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Achieving Improvements through Clinical Governance:
A Progress Report on Implementation by NHS Trusts
This report has been prepared under Section 6 of the National Audit Act 1983 for presentation to the House of Commons in accordance with Section 9 of the Act.

John Bourn
Comptroller and Auditor General

15 September 2003

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The aim of clinical governance is to secure better quality care from the £54 billion a year spent on healthcare services and, through improved accountability, to give patients and the general public greater confidence in NHS services.

In 1997, Sir Liam Donaldson, now the Department of Health's Chief Medical Officer, drew attention to the fact that quality did not seem to be as high on the agenda of the NHS as financial and workload targets and that approaches to quality were very fragmented and lacked coordination; and pointed out that the management view of quality was very different from the medical view. He called for a programme of change and proposed the concept of clinical governance.

The key principles of clinical governance (Appendix 1) are: a coherent approach to quality improvement, clear lines of accountability for clinical quality systems and effective processes for identifying and managing risk and addressing poor performance. It involves putting in place the information, methods and systems to ensure good quality so that problems are identified early, analysed and action taken to avoid any further repetition. The Department of Health (the Department) expects clinical governance to integrate the previously rather disparate and fragmented approaches to quality improvement, such as clinical audit, risk management, incident reporting and continuing professional development into a single system and to ally it to accountability for quality.

Clinical governance requires a change in the culture of NHS organisations, to one “where openness and participation are encouraged, where education and research are properly valued, where people learn from failures and blame is the exception rather than the rule, and where good practice and new approaches are freely shared and willingly received.”
In 1997, the Government introduced a 10 year programme to improve continuously the overall standard of clinical care; reduce variations in outcomes of, and access to, services; and ensure that clinical decisions are based on the most up-to-date evidence of what is known to be effective. \(^3\) \(^4\) \(^5\) It introduced new policies, programmes and structures to support a comprehensive and systematic approach towards assuring and improving the quality of clinical services. Clinical governance was designated the centrepiece of this programme.\(^6\)

The government's strategy has three main strands:

- **Establishing clear national standards** through National Service Frameworks, and the National Institute for Clinical Excellence;

- **Ensuring local delivery of those standards** through clinical governance, underpinned by lifelong learning and strengthened and modernised systems of professional self-regulation. Support is provided through: the Clinical Governance Support Team, now part of the NHS Modernisation Agency (provides expertise, information, advice and training to clinical and management teams); the National Patient Safety Agency created to implement a mandatory reporting system to collect and learn from data on adverse incidents, and to develop and implement solutions for improving patient safety; and the National Clinical Assessment Authority (provides an expert advice and assessment service to NHS employers with concerns over the performance of individual doctors and dentists); and

- **Effective monitoring** through: The Department’s regional offices, until March 2002 and, following the reorganisation implementing the Shifting the Balance of Power\(^7\) programme, through strategic health authorities; the Commission for Health Improvement, which aims to improve quality by reviewing the care provided and identifying notable practice and areas where care could be improved; NHS Performance Assessment (star ratings); and the National Survey of Patient and User Experience which is intended to deliver annual feedback on the things that matter to patients, carers and service users.

Given the importance of clinical governance to the government’s programme for modernisation of the NHS, we examined trusts’ progress in putting the required structures in place and progress in improving the quality of patient care. We took into account that the introduction of clinical governance has taken place against the background of considerable organisational change, particularly since 1997, and an increase in regulation and performance monitoring.

We focused this examination on secondary and tertiary care, where systems have had time to bed in. There are important differences in the implementation of clinical governance in primary healthcare, and because of this and the impact of major organisational changes from April 2002, including the creation of primary care trusts, we propose to examine that sector later.

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\(^{3}\) The New NHS Modern and Dependable: Cm 3807, 1997.


\(^{5}\) The NHS Plan, Cm 4818 I, 2000.


\(^{7}\) Shifting the Balance of Power is a programme of change that aims to give locally based primary care trusts the role of running the NHS and improving health in their areas. This programme has involved abolishing from March 2002 the Department of Health’s regional offices and, from September 2002, the former health authorities; and establishing strategic health authorities.
Early identification and remedying of poor performance of clinicians is an integral part of clinical governance. Because this component is allied to disciplinary matters and sometimes suspensions, we have examined this aspect - including the contribution of the National Clinical Assessment Authority to that work - in a separate examination of the management of suspension of clinicians (to be published in autumn 2003). We are planning to examine in 2004 issues surrounding organisational learning as applied to patient safety.

The main sources of evidence for this report were a census of NHS acute, mental health and ambulance trusts (working with the Manchester Centre for Healthcare Management, University of Manchester); a survey of board members and senior managers at a representative sample of NHS trusts (conducted on our behalf by the Health Services Management Centre, University of Birmingham); a review of reports published by the Commission for Health Improvement; interviews with Department and NHS staff and with other relevant bodies; and through consulting our expert panel. Our methodology is set out in more detail at Appendix 2.

Given the challenge of changing cultures and embedding new processes throughout trusts, this is very much a progress report on the implementation of clinical governance. Our main findings are summarised in paragraphs 12 to 34 below, and our recommendations are provided in paragraph 35.

Overall conclusions

Our examination has confirmed that, while each component predated the formal introduction of clinical governance, since 1999 the machinery - the structures and organisational arrangements to make it happen - has been put in place. Virtually all trusts have the necessary foundations, although the components are not fully embedded within all clinical directorates.

The initiative has had many beneficial impacts. Clinical quality issues are now more mainstream; there is greater or more explicit accountability of both clinicians and managers for clinical performance; and there has been a change in professional cultures towards more open, transparent and collaborative ways of working. Moreover there is evidence of improvements in practice and patient care, though trusts lack robust means of assessing this and overall progress.

However, our research and the outcome of the Commission for Health Improvement’s reviews indicate that progress in implementing clinical governance is patchy, varying between trusts, within trusts and between the components of clinical governance. There is, not surprisingly, scope for improvement in: the support provided to trusts; putting in place overall structures and processes; communications between boards and clinical teams; developing a coherent approach to quality; and improving processes for managing risk and poor performance. There is also a need to improve the way that lessons are learnt both within and between trusts; and to put those lessons into practice. Overall, the key features of those organisations that have been better at improving the quality of care are quality of leadership, commitment of staff and willingness to consider doing things differently.
Support in implementing clinical governance

15 NHS trusts have found Departmental and regional office guidance and assistance in implementing clinical governance useful, but many would welcome future support on a wide range of issues, particularly concerning the embedding of clinical governance in healthcare organisations and communities and networks. Following the recent organisational changes associated with Shifting the Balance of Power, the Clinical Governance Support Team now expects to fulfil this role alongside the strategic health authorities.

16 The 43 per cent of NHS trusts that have used the Clinical Governance Support Team development programmes have generally found them very useful, and rate them quite highly, particularly those aimed at clinical teams. They report a significant level of change resulting from their involvement with the Team, though it is not clear how much wider impact the development programmes have in participating organisations. While many NHS trusts have yet to use the programmes, a further 45 per cent indicated that they planned to do so.

Progress in establishing structures and frameworks for clinical governance

17 Clinical governance is well established and embedded in the corporate systems of the vast majority of NHS trusts, with board level executive and non-executive leadership, trust wide committee structures, and a strong executive function in the form of a clinical governance department or unit.

18 Clinical governance has delivered a range of achievements, but most NHS trusts still see them in terms of structures and processes - which though important and very necessary to the objective of improving patient care, are not necessarily sufficient in themselves to ensure that objective is achieved. There are doubts whether there has been sufficient progress in improving systems in clinical areas across trusts. And there is substantial scope for improvement in leadership, particularly in communications between boards and clinical teams, and in collaborating with other agencies.

19 Funding for clinical governance is largely an intra-trust function, with funding generally provided either centrally or at a directorate level. Likewise, the planning, monitoring and management of clinical governance is also largely trust-driven with relatively little input from other stakeholders such as health authorities and primary care trusts.

20 Because clinical governance is, or should be, an integral part of the way in which trusts deliver services it does not lend itself to being costed separately (nor are we suggesting that it should be). There is also ambiguity about what should be included in such costing. However, some 30 trusts have attempted to assess the cost of supporting the implementation, and the average estimate - of around £326,000 per NHS trust a year - suggests the annual cost in secondary and tertiary care is likely to be at least £90 million a year. This probably significantly understates the actual cost because the estimate excludes clinical and managerial staff time and the cost of the main bodies established to support the implementation of clinical governance, which was some £60 million in 2002-03.
Responsiveness to internal and external evaluations of clinical governance and quality

21 Reviews by the Commission for Health Improvement, the NHS performance (star) ratings, the Controls Assurance self-assessment process and operation of the Clinical Negligence Scheme for Trusts provide an important focus and stimuli for improvements in clinical governance. Over three quarters of NHS trusts reported taking some action to make change happen following an external review, though the scale and significance of the changes is difficult to gauge.

22 NHS trusts acknowledged that the Controls Assurance and Clinical Negligence Scheme for Trusts and the performance (star) ratings have had beneficial impacts on their performance. But trusts assessed the Commission for Health Improvement clinical governance reviews as having the greatest impact on them. While they rarely reveal wholly new information about an organisation, they appear to have the effect of making knowledge about performance more explicit and visible, and thus stimulate meaningful changes in NHS trusts. However, many trusts’ progress in implementing their Commission for Health Improvement action plans seems relatively slow. Strategic health authorities, which are now responsible for such follow-up, will need to ensure that trusts take timely action.

23 Indeed, the remits of the increasing numbers of inspection bodies that provide external evidence of achievements in clinical governance and quality often overlap. The NHS Reviews Co-ordination Group which was set up voluntarily by its members to improve the efficiency of scrutiny in one area, risk management, has identified scope for improved co-ordination. And the joint Department of Health/Cabinet Office report on inspection of the NHS proposed a Healthcare Inspection Concordat. That concordat, to be implemented in December 2003, is intended to reduce unnecessary burdens imposed by the inspection process. The reforms of the inspection system, with the creation of the new Commission for Healthcare Audit and Inspection and the Commission for Social Care Inspection should also address some of these concerns.

The contribution made by the components of clinical governance

24 Most of the individual components of clinical governance are in place in most NHS trusts, though the coverage of each component within individual trusts varies from those with less than 20 per cent coverage to ones with over 80 per cent. But, for trusts as a whole, there is noticeable progress in the development of a more co-ordinated, coherent and consistent strategy.

25 On the whole, those functions which serve some statutory or external requirement (such as risk management, claims and complaints) appear to be most robust. Those which are newer, and which though clearly desirable may not yet be consistently seen as essential (such as patient and public involvement, and knowledge management, including sharing of good practice) are less well developed in many trusts. And, although medical audit was formally introduced some 14 years ago, clinical audit remains underdeveloped in many trusts. As a result clinical directorates and trusts are not exploiting in full its capacity to drive improvements in the quality of care.

8 Making a Difference - reducing burdens in healthcare inspection and monitoring, Department of Health/Cabinet Office, July 2003; available at www.cabinet-office.gov.uk.
26 Trusts have made limited progress in involving patients and the public in the NHS. The Department has, however, introduced a number of initiatives to increase patient involvement in their care and to enable community involvement in their local health services, including the introduction of the Patient Advice and Liaison Service, Independent Complaints Advocacy Services, Patients’ Forums and the Commission for Patient and Public Involvement in Health.

27 In contrast, risk management systems have developed substantially since 1999, and are reasonably well established in most trusts. Trusts’ performance is taken into account in reviews by the Commission for Health Improvement, in trusts’ Controls Assurance self-assessments, in assessments by the Clinical Negligence Scheme for Trusts and in NHS performance (star) ratings. Since the Committee of Public Accounts raised concerns about risk management in their hearing on the Clinical Negligence Scheme in 20019, there has been some progress with most trusts aiming for a higher rating, but one in five trusts have not achieved any level, and most have yet to move beyond level 1.

28 In 17 per cent of trusts, the proportion of clinical directorates using clinical risk management is still 60 per cent or below. And, while trusts have improved the recording, collating and review of data, training in risk management is still weak as is performance in moving from identifying risks to taking action to improve quality.

29 Effective clinical governance requires trusts to generate, identify and use relevant information. It involves trusts bringing together information generated by the components of clinical governance, so that they can assess quality and performance of services; and obtain the information needed to enable evidence-based clinical decision making. It also involves identifying, disseminating and learning from good practice. A number of recent National Audit Office reports have concluded that the NHS does not perform well in this respect.

