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Learning from regulatory interventions in healthcare

The Commission for Health Improvement and its clinical governance review process

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Abstract

Purpose – This paper aims to present the findings from research commissioned by the Commission for Health Improvement (CHI), which set out to examine the impact of CHI's clinical governance reviews on NHS trusts in England.

Design/methodology/approach – This paper, giving a stratified random sample of 30 NHS trusts, was taken from a set of 75 trusts reviewed by CHI during a period from 2001 to 2003. Documents from these trusts' reviews were analysed. A postal questionnaire was sent to key stakeholders with an involvement or direct interest in each trust's review. Semi- structured telephone interviews were held with five to six people from each of four trusts selected as case studies.

Findings – In this paper the clinical governance review process was characterized by wide variability in methods, application and effects, in the initial CHI visit and report, and the subsequent NHS trust action plan and SHA progress review. The recommendations made by reviews for change in an NHS trust were often of a nature or expressed in terms, which made measuring their subsequent implementation and impact problematic. CHI recommendations concentrated on management and support processes rather than on direct patient care and outcomes. Trusts were generally willing to accept and then enact CHI review recommendations.

Practical implications – The paper concluded that a more focused and controlled review process would support greater change and improvement. There was evidence to suggest that this kind of regulatory intervention can have largely positive impacts on the organisational performance of NHS trusts, although these positive effects were mainly indirectly related to the delivery of patient care and health improvement. Any future review or inspection processes should place a greater focus upon patient outcomes if such reviews are to demonstrate their value in making a contribution to improving health.

Originality/value – The paper shows that, internationally, there have been few empirical studies analysing the work of health care regulators and their impact on the organisations they regulate. While the work of CHI has been examined by others, this study is the first empirical and largely quantitative analysis of CHI's regulatory regime and its impact within the English NHS. The article is also published at a time when there is much debate about regulatory functions and forms for health and social care.

Keywords Regulation, Inspection, Clinical governance

Paper type Research paper

This paper presents the findings from research commissioned by the Commission for Health Improvement (CHI), which set out to examine the impact of CHI's clinical

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governance reviews on NHS trusts (Benson *et al.*, 2004). Internationally, there have been few empirical studies analysing the work of health care regulators and their impact on the organisations they regulate (Walshe, 2003b). While the work of CHI has been examined by others (Day and Klein, 2004), this study is the first empirical and largely quantitative analysis of CHI's regulatory regime and its impact within the English NHS.

CHI was established by the Health Act 1999 as the regulatory body for the NHS in England and Wales and worked for five years until it was replaced in April 2004 by the Commission for Healthcare Audit and Inspection which is now known as the Healthcare Commission (see section below). Its main aim was to bring about demonstrable improvements in the quality of patient care (Commission for Health Improvement, 2001).

The role of the Commission for Health Improvement (CHI)

- Clinical governance was defined for England and Wales in 1998 as "a framework through which NHS organisations 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".
- CHI was established in 1999 as the regulatory agency for the NHS in England and Wales and was wound up in March 2004.
- CHI's primary aim was to help bring about demonstrable improvement in the quality of NHS patient care throughout England and Wales.
- CHI's statutory functions included undertaking a rolling programme of four yearly clinical governance reviews of NHS organisations.
- CHI undertook 378 clinical governance reviews of NHS organisations during its lifespan.
- These clinical governance reviews each resulted in a published report and action plan and were used to help to determine NHS organisations performance or "star" ratings.
- The Healthcare Commission replaced CHI in April 2004 and in the short term it continued with clinical governance reviews while planning a new system of regulation.
- Department of Health (2005, October) establishes a review of regulation across health and social care.

One of its core statutory functions was to review all statutory NHS organisations in England and Wales to monitor and report on the progress of clinical governance (Department of Health, 1998). By April 2004 CHI had conducted 378 clinical governance reviews. For each review, a team of CHI appointed reviewers visited an organisation and assessed its systems and practices against a framework of seven key areas: patient and public involvement; risk management; clinical audit; clinical effectiveness; staffing and staff management; education, training and continuing personal and professional development; and the use of information to support clinical governance and health care delivery (Commission for Health Improvement, 2002). The process was co-ordinated by a CHI review manager. The review panel would then

complete a report that gave an assessment of the organisation against the seven areas of clinical governance. Their review helped to determine the NHS performance rating (also known as "star ratings") for the organisation. These ratings (first introduced for acute trusts in 2001) were linked to financial rewards for high performing organisations and to interventions and sanctions against poorly performing NHS trusts.

