

The external review of quality improvement in health care organizations: a qualitative study

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Abstract

Objective. To explore the use of external approaches to quality improvement in health care organizations, through a descriptive evaluation of the process and impact of external reviews of clinical governance arrangements at health care provider organizations in the National Health Service (NHS) in England.

Design. A qualitative study, involving the use of face-to-face and telephone interviews with senior managers and clinicians in health care provider organizations and with members of a regional clinical governance review team.

Setting. The West Midlands region of England, in which there are 47 NHS trusts (health care provider organizations).

Study participants. A total of 151 senior clinicians and managers at NHS trusts in the West Midlands and 12 members of a specially constituted regional clinical governance review team.

Intervention. Clinical governance review visits which were undertaken by the regional clinical governance review team to all NHS trusts between April 1999 and February 2000. Interviews with senior managers and clinicians took place before and after the review visits had taken place; interviews with members of the clinical governance review team took place when they had undertaken most of their visits.

Results. The prospect of external review produced mixed reactions in health care provider organizations, and preparing for such a review was a substantial and time-consuming task. The review itself was often productive, although differences in attitudes and expectations between health care provider organizations and review team members created tensions, especially when the results of the review were reported back. External reviews rarely generated wholly new knowledge, were more confirmatory than revelatory, and did not usually lead to major changes in policy, strategy or practice.

Conclusions. External review systems are widely used in health care to promote quality improvement in health care provider organizations, but their effectiveness is little researched and the optimal design of systems of external review is not well understood. More attention to the design and impact of external review would help to maximize its benefits and minimize costs and adverse effects.

Keywords: accreditation, clinical governance, external review, quality improvement, qualitative methods, regulation, United Kingdom

External approaches to quality improvement are widely used in many countries' health care systems, and have a long and varied history [1]. A number of different and overlapping terms are sometimes used to describe activities which we might recognize as different forms of external review, such as accreditation, inspection, regulation, audit, or external peer review [2]. Just as there is great diversity in the terminology

employed, there are also great differences between the agencies which undertake these activities and between the approaches and methods used [3]. For example, some systems of external review have a statutory basis in law and are effectively mandatory while others are voluntary; some are undertaken by independent or professional organizations while others are led by government agencies; some are

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Table 1 An evaluative framework for comparing approaches to external review

Purpose: what are the aims and objectives of the system for external review, and how explicitly are they defined?
Organization: who undertakes the organization or implementation of the system for external review, and what is the position and nature of the organization that undertakes this task?
Overall approach: when and how are external reviews initiated, and to what extent are they used universally or targeted, linked to incentives or sanctions of any kind, and made voluntary or mandatory for the organizations reviewed?
Methods: what form does the process of review itself take, in terms of the explicitness of measurement, the use of different sorts of data and data sources, the focus or target of measurement, and the homogeneity of method across reviews?
Results: what is done with the results of the external review, to what organizations or stakeholders are these results provided, and how are they used to bring about change or improvement?

confidential while others are entirely open to public scrutiny; some measure systems for quality improvement while others measure the quality of care directly; some make use of formal and explicit standards and measurements while others rely heavily on subjective reviewer judgements; and some result in little or no formal action while others are linked to significant financial or non-financial incentives and sanctions. Though all involve some kind of review of an organization's performance by an external or outside body, they may have little more than that in common. In recent years there has been a dramatic international growth in the use of accreditation [4] and other forms of external review, despite an almost complete absence of research which demonstrates its value or informs its implementation [5].

The diversity of approaches and methods noted above makes understanding and analysing the use of external review complex. It may be helpful to use the evaluative framework set out in Table 1, which is based upon published work [6,7]. This suggests that external review programmes are described under five main headings: their purpose, the organization or agency which runs them; how the overall approach to review is structured; what measurement methods are used within the review; and how the results of the review are presented, disseminated and used.

This paper provides a brief overview of the use of external review in the National Health Service (NHS) in England, and then describes one particular example of its implementation, a programme of clinical governance review visits to NHS trusts in one region of England, using the framework in Table 1. It then presents the results of a qualitative study which explored this process of external review and its impact on the organizations which took part, and it concludes by outlining the policy implications of those findings and the need for further research in this area.