30 The Commission for Health Improvement also has concerns about trusts’ use of information, particularly that trust boards did not have the information they needed to manage strategically. Furthermore, the failure to share learning across and between organisations was one of the six most common themes emerging from the Commission for Health Improvement’s clinical governance reports, raised at more than 90 per cent of reviews. They also commented at many organisations on weaknesses in dissemination of national guidance on effectiveness. Their first annual report on the NHS states - “the NHS was not good at learning from itself with examples of good practice often not replicated in the same hospital, let alone the same town”10.

31 While there are important sources of information on good practice, such as the Commission for Health Improvement reports, presentations and press releases, the tracking report they maintain is not published, and the examples in it are not highlighted in a concerted manner that would enable trusts to make good use of them. The Clinical Governance Support Team has published a number of articles and examples of good practice which are also available on its website (www.cgsupport.org).

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32 To date, few trusts have developed internal indicators of progress in implementing clinical governance. Trusts generally gain assurance through regular updates and reports to the board. The Commission for Health Improvement found that a third of the organisations reviewed had a lack of connection between the policies that the board has agreed and what happens on the front-line. The Clinical Governance Support Team is developing a model form of report that could provide one solution to this issue.

33 The clinical governance strategy has changed the way trusts deal with quality of care. To date, most of those changes have been to processes. There are, however, clear indications that there have been changes to the culture of trusts, in that boards have become more involved in clinical concerns; clinicians have begun to see those concerns as corporate rather than professional and personal; and attitudes of staff within trusts have become less defensive and more open. The components of clinical governance have been substantially developed and used more effectively and as a result trusts have made many changes to patient care.

To maintain the momentum, a number of barriers will need to be overcome

34 Trusts identified a number of barriers that need to be overcome in achieving further improvements. The most common themes were lack of resources and cultural difficulties. The other main barriers or problems cited were conflicting priorities, particularly the concentration on short term waiting targets, organisational changes and mergers, the size, spread and heterogeneity of trusts and a lack of organisational direction and impetus for clinical governance. It is difficult to unpick the relative importance and merits of these barriers, but improving the rate of progress will require action on all of them.
We therefore make the following recommendations:

The Department of Health should:

- ensure that the Clinical Governance Support Team continues to develop and enhance its advice and support function, taking account of the findings of the Judge Institute of Management, including how to satisfy the present unmet demand from trusts;
- explore with the Clinical Governance Support Team more effective ways of disseminating good practice, including examples identified by the Commission for Health Improvement;
- in the light of the Department of Health/Cabinet Office report on inspection, promote the actions and recommendations of the NHS Review Co-ordination Group, to ensure that the opportunities for rationalising the burden of inspection are maximised;
- evaluate the impact of the various patient empowerment initiatives and develop a set of good practice guidelines to help trusts make improvements on this issue; and
- consider providing awards to trusts on the theme “doing things better”.

The Commission for Health Improvement, or its successor body, should:

- consider including questions about staff and patient attitudes and experience of clinical governance in their staff surveys, and identify the main barriers to further progress and ways of overcoming these barriers; and
- consider how to build on the work of the NHS Reviews Co-ordination Group as part of its proposed leadership of inspection role.
executive summary

Trusts should:

- review the information requirements on quality issues required by their board and establish systems to ensure that such information is provided on a regular basis;
- consider developing with their clinical teams systems of internal reporting on quality on the lines being developed by the Clinical Governance Support Team;
- maximise the benefits to be derived from clinical audit, through developing an annual programme based on an agreed trust-wide strategy, endorsed at board level, which includes training requirements and encourages a multi-professional approach to the audits;
- ensure that there is an open and transparent system of support for continuing professional development which ensures that the needs of all staff groups, as identified and endorsed in their annual performance development plans, are met in an equitable way;
- benchmark key clinical governance initiatives with similar trusts and build on and share examples of good practice; and
- ensure that they agree with the trust board an action plan, timetable and priorities for implementing the findings of inspection reports, such as those of the Commission for Health Improvement, and allocate clear responsibility for monitoring implementation.
1.1 This part of our report outlines the key role clinical governance plays in helping to deliver improvements in the quality of patient care, the arrangements established by the Department to implement clinical governance and the scope and methodology of our examination.

1.2 Clinical governance is the "system through which NHS organisations are accountable for continuously improving the quality of services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish". Its purpose is to secure better quality care from the £54 billion a year spent on healthcare services and, through improved accountability, improve patients, and the general public’s confidence in NHS services.

1.3 The main principles of clinical governance (Appendix 1) are: a coherent approach to quality improvement, clear lines of accountability for clinical quality systems and effective processes for identifying and managing risk and addressing poor performance. Clinical governance requires a change in the culture of NHS organisations, to one where "openness and participation are encouraged, where education and research are properly valued, where people learn from failures and blame is the exception rather than the rule, and where good practice and new approaches are freely shared and willingly received."

1.4 The main components of clinical governance can be grouped as follows:

- Learning mechanisms (clinical risk management, clinical audit, adverse incident reporting, learning networks, continuing professional development);
- Patient empowerment (better information; patient complaints, patients’ views sought and patients involved throughout the NHS); and
- Knowledge management (information and information technology, research and development, education and training).

1.5 Some of these components have been in operation for many years. For example, clinical audit was formally introduced into the NHS in 1989-90 and was in use in parts of the NHS well before that time, and we reported in 1995 that NHS trusts had made progress towards establishing it as a routine part of clinical practice.

1.6 During the 1990s, NHS managers were accountable for meeting targets related to financial and workload concerns with quality subsumed under organisational performance. However, a number of prominent service failures in standards of NHS care, for example the quality failings in cervical smear screening and reporting at Kent and Canterbury Hospital, caused public and professional concerns and threatened to undermine confidence in the NHS. In response to these concerns and concerns that approaches to quality were fragmented and lacked co-ordination and that the managerial view of quality was different from the medical view, Sir Liam Donaldson, now the Department’s Chief Medical Officer, introduced the concept of clinical governance in 1997.

1.7 The government subsequently introduced new policies, programmes and structures to support a comprehensive and systematic approach towards assuring and improving the quality of clinical services. This included a 10 year programme to improve continuously the overall standard of clinical care; reduce variations in outcomes of, and access to, services; and ensure that clinical decisions are based on the most up-to-date evidence of what is known to be effective.
1.8 The government’s strategy has three main strands:

- **Establishing clear national standards** through National Service Frameworks, and the **National Institute for Clinical Excellence** (set up in 1999). The latter has the role of providing patients, health professionals and the public with authoritative, robust and reliable guidance on current best practice, covering individual health technologies and the clinical management of specific conditions;

- **Ensuring local delivery of those standards** through clinical governance, underpinned by lifelong learning and strengthened and modernised systems of professional self-regulation. Support is provided through:
  - the **Clinical Governance Support Team** (1999) now part of the NHS Modernisation Agency, supports the development and profile of clinical governance, provides information, and creates, captures and spreads ideas and good practice. It provides a number of major programmes - including team development and board development - and specific support to help turn around zero starred trusts. In addition, there have been more specific programmes in specialist areas including stroke and obstetrics;
  - the **National Patient Safety Agency** (2001) created to implement a mandatory reporting system to collect and learn from data on adverse events and near misses. The purpose is to disseminate lessons learnt and reduce the risk of harm to patients, thus improving the quality of care and patient safety; and
  - the **National Clinical Assessment Authority** (2001) to provide a support and expert advice and assessment service to health authorities, primary care trusts and hospital and community trusts that are faced with concerns over the performance of individual doctors. From April 2003, the Authority has also provided a service for hospital and community dentistry.

- **Effective monitoring** through:
  - the **Department’s regional offices**, which reviewed all baseline assessments and development plans prepared in 1999 and until March 2002 development plans and progress against them. Strategic health authorities have since taken over responsibility for performance, managing local services and ensuring the delivery of safe, high quality services through effective clinical governance arrangements in NHS trusts. But they had not taken on that role at the time of our fieldwork; during the transitional period (between April and September 2002) NHS resources were put elsewhere, and monitoring was not robust;
  - the **Commission for Health Improvement**, which aims to improve quality by reviewing the care provided and identifying notable practice and areas where care could be improved. It carries out clinical governance reviews of individual trusts and reports publicly on their progress. Further details are at Appendix 3. By the end of November 2002, the Commission had reported on 153 acute and combined trusts, 14 mental health trusts, nine ambulance trusts, six NHS Direct providers, eight primary care trusts and three health authorities. This represented over 60 per cent of NHS acute, mental health and ambulance trusts. The results are published on their website (www.chi.nhs.uk);
  - **NHS Performance Assessment**. The first set of performance ratings for 2000-01, presented in terms of stars (from none to three), was published in September 2001, for acute trusts only. For the 2001-02 ratings, coverage widened to include specialist, ambulance and mental health trusts (for the last group, indicative ratings only were given). For acute and specialist trusts, the performance rating awarded depends on a combination of the results of any Commission for Health Improvement review in the year, and performance against key targets and a "balanced scorecard" of other measures. The key targets are mainly concerned with activity and finance, but the balanced scorecard includes a number of measures of quality (see Appendix 4); and
  - the **National Survey of Patient and User Experience**. The White Paper The New NHS, Modern, Dependable announced the introduction from 1998 of annual national surveys of patients’ and users’ experience. The results were to be published nationally and locally. The results for the 1998, 1999 and 2000 surveys were published nationally; those undertaken in 2001 and 2002 have not been published, although the Department has supplied local results to strategic health authorities to enable NHS trusts to improve their performance.

1.9 Clinical governance was seen as the centrepiece of this strategy. The Chief Medical Officer issued guidance on clinical governance in March 1999, and implementation began in 1999-2000. The Department did not earmark additional funding for implementation, but did fund the establishment of new bodies, such as the National Institute for Clinical Excellence and the Commission for Health Improvement, to support and monitor its implementation and operation.

1.10 The Department reinforced the priority to be given to quality by introducing a statutory duty for quality of care (Section 18 of the Health Act 1999), which makes NHS chief executives accountable for assuring the quality of services provided by their trusts. All NHS organisations have to submit a Statement on Internal Control as part of their audited annual financial statements. This acknowledges the trust board’s responsibilities for internal control, and provides assurance that the trust has attained the required level of control and risk management; or has an action plan to ensure that it will do so. Trusts gain the assurance necessary to make that statement through self-assessment against standards set by the Department. The three core standards focus on (corporate) governance, financial management and risk management. The risk management standard covers all risks, including clinical risks.

1.11 The guidance on clinical governance also required NHS organisations to provide a public account in an annual report of what they are doing to improve and maintain clinical quality. As a minimum, starting with 1999-2000, trusts had to report on where they were at the start of the strategy, what progress they had made and what development plans they had for the coming year. The Department published further details about what should appear in trusts’ annual reports in November 2002.

Implementation of clinical governance has taken place against a background of organisational changes and increased oversight and regulation

1.12 The introduction of clinical governance has taken place against a background of substantial organisational change (Figure 1).

1.13 Research demonstrates that NHS reorganisations tend to distract managers from tackling service development matters. In addition to the structural changes to the NHS as a whole, 85 new trusts were created through mergers of 191 former trusts during the period April 1999 to July 2002. Those mergers brought together trusts that had taken differing approaches to implementing clinical governance.

