Can clinical governance deliver quality improvement in Australian general practice and primary care? A systematic review of the evidence

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Improving the quality of primary health care is a complex undertaking. Over the past decade, clinical governance has been promoted as a systematic, integrated approach to assuring safe, good quality health care.[1] Its intent is to move beyond the organisational "magic bullet" of single strategies (eg, professional education, audit, or risk management) to a systematic, multifaceted approach to quality improvement using a range of locally implemented strategies.

In Australia, most work on clinical governance has been in hospitals[2] In the past 5 years, however, there has been an emerging interest in clinical governance in primary health care. Failures in health care delivery occur frequently in primary health care, just as they do in hospitals. In a study using anonymous reporting of adverse outcomes in Australian general practice, errors were estimated to occur in one in 1000 consultations;[3] of 433 errors, nearly 70% were attributed to failures in the processes of health care, and 30% to the failure of individual general practitioners' knowledge and skills.[4] Partly in response to this, the Royal Australian College of General Practitioners (RACGP) recently introduced clinical governance into its accreditation standards.[5] The Victorian Healthcare Association has developed a range of resources and guidelines for clinical governance in community health.[6] Improving quality, safety, accountability and performance is one of the four priorities in the draft national primary care strategy.[7] The final report of the National Health and Hospitals Reform Commission (NHHRC) advocated strategies and infrastructure for quality improvement, and these are integral elements of the NHHRC's recommendations on continuous learning, monitoring and interprofessional and intersectoral collaboration.[8]

Given the policy development in this area, there is a need to clarify models of clinical governance and the evidence relating them to quality improvement. Here, we review the literature on different models of clinical governance, exploring their relevance to the Australian primary care sector, and their potential impacts on quality and safety.

ABSTRACT

Objectives: To review the literature on different models of clinical governance and to explore their relevance to Australian primary health care, and their potential contributions on quality and safety.

Data sources: 25 electronic databases, scanning reference lists of articles and consultation with experts in the field. We searched publications in English after 1999, but a search of the German language literature for a specific model type was also undertaken. The grey literature was explored through a hand search of the medical trade press and websites of relevant national and international clearing houses and professional or industry bodies. 11 software packages commonly used in Australian general practice were reviewed for any potential contribution to clinical governance.

Study selection: 19 high-quality studies that assessed outcomes were included.

Data extraction: All abstracts were screened by one researcher, and 10% were screened by a second researcher to crosscheck screening quality. Studies were reviewed and coded by four reviewers, with all studies being rated using standard critical appraisal tools such as the Strengthening the Reporting of Observational Studies in Epidemiology checklist. Two researchers reviewed the Australian general practice software. Interviews were conducted with 16 informants representing service, regional primary health care, national and international perspectives.

Data synthesis: Most evidence supports governance models which use targeted, peer-led feedback on the clinician's own practice. Strategies most used in clinical governance models were audit, performance against indicators, and peer-led reflection on evidence or performance.

Conclusions: The evidence base for clinical governance is fragmented, and focuses mainly on process rather than outcomes. Few publications address models that enhance safety, efficiency, sustainability and the economics of primary health care. Locally relevant clinical indicators, the use of computerised medical record systems, regional primary health care organisations that have the capacity to support the uptake of clinical governance at the practice level, and learning from the Aboriginal community-controlled sector will help integrate clinical governance into primary care.

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METHODS

The key question we examined was: What models of clinical governance deliver quality of care? We undertook a systematic review and realist synthesis of the literature.[9] Realist synthesis is particularly relevant for complex social interventions, as it aims to develop explanatory analyses of why and how these interventions may work in particular settings and contexts. It is therefore relevant for policymakers who are keen to explore whether or not a model may work in a given context.[10] Realist synthesis involves developing theories and models of how mechanisms work, using careful analysis of the literature and interviews with stakeholders.

We developed an operational definition of clinical governance by reviewing health policy on clinical governance in Australia, the United Kingdom and New Zealand (Box 1). We also reviewed the seminal papers on clinical governance referenced in those pol-

> **1 Definition of clinical governance used in this review**
>
> - Clinical governance is a systematic and integrated approach to ensuring services are accountable for delivering quality health care.
> - Clinical governance is delivered through a combination of strategies including: ensuring clinical competence, clinical audit, patient involvement, education and training, risk management, use of information, and staff management. ◆

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2 Quality dimensions (adapted from National Health Performance Framework, Australia 2001)[18]

