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Dear Secretary of State

The final report of the NHS Next Stage Review, *High Quality Care for All*, made clear that quality should be at the heart of everything the NHS does. By quality, we mean ensuring that patients receive safe and effective care and that their experience is as positive as possible. A relentless focus on quality and productivity, connected and driven by innovation and prevention, is central to how the NHS is seeking to improve. There is strong evidence that the service is rising to this challenge. However, progress has not been universally strong.

In March 2009, your predecessor asked the National Quality Board (NQB) to take forward a review of the systems and processes in place in the NHS for safeguarding quality and preventing serious failures. This followed events at Mid Staffordshire NHS Foundation Trust, where independent reports have shown that a comprehensive failure of leadership to improve quality, and a breakdown in systems designed to detect and respond to the signs of serious failings, compromised all three dimensions of quality.

On behalf of the NQB, we are pleased to present this report, which represents the conclusion of our review.

The NQB has now operated for almost a year and has worked hard to establish a work programme focused on three core functions:

- aligning the system around quality;
- advising on priorities for quality improvement; and
- overseeing the development of tools and system levers to support the frontline NHS in bringing about continuous quality improvements.

Our first annual report was published on 8 February 2010 and, in setting out our current and future work programme, demonstrates the NQB’s ability to drive quality improvements, which stems from its unique composition. For the first time, the NQB brings together the leaders of the national organisations tasked with safeguarding and improving quality and the specialist expertise and challenge of lay and expert board members. We are uniquely placed to align the system around quality.

In conducting this review, we did not seek to examine further or pass new judgements on what happened at Mid Staffordshire NHS Foundation Trust. Three reports have already been published and a further independent inquiry will also be reporting to you. Instead, we have built on the analysis and recommendations of these reports and used this review not simply to write a report, but to...
work closely and constructively together to ensure that our systems and processes – some long-standing, others new – are aligned around improving quality and ensuring safe care.

In this report, we have taken the opportunity, based on our collective work, to describe how the system should work in future in order to prevent – and, where necessary, respond to – serious failures in quality. An important part of this has been to provide clarity around the roles and responsibilities of individuals and organisations for safeguarding quality, in the face of a changing regulatory regime.

Since the events in Mid Staffordshire, important changes have been introduced to strengthen significantly the system’s ability to safeguard and improve quality, and further changes will come into effect from April 2010. Specifically:

- The new regulator for health and social care, the Care Quality Commission (CQC), was established on 1 April 2009. With tough new enforcement powers, it will oversee the introduction of a new approach to regulation – the system of registration – from April 2010.

- A new performance framework for the NHS was introduced in April 2009, supporting the swifter detection of underperformance and the action needed to remedy it.

- Professional standards and obligations will be strengthened by the new revalidation system for doctors, to be in operation from 2011/12.

The system we describe in this report is not fully operational – it is in transition. It will need to evolve in order to respond to new challenges and must be kept under constant review, taking account of new evidence of how best to secure high quality care. However, as members of the NQB, we are confident that this system is fit for purpose and can work if everyone plays their part.

While systems and processes are important, the report highlights the extent to which success or failure rests on the values and behaviours of staff in putting patients and service users first, and the culture both within and between organisations.

We have seen the consequences of different parts of the system not fulfilling the roles and responsibilities we describe in this report:

- Where staff have not been encouraged to focus on high quality care for their patients and have not been supported to be open and learn from mistakes, patients have borne the brunt of those failings.

- Where providers and commissioners have failed to listen to and proactively engage with patients and the public, patients have borne the brunt of those failings.

- Where the ambitions of both individuals and organisations have taken precedence over a focus on quality, patients have borne the brunt of those failings.

- Where the system has failed to share information on risk and work collaboratively to rectify problems, patients have borne the brunt of those failings.

To create a self-improving and responsible NHS, we need to aim for a culture of open and honest cooperation. This means individuals and organisations being open and honest about the quality of care being provided to patients and the whole system working collaboratively to address concerns and raise standards. This means staff having the confidence to raise concerns about poor performance and unacceptable levels of care, rather than waiting for patients and their families to notice the fault lines.

We also need to consider the impact of restructuring the management and regulation
of the NHS, as the distraction and confusion this creates can pose one of the greatest risks to quality. Careful consideration needs to be given to the consequences for quality if further reorganisation of this kind is to be embarked upon.

