# APPENDIX A

# Literature Search Strategy

Challenges presented by the topic and nature of the literature for this review were two-fold:

1. Devising a robust and sensitive search strategy around covert coverage of clinical governance. The literature contains relatively little material that is badged overtly as clinical governance – especially with respect to primary care settings – and this tends to be drawn from the UK. Much of the less obvious material deals with individual elements of clinical governance rather than a holistic approach.
2. Filtering the large volume of material which is generated by a sufficiently sensitive search strategy, in order to be appropriately specific and focus on material which is germane to the research questions and manageable in terms of volume.

To address these challenges a two-fold search strategy was used – consisting of both an 'overt' and a 'covert' search.

The following databases were explored using both the covert and overt search strategy:

Australian Public Affairs - FT
Blackwell / Wiley Interscience
Business Source Premier
CINAHL Plus
Cochrane (DSR / DARE / EPOC / HTAB)
ECONlit
Elsevier / Science Direct
Embase
European Business Review
Health Economics Network
Informaworld
Informit
Ingenta Connect
International Bibliography of Social Sciences
Legal Online
Legal Scolarship Network
Medline
ProQuest (ABI Inform Global / 5000 Int)
PsychInfo
Scopus
Social Science Citation Index
Soc Sci Research Network
SocINDEX
Sociofile
Wolters Kluwer Health

Searches were limited to papers with English language abstracts. A limited search of the German language literature for a specific model type was also undertaken at the recommendation of a member of the International Reference Group. Further articles were identified through a snowballing strategy from relevant papers and policy documents. English language grey literature was identified using the overt search terms outlined in Figure1a, through a hand search of the medical trade press (Medical Observer, Australian Doctor, Family Practice News) and websites of relevant clearing houses, online repositories and professional or industry bodies. These include the following:

Centre for Reviews & Dissemination
Australian Primary Care Collaboratives
Institute for Healthcare Improvement (US)
Open SIGLE
ClinMed Net Prints
NLH (UK)
Clin Gov Support Team (NHS)
National Guidelines Clearing House (USA)
Participate in Health Clearing House (AUS)
Australian Resource Centre for Hospital Innovations
RACGP
AMA
AGPN

While the search strategy for overt coverage of clinical governance was straightforward, the search strategy for covert coverage of clinical governance was more complex. It is presented schematically in Figure 7.1.

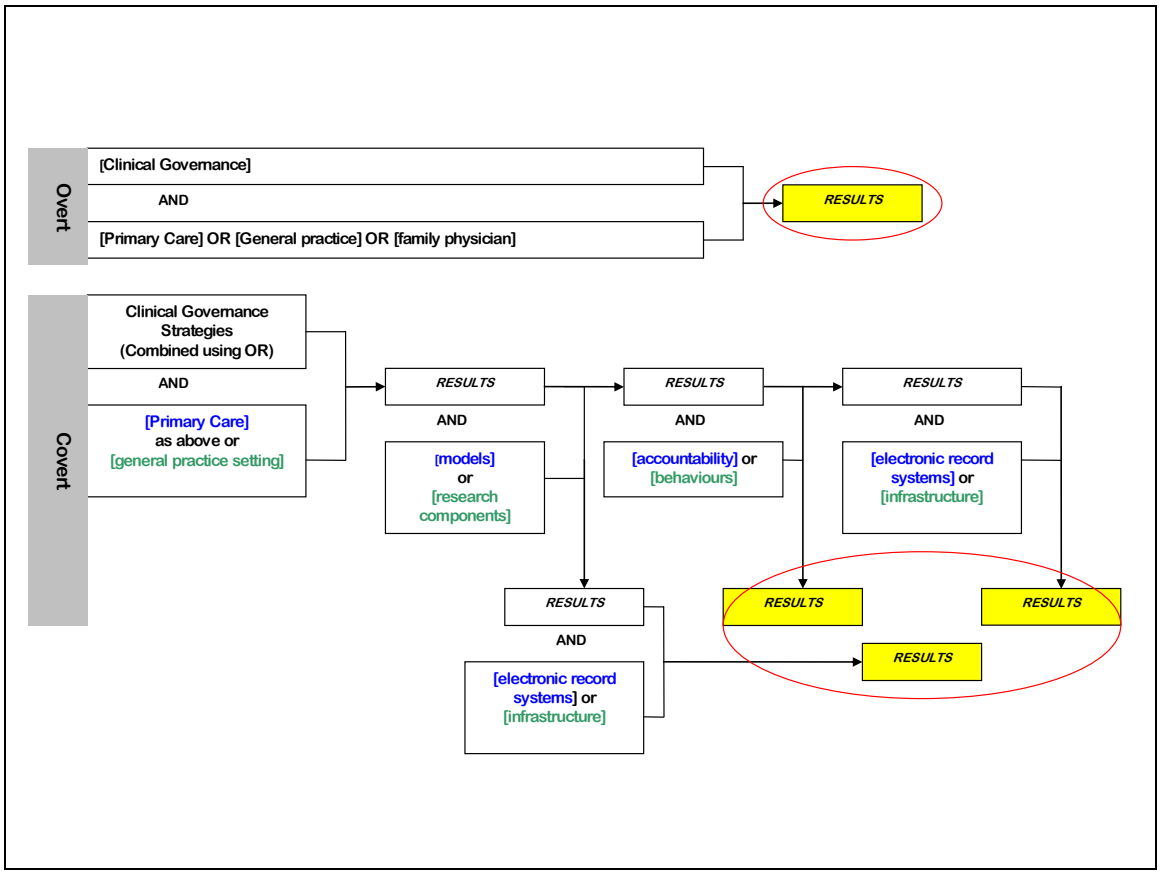


***Figure 7.1: Flow chart of data search strategy for covert and overt search***

In brief, using the overt search strategy, papers referencing the term 'clinical governance' were sourced, and then filtered using a series of terms used internationally to signify primary care or general practice equivalent modes or settings.

In the covert strategy, papers were sourced using a series of terms to denote individual elements or strategies of clinical governance activities (these terms are outlined in Table 7.1 and 7.2). These were then filtered through a sequential process, first determining their relevance to primary care or general practice settings, then consecutively by reference to terms denoting the concept of (i) a model or systematic approach, and (ii) accountability or responsibility. Where further filtering was required on the basis of numbers, an additional filter seeking reference to information technology or infrastructure was applied.

Because date filters could not be universally applied to all databases, these were utilised at the point of screening. Where possible MeSH terms were used to guide searching, however these are generally health specific and were not available on all databases. These are denoted in green on the diagram above. In other cases, searches were based on keywords, title and abstract (denoted in blue). MeSH terms used are presented in Table 7.1 below. Key word search terms are presented in Table 7.2.

Since the first part of this study was essentially descriptive, the abstracts of all papers describing clinical governance were screened and included for review if they met the screening criteria, which were:

- nature of the article (evidence or analysis vs opinion)
- notion of a *clinical governance model,* or
- the purpose or intent of the application of the CG tool or strategy.

| *Clinical Governance components* | *MeSH Subheadings* | *Subject code* |
|---|---|---|
| *Activities* | | |
| Health care quality access & evaluation *N05* | Quality assurance, health care[1] | *N05.700* |
| Social control, formal *N03.706* | Accreditation | *N03.706.110.070* |
| | Peer review, health care | *N03.706.700* |
| | Jurisprudence | *I01.880.604.583* |
| | Social control policies | *I01.880.604.325* |
| Organization and administration *N04.452* | Risk management | *N04.452.871* |
| | Safety management | *N04.452.884* |
| | Management audit | *N04.452.500* |
| Data Collection *L01.280* | Medical records | *L01.280.900.968* |
| *Infrastructure* | | |
| Medical informatics applications *L01.700.508* | Decision support techniques | *L01.700.508.190* |
| | Community networks | *L01.700.508.300.184* |
| Information systems *L01.700.508.300* | Decision support systems, clinical | *L01.700.508.300.190* |
| | Reminder Systems | *L01.700.508.300.790* |
| | Knowledge bases | *L01.700.508.300.550* |
| *Behaviours / principles* | | |
| Ethics, Morals K01.316.630 | Social Responsibility | *K01.316.630.595* |
| Behaviour, Communication *F01.145.209* | Disclosure | *F01.145.209.259* |
| *Research components* | | |
| Health services administration *N04* | Models, organisational | *N04.452.534* |
| Investigative techniques *E05* | Models, organisational | *E05.599.670* |
| Science *H01.770* | Research | *H01.770.644* |
| Health care quality access & evaluation *N05* | Health services research | *N05.425* |
| Quality of health care *N05.715* | Health care evaluation mechanisms | *N05.715.360* |
| *General Practice setting* | | |
| Comprehensive health care N04.590.233 | Primary Health Care | *N04.590.233.727* |
| Occupational groups M01.526 | Physicians, Family | *M01.526.485.810.770* |
| Health personnel N02.360 | | *N02.360.810.770* |
| Health occupations, medicine | Family Practice | *H02.403.776.230* |

***Table 7.1: MeSH terms used in overt and covert search strategies***

| | |
|---|---|
| **Overt search** | |
| [Primary Care] | "primary care" OR "primary health care" OR "general practice" OR "family medicine" |
| [Clinical Governance] | "clinical governance' |
| **Covert search** | |
| [Primary Care] | "primary care" OR "primary health care" OR "general practice" OR "family medicine" |
| [quality] | "quality improvement" OR "quality health care" OR "quality control" OR "quality care" OR "quality assurance" OR "quality management" OR " quality of service" OR "patient safety" OR "accreditation" OR "standards" |
| [models] | "models" OR "examples" OR "theories" |
| [accountability] | "accountability" OR "standards" OR "accreditation" OR "audit" OR "measurement" OR "reporting" |
| [ER systems] | "electronic health record" OR "electronic patient record" OR "information systems" |

***Table 7.2: Key word search terms –overt and covert strategies***

The screening strategy, using this approach, included papers that suggested the presence of a 'clinical governance model' based on the working definition of a model as *a set of replicable*

*strategies and approaches which are used together to produce an intended outcome.* This definition implies that a model is purposeful, and may often consist of more than one strategy, or approach. We had also determined to take a structuralist – functionalist to considering the literature, examining component, context and purpose. This meant then that for the purposes of screening, and referencing the conceptual model of clinical governance we had developed, a clinical governance model might be:

> "a group of identifiable activities / tools / strategies which are used in a strategic or purposeful manner to improve the quality or safety of clinical care, improve understanding of or accountability for this care, or improve patient satisfaction with care."

To this end, articles were screened according to the following formula, where a model was deemed to be in effect if the article described either :

- one element from the 'purpose' domain + two or more elements from the 'strategy' domain
- one element from the 'purpose' domain + one element from the 'strategy' domain + one element from the 'structure' domain

This approach recognises the system-level interaction of different components of a clinical governance model, and would prevent an excessive focus on papers that simply explored the use of singular strategies or tools (eg audit). The inclusion of an element from the "purpose" domain would ensure that publications were oriented towards a central governance concern. Ten per cent of abstracts were screened by a second author to cross-check screening quality.

Papers were reviewed and coded using standard data extraction sheets (Appendix B) for:

- study type, quality and relevance,
- health service type,
- elements of quality[2]
- strategies used in the model, and
- relevance to the Australian context

Because this study was a realist review, we included studies that were of "low quality", including expert commentary and descriptions of programs. The highest quality studies were well theorised and analysed case studies, and occasional intervention studies, both of which included more detail on context which enabled us to understand mechanisms.
Commentaries and descriptions of programs were used to develop the models, whereas the high quality case studies and intervention studies were used to answer our questions on which models may work for indigenous and rural communities, and what drivers were needed to make clinical governance routine in Australian primary health care services.

