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Commission for Health Improvement

INTERIM REPORT

Learning from CHI: the impact of healthcare regulation

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Contents

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Executive summary

This report presents the early findings from research commissioned by the Commission for Health Improvement (CHI) in 2003 which set out to examine and explore the impact of CHI's clinical governance reviews and their recommendations on NHS trusts. This is an interim report, produced to allow our early findings to be published before CHI hands over its responsibilities to the new Healthcare Commission. A final version, revised to incorporate further analysis, to contextualise the findings and recommendations, and to respond to comments on this draft from a range of stakeholders will be published in due course.

This review is only one component (albeit an important one) of the wider impact of CHI on the NHS. This research has focused on measuring primarily the specific changes and improvements in patient care resulting from CHI's clinical governance review process. It has involved a detailed examination of the specific recommendations (termed key areas for action) identified in CHI clinical governance reports and the way that NHS trusts have responded to them. Our research brief set out four key areas that were to be assessed:

- the range, nature and appropriateness of the action points generated by CHI for individual trusts as a result of the review process
- the appropriateness, resource implications and viability of trust action plans developed in response to CHI reviews
- the extent of implementation of action plans to date, barriers to progress made and expectations for the future
- the impact of the action plans on all aspects of trust organisation and attributable effects on patient care

The research focused on a sample of 30 NHS trusts that underwent CHI clinical governance reviews in 2001 or 2002, and who all underwent a review of their progress in mid 2003, which was undertaken by their strategic health authority and CHI. We used the extensive available data sets for each NHS trust, supplemented by additional data from a questionnaire survey and a series of interviews with some case study NHS trusts. Our main findings were as follows.

- CHI review reports varied greatly in structure and presentation. There were marked differences that resulted in part from changes in the review process over time and from differences between the context and situation of the NHS trust being reviewed, but which we believe also resulted from variations in the quality, rigour and effectiveness of the clinical governance review and probably reflected differences between review teams.
- There was widespread acceptance of CHI's recommendations. Most NHS trusts accepted the diagnosis and prescription for action contained in their CHI review report, either wholly or for the most part, and many indicated that the recommendations covered issues that were known locally to be problems and had been raised before.

- Most of CHI's recommendations focused on systems, processes and management. The great majority of recommendations dealt with managerial or administrative systems or processes, strategic or management issues or care processes. There were very few recommendations that directly addressed issues to do with the quality or nature of patient care, and our measures of the impact of CHI are therefore inevitably dominated by such matters of process. There was an implicit but largely untested assumption that the recommendations would, indirectly, bring about improvements in patient care.
- The nature of CHI's recommendations and the way they were expressed varied greatly. 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). But 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.
- NHS trusts' action plans were very variable in structure, presentation and content. Action plans varied widely in the way they were structured and presented and the level of detail and specific action they contained. It was often difficult to see the connections from the clinical governance review report to the action plan and to be sure that it covered all CHI's recommendations.
- NHS trusts' action plans mostly addressed CHI's recommendations. However, some recommendations were omitted or recast, and the level of detail in responses was often poor. Some action plans essentially restated the recommendations rather than outlining the proposed action, and the timescale for action was sometimes unclear or rather arbitrary.
- Most of CHI's recommendations have been acted upon. The great majority of CHI's recommendations have resulted in some action, and most have been largely or fully implemented, though progress varies widely across NHS trusts. It appears that much of the change that has happened is attributed by many stakeholders to CHI's intervention, for example the clinical governance review and the resulting report, as well as the subsequent CHI/strategic health authority progress review. It is, however, hard to tell how much of the change might have happened anyway.
- There are some important factors involved in securing change. We should be cautious about attributing causation to any single factor, but the findings suggest that CHI clinical governance reviews are more likely to result in change and improvement if the recommendations are clearly defined and focused on measurable and deliverable issues, if the NHS trust's action plan addresses the recommendations effectively and in some detail, if a relatively short timescale for action to be completed is set and if the NHS trust has the internal capacity and capability to monitor, follow up and implement change itself.

We make five main recommendations for future policy and practice, which are particularly directed at the new Healthcare Commission, which takes over CHI's responsibilities for healthcare regulation from April 2004.

- Invest more regulatory effort and attention in other parts of the regulatory cycle, apart from inspection and review; particularly the selection of organisations for

review or intervention, so that regulatory resources are more carefully targeted, and the follow up of recommendations for change, so that it can be assured that required action and improvement have been undertaken rigorously and effectively.

- Make regulatory interventions, particularly inspections or reviews, 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, building 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.
- Make sure that all recommendations are constructed, expressed and communicated clearly in terms that facilitate their implementation. Recommendations should be cast clearly in terms that 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 that will impact on patient care. Where recommendations concern issues of system or process, the intended benefit to patients should be clear.
- Make sure that NHS trusts 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. Require NHS trusts to account for progress against that original report more explicitly.
- Shorten the regulatory cycle of attention, intervention and action to ensure that progress in making changes and improvements is faster and that there are not fallow periods during which little progress is likely to be made.

1. Introduction

1.1 Background and research aims

This report presents the findings from research commissioned by the Commission for Health Improvement (CHI) in 2003 and set out to examine and explore the impact of CHI's clinical governance reviews on NHS trusts. This is not a simple or straightforward subject for evaluation and, to set the context for the research and its findings, it is important to consider how regulation by organisations like CHI influences the behaviour of regulated organisations and what effects it is known to have on their performance. This is an interim report, produced to allow our early findings to be published before CHI hands over its responsibilities to the new Healthcare Commission. A final version, revised to incorporate further analysis, to contextualise the findings and recommendations, and to respond to comments on this draft from a range of stakeholders will be published in due course.

The research literature on regulation suggests that regulators like CHI have a wide range of impacts or effects on the organisations they regulate and cause changes in a number of different ways (Walshe, 2002a). Table 1 below summarises some of the beneficial and adverse effects that have been identified in past research and shows that the interaction of a regulator and the organisations it regulates can be complex and multifaceted. It is therefore important that any evaluation adopts a broad and inclusive definition of impact that recognises both the potential positive and negative consequences of regulatory intervention. Some of the effects outlined in the table are more readily measurable and quantifiable than others, and there is, of course, a risk that evaluation focuses on those effects and pays less attention to those that may be equally or more important but are less amenable to assessment.

Table 1. Summary of reported positive and negative effects of regulation.

Positive effects	Negative effects
1. Specific changes and improvements in patient care resulting from regulatory attention 2. Causing organisational reflection and comparison with regulatory standards and with the performance of others. 3. Giving important or longer term issues greater organisational priority than they would otherwise receive 4. Providing leverage for change for groups or individuals within regulated organisations 5. Driving continuing improvement as regulatory standards are continually updated and improved	1. Temporary rather than sustained performance improvement, which disappears after regulatory intervention 2. Pointless conformance behaviours, in which things are done solely to satisfy regulators that have little or no value for patients or the organisation 3. Defensive or minimal compliance in which standards effectively act as a limit on, rather than a stimulus for, improvement. 4. Creative compliance, in which organisations appear to comply with regulatory requirements by making superficial changes 5. Prevention of innovation or improvement, in which regulatory standards discourage or prevent change 6. Distortion of organisational priorities as organisations respond to issues raised by regulators instead of dealing with internally identified issues 7. Opportunity costs as organisations invest considerable resources, particularly clinical and managerial time, in interacting with the regulator

It is also clear from studies of regulation in other settings that regulators bring about change in regulated organisations through a number of different mechanisms or channels, although attention is often focused mainly on changes resulting directly from a regulatory intervention such as an inspection (Walshe, 2003b). Table 2, below, outlines four main forms or types of effect through which regulators impact on organisations, and offers some examples drawn from the work of CHI. First, their existence and the directions or guidance they publish produce change through voluntary or self compliance without any direct regulatory intervention or interaction with individual organisations. Second, organisations prepare for such interactions, therefore changes happen before the regulator actually comes into direct contact with the organisation or makes any assessment of it. Third, regulators report on what they find and often make recommendations that directly result in consequential change. Fourth, a number of other changes or consequences indirectly resulting from the regulatory intervention may take place, which, while they were not explicitly sought or stated, are certainly an effect of the regulator's actions. It is important to recognise the relative contributions of these different ways of regulatory effect. Attention is usually focused on the third area – direct intervention effects – but some would argue this may not be the most substantial or significant area of change. In most settings, the existence effects (and what is sometimes called voluntary or self compliance by regulated organisations) probably produce the greatest volume of change overall.

Table 2. How regulators effect change in regulated organisations.

Effect	Description	Examples from CHI's work in the NHS
Existence effects	Changes in regulated organisations that take place because of the existence of the regulator or because it issues guidance or directions with which they voluntarily comply	NHS trusts introduce systems of clinical governance influenced by publications from CHI, such as the review guide and reports on investigations and reviews in other trusts
Preparation effects	Changes in regulated organisations that take place because they know that, at a defined point in the future, they will be subject to some form of regulatory intervention such as inspection or review	NHS trusts prepare for their CHI clinical governance review by undertaking self assessments and making changes well before the CHI review takes place
Direct intervention effects	Changes in regulated organisations that take place at the direct initiation or recommendation of the regulator following a regulatory intervention	CHI's review report makes a series of specific recommendations for key areas of action, and NHS trusts prepare an action plan showing how they plan to achieve those actions
Indirect intervention effects	Changes in regulated organisations that are a consequence of a regulatory intervention but are not directly recommended or explicitly sought	Following a CHI review, NHS trusts may make senior leadership changes that were not explicitly recommended. They may also change their behaviour or approach to future regulatory interventions because of their experience

This research has focused on measuring primarily the specific changes and improvements in patient care resulting from CHI's regulatory attention (see Table 1) and the direct intervention effects of CHI's clinical governance review process on NHS trusts (see Table 2). It has involved a detailed examination of the specific recommendations (termed key areas for action) identified in CHI clinical governance reports and the way that NHS trusts have responded to them. Our research brief set out four key areas that were to be assessed:

- the range, nature and appropriateness of the action points generated by CHI for individual trusts as a result of the review process
- the appropriateness, resource implications and viability of trust action plans developed in response to CHI reviews
- the extent of implementation of action plans to date, barriers to progress made and expectations for the future
- the impact of the action plans on all aspects of trust organisation and attributable effects on patient care

It is important to recognise that CHI will have affected the performance of NHS organisations in other ways, as tables 1 and 2 describe, but this research has not set out to measure or assess those other forms of effect. In some of our data collection (notably our case study interviews, which are described later), we have garnered some information relevant to these other forms of effect, which is presented alongside other findings, but this was not the primary purpose of the evaluation.