Of course, the culture of open and honest cooperation we seek will not come about as a result of a single report. But, the process of the review itself and the co-production of this report has been hugely important and has been made possible by the existence of the NQB. At a national level, this report therefore marks the beginning of a new way of working which we, as leaders of the national system, are committed to spreading throughout our organisations and nurturing across the NHS.

Aligning the system is not a straightforward task given the complexity involved in modern healthcare systems. Nonetheless, we are resolute in our ambition to do so. This review has flushed out tensions and misperceptions and has uncovered ambiguities around how the system is meant to work. We have worked hard collectively to remove these, and the process of this review has been an important part of taking action.

This task will continue as we embed the new systems this report describes. We therefore commend this report and its recommendations to you and we seek your support for our continuing drive to improve quality and ensure that our NHS provides the best possible care to the patients it serves.
Executive summary

In March 2009, the Secretary of State for Health asked the National Quality Board (NQB) to conduct a review into the systems and processes in place for safeguarding quality in the NHS. This followed the publication of a report by the Healthcare Commission confirming serious failings at Mid Staffordshire NHS Foundation Trust between 2005 and 2008.\(^1\)

The Secretary of State also commissioned two further rapid reviews at this time – one by Dr David Colin-Thomé and the other by Professor Sir George Alberti. While we have not sought to affirm or re-open the ground covered by these reviews, their recommendations and findings informed the scope of our review. In particular, this report seeks to respond to a recommendation made in Dr Colin-Thomé’s report into the failures at Mid Staffordshire NHS Foundation Trust:\(^2\)

> “A key lesson has been about the need for clarity of role and responsibility to ensure that each organisation understands where it fits and what accountability it has. This was not clear in Mid Staffordshire and there were cases of issues falling between organisations.”

This recommendation has been tackled head on. The ten months of the review itself have been used to examine, work on, and improve the alignment between the different national organisations that have an impact on frontline services as well as how the national, regional and local parts of the NHS work individually and together to safeguard quality.

Concluding this important process, this report:

- recognises that, since the events at Mid Staffordshire NHS Foundation Trust, important changes have been made and continue to be made to improve quality and safety in the NHS (including the rollout of national, regional and local quality initiatives following on from the NHS Next Stage Review; the establishment of a new regulator that will oversee the introduction of a new system of registration for NHS providers from April 2010; and the development of a new system of revalidation for healthcare professionals);
- acknowledges that safeguarding quality is a continuous process – we must constantly seek to improve the way we do this, in every part of the system;

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\(^1\) Investigation into Mid Staffordshire NHS Foundation Trust, Healthcare Commission, March 2009: www.cqc.org.uk/usingcareservices/healthcare/concernsabouthealthcare/midstaffordshirenhsfoundationtrust.cfm

Review of early warning systems in the NHS

- provides a description of the roles and responsibilities of individuals and organisations across the NHS in relation to identifying and preventing serious failure – looking at both the systems and processes being used and the values and behaviours that need to be exhibited in order to ensure an effective early warning system;

- recognises that no system can be 100% failsafe and so sets out what should happen in the event of an actual or potential serious failure being identified; and

- contains a focused set of recommendations for how the system could be further adapted to improve its ability to spot failings at an early stage and ensure that swift remedial action can be taken.

5. Given that a number of significant changes to the performance and regulatory system have come into effect since the events at Mid Staffordshire NHS Foundation Trust occurred, with further changes planned during 2010 and beyond, the report does not dwell on the past. Rather, it seeks to describe the system as it will be from April 2010 onwards – looking forward to the future, while learning the lessons from the past. Chapter 1 sets out in more detail the changes to the system and the approach we took to conducting this review.

6. Overall, the report recognises that quality is a moving target and that the descriptions included will therefore need to be reviewed periodically to ensure that they continue to reflect the reality of the NHS. Many lessons have already been learnt from the events at Mid Staffordshire. This report recognises progress and identifies areas for further development. The review did not, however, seek to analyse still further the specific incidents at Mid Staffordshire NHS Foundation Trust.

Summary of findings

7. Ensuring that NHS patients receive high quality care is an inherently complex and fragile operation. Robust systems and processes to monitor, performance manage and regulate the quality of care provided to patients are therefore essential. However, this review has confirmed that the success of these systems and processes is almost entirely dependent on the values and behaviours of the staff working throughout the system. Strong leadership at every level is needed to ensure that values and behaviours that put patients first can prevail.

