Implementing clinical governance in English primary care groups/trusts: reconciling quality improvement and quality assurance

S M Campbell, R Sheaff, B Sibbald, M N Marshall, S Pickard, L Gask, S Halliwell, A Rogers, M O Roland

Objectives: To investigate the concept of clinical governance being advocated by primary care groups/trusts [PCG/Ts], approaches being used to implement clinical governance, and potential barriers to its successful implementation in primary care.

Design: Qualitative case studies using semi-structured interviews and documentation review.

Setting: Twelve purposively sampled PCG/Ts in England.

Participants: Fifty senior staff including chief executives, clinical governance leads, mental health leads, and lay board members.

Main outcome measures: Participants’ perceptions of the role of clinical governance in PCG/Ts.

Results: PCG/Ts recognise that the successful implementation of clinical governance in general practice will require cultural as well as organisational changes, and the support of practices. They are focusing their energies on supporting practices and getting them involved in quality improvement activities. These activities include, but move beyond, conventional approaches to quality assessment (audit, incentives) to incorporate approaches which emphasise corporate and shared learning. PCG/Ts are also engaged in setting up systems for monitoring quality and for dealing with poor performance. Barriers include structural barriers (weak contractual levers to influence general practices), resource barriers (perceived lack of staff or money), and cultural barriers (suspicion by practice staff or problems overcoming the perceived blame culture associated with quality assessment).

Conclusion: PCG/Ts are focusing on setting up systems for implementing clinical governance which seek to emphasise developmental and supportive approaches which will engage health professionals. Progress is intentionally incremental but formidable challenges lie ahead, not least reconciling the dual role of supporting practices while monitoring (and dealing with poor) performance.

Strategies to improve quality of care now play an important role in healthcare policy in the UK and internationally. There is evidence of variation in quality of care and medical errors in most healthcare systems, and this has prompted governments to seek improvements in quality of care. Moreover, societal changes have meant that people are now more consumer orientated, less deferential to, and expect greater accountability from, professionals.

Clinical governance represents an organisation-wide strategy for improving quality within the National Health Service (NHS) in the UK. Clinical governance is “a framework through which NHS organisations are accountable for continually improving the quality of their services, safeguarding high standards by creating an environment in which excellence in clinical care will flourish”. It seeks to combine previous managerial and professional approaches to quality management, such as quality assurance and quality improvement. Quality assurance refers to initiatives designed to assure minimum standards of (existing) care and the mechanisms created to identify and deal with those whose performance does not meet these standards. Quality improvement refers to approaches which seek to improve care, and prevent poor care, on a continuous basis as part of everyday routine. Both approaches seek to safeguard standards and improve quality of care.

Clinical governance forms part of a wider agenda, set by government, which places attention equally upon accountability for existing care and improving future care (box 1). This agenda includes national standards and guidelines and systems for monitoring quality and performance. These provide the structure which offer the opportunity for improvements in care, to implement processes to improve care, and to monitor the outcomes (box 2).

Primary care groups and trusts (PCG/Ts) set up in 1998 are charged with implementing clinical governance in primary care. The overall project aims to observe a group of PCG/Ts longitudinally as they discharge their core functions. The work presented in this paper describes progress made up to December 2000 and the approaches being used to implement clinical governance. It investigates the concept of clinical governance being advocated by PCG/Ts and potential barriers to its successful implementation, and then sets these issues within the available evidence for whether the strategies being used are likely to lead to the organisational and behavioural changes needed to facilitate quality improvement.

METHODS

The research presented in this paper uses a qualitative design employing semi-structured interviews and documentation review. A qualitative multiple case study approach was used in a purposive sample of 12 PCG/Ts chosen to reflect a range of characteristics including size, rurality, and group/trust status. Repeat visits to the sites will be conducted in autumn 2001 and autumn 2002.