Identifying the recommendations made in CHI clinical governance reviews and tracking related changes in NHS trusts helps us to understand what has happened but may not provide a clear explanation of how or why it happened. The central challenge for any evaluation of a regulatory intervention is what is sometimes termed the counterfactual – what would have happened if the regulator had not been there to raise the issue, make the recommendation, press for action or whatever. To tackle this problem, and to make a meaningful assessment of the added value or additionality of the regulatory intervention, we must endeavour to measure or assess the causation of change. This is difficult because the changes take place over a varying timescale, with many other concurrent activities and interventions that can bear upon them. Ultimately it is important that all stakeholders in an evaluation such as this one recognise that we are dealing with complex social systems and interventions, and so understanding causation is best done by mapping the processes and mechanisms by which change has been brought about.

1.2 Methods and data sources

At the time this research was commissioned in 2003, there were around 270 NHS trusts and about 300 primary care trusts (PCTs) 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 that 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, Cortvriend and Mahon, 2003). We did not include PCTs in the study because none had undergone clinical governance reviews more than 12 months before the research, so none of them would have had a sufficient time period for changes to be effected. There were about 120 NHS trusts that had undergone a CHI clinical governance review at least 12 months previously, and, of those, 94 NHS trusts had been subject to a follow up review by CHI and their strategic health authority in mid 2003 for the purpose of

examining their progress since the review and determining whether it should affect their star ratings in 2003 (CHI, 2004). Because this process of follow up review provided a substantial data set on the progress and implementation of change, we chose to focus our study on that group of NHS trusts.

We selected a stratified random sample of 30 NHS trusts from this group of 94 trusts, aimed at ensuring a broad representation of trust types and service areas, geographic area and reported performance in clinical governance. Some key characteristics of the sample (alongside data for the rest of this cohort of NHS trusts) are presented in Table 3.

Table 3. Some characteristics of the sample of NHS trusts used in the research.

		Trusts in sample (*n* = 30)	Trusts not in sample (*n* = 64)
Trust types	Acute	27 (90%)	55 (86%)
	Specialist	3 (10%)	4 (6%)
	Community	0 (0%)	1 (2%)
	Mental health	0 (0%)	4 (6%)
Star ratings in 2002	0	1 (3%)	4 (6%)
	1	5 (17%)	11 (17%)
	2	15 (50%)	35 (55%)
	3	9 (30%)	14 (22%)
Year of CHI review report	2001	10 (33%)	29 (45%)
	2002	20 (67%)	35 (55%)
Clinical governance review ratings:			
Patient, service user, carer and public involvement	1	6 (20%)	19 (30%)
	2	23 (77%)	41 (64%)
	3	1 (3%)	4 (6%)
	4	0 (0%)	0 (0%)
Risk management	1	3 (10%)	17 (27%)
	2	24 (80%)	36 (56%)
	3	3 (10%)	11 (17%)
	4	0 (0%)	0 (0%)
Clinical audit	1	6 (20%)	13 (20%)
	2	19 (63%)	45 (70%)
	3	4 (13%)	6 (9%)
	4	1 (3%)	0 (0%)
Staffing and management	1	5 (17%)	14 (22%)
	2	20 (67%)	41 (64%)
	3	5 (17%)	9 (14%)
	4	0 (0%)	0 (0%)
Education and training	1	0 (0%)	4 (6%)
	2	20 (67%)	44 (69%)
	3	10 (33%)	16 (25%)
	4	0 (%)	0 (0%)
Clinical effectiveness	1	5 (17%)	18 (28%)
	2	16 (53%)	31 (48%)
	3	8 (27%)	14 (22%)
	4	1 (3%)	0 (0%)
Use of information	1	11 (37%)	27 (42%)
	2	17 (57%)	31 (48%)
	3	2 (7%)	6 (9%)
	4	0 (0%)	0 (0%)

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

- the CHI clinical governance review report and any associated documentation that was available or published in support of that report
- the NHS trust's action plan, produced in response to the CHI clinical governance review
- follow up data collected by strategic health authorities, CHI or other organisations on the subsequent implementation of the action plan, where such data was

available, or routine data collected for operational or performance management purposes

- our own data collection, based on a postal survey as well as telephone and/or face to face interviews with key informants in NHS trusts and other organisations in the local NHS community

Most of the existing available data sources (documents, reports and databases) were primarily qualitative or narrative in nature. We designed a structured data collection process to summarise, enumerate, categorise and rate changes that follow the CHI clinical governance review in ways that facilitated a more structured and quantitative assessment of both the process of change and its impacts and which enable comparisons and aggregation across NHS trusts to be undertaken. Our data set, collected for each key area of action identified in the clinical governance review reports for our sample of 30 NHS trusts, was designed to:

- describe the key area of action itself in brief narrative form
- categorise the type or nature of change proposed in terms of scale and content
- categorise the relative importance or significance of the key area of action within the report
- categorise and describe the measurability or assessability of the changes recommended in the key area of action
- indicate whether the key area for action was accepted by the NHS trust and reflected in the action plan
- describe how the key area for action was to be addressed in the action plan in brief narrative form
- record the intended timescale for action
- categorise the type or nature of the proposed action in terms of scale and content
- record the availability of routine or other data sources to track the implementation of the change element, and record the data concerned where it is available
- describe and categorise the progress of the change and any barriers encountered

In addition, we designed a questionnaire for each trust to seek further information about a randomly selected group of the key areas of action identified in the CHI review report. Our questionnaire asked the respondent to rate the validity of the recommended change – whether it was a newly identified issue or pre existed the CHI report, the degree of change that has subsequently taken place and the extent to which that change has been driven by the CHI review (as opposed to other factors) – and sought free text comments on the change and the CHI review. For each of the 30 NHS trusts in our sample, this questionnaire was sent separately to the clinical governance lead in the NHS trust, the lead person at the strategic health authority responsible for the progress review, and the clinical governance lead in the closest related PCT. This provided three separate perspectives on change and impact on performance.

Finally, we chose four NHS trusts to act as case studies, selected to give a range both of reported performance in clinical governance and to represent the variation we found

in the review and reporting process. For each of these four NHS trusts, we identified around six people with whom we undertook a telephone interview using a semi structured interview schedule that covered their general impressions of the CHI review, the development and implementation of the trust's action plan, the extent to which the CHI review had contributed to change and improvement at the trust, what learning might be drawn from their experience and any other issues the interviewee wished to raise. The data set on which this evaluation has been based, and from which the results and findings presented in sections 2, 3 and 4 of this report are drawn, is summarised in Table 4.

Table 4. Evaluation data set summary.

Documentary review	Data on all 30 NHS trusts was collated, including CHI review scores, star ratings, review dates, etc. Data was extracted from CHI clinical governance reports, NHS trust action plans, strategic health authority progress reviews and CHI progress review summaries. For each key area of action (KAA) identified in the report, a data set was collated, including its title and description, status, review area, breadth and depth of change required, measurability of change required, action plan points and summary, whether action plan addressed KAA, timescale and clarity, rating of progress review and nature of evidence of progress
Survey of key stakeholders	Identified contact points in each NHS trust, a related PCT and the appropriate strategic health authority completed a postal questionnaire. For a sample of KAAs they rated the acceptance of the recommendation, whether it was a new recommendation, its implementation and what caused or contributed to its implementation. For the CHI review as a whole, they additionally commented on beneficial and adverse impacts and learning from the process
Case studies of selected trusts	About five or six people were interviewed for each of four NHS trusts selected as case studies. Interviewees included the chief executive, medical director, clinical governance lead, clinical lead for a reviewed clinical area and the CHI review manager and assistant director. A semi structured interview schedule was used covering general impressions, action plan development and implementation, contribution of CHI review to change and improvement and learning from the process

To ensure the consistency and reliability of the data collection process in the documentary review, we developed a detailed data guide and piloted data collection on three NHS trusts, with three researchers each independently reviewing and collating information and then comparing the results in order to revise the data collection guide and standardise the process. Data from each NHS trust in the main sample was then collected, and any areas of uncertainty or ambiguity were reviewed by two or more researchers. This research has been undertaken to a very demanding timescale, particularly given that the second and third components outlined above required ethical approval from an NHS Multicentre Research Ethics Committee before they could be undertaken. The policy context, with the transfer of responsibilities to the new Healthcare Commission in April 2004, meant we needed to produce this report by March 2004. At this point in time, data collection is ongoing in the survey and case study components, but we do not anticipate that additional data will make any substantive differences to the report's findings and recommendations.

1.3 Structure of the report

The rest of this report presents the results and findings from the research and then draws together our main conclusions and their implications for future policy and practice. It does so in four main sections, as follows.

- Section 2 presents our analysis of the CHI clinical governance review process and the reports it produces. It first examines the experience of the CHI review process and the nature of the resulting reports, then it focuses in detail on the key areas for action that encapsulate CHI's recommendations.
- Section 3 explores the nature of the action plans that NHS trusts produced following their CHI clinical governance review and its report. It analyses the structure, content and presentation of those action plans and then examines their early implementation.
- Section 4 describes how the implementation of these actions has been progressed and the extent to which they have resulted in changes and improvement. It reports on the nature and degree of change we found and draws on a range of data to report on the characteristics that appear to be associated with successful change and improvement, as well as the extent to which CHI's intervention in NHS trusts appears to have brought about change.
- Finally, section 5 draws together our main conclusions from the research and examines the implications for future policy and practice, particularly in the context of the transition to a new healthcare regulator, the Healthcare Commission.

2. CHI clinical governance reviews and their recommendations

2.1 The review process and the review report

The CHI clinical governance review process has been extensively described elsewhere (CHI 2002) and the experiences of NHS organisations and their views of the process have been explored in two studies by the NHS Confederation (NHS Confederation, 2002). Our analysis is therefore largely focused on the review reports themselves, though our case study interviews provided some additional insights into the clinical governance review process itself.

The CHI clinical governance review process, and the structure of the reports produced, has changed substantially over the almost four years CHI has been operating. The whole process was substantially revised and redesigned in 2001, but other smaller changes have been made at other times. We found it difficult to categorise reports as being in an old or new format and found that, while the clinical governance review redesign in 2001 had produced a significant change, there were many other changes and variations too. It also seemed that, while reports have followed a common structure and template to some degree, individual CHI review teams have had considerable discretion in how they have presented their findings.