8. As part of this, Chapter 2 sets out how the NHS needs to embrace a culture of open and honest cooperation – a culture where individuals and organisations are transparent about the quality of care being provided to patients, and the whole system works collaboratively to share information, address concerns and raise standards. Being open and honest about where there may be shortfalls in quality is central to putting patients first.

9. This culture of open and honest cooperation requires a mature, two-way dialogue between patients and the public and the NHS. Chapter 3 highlights the importance of listening to and engaging with patients, service users and the public about the quality and design of services and sets out some of the formal mechanisms in place to support this.

10. Listening to patients’ experiences and concerns is a key part of the early warning system. However, relying on patients alone to hold the system to account, even with the major increases in information being made available, cannot be sufficient. There will always be an asymmetry of information and understanding on the part of patients compared with others who work in or with
the system. **There must be a robust performance and regulatory framework in place to safeguard quality, which is described in Chapter 4.**

11. The new system of registration, to be introduced from April 2010, will set the bar on quality by identifying the essential levels of quality and safety that all providers must meet. This report is primarily concerned with serious breaches in registration, that is where breaches are significant and sustained, indicating systemic failings in quality within an organisation. While the CQC is responsible for assessing compliance with registration, all parts of the system have a part to play in identifying early warning signs and preventing failure.

12. **Chapter 5 describes these roles and responsibilities in detail. In doing so, it restates and reinforces the reality that NHS staff and clinical teams are the first line of defence in preventing serious failure in the NHS.** It is their responsibility and duty to speak up when they have a concern, as well as striving to deliver continuous improvements in the quality of care they provide.

13. However, ultimate responsibility for safeguarding the quality of care provided to patients rests with the provider organisation through its board. Boards should be:

- ensuring that their organisation meets the essential levels of quality and safety as set out by the new system of registration. An organisation is much less likely to experience a serious failure if it is genuinely meeting these requirements; and

- continuously striving for quality improvement. By driving quality improvement (across the three domains of quality – effectiveness, safety and patient experience) through measuring and scrutinising indicators of quality on an ongoing basis and acting on that information, boards will be able to spot early signs of failure and take mitigating action.

14. Commissioners and system managers (primary care trusts (PCTs), strategic health authorities (SHAs) and the Department of Health) are responsible for securing the provision of high quality care at local, regional and national levels:

- **PCT commissioners** secure provision of services to meet the needs of local populations by commissioning from registered providers. They then assure themselves that providers are meeting their contractual obligations, through contract management, soft intelligence and other information. They have a statutory duty to secure continuous improvement in the care that they commission (as well as that which they provide).

- **SHAs** are accountable to the Secretary of State for the operation of the NHS in their region. They do this by assuring themselves that PCTs are commissioning high quality services that meet the needs of the population and that they are holding all providers to account for performing against their contracts. They also directly manage the performance of NHS trusts via the NHS Performance Framework.

- **The Department of Health** is accountable to Parliament for the provision of health services to the population of England. It designs the health system, including setting registration requirements in legislation, setting out national priorities through the NHS Operating Framework, and delegating responsibility to regional and local levels. It is the responsibility of the Department of Health to ensure that there are effective flows of information on emerging concerns and risks throughout the system.
15. The regulators ensure that providers are adhering to their statutory obligations:

- **The CQC** is the independent regulator for health and adult social care in England. It registers all providers of health and adult social care against registration requirements (essential levels of quality and safety), and attaches conditions to registration where appropriate. It then monitors ongoing compliance against these requirements and takes enforcement action where necessary. The CQC also has a range of functions to encourage improvement in health and adult social care services, for example through reviews of the quality of care. In its work, the CQC aims to focus on outcomes and the experience of people using services.

- **Monitor** is the independent regulator of NHS foundation trusts. It determines whether NHS trusts are ready to become NHS foundation trusts, authorising those that meet certain pre-determined criteria. In due course, it will also be able to effect the de-authorisation of a foundation trust in cases of serious failure. Monitor sets the regulatory and reporting framework for all NHS foundation trusts via its Compliance Framework, which it uses to monitor whether or not NHS foundation trusts are complying with their terms of authorisation. As part of this Compliance Framework, all foundation trusts must comply with the CQC’s registration requirements and the obligation to monitor and improve quality of care. Monitor looks to the CQC for judgements as to whether an NHS foundation trust is complying with their registration requirements and, more generally, in relation to the quality of care provided. Monitor can take regulatory action where issues with quality raise concerns about the trust’s governance, but will look to the CQC to act on breaches in registration.