# Literature search results

| | Overt Search | Covert Search | Snowball | **TOTAL** | Grey Literature |
|---|---|---|---|---|---|
| Abstracts retrieved | 1416 | 2254 | | **3670** | |
| Screened for review | 258 | 285 | 96 | **639** | 39 |
| Included Papers | 141 | 128 | 48 | **317** | 2 |
| High quality | 59 | 58 | 21 | **138** | 0 |

[2] National Health Performance Committee (2001), National Health Performance Framework Report, Queensland Health, Brisbane.

## *Included papers – data*

| | | COMMENTARY | CASE-STUDY | OBSERVATION | INTERVENTION |
|---|---|---|---|---|---|
| COUNTRY | Australia | 19 | 7 | 8 | 1 |
| | NZ | 2 | 2 | 4 | 0 |
| | UK | 61 | 28 | 49 | 9 |
| | Sweden | 2 | 3 | 1 | 0 |
| | Europe | 8 | 0 | 1 | 5 |
| | Africa | 2 | 0 | 1 | 0 |
| | Asia | 0 | 0 | 1 | 1 |
| | Canada | 3 | 1 | 2 | 0 |
| | USA | 33 | 7 | 17 | 8 |
| | Bahrain | 0 | 1 | 0 | 0 |
| | Israel | 0 | 0 | 0 | 1 |
| | International | 22 | 2 | 3 | 2 |
| TOTAL | | 152 | 51 | 87 | 27 |
| YEAR | Pre 1999 | 9 | 4 | 3 | 2 |
| | 2000-2004 | 63 | 24 | 37 | 12 |
| | 2005-2009 | 80 | 23 | 47 | 12 |
| | | | | | |
| HEALTH SETTING* | General Practice | 61 | 23 | 57 | 18 |
| | Community Health | 18 | 3 | 9 | 3 |
| | Hospital | 35 | 11 | 17 | 1 |
| | National / macro / system level organizations eg, NHS | 18 | 0 | 1 | 0 |
| | Regional / meso level organizations eg, PCGs & trusts | 2 | 7 | 5 | 1 |
| | Mental Health | 2 | 3 | 0 | 0 |
| | Indigenous Health | 1 | 0 | 2 | 0 |
| | Other eg veterans, schools, paediatrics, long term care, local govt | 9 | 0 | 1 | 4 |
| | Multiple | 0 | 7 | 0 | 0 |
| | Not specified | 33 | 7 | 0 | 1 |
| APPLICABILITY TO | Primary Care | 66 | 21 | 39 | 20 |
| | Rural | 32 | 12 | 24 | 10 |
| | Indigenous | 34 | 6 | 22 | 8 |

** More than one health setting may be addressed by a single paper*

# APPENDIX B
# Data Extraction Forms

## CASE STUDY

**Reviewer**

**Authors**

**Title**

**Source**

**Medium**

☐ Journal ☐ Website ☐ Book ☐ Report ☐ Other _____

**Country** **Year**

**Type of case study**

☐ Single case ☐ Multiple cases, one location ☐ Multiple cases & locations

**Type of health system**

☐ Hospital ☐ Community health centre ☐ General practice

☐ Other _____

**Governance focus addressed (check as many as applicable)**

☐ Leadership ☐ Teamwork

☐ Effective communication ☐ Systems approach

☐ Patient focus ☐ Ownership

**Governance strategies addressed at the micro level (check as many as applicable)**

☐ Audit ☐ Risk management

☐ Patient engagement ☐ Use of information

☐ Clinical competence ☐ Education and training

☐ Staff management ☐ Other _____

**Governance strategies at the macro level (check as many as applicable)**

☐ Regulation ☐ Health care funding ☐ Workforce training

☐ Cultural expectations ☐ Medicolegal ☐ Other policy issues

☐ Evidence as a driver of practice

**Are the reasons for choosing this case study clearly described?**

☐ Not at all, or barely described (0) ☐ Moderately described (1) ☐ Clearly described (2)

**Is the data collection technique clearly described**

☐ Not at all, or barely described (0) ☐ Moderately described (1) ☐ Clearly described (2)

**Were a range of data sources used to construct the case study?**

☐ Less than 2 datasources (0) ☐ 2-3 data sources (1) ☐ More than 3 data sources (2)

**Is the data analysis technique clearly described?**

☐ Not at all, or barely described (0) ☐ Moderately described (1) ☐ Clearly described (2)

**Are the results clearly described?**

☐ Not at all, or barely described (0) ☐ Moderately described (1) ☐ Clearly described (2)

**Research rating (sum)** _____

***Should I go on?***

***Research rating score: ≤ 3: Study is of insufficient quality → EXCLUDE***

**Is the context of the research clearly described?**

☐ Not at all, or barely (0) ☐ Moderately described (1) ☐ Clearly described (2)

**Are the results applicable to the Australian PRIMARY health care setting?**

☐ Not at all, or barely (0) ☐ Moderately applicable (1) ☐ Highly applicable (2)

**Are the results applicable to the Australian geographical setting (highly urbanized with widely small dispersed rural centres)?**

☐ Not at all, or barely (0) ☐ Moderately applicable (1) ☐ Highly applicable (2)

**Can the results be used in Indigenous settings?**

☐ Not at all, or barely (0) ☐ Moderately applicable (1) ☐ Highly applicable (2)

**Applicability Rating (sum)** _____

**Overall rating (Applicability + Research Quality)** _____

**What elements of quality of health care does it address?**

☐ None ☐ Effectiveness ☐ Appropriateness ☐ Efficiency ☐ Responsiveness
☐ Accessibility ☐ Safety ☐ Continuity ☐ Capability ☐ Sustainability

**Does the paper address barriers or facilitators of change?**

☐ No ☐ Briefly ☐ Yes, but only in general ☐ Yes, with specific examples

**If an intervention is described was it successful?**

☐ No ☐ Partially successful ☐ Very successful ☐ N/A

**Does this paper provide information that may be of value in considering costs of CG**

☐ Costs not an overt or covert focus of the paper ☐ Explicitly addresses cost issues ☐ May be used to consider issues of cost, though not a major focus

**Comments**

*Sources:*
*Atkins C, Sampson J.* ***Critical appraisal guidelines for single case study research.*** *ECIS 2002, Gdansk, Poland.*
*http://is2.lse.ac.uk/asp/aspecis/20020011.pdf*
*Mays N, Pope C. Qualitative research: rigour and qualitative research.* ***BMJ*** *1995;311:109-112*

## COMMENTARIES

**Source**

**Reviewer**

**Authors**

**Title**

**Source**

**Medium**

☐ Journal ☐ Website ☐ Book ☐ Report ☐ Other _____

**Attributes**

**Country** **Year**

**Type of commentary (check as many as applicable)**

☐ Cochrane review
☐ Non-Cochrane review
☐ Theory of clinical governance
☐ Commentary on experience
☐ Cross country comparison
☐ Cross-sectoral comparison

**Type of health system**

☐ Hospital ☐ Community health centre ☐ General practice
☐ Other_____

**Governance focus addressed (check as many as applicable)**

☐ Leadership
☐ Effective communication
☐ Patient focus
☐ Teamwork
☐ Systems approach
☐ Ownership

**Governance strategies addressed at the micro level (check as many as applicable)**

☐ Audit
☐ Patient engagement
☐ Clinical competence
☐ Staff management
☐ Risk management
☐ Use of information
☐ Education and training
☐ Other _____

**Governance strategies at the macro level (check as many as applicable)**

☐ Regulation ☐ Health care funding ☐ Workforce training
☐ Cultural expectations ☐ Medicolegal ☐ Other policy issues
☐ Evidence as a driver of practice

**Research rating**

**Are the goals of the commentary clearly described?**

☐ Not at all, or barely (0) ☐ Moderately described (1) ☐ Clearly described (2)

**Do the writers have expertise in fields relevant to clinical governance or PHC?**

☐ Neither (0) ☐ Primary care (1) ☐ CG (1) ☐ Both (2) ☐ Unclear

**Research rating (sum)** _____

***SHOULD I GO ON?***
***If expertise is unclear, confer with other reviewer.***
***If expertise is rated, and research rating ≤ 2: Commentary of insufficient value → EXCLUDE***

Applicability rating

**Is the context of the research clearly described?**

☐ Not at all, or barely described (0) ☐ Moderately described (1) ☐ Clearly described (2)

**Are the results applicable to the Australian PRIMARY health care setting?**

☐ Not at all, or barely (0) ☐ Moderately applicable (1) ☐ Highly applicable (2)

**Are the results applicable to the Australian geographical setting (highly urbanized with widely small dispersed rural centres)?**

☐ Not at all, or barely (0) ☐ Moderately applicable (1) ☐ Highly applicable (2)

**Can the results be used in Indigenous settings?**

☐ Not at all, or barely (0) ☐ Moderately applicable (1) ☐ Highly applicable (2)

**Applicability Rating (sum)** _____

**Overall rating (Applicability + Research Quality)** _____

Research questions

**What elements of quality of health care does it address?**

☐ None ☐ Effectiveness ☐ Appropriateness ☐ Efficiency ☐ Responsiveness
☐ Accessibility ☐ Safety ☐ Continuity ☐ Capability ☐ Sustainability

**Does the paper address barriers or facilitators of change?**

☐ No ☐ Briefly ☐ Yes, but only in general ☐ Yes, with specific examples

**Does this paper provide information that may be of value in considering costs of CG**

☐ Costs not an overt or covert focus of the paper ☐ Explicitly addresses cost issues
☐ May be used to consider issues of cost, though not a major focus

**Comments**

*Source: Satherley D et al. Supporting evidence-based service delivery and organization: a comparison of an emergent realistic appraisal technique with a standard qualitative critical appraisal tool.* ***Int J Evid Based Healthc****. 2007;5: 477–486*

## STUDIES OF INTERVENTIONS: EXPERIMENTS AND QUASI-EXPERIMENTS (LEVELS OF EVIDENCE 1-3; NHMRC 2002)

**Source**

**Reviewer**

**Authors**

**Title**

**Source**

**Medium**

☐ Journal ☐ Website ☐ Book ☐ Report ☐ Other _____

**Attributes**

**Country** **Year**

**Type of evidence**

☐ Level 3 (3) *Comparative studies, 2+ single arm studies, interrupted time series without a control group*

☐ Level 3 (2) *Systematic review of comparative studies, cohort studies, case control studies or interrupted time series with a control group*

☐ Level 3 (1) *Evidence from well-designed pseudo-RCTs (e.g. alternative allocation)*