As a result, the 30 CHI review reports we have used in this research 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 from five to 57 areas. Some had executive summaries that highlighted the highest priorities for action, while others did not. Where those summaries existed, they sometimes duplicated recommendations covered in the main body of the report and sometimes did not. The space and detail that the reports devoted to the different areas of clinical governance (patient and user involvement, risk management, clinical audit, staffing and management, education and training, clinical effectiveness, the use of information, service user experience and strategic capacity) varied widely, and they structured their assessments of issues differently too, grouping them under different areas in different reports. Some reports clearly identified and labelled all their recommendations as key areas of action (KAAs), while others embedded some recommendations within the narrative. These KAAs were not numbered sequentially in any of the reports we reviewed, therefore we (and presumably other users of these reports) needed to trawl through reports carefully and sometimes repeatedly in order to ensure no KAAs were missed. A few reports included an appendix that listed all the KAAs from the main report, which we found very helpful.

It is difficult to assess to what degree all this variation is a necessary response to the undoubted variation that is found in NHS trusts and their clinical governance arrangements, or whether it represents variations in the style and approach of different clinical governance review teams, or a combination of the two. Undoubtedly it raises the question of how reliable the review process is (or can be) and whether there is some trade off to be made between validity and reliability in the review process. In other words, it may be difficult to design reviews that measure things meaningfully and give consistent results. Whatever the policy intent, it seemed to us that the design of the

clinical governance review process in the widest sense had produced a fairly heterogeneous and individual style of report.

All our interviewees indicated that, in general terms, the clinical governance review process was appropriately designed and fairly administered by CHI, and the main substance and findings presented in the resulting review report were generally accepted. Indeed, interviewees reported little surprise at the content of review reports: they generally confirmed rather than contradicted local views about the issues covered.

> "The trust accepted the recommendations because they 'really came from us'. There is lots of dialogue between clinicians and managers in the trust, 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, eg 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."

This was generally confirmed by data from our questionnaire survey, in which stakeholders from NHS trusts, PCTs and strategic health authorities(StHAs) were asked, for a random sample of KAAs, whether they agreed with the recommendation as it was presented. As Table 5 shows, respondents from NHS trusts agreed in whole or in part with over 90% of KAAs. It is notable that levels of knowledge and understanding in PCTs and strategic health authorities were much lower, with those stakeholders unable to offer a view on a quarter (25%) and almost a half (40%) of KAAs.

Table 5. Stakeholder agreement with CHI key area for action recommendations.

	Yes, fully agree	Agree in part	Do not agree	Do not know
NHS trusts	56 (51%)	45 (41%)	10 (9%)	0 (0%)
PCTs	17 (53%)	6 (19%)	1 (3%)	8 (25%)
StHAs	37 (57%)	1 (2%)	1 (2%)	26 (40%)
All	110 (53%)	52 (25%)	12 (6%)	34 (16%)

Interviewees made a number of other comments about the review process itself, which are summarised in Table 6 and are largely confirmed by both the NHS Confederation studies cited earlier and more recent work by Day and Klein (Day and Klein, 2004).

Table 6. Some key issues concerning the CHI clinical governance review process.

Workload involved in preparation	"It was very labour intensive. We produced a phenomenal amount of information, both hard copy and electronic for CHI. They produced a very small briefing document that actually went to the reviewers, which was a little disappointing because I had two of my (senior) staff doing nothing else for about 80% of their time for six months. What was actually produced in the brief, some of it wasn't accurate and we kept having to go back, but we got there in the end."
Expertise and understanding of the review team	"The review team were very open to challenge. Colleagues in some other trusts may not have challenged the reviewers at the time but waited until the report was written, and this is less satisfactory. The trust coordinator should be proactive and not let the review team go away with the wrong impression." "…their depth and skill and expertise was patchy, for example I am actually the nurse on the board and the questions that were asked about nursing should have been strategic, but I was asked about very operational issues… My interviewer's knowledge of research in the NHS was non existent. They knew nothing about the governance arrangements that were coming in around research, nor the clear criteria around funding for research, which are the things we should be tested on."
Rigour of the process/data behind review recommendations	"…one of the things it said in our report was around privacy and dignity. The issue of privacy and dignity was not across the trust at all, it was in one small department where we had got curtains and not walls and we did something about that."
Mismatch of trust and CHI expectations	"…the trust did not really expect that the review would concentrate upon, not just the strategic issues and the processes/systems involved with clinical governance, but also the impact on the patient experience. The trust was surprised by this second emphasis of the review process on the operational practice of the trust."
Adaptation of the review process to local context	"…one of the fundamental problems with process was one size fits all. You have effectively the same level of resources whether you were doing a small single sited new trust or a massive teaching/tertiary centre."
Duplication of other forms of inspection or oversight	"The only criticism of the process was being 'assessed to death' by Clinical Negligence Schemes for Trusts, Improving Working Lives, Investors in People. All the different assessment things were being constantly assessed one week after the other and then CHI come in, and a lot of the stuff we were having to reproduce again in a slightly different format for CHI."

2.2 An analysis of key areas for action

Across the 30 NHS trusts whose CHI clinical governance reviews form the basis for this research, CHI identified a total of 958 KAAs. This is an average of about 32 per NHS trust, although the actual number varied widely from five in one trust to 57 in another, as Table 7 shows. However, as was noted above, some of these recommendations were duplicated by being presented both at the front of the report in an executive summary and in the body of the report. We found that such executive summaries sometimes wholly duplicated individual KAAs from the main report, sometimes compounded them (combining several KAAs in the body of the report into a single KAA in the executive summary) and sometimes identified new recommendations that did not appear separately in the body of the report. To avoid double counting recommendations, we identified those KAAs that appeared to be duplicates and found there were 159 duplicate KAAs, with 809 unique or non duplicated KAAs, which effectively constitute the body of changes that CHI recommended to this group of NHS trusts. Most of our analyses in this report are based on this group of 809 KAAs. Just over a quarter (29%)

of these KAAs were identified as particular priorities for action by being placed in the executive summary of the report.

Table 7. Summary of key areas of action identified in CHI review reports for NHS trusts.

Trust	Total KAAs	Duplicated KAAs	Unique KAAs	KAAs identified as a priority
29	57	2	55	11
24	55	7	48	13
12	52	9	43	7
3	51	15	36	20
4	50	8	42	7
7	49	4	45	5
28	49	8	41	10
27	41	9	32	8
6	40	12	28	10
2	39	5	34	4
14	39	0	39	6
25	38	9	29	10
5	35	10	25	7
15	33	5	28	6
18	33	2	31	6
16	32	4	28	7
23	31	3	28	10
13	30	1	29	28
22	29	12	17	12
17	28	9	19	12
1	24	4	20	13
21	24	1	23	8
30	23	1	22	4
9	16	6	10	0
20	16	2	14	2
10	12	0	12	0
8	9	0	9	0
19	9	0	9	9
26	9	1	8	8
11	5	0	5	5
All trusts	958	149	809	248

In each clinical governance review report, KAAs were mainly presented across nine areas of clinical governance: patient and user involvement, risk management, clinical audit, staffing and management, education and training, clinical effectiveness, the use of information, service user experience and strategic capacity. We allocated those KAAs that were only in report executive summaries to one of these areas. We found there was some overlap between areas; for example, KAAs that might be placed in staffing and management by one review could be put in education and training by another. As Table 8 shows, across all NHS trusts, the key areas of action recommended by CHI were relatively evenly distributed across the nine identified areas of clinical governance,

although the most KAAs fell into the areas of service user experience and the use of information, and there were fewest in the areas of strategic capacity and education and training. Table 8 offers examples of KAAs in each clinical governance area to illustrate their typical content, although the actual content of KAAs in each area varied very widely.

Table 8. Key areas of action analysed by clinical governance review area.

Area	Examples	No (%)
Patient, service user, carer and public involvement	To develop and implement a user involvement strategy Urgent action is required to ensure that the do not resuscitate and consent policies are fully adopted throughout the organisation	89 (11%)
Risk management	The trust must ensure that feedback is given to staff following a complaint or incident involving them The trust should ensure that all staff report incidents and near misses on the identifier form and there are no separate mechanisms of reporting occurring	108 (13%)
Clinical audit	The trust should promote multidisciplinary audit across all clinical teams The trust should develop strategies for involving patients in all parts of the audit cycle	75 (9%)
Staffing and management	Effort needs to be made to ensure that all staff receive an annual appraisal Further work is required to address the issue of staff shortages in key areas such as A&E	115 (14%)
Education and training	The trust will need to ensure that staff in all areas attend mandatory training To undertake a trust wide training needs analysis and the development of trust wide education and training strategy	68 (8%)
Clinical effectiveness	The trust should implement a strategy for the future development of multidisciplinary integrated care pathways A research and development strategy should be agreed and implemented	67 (8%)
Use of information	Action should be taken to ensure the trust complies with Caldicott requirements The information management and technology strategy needs to be reviewed to ensure it meets clinical governance needs	103 (13%)
Service user experience	Environment: general appearance needs improvement, and there is a severe lack of privacy for patients in A&E Action should be taken to identify the causes of the day case overstays and take appropriate steps to reduce the overstay	124 (15%)
Strategic capacity	Action is required to increase the involvement of stakeholders in the clinical governance process Urgent action is needed to implement a coordinated strategy that pulls together all elements of clinical governance into a cohesive approach.	60 (7%)

We categorised all KAAs according to the type of change that they sought, using a classification we developed and tested during piloting. The five types of change were: strategic/board level leadership; administrative or management process; patient care system or process; environment or facilities; and patient experience or outcomes. The distribution of KAAs across these categories is shown in Table 9, which again offers a few typical examples in each category. It can be seen that over two thirds of KAAs were classified as management/administrative system or process changes. Very few KAAs directly sought changes in patient experiences or outcomes. This may be unsurprising, given that the focus of the review process was on clinical governance and not directly on the quality of care or services themselves, but it has important consequences for our ability to track the impact of CHI clinical governance 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 clinical governance reviews because so few of the recommendations relate directly to the quality of patient care or clinical practice.

There is an essential but implicit assumption underlying CHI's clinical governance reviews, and their recommendations that action on management and administrative systems or processes will indirectly bring about improvements in patient care. For example, as can be seen in Table 9, the introduction of a trust wide protocol for complaint investigation is presumably intended to result in complaints being investigated more effectively and efficiently, giving complainants better and more immediate responses to their concerns and causing the NHS trust to make better use of feedback to bring about improvements. Such assumptions may have high face validity but they are, of course, open to question both at a general level (what evidence is there that better complaints management actually results in better patient care?) and at the level of the specific trust (did the changes made to this NHS trusts' complaints management actually result in any improvements thatthey can specify or enumerate?).