16. The different roles and responsibilities described mean that different parts of the system hold different information and intelligence on the risks within provider organisations. The overall system therefore needs to work together to share this information. Chapter 6 sets out some of the formal mechanisms for facilitating this in order to ensure that risks are identified early and appropriate action is taken to secure improvements.

17. However, no system can be 100% failsafe. Some serious failures will be unpredictable, and therefore cannot be entirely prevented. There will be instances where a failure occurs as a result of several unforeseen circumstances happening simultaneously. In such instances, though few and far between, there needs to be a system-wide response with three key objectives:

- safeguarding patients – the responsibility for this primarily rests with the organisation that provides the care. The CQC has a wide range of enforcement powers where there are concerns that a provider may not be achieving this;

- ensuring continued provision of services to the population – the responsibility for this rests firmly with the SHA and the PCT; and

- securing rapid improvements to the quality of care at the failing organisation – the responsibility for this falls to the PCT and the SHA, and to Monitor in relation to NHS foundation trusts.

18. In the event of a serious failure, a single organisation needs to take responsibility for ensuring that the management and regulatory responses remain aligned and coordinated at all times. We recommend that the SHA should take on this coordinating role given its
accountability for the overall operation of the NHS in the region, including maintaining provision of services to the local population at all times. In this role, the SHA does not direct the regulators, who are free to act within their statutory frameworks, but works alongside them to ensure that an efficient and effective system-wide response is taken.

19. **Chapter 7 brings all the component parts of the early warning system together.** In doing so, it makes clear that safeguarding quality is not the responsibility of a single organisation or reliant on a single process. Its success is dependent on the culture within and between organisations which, in turn, needs to be underpinned by robust systems and processes and clarity around roles and responsibilities. It is a collective endeavour and a collective responsibility.

20. **In this chapter, we also set out seven recommendations for how the system could be strengthened further in order to safeguard the quality of care provided to patients.** These recommendations focus on:

- the role of the professions in safeguarding and driving quality;
- the need to provide trust boards with further support in governing for quality;
- how we might further strengthen the engagement and involvement of patients in the early warning system;
- how the performance and compliance frameworks for NHS trusts, NHS foundation trusts and commissioners consider quality of care; and
- the need for a single organisation to hold the ring in the event of a serious failure to ensure that the management and regulatory responses are aligned and remain coordinated at all times.

21. We believe that the system described in this report, which will be in place from April 2010, is better than anything that has gone before. If the different parts of the system fulfil their roles individually and work together in a culture of open and honest cooperation, the system should minimise the risk of serious failures occurring, identify those that do at an early stage and take appropriate coordinated action for the benefit of patients.
Chapter 1:
Introduction and approach

1.1 In March 2009, the Secretary of State for Health asked the NQB to:

“look at how we can ensure that any early signs that something is going wrong [in the NHS] are picked up immediately, that the right organisations are alerted, and action is taken quickly”.³

1.2 This followed the publication, on 17 March 2008, of a report by the Healthcare Commission of its investigation into high mortality rates at Mid Staffordshire NHS Foundation Trust between 2005 and 2008.

1.3 Alongside the NQB’s review, the Secretary of State also commissioned two rapid reviews into the serious failings in emergency care at Mid Staffordshire NHS Foundation Trust:

- Professor Sir George Alberti, former National Clinical Director for Emergency Care, was asked to review the hospital’s procedures for emergency admissions and treatment and its progress against the recommendations in the Healthcare Commission’s report. He reported in April 2009.⁴

- Dr David Colin-Thomé, National Clinical Director for Primary Care, was asked to investigate the circumstances surrounding Mid Staffordshire NHS Foundation Trust with a view to learning why the PCT and SHA, within the commissioning and performance management systems in which they operated, failed to expose what was happening in this hospital. He also reported in April 2009.⁵

1.4 Collectively, these reviews provide the backdrop to the NQB’s review. While no attempt has been made to affirm or re-open the ground covered by these reviews, their recommendations and findings have been taken into consideration and, in part, have informed the scope of the NQB’s review. Figure 1 provides a brief overview of some of the findings from these reports.

