National Audit Office

IMPROVING QUALITY AND SAFETY

Progress in Implementing Clinical Governance in Primary Care: Lessons for the New Primary Care Trusts

LONDON: The Stationery Office
£13.50

Ordered by the
House of Commons
to be printed on 8 January 2007

SUMMARY

1 The Health Acts of 1999 and 2003 set out a statutory 'duty of quality' for all providers of NHS services. At the local NHS level, this duty of quality is discharged largely through implementing clinical governance **(Figure 1)**. Since the first Primary Care Trusts (PCTs) came into being in 2001, they have had the dual role of providing primary care services and commissioning services on behalf of their local health economy with accountability for PCT performance vested in the PCT Chief Executive **(Figure 2 on page 6)**. Clinical governance, implemented effectively, can provide PCT Chief Executives with assurance that healthcare, whether provided directly or commissioned from other providers, is both safe and of good quality.

Clinical governance is "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"

Source: A First Class Service – Quality in the new NHS, Department of Health, 1998

1 Why implementing clinical governance is important for quality in the NHS

"The scope of the new quality programme which is emerging in the NHS is bold and broad-based. Underpinning this has been the concept of clinical governance – a unifying concept for quality which provides organisations with a systematic means for ensuring that they comply with their statutory duty. It aims to effect a change of culture in 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."*

Sir Liam Donaldson, Chief Medical Officer[1]

"In my view, if properly developed and well resourced, clinical governance could provide the most effective means of achieving two important aims. First, it could enable PCTs to detect poorly performing or dysfunctional GPs on their lists. It could also help practices to discover any problems or weaknesses among their own number. Second, it could have the beneficial effect of helping doctors who are performing satisfactorily to do even better."

Dame Janet Smith, fifth Shipman report[2]

The NHS has one of the strongest and most transparent systems for quality in the world: clear national standards, strong local clinical governance arrangements (to assure and improve quality locally), robust inspections and rigorous patient safety arrangements. … We will continue to give a high priority to clinical governance and patient safety. The programme of patient safety launched by the Chief Medical Officer's report *An organisation with a memory* is becoming integral to local services.

Department of Health[3]

"Clinical governance is deeply embedded in some services but is largely lacking in others … few Chief Executive Officers match the depth of their fear of missing budgetary and productivity targets with the strength of their passion to improve quality and safety of services for their consumers."

Sir Liam Donaldson, Chief Medical Officer[4]

"For many, clinical governance is seen as the organisational conscience, and, at its most idealistic, the 'beating heart' of care. … It encapsulates an organisation's statutory responsibility for the delivery of safe, high quality patient care and it is the vehicle through which … accountable performance is made explicit and visible."

Professor Aidan Halligan, former Director of Clinical Governance for the NHS[5]

NOTES

1 *National Standards, Local Action: Health and Social Care Standards and Planning Framework 2005-06–2007-08*, Department of Health, 2004.

