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# Softly, softly, the way forward? A qualitative study of the first year of implementing clinical governance in primary care

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The aim of this study was to explore the views of Primary Care Organisation (PCO) clinical governance leads on the implementation and development of clinical governance within primary care in the south west region. A grounded theory study using focus groups, research interviews and negotiated feedback reports was designed for use in the primary care setting. The subjects were a purposeful sample of 16 PCG-level clinical governance leads. Four main categories emerged from the data. These included: (1) defining clinical governance; (2) the process of implementing clinical governance; (3) positive aspects of clinical governance; and (4) concerns about delivering clinical governance. At the time of collecting the data (approximately 1 year after the introduction of clinical governance), there was evidence of a culture in primary care where clinicians valued efforts to improve the quality of patient care and enjoyed their own involvement in decision-making at a grass-roots level. However, whilst the concept of clinical governance was received with enthusiasm, the delivery of clinical governance faced challenges. These challenges included the paucity of ear-marked funding, the speed of implementation, the volume of work, and the impact on the clinical governance lead's relationships at home and at work and on his/her emotional wellbeing.

**Key words**: clinical governance; primary care

## Introduction

It is not yet known how the whole concept of clinical governance will evolve and be implemented on the ground within Primary Care Organisations (PCOs) and individual primary care practices, whose activities will form the core for the drive in quality improvement. Clinical governance emerged initially with a political description (Department of Health, 1998), and was quickly reconfigured with public health components (Scally and Donaldson, 1998). In addition to the central guidance which defined the tasks to be undertaken, various authors have produced guidance and theoretical models for implementing clinical governance (Baker *et al*., 1999; Malcolm and Mays, 1999; Walshe, 2000) and have clarified the wider issues of quality improvement (Greenhalgh and Eversley, 1999; Rosen, 2000) and accountability arrangements (Allen, 2000). Leaders in the field of primary care have flagged up a number of challenges to the development of clinical governance, including the move from uni- to multi-professional learning, dealing with underperforming colleagues and the concern of undersupported and undertrained clinical governance leaders (Huntington *et al*., 2000; Pringle, 2000).

It is only recently that attempts have been made to ground the components of clinical governance in more than simply theoretical terms. First of all, researchers have concentrated on the various individual methods for achieving clinical governance, such as Significant Event Auditing (Stead *et al*., 2001; Sweeney *et al*., 2000), conventional auditing (Hopayian and Morley, 2001; Jiwa and Mathers, 2000), and patient feedback (Greco *et al*., 1999; 2000). In addition, the literature boasts many use-

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ful descriptive accounts of the experiences and progress of single or small clusters of PCOs (for example, Ayres *et al*., 1999; Cunningham, 2001; Spurgeon and de Luc, 2000), and these accounts serve as a useful mechanism for the sharing of good practice.

Whilst the sharing of theoretical models, and practical tools (methods) and experiences is useful in helping individuals and organizations develop strategies to meet the challenges of clinical governance, there exists a paucity of empirical research on the experience and process of implementing the new quality guidelines 'on the ground'. However, the limited amount of research available suggests that clinical governance leaders may experience concerns about the implementation of the process at a local level. For example, several small- and medium-scale studies in primary care, have concluded that clinical governance leaders experienced concerns that were due to a shortage of resources, the size of the workload and difficulties experienced in moving primary care professionals towards an open and participative culture (Hayward *et al*., 1999; Taylor, 2000; Walshe *et al*., 2000).

## Aims

This study aimed to give a voice to the people at the 'coal face' who are attempting to operationalize the Government's theoretical document and to unwrap the cultural roll-out of clinical governance. Specifically, the aims of the study were:

(1) to identify how clinical governance evolved within PCOs in the south west region;
(2) to explore the development of the central activities at the core of the process within the study population;
(3) to ascertain both the positive and negative influences that impact of the evolving process within primary care in the south west region.

## Method

### Methodological approach

To capture the complexities of implementing the process of clinical governance in a large multiprofessional organization, the investigation was guided by a grounded theory approach to data analysis (Glaser and Strauss, 1967). Grounded theory has two meanings when associated with the seminal work of Glaser and Strauss. First, it involves the notion of grounding theory in experiences, accounts and local contexts; it is a general methodology for developing theory that is grounded in data which has been systematically collected and analysed. Second, the term 'Grounded Theory' is used to describe a particular set of methodological strategies for handling and making sense of poorly structured qualitative data (see Data Preparation and Analysis).