Quality dimension	Description
Efficiency	An individual or service can achieve desired results with the most cost-effective use of resources
Effectiveness	An individual or service can achieve desired health outcomes
Capability	An individual or service has the skills and knowledge to provide a health service
Accessibility	A service allows people to obtain health care irrespective of income, geography or cultural background
Safety	An individual or service avoids or reduces to acceptable limits the actual or potential harm from health care management
Appropriateness	An individual or service provides care, intervention or action that is relevant to the client's needs and based on established standards
Continuity	An individual or service can provide uninterrupted, coordinated care or service over time
Responsiveness	An individual or service provides respect for persons and is client orientated
Sustainability	A service can provide infrastructure such as workforce, facilities and equipment to respond to current and emerging needs ◆

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icy documents,[11-16] and in the position documents on systematised quality approaches in health care in the United States.[17] Our definition of quality used the nine dimensions from the 2001 National Health Performance Framework[18] (Box 2).

Eligible studies

Studies were included if they were identified through the search term "clinical governance" or used a combination of strategies outlined in the definition to improve quality or accountability, and were either conducted in or applicable to the primary care sector. Studies were excluded if they focused on single strategies, or did not aim to improve quality or accountability. Search terms and strategy, and data analysis methods can be viewed in the complete report at http://www.anu.edu.au/aphcri/Domain/Drivers%20of%20successful%20primary%20health%20care/Access_best_practice_policy_options.pdf

Information sources

We searched 25 electronic databases, scanning reference lists of articles and consultation with experts in the field. Our search was largely limited to publications in English after 1999. A search of the German language literature for a specific model type was also undertaken on the recommendation of a member of our international reference group. The grey literature was explored through a hand search of the medical trade press and websites of relevant national and international clearing houses and professional or industry bodies.

Data extraction

All abstracts were screened by one researcher, and 10% of abstracts were screened by a second researcher to cross-check screening quality. Studies were reviewed and coded by four reviewers using standardised data extraction sheets and a data dictionary to record study type and quality, health service type, elements of quality in health care and relevance to the Australian context. Indicators that a study might be relevant for the Australian context were: (i) heterogeneous services with different systems of funding and governance; (ii) cultural separation of medical professionals from bureaucracy; and (iii) loose networks of primary care services. We included well-theorised and contextualised case studies and descriptive studies. All studies were rated using standard critical appraisal tools such as the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)[19] checklist. Two authors (C M P, S de L) also undertook a review of Australian general practice software for its potential contribution to clinical governance.

Development of models of clinical governance and their relevance to Australia

An iterative process was used to develop models of clinical governance suited to Australia, in which the mechanisms underpinning successful models were subjected to further review. Interviews were held with 16 key informants to review the relevance of the models and interrogate their feasibility. Interviewees were selected to illuminate clinical governance processes at:
- the service level (managers and clinicians in four key clinical services identified by their peers as being experienced in clinical governance);
- the regional level (representatives of regional health bodies — the Victorian Healthcare Association, a state-level Aboriginal service, National Aboriginal Community Controlled Health Organisation, Australian Primary Care Collaboratives, and Pegasus Health (a New Zealand not-for-profit organisation that supports 95 practices in the Christchurch/Canterbury area); and
- the national level (representatives of accreditation bodies, GP education bodies, Kaiser Permanente [a US integrated managed care consortium], the UK General Medical Council, and the UK National Primary Care Research and Development Centre).

