the purposes of informing practice, both at a local and regional level. At a local level the packages perform reasonably well. Although the use of audit tools is not widespread, those packages that enable an audit function cover about 90% of the market, so availability is widespread (although only half of practices currently participate). However all systems require an external tool to do so, in part because of the closed database structures used by programs (perceived as done to ensure vendor tie-in), and the differing use and implementation of coding systems within each program. In addition, although the use of audit is seen as a tool to improve data, there are few or no internal checks built into programs to ensure data quality. No program used SNOMED-CT, despite this being the Australian standard for several years. No program requires diagnoses to be coded. This data quality and use issue will become a major problem as the importance of information technology in supporting clinical governance grows.

Recommendations:

1. Single coding system should be adopted, or minimum require coding systems which allow data mapping – minimum should be compatibility with the Unified Medical Language System (UMLS).
2. It should be possible to run the same clinical audit search query on different practices.
3. Remote searching and uploading (with appropriate safeguards and permissions should be possible.
4. Initially training, then recording problem titles and linking prescribing should be subject of financial incentives to establish data quality

Knowledge management in primary care

The second element of the use of information within the consultation is characterized by the sheer complexity and variety of information provided within the systems. GPs manage complex information systems and need training in how to retrieve information and manage knowledge⁷⁹.

Information about immunization alone is reasonably consistent between different vendor systems. However, there is enormous variability in: the variety of drug information, the differing use of drug interactions, the use of different sources (on-line, text based or none at all) of information. This leads to a lack of consistency. The recent Practice Incentive Program (PIP) Payment⁸⁰ is an attempt to ameliorate this, in that it guarantees access to a consistent set of databases, but it sets no guides to its use or integration within the system, and in the case of the Australian Medicines Handbook, introduces a new drug database that is different to the most widely used one (MIMS).

Recommendations:

1. Standardised alerts to reduce prescribing errors should be introduced
2. Any alerting system should have a monitoring system to detect those alerts which are ignored and those which result in a change in action.
3. Incentivised, but optional, audit packages should be introduced which are integrated into IT systems

Standards and requirements for accreditation of GP computer systems

In many ways this situation reflects the fact that whilst there are standards for almost every other part of medical practice, there are no standards for clinical software. All of the packages bar one are locally developed, initially small operator designed systems, and reflect that design philosophy. There is no requirement to provide any specific functionality at all, no set of criteria over information use, and no standards governing usability.

Recommendations:

1. There should be incentives for systems to facilitate clinical governance
2. Key areas are: (1) Evolution to a single coding system; (2) Able to process common national audit programmes; (3) Common prescribing alerts
3. Adoption of international standards wherever possible.

SUMMARY

Information Technology facilitates the use of routine data to measure quality. However, considerable input is needed into a wide range of structures and processes to improve data quality to a point where data collected in routine practice can be used for immediate quality improvement. Good quality information technology has the capacity to offer benchmarking for services, though careful management will be needed to ensure that the dataflows to the meso-level continue to be aimed at quality improvement for patients.

CHAPTER SIX

POLICY DRIVERS FOR CLINICAL GOVERNANCE

This chapter reviews policy options for introducing and expanding clinical governance across the three structural levels (practice, regional, and national). Cost considerations are considered in the conclusion.

The policy landscape, including the new opportunities offered by information technology and the recommendations of the National Health and Hospital Reform Commission are presented in the first chapter. Attempts to introduce large policy changes may be met by a response from professionals that is animated by concerns about autonomy and control⁸¹. Health professionals have been anxious, and highly vocal, about the introduction of Medibank⁸², subsequently Medicare, vocational registration for doctors, and models of parallel care such as nurse practitioners⁸³. Models which are, or can be, characterized as highly bureaucratic or controlling will need some initial selling to the public and to health professionals.

At the same time, Australians have a high level of acceptance for regulatory intervention into individual lives to protect and promote health⁸⁴. Legislation to mandate seatbelts and the wearing of helmets, which were regarded initially as bureaucratic and controlling, have transmuted now into self-regulatory practices. These two elements – the transmuting of external regulation into self-regulation and the professional valorising of autonomy – together suggest that it would be possible in Australia to introduce clinical governance with a combination of managerial and professional foci, but it would be prudent to start softly.

Although we view clinical governance as an activity that grows from ownership on the ground of clinical care and its improvement, we view the policy changes to drive it as occurring in a top-down fashion to create a milieu in which the processes of clinical governance become second nature to an organization.

STRATEGIES TO DRIVE CLINICAL GOVERNANCE AT THE MICRO LEVEL

Two major changes need to occur at the practice level to drive clinical governance, related to *activities* and *infrastructure*.