The qualitative data gathered in the study were ideally suited to capturing perceptions and experiences of a complex, dynamic and developmental phenomenon (Bryman, 1988). However, this type of study, whilst high in terms of validity, has limitations in terms of its generalizability. Although there is little reason to suspect that PCO clinical governance leads from around the country are markedly different to PCO clinical governance leads in the south west region, we have no evidence to suggest that they are similar. We can only assume that these findings are transferable to others in similar settings with comparable resources and similar managerial support systems (Strauss and Corbin, 1990). However, we would argue that all research is context-dependent.

### Sampling

Participants were recruited from three different sources within the south west region. First, PCO clinical governance leads from the Bristol area were selected to represent the views of individuals working in an urban area. Second, PCO clinical governance leads from the South Devon area were recruited to represent the views of people working in a rural environment. Within this broad sampling frame of urban and rural, we recruited participants to represent a range of criteria, including gender, occupational group, size of PCO and size of practice. Finally, clinical governance leads within primary care from across the south west region who had attended a series of NHS Executive south west-funded Action Learning Sets (ALS) on clinical governance agreed to participate in the study.

### Procedure

All 10 PCO clinical governance leads from South Devon PCOs were invited to attend a focus


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group and six of these individuals attended. Two people who were unable to attend the focus group were interviewed in an attempt to verify the views gathered during the focus group. Similarly, a group of all 13 PCO clinical governance leads from Bristol PCOs were invited to attend a second focus group, but only three people were able to attend on the day. Again, two people who were unable to attend the focus group were then interviewed. Three out of the seven clinical governance leads who generally attended the ALS on clinical governance participated in the third focus group. A brief report summarizing the finding of the study was prepared and circulated to the 26 PCO clinical governance leads who had been invited to participate in this phase of the study. The report aimed to provide feedback to participants and to check researcher interpretations. All recipients were encouraged to comments on the accuracy and validity of the report.

### Data preparation and analysis

Both focus groups and one-to-one interviews were recorded and transcribed in full immediately after data had been collected. Each transcript was subject to a grounded theory analysis prior to conducting the next focus group/interview. In this way, each interview or focus group shaped the subsequent stage of data collection.

Grounded theory offers a clear strategy for the systematic analysis of poorly structured qualitative data, and is particularly valuable where there is little pre-existing knowledge of a phenomenon. Analytical strategies within grounded theory are presented to the researcher as 'aids to analysis' rather than as 'methodological straightjackets'. These strategies describe the systematic development of an open-ended coding system in which the analyst works rigorously through the data in an attempt to generate categories that refer to both low-level concepts and more abstract categories. Analysis involves initial indexing (coding), the development and extension of categories (including memo-writing and the writing of definitions), and drawing of theoretical outcomes (Table 1).

Trustworthiness of the data was ensured in a number of ways. Two methods of data collection, semi-structured interview and focus groups, were used to provide method triangulation. Data were further triangulated by the use of multiple informants. As a means of achieving a greater level of coherence and internal consistency, at regular intervals, the findings were presented back to the research team (the research team consists of two GPs and two academics) and to the research steering group (the steering group is made up of the research team plus members from the Departments of Public Health and R&D at the NHS executive South West), the members of which were invited to comment on the findings. Where disagreements occurred amongst team members, these were aired at research and steering group meetings and were used to further direct the line of enquiry. In addition, all participants were sent short summaries of our preliminary findings by way of 'negotiated feedback' so that they could validate (or otherwise) our interpretations of what they had told us. Finally, trustworthiness was enhanced by the meticulous collating of emerging themes and theories with the data.

### Participant profile

A total of 16 PCO clinical governance leads, representing 11 different PCOs took part in the study. An equal number of male and female leads contributed data. The majority of participants were GPs, worked full-time and were between 40 and 49 years of age (Table 2). The average tenure as a PCO lead was 12.1 months, and the majority of PCOs had earmarked between one and two sessions (half to 1 full day) per week to clinical governance activities (Table 3).