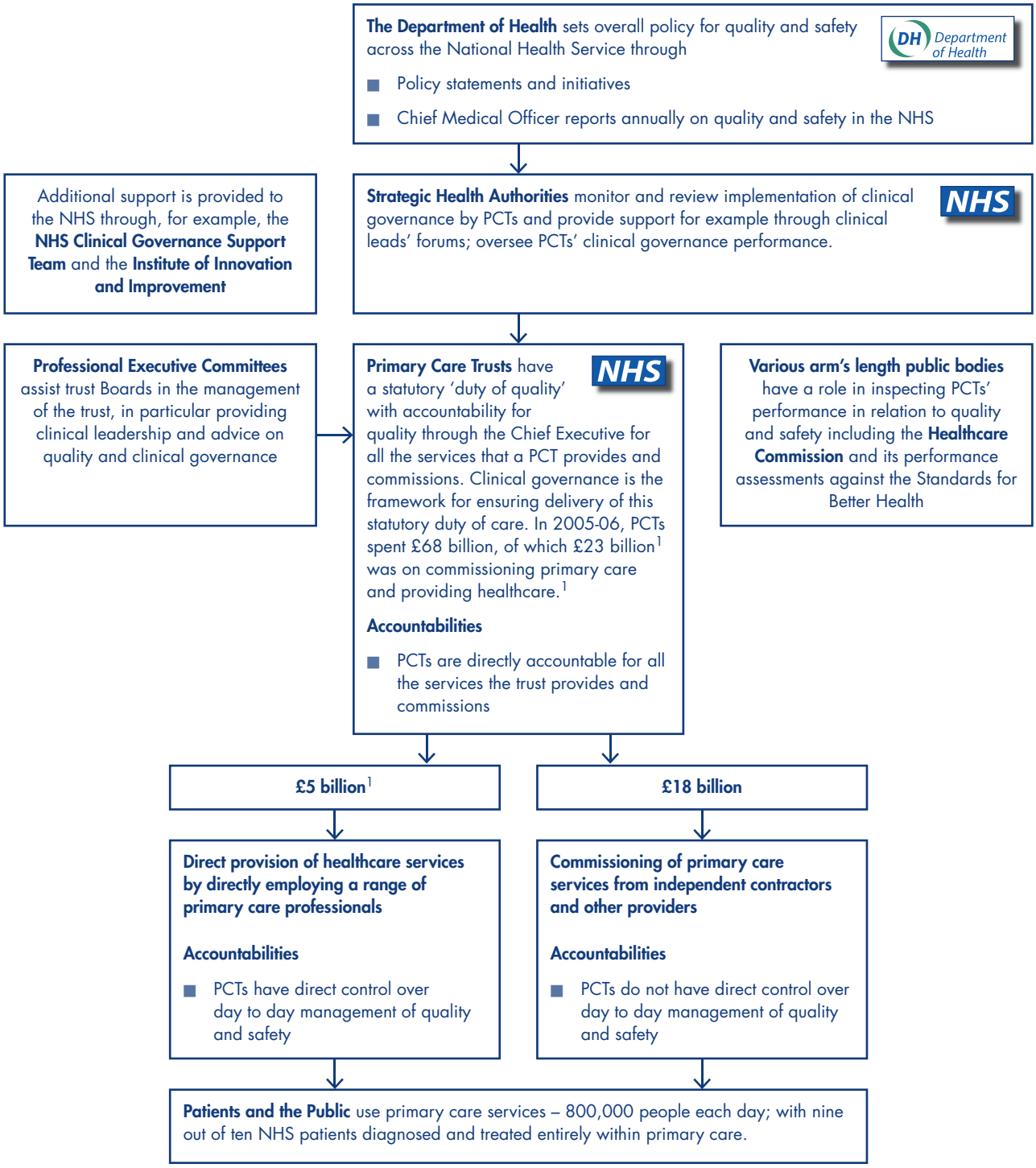
2 *Safeguarding Patients: Lessons from the Past – Proposals for the Future*, Shipman Inquiry, 2004.

3 *Our health, our care, our say: a new direction for community services*. Department of Health, January 2006.

4 *Good doctors, safer patients: Proposals to strengthen the system to assure and improve the performance of doctors and to protect the safety of patients*, A report by the Chief Medical Officer, Department of Health, July 2006.

5 *Clinical governance: assuring the sacred duty of trust to patients*, Professor Aidan Halligan, 2005.