### Major organisational changes affecting the NHS, 1999-2003

<table>
<thead>
<tr>
<th>Year</th>
<th>Description</th>
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<tbody>
<tr>
<td>1995-2002</td>
<td>Reconfiguration of acute services involving extensive reorganisation of acute NHS trusts and a succession of mergers and restructuring.</td>
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<tr>
<td>1997-2000</td>
<td>Abolition of General Practitioner fundholding and its replacement initially with primary care groups and subsequently, in some areas, by primary care trusts. Parallel progressive abolition of NHS trusts in community care as functions taken over by primary care groups/trusts. Formation of new mental health NHS trusts and, in some areas, care trusts working across health and social care.</td>
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<tr>
<td>2000</td>
<td>Abolition of the NHS Executive and the incorporation of its functions into the Department of Health.</td>
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<tr>
<td>2001</td>
<td>Abolition of the NHS Executive regional offices, devolution of some functions to new strategic health authorities, and the creation of four new regional directorates of health and social care in the Department of Health (changes taking effect from 2002-03).</td>
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<tr>
<td>2001</td>
<td>Reorganisation of health authorities into strategic health authorities, going from around 100 to 28 strategic health authorities in England, and the devolution of many responsibilities of health authorities to primary care trusts (changes took effect from 2002).</td>
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<tr>
<td>2001</td>
<td>Creation of primary care trusts in all areas, replacing primary care groups, including some further mergers and restructuring in community and mental health services, and transfer of responsibilities from health authorities.</td>
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<tr>
<td>2002</td>
<td>Announcement of intention to create new foundation NHS trusts with different legal, governance and financial structures, initially in acute services but subsequently in other areas of healthcare provision.</td>
</tr>
<tr>
<td>2003</td>
<td>Announcement of abolition of the four regional directorates of health and social care.</td>
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Source: Walshe, K. Manchester Centre for Healthcare Management

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19 Health Service Circular 1999/065 Clinical Governance: Quality in the new NHS.
20 Department of Health guidance on reporting on clinical governance November 2002.
One in six chief executives responding to our survey in 2002 cited organisational change or merger as a barrier to the progress of implementing clinical governance. The Commission for Health Improvement found that the impact of merger, reconfiguration, rebuilding and site closure on different aspects of the organisations’ activities had sometimes not been anticipated and managed.22

There are a large number of regulatory and inspection bodies whose remits are to examine some or all of the components of clinical governance (Figure 2). While many of these were established after 1999, in response to the need to ensure local delivery of the national quality standards (paragraph 1.9 refers) others have more long established roles and responsibilities, such as the Health and Safety Executive and the Audit Commission. Each inspection visit to a trust imposes a burden on trust resources. For example, 45 trusts provided us with an estimate of the costs to them of a Commission for Health Improvement review. These estimates ranged up to £250,000 with a median value of £50,000.

The increase in inspection and regulation of the sector has also created a risk of overlap and duplication. For example, examinations of risk management form part of Commission for Health Improvement reviews, performance assessment for star ratings, assessment by the Clinical Negligence Scheme for Trusts and self-assessment for Controls Assurance. However, the star ratings use the Clinical Negligence Scheme for Trusts assessment.

In recognition of the burden and overlap of inspection, in 2001 the main inspection bodies formed the NHS Reviews Co-ordination Group,23 to improve the efficiency and effectiveness of scrutiny by rationalising reviews of risk management in health bodies, improving co-ordination and reducing duplication. More generally, they are co-operating to find ways of sharing evidence and harmonising criteria to reduce the overall burden of inspection. The Group has:

- agreed and published principles of agreement between the reviewing bodies;24
- carried out a survey of NHS bodies and their reviewers to establish the extent to which the principles are applied in practice. The report of the survey is expected later in 2003. It will include actions for each reviewing organisation to take forward, actions for the Commission for Healthcare Audit and Inspection and actions for the Group as a whole; and
- mapped coverage of infection control by reviewing organisations. The report is expected by the end of 2003.

The work of the NHS Reviews Co-ordination Group is supported by the Cabinet Office’s Regulatory Impact Unit. Indeed, the Public Sector Team of the Regulatory Impact Unit and the Department have conducted a joint project focusing on healthcare inspection. Its purpose is to help deliver practical changes (actions) that reduce or remove unnecessary or bureaucratic burdens in the NHS caused by inspection, accreditation, or audit. Their report25 noted that, while NHS front-line staff and management acknowledged the value added by inspection in driving up standards in healthcare, enhancing public accountability and ensuring patient safety, they saw several recurring themes as hampering the effective delivery of healthcare. They were:

- multiplicity, overlap and lack of co-ordination between reviewing organisations and their functions;
- duplication and inconsistency in requests for data and information;
- proportionality and transparency of reviews;
- burdens of preparation for reviews;
- benefits of review outputs and quality of review reports and action plans; and
- quality of review teams.

The Cabinet Office agreed a total of 55 actions with the Department of Health and other stakeholders to reduce burdens and free up front-line staff to focus on healthcare standards and patient care. The main action concerning inspection was that the Department and the Cabinet Office would, by December 2003, facilitate with stakeholders, including the shadow Commission for Healthcare Audit and Inspection, the development of a draft Healthcare Inspection Concordat, to improve co-ordination between reviewing bodies.

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23 The audit and inspection bodies involved are the Audit Commission, the Commission for Health Improvement, the National Assembly for Wales, the Department of Health, the Health and Safety Executive, the NHS Litigation Authority and the Welsh Risk Pool.
1.20 The decision to unify work under the Commission for Health Improvement and, later, the Commission for Healthcare Audit and Inspection also has the potential to reduce duplication. In March 2003, the government published the Health and Social Care (Community Health and Standards) Bill, which includes provisions to establish a new healthcare inspectorate, the Commission for Healthcare Audit and Inspection. They intend that body to take on the work carried out by the Commission for Health Improvement and the national value for money work of the Audit Commission, along with other inspection work, such as that of the Mental Health Act Commission and the National Care Standards Commission (in respect of private and voluntary healthcare). Responsibility for performance (star) ratings was transferred to the Commission for Health Improvement with effect from the 2002-03 ratings.
We have previously examined aspects of clinical governance in England

1.21 We have previously examined components of clinical governance, such as our report on clinical audit in 1995\(^{26}\) and in reports that highlight concerns about governance, such as those on cervical screening\(^{27}\), hospital acquired infection\(^{28}\), hip replacements\(^{29}\) and waiting times\(^{30}\). Our report Handling Clinical Negligence Claims in England (HC 403, 2000-01, May 2001), drew attention to the scale of claims against the NHS resulting in part from failures of governance and quality assurance. The Committee of Public Accounts' report on the same subject (HC 280 2001-02, June 2002) highlighted the need to reduce the incidence of negligence; noted the initiatives the Department had launched to improve clinical governance; and stressed the need for stronger risk management at trusts. A summary of key findings and recommendations from our earlier work and that of the Committee of Public Accounts on clinical governance issues is on our website at www.nao.gov.uk.

We are undertaking a series of studies looking at aspects of clinical governance in England

1.22 Given our earlier work and the importance of clinical governance to the government's programme for modernisation of the NHS, we examined trusts' progress in putting the required structures in place and the progress made in improving the quality of patient care.

1.23 We focused this examination on secondary and tertiary care, where systems have had time to bed in. There are important differences in the implementation of clinical governance in primary healthcare, and because of this and the impact of major organisational changes from April 2002, including the creation of primary care trusts, we propose to examine that sector later. We have not examined the role of strategic health authorities in relation to clinical governance in NHS trusts. The Audit Commission has, however, examined the authorities' role, which is essentially one of support and performance management. The Commission expects to publish its findings later in the year.

1.24 Early identification and remedying of poor performance of clinicians is an integral part of clinical governance. Because this component is allied to disciplinary matters and sometimes suspensions, we have examined this aspect - including the contribution of the National Clinical Assessment Authority to that work - in a separate examination of the management of suspension of clinicians (to be published in autumn 2003). We are planning to examine in 2004 issues surrounding organisational learning as applied to patient safety.

1.25 Other healthcare organisations have also introduced clinical governance: the NHS in Northern Ireland, Scotland and Wales, the independent sector in the United Kingdom and in other countries (Appendix 5).

Our methodology

1.26 The main sources of evidence for this report were a census of NHS acute, mental health and ambulance trusts (working with the Manchester Centre for Healthcare Management, University of Manchester); a survey of board members and senior managers at a representative sample of NHS trusts (conducted on our behalf by the Health Services Management Centre, University of Birmingham); a review of reports published by the Commission for Health Improvement; interviews with staff at the Department of Health and its regional offices and other relevant bodies; and through consulting our expert panel. Summaries of these are published on our website www.nao.gov.uk. Our methodology is set out in more detail at Appendix 2.

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2.1 This part of our report looks at the effectiveness of support provided to NHS trusts; progress in developing structures and frameworks; and trusts’ responsiveness to internal and external evaluations of clinical governance and quality.

Effectiveness of support provided to NHS trusts

2.2 Ninety per cent of trusts reported that the guidance provided by the Department was fairly, very, or extremely useful. Most trusts indicated that they would welcome further guidance or assistance on a range of specific problems or issues - from the safety of medical devices to the confidentiality of clinical records and data. There were some common themes about where guidance would be helpful, particularly the embedding or linking of clinical governance within organisations and between them; the resourcing of clinical governance amid many competing claims on resources; and clarification of the requirements to report on clinical governance through an annual report, to the Department of Health, to health authorities, and to the Commission for Health Improvement.

2.3 The Clinical Governance Support Team has been developing a stronger advisory and support role; and plans to meet the demand for support and advice by providing direct help, through its development programmes, practical tools and disseminating good practice examples. The Department of Health issued further guidance on reporting in November 2002.

2.4 At the time of our survey in autumn 2002, around 20 per cent of trusts had used the Clinical Governance Support Team’s board development programme and 40 per cent had sent teams to the team development programme, with many more planning to do so. However, some trusts (24 per cent in the case of the board development programme and 12 per cent for team development) had neither used the programme nor had plans to do so, largely because they did not consider this to be necessary.

2.5 Most trusts who had used the programmes rated them highly. In particular, 51 per cent saw the clinical team development programmes as very or extremely useful. Most trusts identified a wide range of changes that had occurred as a result of their participation. While many were specific improvements to the particular services or areas of care from which the clinical teams participating had been drawn - an example of which is at Case Example 1 - other more general improvements included an increase in staff awareness and understanding, greater engagement with the ideas and processes, and team building and improved team working.

2.6 The Department has commissioned the Judge Institute of Management (part of the University of Cambridge) to evaluate the impact of the clinical governance development programme on participating organisations. They submitted their interim report31 in July 2002. In it, they highlighted the complexity of the concept of clinical governance and that the understanding of what clinical governance means and involves differed across and within trusts and teams. They also reported some uncertainty about the links between the organisational and clinical aspects, with some clinicians seeing it as a managerial agenda and managers as primarily a clinical matter.

Progress in establishing structures and frameworks

2.7 While structures and organisational arrangements do not of themselves guarantee the progress of clinical governance, they are a necessary foundation. The Department of Health’s 1999 guidance required trusts, by April 2000, to identify lead clinicians for clinical governance; set up appropriate structures for overseeing it; and clarify reporting arrangements within boards and produce annual reports.

2.8 At the time of our census (July - December 2002) all trusts had nominated a named executive director with lead responsibility for clinical governance at board level. In most cases this was the medical director (56 per cent) or director of nursing (27 per cent). In addition, 87 per cent of trusts had a named lead non-executive director for clinical governance.

2.9 Over 90 per cent of lead executive directors for clinical governance had this responsibility explicitly stated in their job descriptions. The median proportion of their time spent on this work was 35 per cent, although individuals varied in their commitment from five per cent to 100 per cent. Two thirds of trusts considered that the time spent was sufficient for the director concerned to fulfil their clinical governance responsibilities, but the remainder felt more input was needed.

2.10 Virtually all NHS trusts had a clinical governance committee (at the time of the census of trusts, three had not) and in line with Departmental guidance all had conducted a baseline assessment of capability and capacity for implementing clinical governance and formulated an action plan in the light of that assessment.

2.11 Most clinical governance committees met once every one or two months (the median was six times a year). But a small minority - about seven per cent - met fewer than four times a year. All trusts considered that clinical governance committees had brought benefits. These included bringing about changes to systems or processes such as incident reporting, complaints handling and patient information and communications. They had also led to structural changes within the organisation, for example restructuring clinical directorates and reorganisation of services. Importantly for the strategy as a whole, trusts considered that the committees had created corporate commitment, direction and momentum for clinical governance.

2.12 Board members and senior managers rated their views of achievement against a set of competencies. They generally confirmed the findings about overall structures, frameworks and processes, in particular that structural changes such as committees and appraisal and complaints systems were now in place. They considered, however, that there was a shortfall in underpinning those organisation-wide systems with systems and nominated leads in clinical areas. They also considered that insufficient progress had been made in moving beyond the structural agenda, for example in improving service quality following reviews of adverse incident data. Overall, they identified a need for ongoing support and development if trusts were to progress further in that direction.

2.13 Although trust board members and senior managers considered leadership and collaboration important, their view was that achievement was quite modest. They concluded that there is substantial scope for improvement, particularly in communications between the board and clinical teams and in collaboration with other agencies.