## Results

Four main themes emerged from these interviews and focus groups, including: (1) defining clinical governance; (2) the process of implementing clinical governance; (3) positive aspects of clinical governance; and (4) concerns about implementing clinical governance. Each of these themes will be addressed in turn.

### Defining clinical governance

Considerable effort was required (by PCO leads) to produce a workable definition from a theoretical concept that was described as 'all encompassing', 'elastic' and 'chaotic'.



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**Table 1** Systematic steps in a grounded theory analysis

| Step | Activity | Function |
|---|---|---|
| 1 | Form categories | Use the data to develop categories that fit the data closely, tentatively label these categories |
| 2 | 'Saturate' categories | Gather examples of each category until it is clear what future instances would be located in each category |
| 3 | Write definitions | Formulate a definition of each category by clarifying the criteria for placing further instances into the category |
| 4 | Use definitions | Use definitions to identify emerging features of importance in further data collection, and as a stimulus to theoretical reflection |
| 5 | Exploit categories fully | Be aware of additional categories suggested by those that have emerged, consider their inverse, their opposite, more specific, and more general instances |
| 6 | Link categories | Consider relationships and develop hypotheses about links between categories |
| 7 | Consider the conditions under which the links hold | Examine any apparent or hypothesized relationship and try to specify the conditions |
| 8 | Link with existing theory (if appropriate) | At this stage (rather than at the outset of the research), make connections to existing theories, try to keep an open mind |
| 9 | Test emerging relationships | Identify the key variables and dimensions, and see if the relationship holds at the extreme of these variables |

*Source*: Adapted from Turner, 1981: 231

**Table 2** Participant profile ($n$ = 16)

*Gender*
Male = 8
Female = 8

*Age range*
30–39 ($n$ = 3)
40–49 ($n$ = 9)
50–59 ($n$ = 4)

*Employment*
Full-time = 11
Part-time = 5

*Occupation*
GP ($n$ = 10)
Nurse ($n$ = 2)
Midwife ($n$ = 1)
Manager ($n$ = 3)

**Table 3** Clinical governance activities

*Length of time as PCO lead*
Range: 2–18 min
Mean: 12.1 min

*Weekly sessions for CG*
Less than 1 ($n$ = 1)
1–2 ($n$ = 11)
More than 2 ($n$ = 3)

Missing data ($n$ = 1)

> I have this visual image of a kind of vast amoeba, you know, which has all these things going through it, pulling in different directions and it does include virtually the world, the universe and everything, and I think it takes the shape, that the people who – often by accident – have got involved in it and are driving it. [nonGP, focus group 1]

There was consensus, however, amongst participants that clinical governance is about improving quality and demonstrating improved quality in the NHS (Table 4). Both the clinical and the managerial input and components are viewed as being of equal importance.

> We need the clinician but we need the non-clinicians who have a different view, who say 'well, why can't you do it this way', or 'you haven't thought of stuff'. As a clinician I see the clinical side of things very clearly, but I often don't see another layer in the jigsaw. [GP, focus group 1]


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**Table 4** Defining clinical governance

A progressive, organizational and developmental process for improving and demonstrating improved quality ('good medicine') in health care

| *Human element* | *Systems element* | *Policing element* |
|---|---|---|
| Professional development | Reviewing systems and practices | Central control |
| Performance management | Identifying neglect | Loss of clinical freedom |
| Health and safety | Information technology | Prescriptive |
| Patient centred | Data driven | 'Big Brother' |

Table 3 illustrates the way in which these PCG leads defined clinical governance as a process consisting of three complementary elements, the human element, the systems element and the policing element. The process was viewed positively as being patient centred and data driven, but not surprisingly, as containing the more negative connotations of 'Big Brother'.

## The process of implementing clinical governance

Clinical governance was seen as requiring long-term cultural change as opposed to 'quick fixes'. PCG clinical governance leads were acutely aware of the pressures that were already imposed on their colleagues across the PCO, and made a conscious effort to introduce clinical governance via a 'softly softly' approach. The need to keep the process as a bottom-up one, to encourage ownership and involvement at all levels of the hierarchy, and to bring 'sceptics' on board was seen as critical if clinical governance was to remain grounded.