2 Roles responsibilities and accountabilities for quality and safety of primary care services



Source: National Audit Office and Department of Health

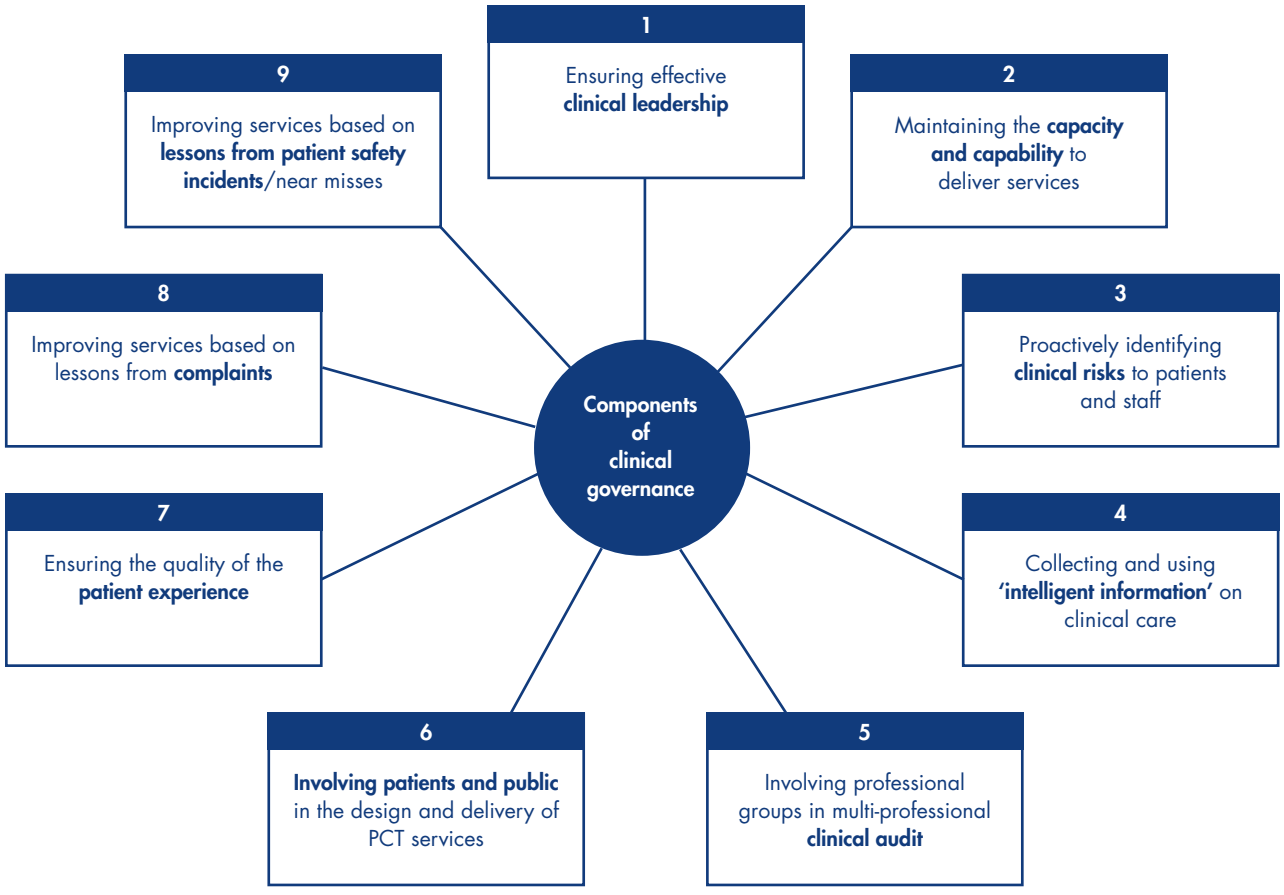
NOTE

1 These figures include all care provided directly by Primary Care Trusts, which include some secondary care (such as community health services).

2 The concept of clinical governance was introduced in 1998 as the centrepiece of the Government's ten year programme to improve continuously the overall standard of clinical care; reduce variations in outcomes of, and access to, services; and ensure that local decisions are based on the most up to date evidence of what is known to be effective.[1, 2, 3] The key principles of clinical governance 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 further repetition.[4]

3 There are a number of models of clinical governance, comprising distinct quality programmes known variously as pillars, elements or components.[5] For the purposes of this review we assessed PCTs' progress in implementing nine key components of clinical governance that the Department of Health (the Department) and our expert panel agreed provided a robust clinical governance framework for the provision of primary care services, consistent with the components of clinical governance identified by the Chief Medical Officer[6] (**Figure 3** and Appendix 1).

3 The key components of clinical governance in primary care



Source: National Audit Office/Health Services Management Centre University of Birmingham

4 In 2003, we published our report *Achieving Improvements through Clinical Governance: A Progress Report on Implementation by NHS Trusts*.[4] This report was the first national evaluation of the impact and importance of clinical governance in acute, mental health and ambulance trusts; however, because many PCTs had only been established for 12 months or so, we excluded them from this review but gave a commitment to examine clinical governance in PCTs at a later date.