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**CASE EXAMPLE 1:**

South Tees Hospitals NHS Trust - Support from the Clinical Governance Support Team

**Situation**

The Friarage Hospital in Northallerton was experiencing problems with long waits for reporting of ultrasound examinations. This was causing frustration for patients and staff. The problem was due to only one of the four radiologist posts at the hospital being filled. There was an unwritten rule that the radiologist had to report on each ultrasound film, which due to lack of consultant cover meant that films were waiting weeks for a report.

**Action taken**

The radiography team, along with other teams at the trust, participated in a Clinical Governance Support Team development programme, which was held at the trust. With the Support Team’s support, and using its methodology, the radiography team undertook a service review that identified the reporting delays as a serious issue; and staff collected evidence on the problem. As a result of this review, the possibility of sonographers doing some of the reporting was discussed and agreed with the radiologist. A new policy for reporting was presented to, and ratified by, the trust board. Sonographers were therefore able to issue ultrasound reports on a trial basis for six months.

**Outcome**

The trial was a success and provided evidence of reduced waiting times. Ultrasound reporting times were reduced from 10 weeks to two to three days, leading to quicker treatment and reduced anxiety for patients and greater job satisfaction for staff. After local negotiations, an interim agreement has been reached to pay sonographers for their new role.

Source: South Tees Hospitals NHS Trust
2.14 The Commission for Health Improvement’s work supports this finding, in that three of the six most frequently raised themes in their reports relate directly to leadership and communication issues. It identified a tendency for boards to be reactive rather than proactive in clinical governance matters (raised in over 90 per cent of reports); a failure to implement policies and strategies (also in over 90 per cent of reports); and a lack of communication from strategic to operational level (in over 80 per cent). It found that, at a third of the organisations it had reviewed, there was a lack of connection between the policies the board had agreed and what actually happened in wards and clinics.

2.15 In addition, the Commission raised concerns at nearly every organisation reviewed about communications between operational and strategic levels in relation to particular components of clinical governance and that while the general quality of leadership is good, it is weakened by the difficulties attracting doctors to take up organisational leadership positions.

2.16 The Department of Health has recognised the importance of good corporate governance for managing a programme of fundamental improvement and modernisation. To help strengthen strategic leadership, the Department and the NHS Appointments Commission have published a guide for NHS board members. The guide aims to draw together the strands of NHS governance to show how clinical governance, risk management, controls assurance and financial and corporate governance provide the essential foundation for good governance.

2.17 Trusts had put considerable resources into supporting clinical governance, but few were able to quantify the annual cost. For the 30 trusts that had estimated their costs, the median was £326,000 a year, which would indicate a cost of some £90 million throughout the secondary and tertiary care sectors of the NHS. Within these trusts the figures varied widely, from a few thousand pounds to £1.3 million, partly because of differences in organisational size and nature, but also because of definitional differences in the costs that were included. Some included the cost of the clinical governance managers and facilitators, while others included the cost of risk management, complaints, clinical audit and other staff. As a result, the reliability of any overall cost estimate based on our survey is limited.

2.18 Other relevant costs include the costs of the main bodies established to support implementation of the clinical governance strategy - the Commission for Health Improvement, the National Patient Safety Agency, the Clinical Governance Support Team and the National Clinical Assessment Authority. In 2002-03, the total cost of these bodies was some £60 million. Trusts also incur costs associated with preparing for and participating in inspections and in working with the support bodies (paragraph 1.11).

Responsiveness to internal and external evaluations of clinical governance and quality

2.19 Reviews by the Commission for Health Improvement, the NHS performance (star) ratings, the Controls Assurance self-assessment process and the Clinical Negligence Scheme for Trusts provide an important focus and stimuli for improvements in clinical governance. Figure 3 shows that trusts rate reviews by the Commission for Health Improvement as having the biggest impact, even though most trusts considered that the reviews rarely identified wholly new information and that the review process had largely confirmed or reinforced their own perceptions of the areas for development or need for change, or their own assessment of the position. Relatively few mentioned receiving positive feedback on their achievements and areas of good practice.

3 Action taken in response to external assessment

Source: NAO census of trusts (July to December 2002)

2.20 Trusts had taken, or planned to take, action in response to the findings of reviews, most commonly reviews or changes to structures and processes within the trust (such as incident reporting or complaints handling) and to specific service areas like orthopaedics and accident and emergency. Many indicated that the review had caused them to examine the trust’s strategic direction and development.

2.21 Trusts are required to prepare an action plan after the Commission’s reviews and to agree it with them and with the strategic health authority. We found that progress on those action plans was limited, even allowing for the fact that many of the reviews were relatively recent (Figure 4). It is now the strategic health authority’s responsibility to follow up the action plan and monitor whether the trust implements it.

Controls Assurance

2.22 The Department’s guidance on clinical governance specified Controls Assurance as a component for managing risk and addressing poor performance, and advocated linking clinical governance and wider controls assurance. NHS boards must take fully into account clinical governance when signing their Statement on Internal Control.33

2.23 Trusts’ self-assessed average score for risk management for 2001-02 was 68 per cent. As this is a self-assessed score and may not be consistent between trusts, its significance lies not in its absolute value, but as a measure of progress. The 2001-02 score represents an improvement over the average of 54 per cent achieved in the first self-assessments in 1999-2000. The process helps identify areas that need attention, so that trusts may deal with them. Following self-assessment in 2001-02, 91 per cent of trusts made changes, most commonly in revision or development of their risk management strategies. Others reported changes to processes and procedures (such as incident reporting) and introducing or developing risk registers.

Part 3

The contribution of the individual components of clinical governance

3.1 This part of our report looks at the relative progress NHS trusts have made in developing the main components of clinical governance and the extent to which this has contributed to improvements in the quality of patient care. We have not audited those individual components.

Progress in implementing the individual components of clinical governance

3.2 The concept of clinical governance brings together a number of components: clinical audit; clinical risk management; adverse incident reporting including clinical negligence, and continuing professional development (both of which include an element of learning from these internal information processes); patient and public involvement (including patient complaints) which provide the perspective of the service users; and knowledge management.

3.3 We looked at the progress across trusts in putting the structures and systems in place for the various components and found that the structural arrangements were most established for clinical risk management, adverse incident reporting and patient complaints and least well established for patient and public involvement (Figure 5). The lack of structures and systems prevents the components being developed and used effectively. Given that clinical audit has been a requirement for trusts since the late 1980s the relatively low compliance for this component of clinical governance is of particular concern.

3.4 In order to establish the extent or reach of each component within each trust we asked trusts to estimate what proportion of their clinical directorates or departments had arrangements for them in place or were regularly involved in these activities (Figure 6). Coverage was best for clinical risk management and adverse incident reporting, but again much less extensive for public and patient involvement. Because of the mandatory reporting requirements for clinical negligence and patient complaints, trusts were not asked about the extent of their coverage across directorates. Nor was the extent and coverage of continuing professional development and knowledge management covered as these are perceived as a staff group or whole trust issue and were therefore addressed separately (paragraphs 3.11 to 3.16 and 3.20 to 3.22 refer).

<table>
<thead>
<tr>
<th>Component</th>
<th>Written strategy in place</th>
<th>Trust-wide committee</th>
<th>Named lead person</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical risk management</td>
<td>92%</td>
<td>93%</td>
<td>96%</td>
</tr>
<tr>
<td>Adverse incident reporting</td>
<td>92%</td>
<td>88%</td>
<td>95%</td>
</tr>
<tr>
<td>Patient complaints</td>
<td>90%</td>
<td>71%</td>
<td>98%</td>
</tr>
<tr>
<td>Clinical audit</td>
<td>64%</td>
<td>76%</td>
<td>92%</td>
</tr>
<tr>
<td>Continuing professional development</td>
<td>67%</td>
<td>65%</td>
<td>88%</td>
</tr>
<tr>
<td>Knowledge management</td>
<td>66%</td>
<td>71%</td>
<td>88%</td>
</tr>
<tr>
<td>Patient and public involvement</td>
<td>63%</td>
<td>54%</td>
<td>88%</td>
</tr>
</tbody>
</table>

Source: National Audit Office census of trusts, July to December 2002
3.5 Trusts’ assessment of the effectiveness of the components of clinical governance in terms of their contribution to bringing about changes in practice and improving patient care showed considerable differences between components (Figure 7). While most trusts were cautious in their assessments, with very few using the endpoints of the rating scale, the most effective components were adverse incident reporting, continuing professional development and patient complaints. Again, patient and public involvement and knowledge management, along with clinical negligence and clinical audit, showed the greatest scope for improvement.

3.6 The Commission for Health Improvement has also found wide variation in progress between trusts. Figure 8 details our analysis of the outcomes of the Commission’s reviews of trusts reported on in the year to November 2002. The average score awarded for all components was 1.92. When applied to an individual trust, that score would mean that some worthwhile progress was being made, but not across the whole organisation. In its report Getting Better? the Commission concluded that the NHS had made a lot of progress, but there was a considerable way to go.

3.7 In the following paragraphs, we look in more detail at the contribution of each of the main components of clinical governance, including case examples that demonstrate how improvements have been achieved.

3.8 Clinical governance aims to change the culture of the NHS, to make it patient centred. The NHS Plan subsequently emphasised the importance of involving and empowering NHS patients. The Department’s guidance stated that, for clinical governance to be successful, all health organisations must demonstrate active working with patients, users, carers and the public.

3.9 As the previous analyses show (Figures 5 to 7), trusts have made limited progress in this area. This slower progress was confirmed by our survey of board members and senior managers who considered that there was a shortfall between achievement and importance in the processes for involving service users and in having criteria for establishing user involvement. Case Example 2 provides an example of increased engagement with patients and the public.
3.10 The Department has, however, put in train a number of changes to enable patients to be as involved as they want to be in decisions about their care, and to enable community involvement in their local health services (Figure 9). From October 2002, the Commission for Health Improvement took over responsibility for patient surveys; and, subject to the passage of the enabling legislation, that responsibility will pass to the new Commission for Healthcare Audit and Inspection. This arrangement should provide an opportunity to help the NHS obtain an independent and comparable measure of future progress in this area.

Use of information and knowledge management, including sharing good practice

3.11 Effective clinical governance requires trusts to generate, identify and use relevant information. It involves trusts bringing together information generated by the different components of clinical governance, so that they can assess quality and performance of services and obtain the information needed to enable evidence-based clinical decision making. There is also a need to ensure that trust boards obtain relevant information to see how well the trust is functioning.

3.12 In response to our census, knowledge management was rated as one of the least developed of the components of clinical governance. Nevertheless, most trusts considered that they made information available to those staff who needed it, and rated their performance as fairly effective in bringing about changes in practice and improvements in patient care. Case Example 3 shows how Kings College Hospital NHS Trust has changed its knowledge management processes. However, while board members and senior managers recognised the importance of identifying and using research evidence and other information on patient incidents, they saw achievement as modest.

CASE EXAMPLE 2: London Ambulance Service NHS Trust - Patient and public involvement

Situation
Because the area the trust serves is large and complex, and it has no premises that are visited by patients, involving patients and the public is not a simple matter.

Action
In 1999-2000, the trust developed a system of feedback from patients called “How did we treat you?”, which involved installing in almost all London hospitals a dispenser enabling patients to feed back their views to the trust. It is now following up that initiative by commissioning the Picker Institute to conduct a major social research project seeking the views of patients and the public about the London Ambulance Service. The trust has set up a Patient Advisory and Liaison Service and has established a patient and public involvement group to co-ordinate the process of piloting patient and public involvement models to fully engage with London’s diverse communities. These models reflect the distinct areas of the trust’s activities: local community involvement in emergency care, public engagement in policy development and the provision of patient transport services.

Outcome
As a consequence of these developments, the trust is now receiving more than 250 enquiries a month from patients and the public. These contributions have led to many improvements to the care afforded to individual patients; and the trust expects patient and public involvement to become increasingly effective as the programme matures.

Source: London Ambulance Service NHS Trust

### Outcome of Commission for Health Improvement’s reviews of trusts reported on in the year to November 2002

<table>
<thead>
<tr>
<th>Overall Finding</th>
<th>Percentage of Trusts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant areas of weakness</td>
<td>7 per cent</td>
</tr>
<tr>
<td>Some Strengths</td>
<td>65 per cent</td>
</tr>
<tr>
<td>Many Strengths</td>
<td>17 per cent</td>
</tr>
<tr>
<td>Significant Strengths</td>
<td>11 per cent</td>
</tr>
</tbody>
</table>

NOTES

1. The Commission allocates scores from I to IV for each of seven aspects. The findings are defined as:
   - Significant areas of weakness: five or more scores of I
   - Some strengths: either one or more Is or no IIIs
   - Many strengths: one or more IIIs and no Is
   - Significant strengths: three or more IIIs and no Is
2. This analysis draws on reports on 115 trusts.