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³ Statement by the Secretary of State for Health, the Rt Hon. Alan Johnson MP, 18 March 2009: www.dh.gov.uk/en/News/Recentstories/DH_096385


### Introduction and approach

#### Figure 1: Overview of the findings from investigations into events at Mid Staffordshire

<table>
<thead>
<tr>
<th>The clinicians</th>
<th>“Clinical governance within the trust was poor and clinicians did not raise concerns about the poor quality of care for patients.” (Colin-Thomé Review)</th>
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<td></td>
<td>“[There was an] over reliance on process measures, targets and striving for Foundation Trust status at the expense of an overarching focus on providing quality services for patients.” (Colin-Thomé Review)</td>
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<td>The board of the hospital</td>
<td>“It was clear from the minutes of the trust’s board that it became focused on promoting itself as an organisation, with considerable attention given to marketing and public relations. It lost sight of its responsibilities to deliver acceptable standards of care to all patients admitted to its facilities. It failed to pay sufficient regard to clinical leadership and to the experience and sensibilities of patients and their families.” (Healthcare Commission investigation)</td>
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<td>“The trust’s board and senior leaders did not develop an open, learning culture, inform themselves sufficiently about the quality of care, or appear willing to challenge themselves in the light of adverse information.” (Healthcare Commission investigation)</td>
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<td>The PCT and SHA</td>
<td>“It is… unfortunate that the main PCT commissioning services (South Staffordshire Primary Care Trust) did not pay more attention to standards and quality of clinical care and comments from patients but focused more on throughput and targets.” (Alberti Review)</td>
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<td></td>
<td>“Locally the PCTs and SHAs did not seek out data to ensure quality of outcomes, either in their roles as commissioner, performance manager or with responsibility for oversight of the local health system.” (Colin-Thomé Review)</td>
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<td>“There was over reliance by the PCTs and the SHAs on Monitor and the Healthcare Commission to ensure quality of care at Mid Staffordshire hospital trust.” (Colin-Thomé Review)</td>
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<td>“[There was a] lack of continuity and handover between organisations when reconfigurations and staff changes took place.” (Colin-Thomé Review)</td>
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<td>The regulators</td>
<td>“The regulators should also have taken a stronger role in sharing their concerns more explicitly with the PCT when they came to light.” (Colin-Thomé Review)</td>
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Terms of reference

1.5 The NQB’s terms of reference were:

- to review in the context of the Healthcare Commission’s investigation into high mortality ratios at Mid Staffordshire NHS Foundation Trust the national systems and processes in place for the early identification of potentially serious failings in patient care and the subsequent response;
- to make findings as to the alignment of those systems and processes across the different national bodies that are responsible for ensuring that patients receive high quality care; and
- to reach conclusions and to make recommendations in relation to the national system which could further secure high quality care across the NHS.

1.6 This document represents our (the NQB’s) report to the Secretary of State for Health.

Approach

1.7 In addition to meeting the specific terms of reference we were set, we have also taken the opportunity presented by this review to tackle, head on, some of the specific findings from Dr Colin-Thomé’s review:

“A number of organisations have been the subject of investigation and review in the Mid Staffordshire case, including the hospital trust, the PCTs, SHAs and regulators. There are lessons to be learnt by all of these organisations, but there are also lessons for the wider system.

“A key lesson has been about the need for clarity of role and responsibility to ensure that each organisation understands where it fits and what accountability it has. This was not clear in Mid Staffordshire and there were cases of issues falling between organisations.”

1.8 This report therefore examines the roles and responsibilities of organisations at local and regional as well as national levels – providers, commissioners, system managers and the regulators. The report focuses on preventing and responding to serious failures in the acute and community services sectors of the NHS. It does not look at safeguarding quality in primary care, which would need to be the subject of future work.

1.9 In taking forward the review, we established a sub-group of NQB members to consider the issues at stake in detail. Bill Moyes (former Executive Chair, Monitor), Barbara Young (former Chair, Care Quality Commission), Naren Patel (Chair, National Patient Safety Agency), Ian Carruthers (Chief Executive, South West Strategic Health Authority) and Una O’Brien (Director General, Policy and Strategy, Department of Health) worked together to describe how the NHS system safeguards quality, and examined any areas that they felt needed strengthening. They then tested their conclusions and descriptions with a range of stakeholders and the NHS to ensure that it reflected the situation on the ground before reporting back to the full NQB.