The use of external review in the NHS in England

External review is widely used in the NHS in England as a mechanism for quality improvement. For example, the medical Royal Colleges inspect arrangements for medical training in health care provider organizations [8]; the ISO9000 quality management standard and other external quality award

schemes (such as 'Investors in People' and the Chartermark) are used [9]; health services accreditation schemes have proliferated over the last 15 years and now exist for many types of health care organization [10]; the NHS Litigation Authority inspects NHS trust arrangements for managing clinical negligence [11]; and there are many formal statutory authorities with the remit to review health care organizations such as the Audit Commission, the National Audit Office, and the Health and Safety Executive.

With such a miscellany of external review activities in the NHS, it is not surprising that there is considerable overlap, duplication of effort and some conflict over the respective roles and responsibilities of agencies involved in external review. From the point of view of the organizations being reviewed, this can be confusing and overwhelming. Since the market-oriented NHS reforms of the late 1980s loosened traditional bureaucratic controls over public sector health care provider organizations and increased local managerial autonomy [12], the use of external review has been increased to compensate for the loss of direct managerial oversight [13], and this has further contributed to a sense of 'inspectorial overload' [14].

Despite the widespread use of external review in the NHS in England, it has not been widely evaluated or researched, and its impact on the organizations that are reviewed is not well understood [15]. For example, we know little about the beneficial or adverse impacts that external review actually has on the performance of reviewed organizations, how much external reviews cost (both for the review agency and the reviewed organizations), and which review methods, approaches or measurement techniques are most valid, reliable and effective in particular contexts. However, there is a large and growing literature on the use of external review and regulation in settings outside health care [16–18].

External reviews of clinical governance in the NHS

In 1997, the current UK government introduced a range of reforms intended to improve the quality of health care in the NHS [19]. At the centre of these new policies was a requirement for health care provider organizations to have

Table 2 An analysis of the clinical governance external review pilot programme for the West Midlands

Purpose	To facilitate and promote the development of clinical governance in NHS trusts in the region, and to help them prepare for the reviews which would be mounted by the Commission for Health Improvement from 2000 onwards.
Organization	NHS Executive in the West Midlands – which has direct managerial responsibility for all NHS trusts in the region. However, the task was devolved to a team with staff drawn from the NHS Executive and from healthcare provider organizations around the region, including senior doctors, nurses and managers.
Overall approach	External reviews of clinical governance arrangements at all NHS trusts were scheduled and undertaken during 1999. These visits were mandatory. A framework for assessment was designed, setting standards across five main areas: (i) the overall approach to clinical governance; (ii) human resources, education, training and development, and appraisal initiatives; (iii) knowledge management, data and information initiatives; (iv) audit, evidence-based practice, research and development initiatives; (v) complaints, risk management and adverse incident initiatives
Methods	Arrangements were made for about four or five members of the clinical governance review team to visit each of the 47 NHS trusts in the West Midlands region, over a period from April 1999 to February 2000. Well in advance of the visit, each organization was asked to provide a portfolio of written evidence structured around the five headings above and mainly consisting of existing documents and reports. The timetable for the day-long visit was then developed, and it generally included presentations, group discussions and one to one meetings with board level managers and clinicians and less senior staff in a range of departments and functions.
Results	At the end of the visit day, the clinical governance review team provided some verbal feedback on what they had observed, and their preliminary findings. About 4 weeks later, a written report containing conclusions and recommendations from the team was sent to the trust, which was expected to respond by setting out an action plan within about 3 months of the visit. The report, action plan and further follow-up were then handed over to Regional Office staff responsible for ongoing performance management.

arrangements for clinical governance in place, which was defined as,

a framework through which NHS organizations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish [20].

Legislation has placed a new statutory duty to provide quality health care on providers, and made their boards explicitly accountable for the quality of care [21].