Source: National Audit Office analysis of Commission for Health Improvement clinical governance review reports

7 per cent
65 per cent
17 per cent
11 per cent

Overall Finding Percentage of Trusts

NOTES

1. The Commission allocates scores from I to IV for each of seven aspects. The findings are defined as:
   - Significant areas of weakness: five or more scores of I
   - Some strengths: either one or more Is or no IIIs
   - Many strengths: one or more IIIs and no Is
   - Significant strengths: three or more IIIs and no Is
2. This analysis draws on reports on 115 trusts.

Source: National Audit Office analysis of Commission for Health Improvement clinical governance review reports

23
3.14 The Commission for Health Improvement also has concerns about trusts’ use of information. A failure to share learning across and between organisations was one of the six most common themes emerging from their clinical governance reports, and was raised in more than 90 per cent of reviews. It also commented at many organisations on weaknesses in dissemination of national guidance on effectiveness. A key concern highlighted in its report of the first three years of inspection work across NHS organisations is that they do not make good use of the information they have and that trust boards do not receive the information they need to manage strategically. The Audit Commission have also reported that, whilst some trusts have given high priority to improving the accuracy of their data, many trusts needed to improve basic processes.35

3.15 The Department’s guidance on clinical governance states that trusts should use the comparisons with others to identify good practice; and learn from it so that their patients can enjoy the benefits of the enhanced quality. The Commission for Health Improvement identify best practice in each clinical governance review report under the heading “something that the rest of the NHS can learn from”. In their quarterly tracking report, they analyse those examples of good practice over the components of clinical governance, patient experience and strategic capacity. The tracking reports are not published and the examples are not highlighted in a concerted manner for trusts to make use of them. The Commission does, however, share information with the NHS, for example, through reports such as Getting Better?, through press releases and by presentations at conferences and other events.

3.16 The Clinical Governance Support Team is fast becoming the best source of good practice examples. It is part of its role to capture and spread good practice in clinical governance. It does so through written material, for example its publication Eurekas and Case Studies36, and its website.

Clinical audit

3.17 While clinical audit was formally introduced in 1993, and medical and nursing and therapy audit predated that, Figures 5 to 7 show that clinical audit is not as well established as might be expected, with half of all trusts reporting its use in more than 80 per cent of their clinical directorates or departments. Most, however, found it fairly effective (or better) in bringing about change. Case Example 4 sets out changes made at Mayday Healthcare NHS Trust.
CASE EXAMPLE 3:  
Kings College Hospital NHS Trust - Use of information and knowledge management

**Situation**
The volume of documents, and the time needed to keep up-to-date with them, led to the trust facing problems of information overload.

**Action**
The trust appointed a full time guidelines co-ordinator and established a sub-committee to oversee a process for clinical knowledge management. And it now has a formal system in place for disseminating and monitoring National Institute for Clinical Excellence guidelines and an intranet giving access to local and NICE guidelines.

**Outcome**
The trust-wide approach to knowledge management has led to changes in patient care in a number of areas. For example, it ensured that the appropriate clinician was made aware of a section of the Department of Health’s bulletin for chief executives that related to guidelines for management of intrathecal chemotherapy. Dissemination of the resulting locally adapted information as a policy now forms part of a training programme for the appropriate medical staff. Staff do not give intrathecal chemotherapy without having been through this programme and the names of the staff are notified to the designated clinical areas. This change has led to risk reduction for patients.

Source: Kings College Hospital NHS Trust

CASE EXAMPLE 4:  
Mayday Healthcare NHS Trust - Improvements identified as a result of clinical audit

**Situation**
Before the introduction of clinical governance, clinical audits at the trust were mostly chosen by clinicians. Their choices were influenced by the medical royal colleges, public health, national audits, claims and complaints, research interests and patterns of clinical activity identified by the trust audit team. Large projects were brought to the trust Audit Committee for approval and funding.

**Action**
With the advent of clinical governance and risk management, the trust moved towards integrating clinical audit planning into the trust annual audit plan, a process that was given added momentum following a Commission for Health Improvement review in 2001. One of the things the Commission highlighted was the fact that the trust was not meeting existing guidelines for treating patients with fractured neck of femur. Following the review, the trust strengthened its Fracture of Neck of Femur Team with the appointment of a dedicated anaesthetist and an orthopaedic nurse practitioner. It introduced protocols for fast tracking fractured femur patients in accident and emergency, and an anaesthetic protocol. It also introduced a multiprofessional care plan for fractured hip and audited fractured femur outcome.

**Outcome**
The operation of a prioritised trust-wide clinical audit plan enabled the trust to bring forward the audit and monitor improvements in patient care. The audit showed that the average waiting time for surgery has improved by 50 per cent, and there has been a 20 per cent increase in the number of patients in this group receiving surgery within 24 and 48 hours of admission. There has been a slight reduction in the length of stay as well. Further improvements are planned and will be audited.

Source: Mayday Healthcare NHS Trust
3.18 The Commission for Health Improvement found that clinical audit was in regular use in less than 60 per cent of directorates or departments, and noted that in half of trusts clinical audit did not involve all relevant clinicians, with adverse consequences for staff and patients. This suggests that trusts are not fully exploiting the capacity of clinical audit to drive improvements in quality of care. Our survey also indicated that training for undertaking clinical audit could be improved.

3.19 Ninety eight per cent of trusts reported some degree of involvement in national clinical audits (Figure 10). However, the response by board members and senior managers highlights concerns that trusts do not always select subjects for audit according to clinical governance priorities.

Continuing professional development

3.20 Continuing professional development underpins the delivery of good quality service, by ensuring that professional staff continue to improve their skills and knowledge. Our census suggested that, while trusts could do more to put written strategies in place and show greater leadership through a trust-wide committee, in practice continuing professional development was fairly or very effective in bringing about change. This was confirmed by the Commission for Health Improvement’s reviews: in the year to November 2002, education, training and continuing professional development was the highest marked component. The difference from other components was not great, though; and the average score reflects only worthwhile achievement in some areas. The Commission for Health Improvement has also expressed concern that some professional groups, frequently doctors and nurses, are better covered than others, such as therapists. Our survey of board members and senior managers suggested that performance in carrying new skills gained through to clinical practice was only moderate.

3.21 The Audit Commission drew attention to disparities in funding of continuing professional development between trusts and that access to education, training and development opportunities varies between trusts, between directorates within trusts and between staff groups. The Committee of Public Accounts Report on Educating and training the future health professional workforce (20th Report, Session 2001-02) drew attention to the Audit Commission’s finding. In response the Department stressed the need for continuing professional development in its framework for lifelong learning for the NHS and in 2002-03 and 2003-04 has made significant additional resources available to support improvements in this area.

Clinical risk management

3.22 The Workforce Development Confederations are responsible for working with local employers in drawing up clear links between investment in the learning environment and achieving national priorities.

3.23 The Department’s guidance identified a need for a systematic assessment of clinical risk, with programmes in place to reduce risk. Board members and senior managers told us that risk management was a highly important component of clinical governance, second only to corporate accountability, and trusts rated it as one of the more effective components in terms of its contribution to bringing about changes in practice and improvements in patient care. However, while risk management is reasonably well established, being used regularly in more than 80 per cent of clinical directorates and departments at two thirds of all trusts, there was a sizeable minority of trusts - one in six - where the proportion of clinical directorates regularly using clinical risk management was 60 per cent or below.

3.24 Although board members and senior managers considered their trusts had performed well in terms of recording, collating and reviewing data, in their view performance was weak as regards training in the use of risk management and, importantly, in moving from identifying measures to improve quality to taking action. This mirrors the finding of our examination of health and safety in the NHS where we found that most trusts had improved their overall approach to risk management but that only 12 per cent of trusts provided induction training in risk management. The Commission for Health Improvement has also commented on poor attendance by some staff groups at mandatory training in over a third of trusts.

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38 HC 609, 2001-02.
41 HC 623, 2002-03 A Safer Place to Work: Improving the management of health and safety risks to staff in NHS Trusts.
3.25 Our census highlighted that the major barriers to effective risk management were a lack of resources (at two thirds of trusts); the culture, behaviour, or attitudes of staff of the organisation (at a third of trusts); and a lack of strategy, processes, or co-ordination (a quarter). The Commission for Health Improvement also commented that some organisations had a culture that was not conducive to reporting risks.

3.26 The Clinical Negligence Scheme for Trusts encourages good quality risk management arrangements at trusts. Since 1997, this risk pooling scheme administered by the NHS Litigation Authority has set standards for members (all NHS trusts are members of the Scheme) to ensure that risk management is conducted in a focused and effective fashion, and thus to make a positive contribution towards the improvement of patient care.

3.27 The Scheme assesses trusts’ performance against the standards and, depending on their level of attainment, assigns them to one of three levels. Level 1 represents basic elements of risk management that should be easily attainable; and levels 2 and 3 are assessed progressively when a trust has been notified that it has achieved the previous level. Those meeting the standards are allowed discounts against their subscription to the Scheme, according to the level achieved. The level of achievement against Clinical Negligence Scheme for Trusts standards is also used by the NHS performance ratings.

3.28 In their report Handling Clinical Negligence Claims in England, the Committee of Public Accounts noted that, by March 2000, almost a quarter of all NHS trusts had not achieved the basic risk management standards set by the Clinical Negligence Scheme for Trusts, and a further two thirds had not achieved more than basic standards; that the Scheme remained voluntary; and that the Department “hoped” that a majority of Scheme members will achieve strong standards by 2003-04.

The Committee recommended that the Department should make membership of the Scheme mandatory, and should set each trust a clear target of raising its risk management standards to the minimum level and then to the highest level.

3.29 Trusts have made some progress since May 2001, but one in five have not achieved any level, and most have yet to move beyond level 1 (Figure 11). However, 81 per cent of trusts reported that they made changes following their Clinical Negligence Scheme for Trusts risk management assessment. Almost half had changed policies and procedures, such as incident reporting and equipment maintenance. Others made changes in areas like health records management (20 per cent) and patient consent procedures (10 per cent); and had increased training and development activity particularly related to risk management (24 per cent). About a quarter were working towards the next higher level of assessment.

### Adverse incident reporting

3.30 One of the aims of clinical governance is to change the culture of the NHS from one of blame to one of learning. This purpose was underlined within the report Organisation with a Memory42 and in the reports dealing with its implementation, Building a Safer NHS for Patients43 and Doing Less Harm44. The National Patient Safety Agency (paragraph 1.5), established following consultation on Organisation with a Memory, has a key role in this process. The Department’s guidance requires reporting of adverse incidents so that they might be identified and openly investigated; and lessons are learnt and applied promptly. Adverse incident reporting is practised widely: almost all trusts report that it is operating regularly in over 80 per cent of their clinical directorates or departments. However dissemination of the results and learning from them are less well developed.

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42 Organisation with a Memory—Report by the Chief Medical Officer, June 2000.
3.31 Over 90 per cent of trusts consider that adverse incident reporting is fairly effective or better, at contributing to changes in practice or improvements in patient care. Board members and senior managers confirmed that reviewing and acting on the lessons learnt is highly important.

3.32 To be fully effective, learning from adverse incidents requires a culture where staff feel able and are willing to report adverse incidents, and trusts develop action plans that improve quality. While board members and senior managers ranked the need for an open and fair culture third in importance out of the 54 propositions put to them, they considered that achievement of those elements needed to make adverse incident reporting effective lagged some way behind. More than half of the trusts responding to our census saw cultural difficulties as being the greatest barrier preventing effective implementation of reporting and learning from adverse incidents. Barts and the London NHS Trust was aware that some clinicians were reluctant to report such incidents; and that there was a belief that no changes resulted from doing so. In response, the Trust promoted a fair and just culture at all levels; provided guidance for staff on what to report and how; and increased feedback to those who report incidents. The outcome was that the number of reports received increased by 40 per cent between 2001-02 and 2002-03. And Case Example 5 presents an instance where an ambulance trust has tackled cultural features that limited willingness to report adverse incidents.

3.33 The National Patient Safety Agency has been charged with developing a new national patient incident reporting system. Following on from piloting this system in 28 hospital and primary care units, the reporting and learning system underwent further testing and development in 2003. The Agency expects it to be implemented across the NHS from late in 2003.