Table 9. Type of change required in key areas of action.

Category	Examples	No (%)
Strategic/ board level/ leadership	Trust board directors need regular reports, involvement and ownership of clinical governance issues The trust needs to ensure that the patient and public involvement strategy is implemented across the organisation.	79 (10%)
Management/administrative system or process	A trust wide protocol to be agreed for investigating complaints Training in risk awareness and assessment should be available for all staff	558 (73%)
Patient care system or process	The trust needs robust discharge arrangements The trust should develop more robust systems for monitoring the prevalence of hospital acquired infections and pressure sores	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 The trust should review urgently its security system and processes	38 (5%)
Patient experience or outcomes	Staff should endeavour to ensure that the dignity of all patients, especially the frail and vulnerable, is not compromised 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	18 (2%)

We categorised all KAAs according to the breadth of change they appeared to require, ranging from changes that seemed to affect just a single individual or a small team, to changes that would affect the whole organisation. Again, this categorisation was not always straightforward in that it could often be argued that a change might be undertaken by one department or team but could have much wider effects, and we opted to classify changes according to the level at which a change in behaviour was required rather than the level at which changes might have such an effect.

As Table 10 shows, we found that most KAAs (66%) appeared to seek change at the NHS trust level, across most or all of the organisation, rather than at a service, departmental or team level. As the examples in Table 10 show, KAAs with a fairly narrow focus on a team or department tended to be more specific about exactly what

was required, while KAAs thatrelated to the whole organisation were understandably less well bounded and perhaps harder to define explicitly.

Table 10. Breadth of change required in key areas of action.

Category	Examples	No (%)
Individual or small team	There should be an IT representative on the clinical governance committee Urgent action should be taken to address a lack of nursing leadership at strategic level	22 (3%)
Single department or service area	To improve the information to patients on expected waiting times for treatment in the A&E department Urgent action is needed to improve timely access to pathology results	115 (14%)
Several departments or service areas	Action is required to identify ways of improving the responsiveness of diagnostic departments Further specialist training must be provided in management of violence and aggression for staff working in high risk areas	141 (17%)
Most or all of the organisation	To develop and implement a user involvement strategy All care professionals must be involved in the use and development of integrated care pathways	531 (66%)

We also classified each KAA according to the depth of change that was sought. This was a difficult judgement for the research team to make, and we are tentative about our conclusions, but essentially we endeavoured to assess whether a KAA required little or no significant change in practice, some change in practice, a major change in practice or a fundamental change in practice. We used examples of the latter three categories drawn from our piloting of data collection to maximise consistency in categorisation by the research team. The results are summarised in Table 11.

It is notable that about 14% of KAAs were categorised as requiring no significant changes in practice. These were often tentative recommendations in nature (consider whether something should be done) or were focused on measurement or evaluation rather than action (review, assess or investigate an area or issue). Most KAAs fell into our two middle categories. Those in the some change group tending to be rather less demanding and more tangential than those in the major change group. Very few changes were placed in the fundamental change category, which we intended should contain those KAAs that demanded complete service redesign or wholesale changes in provision.

Table 11. Depth of change required in key areas of action.

Category	Examples	No (%)
No significant change in practice	Formally assess the success of the 'cook chill' programme Consideration should be given to logging compliments	115 (14%)
Some change in practice	Training in risk awareness and assessment should be available for all staff The trust needs to achieve consistency in levels of appraisals being done within the divisions	391 (48%)
Major change in practice	A clinical audit strategy should be developed and implemented Action is required to address the shortages of clinical staff across the trust	297 (37%)
Fundamental change in practice	The trust must find ways to provide overall feedback to all staff to ensure learning between teams as well as within teams To promote multidisciplinary working encompassing all professional groups of staff	6 (1%)

We also attempted to categorise the extent to which the changes proposed in KAAs would be measurable. This too could be a difficult assessment, but we developed a classification scale ranging from those KAAs that we judged would be clearly measurable using available data sources or objective measures (an example might be a KAA concerning operation cancellation rates or outpatient did not attend rates) to those that seemed largely or wholly unmeasurable (such as those concerning the organisational culture, leadership style or staff attitudes).

Table 12. Measurability of change required in key areas of action.

Category	Examples	No (%)
Clearly measurable by available data and objective data sources	Urgently monitor and improve staff uptake of mandatory training and updates The trust should ensure that cancellations of operations are kept to a minimum	110 (14%)
Largely measurable though some need for judgement	Ensure information gained through benchmarking is utilised as a performance monitoring tool 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 To implement a multidisciplinary research strategy within the organisation	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%)

The results are summarised in Table 12, which offers some examples of typical KAAs in each category. It can be seen that relatively few (14%) KAAs were seen as straightforwardly measurable, but almost half (47%) were judged to be largely measurable but require some use of judgement (and a degree of concomitant subjectivity). It was clear that some of the less obviously measurable KAAs tackled very important issues, therefore it would not be appropriate to suggest that KAAs with low measurability should not be included. However, it was evident that some KAAs could

perhaps have been recast or reworded in terms that would have made the changes they sought more measurable.

Each of the attributes of the key areas of action contained in CHI review reports that we have examined in this section can be analysed across the nine areas of clinical governance identified and discussed earlier. Table 13 presents a summary of such an analysis, and it can be seen that there are some substantial differences in some areas. For example, KAAs concerning strategic capacity were much more likely to be highlighted as a priority by being placed in the executive summary of the report, while those on clinical effectiveness were rarely so prioritised. Across all areas, apart from service user experience and strategic capacity (for understandable reasons), the changes sought tended to entail management systems or care process changes. The breadth of change required was greatest in areas such as patient/user involvement and staffing and management, and least in service user experience, perhaps because those recommendations were often focused on specific, departmental issues. Interestingly, the areas where the changes recommended were seen as most major or fundamental were clinical audit, clinical effectiveness, patient/user involvement and the use of information. The most measurable areas of change were found in service user experience, risk management and education and training, while the least measurable KAAs were found in the area of strategic capacity.

Table 13. Comparison of characteristics of key areas of action by clinical governance area.

Area	Highlighted as a priority (%)	Involving system or process change (%)	Requiring change in most/all of organisation (%)	Requiring major or fundamental change (%)	Clearly or largely measurable (%)
Patient, service user, carer and public involvement	33	90	79	45	43
Risk management	19	93	74	36	71
Clinical audit	19	96	73	55	60
Staffing and management	34	90	66	26	60
Education and training	21	93	78	24	68
Clinical effectiveness	13	88	75	46	54
Use of information	30	91	75	45	67
Service user experience	27	63	28	31	73
Strategic capacity	60	42	58	35	30
All areas	28	83	66	37	60

This analysis suggests that KAAs concerning service user experience and strategic capacity tended to be qualitatively different from those in the other areas. KAAs concerning service user experience tended to be fairly concrete and specifically focused on a particular aspect of care that made them measurable and meaningful, but meant

their importance or contribution to wider NHS trust performance might be quite marginal. KAAs concerning strategic capacity tended to be seen as the highest priorities for action by CHI review teams, but generally concerned strategic issues that were not as concrete or definable; they demanded less clearly specifiable forms of change or action and so their completion was likely to be less measurable.

3. NHS trusts' responses: action planning

3.1 Trust action plans: structure, content and presentation

NHS trusts have been required to respond to the CHI clinical governance review and the resulting report by producing an action plan. The aim of the action plan has been to show how the NHS trust plans to address or tackle the key areas for action raised by CHI in its report, and to act as a tool for both the NHS trust and other stakeholders to monitor or track its progress. These action plans have been published, generally alongside the CHI review report itself.

The development of action plans has been led by NHS trusts, although CHI has offered some support and had some involvement in action planning days organised with NHS trusts. Interviewees typically described a process in which key stakeholders within the trust were brought together to set the main direction for the action plan and then work in smaller groups in parallel on the development of specific sections or parts that were then brought together into the final document. For example:

> "I attended the action planning day, which they held at the trust but with people from patient groups there and people from the health community as well, and then sensibly broke up into discrete areas in a workshop based way. They had done a fair amount of work before the day, so it was not entirely started from scratch but gave further shape to the preliminary conclusions on actions to be taken, then was pulled together in a plenary session, so it was a very standard way of pulling together an action plan."

> "We did it on two levels. We did a strategic response and an operational response, and the strategic response we had some time out with the board and we used CHI at the first stab at it, which was not totally successful, and then the second stab we used the clinical governance support team, which was much better. Then from that strategic response, which was fairly high level, we developed an action plan that fitted within the organisation, ie within the directorates, so that there was ownership and it did not go in the public domain, that was an internal working document. People knew what they were responsible for and had got timescales and timelines to deliver things. We did workshops with the staffing in the directorates to develop that."

NHS trust action plans were generally structured as a point by point response to each key area for action noted in the CHI review report. For each KAA, there would generally be a list of several action points specifying what action was to be taken and often naming those individuals responsible for leading action, and setting a date in the future by which the action was expected to be completed. Just as CHI review reports were found to be highly heterogeneous, there was a great variety in the presentation, format and style of the trust action plans. For example, the shortest trust action plan we reviewed addressed 17 key areas of action, with 45 action points over four pages. In contrast, the longest action plan we reviewed took 89 pages to address 43 KAAs, with 113 action points that were further broken down into 139 objectives and, supporting these, 362 numbered points. The average length of a trust action plan from the sample was 22 pages. The longer action plan identified a number of prioritised objectives for each KAA and then further broke these down into actions planned, while, in contrast,

the shorter action plan identified objectives only and did not break these down into smaller steps; neither did it prioritise the objectives nor note any expected outputs and outcomes (which the longer example had done). Both examples were clear throughout in naming key senior personnel with responsibility for each objective. However, the longer example was much clearer about the deadlines it set for the completion of parts of an objective than the shorter action plan. These two action plans clearly served different purposes. The longer action plan was a highly detailed and explicit prescription for action, which made it very clear exactly what should be happening, when it should happen and who was responsible. It would probably be very useful (if perhaps a little too detailed) for monitoring by the trust and other stakeholders. However, it was perhaps rather inflexible, mechanistic and bureaucratic in its design, and gave managers responsible for implementing the action plan remarkably little scope for autonomy or decision making.