In addition, the reforms created a new organization called the Commission for Health Improvement (CHI) which is tasked with undertaking external reviews of clinical governance in health care organizations. Some have seen CHI as a new national health care inspectorate [15]. In the West Midlands region of the NHS, a pilot programme of external reviews of clinical governance was established by the NHS Executive in 1999. The pilot programme is described in Table 2, using the framework which was outlined in Table 1. It can be seen that it followed a relatively conventional format for external review; a standards-based assessment framework was developed, and then survey or review visits were made to all 47 NHS trusts in the region, at which their performance was assessed against the framework. As part of a larger research

project, describing and evaluating the development of clinical governance in the NHS in the West Midlands [22], we established a qualitative research study to explore both the process of external review and its impact on NHS trusts.

Methods

All 47 NHS trusts in the West Midlands agreed to take part in the research. We undertook interviews at each NHS trust before they had their clinical governance review team visit and again afterwards. We interviewed the chief executive, medical director and/or director of nursing, clinical governance lead (which in many cases was one of the former individuals), and a non-executive director. We also interviewed members of the clinical governance review team when they had completed most of their visits. In total, 47 NHS trusts were visited and 151 individuals were interviewed; 12 members of the clinical governance visiting team were also interviewed. Each interview was undertaken by a team of two researchers drawn from four members of the research team (K.W., L.L., T.F., L.W.), except in instances where the scheduling of visits meant that only one researcher could be present. All interviews used an interview schedule (summarized in Table 3), and most lasted approximately 45–60 minutes.

Table 3 Outline of interview schedules

NHS trust research visit interview schedule themes	Views and expectations of clinical governance review team visit Preparation for the clinical governance review team visit Other issues raised by interviewee
NHS trust follow-up telephone interview schedule themes	The visiting team – make up and general approach The visit programme – structure, content and realization Feedback from the visit team – verbal and written, responses to feedback Impact of the visit on the NHS trust and its approach to clinical governance Other issues raised by interviewee
Clinical governance review team interview themes	How they became involved in the clinical governance team. Purpose of clinical governance visits. Preparation for clinical governance visits – including use of portfolio. Visit programme – structure, content, realization, resulting understanding Feedback – verbal and written, responses to feedback Impact on the visited NHS trust and its approach to clinical governance Other issues raised by interviewee

Each interview was tape recorded, after first seeking the interviewee's consent. Interviews were generally undertaken by two researchers, one of whom led the questioning and discussion, while the other made a written record of the responses of the interviewee, using the interview schedule as a framework. Notes taken by both the interviewing researcher and the note-taking researcher were then transcribed.

All the transcribed interview records were then imported into the Ethnograph [23], a computer software package for managing and analysing qualitative research data and a content analysis of the interview records was undertaken. One researcher (K.W.) read the interview records and progressively developed a thematic framework which was used to code and group the issues and themes raised by interviewees. All members of the research team read a sample of interview records and then discussed the coding process. The results presented below outline the themes and issues which emerged from the interviews, and example quotations from interviewees are used for illustrative purposes.

Results

Attitudes and expectations of reviewed organizations

The responses of NHS trusts in the West Midlands to the prospect of the NHS Executive's clinical governance review team and its visit varied widely, but most expressed rather mixed feelings and expectations. To some extent, their attitudes depended on whether they felt ready for such a visit, and what its outcome might be. Many drew comparisons with other external reviews, inspections or visits that they had experienced. Where these past experiences were positive, those interviewed were more likely to view the coming clinical governance team visit positively. Where they had been negative, interviewees were more likely to be sceptical about the value of the forthcoming visit, or even hostile to the

idea. There was often a sense of inspection overload, and some cynicism about the value of such inspections. However, some interviewees had a much more positive perspective on external reviews or inspection, seeing the visiting team as a 'critical friend' able to raise concerns without being punitive or unpleasant.

Preparing for the clinical governance review visit

NHS trusts were required to assemble a portfolio of evidence in advance of the visit itself, and these were often very sizeable documents consisting of several hundred pages of evidence. Most of these materials had been collated rather than written specifically for the clinical governance review, but some NHS trusts had written additional documentation for the portfolio. Interviewees were concerned about the time required and the workload involved in producing the portfolio of evidence, though some felt the process had some benefits for the NHS trust because it forced them to take stock of their current position. In most NHS trusts responsibility for assembling the portfolio of evidence had been delegated to a middle or junior management level, suggesting it was seen as an administrative task, rather than a creative or strategic challenge which needed more senior input.