CASE EXAMPLE 5:
Greater Manchester Ambulance Service NHS Trust - Adverse clinical incidents

Situation
A high percentage of adverse clinical incidents in the Service resulted in disciplinary action, as there were no alternative options available for managers to progress such issues. Therefore incidents had a very negative effect on team morale. Managers felt that many less serious incidents were not being reported. There was no procedure in place for learning from reported incidents.

Action taken
The trust decided to explore the handling of clinical incidents with the Clinical Governance Support Team; and a team from the trust joined the development programme in February 2001. It became clear that a move towards a ‘fair blame’ culture was required, where all incidents could be learnt from. The Trust Board has now approved and introduced an ‘Untoward Incident Policy’ which includes a Trust Review Panel deciding on the appropriate course of action to take and an eight-stage de-brief procedure designed to take staff through the stages of the incident and identify what could be done to prevent such incidents recurring. Staff are provided with the option of peer support throughout the de-brief.

Outcome
Staff are now far more comfortable reporting incidents. More incidents are being reported and lessons are being learnt from them so that the service can be improved. For example, a paramedic in the field terminated a resuscitation for ‘humane’ reasons. This contravened procedure and could previously have led to disciplinary proceedings. However, de-briefing confirmed that, although procedures should be adhered to at all times, the action taken was justified and changes to the policy are now being reviewed. Senior staff felt that with the new de-brief procedure staff morale has improved.

Source: Greater Manchester Ambulance Service NHS Trust
3.34 The Chief Medical Officer's report, An Organisation with a Memory, also noted that data from litigation claims represent a potentially rich source of learning from failure. We found however, that trusts considered such claims only moderately useful in leading to change or improvement. Case Example 6 shows how a NHS trust has made increasing use of clinical negligence claims as a source of good practice lessons.

Patients' complaints

3.35 Properly accountable and learning NHS organisations need to have complaints systems that are accessible to patients; and to learn lessons from complaints and take action to avoid recurrences. Trusts see patients' complaints as a good source for lessons. 90 per cent rated their systems as fairly effective, or better, at leading to changes in clinical practice and patient care. Trust board members and senior managers confirmed that complaints provide useful information, but were less optimistic about the extent to which reviews led to improvements in quality. Case Example 7 provides an example of how one trust deals with the causes of justified complaints.

3.36 The NHS Complaints procedure currently operated by trusts was introduced in 1996. An independent evaluation commissioned by the Department of Health resulted in a report in 2001 that pointed to slowness, poor communication and lack of independence, and in his 2001-02 annual report the Health Service Ombudsman reached similar findings. The NHS Plan committed the Department to act on the result of the independent evaluation, and the new Commission for Healthcare Audit and Inspection will have among its responsibilities the independent scrutiny of complaints. The Department are now considering what this role will entail and how it will fit in the context of wider reform to the complaints procedure.

CASE EXAMPLE 6:
Barnsley District General Hospital NHS Trust
- Clinical negligence claims

Situation

Although some lessons were learnt on an individual basis, the trust made little use of clinical negligence claims as a source of lessons about good practice.

Action

With the launch of clinical governance, and further encouraged by their Commission for Health Improvement review and Clinical Negligence Scheme for Trusts risk management assessments, the Trust has become more active in drawing on the lessons to be learnt from claims. There has been improvement to the governance structure resulting in a change of culture. Clinicians respond more promptly and positively and are prepared to review cases more openly within directorate forums to avoid recurrence of incidents and to provide impetus to service improvements and patient safety. Those reviews are, increasingly, bringing about changes in practice.

Outcome

This more vigilant and active approach has led to improved patient safety through, for example:

- revising clinical protocols (for example on swab counting, lumbar punctures and psychiatric referral);
- liaising with specialist centres on guidelines, for example for aortic aneurisms and the process for radiology and magnetic resonance imaging reports; and
- upgrading the computed tomography scanner.

And changes have been made to the information provided to patients by:

- improving advice and consent procedures; and
- producing patient information leaflets.

Source: Barnsley District General Hospital NHS Trust
CASE EXAMPLE 7:
Basildon & Thurrock University Hospitals NHS Trust - Patients' complaints

Situation
The Trust has always had a proactive mechanism to ensure that action is taken to reduce the risk of repetition of incidents that led to patients' justified complaints.

Action
Where appropriate, the chief executive requires an action plan to deal with the causes of justified complaints to be submitted alongside the draft letter to the complainant. Quality management staff monitor performance against those plans; and, in the case of more serious complaints, the action required appears on the risk register until that action is taken.

Outcome
This active approach to dealing with the causes of complaints has led to better communications with patients when adverse incidents occur and to improved patient safety through, for example:

- undertaking urgent computed tomography scans within 48 hours;
- immediately referring to a senior doctor any patients returning to the Accident and Emergency department within six weeks;
- purchasing buffers for cot sides in the Accident and Emergency department;
- including on the children’s head injury card an instruction to guardians that the child should be woken every two hours; and
- amending the insulin regime for children undergoing surgery.

Source: Basildon and Thurrock University Hospitals NHS Trust
Implementing clinical governance has raised the profile of quality as an issue for NHS trust boards

4.1 This part of our report looks at the overall impact so far of the clinical governance strategy and the barriers that need to be overcome if further improvements are to be made.

The impact so far

4.2 The launch of the clinical governance strategy and the introduction of board accountability for quality have underlined the need for trust boards to be engaged in quality of care. On average, clinical governance featured as a formal board agenda item six times a year, with boards receiving written reports on its progress at each of these meetings. Chief executives consider that the strategy had led to boards being better informed about quality of care, and to greater corporate ownership and management of quality issues.

Implementation of clinical governance has led to culture changes

4.3 While cultural difficulties form one of the major barriers to implementing clinical governance, the strategy has contributed to changes in culture within trusts. One consequence of boards' involvement in quality issues is that they now see clinicians as being more accountable to them. Chief executives considered that clinical governance had brought about positive changes in organisational culture, with closer working between clinicians and managers, greater "buy-in" to clinical governance from clinicians and a shift to see clinical issues as corporate, and not professional and personal. In turn, clinical governance leads noted that it had led to less defensive and more open attitudes, with some improvement in the degree of staff and patient involvement in decision taking.

Trusts have made improvements to the component parts of clinical governance

4.4 All of the components of clinical governance predated the launch of the strategy, but in almost all of them trusts reported two key changes since 1999:

- an increasing systematisation of methods and processes, aligning and co-ordinating activity across the trust; and
- a growing acceptance by staff of the purpose and nature of the components and their place in healthcare organisations.

4.5 In addition, many trusts reported component-specific changes, for example the development of greater in-house capacity to plan and provide continuing professional development, changes to systems and processes to disseminate information and increased access to information.

There are examples of changes being made to clinical care

4.6 The central purpose of clinical governance is to deliver improved care to patients. About three quarters of trusts identified specific improvements in care as an outcome of their implementing the strategy.

4.7 Trusts provided many examples of changes. These changes included actions to improve the quality of patients' experience. For example, one trust instanced alleviating patients' anxiety by introducing contact cards so that they could raise any concerns they had after treatment; another had improved facilities for parents on children's wards. They had also made changes to the medical care provided, such as introducing 24 hour recovery nurse care in theatres, and improving responses to the problem of pressure sores.
4.8 Although progress has been made in improving patient care, our census of trusts and survey of board members and senior managers confirmed the scope for further improvement. For example, while 57 per cent of chief executives said the number of unjustified variations in clinical practice had fallen, only a third considered there had been a reduction in the use of ineffective investigations and treatments. Few chief executives considered that patients would yet have noticed the changes: 29 per cent judged that patient satisfaction had increased and 14 per cent that they had received fewer patient complaints as a result of clinical governance. In its report on the first three years of its inspections, the Commission for Health Improvement said that the improvement in NHS services was not yet affecting front-line delivery of services on a large enough scale to impact on most members of the public.

4.9 For each trust that participated in our survey of board members and senior managers, the Health Services Management Centre calculated the average score out of 10 for each of the aspects measured (corporate accountability, risk management, performance improvement, leadership and collaboration and quality improvement). The results were aggregated, giving each trust a score out of 50. Figure 12 shows the scores, ranked from lowest to highest, achieved by the 100 trusts surveyed. Most scores fell between 26 and 37, indicating considerable room for improvement.

### Barriers to further improvement

4.10 Our census of trusts asked chief executives what were the main barriers preventing or impeding the successful implementation of clinical governance; and it asked clinical governance leads what were the main barriers to establishing and using each of the components of clinical governance. Two problems featured at the head of both lists: lack of resources and cultural difficulties. Other major barriers cited by chief executives included the size of the priorities agenda and conflicts within it, organisational changes and mergers, and the size, spread and heterogeneity of the trust. Clinical governance leads also found lack of strategy and lack of expertise in the particular component impeded progress.

4.11 Lack of time and resources was by a substantial margin the most frequently cited barrier. Trusts were concerned about direct shortages, such as of clinical and administrative support staff; and shortage of time arising from patient care taking priority over and thus crowding out clinical governance activities. Resource constraints also resulted from conflicting priorities. Trusts reported that the pressures of the wider agenda, and focus on national targets and performance indicators, led to clinical governance components being seen as less of a priority. As noted in part 3, our survey, and Commission for Health Improvement reviews, found barriers to

![Figure 12: Survey of trust board members and senior managers - trusts' ranked aggregate scores for achievement](image-url)

**NOTE**

This graph shows the scores for each of the 100 trusts participating in the survey.

Source: Health Services Management Centre, University of Birmingham: analysis of results of survey conducted on behalf of the National Audit Office

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continuing professional development, largely caused by workload or organisation of working commitments, which conflict with training.

4.12 Cultural constraints largely arose from inhibitions about reporting and learning from incidents and being open about poor performance. For example, there were concerns about the tendency on the part of the media, public and government to apportion blame, and about the threat of litigation. Senior managers considered an open and fair culture for reporting adverse incidents highly important but that achievement failed to match that importance. There were also difficulties in fully engaging staff in the clinical governance strategy.

4.13 Clinical governance leads considered the lack of strategy or direction for components of clinical governance was an important barrier. They instanced a lack of a cohesive agenda for clinical teams and departments, fractured approaches to priority setting for clinical audit, and fracturing of systems for “clinical” and “non-clinical” risk management.

4.14 Most trusts do not have internally generated indicators of progress in implementing clinical governance. Trusts generally gain assurance through regular updates and reports to the board.

4.15 The Clinical Governance Support Team is developing a model form of report that could provide one solution. The report would entail measuring performance against a small number of meaningful targets or indicators. It is planned that this model will augment the quantitative targets that feature in performance assessments with specialty-specific quality indicators.
Main Components of Clinical Governance

1. **Clear lines of responsibility and accountability for the overall quality of clinical care through:**
   - The NHS trust chief executive carries the ultimate responsibility for assuring the quality of services provided by the trust.
   - A designated senior clinician responsible for ensuring that systems for clinical governance are in place and monitoring their continued effectiveness.
   - Formal arrangements for NHS trust and primary care trust boards to discharge their responsibilities for clinical quality, through a clinical governance committee.
   - Regular reports to NHS boards on the quality of clinical care given the same importance as monthly financial reports.
   - An annual report on clinical governance.

2. **A comprehensive programme of quality improvement activities which includes:**
   - Full participation by all hospital doctors in audit programmes, including specialty and sub-specialty national audit programmes endorsed by the Commission for Health Improvement.
   - Full participation in the current four National Confidential Inquiries.
   - Evidence-based practice is supported and applied routinely in everyday practice.
   - Ensuring the clinical standards of National Service Frameworks and National Institute for Clinical Excellence recommendations are implemented.
   - Workforce planning and development (i.e. recruitment and retention of appropriately trained workforce) is fully integrated within the NHS organisation’s service planning.
   - Continuing professional development: programmes aimed at meeting the development needs of individual health professionals and the service needs of the organisation are in place and supported locally.
   - Appropriate safeguards to govern access to and storage of confidential patient information as recommended in the Caldicott Report on the Review of Patient-Identifiable Information.
   - Effective monitoring of clinical care with high quality systems for clinical record keeping and the collection of relevant information.
   - Processes for assuring the quality of clinical care are in place and integrated with the quality programme for the organisation as a whole.
   - Participation in well-designed, relevant research and development activity is encouraged and supported as something which can contribute to the development of an “evaluation culture”.