☐ Level 2 *At least one well designed RCT*

☐ Level 1 *Evidence from a systematic review of all relevant RCTs*

**Type of health system**

☐ Hospital ☐ Community health centre ☐ General practice

☐ Other _____

**Governance focus addressed (check as many as applicable)**

☐ Leadership ☐ Teamwork

☐ Effective communication ☐ Systems approach

☐ Patient focus ☐ Ownership

**Governance strategies addressed at the micro level (check as many as applicable)**

☐ Audit ☐ Risk management

☐ Patient engagement ☐ Use of information

☐ Clinical competence ☐ Education and training

☐ Staff management ☐ Other _____

**Governance strategies at the macro level (check as many as applicable)**

☐ Regulation ☐ Health care funding ☐ Workforce training

☐ Cultural expectations ☐ Medicolegal ☐ Other policy issues

☐ Evidence as a driver of practice

**Are the goals clearly described?**

☐ Not at all, or barely described (0) ☐ Moderately described (1) ☐ Clearly described (2)

| | |
|---|---|
| Research rating | **Is the data collection technique clearly described?**<br>☐Not at all, or barely described (0) ☐Moderately described (1) ☐Clearly described (2)<br><br>**Do the data collection methods used appropriately measure the subject matter?**<br>☐Not at all, or barely (0) ☐Moderately (1) ☐Clearly (2)<br><br>**Is the data analysis technique clearly described?**<br>☐Not at all, or barely described (0) ☐Moderately described (1) ☐Clearly described (2)<br><br>**Are the outcomes of the research clearly described?** *(based on Rychetnik et al. 2002)*<br>☐Not at all, or barely described (0) ☐Moderately described (1) ☐Clearly described (2)<br><br>**Are unanticipated findings described?**<br>☐Not at all, or barely described (0) ☐Moderately described (1) ☐Clearly described (2)<br><br>**Research rating (sum)** _____ |
| | ***SHOULD I GO ON?***<br>***Research rating score ≤ 5: Study is of insufficient quality → EXCLUDE*** |
| Applicability rating | **Is the research context clearly described?**<br>☐Not at all, or barely described (0) ☐Moderately described (1) ☐Clearly described (2)<br><br>**Are the results applicable to the Australian primary health care setting?**<br>☐Not at all, or barely described (0) ☐Moderately described (1) ☐Clearly described (2)<br><br>**Are the results applicable to the Australian geographical setting (highly urbanized with widely small dispersed rural centres)?**<br>☐Not at all, or barely described (0) ☐Moderately described (1) ☐Clearly described (2)<br><br>**Are results applicable to Indigenous Australian health care settings?**<br>☐Not at all, or barely described (0) ☐Moderately described (1) ☐Clearly described (2)<br><br>**Applicability Rating (sum)** _____ |
| | **Overall rating (Applicability + Research Quality)** _____ |
| Research questions | **What elements of quality of health care does it address?**<br>☐ None ☐ Effectiveness ☐ Appropriateness ☐ Efficiency ☐ Responsiveness<br>☐ Accessibility ☐ Safety ☐ Continuity ☐ Capability ☐ Sustainability<br><br>**Does the paper address barriers or facilitators of change?**<br>☐ No ☐ Briefly ☐ Yes, but only in general ☐ Yes, with specific examples<br><br>**Does this paper provide information that may be of value in considering costs of CG**<br>☐ Costs not an overt or covert focus of the paper ☐ Explicitly addresses cost issues<br>☐ May be used to consider issues of cost, though not a major focus |
| | **Comments** |

*Source: NHMRC. How to review the evidence: systematic identification and review of the scientific literature. Canberra: NHMRC, 2000*

## OBSERVATIONAL DESCRIPTIVE STUDIES (INCLUDES SURVEYS)

**Source**

**Reviewer**

**Authors**

**Title**

**Source**

**Medium**

☐ Journal ☐ Website ☐ Book ☐ Report ☐ Other _____

**Attributes**

**Country** **Year**

**Type of health system**

☐ Hospital ☐ Community health centre ☐ General practice

☐ Other _____

**Governance focus addressed**

☐ Leadership ☐ Teamwork

☐ Effective communication ☐ Systems approach

☐ Patient focus ☐ Ownership

**Governance strategies addressed at the micro level**

☐ Audit ☐ Risk management

☐ Patient engagement ☐ Use of information

☐ Clinical competence ☐ Education and training

☐ Staff management ☐ Other _____

**Governance strategies at the macro level**

☐ Regulation ☐ Health care funding ☐ Workforce training

☐ Cultural expectations ☐ Medicolegal ☐ Other policy issues

☐ Evidence as a driver of practice

**Research rating**

**Are the goals of the study clearly described?**

☐ Not at all, or barely described (0) ☐ Moderately described (1) ☐ Clearly described (2)

**Is the study population clearly described?**

☐ Not at all, or barely described (0) ☐ Moderately described (1) ☐ Clearly described (2)

**Have the data collection methods been clearly described?**

☐ Not at all, or barely described (0) ☐ Moderately described (1) ☐ Clearly described (2)

**Are the statistical methods (including those controlling for confounding) well described?**

☐ Not at all, or barely described (0) ☐ Moderately described (1) ☐ Clearly described (2)

| | |
|---|---|
| | **Are the outcomes of the research clearly described?**<br>☐ Not at all, or barely described (0) ☐ Moderately described (1) ☐ Clearly described (2)<br>**Are unanticipated findings described?**<br>☐ Not at all, or barely described (0) ☐ Moderately described (1) ☐ Clearly described (2)<br>**Have potential confounders and effect modifiers been considered in the analysis?**<br>☐ Obvious confounders missed (0) ☐ Some coverage of confounders (1)<br>☐ Confounders considered and accounted for (2)<br>**Research rating (sum)** _____ |
| | ***SHOULD I GO ON?***<br>***Research rating score ≤ 5: Observational study is of insufficient quality → EXCLUDE*** |
| Applicability rating | **Are the results applicable to the Australian primary health care setting?**<br>☐ Not at all, or barely (0) ☐ Moderately applicable (1) ☐ Highly applicable (2)<br>**Are the results applicable to the Australian geographical setting (highly urbanized with widely small dispersed rural centres)?**<br>☐ Not at all, or barely (0) ☐ Moderately applicable (1) ☐ Highly applicable (2)<br>**Are results applicable to Indigenous Australian health care settings?**<br>☐ Not at all, or barely (0) ☐ Moderately applicable (1) ☐ Highly applicable (2)<br>**Applicability Rating (sum)** _____ |
| | **Overall rating (Applicability + Research Quality)** _____ |
| Research questions | **What elements of quality of health care does it address?**<br>☐ None ☐ Effectiveness ☐ Appropriateness ☐ Efficiency ☐ Responsiveness<br>☐ Accessibility ☐ Safety ☐ Continuity ☐ Capability ☐ Sustainability<br>**Does the paper address barriers or facilitators of change?**<br>☐ No ☐ Briefly ☐ Yes, but only in general ☐ Yes, with specific examples<br>**Does this paper provide information that may be of value in considering costs of CG**<br>☐ Costs not an overt or covert focus of the paper ☐ Explicitly addresses cost issues<br>☐ May be used to consider issues of cost, though not a major focus |
| | **Comments** |

*Source: Cochrane Collaboration: STROBE checklist on cross-sectional, cohort and case control studies*

# APPENDIX C
# Glossary : Data Dictionary of Key Concepts

**Australian geographic setting**

Australia has a land mass approximately equal to that of the United States, covering 7.7 million square kilometers. Circling the mainland are 12,000 islands, notably the state of Tasmania to the South and the 274 Torres Strait Islands to the north. As of 30 June 2008, Australia had an estimated population of 21.4 million, 85% of whom live on the coast. At that time the Australian Capital Territory (ACT) had the greatest proportion of its population living in the major cities (99.9%), Tasmania the highest percentage (64.7%) living in inner regional Australia, as well as the oldest population (median age of 39.4 years). The Northern Territory had the highest proportion of its population living in outer regional (55.4%), remote (21.7%) and very remote (22.9%) regions of Australia, and the youngest population (median age 31.1 years). New South Wales (NSW) has the largest population of Indigenous Australians (152,700 people), followed by Queensland (144,900 people), while the ACT has the smallest population of Indigenous Australians (4,300 people).[3]

**Australian primary health care setting**

The PHC context in Australia, especially relative to the general practice sector, is influenced by several key factors:

- A state / federal divide in funding and accountability, where state governments are generally responsible for publicly funded acute care services, but primary care is administered at the federal level and largely as a private health care enterprise. 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

[3] Pink B. *Australian social trends June 2009*. Canberra: Australian Bureau of Statistics; 2009.
Australian Bureau of Statistics. *Regional population growth, Australia, 2007-08*. Canberra: Australian Bureau of Statistics; 2009.
Australian Bureau of Statistics. *Experimental estimates of Aboriginal and Torres Strait Islander Australians, Jun 2006*. Canberra: Australian Bureau of Statistics; 2008.

for GPs and practices is voluntary.

- 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.

As a result, GPs are adapted to a situation of relatively high autonomy and may be culturally unsuited to top down governance approaches which are potentially unpalatable. There is also a question about an element of the Australian constitution prohibiting civil conscription. This is largely dismissed as irrelevant to policy implementation, but means that coercive pressure applied to GPs may be subject to a challenge under constitutional law.

**Case study**

The collection and presentation of detailed information about a small group or program, often using accounts of the participants themselves, interviews and document analysis. Much health service evaluation is constructed through a case study format (Study type).

**Clinical competence**

This category is potentially related to education and training intiatives, but distinct in that it deals largely with the skills /attributes of the practitioners, and ensuring these. Examples would be:

- Credentialling programs
- Peer review (possibly including qualified privilege)
- Competency based assessment
- Experiential placements for skills development (as distinct from training)
- Recruitment strategies (getting the right person for the job)
  Psychological profiling / assessment (micro level)

**Confounding and effect modification**

*Confounding*: a confounding variable is associated with both the probable cause and the outcome, but isn't an intermediary, and may make the relationship between probable cause and outcome spurious. *Effect modification* occurs when the effect of an exposure is different among different subgroups (in clinical governance studies, effect modification would occur if for example, the outcomes were different in different cultural groups)

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| **Cultural Expectations** | Common sense understandings of the "right" behaviours of health workers and health services, which reflect prevalent cultural notions. An example is the different notions of the "ideal" doctor-patient relationship, which can vary from medical parentalism to the patient-doctor partnership model. (macro level) |
| **Education and training** | Includes any activity that is targeted either at educational preparation of health care staff (including non-clinical personnel) or ongoing training such as professional development, inservice education, teaching and learning, gaining additional qualifications. It may include activities occurring in recognized educational institutions or on the job, and be either formal or informal (micro level). |
| **Evidence as a driver for practice** | Evidence based medicine (or practice) is defined as the *"… conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research."*[4] Evidence is categorised according to the level of evidence (LOE) range, established by the Centre for Evidence Based Medicine.[5] LOEs range from the level one (randomised control trials, and more recently, systematic reviews of randomised control trials, the highest level of evidence) to level five (expert opinion). Systematic reviews, such as those produced under the Cochrane Collaborative, predominately incorporate level one evidence of interventions. There has been an increased recognition, however, of the value of integrating qualitative studies into systematic reviews as a way of including the *"… experience of all those involved in providing and receiving interventions and studies using multiple methods to evaluate the factors that shape the process of implementing interventions* [these are said to play an] *important role* [in] *ensuring the systematic reviews are of maximum value to policy and practice decision-making."*[6] |
| **Health care funding** | Nearly 70% of all health expenditure in Australia is funded by the federal and state governments. The Commonwealth Government contributes two thirds of the funding for health care, |

[4] Sackett DL, Rosenberg WMC, Gray JAM, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. *BMJ*. 1996;312(7023):71-2.

[5] Centre for Evidence Based Medicine (CEBM) http://www.cebm.net/index.aspx?o=1001

[6] Joanna Briggs Institute. *What is qualitative research? What is its role in evidence review?* Adelaide: Joanna Briggs Institute; 2009. Available: http://www.joannabriggs.edu.au/cqrmg/role.html (Accessed 3 July)

predominately through direct funding to the states and territories ($64 billion in 2009-2010), and via the provision of Medicare and the Pharmaceutical Benefits Scheme (PBS) to citizens. Medicare covers payments for services provided by doctors, optometrists and selected health professionals such as clinical psychologists, while the PBS covers prescription medications. In both cases there may be an additional contribution required from the patients themselves, depending on the services and health professionals involved. As well as providing funding streams, the Commonwealth government is actively involved in public health, health research, quarantine issues, national level health information management and policies. The states and territories are responsible for the provision and management of publicly funded acute, psychiatric, community and public health services including environmental, maternal and child, school and dental health.[7]

**Indigenous Settings**

Indigenous Australians (approximately 1.5% of the Australian population) have significantly worse health outcomes than do non-Indigenous Australians, with a seventeen year life expectancy gap). Indigenous Australians have significantly higher GP attendance rates for trauma, diabetes, renal disease, infectious disorders, and psychological conditions, including substance dependence.