Following the publication of its report by the CHI review panel, CHI would work with the reviewed organisation to develop an action plan. Both the report and the action plan were then published. Responsibility for reviewing subsequent progress against this action plan rested with the Department of Health and health authorities (a role taken on by strategic health authorities when they came into being in 2002).

The new Healthcare Commission, which took over, the work of CHI in April 2004 continued at least in the short term with the programme of clinical governance reviews with very little modification (Healthcare Commission, 2004). Following consultation, the Commission redesigned the system for assessing health services and is now piloting "improvement reviews" (Healthcare Commission, 2005).

The research literature on regulation suggests that regulators like CHI can have a wide range of effects on the organisations they regulate, and cause changes in a number of different ways, such as stimulating organisational reflection on comparative performance, highlighting important issues and giving them greater organisational priority, and providing leverage for change in professionally dominated organisations (Boyne *et al.*, 2002; Walshe, 2003b; Freeman and Walshe, 2004; Davis *et al.*, 2004). This research focused primarily on assessing the direct intervention effects on NHS trusts resulting from clinical governance reviews. It involved a detailed examination of the specific recommendations (termed "key areas for action" or KAAs) identified in CHI review reports and the way that NHS trusts responded to them. The four key aims of the research were to assess:

(1) The range, nature and appropriateness of the action points generated by CHI for individual trusts as a result of the review process.

(2) The appropriateness, resource implications and viability of trust action plans developed in response to CHI reviews.

(3) The extent of implementation of action plans to date, barriers to progress made and expectations for the future.

(4) The impact of the action plans on all aspects of Trust organisation and attributable effects on patient care.

Methods

At the time this research was commissioned in 2003, there were approximately 270 NHS trusts in England. Because the primary aim of the research was to explore the effects or impact of CHI clinical governance reviews (and particularly their recommendations), we chose to focus the study on those NHS trusts which had undergone a CHI clinical governance review at least 12 months before the research commenced. Other studies have shown that it takes at least that length of time for changes responding to the clinical governance review to start to take effect (Walshe, 2003a). We did not include primary care trusts (PCTs) because none had undergone clinical governance reviews more than 12 months before the research, and so none

would have had a sufficient time period for changes to be effected. About 120 NHS trusts had undergone a CHI review at least 12 months previously, and of those, 94 had been subject to a follow up review by CHI and their strategic health authority (SHA), for the purpose of examining their progress since the review and determining whether it should affect their NHS performance rating (Commission for Health Improvement, 2002). Among the 94 trusts there were no ambulance trusts and few community trusts (1) or mental health trusts (4). Seven trusts had since merged and a further eight trusts were already involved in another research project related to CHI, leaving 75 trusts available for us to study.

Study design and sample

We selected a random sample of 30 NHS trusts from this group of 75 trusts, stratified by trust type (acute, acute teaching, and specialist), checking that the sample covered a range of geographic areas, and reflected the distribution of performance ratings for all NHS Trusts (which reflect, in part, performance in clinical governance, as noted earlier).

The evaluation set out to make full use of the substantial set of data about CHI clinical governance reviews which was already available, and to collect new primary data only in areas where it was necessary to do so. We drew on four main data sources:

(1) The CHI clinical governance review report.

(2) The NHS trust's action plan, produced in response to the CHI review report.

(3) Follow-up data collected by strategic health authorities and CHI on the subsequent implementation of the action plan.

(4) Our own data collection, based on a postal survey and telephone interviews with key informants in NHS trusts and other organisations in the local NHS community.

Document review

Data on all 30 NHS trusts in the sample was collated including the date of the review, the corresponding review scores, and their 2002 NHS performance rating (to which those review scores contributed). For each KAA identified in the review report a data set was created, consisting of the KAA's description, urgency level, the clinical governance area to which it related (see next section), the breadth and depth of change required, measurability of change required, summary and number of actions in the trust plan, the extent to which the action plan addressed the KAA, the timescale and clarity of actions, the progress made, and the nature of the evidence of progress. We developed our own scales for each of these data items and categorised each KAA, with a sample of these categorisations being checked by a second researcher from the team and differences resolved through discussion.