3. **Clear policies aimed at managing risks:**
   - Controls Assurance, which promotes self-assessment to identify and manage risks.
   - Clinical risk systematically assessed with programmes in place to reduce risk.

4. **Procedures for all professional groups to identify and remedy poor performance, for example:**
   - Critical incident reporting ensures that adverse events are identified, openly investigated, lessons are learnt and promptly applied.
   - Complaints procedures, accessible to patients and their families and fair to staff. Lessons are learnt and recurrence of similar problems avoided.
   - Professional performance procedures, which take effect at an early stage before patients are harmed and which help the individual to improve their performance whenever possible, are in place and understood by all staff.
   - Staff are supported in their duty to report any concerns about colleagues’ professional conduct and performance, with clear statements from the board on what is expected of all staff. Clear procedures for reporting concerns so that early action can be taken to remedy the situation.
Most of the evidence used in this report was collected in 2002 through:

- A census of NHS acute, mental health and learning disability and ambulance trusts;
- A survey of trust board members and senior managers;
- Interviews and examination of documents at the Department of Health and its former regional offices;
- Drawing on the work of the Commission for Health Improvement (Appendix 3); and
- Consulting experts and other stakeholders.

### Census of NHS trusts

We obtained data and information from trusts through a postal census, using a questionnaire. Trust clinical governance leads completed most sections, but we provided for input from chief executives. Chief executives, who are trusts' accountable officers, signed off the questionnaires as a whole. We identified 270 eligible trusts, all of which responded - almost all between July and December 2002. We commissioned the Manchester Centre for Healthcare Management to undertake the census on our behalf. In addition to handling the administration, the Centre provided advice on the content and format of the questionnaire and on interpretation of the results; and wrote a report on the findings.

The areas covered in the census were support provided to trusts to implement clinical governance; the establishment of structures and frameworks; resources and processes; external evaluations; and chief executives' comments. The results are used throughout this report.

### Survey of trust board members and senior managers

The University of Birmingham Health Services Management Centre conducted on our behalf a survey of board members and senior managers of trusts. The survey was carried out between May and July 2002. The Centre used a questionnaire they had already developed. Up to 10 board members and 10 directorate level managers/clinical governance leads from each of a stratified sample of 100 NHS trusts (68 acute, 21 mental health/learning disability and 11 ambulance) were invited to complete questionnaires. In total, 1,177 (61.4 per cent) responded. Details of the results of this survey are on our website.

### Interviews and examination of documents at the Department of Health and its former regional offices

We interviewed key staff at the Department of Health; at the NHS Modernisation Agency (Clinical Governance Support Team) and three of the former regional offices (South East, Trent and West Midlands). We also reviewed work carried out by the regional offices on baseline assessments and development plans.

### Drawing on the work of the Commission for Health Improvement

The Commission for Health Improvement commission "tracking reports" that analyse the findings from their clinical governance reviews. We used those as a source of evidence of trusts' progress in implementing clinical governance. Details of their clinical governance reviews, and of the main themes emerging from them, are at Appendix 3. We also maintained contact with the Commission throughout the study, to draw on any relevant information they had, and to minimise the extent of any duplication. And we have included comments from their report Getting Better? - A report on the NHS, published in May 2003.
Consulting experts and other stakeholders

7 We had the benefit of an expert panel, who advised us on the scope, findings and conclusions of our examination. And we consulted other people and organisations in the course of our work.

8 We are grateful to the following members of our expert panel who advised us during our study:

Mr Andrew Barker, Director of Corporate Affairs, The London Clinic

Mr David Bawden, Development Manager, Commission for Health Improvement

Miss Helen Davis, Senior Lecturer in Orthoptics, Royal Hallamshire Hospital - representing the Health Professions Council

Professor David A Haslam, Chairman, the Royal College of General Practitioners

Professor David Hatch, Chairman of the Committee on Professional Performance, General Medical Council

Professor Sir John Lilleyman, President of the Royal College of Pathologists and Vice-Chairman of the Academy of Medical Royal Colleges - representing the Academy of Medical Royal Colleges

Mr Bill Murray, Chief Executive, South Tees Hospitals NHS Trust

Ms Sue Osborn and Mrs Susan Williams, Joint Chief Executives, National Patient Safety Agency

Ms Susan Savage, formerly with the Nursing and Midwifery Council

Dr Alastair Scotland, Chief Officer and Medical Director of the National Clinical Assessment Authority

Mr Mike Stone, Chief Executive, the Patients’ Association

Dr Jose Westgeest, formerly with BU PA, representing the Independent Healthcare Association

Mr Julian Brookes (then with the Department of Health), Mr Stuart Emslie (then with the Department of Health), Dr Aidan Halligan (now Department of Health, then Head of the Clinical Governance Support Team) and Ms Susan Went (then with the Department of Health) who acted as observers.

9 We are also grateful to the following people who provided us with information and advice:

Ms Jocelyn Cornwell, Commission for Health Improvement

Professor Sandra Dawson and Mr Tom Smith, the Judge Institute of Management, University of Cambridge

Mr Stephen Eastham, Boots the Chemists Ltd.

Mr Joseph Farrington-Douglas, Regulatory Impact Unit, Cabinet Office

Professor Jenny Firth-Cozens, University of Northumbria at Newcastle

Mrs Elizabeth Fradd, Commission for Health Improvement

Mr Roger Goss, Patient Concern

Ms Sheila Leatherman, University of North Carolina at Chapel Hill and University of Cambridge

Ms Katrina Neal, formerly with the Nursing and Midwifery Council

Professor Ellie Scrivens, Keele University and Director of the Controls Assurance Support Unit

Dr Jonathan Secker Walker, University Hospital of Wales

Ms Hilary Scott, formerly Deputy Health Service Ombudsman

Ms Helen Sheldon, College of Health

Professor Peter Spurgeon, Health Services Management Centre, University of Birmingham

Dr Grace Sweeney, University of Exeter

Miss Sally Taber, Independent Healthcare Association

Professor Brian Toft, Marsh Risk Consulting Practice

Dr Kieran Walshe, Manchester Centre for Healthcare Management, University of Manchester

Ms Jo H Wilson, Marsh Healthcare Services
The Commission for Health Improvement uses a systematic framework for assessing clinical governance in trusts. It aims thus to ensure that the judgements made in reports of reviews are reliable, fair and consistent; and that consistent messages are given to trusts about clinical governance. It developed the assessment framework in consultation with the National Clinical Governance Support Team in England and the Clinical Governance Support and Development Unit in Wales.

Scope

2 The Commission for Health Improvement evaluates clinical governance by exploring three key areas:

- **Strategic capacity**: how far does the trust’s leadership set a clear overall direction that focuses on patients? How well is it integrated throughout the trust?

- **Resources and processes**: how robust are its processes for achieving quality improvement, such as consultation and patient involvement and clinical audit? How effective are the trust’s arrangements for staff management and development?

- **Information**: what information is available about the patient experience, outcomes, processes and resources, and how does the trust use it strategically and at the level of patient care?

3 Each of these areas comprises a number of components that the Commission for Health Improvement examines in every trust. The Commission has so far identified seven components of ‘Resources and processes’ and ‘Use of information’ (Figure 13). It is carrying out work to identify the components of ‘Strategic capacity’.

4 The Commission for Health Improvement’s review teams assess how well clinical governance is working throughout the trust by making enquiries about each of these seven components at corporate and directorate levels and in clinical teams. This involves collecting information systematically about review issues that have been defined for each component. The Commission propose to introduce similar methods to assess information collected about components of strategic capacity in future rounds of reviews.

### Components of clinical governance - resources and processes and use of information

<table>
<thead>
<tr>
<th>Component</th>
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<tbody>
<tr>
<td><strong>Resources and Processes</strong></td>
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<tr>
<td>(i) Processes for quality improvement</td>
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<tr>
<td>Patient and public involvement</td>
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<td>Clinical audit</td>
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<tr>
<td>Risk management</td>
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<td>Clinical effectiveness programmes</td>
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<tr>
<td>(ii) Staff focus</td>
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<tr>
<td>Staffing and staff management</td>
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<tr>
<td>Education, training and continuing professional and personal development</td>
</tr>
<tr>
<td><strong>Use of information</strong></td>
</tr>
<tr>
<td>Use of information to support clinical governance and health care delivery</td>
</tr>
</tbody>
</table>

Source: Commission for Health Improvement
Scoring

5 There is wide variation within trusts in progress made in developing the component parts of clinical governance. At this stage of development, the Commission believe it is most useful to trusts to assess each component separately to help them prioritise their development of clinical governance and will not make judgements to produce an overall rating for a trust. On the basis of the evidence collected, the Commission’s reviewers assess each component against a four point scale:

1 - Little or no progress at strategic and planning level, or at operational level

The lack of strategy and implementation means that the organisation does not have the systems and processes for it to be sure that adequate quality of care and services are (or are not) being achieved. Systems for improving the quality of care and services through systematic learning do not exist or are underdeveloped. There may be isolated examples of strategy development or where progress has been made implementing elements of clinical governance often the result of an individual’s enthusiasm and initiative, rather than part of organisational development.

2 - Worthwhile progress and development at strategic and planning levels but not at operational level/Worthwhile progress and development at operational level but not at strategic and planning levels/Worthwhile progress and developments at strategic and planning levels at operational level but not across the whole organisation

The organisation does not have comprehensive systems and processes for it to be sure that adequate quality of care and services are (or are not) being achieved. Systems for improving the quality of care and services through systematic learning are not fully developed. However, there will be examples where:

- a coherent strategy has been developed but where implementation of it has not yet occurred; or
- parts of the organisation have implemented sound systems and processes but these are not connected to strategy development; or
- there is co-ordinated strategy development and implementation, but not covering all aspects of the component of clinical governance or not involving all parts of the organisation.

3 - Good strategic grasp and substantial implementation. Alignment across the strategic and planning level, and the operational level, of the trust

The activity is explicitly part of the organisation’s strategy for clinical governance and systems and processes are implemented in most parts of the organisation. The organisation’s systems provide it with information that the quality of care and services are (or are not) being achieved in most parts of the organisation. There are systems for identifying and correcting deficiencies and for taking preventative measures to ensure that they do not recur, though systems for improving the quality of care and services through systematic learning may not be fully developed.

4 - Excellence - co-ordinated activity and development across the organisation and with partner organisations in the local health economy that is demonstrably leading to improvement. Clarity about the next stage of clinical governance

There is good understanding across the organisation - at board, executive team and clinical team levels - about the place that the activity plays in safeguarding and improving the quality of care and services. There is co-ordinated development across the organisation and with partner organisations in the local economy, for example other NHS organisations, local authorities, voluntary groups.

Systems and processes are mature such that there is systematic learning from them that has led to strengthening of patients’ safety and to improvements in the quality of care and services.

Findings

6 The Commission’s tracking reports contain a summary of themes emerging to date. Figure 14 sets out those themes, together with the average mark awarded for each component over the year to November 2002.
Main themes identified by the Commission for Health Improvement and average scores in the year to November 2002

<table>
<thead>
<tr>
<th>Component</th>
<th>Average score¹</th>
<th>Main themes emerging from 193 reviews²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education, training and continuing professional development</td>
<td>2.19</td>
<td>In some NHS organisations, education, training and continuing personal and professional development do not reflect clinical governance priorities or draw on other clinical governance components such as audit, complaints and patient surveys, or staff surveys. They called on nearly half of the organisations reviewed to address poor opportunities for training for some staff groups compared to others. There were barriers to access for training in some organisations, caused by workload and organisation of working commitments, which can conflict with training.</td>
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<tr>
<td>Research and effectiveness</td>
<td>2.01</td>
<td>It asked 171 NHS organisations to address concerns about effectiveness or research. It expressed concern about the dissemination of national guidance on effectiveness in many organisations.</td>
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<tr>
<td>Risk management</td>
<td>1.94</td>
<td>It called for action in 188 NHS organisations. Most concerns raised related to approaches to risk management that were reactive rather than proactive (for example a failure to monitor and learn from incidents); or policies not being implemented or formulated. Some organisations had a culture that was not conducive to reporting potential risk. The Commission asked over a third of organisations to address poor attendance by some staff groups at mandatory training.</td>
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<tr>
<td>Staffing and staff management</td>
<td>1.93</td>
<td>It asked 187 NHS organisations to address concerns about staffing and staff management:</td>
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<td></td>
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<td>- Many organisations had not approached workforce planning systematically, involving all disciplines and ideally the whole local health community; and</td>
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<td></td>
<td>- There are problems in recruitment and retention in many disciplines throughout the NHS, and few organisations are attempting creative approaches to these problems locally.</td>
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<tr>
<td>Clinical audit</td>
<td>1.90</td>
<td>It called for action in 180 organisations. It had three major concerns:</td>
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<td>- Organisations do not always select audit topics according to clinical governance priorities;</td>
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<td></td>
<td></td>
<td>- In some organisations audit was not linked to other clinical governance components such as risk management and research; and</td>
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<td></td>
<td>- In at least half of reviewed organisations audit was not planned or conducted with the involvement of all relevant disciplines, with consequences for staff and patients.</td>
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<tr>
<td>Patient and public involvement</td>
<td>1.77</td>
<td>It asked 184 NHS organisations to take action about consultation and patient involvement. It noted that some did not encourage patient and public input to service development.</td>
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<tr>
<td>Use of information</td>
<td>1.71</td>
<td>It urged action to be taken on the use of information in 188 of the organisations reviewed. It was particularly concerned that boards often did not receive and disseminate the information from clinical governance and service activities that allowed them to be proactive and strategic. It also found the recording systems for components such as managing audit were inadequate.</td>
</tr>
</tbody>
</table>

NOTES

1. The figures here are averages for reports on acute, mental health and learning disability and ambulance trusts published in the year to November 2002.