It was noted earlier that some CHI clinical governance review reports included recommendations (or observations that might be read as recommendations) that were not marked or labelled as a KAA but were embedded in the text. For example, two such recommendations that were not presented as KAAs but were taken up by the NHS trust concerned were as follows.

- Results of all tests and investigations are not currently transmitted electronically to all GPs, and both GPs and patients report considerable delays in receiving results.

- The signage is generally confusing throughout the hospital. A review of the internal signage and a new map is required to help patients find their way around the new hospital.

In the main, NHS trust action plans did not respond to such embedded recommendations but, in a small number of action plans, NHS trusts did tackle such issues. This may have demonstrated that those organisations were trying to take full account of all of the CHI team's analysis and suggestions in comparison with other NHS trusts who had focused solely on the KAAs in the development of their action plans. However, it probably also reflects some lack of clarity both within CHI review reports and in the guidance to NHS trusts about the intended scope of their action plans.

The structure and ordering of NHS trust action plans also varied. Most (but not all) were structured around the KAAs in the order or sequence in which they had been presented in the CHI review report. However, the fact that many CHI review reports duplicated some KAAs in both an executive summary and the main report (as discussed earlier) led some trusts to revise the ordering and made sequencing more complex. In some cases, the logic behind the design and presentation of the action plan was not immediately obvious. Because CHI review reports did not generally number KAAs, it was often difficult to follow the connection between the CHI review report and its KAAs and the action plan, and it was hard to see whether all the KAAs identified by CHI were actually covered in the action plan.

3.2 An analysis of action planning and implementation

We undertook a detailed documentary analysis of our sample of 30 NHS trust action plans, linking the information they contained to the data we had already collected from CHI clinical governance review reports and assessing the numbers and content of action points, the extent to which action plans addressed the KAA recommendations and the clarity and nature of timescales they set.

The level of detail contained in trust action plans for each KAA varied widely, as Figure 1 illustrates. It can be seen that, most commonly, KAAs had two or three specified action points (which, it might be thought, does not constitute a particularly detailed level of action planning). Indeed, 130 KAAs (16%) had a single action point that was often simply a restatement or reiteration of the KAA itself. However, there were some KAAs (31, 4%) for which there were much more detailed action plans containing 10 or more separate points. Different trusts took quite different approaches; for example, one responded to the following KAA:

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

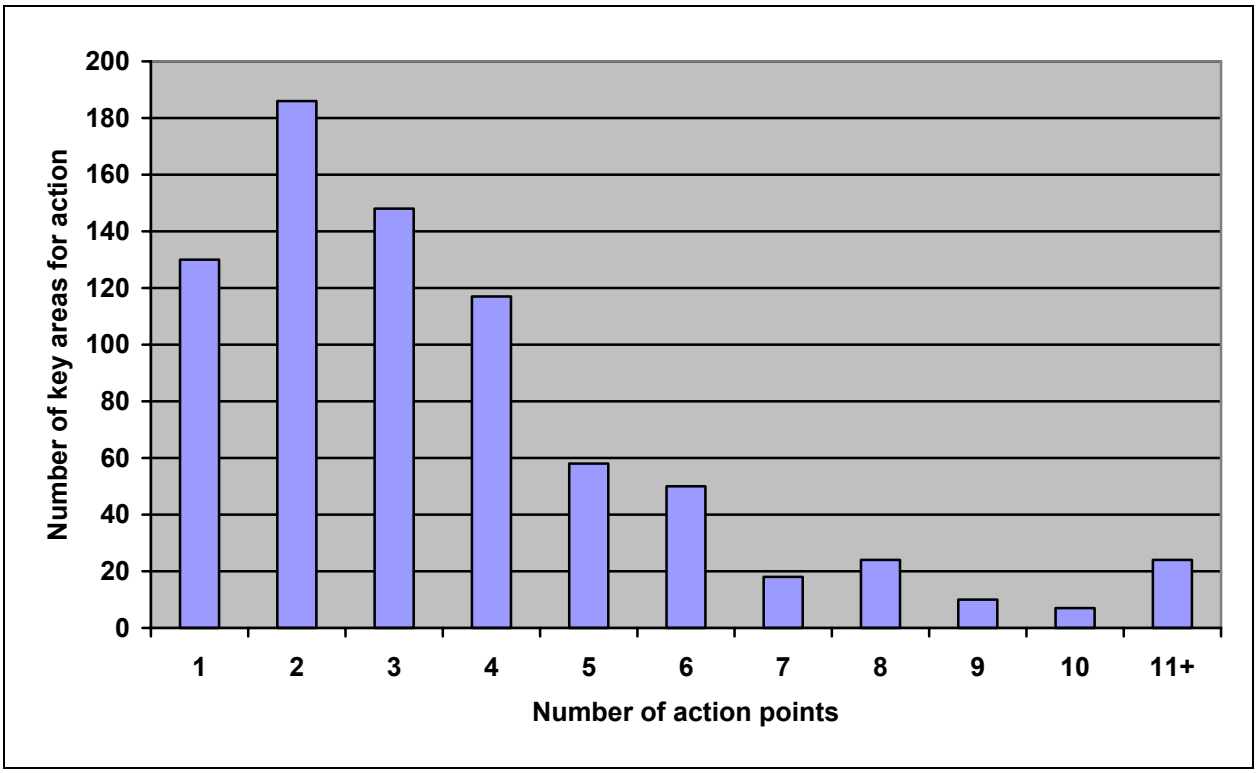
by offering a single action point, while another NHS trust responded to the following KAA:

> The implementation of the strategy for public involvement continues and the recommendations within it implemented with realistic timescales and are regularly monitored and evaluated

with an action plan containing 10 separate action points. The variation in action planning across trusts is discussed further below.

It should be noted that there were 38 KAAs (5%) for which we could find no corresponding action points in the NHS trust's action plan. It has already been noted that the structure and presentation of CHI review reports and action plans made the links between the two somewhat obscure and hard to follow, and it appears that, perhaps for this reason, some KAAs were either inadvertently overlooked or simply not included. This is an important finding because the subsequent progress monitoring of action plan implementation by CHI and strategic health authorities has tended to take the action plan as its starting point rather than the CHI review report itself.

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



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

More subtly, we also found that some action plans reinterpreted or refocused the recommendations from CHI in their clinical governance review reports, sometimes changing the nature significantly or omitting part of the content. For example, one trust responded to a KAA:

> The trust must continue its work in developing corporate clinical risk management systems specifically relating to trend analysis of complaints and clinical incidents. It is also important that issues relating to supervision of locum senior house officers (SHOs) are addressed.

by recasting the wording as shown below, and apparently excluding a part of the recommendation:

> The trust must continue its work in developing corporate clinical risk management systems specifically relating to trend analysis of complaints and clinical incidents.

To evaluate the extent to which trust action plans tackled the recommendations in KAAs, we assessed the action points for each KAA and classified them into four groups: those that were clearly not addressed by the action plan, those that were partly addressed, those that were mostly addressed and those that were completely addressed. Again, we used examples drawn from piloting to guide our research team in their categorisation and compared our results during piloting. The results are presented in Table 14.

Table 14. Extent to which action plans address key area of action recommendations.

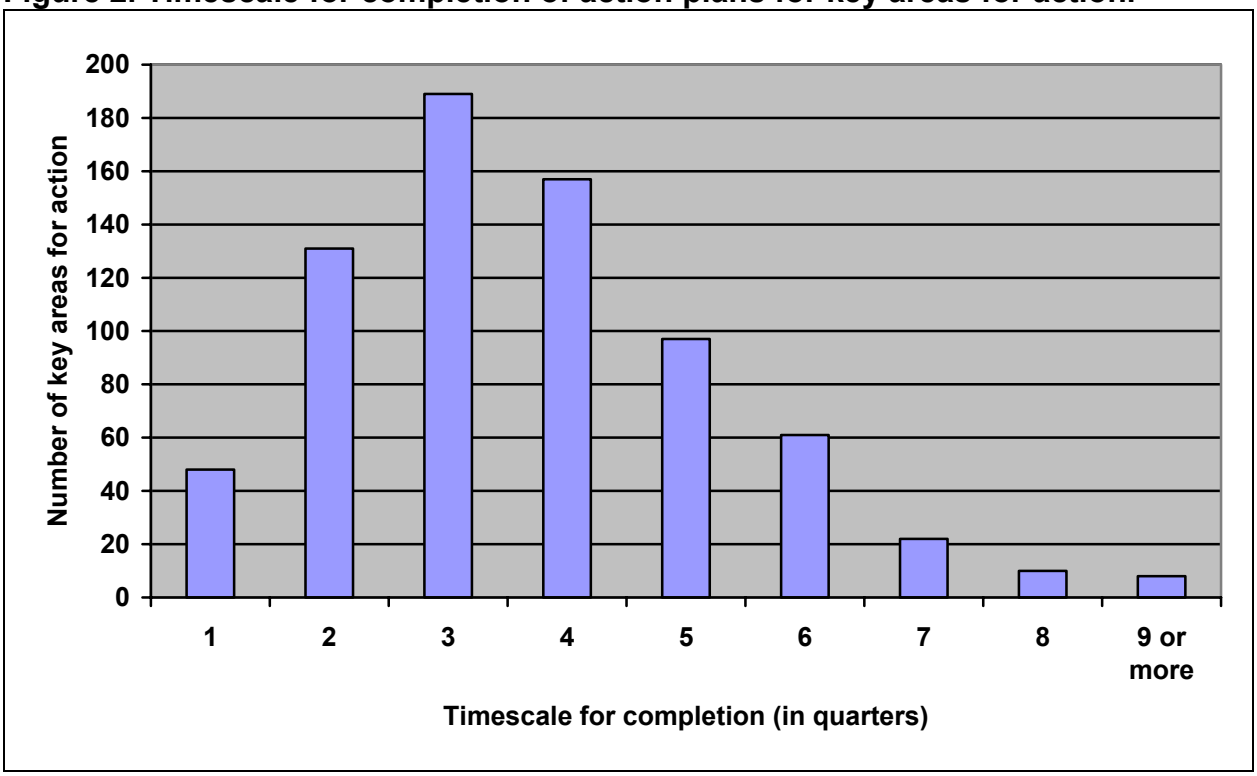
Category	Examples *with commentary on action plans*	No (%)
Not addressed	Most of these KAAs had no action points/plans. Action should be taken to revise the complaints leaflet and consideration given to ensure that people who do not have English as a first language are able to access the complaints process. *Trust action plan states current service provision, not how this will be improved.*	40 (5%)
Partly addressed / to some extent	Action is needed to ensure informal complaints are recorded in a manner that does not prejudice the patient and allow trends to be analysed. *Trust action plan proposes providing log books.* The trust must ensure that the human resources strategy is fully implemented across the organisations. *Trust action plan proposes monitoring performance indicators regularly.*	141 (17%)
Mostly addressed	Urgent action should be taken to establish central support for training and education and to implement a training plan for all staff. *Trust action plan proposes creating a training plan.* The trust needs to ensure pressure sore prevention is given a high priority. *Trust action plan proposes appointing nurse consultant and reviewing strategy.*	255 (32%)
Completely addressed	There should be an IT representative on the clinical governance committee. *Trust action plan says IT representative now on all key committees.* Rigorously enforcing the attendance at mandatory training. *Trust action plan stresses personal accountability, people allocated to attend, identify mandatory topics, identify site closure days. Monitoring and reporting of attendance.*	373 (46%)

It can be seen that the great majority of KAAs (78%) were mostly or completely addressed by the action plans produced by NHS trusts, although a significant minority were either only partly addressed or not addressed at all. As the examples cited in Table 14 illustrate, the main causes of an action plan failing in part or wholly to address the recommendation contained in the KAA seemed to be either that the plan only promised some kind of measurement or assessment activity (review, evaluate, assess or whatever) when the KAA required a change in practice, or that that action plan tackled a part of the KAA but left other parts of it unaddressed.