1.10 Rather than providing a description of the system that was in place at the time when the failures at Mid Staffordshire NHS Foundation Trust occurred, the report looks forward to the system that will be in place from April 2010 onwards. While many components of the system remain in place, there have nevertheless been some important changes to the health
landscape recently, with others due to be implemented from April 2010 onwards.

**A new statutory framework for quality**

1.11 The Health and Social Care Act 2008 included various provisions aimed at both enhancing the mechanisms for safeguarding quality and strengthening the focus of the NHS on quality improvement:

- Sections 1–7 established the CQC, the new regulator for health and social care in England. The CQC has taken over from the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission. The CQC was established in shadow form on 1 October 2008 and became fully operational on 1 April 2009.

- Sections 8–44 established a new system of registration. From 1 April 2010, all NHS trusts (including PCTs as providers) that provide regulated activities must be registered with the CQC under the new system. Adult social care and independent healthcare providers will follow from 1 October 2010. Some additional services will come into scope of registration over time, including primary dental care providers in April 2011 and primary medical care providers in April 2012. For NHS trusts, the registration requirements will replace the Standards for Better Health.

- Section 45 provides for the Secretary of State to publish statements of standards in relation to the provision of NHS care. The Secretary of State can delegate this function and it is likely that he will do so to the National Institute for Health and Clinical Excellence (NICE) in the form of NICE quality standards. These will provide a definitive definition of high quality care for a particular pathway of care, with four topics selected in 2009/10 to pilot the production process (venous thromboembolism prevention, dementia, stroke and neonatal care).

- Section 139 sets out a duty on PCTs to make arrangements to secure continuous improvement in the quality of the healthcare that it provides and commissions. In doing so, the PCT must have regard to any standards made under Section 45.

1.12 This last statutory duty is reflected in the NHS Constitution, where the NHS makes commitments to the public to continuously drive quality improvement:

> **You have the right** to expect NHS organisations to monitor, and make efforts to improve, the quality of healthcare they commission or provide.

> **The NHS also commits:** to continuous improvement in the quality of services you receive, identifying and sharing best practice in quality of care and treatments (pledge).“

1.13 The full set of rights and pledges in the NHS Constitution are underpinned by a legal duty on providers and commissioners of NHS services to have regard to the new NHS Constitution (Section 2, Health Act 2009).

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7 Registration against infection control regulations was introduced in April 2009. The CQC registered all 388 NHS trusts, with 21 trusts being registered with conditions. The regulations setting out the full registration requirements will come into force from April 2010, subject to final Parliamentary approval.
Wider changes to the NHS landscape

1.14 In addition to the changes introduced by the Health and Social Care Act 2008, further improvements to the system have and will come into effect:

- **Quality is now the organising principle of the NHS, as established in *High Quality Care for All***: New quality initiatives are being rolled out nationally, regionally and locally as part of the quality framework described in this report. These include:
  - the publication of the first set of Quality Accounts by secondary care providers from April 2010;
  - the establishment of regional Quality Observatories to support the local NHS in measuring for quality improvement;
  - the publication in spring 2010 of the first four NICE quality standards;
  - the development of an assured menu of Indicators for Quality Improvement to provide clinical teams with robust indicators to use in measuring the quality of their care and driving improvement; and,
  - the introduction of CQUIN agreements between PCTs and providers from 2009/10.

- **The NHS Performance Framework for acute trusts was introduced in April 2009 and will be extended to apply to PCT commissioners and mental health trusts from 2010.** The framework identifies underperformance using a series of indicators and ensures early intervention by specifying when, but not how, SHAs and PCTs should intervene. It will cover NHS providers and commissioners. NHS foundation trusts will not be assessed under this framework as they are assessed under Monitor’s Compliance Framework.

- **The revalidation of doctors will be introduced, led by the General Medical Council (GMC).** Where clinicians fail to observe professional standards, action may be taken against them by their regulatory body. From 2011/12, revalidation will help strengthen professional standards by reaffirming every five years that doctors are fit to practise.

- **Subject to Parliamentary approval, from 1 April 2010, all NHS organisations will be required to notify the CQC about serious patient safety events.**

1.15 In testing the early warning system described in this report, we have asked the question: Would effective operational delivery of the roles and responsibilities described here ensure the earlier identification of potential failings in patient care and action to protect patients?