> It will only work well if people own it and have a part in doing it. If it is driven at a pace beyond which people feel comfortable then it may turn out to be a series of tick boxes. [nonGP, focus group 1]

Table 4 illustrates the process of implementing clinical governance. In the main, PCO clinical governance leads aimed to act as advocates for their practices, to nurture the developmental and cultural aspects of the process, and to encourage long-term, as opposed to short-term, gains. Furthermore the leads employed a number of tools and strategies to facilitate the implementation of clinical governance (Table 5). The use of peer pressure, inter-PCG competitiveness, and individual professional pride appeared to be the most positive and productive strategies for engaging co-operation.

> It should be about, how can we help, not how can we punish. Especially for nontraining practices, having people from outside and questioning your daily routines, yes I can imagine this might scare people witless. I don't think they have anything to fear if it is done properly . . . it's an opportunity to share ideas and yes, maybe change things, but almost certainly better for them and certainly better for the patients. [GP, focus group 2]

The 'softly, softly' approach was also viewed as the only possible option available to the PCO leads themselves, as workload and shortage of protected time meant that they were unable to chase up practice members on a continuous basis. In addition, participants recognized that change takes time and that leads need to develop confidence in order to facilitate the changes required with the clinical governance framework.

> That hearts and minds thing is a time thing as well. . . . it takes time for people to absorb new ideas, to feel comfortable with them, to slot them into practice. That sort of incubating change time, growing time, maturation time . . . [GP, focus group 1]



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**Table 5** The process of implementing clinical governance

A progressive, developmental and accumulative process of implementation

| *Use of Tools* | *Use of Strategies* | *Ethos/Approach* |
|---|---|---|
| Education | Peer pressure and professional pride | Encouraging, facilitating, supporting, engaging, inspiring, reflecting |
| Audit | Mentoring and supervision | Arm twisting! |
| Information management | Involving others | Being a resource, an advocate |
| National and local guidelines | Sharing experiences and knowledge | |

Moving slowly – a step at a time

Two less positive trends emerged from the data, and these impacted on the way in which clinical governance was implemented within the study samples. First, there appeared to be a lack of awareness with regards to the 'carrots and sticks' that could be used to facilitate the development of the process. The majority of participants were uncertain as to how they could encourage resistant colleagues to develop the process on the ground, and lacked clarity about any levers (for example, financial incentives, publication of league tables) that they had the authority to use. In the absence of clear levers, participants relied on the goodwill of their 'independent contractor' colleagues to move the process forward.

> Are there sanctions? What are they? You know, sticks and carrots stuff.
>
> [GP, focus group 2]

> If we get to the end of the year and I find that two of the practices are not holding regular significant event audit meetings – perhaps have no intention of doing so – I am not quite sure what to do next at that point, because they are not under performing in the sense that they are positively dangerous and need to be reported to somebody. I don't know.
>
> [GP, focus group 2]

Second, this sample of PCG clinical governance leads appeared to lack clarity in terms of their level of responsibility for the implementation of the process within their PCG. Accountability arrangements form one of the central planks of the quality agenda, yet these clinical governance leads were not clear about their level of responsibility for the development of the clinical governance within their own organization. Participants reported that accountability arrangements had not been made clear to them; the process of being appointed to the role of clinical governance lead had frequently been ad hoc. The majority of participants had not received clear guidance of the roles and responsibilities inherent in the job.

> I am a volunteer. I have done the best that I feel I was able to do in terms of central guidance and policy with the resources available. . . . If anyone had said 'I don't think you're doing your post very well', then I would have said 'fine, get on with it'. So in terms of my own performance, I don't feel particularly troubled or threatened, because I am a member of a PCG all of which is a sub-committee of an area health authority.
>
> [GP(2), interviewee]

> . . . one of the things I think was a concern when clinical governance first started was the sense of the clinical governance lead being responsible and people said 'well I don't want that job because I don't want to put my head above the parapet and to be the one who is on the line'. [GP, focus group 2]

## Positive aspects of clinical governance

On the whole PCO clinical governance leads were positive about the concept of clinical govern-



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ance, recognizing the need for a national quality framework in the aftermath of recent public concerns about the quality of health care provision.