Most action plans contained some information about the timescale within which action was to be completed, although once again the level of detail provided varied widely. Most NHS trusts specified a date for each action point, but some were left without a date for completion and others were sometimes labelled ongoing. We classified the timescales presented by trusts for each KAA in two ways. Firstly, we categorised them as specific (meaning there were dates specified for all action points), fairly specific (where some or most action points had completion dates but some did not) and unclear (where little or no completion date information was provided). Secondly, we recorded the actual completion date proposed for each KAA. This was sometimes complex because a KAA might have several action points, all with different completion dates. After experimenting with a number of options during piloting, we opted in the end to record the median completion date for each KAA.

Most action plans had clear timescales specified for most KAAs. Across all NHS trusts in our sample, 70% of KAAs were rated as having a specific timescale, 22% as fairly specific and only 8% as unclear. The lengths of timescale varied widely, as Figure 2 shows. Overall, nearly two thirds of KAAs (64%) were expected to be completed within one year of the CHI clinical governance review, and the great majority (85%) within 18 months. Given that CHI reviews were scheduled to take place once every four years, this might suggest that, for most organisations, there would be a plateau period after they had completed the proposed actions before the preparation for the next cycle of CHI review would begin.

Figure 2. Timescale for completion of action plans for key areas for action.



[Note: Figure excludes KAAs for which there was no timescale recordable.]

The variation in trust action plans in terms of both content and presentation has already been noted, but it is further illustrated by the analysis in Table 15, which shows a number of the data items that have already been discussed, here analysed by NHS trust. On almost every measure, trusts varied widely in their behaviours or performance.

Table 15. Analysis of the content of action plans by NHS trusts.

Trust	Unique KAAs	Action points	KAAs with no action points	Average no. of action points per KAA addressed in action plan	KAAs with specific timescale for action	Average timescale (months)
29	55	247	1 (2%)	4.6	31 (57%)	8.9
24	48	156	0 (0%)	3.3	41 (85%)	14.1
7	45	87	6 (13%)	2.2	29 (74%)	8.4
12	43	160	0 (0%)	3.7	41 (95%)	11.7
4	42	88	0 (0%)	2.1	38 (91%)	9
28	41	226	0 (0%)	5.5	39 (95%)	6.2

14	39	117	0 (0%)	3.0	25 (64%)	6
3	36	195	1 (3%)	5.6	32 (91%)	13.6
2	34	141	0 (0%)	4.1	16 (47%)	12.8
27	32	107	0 (0%)	3.3	30 (94%)	7.4
18	31	79	0 (0%)	2.5	20 (65%)	13.8
13	29	46	10 (34%)	2.4	10 (53%)	6.5
25	29	84	0 (0%)	2.9	20 (69%)	5.9
6	28	89	0 (0%)	3.2	23 (82%)	10.9
15	28	63	3 (11%)	2.5	6 (24%)	13.4
16	28	85	4 (14%)	3.5	24 (100%)	16
23	28	96	0 (0%)	3.4	15 (54%)	9.5
5	25	57	10 (40%)	3.8	8 (53%)	10.9
21	23	53	0 (0%)	2.3	13 (57%)	9.7
30	22	80	1 (4%)	3.8	8 (38%)	9.7
1	20	48	0 (0%)	2.4	18 (90%)	12.8
17	19	71	0 (0%)	3.7	18 (95%)	9.2
22	17	42	1 (6%)	2.6	7 (44%)	9.6
20	14	42	0 (0%)	3.0	14 (100%)	12.4
10	12	113	1 (8%)	10.3	2 (18%)	6.4
9	10	40	0 (0%)	4.0	0 (0%)	8.2
8	9	25	0 (0%)	2.8	4 (44%)	7
19	9	30	0 (0%)	3.3	5 (56%)	7.9
26	8	124	0 (0%)	15.5	0 (0%)	29.5
11	5	52	0 (0%)	10.4	1 (20%)	5.4
Total	809	2843	38 (5%)	3.7	538 (70%)	10.1

As Table 15 shows, NHS trusts had to respond to between five and 55 unique KAAs. Most produced a number of separate action points for each KAA, so the resulting action plans contained between 25 and 247 action points. As has already been noted, not all KAAs were covered by action plans, but this tended to be found only with a minority of NHS trusts: 20 (67%) of the 30 action plans we reviewed did cover every KAA but the rest (10, 33%) omitted one or more KAAs. In a very small number of trusts, there were significant numbers (a third or more of KAAs) that were not addressed.

The degree of detail contained in NHS trust action plans varied widely. On average there were 3.7 action points per KAA, but this ranged from a very high level of detail in some trusts (15.5 action points per KAA) to a very low level of detail in others (2.1 action points per KAA). Similarly, the clarity of timescale for action plans varied too, with a mean of 70% of KAAs having a specific timescale but the proportion with a specific timescale varying across trusts from 0% to 100%. Similarly, the mean timescale for implementation of KAAs varied across NHS trusts, from a low of 5.4 months to a high of 29.5 months, while the mean was 10.1 months.

There was also some variation (though rather less) in the content of action plans by clinical governance area, as |Table 16 shows. In broad terms, the table suggests that KAAs that were not addressed by action plans were more often found in the areas of clinical effectiveness and strategic capacity. There was little difference in the level of detail of action planning across clinical governance areas, but clinical effectiveness emerged as the areas where rather fewer KAAs were mostly or completely addressed and (along with strategic capacity) as the areas with rather less specific timescales for action.

Table 16. Analysis of characteristics of action plans by clinical governance review area.

Area	KAAs with no action points (%)	Average no. action points per KAA addressed in action plan	KAAs mostly or completely addressed (%)	KAAs with specific timescale (%)	Average length of timescale (months)
Patient, service user, carer and public involvement	3	3.8	83	69	10.4
Risk management	2	4.2	83	68	10
Clinical audit	4	3.8	77	63	9.9
Staffing and staff management	2	3.3	79	70	9.6
Education and training	1	3	79	71	10.5
Clinical effectiveness	13	3.6	61	61	11.7
Use of information	7	3.8	77	70	10.1
Service user experience	2	3.8	80	68	8.4
Strategic capacity	10	3.5	72	58	10.1

4. Implementation and change: the impact on NHS trusts' performance

4.1 Evidence of reported implementation and change

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 with each NHS trust's strategic health authority. The primary purpose of the progress review was to determine whether their NHS performance (or star) 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 or 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 17 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.

Table 17. CHI progress review ratings of NHS trusts by clinical area.

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 staff 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%)

In our questionnaire survey of stakeholders, respondents were asked to rate the progress made in implementing a randomly selected sample of KAAs, and the results are shown in Table 18, analysed by stakeholder organisation. It can be seen that, overall, about 42% of KAAs were rated as fully implemented, 40% as mainly implemented and only 15% were either not or were partly implemented. It is interesting but unsurprising that PCT respondents (who were rating progress in their local major NHS trust) were rather less likely to know about progress and were more cautious about claiming that KAAs had been fully implemented. It should be remembered that many of

these PCTs did not exist at the time when the clinical governance reviews took place, and that many KAAs concerned issues mainly of internal concern to the NHS trust.

Table 18. Stakeholder ratings of implementation of CHI key areas for action.

	Little or no action	Some implementation but much to be done	Mainly implemented but some still to do	Implemented	Don't know
NHS trusts	0 (0%)	11 (10%)	45 (41%)	55 (50%)	0 (0%)
PCTs	0 (0%)	11 (34%)	12 (38%)	5 (16%)	4 (13%)
StHAs	2 (3%)	7 (10%)	28 (39%)	30 (42%)	4 (6%)
All	2 (1%)	29 (14%)	85 (40%)	90 (42%)	8 (4%)

We categorised the progress made for each KAA, drawing on the documentation from the CHI review report, action plan and CHI/strategic health authority progress review, and using a similar scale to that used in the questionnaire survey. Progress was rated as not reported on if there was no data available in the documents on the specific KAA, and was otherwise rated as showing no significant action, some implementation, mainly implemented or fully implemented. The results, along with some examples in each category, are shown in Table 19.

It is notable that we were unable to determine what progress had been made for 31% of KAAs from the available documentation. This varied substantially from NHS trust to NHS trust and seemed to be as much a reflection of the quality and thoroughness of the CHI/strategic health authority review as an indication of trust performance or behaviour. It cannot be assumed that little or no progress had been made on these KAAs (almost a third of all KAAs) and, indeed, our data collection sometimes suggested that actions had been implemented but, in the absence of a clear, independent assessment in the progress review, we were unable to confirm this.

Of those KAAs that were reported on, only a very small minority (12, 2%) showed no significant evidence of implementation. About 22% had been partly implemented, 30% mainly implemented and 15% fully implemented. In general terms, this suggests that some progress had been made across virtually all KAAs, and about half (45%) were wholly or mostly implemented.

Table 19. Progress ratings of key areas of action.