1.16 We believe the system described in this report, if implemented consistently and openly by all parts of the NHS, should fulfil this purpose. However, the journey for improved quality is a constantly moving target and this is a new and evolving system. The descriptions in this report represent where the NHS is now and will be in the near future. Given that some elements are not yet in place, the roles and responsibilities described will need to be periodically reviewed to ensure that the system is indeed safeguarding patients.

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9 Indicators for Quality Improvement can be found on the NHS Information Centre’s website: https://mqi.ic.nhs.uk/

10 Commissioning for Quality and Innovation payment framework.

11 As the majority of English NHS trusts currently report such incidents to the National Patient Safety Agency (NPSA), their reporting requirements can be met by continuing to report, as defined in the CQC’s guidance on compliance with *Essential standards of quality and safety*, via NPSA reporting systems. The NPSA will then forward information as appropriate to the CQC.
Chapter 2: Putting patients first: A culture of open and honest cooperation

2.1 The serious failures at Mid Staffordshire NHS Foundation Trust did not occur simply because of a breakdown in the formal systems and processes in place for safeguarding quality. As Dr Colin-Thomé found through his review, they occurred largely because the culture of the organisation did not prioritise providing high quality care to the patient; staff were not encouraged to be open and to learn from mistakes; and the mechanisms to listen to patients and take real notice of patient experience were poor or inadequately used.

2.2 These findings chime with our own assessment of what is important for preventing serious failures in the NHS in the future. We are clear that the scale and complexity of the NHS system means that formal mechanisms for safeguarding quality are essential and that these need to be underpinned by clarity around roles and responsibilities. Chapters 4, 5 and 6 of this report cover this in detail. However, the values and behaviours of individuals and the culture of the organisations they work within are as important, if not more so, in preventing serious failure.

2.3 This chapter looks at what it means to put patients first and the culture that is needed right across the NHS system to make this a reality.

Putting patients first

2.4 The basic principle must be that the patient, and the journey of the patient through the care process, should be the primary concern of all individuals and organisations.

2.5 Patients, users and carers are the reason for the NHS existing and its staff being employed, and as such must be at the centre of all that the NHS and its staff do. There can be no caveats on this principle. As the NHS Constitution states:

“The NHS belongs to the people.”

2.6 The patient’s care pathway is therefore crucial. Pathways of care are the mechanism for navigating patients between self and primary, social and acute care. It is this journey through the system that will determine the patient’s overall experience of the treatment and care that they receive. Pathways of care should meet the needs of the patient – the patient should not be inconvenienced by a fixed or inflexible pathway of care. There must, of course, be standardisation in pathways to deliver best

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value for money, but in commissioning services, PCTs should commission pathways that deliver high quality care to patients.

2.7 Most fundamentally of all, the quality of care provided to patients should never be compromised by the ambitions or management pressures of the organisations commissioning or providing the services. This does not mean, for example, that they should disregard the need to deliver value for money, but rather that the survival or profitability of the organisation should not be the principal driver for providers or commissioners in providing care to patients. Organisations need to look beyond their organisational boundaries and concerns about their autonomy, and always consider the needs of the patient first.

A culture of open and honest cooperation

2.8 An organisation that is truly putting patients first will be one that embraces and nurtures a culture of openness and learning.

2.9 The NHS is a complex system, not a single organisation; therefore, this culture needs to reach beyond organisational boundaries. The whole system – from individual clinicians to politicians in government – has a part to play in fostering a culture of openness, transparency and cooperation. We need to shift the culture of the system from one of reluctance and blame, where failings automatically result in a race to point the finger, to one of openness, learning and continuous improvement.

Safety in high risk systems

The openness of a culture – its ability to support the exchange of information at all levels, without fear, and against authority gradients – is known to be associated with safety in high risk systems. So-called ‘high reliability organisations’ have been found to exhibit at least five characteristics related to such openness and the actions that follow, and the findings have been generalised to healthcare settings. The five characteristics are:

- a constant awareness of the possibility of hazard and harm, and a sensitivity to early signs of failure;
- the willingness and capacity to look beyond first impressions, labels and old beliefs;
- an ability to remain closely in touch with activities and facts ‘on the ground’ in the daily operations of an organisation;
- support for continual learning, growth and adaptation, even under stress, as facts and contexts change; and
- valuing relevant knowledge, skills and observations, no matter where they lie in an organisation, even if at the lowest levels in a hierarchy.

2.10 But what does a culture of open and honest cooperation look like or mean for the NHS?

- Healthcare professionals and all NHS frontline staff feel able to raise concerns about the quality of care at an early stage.