A member of the research team (SC, SH, MM, AR, SP, RS), each an experienced interviewer, visited each site between August and December 2000 and interviewed key senior managers using a standardised interview schedule (box 3). Those
Box 1 Organisations/initiatives discussed

Clinical governance
A framework through which NHS organisations are accountable for continually improving the quality of their services, safeguarding high standards by creating an environment in which excellence in clinical care will flourish. Combination of quality assurance (e.g. minimum standards) and quality improvement initiatives.

Primary care groups/trusts (PCG/Ts)
Primary care groups and trusts are responsible for implementing clinical governance in primary care. PCGs were created in 1998 with geographical groupings of about 30 general practitioners covering 100 000 patients, responsible for resource allocation to general practice and an advisory role on secondary/hospital and specialist care. PCGs are responsible for the overall healthcare budget for their populations, for primary and community care, and for commissioning specialist and secondary care. All PCGs will become PCTs by April 2004.

Personal Medical Services
An initiative, begun in 1998, that introduces new flexibility to primary care by allowing practices or groups of practices to negotiate new contracts for service provision different from general medical services.

General Medical Services
Standard general practice services provided by general practices governed by the “red book” contract.

National Service Frameworks (NSFs)
NSFs set minimum standards for the delivery and monitoring of health services (including primary care), confer a statutory duty on all NHS organisations, and constitute a key means of ensuring the implementation of clinical governance.

Box 2 Clinical governance in the United Kingdom

NHS
- National Service Frameworks: setting national standards and developing national guidelines
- National Institute of Clinical Excellence
- Clinical governance: strategies for delivering and improving care (including quality improvement and quality assurance activities)
- National Performance Framework: monitoring performance, quality
- Commission for Health Improvement
- National patient surveys

Box 3 Interview schedule: topic headings used at each site

- What do you understand by the term clinical governance?
- What are your clinical governance priorities? How were they chosen? How are they being implemented?
- What organisational factors have influenced the implementation of clinical governance?
- How are users’ views being fed into the clinical governance agenda?
- What do you believe to be the successes of the PCG or PCT with respect to clinical governance?
- What do you believe to be the failures of the PCG or PCT with respect to clinical governance?
- What were (and are) the barriers to implementing clinical governance?
- How do you see clinical governance developing in the future?

RESULTS
Concept of clinical governance
Most PCG/Ts emphasised that their priority was to establish the sustainable infrastructures and changes in culture necessary to implement quality improvement rather than quality assurance strategies. “Bottom up” and “softly softly” approaches were advocated to generate trust, goodwill, confidence, and rapport in practices by promoting a developmental, facilitative, and supportive climate. This was based on cooperation and informal persuasion, using (protected time for) joint learning and education, mentoring, and reflection on an informal and incremental basis. In essence, PCG/Ts are advocating the use of “the carrot and not the stick”.

A lot of it was achieved and is still being achieved on goodwill” (site J, clinical governance lead)

Many interviewees were seeking to develop values rather than set specific priorities, and to develop an atmosphere in which practice staff viewed active engagement with clinical governance activities and involvement with their PCG/T as a positive and mutually beneficial experience. Meetings with practice clinical governance leads (invariably doctors) were a common device to open channels of communication with practices:

“(We need) to try to develop a rapport with all clinicians, to try and involve all professions and to try and develop an . . . atmosphere of trust” (site B, mental health lead)

Some practitioners argued that this strategy will be undermined unless a perceived blame culture—which is seen by many health practitioners to pervade the health sector—is replaced by a non-judgmental open and participative culture. Most of the senior managers in the sample were aware that many practitioners associate clinical governance with quality assurance and that it perpetuates a blame culture associated with monitoring performance (policing, accountability, the “big stick”) rather than quality improvement. Some interviewees stated that the government’s main agenda for clinical governance was policing orientated quality assurance; this generated suspicion among health professionals. Indeed, several managers stressed that they saw their role as a “buffer” between government and practices.

“I think people perceive the sort of wider government agenda as being much more about policing and about holding people to account, and making doctors, or all clinicians really, act in certain ways and...” (site B, mental health lead)
implementing—whilst laudable—would work.