5 In July 2005, the Department announced that, as part of the NHS Reform agenda the number of Strategic Health Authorities would be reduced from 28 to 10 with effect from 1 July 2006 and that PCTs would be reconfigured and reduced to around 150 from 1 October 2006.[7, 19] The Department considered that primary care had reached an important cross-road and that there was a need for profound organisational change to enable them to respond effectively to their responsibilities for implementing key national initiatives such as Choice, Payment by Results and Practice Based Commissioning and for managing contracts with General Practitioners, dentists and pharmacists.

6 The NHS Reform agenda involves a radical shift in emphasis, from top-down targets and performance management, to bottom-up leadership and innovation. It also involves giving patients more choice as well as a real voice.[8] We identified a unique window of opportunity to examine progress in implementing clinical governance in the 303 PCTs prior to the reconfiguration. Our aim was to provide a comprehensive assessment of progress, what had been done well, what had been done less well, the lessons learned and the risks that will need to be managed if quality and safety is to be fully embedded in the new Primary Care Trusts.

7 The main fieldwork for our study took place between October 2005 and January 2006. Our methodology (Appendix 1) included a census of PCT Chief Executives and clinical governance leads together with surveys of members of the PCT Professional Executive Committee (PECs) and PCT Boards and a survey of different staff groups in selected PCTs. We also commissioned surveys of front-line staff (GPs, practice nurses and pharmacists) and a sample of patient and carer groups and held focus groups and workshops with patient support groups. Our consultants, from the University of Birmingham Health Services Management Centre (HSMC), provided a detailed analysis of the PCT census and survey findings, including an assessment of differential levels of progress in which PCTs are allocated to one of five bands of overall performance (Bands A to E).[9] Detailed reports on each of these strands of research are available on our website www.nao.org.uk.

8 At the same time as we were planning our review of clinical governance, the Healthcare Commission was undertaking its first review of PCTs' compliance with the new Standards for Better Health.[10] We therefore collected as much information as possible from secondary sources and consulted with the Healthcare Commission to ensure that our survey questions were relevant and compatible with their review of the Standards for Better Health.[11]

9 In our 2003 study of the acute sector (paragraph 4), we found that because clinical governance was an integral part of the way in which trusts deliver services that it did not lend itself to being costed separately and few trusts could provide any cost estimates. Our preliminary work in developing the survey questions for the primary care study revealed that PCTs were unable to provide any estimate of the cost of clinical governance structures and processes or the management time taken up in implementing them. However, as clinical governance is key to PCTs meeting their statutory 'duty of quality', if properly developed and well resourced its implementation should deliver benefits that will outweigh the costs, a sentiment echoed by Dame Janet Smith in her fifth Shipman report.

Main findings

On progress in establishing structures and implementing clinical governance

10 Almost all PCTs have structures and processes in place for implementing clinical governance at PCT level, with named individuals responsible for progress. Ninety per cent or more of PCTs responding to our survey reported that they had the requisite structures and processes in place across the key components of clinical governance. Whilst almost all PCTs had a named lead member of staff for each component, the structures and processes were not always supported by written strategies about how to implement or sustain implementation of clinical governance. PCTs rated the effectiveness of these structures and processes as moderate to good in helping them to manage risks and improve the patient experience (paragraphs 1.19 to 1.22).

11 Implementation of clinical governance is weaker where PCTs have to work with others to deliver services with PCTs needing to build quality, more explicitly, into commissioning decisions. Where PCTs had to work with other PCTs or other agencies they were least likely to have implementation plans for components of clinical governance in place. Strategic Health Authorities expressed concerns about readiness for commissioning in their areas, for example whether appropriate clinical governance indicators would be used in commissioning arrangements. The recent publication of the *Intelligent Commissioning Board: Understanding the information needs of Strategic Health Authorities and PCT Boards*[12] provides a navigation aid for the new Boards aimed at ensuring quality is more consistently delivered through commissioning and provision of healthcare (paragraphs 1.23 to 1.29).

12 PCTs ranked in the lowest performance band for clinical governance were consistently least effective across all clinical governance activities whereas PCTs ranked in the highest performing band were strong across the board. The characteristics of PCTs rated band A as opposed to band E were that they: displayed effective clinical leadership, maintained the capacity and capability to deliver services, improved services based on lessons from complaints and patient safety incidents and gave a high priority to learning from the patient experience. In addition, PCTs in the highest band were found generally to perform better when compared to a range of other performance indicators, such as staff survey results, number of complaints received, Healthcare Commission ratings, and GP vacancy levels (paragraphs 2.3 to 2.8).