The suite of reflective activities that enable general practices to improve the quality of their work rest upon:

- Willingness to undertake quality improvement with a whole-of-practice focus. Clinical improvement activities (e.g. better cardiovascular disease risk management) may primarily involve clinicians. Other quality domains (e.g. accessibility or continuity of care) will require approaches that will need to engage the whole practice, including receptionist staff. This requires protected time for reflection and a capacity for the whole practice to reflect and improve their practice.
- Clinical leadership. Leadership approaches that recognize that each practice micro-culture arises in a particular historical and social context also enable the construction of practice level systems for organising clinical decision making and accountability. We argue that such leadership is the most effective way of achieving sustained improvements in primary care quality. Effective clinical leadership generally evolves from existing practice leaders, who need not necessarily be doctors. If the person designated as leader is unprepared or unsupported in leadership, then clinical governance will probably be dismissed as being of poor relevance. Networks that assist in information exchange and norm setting are important resources for clinical leaders.

The two elements of infrastructure which are likely to support clinical governance are:

- Information systems that can readily provide data back to services, and
- Management capacity to provide ongoing scrutiny of the service as a quality-delivering organization. The structure of Australian fee-for-service general practice tends to confine GPs to booked clinical care, leaving nurses or managers to undertake the quality work involved with continuity of care, safety and accessibility. In the hospital setting, clinicians can be released from direct clinical care to develop these processes.

The drivers of these changes at the service level primarily occur at the regional level (Divisions of General Practice, regional community health services, education providers) or at the macro-level (government funding policy, national standards and performance indicators).

STRATEGIES AT THE REGIONAL LEVEL TO DRIVE CLINICAL GOVERNANCE

1. Create networks of support for clinical governance

There is good evidence that peer networks, if properly resourced and encouraged to be reflective, support practitioners to develop innovative ways of implementing evidence, or developing novel solutions to service problems. The Australian Health Care Collaboratives offer one example of a collaborative change model, albeit one which necessarily has a narrow clinical focus. Divisions of General Practice and regional state health authorities are well placed to develop and resource broader networks, and many are doing so already. The disconnect between private practitioners and state-funded health services could be partly addressed by encouraging these two network organizations to collaborate in developing governance, possibly by tracing patient journeys across the two sectors and identifying risk points.

2. Educate clinical leaders in inculcating cultures of change in practice

Many practitioners, especially in the community health sector “leak into quality”, in the words of one informant. Their roles and responsibilities as clinical leads are poorly characterized, and the educational background one needs to do this work is unstated. There is a need to develop ongoing education for clinical leaders, which may be accomplished by partnering with universities or representative/industry bodies for these services.

3. Identify and disseminate an evaluation of medical software

for its utility in relation to clinical governance, through academic detailing. Practices are familiar with the role of Divisions in supporting informatics in their services, and this model could be expanded to include state-funded primary care services.

STRATEGIES AT THE MACRO LEVEL TO DRIVE CLINICAL GOVERNANCE.

These drivers are those that provide a financial or professional incentive to engage in clinical governance.

1. Incorporate clinical governance into general practice accreditation

by developing a set of standards around these that are able to be reported against. These standards are likely to be measured using narratives of quality improvement, rather than ticking boxes.

2. Develop a funding model that accords some funding to clinical leadership

Engaging in clinical governance should be a net income producer for practices, rather than a financial drain. Funding mechanisms could include: Medicare service incentive payments provided to accredited and non-accredited general practices which engage in clinical governance; higher private insurance rebates for attending allied health practices that engage in clinical governance; packages of funding for organisations associated with achievement of process indicators for clinical governance or for reaching certain quality targets. The business case for clinical governance should then be disseminated to services. Funding should be available to develop

Primary care leaders, who should come from general practice and academia. Universities traditionally have ten times the professors of medicine as they do professors of general practice.

3. Develop a robust process for developing and adjusting indicators

to be locally relevant and useful for the service to report against. Indicators need to be limited and streamlined, so that services do not become over-burdened by the response and reporting burdens, and should be developed in cooperation with representative/industry bodies. Funding for attaining the indicators should be returned to practices quarterly, so that they have an income stream to undertake governance. This is of particular importance in services with multiple funders, such as Aboriginal community controlled services, or some community services.

4. Encourage standardisation in the medical software market and provide incentives for incorporation of clinical governance tools.

Vendors need to be encouraged to improve the capacity and capability of their products to support clinical governance. The software market is highly competitive, and government should harness this competitiveness by making clinical governance a specification for evaluating and acquiring software for the health sector. The focus of these standards should be: (1) Improving coding and the consistency of coding; (2) Effective tools to extract and aggregate routinely collected data; (3) New methods of usability testing – especially focusing on improved information support in the consultation, especially improving prescribing safety.

5. Consider, develop and trial more innovative funding models to drive quality

Block payments for quality and pay for performance models already exist, and can be fine-tuned to this purpose. One challenge with pay for performance is that the behaviours that are paid for need careful definition to avoid perverse incentives. McLellan's study of performance-based contracted in substance treatment services provides a positive example of clearly articulated pay for performance. Market based control mechanisms, such as a cap-and-trade model⁸⁵ where quality credits can be traded between health care services, also warrant consideration. This would enable high quality services (which would be sellers of "quality credits") to distinguish themselves in the marketplace and to receive a direct financial dividend from their quality service. It would also send a signal to the public about the services that might not be as engaged in high quality service in all areas, but which might have quality credits in relation to particular aspects of care, such as efficiency or accessibility.