CHI framework for clinical governance

- Patient, service user, carer and public involvement.
- Risk management.
- Clinical audit.
- Staffing and management.

- Education and training.
- Clinical effectiveness.
- Use of information.
- Service user experience.
- Strategic capacity.

Survey of key stakeholders

Contact points responsible for clinical governance were identified in each NHS trust, a related PCT and the appropriate SHA using Binleys database (Binleys Ltd, 2003). Each contact was sent a postal questionnaire about six KAAs selected at random from the review report for the relevant NHS trust. Contacts were asked to rate the level of acceptance of the KAA recommendation by the NHS trust, whether it was a new recommendation, the extent of implementation, and what caused implementation. They were also asked to comment on beneficial and adverse impacts and learning from the CGR process as a whole. The survey was distributed to 90 people and a total of 40 responses (44 percent) were received, after a remailing and several telephone reminders. Response rates by type of organisation were: PCTs 17 percent, NHS trusts 64 percent and SHAs 46 percent. The low response rate reflected problems finding respondents who knew about the review because of the passage of time and the pace of organisational changes, particularly in primary care.

Case studies of selected trusts

Four NHS trusts were selected as case studies, based on two factors: reported performance in clinical governance from their review report, and the quality of their action plan in response to the CGR report, both assessed by the researchers.

Five to six people were identified at each trust, including the chief executive, medical director, clinical governance lead, clinical lead for a specific clinical area reviewed during the CGR, and the CHI review manager (the co-ordinator of a CG visit and report) and assistant director. A semi-structured interview schedule was used. This covered general impressions, action plan development and implementation, contribution of the CHI review to change and improvement, and learning from the process. Because of the passage of time since the clinical governance review, some people could not be identified for interview at some sites. A total of 17 interviews were carried out.

Results

The clinical governance review process was highly variable

There was great variation in the way the clinical governance review process worked, from the initial CHI visit and report, through to the NHS trust action plan and the SHA review. Interviewees often reported that the quality of the review process and its outcomes varied. This seemed to result from differences between review teams, with individuals varying greatly in their backgrounds and experience, as well as differences in the attitudes and performance of NHS trusts being reviewed. The apparent variation in the CHI review process has been raised by other studies (NHS Confederation, 2002).

As a result, the 30 CHI review reports we sampled varied very substantially in their design, presentation and content. For example, they ranged in length from 20 to 80 pages, and in the number of "key areas for action" they identified was from five to 57.

Some had executive summaries that highlighted the highest priorities for action, while others did not. Where these summaries existed, some duplicated recommendations covered in the main body of the report and others did not. The space and detail, which the reports devoted to different areas of clinical governance (risk management, clinical audit, staff management, etc.) varied widely, and they structured their assessments of issues differently too, grouping them under different areas in different reports. Recommendations were presented in different ways, and were not always clearly identified as KAAs, with consequences for subsequent action planning and implementation. This wide variation may have been due in part to changes in the review process over time, as CHI developed it in the light of experience, having had a relatively short period to design the process initially, as well as to differences in the contexts of the reviews, and multiple review authorship.

NHS trust action plans varied as well

Each trust reviewed by CHI was required to produce an action plan to address the KAAs noted in the review. The CHI review manager was usually involved in the production of this plan and a range of stakeholders in addition to trust senior management were involved in the development of the plan. Trust action plans had no standard template, and therefore varied widely in the way they were structured and presented, and in the specificity of the actions they contained. The shortest action plan addressed 17 KAAs with 45 action points over four pages, while the longest took 89 pages to address 43 KAAs with 113 action points, which were further broken down into 139 objectives and then 362 tasks. Some actions had specific timescales, others had vague timescales or no timescale at all. It was sometimes hard to see whether all of the KAAs were covered in the action plan, as CGR reports did not generally number KAAs, and KAAs were sometimes reworded, combined, split or omitted in action plans.