The government and region talk about a ‘no blame culture’, yet every week there’s a story in the press about ‘this doctor did that and got struck off’, so the words from one side and what we actually experience on a daily basis are not the same. To get people to discuss problems is very hard because we are constantly being slated” (site L, clinical governance lead).

Most interviewees—especially clinical governance leads—therefore felt that the successful implementation of clinical governance depends on “getting the culture right”, with all practices becoming involved in quality improvement activities. This applies particularly to general practitioners who are also being asked to buy into a corporate philosophy alien to their independent contractor status. Few doctors were felt to be against quality improvement, but many were thought to be cautious of how it would be implemented, and some were thought to be scared of the current focus on revalidation and reappraisal. While core staff (general practitioners, practice nurses, and practice managers) are increasingly supportive of clinical governance, many remain suspicious and wary and disengagement could lead to exacerbating recruitment and retention difficulties in general practice.

However, one clinical governance lead doubted whether the developmental, corporate, and supportive ethos being promulgated—whilst laudable—would work.

“... it will all get more trusting and ‘lovey-dovey’ and multidisciplinary, and all the doctors and nurses will meet together... pie in the sky really, isn’t it?” (site L, clinical governance lead).

Moreover, while most senior managers stressed processes for overall quality improvement, overlapping systems for undertaking quality assurance were also being developed in order to detect and manage poor performance. These reflected the dual role of clinical governance (current accountability and future improvement). Some participants emphasised these implicitly but for others, especially chief executives, quality assurance systems were seen as an explicit part of clinical governance—for example, monitoring performance against standards or milestones and analysis of complaints; in essence, a systems based performance management and monitoring approach for “making sure things do not go wrong” (site K, clinical governance lead) and for ensuring minimum standards.

Others were even more explicit:

“...At the end of the day you have to demonstrate what you’ve done. And we’re not just in the ministry of nice feelings... we need to see quality and excellence as a result” (site E, lay member).

There was some evidence that some PCG/Ts want to play down this role. One participant (site I, chief executive) aimed to “dumb down” the policing function so as not to generate fear of the “big stick” and policing by practice staff, particularly amongst general practitioners. Another chief executive stressed the need to foster a concept of clinical governance that is open and not threatening, while admitting that the aim is to introduce clinical governance like a “Trojan horse” so that “people are not aware of being worried about it” (site J, chief executive).

Some interviewees stressed that performance management and monitoring was a separate agenda to developing and supporting practices, and that they should be implemented by different personnel. However, most stressed that clinical governance involves both quality assurance and improvement, but they are seeking to ensure that the former does not subsume the latter:

“The first and most important thing is that it is not a ‘big brother’ approach. It’s actually an open culture” (site G, chief executive).

Strategies for dealing with poor performance illuminate this dual role. Most interviewees stressed that, so far, the issue of poor performance had not arisen. For those where it had, it was felt important to keep dialogue open and to offer support and advice via informal non-judgemental visits. However, there was a perception that PCG/Ts will need to become more hard edged in the future. There was also some doubt cast as to whether the same organisation can administer both support and sanction, and that it was impossible for the same person to perform both roles.

**Approaches used to implement clinical governance**

PCG/Ts are using a variety of approaches for implementing clinical governance: “The list is endless, quite frankly” (site H, chief executive). The main approaches identified in this study are listed in box 4; the figures in parentheses show how prevalent these approaches are within a wider random sample of 72 PCG/Ts.\(^{10}\)\(^{14}\)

Other strategies included the use of Personal Medical Services (PMS) pilot contracts (29%), user evaluations (48%), and audit (43%).\(^{14}\) Some approaches were advocated by some PCG/Ts but not by others (including league tables and financial incentives), indicating that PCG/Ts do have autonomy in implementing clinical governance.