2. These themes were based on the 193 clinical governance reviews the Commission had reported on to November 2002.

Source: Commission for Health Improvement Tracking Report, November 2002 (unpublished) and National Audit Office analysis of Clinical Governance Review reports
**Figure 15** sets out the targets and indicators used in assessing performance ratings. Commission for Health Improvement reviews are taken into account for those acute and specialist trusts where a report has been published since the last ratings were calculated. (For 2002-03 this approach was extended to mental health trusts, but not ambulance or primary care trusts). If the review shows significant weaknesses against five or more of the seven components of clinical governance, the trust is awarded no stars. Those trusts that pass this stage are assessed on their performance against the key targets. Performance against the balanced scorecard is used to refine the judgement on the ratings.

### Targets and indicators used in assessing performance ratings

<table>
<thead>
<tr>
<th>Key targets</th>
<th>&quot;Balanced scorecard&quot; indicators:</th>
</tr>
</thead>
<tbody>
<tr>
<td>No patients waiting more than 18 months for inpatient treatment</td>
<td>&quot;Clinical Focus&quot;</td>
</tr>
<tr>
<td>Fewer patients waiting more than 15 months for inpatient treatment</td>
<td></td>
</tr>
<tr>
<td>No patients waiting more than 26 weeks for outpatient treatment</td>
<td></td>
</tr>
<tr>
<td>Fewer patients waiting on trolleys for more than 12 hours</td>
<td></td>
</tr>
<tr>
<td>Less than one per cent of operations cancelled on the day</td>
<td></td>
</tr>
<tr>
<td>No patients with suspected cancer waiting more than two weeks to be seen in hospital</td>
<td></td>
</tr>
<tr>
<td>Improvement to the working lives of staff</td>
<td></td>
</tr>
<tr>
<td>Hospital cleanliness</td>
<td></td>
</tr>
<tr>
<td>A satisfactory financial position</td>
<td></td>
</tr>
</tbody>
</table>

### "Balanced scorecard" indicators:

**Clinical Focus**
- Risk of clinical negligence
- Deaths within 30 days of surgery for patients admitted on an unplanned basis
- Deaths within 30 days of a heart bypass operation
- Emergency re-admissions to hospital following discharge
- Emergency re-admissions to hospital following discharge for children
- Emergency re-admission to hospital following treatment for a fractured hip
- Emergency re-admission to hospital following treatment for a stroke
- Returning home from hospital following treatment for a fractured hip
- Returning home from hospital following treatment for a stroke

**Patient Focus**
- Inpatients waiting less than six months for treatment
- Total inpatient waits
- Outpatients seen within 13 weeks
- Total time in accident and emergency
- Cancelled operations not admitted within a month
- Heart operation
- Breast cancer
- Delayed discharges
- Inpatient survey of patients - co-ordination of care
- Inpatient survey of patients - environment and facilities
- Inpatient survey of patients - information and education
- Inpatient survey of patients - physical and emotional needs
- Inpatient survey of patients - prompt access
- Inpatient survey of patients - respect and dignity

**Capacity and Capability Focus**
- Data quality as measured by the hospital inpatient activity data
- Staff satisfaction as measured by the staff opinion survey
- Compliance with the New Deal on junior doctors' hours (working a maximum 56 hour week)
- Compliance with targets on confidentiality and information governance
- The sickness/absence rate for directly employed NHS staff

Source: Department of Health
Northern Ireland, Scotland and Wales also have clinical governance strategies. This appendix summarises the approach each country has taken.

Northern Ireland

2 The Northern Ireland Department of Health, Social Services and Personal Safety issued guidance on clinical and social care governance - Governance in the Health and Personal Social Services - in January 2003. That guidance described clinical and social care governance as: “a framework within which Health and Personal Safety Service organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care and treatment. Clinical and social care governance is about organisations taking corporate responsibility for performance and providing the highest possible standard of clinical and social care.”

3 The guidance recognised that many organisations would have developed their own systems based on the earlier guidance for England, Scotland and Wales, but sought to bring consistency to the work already begun. It required the appointment of a senior professional at board level to provide leadership in relation to clinical and social care arrangements and processes; the designation of a committee to be responsible for the clinical and social care governance of the organisation; an evaluation of the current clinical and social care governance arrangements in the organisation to establish the baseline from which the developments must begin; the formulation of a plan for the development and maintenance of clinical and social care governance arrangements; and a system to deliver routine progress reports to the board and a formal progress report within the organisation’s annual report. It also underlined a proposed statutory duty of quality and explicitly linked clinical and social care governance and controls assurance. The statutory duty of quality was subsequently commenced on 25 April 2003. It places a requirement on Health and Personal Safety Service organisations to put and keep in place arrangements for improving and monitoring the quality of health and social care services they provide to individuals.

Scotland

6 The Chief Executive, Chief Medical Officer and Chief Nursing Officer of the Scottish NHS issued Guidance on Clinical Governance in November 1998. That guidance described clinical governance as “corporate accountability for clinical performance, making quality of care an integral part of the NHS governance framework”; and stated that, from April 1999, the corporate governance of all NHS bodies in Scotland would encompass both financial and quality issues.

7 The guidance made the trust chief executives be responsible to the trust board for delivery; and required trusts to establish clinical governance committees responsible for the oversight of the clinical governance of the trust so as to assure the board that the arrangements are working and to bring to the full board regular reports on the operation of the system and specific reports on any problems that emerge. Trusts are also required to include a specific section in their annual report giving a full account of their activities related to clinical governance. Trusts have a statutory responsibility for quality of care.
8 The Clinical Standards Board for Scotland had the remit to develop and run a national system of quality assurance of clinical services. In partnership with healthcare professionals and members of the public, it set standards for clinical services, assessed performance throughout NHS Scotland against those standards and published the findings. Two rounds of visits to each trust to assess performance against generic - clinical governance - standards have been completed. From January 2003, the Board was incorporated in the NHS Quality Improvement Scotland, a special health board. That Board is also developing a capacity to provide support and good practice information to trusts.

Wales

9 The Welsh Office issued guidance on clinical governance - Quality Care and Clinical Excellence - in March 1999. That guidance described clinical governance in the same terms as those used in England: “a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish”.

10 The guidance required trusts and local health groups to identify a senior clinician to lead the implementation of clinical governance; establish a clinical governance committee of the board responsible for overseeing clinical governance within the trust; conduct a baseline assessment of the capability and capacity for implementing clinical governance; formulate an action plan in the light of that assessment; and publish an annual report on progress. It also underlined trusts’ statutory duty of quality and linked clinical governance and controls assurance.

11 There is a Clinical Governance Support and Development Unit for Wales, located within the Assembly for Wales.

12 The Commission for Health Improvement carries out clinical governance reviews covering all NHS trusts and health authorities in Wales.
Reports

The Comptroller and Auditor General has to date, in Session 2002-2003, presented to the House of Commons the following reports under Section 9 of the National Audit Act, 1983:

**Agriculture**
Reaping the Rewards of Agricultural Research ........HC 300
Fisheries Enforcement in England .........................HC 563

**Cross-Government Reports**
The Invest to Save Budget ....................................HC 50
Using call centres to deliver public services ............HC 134
Progress in making e-services accessible to all -
encouraging use by older people ..........................HC 428
Improving effective services for Older People ..........HC 518
Getting the evidence:
Using research in policy making ............................HC 586-I
Getting the evidence: Using research in policy making
An international review on Governments' research
procurement strategies ............................................HC 586-II
Purchasing and Managing Software Licences ..........HC 579

**Culture, Media and Sport**
Community Fund: Review of grants
made to the National Coalition of
Anti-Deportation Campaigns .................................HC 519
Film Council:
Improving access to, and education about the
moving image through the British Film Institute ....HC 593
Progress on 15 major capital projects funded by
Arts Council England ...........................................HC 622
The English national stadium project at Wembley....HC 699

**Defence**
Major Projects Report 2002 ....................................HC 91
Ministry of Defence: The Construction of Nuclear
Submarine Facilities at Devonport .........................HC 90
Through-Life Management ....................................HC 698
Ministry of Defence: Compensation claims ............HC 957

**Environment**
Protecting the Public from Waste ..........................HC 156
Warm Front: Helping to combat fuel poverty ..........HC 769

**Europe**
The European Court of Auditors report
for the year 2001 .....................................................HC 701

**Housing**
Improving social housing through transfer ..............HC 496

**Inland Revenue**
Tackling Fraud against the Inland Revenue ..............HC 429

**Law, Order & Central Institutions**
Community Legal Service: the introduction
of contracting .......................................................HC 89
New IT systems for Magistrates’ Courts:
the Libra project ..................................................HC 327
Modemising procurement in the Prison Service ........HC 652

**National Health Service**
Facing the Challenge: NHS Emergency Planning
in England .............................................................HC 36
Innovation in the National Health Service
- the acquisition of the Heart Hospital ....................HC 157
Safety, quality, efficacy: regulating medicines
in the UK ............................................................HC 255
Ensuring the effective discharge of older patients
from NHS acute hospitals ....................................HC 392
Safer Place to Work: Protecting NHS staff from
violence and aggression .......................................HC 527
A Safer Place to Work: Improving the management
of health and safety risks to staff in NHS trusts ....HC 623
Hip replacements: an update ....................................HC 956
Achieving Improvements through Clinical Governance:
A Progress Report on Implementation by
NHS Trusts ..........................................................HC 1055

**Overseas affairs**
Maximising impact in the water sector .................HC 351

**Public Private Partnership**
The PFI Contract for the redevelopment of
West Middlesex University Hospital ....................HC 49
PFI: Construction Performance ...............................HC 371
PPP in practice: National Savings and Investments’ deal
with Siemens Business Services, four years on ....HC 626
Northern Ireland Court Service
PFI: The Laganside Courts ....................................HC 649
The Operational Performance of PFI Prisons ...........HC 700
PFI: The New Headquarters for the Home Office ....HC 954
Government Communications Headquarters
(GCHQ): New Accommodation Programme .............HC 955
Reports

The Comptroller and Auditor General has to date, in Session 2002-2003, presented to the House of Commons the following reports under Section 9 of the National Audit Act, 1983:

**Regulation**
- The Office of Fair Trading: Progress in Protecting Consumers’ Interests ...
  - HC 430
- Department of Trade and Industry:
  - Regulation of weights and measures ...
    - HC 495
- The New Electricity Trading Arrangements in England and Wales ...
  - HC 624
- The Office of Telecommunications:
  - Helping consumers benefit from competition in the telecommunications market ...
    - HC 768

**Social Security**
- Tackling Pensioner Poverty: Encouraging Take-up of Entitlements ...
  - HC 37
- Department for Work and Pensions:
  - Tackling Benefit Fraud ...
    - HC 393
  - Improving service quality: Action in response to the Inherited SERPS problem ...
    - HC 497

**Trade and Industry**
- The Department for Trade and Industry:
  - Regional Grants in England ...
    - HC 702

**Transport**
- Highways Agency: Maintaining England’s Motorways and Trunk Roads ...
  - HC 431