The level of detail contained in trust action plans for each KAA varied widely, as Figure 1 illustrates. Most commonly, KAAs had two or three specified action points. But 130 KAAs (16 percent) had a single action point, which was often simply a restatement or reiteration of the KAA itself. However, there were some 31 KAAs (4 percent) for which there were much more detailed action plans containing ten or more separate points. Different trusts took quite different approaches – for example, one responded to the KAA:

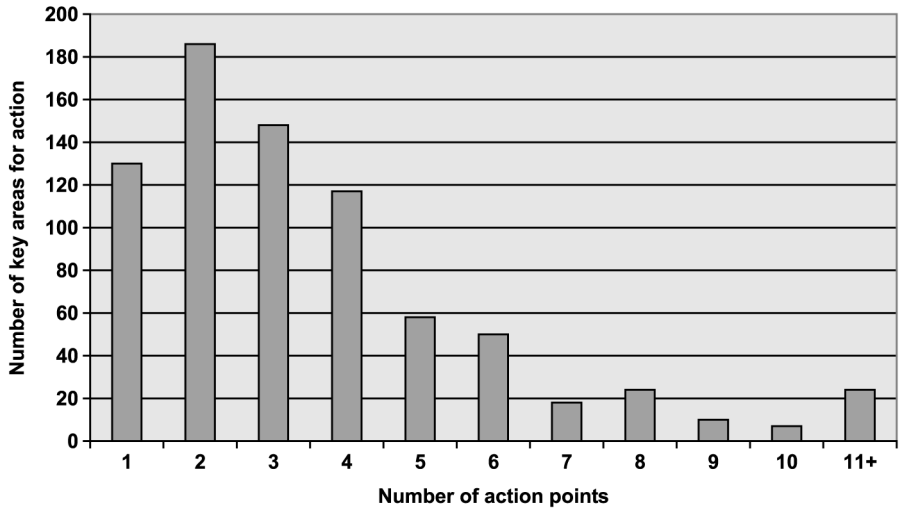
> Action should be taken to develop a clear strategy for involving patients and the public to monitor and improve services.

By offering a single action point, while another NHS trust responded to the KAA:

> The implementation of the strategy for public involvement continues and that the recommendation within it, are implemented with realistic time scales and are regularly monitored and evaluated.

With an action plan containing ten separate action points. The variation in action planning across trusts is discussed further below.

Some KAAs appeared to be missed altogether – there were 38 KAAs (5 percent) for which we could find no corresponding action points in the relevant NHS trust's action plan.



Note: Figure excludes KAAs for which there were no action points

Figure 1.
Analysis of number of action points responding to each key area for action

Therefore despite the action plans mostly addressing the CHI recommendations, some recommendations were omitted or recast, and the level of detail in responses was often poor. The timescale for action was sometimes unclear or rather arbitrary in the action plans.

Many changes that reviews recommended were not amenable to measurement

We categorised the extent to which the changes proposed in KAAs would be measurable (see Table I).

Some of the less obviously measurable KAAs referred to very important issues but it was evident that some KAAs were unnecessarily vague, and that others could either have incorporated more detail or been broken down into a greater number of more

Category	Examples	No.	(%)
Clearly measurable by available data and objective data sources	The trust should ensure that cancellations of operations are kept to a minimum	110	(14)
Largely measurable though some need for judgement	To improve the verbal and written communication between the A&E department and the wards in particular, when transferring patients	378	(47)
Might be measurable but relies on opinions/subjective assessment	To develop and implement a user involvement strategy	301	(37)
Not measurable because very subjective and open to contest and interpretation	Develop a listening culture at every level of the organisation. CHI expects this to be led by the Chairman	20	3

Table I.
Measurability of change required in key areas of action

focused and easily measurable KAAs, or been expressed in terms of more specific outcomes. Although some recommendations were highly specific and very clear in both their purpose (what the aim of change should be) and their prescription (what should be done), many were not clear about one or other of these aspects, sought quite generalised change at the organisational level, and were not easily amenable to measurement or progress monitoring.