Category	Examples *with commentary on progress of implementation*	No. (%)
Not reported on	Action needs to be taken to ensure that all clinical teams share relevant methodologies for accessing information. *This was not reported on in the StHA report.* It is important that the trust considers, as a matter of priority, the introduction of formal systems to monitor the scientific validity and ethical basis of projects and ensure data protection issues are considered. *No specific section in StHA review on research issues – only addressed in passing re data protection.* Management of the bank nurses needs to be evaluated in order to provide leadership, day to day management and development opportunities. *Not reported on within the StHA, but action noted as completed within the June 2003 trust progress report.*	253 (31%)
No significant action taken	Some of the areas visited required a refurbishment, for example, A&E and the stroke rehabilitation gym. *Visual evidence reported – presumably a visit – no reporting on the A&E or the stroke rehabilitation gym.* Local induction needs to be undertaken and documented for all staff. *Not addressed yet by the time of the StHA report.*	12 (2%)
Some implementation, much remains to be done	Improve the supervision arrangement for staff. *Seems to be at the start of this with a draft strategy out for consultation on supervision.* The trust must complete the current security review across the whole site and produce a detailed action plan to ensure that neither patient nor staff safety is compromised. The trust should explore ways of enabling staff to report all incidents of aggression and violence and ensure that staff are supported through any follow up process. *Policy and action plan still to be finalised at the time of the StHA report and implementation still to be done.*	179 (22%)
Mainly implemented	The trust needs to develop a culture of continuous quality improvement. *Large majority of objectives have progress, with a small minority where more progress is needed.* The trust must continue its efforts to introduce individual performance review (IPR) and continuous professional development (CPD) and to concentrate on training and development issues across all staff groups, with the establishment of a trust wide linked plan to the human resources strategy. *20% of staff appraisal in 2000, 65% in February 2003. HR strategy and annual report 2003. Staff Development Manager appointed.*	239 (30%)
Implemented	Continued action is required to ensure staff have support so they can involve users within their area of care and therefore to fully implement the user involvement strategy across the trust. *Excellent progress seems evident and a wealth of documentary evidence given.* The reception desk needs to be more welcoming. *Visual evidence – presumably a visit by the StHA.*	121 (15%)

Tables 20 and 21 present analyses of these progress ratings by clinical governance area and by NHS trust. They also show the proportion of KAAs for which the progress review by CHI and the strategic health authority drew upon documentary evidence to demonstrate progress (such as copies of documents, minutes of meetings, etc) and the

proportion for which it drew on quantitative evidence of progress (such as a change in a rate, number or other statistic bearing on the issue at hand). There is some variation in the implementation of change across clinical governance areas, with KAAs in strategic capacity being very likely to be largely or wholly implemented, while KAAs in clinical effectiveness were much less likely to have been implemented. There was also some substantial variation in the proportion of KAAs that were not reported upon, with those in clinical effectiveness, education and training and service user experience being particularly likely to not be reported. In most areas, progress was usually demonstrated by reference to documentary evidence such as reports, policies, minutes of meetings, etc. There was rather less use of quantitative evidence, such as statistics, to show progress.

Table 20. Progress rating and evidence of progress of key areas for action analysed by clinical governance area.

Area	Not reported on	No significant action taken	Some implementation, much remains to be done	Mainly implemented	Implemented	% with quantitative evidence of implementation	% with documentary evidence of implementation
Patient, service user, carer and public involvement	25%	0%	17%	42%	16%	12%	88%
Risk management	25%	1%	19%	36%	18%	12%	83%
Clinical audit	25%	4%	35%	25%	11%	12%	77%
Staffing and staff management	30%	3%	24%	33%	10%	26%	75%
Education and training	40%	1%	19%	29%	10%	12%	80%
Clinical effectiveness	40%	0%	33%	21%	6%	2%	87%
Use of information	32%	2%	25%	23%	18%	6%	82%
Service user experience	37%	1%	20%	24%	18%	23%	85%
Strategic capacity	34%	0%	5%	31%	29%	5%	84%

As has already been noted, there were very substantial differences across NHS trusts, which are shown in Table 21. In seven of our sample of 30 NHS trusts, the data available from the progress review left us unable to assess and report on progress for a majority of KAAs; yet, for nine NHS trusts, there was complete reporting on all KAAs. The proportion of KAAs that had been mainly or fully implemented varied from NHS trust to NHS trust, from a high of 100% to a low of 0%, as Table 21 shows. Similarly, the proportion of KAAs for which documentary or qualitative evidence of progress was provided varies widely between NHS trusts.

Table 21. Progress rating and evidence of progress of key areas for action analysed by NHS trust.

NHS trust	Not reported on	No significant action taken	Some implementation, much remains to be done	Mainly implemented	Implemented	% with quantitative evidence of implementation	% with documentary evidence of implementation
1	75%	5%	20%	0%	0%	0%	0%
13	69%	0%	4%	7%	21%	0%	100%
19	67%	0%	22%	11%	0%	0%	0%
4	59%	0%	9%	26%	5%	18%	100%
24	58%	4%	19%	15%	4%	5%	0%
14	54%	0%	10%	26%	10%	17%	89%
12	53%	2%	19%	23%	2%	20%	45%
2	47%	3 %	12%	32%	6%	28%	83%
29	47%	0%	31%	20%	2%	10%	97%
6	46%	0%	11%	36%	7%	0%	93%
20	43%	0%	0%	43%	14%	37%	87%
5	36%	4%	12%	40%	8%	31%	75%
30	36%	0%	32%	23%	9%	7%	100%
15	32%	0%	32%	29%	7%	10%	95%
16	31%	4%	27%	35%	4%	11%	89%
10	25%	8%	33%	33%	0%	22%	100%
7	16%	2%	16%	33%	33%	19%	94%
17	16%	0%	10%	47%	26%	0%	0%
27	16%	3%	25%	28%	28%	22%	89%
23	11%	0%	21%	43%	25%	4%	76%
3	3%	0%	11%	53%	33%	11%	94%
8	0%	0%	33%	44%	22%	22%	100%
9	0%	0%	40%	40%	20%	0%	60%
11	0%	0%	0%	60%	40%	40%	80%
18	0%	3%	45%	42%	10%	6%	97%
21	0%	0%	78%	17%	4%	26%	96%
22	0%	0%	37%	25%	37%	31%	87%
25	0%	0%	0%	17%	83%	7%	90%
26	0%	0%	25%	37%	37%	12%	100%
28	0%	2%	44%	49%	5%	10%	95%

In our case study interviews, it was evident that the CHI/strategic health authority review process, through which the progress in implementing CHI review recommendations was assessed for the NHS performance ratings, had been demanding both in terms of content and timescale. Some interviewees' comments suggest that different strategic health authorities took markedly different approaches to the review, both in the information they sought and the way in which they conducted it. For example:

> "My main comments were the lack of notice we were given for the review, so it was the second week in April that we got a phone call from the StHA to say that CHI were going to have an interim review. I then had to chase our StHA several times for a date from them and ultimately we got five days notice and it was then tagged onto another meeting we were having (in May). It was like being asked to sit an exam without knowing what the subject was… We were the first interim review the StHA

had done, so for them it was very new; they had not developed any format by which they wanted the evidence presented."

"Monitoring by the StHA has been light touch. …[I] like to think that the StHA believes that we deliver, but the StHA had kept the review on their radar screen and have enquired occasionally about it. The StHA did what they had to do."

Following the progress reviews, it appears that most strategic health authorities have continued the progress review process, seeking further reports on the implementation of clinical governance review report recommendations, often as part of their wider approach to performance management.

4.2 The impact of CHI on NHS trusts' performance: what caused change to happen?

It is clear from these earlier analyses that the implementation of KAAs is a complex and sometimes uncertain process. We explored the bivariate relationships between the progress in implementation (rated as shown in Table 19) and a number of the other characteristics or variables in the data set, and the results are summarised in Table 22. It can be seen that KAAs were more likely to have been implemented if the action plan addressed the KAA properly, if the change was rated as measurable, if the timescale for action to be taken was not too long and if there was documentary evidence of progress. Implementation also varied significantly across the nine clinical governance review areas and between trusts. Interestingly, KAAs were more likely to have been implemented at NHS trusts with higher NHS performance (star) ratings in 2002.

Just as importantly, a number of other characteristics were not associated with progress in implementation. For example, the making of a particular KAA a priority for action was not associated with greater progress in implementation, nor was the level of detail contained in the action plan (measured by the number of action points it contained) or the type, depth and breadth of change required, or the clarity within which the timescale for action was stated.

These results were generally supported by multivariate analysis, using multinomial logistic regression, which again suggested that whether the action plan addressed the KAA and the timescale for the action plan was significantly associated with progress ratings.

Table 22. Correlations between progress in implementing key areas for action and other characteristics.

Not correlated with progress rating of KAA	Correlated with progress rating of KAA
Whether KAA identified as a priority Number of action points for KAA Depth of change required by KAA Breadth of change required by KAA Type of change required by KAA Clarity of timescale Quantitative evidence of progress	Whether action plan addresses KAA (Rsq = 0.25, $p<$ 0.001) Measurability of change (RSq –0.93, p=0.029) Documentary evidence of progress (RSq = -0.22, p<0.001) Timescale for action plan (RSq = -0.20, p<0.001) Clinical governance review area (Xsq = 38.1, p<0.001) NHS trust (Xsq = 136.2, p<0.001) NHS performance (star) ratings (RSq = 0.123, p=0.003)

It was noted earlier that it is important to consider the added value or additionality of the CHI review process; whether, without the spur of regulatory attention and intervention, the changes and improvements that have happened might have happened anyway. We examined this in our questionnaire survey in two ways: by asking respondents about whether the recommendations in CHI review reports were new or not, and by seeking their views on what had caused change to happen. As Table 23 shows, respondents from PCTs and strategic health authorities generally lacked the knowledge of context and background to be able to tell whether the KAA recommendations had been raised before. NHS trust respondents were generally better informed, and it will be noted that they rated 46% of KAAs as having been raised many times before within the trust, and 31% as having been raised once or twice before. These results fit with the finding from our case study interviews, reported in Section 2, that CHI review reports and their recommendations tended to confirm local understanding and knowledge of the problems and need for action rather than to contradict or confound them. Of course, the fact that an issue had been raised in an NHS trust in the past, perhaps on many occasions, is no reason to conclude that action would have followed without CHI's intervention. Indeed, the converse could be argued: that longstanding problems that had been raised but not solved locally were eventually addressed (perhaps successfully) through CHI's external review.

Table 23. Stakeholder ratings of new nature of changes identified in KAAs.