Despite all this preparation, it seemed the portfolio was often not much used during or after the visit itself. Members of the clinical governance review team reported that they generally spent about 2–3 hours before each visit, often on the night before the visit itself, reading the portfolio of evidence. They felt that as they gained in experience, they became more skilled in reading and interpreting the portfolio and particularly in spotting issues which needed to be followed up or areas where information was missing. The review visit itself was a very busy day with little or no time spent on the portfolio of evidence.

Interviewees thought the portfolio was good at describing formal structures and arrangements, and setting out procedures or systems for doing things, but not so good at

Table 4 Learning points on the visit process from interviewees

Clinical governance review team	NHS trusts
Need for dialogue not presentations – ‘the shorter the presentations, the more information the clinical governance review team got’	Presentations – ‘were very good – the [clinicians] passed around papers of an audit they had done. Team were very impressed with it. There was an openness here. It gave us a good openness with the work and allowed us to get into dialogue.’
Presentations – ‘of mixed value. Often acted as a settling mechanism and a vehicle for focusing on certain areas – served as process function rather than the actual content.’	Contact with frontline staff – ‘Afternoon session was “hairy” for us as it was not planned.’
Honesty and openness – ‘The trusts that got the best out of it opened up to their whole organization’	Impact of individuals – ‘Visit to one area did not go well because of attitude of nurse in that area.’
Contact with frontline staff – ‘In the afternoon when we visited people their responses were interesting. Usually found a lot of impressive people . . . interesting to see how much support’ [for clinical governance]	Public process – ‘Felt that external people were looking at our dirty washing!’
Top team – ‘Seniority of people involved very good – need to get ownership at this level, chairs, non-executives and chief executives etc.’	
Teamwork – ‘Team meeting at outset useful . . . [and] feedback from reference group.’	
Workload – ‘It was ambitious to do so much in a single day – very exhausting.’	

demonstrating that those things actually worked, or giving any insight into how well they worked. Members of the clinical governance review team expressed rather mixed views of how well the impression given by the portfolio of evidence was supported by their impression of the NHS trust gained from the review visit itself, but most felt that it largely correlated.

Views of the review visit itself

We asked members of the clinical governance review team and interviewees within the NHS trusts to reflect on the visit process itself and to identify learning points from it for them, their organization, or the process itself, and their responses are set out in Table 4. The clinical governance review team members valued the opportunities for dialogue, contact with frontline clinical staff, honesty on the part of those they met, and the presence of senior managers and clinicians. They were less impressed with the presentations made during the day, especially if they reduced the scope for other activities. In contrast, NHS trusts valued the presentations and saw them as their opportunity to showcase their work in a managed environment. They also valued dialogue and the contact with frontline staff, but were concerned about the impact of individual clinician’s behaviour which might be out of tune with what they saw as broader clinical opinion. Some found the public nature of the review process, with issues being aired or investigated in front of a variety of people

from within the NHS trust and sometimes some from outside as well, rather uncomfortable.

Interviewees suggested a number of ways in which the review process could have been modified to make it work better in future. For example, more opportunity to get information from external stakeholders, more preparation time on both sides, more clinician input into the presentations and dialogue during visits, and the use of more review team members with specialist knowledge of the area being reviewed were all cited as potential improvements.

Overall, most NHS trusts believed strongly that the clinical governance review had given a true picture of clinical governance in their organization. The members of the clinical governance review team also generally felt that the visits gave them a true picture of clinical governance in the organizations they reviewed, though they sometimes distinguished between the image presented by the NHS trust and its senior management, and the impression gained from visits to departments and interaction with clinical staff. Where they felt a true picture was not obtained, they generally believed in their own ability to identify this situation even if the duration of the visit did not allow them to investigate or resolve it.

Verbal and written feedback from the review visits

When we asked NHS trust interviewees to reflect on the verbal and written feedback which they received after the

Table 5 Views from NHS trusts on verbal and written feedback from external review. et al.