Most Indigenous Australians live in urban settings, with a smaller proportion living in rural and remote Australia. Key features of the health care setting are: conspicuous health disadvantage, specialized services that enshrine patient responsiveness, but are relatively under-funded, and often distance from tertiary health services. Indigenous Australians are served by mainstream general practice, but also by a network of community-controlled services, in which doctors and nurses are employed by a community board. All the services employ Aboriginal Health Workers, and they play a key culture-broking role. In practice, this task is enormously demanding, and sustainability of these positions can be difficult. Patients at these services often request gender-concordant consultations; in some remote communities this requirement for same-sex health practitioners is non-negotiable.

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[7] Financing and Analysis Branch of the Commonwealth Department of Health and Aged Care. T*he Australian health care system: an outline.* Canberra: Commonwealth Department of Health and Aged Care; 2000.
Australian Institute of Health and Welfare. *Australia's health 2008*. Canberra: Australian Institute of Health and Welfare, 2008.

The community controlled services are networked through a national organization, the National Aboriginal Community Controlled Health Organisations (NACCHO). NACCHO is functional and provides leadership on clinical governance issues (including spearheading a national multi-centre RCT examining the use of ciprofloxacin eardrops for chronic suppurative otitis media, a study which led to changes in national policy and pharmaceutical procurement

Services for Torres Strait Islanders are much more the responsibility of one state (Queensland). An additional challenge for CG in TSI settings is that they are also accessed by nationals of Papua New Guinea who cross the Strait by boat to use these services (Applicability).

**Leadership**

Leadership, along with collaboration, is one of the five personal pillars of clinical governance[8] and is considered a prerequisite for the successful improvement of healthcare services in general.[9] Within this context leadership involves the breaking down of professional and directorate (service) barriers so that "*… a culture of shared clinical governance is cultivated in which staff are empowered to accept responsibility and accountability at all levels of the hierarchy.*"[10] Clinical leadership is defined as "*… both a set of tasks required to lead improvements in the safety and quality of health care, and the attributes required to successfully carry this out …* [as] *clinician input into safety and quality improvement is critical for predicting the 'bedside impact' of changes, and for promulgating new ideas within and across clinical and professional boundaries. It is also vital for sustainability of change …."*[11] Leadership tasks include being able to develop a positive vision (where are we going), method (the way that improvement will happen), and behaviour (what we need from each other) towards clinical governance and quality improvement.[12] Strong and effective leadership is considered particularly important in times of health service reform and uncertainty. Leadership within a clinical context requires the ability to demonstrate (amongst other skills): adherence to, and role modeling of, key principles; constancy of purpose despite obstacles and difficulties; skills in directing,

[8] Kapur, N. On the pursuit of clinical excellence. *Clinical governance: an international journal*. 2009;14(1): 24-37.
[9] Crump, B. How can we make improvement happen? *Clinical governance: an international journal*. 2008;13(1): 43-50.
[10] Millward, L.J. Bryan, K. Cl. Clinical leadership in health care: a position statement. *Leadership in Health Services.* 2005;18(2): xiii-xxv.
[11] Victorian Quality Council. *Developing the clinical leadership role in clinical governance:a guide for clinicians and health services*. Melbourne: Metropolitan Health and Aged Care Services Division, Victorian Government Department of Human Services; 2005
[12] NHS. *Inspiring leaders: leadership for quality.* Department of Health, London.

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| | supporting and delegating; and sensitivity to the needs of other team members.[6] |
| **Medicolegal Issues** | Refers to the legal aspects of the *practice* of medicine, failures of which may leave the doctor or service liable to being sued. Includes references to tort (personal injury) law, and legal precedents as drivers for clinical governance (macro level). |
| **Observational descriptive studies** | This study type includes: surveys using questionnaires, or audits. In comparison with single case studies, which are primarily qualitative, this category includes studies which are primarily quantitative. If the study includes a before and after component (Level of evidence: 3c) for an intervention, or anything more involved, assess it using the Experiments and Quasi-experiments proforma (study type) |
| **Other policy issues** | This category is designed to capture initiatives which operate aspolicy level interventions but are not achieved through funding, regulation or education. Given that the money is often where the policy really is, these are likely to be 'softer' clues or weak signals and may be pre-emptive. Examples might include: advertising, policy papers, parliamentary briefings or research papers, media announcements, study tours, commissioned research, evaluation reports, other pointers to directional shifts in thinking, indirect pressure (ie., through modifying patient behaviour) or even policy influencing behaviour or lobbying by third parties. The best current examples here are NHHRC and the PHC Strategy (macro level). |
| **Ownership** | Clinicians' sense of ownership of, and engagement in, quality and safety improvement activities is an essential, but as yet not fully realized, element in the implementation of clinical governance.[13] A number of affective and procedural factors influence clinicians' commitment to quality improvement strategies: being able to see the benefits for their own practice and their patients, of proposed changes or strategies; having the time and space to review existing practices, and integrate new ones; and having a degree of control over the implementation and adaptation of changes to suit the particular clinical setting and staff involved.[14] |

[13] Davies H, Powell A, Rushmer R. Healthcare professionals' views on clinician engagement in quality improvement: A literature review. London: The Health Foundation; 2007; Halligan A, Donaldson L. Implementing clinical governance: turning vision into reality. *BMJ*. 2001;322(7299):1413-7

[14] Ham,C. Improving the performance of health services; the role of clinical leadership. *Lancet*. 2003;361;1978-1980

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| **Patient engagement** | Engagement of patients in the activities of the service, for example through patient advisory committees, patient partnerships or patient-held records (micro level) |
| **Patient focus** | A focus on being able to recognize and respond to patient needs, and/or direction-setting by patients (governance focus) |
| **Regulation** | A principle, rule, or law designed to govern procedures or behaviour in general practice. Includes professional regulation and O & S regulation (eg related to hazardous wastes and sharps management) (macro level). |
| **Quality of health care** | In Australia, the National Health Performance Committee has established a National Health Performance Framework which proposes nine dimensions of quality for assessing health system performance[15]. These are:<br>1. **Effectiveness** – the degree to which c**are, intervention, or activity achieves the desired outcome**<br>2. **Appropriateness –** the degree to which care/intervention/action provided is relevant to client's needs and based on established standards<br>3. Efficiency - achieving desired outcome with most cost-effective use of resources<br>4. **Responsiveness –** where a service provides respect for persons and is client orientated and includes respect for dignity, confidentiality, participation in choices, promptness, quality of amenities, access to social support networks, and choice of provider.<br>5. **Accessibility –** the ability of people to obtain health care at the right place and right time irrespective of income, physical location and cultural background.<br>6. **Safety –** the avoidance or reduction to acceptable limits of actual or potential harm from health care management or the environment in which health care is delivered.<br>7. **Continuity** – the ability to provide uninterrupted, coordinated care or service across programs, practitioners, organisations and levels, over time.<br>8. **Capability** – an individual or service's capacity to provide a health service based on skills and knowledge.<br>9. **Sustainability** – the system or organisations capacity to provide infrastructure such as workforce, facilities and |

[15] National Health Performance Committee (2001), National Health Performance Framework Report, Queensland Health, Brisbane.

equipment, and be innovative and resp9ond to emerging needs (research, monitoring).

**Risk management** Risk management is another of the core elements in clinical governance frameworks. Its focus is the: identification of circumstances which put patients at risk of harm; rating of those clinical risks; reporting of risks (through incident reporting systems); monitoring and managing of risks; prioritising of clinical risks and responses; and the development and implementation of action plans and strategies to prevent or control those risks.[16]

**Staff management** Managerial activities that enhance staff participation in workplace, including meetings, role definitions, lines of communication, and processes that enhance interdisciplinary work (micro level)

**Systems approach** The systems approach views healthcare errors as resulting from poorly designed systems rather than individual clinicians. Systems problems can include lack of teamwork, poor communication and documentation, badly designed work schedules, and variations in the design and or use of equipment. The best known systems approach model is Reason's Swiss chess model, where each slice of cheese is a barrier to a particular risk. Each of these layers works together, so that if one fails, another prevents the error from 'slipping through the holes'. When the holes line up, however, that is, where the gaps in the barriers line up, or where a barrier is removed, errors will occur.[17]

**Teamwork** Teamwork is seen as a foundation stone for clinical governance in that it is required to implement and sustain effective CG approaches[18] – especially at an organisational level. There is also a reciprocal relationship in that the larger and more diverse a 'team' becomes, the greater the need for clinical governance strategies that establish, define and monitor what 'good' care looks like.

Teamwork has become a polysemic term, subject to many related meanings, especially in health care. Taking the broadest definition of a team, it may something that exists any time two or

[16] O'Connor, N. Paton, M. 'Governance of' and 'governance by': implementing a clincial governance framework in an areas mental health service. *Australasian Psychiatry*. 2008;16(2):69-73

[17] Reason J. Human error: models and management. *BMJ*. 2000;320:768-770

[18] Braine, M. E. Clinical governance: applying theory to practice. Nurs Stand 2006; **20**(20): 56-65

more people are working together with a shared purpose[19], or it may be much more specific – stipulating shared goals and accountability, surrendered autonomy, agreed leadership or interdependent practice[20] .

According to the literature, the way teams are designed depends greatly on the task that needs to be performed and when and where it is being performed. In healthcare, teamwork is the ongoing process of interaction between team members as they work together to provide care to patients. A review by… found that while *teamwork* and *collaboration* are often used as synonyms in casual discussion, they are not synonymous. Critically, inter-professional collaboration is both a process affecting teamwork and an outcome in and of itself(1). Collaboration can take place whether or not health professionals consider themselves to be part of a team. For example, in primary healthcare, where professionals including a GP, a physiotherapist and a dentist may all provide care to the same patient in concert, yet may not see themselves as a functioning team. On the other hand, effective teamwork rarely happens where there is no collaboration[21].

As a result, the lexicon of teams contains a range of terms that denote different ways of working together for the good of others, and emphasise different elements. "Multidisciplinary teams" emphasise process issues, "communities of practice" are animated by concerns about language and knowledge transfer, while "collaborations" highlight relationships. 'Teamwork' in primary care may encompass shifting notions of teamwork including the idea of instances of teamwork or collaboration (much like episodes of care) rather than necessarily focusing on organisational development approaches to team process.