> I think in some ways it helps to have a national agenda for a National Health Service, and I'm quite glad of relatively specific advice, because I think the bewilderment about clinical governance is helped by being given quite specific advice that I can then go to practices with and say, 'these are the protocols, this is the cholesterol level, this is the blood pressure, this is the national audit requirement'. And I think in many ways that sort of focus actually helps us through the bewilderment that quite a few of us expressed at the beginning about 'what does this really mean?' [GP, focus group 1]

Clinical governance was perceived to offer many positive outcomes in the longer term (Table 6), although these outcomes tended to be rather intangible. Few participants could identify any short-term, more tangible outcomes.

> It gets rid of some of the tribalism and also it actually uses best practice from some of the different professionals . . . I think if we can actually encourage people to work better together and celebrate the differences, rather than get all stroppy about them, then it's going to make life better. [nonGP(03), interviewee]

Many participants felt that they made personal gains by being involved in an 'exciting and challenging agenda', and felt satisfied at the prospect of making a difference to the service that their patients received. The networking and sharing aspects of clinical governance were valued in so far that participants experienced a sense of reduced isolation. To this end the development of PCOs was highly praised. In particular, it was felt that the PCO offered an ideal venue for quality improvements, in that it was large enough for clinical governance to have an impact, but small enough to remain manageable for both clinicians and managers.

> We now talk to each other and share information and ideas. We now have contact with our neighbouring practices, it's good, we don't all go reinventing the wheel. That's one of the big advantages with PCGs – they are small enough to be manageable and large enough that we can make a noticeable difference. [nonGP, focus group 2]

Finally, participants experienced little resistance to change from colleagues at a PCO or practice level, who welcomed the quality agenda and recognized the need to improve the quality of services. All of the PCO leads in this sample experienced good support from the PCO management team. In addition, participants felt that the process was grounded by service-users, clinicians and managers in so far that they viewed the process as a 'bottom-

**Table 6** Positive aspects of clinical governance

| Conceptual Basis | Delivery | Personal Gains | Expected Outcomes |
|---|---|---|---|
| Conceptual clarity, thoughtful, considered | Clinicians care about quality | Challenging, exciting and satisfying | Patient safety, staff safety, improved work conditions |
| Concrete, structured, linking GPs to a quality framework | Involving service users | Making a difference to the service | Reduced tribalism, working together |
| All working towards common goals | Grounded by clinicians and managers | Reduced isolation (teamworking, networking) | Greater links to wider services |
| Clear and explicit NSFs | Managerial support (at PCG level)<br>Sharing skills and data across practices | Empowering (NSFs) | |



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up' one, where both users and professionals valued the opportunity to shape the development of clinical governance.

## Concerns about implementing clinical governance

PCO clinical governance leads expressed several concerns about clinical governance, including difficulties with implementation, ambiguity in the role of clinical governance lead, long-term uncertainty, relationship consequences and the emotional impact of the role (Table 7). In addition, participants were influenced by concerns regarding the wider political and professional agenda. Three of these issues deserve particular attention. First, the speed of implementation, the lack of adequate and earmarked funding, the lack of direction and the paucity of volunteers for the role of clinical governance lead served to create a sense of powerlessness in the lead and discussions of 'conspiracy theories' (Big Brother) amongst participants.

> I feel this is potentially the most threatening intervention to hit general practice, out of all the changes that have gone before, because this is saying 'OK, we are going to give you these targets, we are going to give you all these National Service Frameworks, expect you to pull your socks up and give a seamless professional service based on all this lovely evidence that is coming out, but we are going to penalise you either by withdrawing staff funding, or effectively at the end of the day, penalising your income if you fail to do this with the monies given you . . . it's a bit like PCGs, they were set up to fail.
>
> [GP (02), interviewee]

Second, two major and inter-related issues of concern for clinical governance leads related to the emotional impact on the individual lead, and to the impact on the lead's relationships with others at work (colleagues and patients) and at home. In terms of emotional impact, several participants described how they felt 'powerless' and 'out of control' with regard to the volume of work and the shortage of resources. Many participants felt that they were expending ever greater efforts at work, but receiving ever decreased feedback in terms of their achievements. As a consequence, leads felt stressed, exposed and vulnerable. Some described how they felt isolated, and on the fringe of their practice.