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- (i) Demoralizing – ‘Feedback was what disappointed us most. Pleasantries, then hit us with a not very good assessment of the day. Thought the team had come with an agenda – do not think the issues could have surfaced during the day ... Pretty negative message after a long day – all felt pretty demoralized. Bad news given first – not very good interpersonal skills.’
 - (ii) Constructive – ‘Constructive – confirmed what we already knew. Felt they had a good overview of what was good and what could be improved.’
 - (iii) Standardized – ‘Feedback seemed a foregone conclusion – they had an established model by the time they got to us so they probably said a standard line to us. I felt it was not ‘trust-specific’ to us.’
 - (iv) Non-specific – ‘It did not make much difference to me – it was brief, it had been a very long day, and it was mostly polite phrases. The value was mostly in the written report. It was not very specific.’
 - (v) Too public – ‘Might have been better not as an open feedback – could have been better done in confidence to chief executive.’
 - (vi) Superficial – ‘It went OK, it was very much the ‘headlines’, it was very superficial and short and everyone was a bit brain dead at the end of the day.’
 - (vii) Straight talking – ‘Very straight with no punches pulled. Some areas of good practice were identified, but we did need to pull together and have better coverage of audit – no joined up thinking. No real surprises for central team but others found it difficult.’
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clinical governance review visit, their perceptions were probably shaped to some degree by the content of the feedback itself. NHS trusts who had been praised or complimented may have had more positive perceptions of the feedback process than those who were criticized either directly or indirectly. The main themes in their responses are set out in Table 5. Although not everyone liked the feedback and the way it was delivered, very few disagreed with the content in any substantive way. Almost no-one indicated that the feedback raised issues of which they were not already aware; they spoke of the feedback confirming things they already knew and bringing issues into the open.

Clinical governance review team members largely concurred, although there were some differences in emphasis and perspective. One difference was that review team members did not perceive the feedback to have been demoralizing or negative, but generally felt it was balanced and non-judgemental. Like interviewees from NHS trusts, clinical governance review team members felt that there had been little disagreement about the content of feedback, and whatever differences had existed were generally minor matters or issues which could be easily resolved. Some team members pointed out that NHS trusts got some informal feedback during the visit itself, through the dialogue with team members, and so the general tenor of the closing verbal feedback was unlikely to be surprising, at least to those closely involved in the review visit. Team members recognized that they had often not brought any new knowledge to the NHS trusts they visited, but they emphasized (rather more than those from NHS trusts we spoke to) the way that they had been able to ‘unlock’ knowledge within the organizations they reviewed, opening up issues or making matters explicit which otherwise would have remained unsaid or unspoken.

The impact of the clinical governance review visit

We asked both NHS trust and clinical governance team interviewees to describe the impact of the clinical governance review visits on NHS trusts, and to consider what changes had resulted from the visit and how it had affected the development of clinical governance. An analysis of their views of the impact of the visit is set out in Table 6.

It can be seen that NHS trust interviewees mainly identified the raised awareness and involvement of clinical governance, the increased local attention to and momentum of clinical governance, and the development of an action plan as positive impacts. They also suggested that the workload associated with the visit and its opportunity costs had some negative impact. Clinical governance review team members identified similar positive impacts, but did not describe any negative impacts. There was generally a sense that the visits produced confirmation and consolidation rather than challenge, and few if any major changes in directions were reported.

Discussion

In our interviews with both clinical governance review team members and NHS trust staff, it became increasingly clear that many decisions about how to structure and implement the external review had been made implicitly, without much deliberate consideration of their consequences. Our study suggests that greater attention to the design and development of external review interventions would be worthwhile, and a more rigorous and evaluative approach to design might result in a more robust and effective external review process.