13 The Professional Executive Committee (PEC) is important for achieving clinical engagement in the PCT clinical governance agenda, yet PEC members are more sceptical about progress than Chief Executives and PCT Board members, and report lower perceived achievement with its implementation. Effective clinical leadership is essential in embedding clinical governance across the PCT; however we found that Professional Executive Committee members reported lower perceived achievement with clinical governance compared to Chief Executives and Board members. The NHS Alliance in its work has reinforced the need for a clear PEC remit and close working between the PEC and the PCT Board if they are to serve collectively the needs of local communities.[13] The Department of Health has recently signalled its intention to review Professional Executive Committees, with a consultation announced in November 2006 and new arrangements planned to come into effect from April 2007[14, 15] (paragraphs 2.9 and 2.10).

14 Clinical governance links between PCTs and independent contractors are undeveloped. We found that whilst independent contractors such as GPs and pharmacists have processes and structures for clinical governance in place, these are not as extensive as at PCT level, tending to concentrate on the more clinical aspects such as complaints, incident reporting, performance evaluation and appraisals. Contractors felt that they receive only limited support from the PCT in helping them embed clinical governance. On incident reporting, a lack of participation in national reporting systems (three quarters of respondents to our GP survey did not routinely report adverse incidents to the National Patient Safety Agency) means that opportunities for learning and development of solutions are being lost across much of primary care. Our survey of GPs found that where GPs were involved in complaints reported to their PCT, just half of GP respondents were routinely informed of the outcome of complaints by the PCT (paragraphs 2.11 to 2.26).

15 Primary Care Trusts have worked hard to get structures and processes in place for clinical governance, but there are barriers to progress going forward. PCT Chief Executives considered the main risks to sustaining progress in clinical governance to be: training in evidence-based practice, benchmarking of commissioning, joint working and leadership development. Front-line staff reported a variety of day to day pressures that made the pursuit of clinical governance and quality goals more difficult. Specific barriers were lack of time, financing and staff. To help ensure that clinical governance becomes more firmly embedded in primary care culture and practice, the NHS Clinical Governance Support Team is working on a range of tools and resources aimed at managers and practitioners in primary care to help them to gain a better understanding of clinical governance and to share experiences and best practice (paragraphs 2.28 to 2.32).

16 The implementation of clinical governance has delivered clear benefits for quality of patient care and has helped some PCTs to deliver efficiency improvements. Eighty two per cent of PCTs responding to our census considered that the implementation of clinical governance had delivered clear benefits for the quality of patient care, with none saying that there had been no impact. Twenty per cent of PCTs considered that clinical governance had delivered efficiency savings for example, reduction in incidents, near misses and consequently litigation. Efficiency savings were also reported from streamlining of prescribing processes and improved referral and appointment systems. Fifteen per cent of GPs identified clinical governance as helping them to deliver efficiency benefits (paragraphs 2.33 to 2.36).

On improving patient and public involvement and the patient experience

17 PCTs have structures and processes for patient and public involvement in place, but patient and public involvement is one of the least well developed components of clinical governance. The Department's NHS Reform agenda has confirmed public involvement as one of the most important components of clinical governance[16] yet, as we found in 2003, this is one of the least well developed. Whilst 98 per cent of PCTs have structures and processes in place to involve patients and the public in the design of services, we found that lack of involvement of service users in service development is one of the higher risks to progress in implementing clinical governance. In giving a commitment to allow patient choice and to give patients a real voice in the design of services under the NHS Reform agenda, patients' expectations have been raised and as yet PCTs are unable to meet these expectations. The Department's July 2006 Commissioning Framework and its October 2006 report *A Stronger Local Voice* set out proposals for strengthening patient and public engagement via Local Involvement Networks as well as the strengthening of duties to consult and to involve the public. These proposals are a key initiative to try and redress the above imbalance (paragraphs 3.7 to 3.9).