**In the context of this study, teamwork may include both multidisciplinary collaboration within a team; interdisciplinary or interpersonal collaboration across or through an organisation; and or shifting instances of teamwork or collaborative care. Teamwork as a clinical governance focus encompasses the relationship and interpersonal variables which enable information sharing, interactive problem solving, openness, respect, trust, cooperation, acknowledgement, individual contributions and cohesive wholes (shared visions etc).**
(macro level)

[19] CHSRF paper
[20] Mohrman et al
[21] Oandasan et al. 2006

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| **Use of Information** | Examples include:<br>• Access to and use of evidence<br>• Information or knowledge management strategies<br>• Communication and information sharing strategies including non-electronic techniques (eg., checklists, assessment forms, sign off sheets)<br>• Information technology and ehealth<br>• Decision support tools<br>• Feedback tools and systems (where not directly related to audit)<br>(micro level) |
| **Workforce training** | This is distinguished from Education & Training (above) primarily by the level at which the intervention operates – in this case the systemic (macro) level rather than the practice (organisational) or individual level. This category is likely to be focused on larger scale workforce cohorts and would include institution of policy incentives for workforce training, setting up or modifying of accreditation or development programs, establishment of new courses or curricula, establishing assessment criteria – for example at a policy or legislative level. (macro level) |

# APPENDIX D

## Summary of high quality studies addressing the process of clinical governance of relevance to Australian primary health care

| | | Authors | Governance model | Quality dimension | Question relevant for this review | Country | Study type | Implications for clinical governance |
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| ACCOUTABILITY ORIETNTATION | *Managerial* | *Russell et al 2009** § | Practice-level organization of interventions and capacity | Capability | What is the impact of organization and funding of primary health care services on quality performance? | Canada | Comparative observational study of process measures for chronic disease management in four different models of primary health care service & nested case studies | Independent of model, high-quality chronic disease management was associated with the presence of *a nurse-practitioner* and *smaller practices* with 4 or fewer FTE GPs. |
| | | *McLellan et al 2008** | System-level external benchmarking + meso level collaboration | Responsiveness Capability | What are the mechanisms through which performance contracting improves quality? | USA | Comparative observational study of five substance dependence services 2001-2006 using annual reports | Performance indicators were *simplified and locally relevant*. Funders *devolved decision-making* to the services on how to meet the indicators, and encouraged *collaboration and information-sharing* between services. |
| | | *Ahgren & Axelsson* | Meso-level networking and collaboration | Capability Responsiveness | What are the determinants of success in integrating care across different services? | Sweden | Multiple comparative case studies of successful and unsuccessful chains of care for different conditions for which clinical guidelines existed. | All successful chains of care had *sufficient resources* to implement the systematized care, an identified prime mover within the organization *[clinical governance leader]*, a *bottom-up approach* in which the local health system developed their own approach, and *trust* between the network of organizations involved in the chain of care. |
| | | *Simoens 2004* § | Meso-level networking across services and | Capability Responsiveness | | Scotland | Intervention: Local Health Care collaboratives. Comparison of | Undertaken 12 months after introduction of LHC cooperatives, so attitudes may by in evolution. The LHC cooperatives had begun collaborating on clinical and social care for |

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| | | collaboration | | | | attitudes to cooperative activities among participating (n=306) and non-participating practices (n=19) using mailed surveys; managers of local health care cooperatives (n=28). | diabetes, cardiac disease, mental illness and the elderly. *Sharing data* and *coordination of existing services* was the most common form of collaboration. *Performance measurement through the LHC cooperative* was the activity *least supported* by GPs. |
| | *Perera et al 2007* | System level external benchmarking | Capability Responsiveness | How are performance indicators which are relevant and useful for primary health care developed and assessed? | New Zealand | Systematic literature review; key informant interviews (n=14), and development and test of an analytical tool for performance indicators relevant for primary health care | Performance indicators can be *customized for primary health care* in such a way that they provide useful feedback for the service and the managerial level. |
| | *Geboers et al 2002* | System level external benchmarking | Capability | | Holland | Exploratory study applying 27 indicators of quality (developed by researchers) to assess 39 small Dutch general practices | As above. After assessment, highly motivated practices often select areas for improvement in which they already excel. |
| | *Nietert P-J et al 2007* | System level external benchmarking | Effectiveness | | USA | Development of SQUID (Summary Quality Index) indicators. | High face validity, utility and acceptability. SQUID indicators do not address interpersonal elements of care. |
| | *Doran et al 2008* | System level external benchmarking | Responsiveness Effectiveness | How do practices use exception reporting? | England | Analysis of national dataset fm National Health Service Information Centre, 2004 | Practices are most likely to use exception reporting in the cases of failure to meet targets for effectiveness, rather than quality process measures such as check-ups and offers of treatment. Exception reporting may allow practices to avoid reporting on effectiveness. |
| | *Rogers et al 2002* | System level external benchmarking | Responsiveness Appropriateness | What supports uptake of national frameworks in health practice | England | Multicase analysis of 12 PCTs use of Mental Health frameworks | Uptake of mental health frameworks lag behind CVD frameworks because of clinician confidence, social aspects of care are marginalized cf medical interventions. |
| | *Paccioni et al* | System level external | Capability | Does engagement by primary care | Canada | Intervention: Accreditation. | Professionals engaged in accreditation felt that they were able to maintain professional control |

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| | *2008 ** | benchmarking | | centres in accreditation increase professional commitment to accreditation? | | Longitudinal comparative case studies in 2 Quebecois primary health care centres. Impact of accreditation of bureaucratic or professional control measured using questionnaires based on Competing Values model. | over the process, while those not undertaking accreditation often felt that it increased managerial control |
| | *Houghton et al 2001* | System-level external benchmarking + meso level developmental support | Capability Responsiveness | What elements of clinical governance are prioritized in establishing a program? | England | Evaluated achievement of CG indicators one year after introduction. 12 Primary Care Trusts | The activities that were prioritized were those addressing capability (eg clinical disease management) and responsiveness (client groups). Least progress was made on safety elements – eg risk assessment and critical incident reporting. |
| | *Wallace et al 2007* | Practice-level organization of interventions and capacity | Safety Capability | What mechanisms determine uptake of risk management activities? | England | Evaluation before and after of uptake of RM activities | Some improvement in breadth of staff involved in activities and in recording. These improvements are probably not mediated by organizational culture, and improvements may require competency training. |
| | *Stevenson et al 2001* § | Practice-level organization of interventions and capacity | Responsiveness Capability | What mechanisms determine improvement in practice after audit? | England | Topic of audit: diabetes Qualitative study using rigorous sampling frame (general practices divided into tertiles according to level of change after audit; 9 interviewees from bottom & top tertiles) | Quality improvements in audit reflect attitudes supportive of teamwork within the practice and the ability to overcome obstacles. A *practice level commitment to team working* overall was more important than a positive attitude to audit |
| | *Lucock et al 2003** | Practice-level organization of interventions and capacity | Capability Effectiveness | | England | Topic: care in mental health services. Case study of integrated system for evaluation of multiple routinely collected data | Measuring performance and outcomes in mental health is possible and in supported practices committed to reviewing clinical care is very productive. The financial costs of this are probably offset by savings for the community service (NB: would not in a private practice) |

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| | | *Amoroso et al 2007* | Practice-level organization of interventions and capacity | Capability<br>Efficiency | | Australia | Topic of audit: chronic disease management. Case studies of 57 general practice (82 GPs) including interviews, completion team climate inventory, record review, and surveys. | GPs identified clinical and team-related improvements. They were reluctant to undertake improvement in where the need related to business, finance or linkages with other services. The translation of need to action was quite weak, with only 38% of practices implementing the activity that they developed after audit. |
| | ***Community*** | *Marshall et al 2002* | System level external benchmarking | Responsiveness<br>Effectiveness | Will patients' decisions about attending particular general practices be influenced by the release of "public report cards" allowing comparison on quality of general practices? | England | Qualitative study. 12 focus groups, with 35 patients, 24 GPs and 18 clinical leads. [NB: no respondent had direct experience of "public report cards"] | *Government-mandated openness about quality was rejected* by patients. Patients saw the idea of "league tables" of health services as politically motivated and were unhappy with the idea that services would compete with one another. |
| | | *Waldau 2007* § | Community-oriented priority-setting and/or management | Responsiveness<br>Efficiency | What determines willingness of clinicians and local administrators to make decisions about prioritizing resource allocation which are open and transparent to the community? | Sweden | Intervention: Implementation of government policy on local decision-making about resource allocation. Timed samples of interviews and surveys 1998-2005 (Interviews with clinical managers (1998, n =6); surveys (2002, n= 86 clinical managers; 102 senior clinicians; 2005, n =105 clinical managers) | In this model prioritizing of decisions is made by local clinicians and administrators and *the processes and reasoning are made open to the local community*. Over the seven years, there was an increase in the comfort of clinicians with prioritising resources for reasons other than individual need, including taking *the evidence base and ethics* into account. |

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| | | *Mandel et al 2004* | System-level external bench-marking with no meso-level development support | | What is the impact of an external QA program on quality of health care outcomes in the military health sector? | Israel | Intervention: Achievement of markers of quality + external review of clinical consultation by observer. Cohort of 99 primary care clinics 2000-1 assessed. Comparisons between 44 multiphysician and 55 single physician clinics. 74 physicians had two assessments. | The major difference in quality appears to be related to the issue of accountability. Single physician clinics (the unit troop clinics) had better markers of quality care in relation to high risk patient surveillance than multiphysician clinics (the home front clinics). This is probably related to the value of patient care and community responsiveness that unit troop clinics have. Authors note they may feel more accountable to their community of reference than the civilian doctor in the home front clnics. |
| | ***Professional*** | *Sheaf & Marshall et al.2004* § | Meso-level networking and collaboration | Capability | What drives *GPs* to take up clinical governance activities? | England | Multiple case study analysis. Maximum variety sample of 12 PCTs/PCGs selected on diversity of ways they organize mental services**.** Semi-structured interviews with 12 chief executives; GP 12 clinical governance leads; two nurse clinical governance leads; nine mental health leads;12 lay representatives; and 2 PCG chairs; document review, data from Manchester's Tracker study of PCGs/Ts | Acceptance of clinical governance is driven through the development of *networks of professionals*, who are mostly medical. This networking is *also needed for nurses* in general practice, whereas in other sectors of the NHS hierarchical CG structures operate. In rural areas, *active attempts may need to be made to establish professional networks with regular communication with other professionals* to drive peer norm setting. |
| | | *Sheaf et al 2003*§ | Meso-level networking and collaboration | Capability | What drives *GPs* to take up clinical governance activities? | England | | Penetration into clinical practice of clinical governance activities through networks of clinical leaders occurs *more rapidly for activities with "clinical legitimation*" (eg heart disease or diabetes care frameworks) than those that require more social care (eg mental health). *Networks* evolved around *existing professional leaders*. In rural areas with high turnover, networks and leadership may need to be more actively fostered. |
| | | *Campbell & Sheaff et al 2002** | System level external benchmarking + meso-level development support for practices | Capability | What drives *GPs* to take up clinical governance activities? | England | | The NHS model combines *quality assurance* (requiring monitoring and assessment) and *quality improvement* (developmental approach, using education and support). Governance leads at the meso level may find themselves *generating hostility from GPs who disengage from quality assurance and health* |