> I have got completely overworked and spent countless hours of my own time doing things and its got out of hand. [GP, focus group 2]

**Table 7** Concerns about clinical governance

| *Practicalities of implementation* | *Role of the lead* | *Relationship consequences* |
|---|---|---|
| Speed and volume | Appointed by 'accident/default' | Partners/colleagues in practice |
| Lack of funding | Steep learning curve, initial lack of confidence | Marriage/home/social |
| Lack of adequate direction | Lack of clarity about 'carrots and sticks' | Patients |
| Doctor–dominated | | |
| Multiplicity of employers | Time to 'absorb, understanding, translate and convey' | 'rowing up stream . . .' |
| *The emotional impact* | *Long-term uncertainty* | *The wider agenda* |
| Increased personal stress, decreased personal achievements | PCG → PCT | Short-term (political) gains |
| Feeling exposed, vulnerable | Succession and lack of continuity | External scrutiny |
| Feeling isolated (an 'outsider') | League tables/'Ofdoc' inspectors | Loss of GP independent contractor status |
| Sense of powerlessness | Accountability and responsibility | CG 'set up to fail' (external control) |
| | Penalties | |


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> I think it has been a personal increase in stress, but at the same time, perhaps a personal decrease in achievements.
>
> [GP, focus group 2]

> On the low points, I think, impact within my partnership, my relationships with my partners. I think they are less sympathetic than they were a year ago. I now think in a different way to the rest of them when there is a practice decision to make, I think about it in a more corporate way, and they still think in a small practice kind of way . . . it's actually changed my relationship with them, so it's put me on the fringe of my practice.
>
> [GP, focus group 2]

## Discussion

These findings suggest that on the whole clinical governance in primary care is viewed as a positive and welcome process, but that is remains doctor-dominated, ill-defined, under-resourced and a challenge to implement.

The largest professional group participating in this study were general practitioners. This reflects the nature of clinical governance posts across the region in which this study took place, and is likely to be reflective of clinical governance structures in primary care in other regions (Wilkin *et al*., 1999). It was not the intention in this study to explore differences in opinion that arose as a function of occupational group, and the small sample size would have rendered such an analysis invalid. However, there appeared few marked differences in the views expressed by participants from different occupational groups. In keeping with the conclusion of Walshe and colleagues (2000), our data suggest that general practitioners are engaged and inspired by the concept of clinical governance, and that they are using their pivotal position in the health service hierarchy to engage other colleagues and practitioners from across the PCO. Huntington *et al*. (2000) flag up the importance of getting the leadership right.

> Political awareness and the ability to work with colleagues with diverse values and competencies is a prerequisite for anyone promoting change. Clinical governance leads need to know when and how to 'sell' the changes in behaviour that are required, and they need to use terms that will appeal to the ethos of the health professional, the small business person and the primary care team.

We would suggest that nurses, health visitors, midwives and managers also play an important role in developing clinical governance, and that their active participation should be encouraged and welcomed. In this sample, the nonGP leads presented as less fearful (than GPs) of the nonclinical aspects of clinical governance (supervision, mentoring, professional development plans) and much less concerned about external scrutiny than their general practitioner counterparts. We would suggest then, that a multiprofessional clinical governance team approach with managerial support may point to the most sustainable and productive model for PCGs as they move to PCTs.

The results of our study show that clinical governance leads have grappled with the relatively theoretical concept and definition of clinical governance, but that they have begun to grasp its inherent clinical and managerial challenges. They view the process as a way of assuring and improving quality, of involving all health professionals in the process, and they are beginning to recognize and overcome managerial barriers. Clinicians in general practice tolerate uncertainty in their work. Perhaps this is why they welcome the national service frameworks and encourage the use of guidelines as these offer clarity, focus and a management plan. Participants involved in this study have adopted a gentle and facilitative approach to the practices on their patch. As has already been stated by several writers (for example, Pringle, 2000; Huntington *et al*., 2000) clinical governance is seen as a process that will grow and develop over several years, facilitated by reflection, access to information, and adequate resources. Leads want to be seen as a resource and advocate for the individual practice, as opposed to 'the enemy', and to represent the practice views at the PCO. Take things slowly, get everyone on board, and settle for long-term cultural change seem to be the main messages in terms of delivery that emerge from our data.