Many of the approaches and much of the infrastructure used in the name of clinical governance in primary care—such as audits, registers, clinical guidelines, risk management, continuous quality improvement, and continuing professional education—are not new.\(^{15}\) However, many strategies being used were seen as new, centring upon the policy objective of fostering a more corporate identity within primary care, the sharing of data, the explicit focus on primary care itself, and the sheer extent and activity of quality assessment (box 5).

Shared learning activities and the openness of shared data about practices were seen as important drivers for change. In particular, half day educational events organised for the whole PCG/T have become a notable initiative. Anecdotal evidence suggests that attendance rates of 95% are not uncommon. Moreover, most PCG/Ts are now sharing anonymised or identifiable data about the performance of individual practices with PCG/T boards (28% anonymised, 36% identifiable), the practices themselves (36%/50%) and the general public (41%)/

**Box 4 Strategies for implementing clinical governance**

- Personal/practice learning plans (93%)
- In-house PCG/T education and training (81%)
- Risk management (76%)
- Half day educational training events involving all practices (57%)
- Complaint analysis (50%)
- Significant event analysis (48%); audit (43%)
- Sharing best practice (62% at PCG/T board level)
- Developing and implementing protocols and guidelines (45%)
- Incentive schemes excluding prescribing (43%)
- Benchmarked data (41%)

Figures in brackets represent the percentage of PCG/Ts using the approach in a wider quantitative survey.\(^{10}\)\(^{14}\)

**Box 5 What is new about clinical governance in PCG/Ts?**

- Explicit focus on primary care
- Corporate approach to quality improvement
- Shared learning (half day educational events)
- Shared information about the performance of practices
- User (patient) involvement in decision making level
- Statutory requirement for quality improvement

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\(^{10}\)\(^{14}\) Figures in brackets represent the percentage of PCG/Ts using the approach in a wider quantitative survey.
9%). While such corporate approaches are “not rocket science, culturally (they are) an enormous leap” in primary care (site F, chief executive). These approaches represent a departure from previous initiatives which tended to be profession-specific, and reflect genuine attempts to foster a corporate ethos. Many interviewees regarded such initiatives as a significant success, as much for their very existence as for their likely impact.

Most senior managers argued that it was counter-intuitive to the concept of clinical governance to set specific priority areas, preferring to emphasise that clinical governance should be a strategic set of values and approaches that are relevant to all aspects of health care (sites A, C, D, E, J, K); in essence, a focus on the process of implementing quality improvement and developing infrastructures and supportive cultures within which quality improvement can prosper, rather than concentrating upon specific areas such as diabetes. However, unsurprisingly, all the PCG/Ts in the sample had a programme of priority areas for quality improvement (box 6). Areas covered by current or planned National Service Frameworks featured prominently.

“There are two answers to that question. The simple answer is . . . coronary disease and mental health. The truer fuller answer would be to say that the first priority . . . is cooperation and involvement, so it’s getting people involved in the process” (site D, clinical governance lead)

**Barriers to the successful implementation of clinical governance**

The 12 case studies highlighted that PCG/Ts face significant barriers in implementing clinical governance (box 7).

These barriers can be divided into structural, resource, and cultural barriers. Structural barriers include weak line management or contractual levers to influence General Medical Services practices, rather than Personal Medical Services practices. Resource barriers include a perceived lack of staff, skills, or information to implement clinical governance. Suspicion by practice staff of the aim of clinical governance, or problems overcoming the perceived blame culture associated with quality assessment, are cultural barriers which will take longer to address. It is arguably the structural barriers that leave PCG/Ts relying on “soft cop” methods such as persuasion and weak incentives.

Some participants felt that clinical governance will fail unless it is funded adequately and argued that the resources available (both budgets and staff) for implementing clinical governance were insufficient. Findings from the annual longitudinal tracker survey found that, 18 months after their creation, 41% of PCG/Ts had no specific budget dedicated to the implementation of clinical governance. For example, some activities depend on all practices having appropriate information technology systems and staff with the skills to use them; however, some interviewees stated that they do not have the funds to make such activities happen.