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| | | | | | | | *funders* who demand more monitoring and achievement of minimum standards |
| | *Sheaf & Sibbald et al 2004* | Meso-level networking and development support for practices | Capability Responsiveness | What drives *GPs* to take up clinical governance activities? | England | Mail survey of 437 GPs in 12 PCTs/PCGs on attitudes, opinions and self-reported activity by GPs in relation to clinical governance | Clinical governance was achieved through a combination of *reasoning about evidence,* professional *norm setting in networks* and *harnessing a professional culture* that fears for and is protective of its autonomy. These drivers may be more useful for clinical care than for conditions that require socially oriented care (eg mental illness). |
| | *Tausch et al 2001*§ | Meso-level networking and collaboration | Effectiveness Appropriateness Sustainability | What drives *GPs* to take up clinical governance activities? | Germany | Evaluation using questionnaires of 243 GPs attending 25 quality outcomes (structure, process, outcome) | No outcome data available. Quality circles are acceptable to GPs esp for developing coherent guidelines; direction of association between job satisfaction and participation unclear (may appeal to the already committed). |
| | *McKay et al 2005* | Practice-level organization of interventions and capacity | Responsiveness | How capable are GPs in the performance and translation of audit data? | Scotland | Compares methods of audit: criterion review (1002) and significant event analysis (883) using peer review. | Notes that there were significant deficits in the ability of GPs to perform audits, especially more experienced ones. Indicates a need for meso level support to assist in competence with audit. |
| | *Avery et al 2007* §* | Practice-level organization of interventions | Responsiveness Safety | What drives implementation of evidence in primary care using IT to promote safety? | United Kingdom | Interviews with 31 stakeholders | Need: better clinical decision making support from software providers, attention to human ergonomics, capacity for audit trails and improvement in inter-operability. This is likely to need regulation to mandate suppliers to reach essential safety requirements. |
| | *Shepherd et al 2002* | Practice-level organization of interventions | Sustainability Efficiency Effectiveness | What are the features of a successful electronic audit? | United Kingdom | Case study of 2 practices | Electronic audit is feasible and much quicker than paper-based audit. Lack of organizational support and computing skills among practice staff is a significant obstacle. |

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| | *Green et al 2006* | Practice-level organization of interventions | Effectiveness Efficiency | What drives implementation of evidence in primary care using IT for chronic disease management? | Canada | Case study of 30 GPs implementing chronic disease management using critical success factor analysis | Factors that indirectly contributed to knowledge translation are : (1) listing and tracking patients, (2) allowing data sharing, (3) demonstrating performance improvement, (4) integration with work flow and (5) minimal requirements of GP time |
| | *Si et al 2008** | Practice-level organization of interventions and capacity using targeted feedback with reflection for entire service | Effectiveness Appropriateness Capability | What drives *GPs* to take up clinical governance activities? | Australia | Chronic disease model in remote Aboriginal communities (ABCD model). Survey and interviews with 12 community services | Strengths and weaknesses in organizational influences; community linkages;self-management; decision support;delivery system design, and clinical information systems. |
| | *Kreichbaum et al 2002*§* | Meso-level networking and collaboration | Sustainability | What drives GPs to engage in collaboration across services? | New Zealand | 4 case studies of GP experience and reasons for engagement with two types of networks involved in governance: CareNet and IPAs | Study showed rapid evolution in networking. Most originally joined for financial reasons, but found that it was having significant impacts on collaboration with evolving coordination of care. |
| | *Fitzgerald et al 2003*§ | Practice-level organization of interventions and capacity | Effectiveness Capability | What drives the implementation of evidence based practice in primary care work? | England | Comparative case study design exploring four innovations in different settings (rural, inner urban & poor, urban and mixed rural and urban). | In all settings, there were difficulties at the practice level in implementing evidence. *Trust* drives willingness to take up evidence (eg doctors from consultants, nurses from doctors); trust between practitioners may be more readily developed when in close contact (occurs in some rural areas; and not in others, where the clinician is isolated). In rural areas, *networks* are likely to be especially important. *Local opinion leaders* can act as facilitators or obstacles to acceptance of innovation |
| | *Macfarlane et al ** | Practice-level organization of interventions and capacity + meso-level | Sustainability | How does an external quality support program impact upon practice-level | England | Illuminative evaluation of the RCGP Quality Team Development program . Comparative study of | The RCGP program appears to enhance *team functioning,* but possibly through *being a motivator rather than an educator*. A standards-based evaluation program that includes team standards is feasible. There are |

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| | | | development support for practices | | team function and clinical governance? | | 12 GP practices and 4 Primary Care Organisations. | no data on late adopters or those who are reluctant to engage with the process. |
| | | *Shershneva et al 2008* | Practice-level organization of interventions and capacity + meso-level development support for practices | Effectiveness<br>Appropriateness<br>Capability | What drives *GPs* to take up clinical governance activities? | USA | Case study of partnership between academy and GPs and PAs on hypertension management. | Sustainability of mediated CME relies on buy-in from GPs and team relationships. |
| | | *Marshall et al 2001** | System level external benchmarking + Practice-level organization of interventions and capacity | Sustainability | What are the cultural changes needed in primary care organisations to implement clinical governance? | England | Case studies: 12 Primary Care Groups or Trusts | Cultural changes needed are: commitment to public accountability, willingness to learn from one another, ability to critique one's own practice. Barriers to practices changing their culture to ones more supportive of clinical governance are their independence and the perceived *burden upon general practice of generating and reporting* on outcomes. |
| | **Comparison of accountability orientations** | *Abbott et al 2007**§ | Comparison of system level benchmarking models (managerial accountability) with networking (professional accountability) | Responsiveness<br>Capability<br>Appropriateness | What is the perceived value of managerial accountability models vs professional accountability models | England | Comparative case studies: QOF vs original systems level benchmarking preceding QOF vs networking among GPs. Constructed through interviews with 2 PCTs. | On interview, sustainability of QI and QA through networks uncertain, though more acceptable to doctors, and enables more responsiveness and appropriate care. Capability appears to be more enhanced by the managerial models. |

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| | | *Contencin 2006* | Comparison of methods used across Europe (peer review; practice audits and practice visits) | Effectiveness<br>Appropriateness<br>Responsiveness<br>Capability | What are the reasons one model is chosen over another | 12 European countries, UK, New Zealand, Australia | Key informants, existing data, case studies | No outcome evidence. The choices made for different programs are determined by the health financing model and culture of the country. |

* Particular relevance to Aboriginal medical services

§ Particular relevance to rural primary health care

# Summary of high quality studies addressing outcomes of clinical governance of relevance to Australian primary health care

| | | Authors | Governance model | Quality dimension | Question | Country | Study type | Implications for clinical governance | Quality of evidence |
|---|---|---|---|---|---|---|---|---|---|
| ACCOUTABILITY ORIENTATION | *MANAGERIAL* | *Campbell et al 2003* | System-level external bench-marking with meso-level development support | Capability<br>Accessibility<br>Responsiveness | What is the impact of clinical governance policies on intermediate measures of quality? | England | Longitudinal observational study, 1998-2001 of 23 general practices. Outcome measures: quality of chronic disease care, elderly care and mental health care, access to care. Assessed through questionnaires and record review. | Improvements occurred in quality and organization of chronic disease care, and access but not in elder care or mental health care. Quality of care in areas that require responsiveness as well as capability and effectiveness, ie *socially oriented care* may *take longer* or *require different strategies.* | No control group. Time frame may have been too short for all indicators.<br><br>Possible impact on **capability** and **accessibility,** found, but not **responsiveness**. |
| | | *Landon et al 2004*§ | Meso-level networking and collaboration | Effectiveness<br>Capability<br>Accessibility | What is the impact of a collaborative QI program across services on quality outcomes? | USA | Intervention: breakthrough series for better HIV management. 44 intervention, 25 control practices. Outcomes: access, prescribing practice of antiretrovirals, viral load, screening and prophylaxis | No change between control and intervention in capability measures, non-significant higher rate of improvement in viral load in intervention practices. | Good quality, but unable to judge processes.<br><br>No impact on **capability** or **accessibility.** Possible impact on **effectiveness**. |

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| | | *Catactutan et al 2006** | System-level external bench-marking with no meso-level development support | Responsiveness<br>Accessibility<br>Capability | What is the impact of accreditation on the quality of urban primary care centres | Philippines | Comparative observational study: 88 unaccredited vs 82 accredited urban primary care centres. Outcomes: preventive, curative and monitoring indicators | Accredited practices provided better curative services, but were less accessible, and undertook less population monitoring than non-accredited practices. | Equivocal effect on **capability** and **responsiveness**, and diminished effect on **accessibility**. Findings relevant for indigenous services and other services with population focus. |
| | | *Gené-Badia et al 2007** | System-level external bench-marking with no meso-level support | Sustainability<br>Responsiveness | What is the impact of economic incentives on quality of professional life and patient satisfaction? | Spain | Intervention: Incentive scheme based on achievement of quality of care indicators and participation in CME program. Before & after study using surveys assessing quality of professional life index and patients satisfaction as outcome measures. Participants: 257 primary care teams (3781 nurses, 3439 doctors). 200 patients in each PCT. | Incentives related to quality of care annual targets may *increase physicians' perception of burden*. Incentives on long-term professional development seem to be related to an *increase in nurses' and doctors' perception of* support from the management structure. There are no clear impacts of these incentives on patient satisfaction. Economic incentives related to quality of care *should not be set too aggressively,* as the burden to perform may lead to professional burnout; and ideally negotiated with clinicians. | No control group. Mixed impact on **sustainability**. No impact on **responsiveness** to patients (as judged by patients). |

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| | | *Scott & Coote 2007* | Meso-level networking and collaboration | Effectiveness<br>Efficiency<br>Capability<br>Accessibility | What is the impact of meso-level support on primary care outcomes | Australia | Regression analysis using national longitudinal data 2002-4. Outcome measures: 14 indicators in infrastructure, team working, access, chronic disease and | Divisions improved care processes as judged by types of Medicare claims, but not outcomes (as identified through receipt of achievement payments) | Increase in **efficiency**. No increase in **effectiveness, capability** or **accessibility**. |
| | | *Cranney et al 1999* | Practice-level organization of interventions and capacity using targeted feedback with reflection for GPs | Capability<br>Effectiveness | Does supported reflection on audit findings within a practice improve outcomes? | England | Topic of audit: hypertension. Intervention: Feedback vs feedback with encouragement to reflect on barriers to improvement. Parallel-arm, randomized, single-blind, controlled trial of practice-based educational visits in 18 practices | Customised feedback focusing on practices (*motivational interviewing for an organization*) resulted in a *modest improvement* in willingness to treat hypertension. However, outcomes were collected only 4 weeks after the intervention; the longer term impact of the intervention is uncertain. | Modest impact on **capability** (in relation to hypertension management). No impact on **effectiveness**, but time frame probably too short. |
| | ***PROFESSIONAL*** | *Ornstein et al 2008* | Practice-level organization of interventions and capacity using targeted feedback with reflection for GPs and meso-level support | Effectiveness<br>Responsiveness<br>Capability | | USA | Studied SQUID indicators (CVD, diabetes, cancer screening, adult immunization, respiratory and infectious disease, mental health, obesity/nutrition, prescribing practice) in 99 practices. Monthly collection of electronic data for 12-42 months. | Significant improvements noted in indicators for most chronic diseases (outcome and process, and prescribing practice). However, low baseline for mental health/substance abuse, with little improvement. High base for CVD so improvement can only be small. | No control. Very large study. Impact on capability, effectiveness, and responsiveness. Although many indicators are significant because of high numbers, level of improvement overall is small esp for most challenging areas. |