But at what cost? McColl and Roland (2000) highlighted a number of challenges to progressing clinical governance in primary care, including lack of resources, poor standardization of data recording and retrieval, the need to develop systems for the



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comparing of data, the need to develop appropriate primary care indicators, and further research on the more nebulous (but no less important) aspects of primary care. In our study, whilst appreciating the need for clinical governance and supporting the notion of linking all health professionals to a quality framework, PCO leads had initially struggled (some said 'floundered') in the role. The speed of implementation, the move from PCGs to PCTs, the volume of work, the lack of guidelines on non-clinical aspects of the framework, and the paucity of ear-marked and adequate funding have caused considerable challenges and concerns for clinical governance leads. One year into the process of clinical governance, PCO leads can identify few benefits to their own surgeries or to the wider organization. Conspiracy theories persist, with many of the participants (who as clinical governance leads are meant to be leading by example) describing their worries about lack of funding for their clinical governance work, and financial penalties for noncompliant practices. Some have described how this impacts on their personal relationships at work, and remarkably, at home. Although we did not collect data on this issue, one can speculate on how these concerns may exert a negative impact on the leads' own clinical work. Indeed a small number of practitioners stated that they may not be available to participate in a follow-up focus group/interview the following year (as part of our ongoing study) as they would seriously consider resigning their clinical governance posts if their concerns were not addressed.

The data from this study, therefore, do suggest that considerable progress has been made in transforming the rhetoric of clinical governance into reality, and that a recognizable continuous quality improvement agenda is emerging as a result. However this progress has a downside, and concerns about the time, effort and personal sacrifices involved, coupled with the possibility that some of the clinical governance leads may relinquish their posts in the near future, might threaten the progress that has already been made.

## Limitations

One of the potential methodological limitations of this study was the pooling of data from two different sources, in so far as the method of data collection is likely to exert an influence on the quality of data collected. Within this study, the one-to-one interviews were conducted after the focus groups and were used to validate the main themes arising from the focus groups and to further clarify and illuminate issues that had arisen. In this way, both methods of data collection were viewed as complementary.

Whilst every effort was made to reduce methodological biases (in particular social desirability and acquiescence) during data collection (Oppenheim, 1966), these may have been introduced inadvertently.

## Conclusions

Following the early development of clinical governance, evidence is beginning to emerge of the development of a culture in primary care where clinicians value the improved quality of patient care and welcome their involvement at a grass-roots level. Clinical governance leads have been successful at engaging the majority of practices and involving these in the development phase of the 10-year agenda. Primary care should build on the inclusive approach taken by PCO clinical governance leads who have made a promising start to developing this cultural change in PCO, whilst acknowledging and responding to the concerns and challenges that they have encountered during the first year. We will conclude with the following observations:

- It seems critical for the continuing development of the process that general practitioners remain engaged and inspired by clinical governance and that they continue to use their hierarchical position to engage other colleagues and practitioners across the organization.
- A clearer understanding of the responsibilities inherent in the role of Clinical Governance Lead would facilitate the selection/appointment process and would help to provide focus for the lead and other members of the PCO.
- PCO leads may benefit from explicit guidelines on the 'carrots and sticks' that they may use, and of the associated consequences of non-compliance.
- PCO clinical governance leads should receive adequate financial resources so that they can


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devote time to the development of clinical governance, whilst being reassured that their partners and patients are not being disadvantaged.
- We would suggest that a multiprofessional clinical governance team approach with managerial support may point to the most sustainable and productive model for PCGs as they move to PCTs.
- Nurses, midwives, health visitors and managers should be encouraged to play a role in developing clinical governance. There is evidence from one of the PCOs in this study that the use of joint leads (GP and nonGP) enhance the process, decrease the workload and sense of responsibility for individuals, and keeps the process grounded and acceptable to colleagues.
- Ownership of the process can be facilitated by encouraging time for reflection and providing adequate financial resources for protected time, training, and dissemination of information at a practice level. It has been suggested that practices would benefit by having half a day per month protected for clinical governance activities.
- It is vital that immediate colleagues of the PCO clinical governance lead should not feel disadvantaged by hosting the lead for the PCO.

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