Recommendations were concerned mainly with systems and processes

Over two thirds of KAAs were management/administrative system or process changes (Table II). Very few directly sought changes in patient experiences or outcomes and this reflects the approach CHI took to the remit of clinical governance reviews. This has important consequences for our ability to track the impact of CHI reviews on NHS trust performance. It is unlikely we can – or should – expect to see direct impacts on the quality of patient care, and clinical changes in practice emerging from CHI reviews, because so few of the recommendations relate directly to the quality of patient care or clinical practice. There was however an explicit assumption in CHI's mission and strategic plan that its recommendations would bring about improvements in patient care.

NHS trusts largely agreed with and implemented CHI's recommendations

Most NHS trusts accepted the diagnosis and prescription for action contained in their review report, either wholly or for the most part, and many indicated that the recommendations covered issues which were known locally to be problems and had been raised before (see next section). We found 78 percent of KAAs were mostly or completely addressed by Trust action plans. Where this was not the case, KAAs were either omitted, or the plan only promised some kind of measurement or assessment activity when the KAA required a change in practice.

Category	Examples	No	(%)
Strategic/board level/leadership	Trust board directors need regular reports, involvement and ownership of clinical governance issues [Identifier 30, IDNO 295]	79	(10)
Management/administrative system or process	A trust wide protocol to be agreed for investigating complaints [Identifier 29, IDNO 297]	558	(73)
Patient care system or process	The trust should develop more robust systems for monitoring the prevalence of hospital acquired infections and pressure sores [Identifier 22, IDNO 376]	86	(11)
Environmental or facilities/equipment	The trust is urged to continue to work with the contractor to continue to improve catering and cleaning standards [Identifier 1, IDNO 325]	38	(5)
Patient experience or outcomes	The trust is not achieving the national standard of patients experiencing a heart attack receiving thrombolytic treatment within 30 minutes of arriving at the hospital [Identifier 1, IDNO 289]	18	(2)

Table II.
Type of change required in key areas of action

Acceptance of CHI's recommendations: views from interviewees

- The Trust accepted the recommendations because they "really came from us" – there is lots of dialogue between clinicians and managers in the Trust, and so the recommendations were already in the Trust's development plan.
- The trust "had no qualms about the recommendations – the main recommendations were not surprises".
- The report was fair and not surprising in its findings. It served to bring some relatively under resourced areas up the agenda, e.g. patient and public involvement.
- When the report was published it did not find anything that was not previously known as an issue by the Trust.

The progress made by the 30 NHS trusts in our sample in implementing their action plans following their CHI clinical governance reviews was assessed in mid-2003 by CHI and the relevant strategic health authority. The primary purpose of the progress review was to determine whether their NHS performance ratings should be affected, but it provided a substantial and useful data set on which we drew for this research. We also collected data in our questionnaire survey on the progress in implementing a sample of KAAs, and we addressed change and implementation in our case study interviews.

CHI itself rated whether on not each NHS trust had made progress in each area of clinical governance as part of the progress review process, and it can be seen from Table III that while some areas (service user experience, strategic capacity) were often not rated, in most areas the majority of NHS trusts were deemed to have made progress. However, these ratings are somewhat undifferentiating, in that they make no assessment of the degree or amount of progress made.

In our questionnaire survey there was a fairly consistent view across NHS trusts, PCTs and SHAs, attributing between half and two thirds of the changes which had occurred to CHI's clinical governance review process (Table IV).

Clinical governance area	Rated as having made progress		Rated as not having made progress		Not rated	
		(%)		(%)		(%)
Patient, service user, carer and public involvement	21	(70)	3	(10)	6	(20)
Risk management	19	(63)	3	(10)	8	(27)
Clinical audit	18	(60)	4	(13)	8	(27)
Staffing and management	20	(67)	5	(17)	5	(17)
Education and training	14	(47)	5	(17)	11	(37)
Clinical effectiveness	12	(40)	4	(13)	14	(47)
Use of information	21	(70)	3	(10)	6	(20)
Service user experience	11	(37)	2	(7)	17	(57)
Strategic capacity	11	(37)	1	(3)	18	(60)

Table III.
CHI progress review ratings of NHS trusts by clinical area

This relatively positive view of the extent to which CHI's clinical governance review had brought about significant change was supported by most of our case study interviews, in which we found that the review had driven some specific changes and improvements – for example:

> What made a big difference in this organisation was seeing it in black and white in terms of lack of leadership and strategic direction... I think that has made a big difference in the review of arrangements for clinical governance in the organisation. They then put in more resource and for example my post was created (Clinical Governance Coordinator, Acute Trust).