INTRODUCING CLINICAL GOVERNANCE AS EVERYDAY PRACTICE

We believe these policy drivers are best introduced in a phased manner that creates a culture of quality while supporting a notion of professional accountability. Managerial and community accountability can be built onto this in the second phase, once professional accountability models have become established. We encourage active seeking of advice from sectors with some experience in disseminating clinical governance about the challenges in this field (Aboriginal medical services, Victorian Healthcare Association and the Australian Defence Forces medical services).

The first phase should involve developing a sense of *shared commitment* to clinical governance within the services. Clinical governance is a poorly understood term, with different sectors of the primary care workforce equating it with bureaucratic control, or medical dominance. In an online survey by the RACGP seeking members' input into standard-setting on clinical governance, about one third of respondents expressed antipathy to the idea (generally casting it as excessively bureaucratic) and one third were ambivalent.

The conversation about clinical governance should be driven by recognised clinical leaders who are able to generate a sense of excitement around the concept. Exemplary narratives offer the best way for participants to understand how the process works and various mechanisms including using the trade professional press should be used to disseminate discussion and narrative around clinical governance.

The second phase involves consolidation of clinical governance, and some can be undertaken in an overlapping manner with the first phase.

Phase 1: Beginning the conversation about clinical governance in the Australian primary care sector

1. Market clinical governance to GPs and primary health care workers through
 - discussion papers and accounts of exemplary practice in the medical and nursing trade press
 - establishing an Primary Care and Clinical Governance website with exemplary stories of clinical governance in primary care
2. Introduce clinical governance into (a) the RACGP standards, to be used in accreditation of general practices and (b) the Australian Council of Healthcare Standards, to be used in the EQUIP accreditation of community health services.
3. Fund Divisions of General Practice and Area Health Services/regional health authorities to undertake clinical governance support for services, using peer networks within and across services, and guided by the standards.
4. Appoint clinical governance lead supports in Divisions of General Practice and regional and national state-funded health authorities. These would be supported by highly skilled clinical governance leads allocated in state and national based organizations, who can develop, provide and model clinical leadership. The work already begun in the Aboriginal community controlled health service sector to deliver quality services warrants further funding in order enhance capacity and infrastructure.
5. Fund academic and service partnerships to produce educational resources for clinical governance that can be accessed by regional clinical governance leads. These should focus on different clinical areas; methods of implementation; and improving informatics.

Phase 2: Consolidating clinical governance in the Australian primary care sector

1. Encourage the development of software functions which provides medical data to services and enables them to develop local responses. This software will also be able to produce data on indicators to be reported against.
2. Develop a minimal set of indicators of good quality, using evidence based tools to assess quality indicators. Input from the Aboriginal community controlled health sector on their experience with indicators may be useful at this point.
3. Develop innovative funding models to reward clinical governance as indicated by activities and achievement. These might include:
 - an incentive payment for participating in clinical governance activities, expanded beyond the SIP model to include non-accredited practices
 - a practice nurse item that incorporated clinical governance activities such as audit or practice education
 - market-based control mechanisms using a system of "quality credits" that could be traded by participating practices, signaling the incorporation of quality into general practices and community services.

COST IMPLICATIONS OF CLINICAL GOVERNANCE MODELS

Professional models of accountability tend to be less expensive than managerial models, as they do not rely so heavily on reporting and monitoring. Excessive reporting burdens have very significant direct and cost implications, in that services sometimes have to appoint staff or divert staff to opportunity extract data.

The first phase of the dissemination strategy described above requires some funding inputs to

the Divisions (Commonwealth) or the regional health services (State), and a commitment of one-off funding to develop the educational materials for these groups. Encouraging competition in the medical software industry around clinical governance support is relatively low cost, as the market will determine the uptake of IT systems provided clinical governance is defined, accepted and has business benefits.

The second phase, when clinical governance is institutionalized requires more government investment. Careful incentives need to be developed to prevent a range of perverse incentives (to measure the wrong thing) or adverse outcomes (loss of team culture because all the reporting is done by nurses, while the income bonus went to doctors⁸⁶) Policy makers will be faced with a decision about whether, and how, clinical governance activities can be covered by expanding the Medicare schedule, or whether it is better to fund regional primary health care organizations directly to support this work.

AREAS FOR FURTHER RESEARCH

The published literature on clinical governance is compromised by its failure to articulate all the dimensions of care, particularly interpersonal dimensions of care, and an excessive focus on measurable aspects of chronic disease management. Although the latter is of course key, the outcomes (often highly variable) need to be interpreted in a more contextualized and realistic manner. Key areas for further research include:

- Community accountability models: outcomes and processes, and how and if they may be used to drive the uptake of clinical governance.
- Comparative usability testing of different vendors computer systems. We need methods of appraising how different features within computer systems facilitate improved standards of care.
- Multimethod studies exploring interpersonal aspects of care, especially continuity, accessibility, and responsiveness.
- Ongoing rigorous and theorized evaluation of the roll-out of quality initiatives in Australian general practice supported by the new institute supporting quality, analogous to the work done by the National Primary Care Research and Development Centre Evaluation in Manchester during the NHS reforms in England.

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