In theory, PCG/Ts have discretion as to how they implement clinical governance, both in terms of local initiatives and in addressing the government’s “top down” framework which includes implementing National Service Frameworks. However, some interviewees expressed scepticism about how much flexibility PCG/Ts will have in practice:

“I think the government’s approach is really . . . it’s all about performance management. The trouble with that, which is very much a ‘top down’ approach, is that if you’re not careful you can squash out all the innovations” (site K, clinical governance lead)

Other participants emphasised that they had had to focus on government set targets such as reducing waiting lists for cancer patients which, while important, were nationally set priorities, at the expense of local priorities.

**DISCUSSION**

Primary care groups/trusts are focusing on setting up systems for implementing clinical governance which seek to emphasise developmental and supportive approaches which will engage health professionals. These approaches incorporate— but move beyond—conventional approaches to quality assessment (audit, incentives) and involve approaches which emphasise corporate and shared learning. However, formidable challenges lie ahead, not least reconciling the dual role of supporting practices while monitoring (and dealing with poor) performance and overcoming structural and cultural barriers.

**Limitation of the study**

The interviews and case studies reflect a purely managerial perspective (key PCG/T senior managers) which may not reflect what is actually happening in practice. The views of primary health care practitioners, users, and local and health authority staff are not represented. However, the study aimed specifically to look at the attitudes and approaches of those responsible for clinical governance at the operational level of PCG/Ts, and to understand how senior managers in PCG/Ts are approaching the implementation of clinical governance.

**Reconciling quality assurance and quality improvement**

The interviews showed that the PCG/Ts have set up a wide variety of approaches for implementing clinical governance which fall into two overlapping systems: systems for ensuring existing quality of care (quality assurance or service development) and strategies to improve future quality of care. The fact that this issue was so prominent in the interviews is unsurprising, given that clinical governance explicitly seeks to combine these two sets of approaches.

Developmental quality improvement strategies and quality assurance monitoring are two sides to the same coin of the process of clinical governance. There is a potential tension between these two sets of approaches which has important implications for the successful implementation of clinical governance. It is based on reconciling different philosophies and sends mixed messages to health professionals, government, and users. It also highlights a potential flaw in the implementation of clinical governance which may find some PCG/Ts generating hostility from both above and below. On the one hand, despite
the educational and supportive approaches being advocated by PCG/Ts, the quality assurance element may threaten to foster continued disengagement and suspicion by some health professionals. However, educational and supportive approaches may fail to satisfy government demands for greater accountability and predefined minimum standards, and those of the public, fuelled by high profile media cases.

Recognising that the successful implementation of clinical governance in general practice will require cultural as well as organisational changes and the acquiescence if not enthusiasm of practices, PCG/Ts are focusing their energies on supporting practices and getting them involved in multiprofessional and corporate clinical governance activities—that is, facilitative non-policing approaches. Such approaches adhere to a “quiet word” system of networking. It may be that such “softly softly” approaches are designed to keep the professions—especially general practitioners—on board, with PCG/Ts seeking to manage the implementation of clinical governance so that health professionals view it as something that they have had a role in formulating themselves, rather than as a policing mechanism. Such a facilitative role may be important because many practitioners perceive that they practise under a blame culture, and there are problems with both the morale of recruitment and retention of general practitioners. Lessons learnt from the introduction of clinical guidelines also emphasise the importance of ongoing implementation strategies and a sense of ownership by those involved. The effective implementation of clinical governance may also be facilitated by taking advantage of quality improvement approaches which may have a long standing role in different localities such as local audit groups.