18 PCTs' level of engagement and collaboration with voluntary organisations that support patients has generally been low. The 14 voluntary groups that we surveyed agreed unanimously that PCTs needed to engage more effectively with them, although those groups that supported patients with a condition which had a national target, such as diabetes, reported a more positive experience. Voluntary groups also considered that collaboration was rarely instigated by the PCT, although we found examples of PCTs collaborating with voluntary groups as they recognise that the services and specialist information voluntary groups offer can complement NHS services[17] (paragraphs 3.10 to 3.14).

19 Patients say that the quality of the patient experience is determined primarily by quality of interpersonal care they receive, with less emphasis on technical aspects of care. To patients, the quality of care experienced is determined primarily by the sensitivity with which healthcare is delivered, with less emphasis on the technical aspects of care or competence. Patients put empathy, understanding and respect as the key to them receiving good quality of care. The most frequent complaints were that clinicians were often insensitive or lacked appropriate knowledge about the condition they were dealing with and therefore tended to dispense treatment rather than care. There were also concerns about timekeeping and the emphasis given to targets. Patients were often confused about how to make a formal complaint, especially when they were dealing with more than one organisation or healthcare provider at the same time (paragraphs 3.15 to 3.18 and 3.26).

20 Patients consider that they have only one journey and are conscious that services are not always joined up to meet their needs. The patient journey or patient pathway can cross different NHS departments and organisational structures and involve a number of different communication and administrative processes, with different primary care healthcare professionals. Smoothing the patient journey requires an improvement in the quality, appropriateness and flow of information between healthcare professionals and for clinicians to have up to date evidence-based practice information (paragraphs 3.21 to 3.25).

21 Patients and carers reported feeling excluded from aspects of the patient's care and that better information would help improve health outcomes. Patients expressed a need to be more informed about the treatment they receive, the options available to them and the qualities of any consultants that they are referred to. Carers believed that they could be more effective if they were informed about treatment and included in decision-making. Carers also felt that they could save NHS staff resources if only they were provided with appropriate training to deal with the condition of the patient they were looking after (paragraph 3.19 and paragraphs 3.29 to 3.31).

Overall conclusions

22 The organisational structures and processes for clinical governance have largely been put in place at PCT level. But progress in implementing the different components of clinical governance varies both within and between PCTs. Whilst quality and safety are now more overtly monitored and managed with more explicit accountability of clinicians and managers for clinical performance, as identified in the Chief Medical Officer's report, more needs to be done to strengthen the systems which provide assurance about the performance of General Practitioners and which protect the safety of patients.

23 The key features of those PCTs that can demonstrate consistent improvements in quality include effective clinical leadership, maintaining the capacity to deliver services, ensuring the quality of the patient experience and improving services based on lessons from complaints and patient safety incidents. The behaviours that were evident in the higher performing PCTs were: availability and accessibility of information to support evidence-based medicine; all staff appraised against an agreed work and development programme; service users involved in service development; clear action plans developed in response to clinical risks; and underperformance by clinical staff addressed by clear management procedures.

24 We identified that the areas of greatest need for attention to ensure quality and safety in future primary care organisations were: leadership development; sustaining partnerships and joint working between health and social care; developing practice based commissioning; and the benchmarking of commissioning. Indeed, the aspects of poorest coverage and lowest perceived effectiveness are those aspects concerned with commissioning for quality. If the Department's central goal of improving quality of patient care and the value for money from public money spent on health services is to be realised, these needs will need to be explicitly addressed. Continued investment of time and resources in clinical governance across primary care services with Board level commitment to evaluating progress will remain a crucial factor in ensuring an effective and safe transition to the new NHS.

Recommendations

25 Improving the quality and safety of healthcare provision has been an explicit component of Department of Health policy for the last eight years. Primary Care Trusts (PCTs) are currently some four years into this journey and the restructuring of Primary Care Trusts provides an important opportunity to take stock of progress and to identify the key issues that the new PCTs will need to focus on. The recommendations below provide a clear steer to enable the new PCTs to create a professional and organisational culture that accepts and promotes accountability and the pursuit of high quality safe care as the behavioural norm.

26 In addition to this report we have produced individual feedback reports for each new PCT to enable them to benchmark their component PCTs' performance prior to the restructuring to help pinpoint the key risks and priorities for improvement.