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| | | *Baker et al 2003* | Practice-level organization of interventions and capacity using targeted feedback with reflection for GPs | Capability Effectiveness | | England | Topic of audit: asthma and angina. Intervention: Guidelines vs Guidelines in prioritized review criteria format vs feedback of practice results + guidelines in prioritized review criteria format | No change in adherence to guidelines (eg capability), but patients in practices who had received more customized feedback had been symptom control for angina but not asthma. | No impact of customized **feedback** on capability. Modest impact on **effectiveness** for one disease group. |
| | | *Valk et al 2004 ** | Practice-level organization of interventions and capacity using targeted feedback with reflection for GPs | Capability Effectiveness | | USA, Netherlands | Topic: diabetes. Cross-country comparison of outcomes of two QI projects, both involving reflection, education on guidelines and audit, with development of practice level responses. Outcomes: no. of diabetes reviews, HBA1c and lipid measurement. | Some improvement in process outcomes (assessment and measurement); modest improvement in HBA1c and lipid levels (noted more in centre with worse baseline measures) | Improvements in both models. No control. Modest impact on effectiveness and capability. Baseline case complexity impacts on success of QI measures. |
| | | *Bailie et al 2007** | Practice-level organization of interventions and capacity using targeted feedback with reflection for entire service | Capability Effectiveness | | Australia | Topic of audit: diabetes in 12 indigenous communities. Outcomes: clinical indicators and management | No improvement in capability (hampered by attrition in clinicians over study improvement). Some evidence of effectiveness.. | No control group. Modest impact on effectiveness. |
| | | *Si et al 2007** | | Capability Effectiveness | | | Topic of audit: preventive measures in 12 indigenous communities. | Improvement in capability in counseling for smoking, alcohol, activity and diet. No improvement in BGL or BP. | No control group. No improvement in effectiveness. |
| | | *Cheater et al 2006* | Practice-level organizational development using targeted feedback for nurses | Capability | | England | Topic of audit: urinary incompetence. Intervention: Mailed personalised feedback vs educational outreach vs mailed personalized feedback + Educational outreach vs Printed educational materials. | For nurses, all methods resulted in improvement in practice, with *printed, non-personal educational material being as effective* as the other three interventions. Nurses *may not need the intensive motivational* | Evidence for positive impact on **capability** of very simple interventions for nurses in general practice |

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| | | | | | | | Cluster-randomised trial wit four arms of 194 community nurses in 157 family practices. 1078 patients. | *interviewing* that doctors or practices overall need to achieve improvement from audit. | |
| | | *Wensing et al 2004* | Meso-level networking and targeted feedback for GPs | Safety Capability | | Germany | Topic of audit: prescribing practices. Intervention: delivery of practice feedback through 11 quality circles. Controlled before and after study. 177 doctors; 100 000 patients | *Educational feedback in small networks* (quality circles) was effective in improving prescribing practice. The quality circle arm *reduced the proportion of patients prescribed medications* & increased use of generics. This intervention's effectiveness rested on its use of *relevant data* fed back at *repeated* meetings, *normalizing* the notion of acting on practice data. | Evidence for improvement in **capability** and **safety** using targeted feedback in a network. |
| | ***COMMUNITY*** | *Crampton et al 2005** | Community-oriented priority-setting and/or management | Accessibility | What elements are associated with quality and access for community-governed nonprofit primary care? | New Zealand | Cross-sectional survey of practice characteristics of 26 non-profit community-governed services and 166 for-profit private general practices | *Community governance* OR *absence of financial incentives for doctors* are associated with increased accessibility, a broader range of services and more quality management. | Some evidence that services that are oriented towards the community have increased **accessibility** |

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| | | *Fraser et al 2002** | Practice-level organization of interventions and capacity | Responsiveness Safety | What mechanisms support patient leadership in ensuring proper use of medications? | England | Case study with before and after measurements of practice-developed interventions to improve anticoagulant use through better transfer of knowledge to patients. 8 practices, 39 GPs. | Effective engagement with patients in their anticoagulant use using a range of strategies, developed by a network of GPs through consultation with patients, and customized for patients and practices. Subjective *ill events of medication* can be *difficult for patients* to judge. | No control. Improvement in **safety,** and patient control (ie **responsiveness**) |
| | | *Van Driel et al 2007* | Meso-level networking without targeted feedback for GPs | Capability | Does networked reflection on clinical evidence support improved prescribing practice? | Belgium | Pragmatic cluster-randomised controlled trial comparing standard dissemination of guidelines by mail for rhinosinusitis vs standard dissemination + one educational meeting using quality circle; 75 doctors in 18 quality circles. Outcome: Prescribing practice for rhinosinusitis. | The additional educational meeting had no impact on treatment of rhinosinusitis. *Established small networks in this healthcare context* may be *ineffective in translating knowledge into practice.* To be effective translational mechanisms, *networks* of professionals may require: support to build reflectiveness among professionals, interdisciplinary participation (include nurses), policy contexts in which GPs have identified roles and responsibilities in the health system (eg gatekeeping, fundholding, or reporting) | No impact. |

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| | ***COMBINED ACCOUNTABILITY*** | *McKinnon et al 2001* | Practice-level organization of interventions and capacity + Community-oriented priority-setting and/or management | Efficiency<br>Safety<br>Capability<br>Responsiveness | Can a locally-driven clinical governance project involving patients improve medication use? | England | Intervention: practice-initiated program to improve prescribing. 2 year before and after study of data for level and cost of prescribing, patient and professional satisfaction within the practice. | This very successful small scale program engaged patients in the rationale for changing prescribing practice (open accountability), professionals in the development of changing practice according to evidence using peer norms and appeals to best practice (professional accountability), and gathered formal data before and after on costs and prescribing practices & engaged the entire practice in the response (managerial accountability). | No control. Improvement in **safety, efficiency, capability** and patient control (ie **responsiveness**) |
| | | *Beilby et al 2006* | Practice-level organization of interventions and capacity using targeted feedback with reflection for GPs AND system-level awareness-raising programs for professionals and public AND meso-level support and training | Safety<br>Capability<br>Efficiency<br>Effectiveness | Can a national, multilevel intervention improve medication use at a national level? | Australia | Intervention: National Prescribing Service which provides targeted feedback for practitioners; educational activities; education programs for the public (including in languages); and systematic level constraints of prescription using evidence based guidelines. Evaluation 1998-2004 | Demonstrated improvements in prescribing practices (capability), cost savings for identified drugs (efficiency). Improvements in safety not demonstrated. Improvements in effectiveness not identified yet. | Marked improvement in **efficiency,** and **capability** demonstrated. No improvement in safety and effectiveness demonstrated yet. |

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| | | *Malcolm et al 2001*§ | Practice-level organization of interventions and capacity using targeted feedback with reflection for GPs AND system-level awareness-raising programs for professionals AND meso-level support and training | Efficiency Capability | Can a regional multilevel intervention improve medication use? | New Zealand | Intevention in one IPA: targeted feedback for professionals, incentives for prescribing, development of guidelines, networks ("cells") of GPs | Demonstrated cost savings (efficiency) and prescribing variation (capability) | Improvements in **efficiency** and **capability.** Noted that improvement occurs most in low expenditure practices (ie already cost sensitive) so may need separate strategies for high and low expenditure practices |

* Particular relevance to Aboriginal medical services

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# APPENDIX E

# Software Assessment Tool

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|---|---|
| **STRUCTURES** | |
| **System architecture** | Interface (GUI, CHUI etc.) |
| | Clinical archetypes |
| | Database (closed, restricted, open API – Local/Hosted) |
| | Coding system |
| | Recalls (set/free) |
| | Shared record capability |
| | Audit trail |
| | Attribution |
| | Security, back-up, system recovery, service support |
| | |
| **Information support** | Information retrieval system |
| | Drug information database |
| | Guidelines |
| | Clinical information |
| | Types |
| | Source (internal/external) |
| | Clinical decision support |
| | Drug/drug interactions |
| | Drug/condition interactions |
| | Drug adverse reaction |
| | Warfarin dosage |
| | Immunisation |
| | Clinical |
| | |
| **System linkage** ***(and if to national / international standards)*** | Patients |
| | Registration database |
| | Unique ID |
| | Laboratory |
| | Imaging |
| | Clinic |
| | In-patients |
| | Email & Web |
| | Referral |
| | Others |
| | |
| **Search function** | Population |
| | Practice |
| | Linked data |
| | Export functionality – and common interlink formats |
| | Others |
| | |
| **Patient access / control** | Access to record (Read only) |
| | Add to record (Write) |
| | Ownership of record (Control access) |
| | Access to pooled quality data |
| | Others |
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| **PROCESSES** | |
| **Quality markers** | Denominator quality |
| | Data quality |
| | Clinical quality–participation in audit–practice /local /national |
| | Fitness for practice – Appraisal / validation |
| | Complaints |
| | Accreditation (of the system) |
| | Training |
| | |
| **Billing** | Routine data used for pay for performance |
| **Pay for Performance** | Local |
| | National |
| | Separate billing process data |
| | Perverse incentives |
| | |
| **Epidemiology /** | Epidemiology / sentinel networks |
| **Health needs assessment** | Health service management / needs assessment |
| | Safety and surveillance |
| | |
| **OUTCOMES** | |
| **1)** | **Surrogate markers of quality** |
| **2)** | **Outcome markers** |

# APPENDIX F

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# APPENDIX G

# Using clinical governance strategies to establish chronic kidney disease (CKD) as a priority for primary care: a case study of the input from a primary care informatics group

**Simon de Lusignan**
*Reader in General Practice and Biomedical Informatics*
General Practice and Primary Care
Division of Community Health Sciences
St. George's – University of London
LONDON SW17 0RE UK

slusigna@sgul.ac.uk
+44 (0)208 725 5661

**Summary:**
**Background:** CKD is an important cause of cardiovascular morbidity and mortality; as well as end stage renal disease. Controlling BP in high risk patients prevents progression and can be carried out in primary care.
Clinical governance is the duty of practitioners to ensure that their patients are managed according to best practice. Best practice is defined from research findings and the consequent development of evidence-based guidance. Many health systems promote evidence-based practice through policy, which may include financial incentives.

**Objective:** This case study describes how a combination of supporting case finding, clinical audit, and research using routinely collected data enabled the development of guidance and policy promoted best practice in CKD.

**Method:** A theoretical model: "*The clinical governance cycle"* suggests the components which should be in place to raise standards in a clinical domain; in a technology enriched environment. In the UK a combination of initiatives were started at several points in the clinical governance cycle: (1) Audit-based education utilising data from computerised primary care record systems to identify cases and to highlight data quality and management issues; (2) Research; (3) A developing evidence-base and policy

**Results:** Audit based education was well received by practices; despite the initial gap between the baseline results and best practice. Findings of the initial audit were also used to define the UK prevalence of CKD, and enabled CKD to become a pay-for-performance quality improvement target in 2006. Subsequent analysis of data is further refining the prevalence of this condition.

**Conclusions:** Simultaneous implementation of initiatives at various points on the clinical governance cycle was associated with a change from CKD being a condition barely recognised in family practice in 2006, to being well managed by 2009. Audit-based education using computer records not only identifies people who are suboptimally managed, it has also provided the data to support the development of the evidence-base and policy.

## Introduction

***Chronic kidney disease:***

Chronic kidney disease (CKD) is an important condition and a new priority for primary care[i]; and clinical governance principles oblige primary care professions to manage patients with this condition according to best practice. People with CKD can be identified from electronic patient record (EPR) systems. A simple formula, requiring age, gender, ethnicity (if Afro-Caribbean) and serum creatinine enables estimation of renal function (strictly estimation of glomerular filtration rate – eGFR); and diagnosis of CKD. Many more people with CKD go on to suffer cardiovascular events than progress to end-stage renal disease. CKD affects between 5% and 10% of the population and is largely looked after in primary care. However, before its introduction into the pay-for-performance targets in 2006 CKD was scarcely recognised in UK primary care and strategies are still evolving as to how this condition might best be managed. A systematic review of the literature has shown that there is a limited evidence base about what quality improvement interventions are most likely to be effective[ii]. Despite its relatively recent identification and our limited armamentarium of quality improvement strategies the principle of "clinical governance[iii]" makes it a professional responsibility of clinicians to manage this condition appropriately; and a managerial duty of health services to create an appropriate policy framework.