These interviews suggest that some senior managers in PCG/Ts, particularly clinical governance leads, are seeking to differentiate the dual role of clinical governance. One possible solution to resolving the tension between the “hard” and “soft” roles would be to divide them between different individuals—for example, clinical governance lead and Chair—or institutions—for example, health authorities and PCG/Ts. Anecdotal evidence suggests that some PCG/Ts are leaving it up to health authorities to address issues of monitoring poor performance. However, PCG/Ts are setting up systems for monitoring performance and quality. Importantly, the government’s management agenda for the NHS does have a strong quality assurance aspect (Commission for Health Improvement and dealing with underperforming doctors). The government explicitly includes both quality assurance and quality improvement as core elements of clinical governance. PCG/Ts will need to balance these dual functions but are aware of the importance of engaging (sometimes reluctant) practices and staff in clinical governance activities and, as such, emphasise quality assurance rather more implicitly. The fact that some PCG/Ts are emphasising their developmental role (“good cop?”) rather than their role in monitoring performance (“bad cop?”) is hardly surprising. Reconciling these two models in practice represents a key task for PCG/Ts in the years ahead. The balance could shift either way. However, it is unlikely that clinical governance leads, or any individual senior manager, will be able to wear both hats without experiencing some conflicts between these two roles.

**Effective strategies for change**

It is interesting to refer to the evidence base of the approaches for implementing clinical governance being advocated and used by PCG/Ts. There is limited evidence for the effectiveness of many of the approaches promulgated in terms of quality improvement or for deriving the changes in organisational and professional behaviour necessary to secure quality improvement. These include audit, feedback, clinical guidelines, local consensus and the influence of opinion leaders, continuous quality improvement, and total quality management. However, there is evidence that strategies that combine continuing education, audit, research, and clinical effectiveness in unified multiprofessional educational strategies which link learning to daily routine lead to changes in behaviour. PCG/Ts are using methods such as audit and clinical guidelines—which are least effective when used in isolation—in combination with a variety of approaches.

Education and learning at the organisation level seem to be the primary drivers for change. Real improvement comes from changing systems. The developmental approaches being used by PCG/Ts, which focus on team and corporate learning, are therefore founded on a sound basis. To be truly effective, primary health care teams need to learn to work, learn, and plan together. Moreover, they require fundamental changes in organisational and behavioural (professional) culture which are far from straightforward and take time to achieve. However, it is unclear whether PCG/Ts will be given the time to implement what are medium to long term strategies, faced with government demands for short term evidence of improvements in quality and public accountability.

The new arrangements represent some significant departures from past policy. Firstly, there is now a statutory duty on all NHS organisations to put in place quality improvement processes: it is no longer the preserve of volunteers or enthusiasts. Secondly, clinical governance is an organisation-wide concept which applies to the whole health service, unlike previous quality strategies which were often fragmented or sector specific. Thirdly, within this organisational focus there is now an explicit agenda for improving the quality of primary care. Lastly, previously independent contractor primary care practitioners and autonomous practices are being asked to work within a corporate philosophy. Clinical governance is part of a wider shift to corporate governance within PCG/Ts with a focus on sharing budgets and collective responsibility for investment decisions and clinical priority areas.

While the findings of this study are rooted within the context of the UK NHS, some are generalisable to all healthcare systems. For example, the effective management of new directives about quality of care and cultural change do not occur overnight but require realistic timetables, resources and, desirably, the co-ownership of both assessors and assessed. There are also difficulties in employing open and non-threatening approaches which engage practitioners while assuring patients that mistakes are not being made. PCG/Ts, in common with all healthcare organisations, need to strike a balance between checking the quality of care being provided by practitioners and trusting health staff to deliver quality improvement.

**CONCLUSION**

PCG/Ts face significant and formidable challenges and barriers to implementing clinical governance. Government will expect them to translate activity into improvements in quality of care and patient outcomes. Changes are beginning...
to take effect. However, so far, activity has been focused on setting up structures and processes rather than tangible outcomes in quality. Successful implementation of clinical governance cannot be imposed by decree. PCG/Ts appear to recognise that it will require cultural changes, clinical and managerial leadership, and engagement by practices and staff. It will also require adequate levels of resources. Moreover, evaluations of the success or failure of clinical governance will require appropriate time sensitive outcomes. The cultural and behavioural changes required for the successful implementation of clinical governance are both a medium and prerequisite for quality improvement, but also a potential obstacle due to the difficulties encountered obtaining such change.

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