27 We have also drawn a number of lessons from this study to inform questions that Chief Executives and Boards of the newly established PCTs should ask themselves in order to assess their progress with clinical governance. These lessons and questions are considered in a separate guide which is published alongside this report.

28 For the implementation of clinical governance to deliver sustained and tangible benefits to patients, we identify the following three issues which the Department, Strategic Health Authorities and PCTs need to focus on, and which are themes running through our recommendations:

- Ensuring that quality remains at the heart of the health agenda in the face of the current round of restructuring and reorganisation of the architecture of provision and commissioning;
- Maintaining and building effective relationships with those from whom primary care services are commissioned, in particular independent contractors. As PCTs take on more of a commissioning role they will need to make quality a cornerstone of the commissioning agenda; and
- Joining up services within and across PCTs to improve the patient experience, thereby increasing the likelihood of seamless care for patients, and improving the scope for delivering efficiencies.

29 In going forward we make the following recommendations:

For the Department of Health:

a In developing its guidance for PCT commissioning, the Department should ensure that quality is an explicit requirement and that there are clear measures in place by which Strategic Health Authorities and regulatory bodies can monitor that PCTs are including quality in their commissioning activities.

For Strategic Health Authorities:

b Strategic Health Authorities should put in place effective oversight of accountability arrangements – as suggested by the Department's proposed *practice-based commissioning governance and accountability framework*[18] – so that clear lines of accountability for clinical governance are in place throughout the system including handling of potential conflicts of interest.

For the new Primary Care Trusts:

c Ensuring that safe and good quality care is delivered requires effective working relationships between Strategic Health Authorities, Primary Care Trusts, and their independent contractors delivering primary care services. Primary Care Trusts, supported by their Strategic Health Authorities, should develop a strategy for engaging independent contractors in the clinical governance agenda.

d Professional Executive Committees are still an important component of establishing a continuing commitment to quality in the new PCTs. However, their skills and leadership need strengthening. As a first step to achieving this, PCTs should select members of Professional Executive Committees using the same recruitment principles as for Board members and ensure that people with leadership, strategic planning and organisational skills are recruited.

e For the implementation of clinical governance to deliver tangible improvements, PCTs should put development programmes in place which emphasise the development of leadership skills for all PCT staff and for staff responsible for managing the commissioning and provision of services. Priorities are for developing skills in the following areas:

- Benchmarking skills, so that benchmarking of commissioning can be undertaken against other PCTs and of provision against other agencies;
- How to work jointly with other local agencies so that clinical governance culture and practice is integrated across different care boundaries;
- How to involve service users in service development; and
- Training of staff in evidence-based practice and in clinical audit, particularly in developing multidisciplinary audits agreed between PCTs and providers.

f PCTs should actively seek the views of patients in their areas and demonstrate how they have built patients' views into the design and delivery of services. PCTs are well positioned to analyse performance across different providers and should identify where and how improvements to the patient journey and the patient experience have been made and amplify the lessons learned to other providers.

g PCTs should engage with voluntary groups supporting carers and patients to identify where they can achieve efficiency gains and more consistent support to patients and their carers from closer joint working. This might include, for example, joint provision of information to providers about support available to patients and consulting voluntary organisations at least twice a year to develop closer understanding of the patient experience.

h PCTs should require all providers to have an active incident reporting system in place that includes both patient safety incidents as well as other untoward events. PCTs should be in a position to demonstrate to SHAs that they have (i) undertaken regular audits to ensure that incidents and untoward events are being captured; (ii) through benchmarking, addressed underreporting, whether by types of staff or by types of incidents; (iii) working with the National Patient Safety Agency, analysed the root causes or contributory factors to serious or recurring incidents and drawn out themes across services so that solutions and/or risk reduction strategies can be developed to address incidents.

i Complaints should be viewed as an important source of customer feedback which enables managers to see the organisation from a fresh perspective and to develop innovative and patient centred improvements. PCTs need to work with their Patient Advice and Liaison Service and their Local Overview and Scrutiny Committee to develop and put in place an effective complaint handling process. They should also identify ways of ensuring that the process is clearly communicated to all patients and carers, including adopting methods to communicate with ethnic minority groups or others who may be unable to frame their complaint or present it effectively because of language or literacy issues.