***General practice is computerised – providing ready access to data:***

UK general practice is universally computerised[iv,v]. Nearly all consultations held in GP's surgeries are directly entered into the computer by the clinician. The central NHS registry and NHS numbers that uniquely identify individuals mean that we have an accurate denominator for practice population. Direct laboratory to computer links mean that pathology results are complete and accurate in GP records. Prescribing data are also complete and financially incentivised quality targets mean that cardiovascular diagnoses and risk factors are recorded much more accurately than ever before. Consequently, routinely collected data from UK primary care are of high quality and are used extensively for research and quality improvement[vi]. Demonstrating that it was possible to identify people with CKD from GP computer records has been critical step to allow systematic identification of people with the condition in primary care and defining the disease prevalence.

## Objective

To report how a series of clinical governance initiatives: audit-based education, research, guideline development and pay-for-performance targets let to the rapid recognition of CKD in primary care and its more optimal management.

## Method

***The clinical governance cycle:***

The clinical governance cycle describes a process of continual quality improvement. It can generally only operate in a computerised environment where patients' notes are held on electronic patient record systems; where there are the search tools available to audit these records; and the opportunity to use routinely collected data for research. In addition, practitioners need to have access to the latest evidence-based guidance; and, the health system needs to have in place, or be prepared to develop policy to support their implementation.

Clinical governance can be looked at as a cyclical process of quality improvement, facilitated by the use of technology.

(1) **On-line information: Evidence-base and policy:** The clinical governance cycle starts with the existing information about a subject. This information (largely on-line) comprises the academic evidence base or policy. Data about the condition and expected prevalence raises awareness of the condition, and policy implies what is expected of a clinician.

(2) **Clinical practice:** Management in clinical is influenced by awareness of a condition. Cases are recorded in the general practice electronic patient record (EPR) systems – some data are coded making them readily machine processable;
(3) **Clinical audit**, which informs practitioners of their quality of care against agreed criteria, is facilitated by computerised records. Data from a single or multiple practices are extracted, pooled and fed back comparing their case identification and management;
(4) **Feedback about performance improves patient care & data quality.** Feedback Improves the quality of data recorded in EPR systems[vii]. We have developed an educational approach to giving feedback within a specific clinical context we have called *audit based education*[viii]. The intention is that standards of care improved for patients: and the cycle is repeated from an improved baseline.

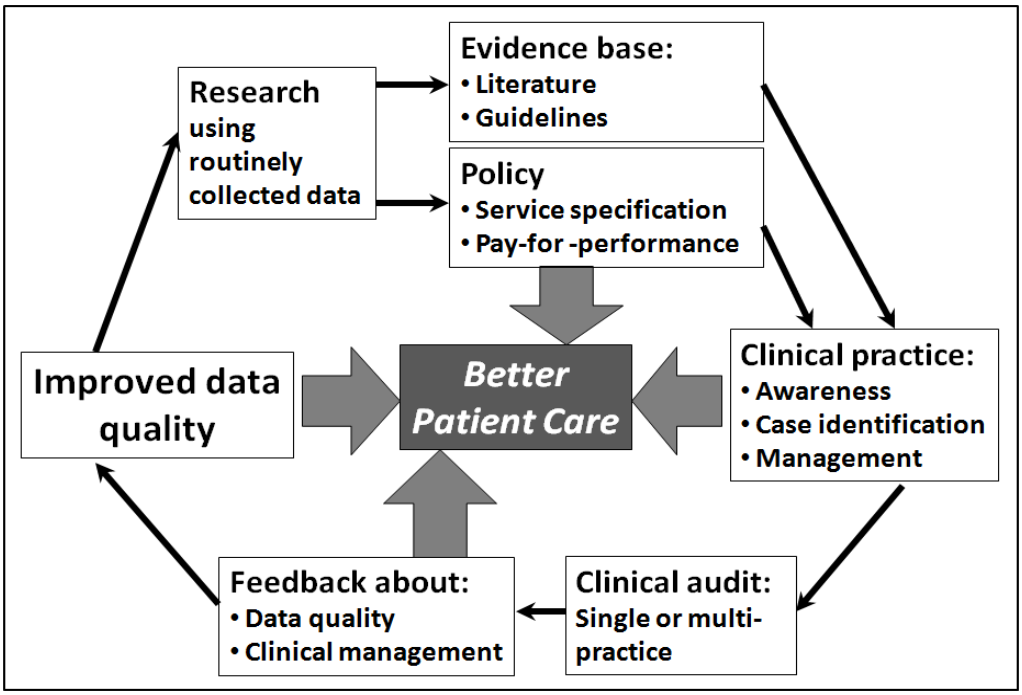


*Figure 1: Clinical governance- represented as a cyclical process of quality improvement*

***Role of informatics***
The stages of the clinical governance cycle described above are all empowered by informatics. Whilst in theory it would be possible to carry out these steps without information technology in practice it was essential.
Without computerised primary care records it would have been impossible to hand search records for the same results, or to process these data in such a timely way. We have considerable experience of processing routinely collected data which we have applied across a number of clinical domains[ix,x].

***Interventions in CKD:***
We have implemented innovations in most part of the clinical governance cycle. These have been published in the peer review literature and reported as the results of this case study. They have been cited within policy and guidance, and the team have contributed to the pay-for-performance guideline development as well as to the supporting documents.

## Results

### *The first half of the clinical governance cycle: Identifying cases of CKD, audit and feedback, using routine data for research*

*1. The first challenge – can we identify people with CKD from GP computer records:*

We were initially asked by a group of enthusiastic specialists if we could find people with CKD from GP computer records. We therefore set up an audit based education initiative as part of the Primary Care Data Quality (PCDQ) programme to find cases and improve quality; and we demonstrated that it was possible to identify the people with CKD[xi]; we were challenged about the validity of these data. We next hand searched 500 paper records to prove the validity of this approach[xii]. We also had to develop a whole range of on-line resources and calculators (for PDAs and mobile phones) to help colleagues convert renal function test results and demographic details into an estimate of glomerular filtration rate (eGFR) as there were no readily available alternative tools at the time – See: http://www.pcel.info/gfr/ )[xiii]

*2. First estimate of the prevalence of CKD:*

We then collected the data from a larger sample of practices which was used to make the first robust estimate of the prevalence of CKD. The NEOERICA study[xiv,xv] defined the contemporary prevalence of CKD and is used in the UK to estimate the prevalence[xvi]. This NEOERICA study estimated the UK prevalence of CKD to be 10.8% for females and 5.8% for males.

*3. Health economic considerations:*

Colleagues from NEOERICA also led a health economic study of the effectiveness of this type of intervention. As dialysis is so expensive, we concluded that a quality improvement intervention in CKD would only have to delay the need for dialysis of one patient for one year per practice of 10,000 to be cost effective[xvii].

*4. A trial to compare quality improvement interventions:*

Subsequently, the QICKD ("Quick" – Quality Improvement in Chronic Kidney Disease) study is comparing quality improvement interventions in CKD. It is a cluster randomised study running across 125 practices in England with a combined registered population base of just under 1 million[xviii].

A preliminary cross sectional study from practices in the southeast England is available online[xix]. These data take better account of fluctuation in creatinine, which probably led the NEOERICA data to over-estimate the prevalence of CKD. The QICKD study baseline data shows a national prevalence for CKD of 7.3% women and 3.5% for men. It will potentially provide useful information as to whether audit-based education is an effective intervention.

### *The second half of the clinical governance cycle: Evidence and policy which create drivers and incentives to change clinical practice (clinical governance)*

*Introduction:*

Over the last decade there has been an impressive growth in the evidence-base about how to manage CKD. This includes a range of guidelines and quality indicators have set out how CKD should best be managed. There have also been policies and incentives to improve management of CKD.

*International guidance from USA – well established evidence-based guidance:*

The National Kidney Foundation – Kidney Disease Outcomes Quality Initiative (NKF KDOQI) guidelines on the definition and management of CKD were started in 1999 when this group changed their focus on patients with earlier stages of chronic kidney disease. Their goal, met in guidance produces in 2000 and 2002 was to reduce the chance of people with early kidney disease progressing[xx].

*UK National guidance:*
The Renal Association and Royal College of Physicians of London produced early guidance on the management of CKD[xxi]. Additionally a service specification for the NHS, a "National Service Framework (NSF)" was written for renal disease - Part 2 addressed CKD. Most recently of all the UK's National Institute for Health and Clinical Excellence (NICE)[xxii] produced evidence based guidance for managing CKD in adults.

*National pay-for-performance quality targets:*
The UK has introduced financially incentivised quality improvement targets for primary care. This scheme started in 2004, and in 2005 SdeL was appointed as "Expert adviser" to help develop "indicators" for CKD. These were introduced in 2006 – though the process was an eye-opener with the potential for key parts of your plan getting included or dropped depending on the global allocation of incentive points across a number of possible clinical targets. However, since 2006 there has been an evolving and ever improving business rules created to improve quality in this condition[xxiii]. There was also a request that more information written about CKD, and so a "Frequently Asked Questions" book was produced to fill this knowledge gap. This publication has been updates in 2009[xxiv].

## Discussion

***Principal findings:***
Multifaceted interventions have been provided to improve quality in CKD. A body of evidence and policy has been created which have led to the rapid inclusion of CKD management into routine clinical care. It has been a remarkable achievement to do this within four years.

The clinical governance cycle – one of continuous quality improvement – empowered by clinical audit – audit-based education, research to generate an evidence base, and supporting policy links the components involved in this change.

***Implications of the findings:***
In common with other complex interventions it is hard to explain whether any or all of the interventions had a causal link with the rapid recognition and improved management of this condition. However, an association is plausible. It is possible that a similar approach in other disease areas may have a similar uptake.

It is also hard to state at what point it became a professional duty to recognise and treat people with CKD; possibly at the time that the National clinical guidance were created.

***Comparison with the literature:***
The interventions described in this paper fit with the classification of clinical governance models recently described – both in terms of conceptual models of clinical governance as well at different levels within the health system. The effect of the interventions have largely taken place within the professional accountability domain; but also developed tools which can be used for management accountability and later, in the community accountability level. The interventions have also been taken up the health service level (pay-for-performance) as well as at the locality (use of tools) and also at the individual practice or practitioner level[xxv].

The UK guidance about the management of CKD is similar to that of other countries; for example there are similar guidelines set out for Australian GPs, published by the Royal Australian College of GPs[xxvi].

The speed with which guidelines for CKD were taken up by primary care and it becoming "normalised" within practice is much faster than that described for the diffusion of innovation[xxvii].

The approach, especially audit-based education, includes many of the features for a successful dissemination of a quality improvement intervention proposed by Berwick[xxviii]. It could also be said to incorporate the "soft" medical leadership described by Sheaff et al.,[xxix] .

***Study limitations:***

This case study describes one group's impact on this disease area. Many others contributed; for example we did not contribute to the development of RCP and NICE guides for the management of CKD.

Audit-based education is yet to be proven to be of benefit in an open trial; though over a decade of uptake points towards its acceptability to practitioners and benefits have been shown in observational studies[xxx].

## Conclusions

Although primary care informatics remains an emerging discipline this case study shows how a small group of researchers may influence quality improvement and help set the clinical standards expected in a clinical domain[xxxi]. Simultaneous implementation of initiatives at various points on the clinical governance cycle are associated with a change from CKD, being a condition barely recognised in family practice in 2006, to being well managed by 2009. Audit-based education using computer records not only identifies people who are suboptimally managed, it has also evidence-base and the development of policy. Clinical governance should be seen as a cyclical process of quality improvement empowered by informatics.

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