Some of the interviewees went further, in noting some changes, which followed the CHI clinical governance review, and its recommendations would not have happened without the catalytic effect of the review and the report:The public involvement stuff, again without the focus of the review they would not have made much progress with that. The concerns about Cardiology were raised by the Deanery before ..... but the review did act as a catalyst to the patient and public stuff in particular (CHI Review Manager, Specialist Acute Trust).Interviewees also identified broader, more cultural and attitudinal changes, which had taken, place through the clinical governance review process and its consequences:

> The review made us even more determined. We thought we had a good culture of clinical governance, and were glad to get peer confirmation of this; now it can be pushed into other areas in a more systematic way. The review and report helped us to win over doubting clinicians, because it was not a "tick box" exercise. This was the biggest impact (Chief Executive, Acute Specialist Trust).

However this generally positive view held by most interviewees was tempered by an interviewee from one trust stressing the negative impact of their review on the organisation:

> I would have to say that in turning ourselves around CHI did more damage than good and that is very much around the morale and feeling absolutely distraught at the report (Deputy Chief Executive and Director of Nursing Services, Acute Teaching Trust).

It appears that much of the change that has happened is attributed by many stakeholders to CHI's intervention – the clinical governance review and the resulting report, as well as the subsequent CHI/strategic health authority progress review, though of course some of these changes might have happened without CHI's intervention.

Conclusions

The wide variability in the clinical governance review process and the consequent variability in NHS trust action plans we found call into question the validity and

Table IV. Stakeholder ratings of what caused a KAA to be implemented

	CHI		Other factors – not CHI		Don't know	
		(%)		(%)		(%)
NHS trusts	59	(52)	51	(45)	4	(4)
PCTs	17	(57)	7	(23)	6	(20)
StHAs	54	(67)	19	(24)	8	(10)
All	130	(58)	77	(34)	18	(8)

reliability of the reviews themselves and their recommendations. However, there was some evidence that these reviews had prompted largely positive changes in the NHS trusts, and had generally beneficial effects. But it was difficult to show that clinical governance reviews had led to direct improvements in patient care. We did not set out to measure the costs of the review process, but we did find a degree of scepticism among NHS trusts about its value and the opportunity costs of management and clinical staff time spent preparing for external scrutiny that could be used in more productive ways.

The impact of reviews like those undertaken by CHI could be maximised through three important steps. First, they should be more consistent in approach, style, methods and products through a combination of rather more explicit standards and measures, more detailed guidelines on the structure, content and presentation of reports or feedback, and changes to the training and selection of review teams. This would build on work in this area already started by CHI. The aim should be to increase the consistency and reliability of reviews, while not diminishing their validity. Second, recommendations should all be clearly constructed, expressed and communicated, in terms to facilitate their implementation. Recommendations should be cast clearly in terms, which make both their purpose (what the aim of change should be) and their prescription (what needs to happen or to be done) explicit. As much as possible, the purpose of change should be explicitly connected with improvements in patient care, or changes, which will impact on patient care. Where recommendations concern issues of system or process, the intended benefit to patients should be clear. Third, NHS trusts should have good, detailed, explicit and comprehensive action plans in place to implement the recommendations from regulatory reviews, but focus follow-up monitoring around the original review recommendations which should therefore set timescales for action and progress checking. They should be required to more explicitly account for progress against that original review report.

This paper was finalised during a period of review in England of regulation for health and social care which included the remit of the Healthcare Commission together with other national bodies including the Commission for Social Inspection, the Mental Health Commission, Monitor (the regulator of NHS Foundation Trusts) and the Audit Commission (Department of Health, 1998). The review's terms of reference included identifying any changes in the functions and form of regulation, which might have the greatest impact on frontline staff whilst improving the assurances for users and the general public. The assurance of the public may be better secured if it is easier to demonstrate the reliability and validity of regulatory interventions to healthcare organisations and systems and this is perhaps where the value of this piece of work lies irrespective to who or what is the successor body(s) of the Healthcare Commission.

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