Interviews (mean length, 57 minutes) were transcribed and coded using an emergent coding framework in NVivo, version 8.0 (QSR International, Melbourne, VIC).
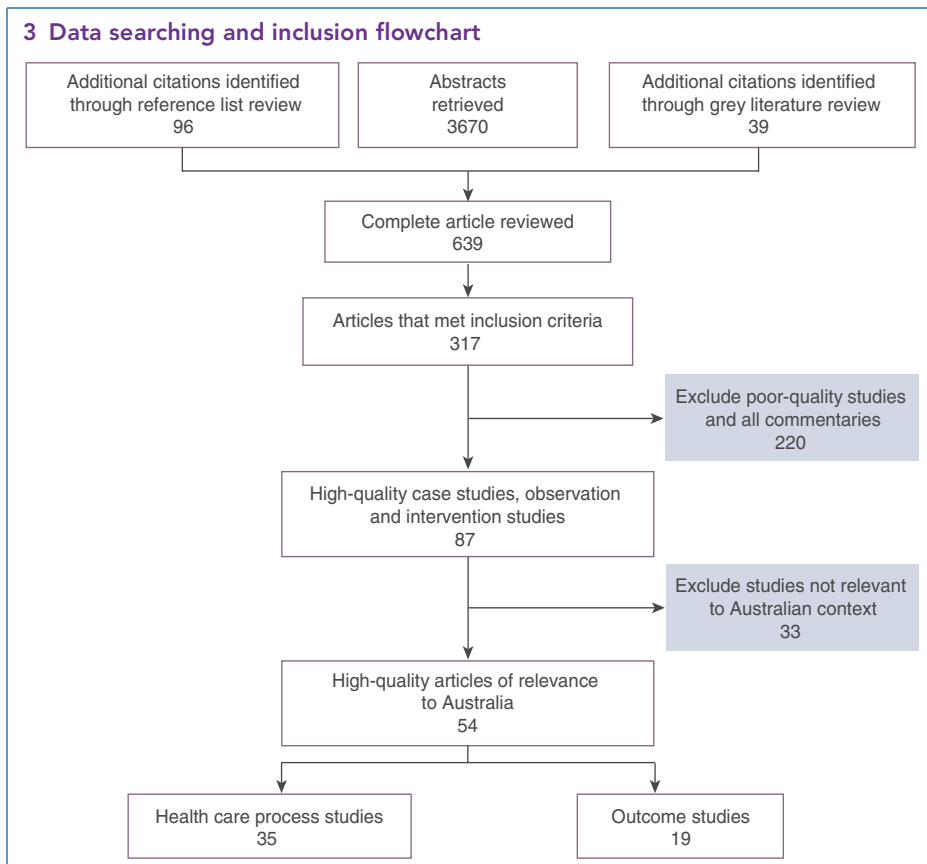
This study was approved by the Australian National University Human Research Ethics Committee.

RESULTS

Eighty-seven studies were assessed as being of high quality (Box 3) and, of these, 19 explored the outcomes of clinical governance. These 19 articles are the focus of this review. Seven were randomised controlled studies, 11 were longitudinal observational studies, and one was a well theorised and constructed case study. Six studies were from England,[20-25] two from the US,[26,27] four from Australia,[28-31] two from New Zealand,[32,33] and one each from Spain,[34] the Philippines,[35] Belgium,[36] and Germany.[37] Only one study compared clinical governance models in two countries, Holland and the US.[38]

Most studies addressed capability.[20-23,25-32,35-37] There were no studies that addressed continuity or appropriateness of care, and few that addressed responsiveness[20,24,25,27,34,35] and accessibility.[20,26,30,33,35] Only four studies addressed safety.[24,25,31,37] Although many studies explored incentive systems, very few

3 Data searching and inclusion flowchart

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┌─────────────────────────┐  ┌─────────────────┐  ┌─────────────────────────┐
│ Additional citations    │  │ Abstracts       │  │ Additional citations    │
│ identified through      │  │ retrieved       │  │ identified through grey │
│ reference list review   │  │ 3670            │  │ literature review       │
│ 96                      │  │                 │  │ 39                      │
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                        ┌──────────────────────────────┐
                        │ Complete article reviewed     │
                        │ 639                           │
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                        │ Articles that met inclusion   │
                        │ criteria                      │
                        │ 317                           │
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                                       │             ┌───────────────────────────┐
                                       ├────────────▶│ Exclude poor-quality      │
                                       │             │ studies and all           │
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                        │ High-quality case studies,    │
                        │ observation and intervention  │
                        │ studies                       │
                        │ 87                            │
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                                       ├────────────▶│ Exclude studies not       │
                                       │             │ relevant to Australian    │
                                       │             │ context                   │
                                       │             │ 33                        │
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                        ┌──────────────────────────────┐
                        │ High-quality articles of      │
                        │ relevance to Australia        │
                        │ 54                            │
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              ┌─────────────────────┐    ┌─────────────────────┐
              │ Health care process │    │ Outcome studies     │
              │ studies             │    │ 19                  │
              │ 35                  │    │                     │
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titioners into clinical governance than "hard governance" measures like assessment of professional competence.[39]

Box 5 outlines the evidence for each model's contribution to the quality domains. Interventions at different levels can improve capability of care, but this improvement appears to be related to the type of care and how easy it is to systematise care processes. Improvements in capability are more easily achieved in prescribing practice than in chronic disease management, where the evidence for improvement is varied and context-dependent. There are fewer data on effectiveness (ie, whether the intervention results in a measurable health improvement) than on capability (ie, whether the intervention results in an improvement in skills or practice), but in two uncontrolled studies, there was an improvement in the outcomes of chronic disease (angina,[20] asthma[20] and diabetes[29]) without an improvement in capability. Both these studies suggest that trends and/or unmeasured contextual effects lead to changes in outcomes irrespective of clinical governance measures.