	Never raised before	Raised once or twice before	Raised many times before	Don't know
NHS trusts	18 (16%)	35 (31%)	51 (46%)	8 (7%)
PCTs	1 (3%)	4 (13%)	7 (22%)	20 (63%)
StHAs	1 (2%)	9 (14%)	8 (12%)	47 (72%)
All	20 (10%)	48 (23%)	66 (32%)	75 (36%)

We sought stakeholders' direct views on the causes of changes for the random sample of KAAs we asked them to consider, and the results are shown in Table 24. It can be seen that, across the three stakeholder groups (NHS trusts, PCTs and strategic health authorities), there was a fairly consistent view that between half and two thirds (50% to 68%) of the changes that had occurred were attributed to the CHI clinical governance review, with the rest seen as resulting from other factors or influences.

Table 24. Stakeholder ratings of what caused change for KAAs to happen.

	CHI	Other factors (not CHI)	Don't know
NHS trusts	54 (50%)	51 (47%)	4 (4%)
PCTs	17 (57%)	7 (23%)	6 (20%)
StHAs	47 (68%)	16 (23%)	6 (9%)
All	118 (57%)	74 (36%)	16 (8%)

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

> "But where they [CHI] scored was things like they said we needed to do a staffing review; in fact, we had done it before we had the CHI review, but they brought it up in the report, which enabled us to use it in our SAFF negotiations to get further investment in staffing. So we used it again as a lever for change but also a lever within the SAFF process. So it worked very well for us … we made sure where we had got areas of concern, the CHI review team also looked at those areas, which it is legitimate to do."

> "What made a big difference in this organisation was seeing it in black and white in terms of lack of leadership and strategic direction and, again, once the execs and board had been on that (development) programme they had a better understanding of what was expected of them and in terms of what the organisation had to do as well. 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 (clinical governance coordinator) was created. There were other posts created, eg a lead for clinical effectiveness…"

> "Really good progress has been made in formalising patient and public involvement; processes are now in place and documented; there is a new patient advice and liaison [PALS] manager, a patient experience panel and a reading panel. The review bumped patient and public involvement [PPI] up the agenda. PPI is now resourced properly (as a result of PALS money rather than the review), and having the PALS manager who is dedicated to PPI is great."

Some of the interviewees went further, noting that some changes that followed the CHI clinical governance review and its recommendations would not have happened without the catalytic effect of the review and the report:

> "…some new things for the trust certainly; one of the things we found, for example, they had a very good approach to education and training and found lots and lots of examples of staff who had been developed within the organisation … but what was apparent was that certain groups of staff were marginalised in this process, eg the portering staff had not received any training at all, even proscribed mandatory training, and that is something I think the trust was not aware of. The public involvement stuff, again, without the focus of the clinical governance 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."

Interviewees also identified broader, more cultural and attitudinal changes that 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. Consultants who thought it was a passing fad now realise that CHI, Clinical Negligence Scheme for Trusts, etc are part of the regulatory framework, so we/they need to be consistent about clinical governance. It is fundamental."

"We took a very proactive stance to the review to raise awareness around the issues of clinical governance because I think that, within the NHS Plan, clinical governance appeared and nobody quite knew what it was. We actually used the whole process, which was about a seven month process in preparation, to raise awareness within the trust, and we did roadshows and all sorts of things. By the time we were actually reviewed, we were very comfortable with the process, and the week the review took place we got comments like people had actually enjoyed the interviews."

Some pointed out that the decision to use the progress made in implementing recommendations from the clinical governance review in adjusting NHS trusts' performance (star) ratings had a profound effect on the priority given to progress monitoring and follow up at NHS trusts, but might also make NHS trusts behave more defensively and cautiously in future in their interactions with CHI or its successor body, the Healthcare Commission.

5. Conclusions and policy implications

This research has examined the impact of CHI's clinical governance reviews on the performance of NHS trusts, from a particular and fairly specific perspective. It has focused on exploring the implementation of recommendations made in CHI's clinical governance review reports and, as was noted in Section 1, has not attempted to made a broader evaluation of impact. With that proviso, it may be helpful to summarise the key findings from the research and then outline their implications for policy, particularly in the context of the transfer of responsibility for healthcare regulation from CHI to the new Healthcare Commission from April 2004.

CHI review reports varied greatly in structure and presentation
There were marked differences that resulted in part from changes in the review process over time and from differences between the context and situation of the NHS trust being reviewed, but which we believe also resulted from variations in the quality, rigour and effectiveness of the clinical governance review and probably reflected differences between review teams. This variation was markedly present in the way that reports presented their recommendations, and so had consequences for the subsequent action planning and implementation. It was not always easy to identify clearly the recommendations within reports.

There was widespread acceptance of CHI's recommendations
Most NHS trusts accepted the diagnosis and prescription for action contained in their CHI review report, either wholly or for the most part, and many indicated that the recommendations covered issues that were known locally to be problems and had been raised before.

Most of CHI's recommendations focused on systems, processes and management
The great majority of recommendations dealt with managerial or administrative systems or processes, strategic or management issues or care processes. There were very few recommendations that directly addressed issues to do with the quality or nature of patient care, and our measures of the impact of CHI are therefore inevitably dominated by such matters of process. There was an implicit but largely untested assumption that the recommendations would, indirectly, bring about improvements in patient care.

The nature of CHI's recommendations and the way they were expressed varied greatly
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). But 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.

NHS trusts' action plans were very variable in structure, presentation and content
Action plans varied widely in the way they were structured and presented and the level of detail and specific action they contained. It was often difficult to see the connections from the clinical governance review report to the action plan and to be sure that it covered all CHI's recommendations.

NHS trusts' action plans mostly addressed CHI's recommendations
However, some recommendations were omitted or recast, and the level of detail in responses was often poor. Some action plans essentially restated the recommendations rather than outlining the proposed action, and the timescale for action was sometimes unclear or rather arbitrary.

Most of CHI's recommendations have been acted upon
The great majority of CHI's recommendations have resulted in some action and most have been largely or fully implemented, although progress varies widely across NHS trusts. 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. It is, however, hard to tell how much of the change might have happened anyway.

There are some important factors involved in securing change
We should be cautious about attributing causation to any single factor, but the findings suggest that CHI clinical governance reviews are more likely to result in change and improvement if the recommendations are clearly defined and focused on measurable and deliverable issues; if the NHS trust's action plan addresses the recommendations effectively and in some detail; if a relatively short timescale for action to be completed is set; and if the NHS trust has the internal capacity and capability to monitor, follow up and implement change itself.

These findings suggest that, while CHI's clinical governance reviews have a significant effect on NHS trusts and their performance, the Healthcare Commission could learn from CHI's experience in designing its regulatory regime. We would particularly highlight five main areas concerning the distribution of regulatory effort and intervention across the regulatory cycle, the design of the inspection and reporting process and the control of variation, the construction and communication of recommendations for action, the arrangements for planning, implementing and monitoring action on those recommendations and the periodicity of the regulatory cycle.

Firstly, it can be argued that far more effort has been invested by CHI (and, indeed, by NHS trusts and other stakeholders) in the CHI clinical governance review process itself, and particularly the visit and report components of that process than in other aspects of the regulatory cycle. CHI was mandated by legislation to undertake a programme of clinical governance reviews of NHS trusts and PCTs at four yearly intervals, and faced a demanding timescale to fulfil this mandate. At the same time, responsibility for monitoring and following up the implementation of CHI review recommendations has been held first by NHS Executive regional offices and health authorities and subsequently by strategic health authorities, and the *Shifting the balance of power* reorganisation has not made continuity of effort or attention in this area easy. We would suggest that the investment of regulatory resources across the regulatory cycle should accord greater attention to the processes by which organisations are identified for regulatory attention or intervention (targeting regulatory resources more carefully) and the way that, after a regulatory intervention such as a review or inspection, recommendations or requirements are then tracked and reported upon to ensure that change and improvement happen.

Secondly, it seems that CHI has been more able to assure the validity of the clinical governance review process (that it does identify real and meaningful problems and makes useful recommendations) than to assure its reliability (that two review teams visiting the same NHS trust would reach broadly similar conclusions and produce similar recommendations). In part, this is because the review process has not been structured around an explicit set of standards or measures. Some caution should be exercised: regulatory reviews that are driven by a highly explicit and detailed set of standards have many disadvantages. However, it would seem that a more consistent approach is needed, and that 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 would be likely to increase the consistency and reliability of reviews. CHI has already taken a number of steps to increase consistency, which could act as a foundation for further development.

Thirdly, if the recommendations from any regulatory intervention are to be seen as its primary purpose, it is essential that those recommendations are constructed, expressed and communicated clearly in terms that facilitate their implementation. Vague or generalised recommendations are unlikely to result in much change, while specific, clearly worded and definitive recommendations are more likely to be effective. It might be suggested that some recommendations concerning issues such as organisational culture, leadership or attitudes, may of necessity appear non specific but are important nonetheless. We would respond that, while a regulatory review may raise such issues as important concerns, it is unhelpful to cast them as recommendations for action unless there is some clarity about what is actually being recommended. We would suggest that recommendations should be cast clearly in terms that 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 that will impact on patient care. Where recommendations concern issues of system or process, the intended benefit to patients should be clear.

Fourthly, it is evident that the quality and effectiveness of action planning, follow up and progress monitoring by NHS trusts is a crucial determinant of the implementation of review recommendations and the degree of change and improvement that results. A good, realistic, detailed and specific action plan is an essential internal tool for the NHS trust in securing implementation, and the regulator should be assured that such a plan is in place. However, we are less sure that the action plan is a suitable vehicle for subsequent progress monitoring because it is so wholly focused on process (the what and how of changes). We would argue that the original review, and particularly its recommendations, should be the primary vehicle for progress monitoring and measurement, and that it would therefore be useful to set timescales for action and progress checking in that original review report and to require NHS trusts more explicitly to account for progress against that original report. Moreover, it is essential that there is clarity about who is responsible for follow up and how the different roles of the Healthcare Commission, strategic health authorities and other stakeholders are meant to inter relate.

Finally, it seems evident that, while the cycle of regulatory attention from CHI has been based through legislation around a four yearly review of each NHS organisation, the great majority of actions arising from regulatory intervention are expected to be

completed within a year. Past research has identified the periodicity of regulatory review as a problem and has highlighted the tendency for organisations to peak in performance at the time of regulatory inspection or review and to fall back afterwards. It seems clear that future regulatory interactions with NHS trusts should be designed around a shorter timescale, with the potential for more immediate and frequent feedback on performance and a more rapid pace of change and improvement.

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