The aim of the external reviews of clinical governance was

Table 6 The impact of external reviews of clinical governance

Clinical governance review team	NHS trusts
Impact on the top team – ‘I am sure it has had a big impact on the lead people in clinical governance – executive directors and so on. Not really on the frontline staff.’	Raised awareness and involvement – ‘Has enabled more people to understand what clinical governance means.’
Change demonstrated – ‘We know there are some trusts whose organizations have changed, where they have responded. You can see it in the action plans.’	Produced an action plan – ‘We have developed an action plan that we have pushed forward. In some areas it has prodded us into action, perhaps quicker than we would otherwise have done.’
Impact on other organizations – ‘Impact on outsiders’ such as CHC etc – able to see how they could influence the trust.’	Created internal momentum or leverage – ‘It has also given us some leverage to get change – use the review team and the visit as the big bad wolf to get people to accept some changes.’
Impact of process as a whole – ‘The process – requirement for a portfolio and visit – has had a lasting legacy.’	Created workload and diverted effort – ‘Amount of time it took and opportunity costs for us. We didn’t learn much that we didn’t know already and it actually delayed the implementation of some parts of our clinical governance strategy. Even if the regional team didn’t want it treated as a royal visit, inevitably it was.’
	Short term or limited effect – ‘At the time had a significant impact, people wanted to know what the feedback was etc. The long term effects are difficult to gauge. Clinical governance support team would say yes, general staff I’m not so sure.’

CHC, Community Health Council.

overtly developmental, and clinical governance review team members reported that this had been reflected in the reality of the visits themselves. However, NHS trusts still viewed and responded to the reviews as inspections, and their reports of the visits themselves stand in contrast to those of review team members. It seems that even when an external review is undertaken with the best of intentions, the process itself can be inherently inspectorial, summative and judgemental, at least from the perspective of the organization being reviewed.

The scale and importance of inspection overload is difficult to assess, but our study confirms that reviewed organizations see it as an important problem. At the least, it leads to a degree of confusion, fatigue and cynicism about the process within the reviewed organization, and it may detract from rather than adding to the quality of health care. If inspection overload is to be prevented or minimized, review agencies need to do more to collaborate and coordinate their activities.

It is clear that external reviews can be costly, and that while the costs to the review agency may be considerable, they are probably much less than the costs to the organization being reviewed. The latter costs may be hidden because they are borne by the organization itself and are not formally accounted for, but they are nevertheless substantial. Decisions about the design of the review process, such as what written evidence or preparatory material to require in advance of a

review, can have a major impact on the overall costs of external review.

It is very difficult to determine the validity and reliability of an assessment provided by external review processes. On the whole, participants in our study reported that the clinical governance reviews gave a fairly representative and realistic picture of clinical governance in their organizations, but it was clear that most also regarded the review process as relatively subjective and open to bias. The results of the reviews were rarely surprising to any of the participants and their findings were not generally challenged by NHS trusts, which may be seen as evidence of their face validity.

The acid test for any system of external review must be its impact on the organizations being reviewed, and especially whether it leads to real and lasting improvement. Our study confirms that measuring such impacts reliably is difficult, and that different stakeholders in the external review process may have quite different subjective perceptions of impact. It suggests that the clinical governance reviews had some impact on the behaviour of NHS trusts in the West Midlands, at least in the short term, and did help to raise awareness of clinical governance and to promote its development in NHS trusts. However, it did not seem that the reviews had created substantial changes in policy, strategy or direction in NHS trusts. Moreover, the study suggests that the external reviews had some adverse effects, and may have diverted attention

from other important local concerns. For those designing external review interventions, the challenge is, therefore, to maximize and sustain their desirable effects while minimizing or preventing their adverse consequences.

Conclusions

It was noted earlier that external review mechanisms are widely used in the NHS in England and in health care systems throughout the world, but that our understanding of the effectiveness of external review in bringing about change and improvement is limited. There is a pressing need for more research into the costs, methods and impacts of systems of external review, to support decision making about the future use of these approaches.

Nevertheless, this and other studies already raise some issues for those involved in external review to consider. First, universal one size fits all' review approaches, in which the same methodology is used for all reviewed organizations regardless of their nature or context, seem at best wasteful of resources and perhaps even positively harmful. A more targeted, focused and contingent approach may be more productive. Secondly, external review rarely generates new knowledge about an organization, but rather it makes explicit or known to others information which already exists. The methods used for data collection should therefore focus on such secondary data meta-analysis, and aim to triangulate using as many different perspectives or viewpoints as they can. Thirdly, even when external review is intended to be developmental and supportive, it is often perceived by those at the sharp end as summative and potentially punitive. Those responsible for external review may need to do more to demonstrate their own commitment to improvement.

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