Most evidence supports governance models which use targeted, peer-led feedback on the clinician's own practice. There is less evidence supporting interventions across entire health systems, such as national level performance indicators, unless this is accompanied by appropriate levels of support, including infrastructure support. Top-down models to drive quality improvement (external accreditation, or economic incentives for quality measures for doctors) resulted in no improvements in a range of

described a clinical governance process, but rather posited a kind of black box between the incentive and the outcome. As a result, only four studies[25,30-32] explored the relationship between clinical governance and efficiency.

The models that emerged from the literature and interviews are summarised in Box 4. The strategies most used were audit, performance against indicators, and peer-led reflection on evidence or performance. Assessment of clinical competence was described relatively infrequently in the studies as a governance strategy; there are more articles describing the "enticement" of prac-

4 Description of clinical governance models

Level at which the model operates	Description of model	Example	Strategies used
National level	National benchmarking with or without regional-level development support	United Kingdom Quality and Outcomes Framework	Reporting against national performance indicators
Regional level	Collaboration with other clinicians or with community, with targeted feedback on practice	Australian Primary Care Collaboratives; the National Aboriginal Community Controlled Health Organisation's quality use of medicines program; New Zealand Pegasus Health's peer-led networks	Comparing practice or practitioner outcomes against one another; peer-to-peer education exercises
Service level	Practice-determined organisation of quality management, using targeted feedback to health care workers with supported reflection	Audit and Best Practice for Chronic Disease (ABCD) project; Breakthrough Series methods	Audit; small group reflection on practice
Multilevel approaches	National level benchmarking and incentive-setting, regional network support, and support for practice-level organisation using targeted feedback	National Prescribing Service	Audit; small group reflection; comparing data on individual practice with regional averages; national performance indicators

5 Impact of models of clinical governance on quality

	Type of model	Evidence for impact on quality			
		May improve	Conflicting or no evidence of impact	May worsen	Authors
National level	National benchmarking with regional level development support	Accessibility; capability	Responsiveness		Campbell et al 2003[20*†]
National level	National external benchmarking with no regional level support		Sustainability; responsiveness		Gene-Badia et al 2007[34]
National level			Responsiveness; capability	Accessibility	Catacutan 2006[35‡]
Regional level	Collaboration with other GPs, with targeted feedback to improve practice	Capability; safety			Wensing et al 2004[37§]
Regional level			Effectiveness; capability; accessibility		Landon et al 2004[26*]
Regional level	Collaboration with other GPs to improve practice, without targeted feedback	Efficiency	Capability; accessibility; effectiveness		Scott and Coote 2007[30]
Regional level			Capability		Van Driel 2007[36§]
Regional level	Collaboration with community to set clinical priorities and/or monitor services	Accessibility			Crampton et al 2005[33]
Service level	Practice-determined organisation of quality management, using targeted feedback to health care workers with supported reflection	Effectiveness	Capability		Bailie et al 2007[29*]
Service level		Effectiveness; capability			Valk et al 2004[38*]
Service level		Safety; responsiveness			Fraser et al 2002[24§]
Service level		Efficiency; safety; responsiveness; capability			McKinnon 2001[25§]
Service level		Capability	Effectiveness		Cranney et al 1999[22*]
Service level		Capability			Cheater et al 2006[23*]
Service level		Capability	Effectiveness		Si et al 2007[28*]
Service level			Effectiveness; responsiveness; capability		Ornstein et al[27]
Service level			Effectiveness; capability		Baker 2003[21*]
Multilevel	National level benchmarking and incentive-setting, regional network support, and support for practice-level organisation using targeted feedback	Efficiency; capability			Malcolm et al 2001[32§]
Multilevel		Efficiency; capability	Effectiveness; safety		Beilby et al 2006[31§]

* Chronic disease management. † Complex care (eg, care of older people, mental health). ‡ Curative services in developing countries. § Prescribing practice. ◆

quality domains, and in one country with limited resources (Philippines),[35] led to a decline in accessibility. Sustainability may also deteriorate under a top-down model of governance without support and infrastructure, a risk also noted at interview by workers within the Aboriginal health sector.

Of the 11 software packages most commonly used in Australian general practice, only four enable the user to participate in regional or aggregated data quality activities. No system had inbuilt data quality checks (eg, "How often are angiotensin-modulating drugs prescribed without renal function being checked?"). Most have some inbuilt searches for items that relate to funding initiatives or chronic disease management. The ability to do other searches was quite variable and often required significant computer and database knowledge. Only one package allowed patient access through a web portal, to which both the practice and the patient must have subscribed. Achieving some degree of standardisation may be an essential step in the implementation of clinical governance.[40]

An emerging theme in the interviews was the lack of clarity around the definition and purpose of clinical governance. Concerns were expressed that the concept might denote governance of or by clinicians, rather than strategic approaches to improving clinical care. There was resistance among professional groups to the idea of externally set performance indicators, which had the capacity to grow beyond indicators which would improve practice. The Aboriginal sector in Australia has pioneered the development of locally relevant performance indicators, and also reported on the organisational costs of reporting to multiple disconnected performance indicators. Many interviewees commented on the difficulties of using information systems to best improve practice in Australia, with a great deal of energy being expended in extracting data from systems that did not intuitively allow this. This was in contrast to other settings (eg, Kaiser Permanente, and Pegasus Health's data on prescribing practice), where regionalised aggregated data were available and could be compared with individual practitioners' data.

DISCUSSION

The evidence in favour of clinical governance in general practice and primary care is fragmented. The largest body of evidence relates to the areas that are most easily measured, such as the quality of prescribing practices. There is less evidence for quality improvement in chronic disease management and complex areas like health care for older people and mental health care. However, the development of outcome indicators in chronic and complex care is challenging, and the lack of evidence of the impact of clinical governance may reflect measurement difficulties rather than a genuine lack of impact. More research is needed into interventions to improve safety, sustainability, efficiency and responsiveness in primary care.

The most acceptable mechanisms to drive clinical governance are those that recognise professional leadership and are perceived as being locally relevant and allowing reflection on one's own professional practice. There is a reasonable evidence base to support the role of well resourced peer support networks to facilitate clinical governance. Clinical governance strategies that rely on guidelines alone have not proven effective among GPs. Performance indicators, clinical standards and guidelines — advocated in the Australian Government's response to the NHHRC report,[41] and in the draft National Primary Health Care Strategy[7] — have a role in guided reflection and quality improvement. However, exclusive or excessive use of these top-down mechanisms can result in opportunity costs for the service,[42] disruption of teamwork if the reporting task is delegated,[43] and constructing clinical activities around indicators rather than need.[44] An increase in the measurement of common chronic conditions that were the subject of incentives, over others that were not, was noted after the introduction of the Quality and Outcomes Framework in the UK.[45]

The Australian Government's response to the NHHRC report proposed combining GPs and state-funded community health systems under the one regional structure, Primary Health Care Organisations (or Medicare Locals).[41] This would provide a platform for regional networks to support clinical governance,[46] and would presumably build on structures such as the Divisions of General Practice network or Victoria's Primary Care Partnerships. The UK experience suggests that networks of practices interact to seek corroboration of the value of new information and evidence within local networks, before these practices establish patterns of clinical governance.[47] Trust may be undermined if regional-level involvement in clinical governance is seen to be only the collection of data for reporting purposes.

A central difficulty in introducing clinical governance is a lack of consensus among primary care workers about its meaning. Clinical governance remains a poorly understood term, often equated with bureaucratic control, or medical dominance.[48] There is a need for regional or national organisations to display leadership in explaining and demonstrating what clinical governance actually involves. Examples of leaders in this area are the RACGP in their standards work and the work of the Victorian Healthcare Association.

The Aboriginal community-controlled sector is in the vanguard of clinical governance in Australia. The development of clinical indicators in some services (eg, Kimberley Aboriginal Medical Services[49]) preceded mainstream work in this area. Across the sector, there has been a concerted and long-term development of capacity and personnel to drive clinical governance activities. The opportunity cost of resource-poor services directing personnel to data collection for reporting purposes rather than for data translation to service improvement is also well understood within the sector. Input from this sector should be sought from others in Australia to inform the implementation of clinical governance across all primary health care.

The lack of good information on practice in Australia is a critical constraint for clinical governance activities. In some organisations in the US and New Zealand, regional networks have access to detailed service-use data. In Australia, this level of feedback is only provided through the National Prescribing Service. In all other areas, specific clinical software is interrogated to generate routine data on individual practices, but the software itself is frequently insufficiently usable by service staff. As a minimum, service providers should have access to their own data on prescribing, tests ordered, referral patterns, and the demographic patterns and illnesses of their patients. Ready extraction of these data with a unified coding system should be built into the standards developed for clinical software.

For clinical governance to become second nature in Australian primary care, health care practitioners need to be actively engaged as partners in quality improvement. The evidence is strongest for improvements that are driven by health professionals at the practice level, with support from regional networks. Such activity at regional and service levels needs support through structural changes initiated at the national level. This should include funding of time for clinical governance, supported by information systems which provide ready access for practitioners to their own clinical data.

COMPETING INTERESTS

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