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• **Clinical teams** understand the quality of service they are providing to patients through routinely measuring and benchmarking their performance with peers across the three dimensions of quality – safety, effectiveness and patient experience.

• **Provider boards** see their fundamental role as ensuring high quality care for patients. As part of this, they routinely:
  – monitor the quality of care being provided across all services within the organisation;
  – challenge poor performance or variation in quality;
  – ask for help and raising concerns should significant problems arise;
  – incentivise and reward high quality care and quality improvement;
  – work with other health and social care organisations to ensure that care is centred on people’s needs; and
  – foster a culture of openness and transparency throughout their organisation.

• **System managers and regulators** work together to share information and intelligence on risk; be seen as a source of advice and support in the event of concerns being raised; and visibly work together to support improvement where potential or actual failures in the quality of care being provided to patients are identified.

• **All parts of the system** are actively listening to and proactively engaging with patients and the public to understand concerns.

2.11 This last point – all parts of the system actively listening to and proactively engaging with patients and the public – is a critical part of putting patients first and forms a crucial component of the early warning system for detecting serious failure described in this report. Further consideration is given to this in Chapter 3.

2.12 Above all else, bringing about this culture relies on strong leadership throughout the NHS and across its organisations. However, a number of new developments, as set out in Chapter 1, will support this culture to grow. For example:

- **Quality Accounts** will drive transparency on the quality of care being delivered across all services within an organisation.
- The assured menu of Indicators for Quality Improvement is providing healthcare professionals and clinical teams with access to data about the quality of care they are providing to patients.
- NICE quality standards will provide healthcare professionals, commissioners and patients alike with a common definition of what high quality care looks like. Where possible, they will be supported by national available indicators so that their implementation can be monitored.
Chapter 3:
Listening to patients, service users and the public

3.1 The previous chapter emphasised the importance of putting patients at the centre of all that the NHS does. This will never be achieved unless every part of the system proactively engages with and actively listens to patients, service users and the public. If NHS providers, commissioners, system managers and regulators are listening to and taking account of what patients and the public are experiencing, they will be able to drive quality improvement based on a better understanding of patient expectations and concerns. **Listening to patient and public concerns will help organisations identify potential risks before they become serious failures.**

3.2 The design of the system recognises the importance of patient and public engagement, and this chapter sets out, as a reminder, the duties and obligations that NHS organisations are under in this respect. The NHS Constitution also reinforces these requirements by committing to patients, service users and the public that:

> "The NHS also commits: to provide you with the information you need to influence and scrutinise the planning and delivery of NHS services (pledge); and to work in partnership with you, your family, carers and representatives (pledge).”

3.3 However, it is crucial that the whole system understands the importance of and value in fulfilling these responsibilities and does not merely seek to meet them in a tokenistic way. In the case of Mid Staffordshire NHS Foundation Trust, Dr David Colin-Thomé’s review found that:

> "A lack of good patient engagement is the key to why Mid Staffordshire hospital trust continued to provide poor care for a protracted period of time.”

**NHS obligations**

**NHS duties of involvement**

3.4 The NHS Constitution clearly sets out how the NHS must take into account the needs of the local population and commits the NHS to being transparent in how decisions are reached:

> "You have the right to be involved, directly or through representatives, in the planning of healthcare services, the development and consideration of proposals for changes in the way those services are provided, and in decisions to be made affecting the operation of those services."

> "You have the right to expect your local NHS to assess the health requirements of the local community and to commission and put in place the services to meet those needs as considered necessary."
Listening to patients, service users and the public

“The NHS also commits: to make decisions in a clear and transparent way, so that patients and the public can understand how services are planned and delivered (pledge).”

3.5 This commitment is underpinned by Section 242 of the consolidated National Health Service Act 2006, which places a duty on NHS trusts, NHS foundation trusts, PCTs and SHAs to make arrangements to involve patients and the public in:

- the planning of service provision;
- the development and consideration of proposals to change service provision; and
- decisions that affect the operation of services.

3.6 All NHS trusts providing services will also have to meet the relevant registration requirement on ‘respecting and involving service users’. This requirement means that people who use services:

- understand the care, treatment and support choices available to them;
- can express their views, so far as they are able to do so, and are involved in making decisions about their care, treatment and support;
- have their privacy, dignity and independence respected; and
- have their views and experiences taken into account in the way the service is provided and delivered.

3.7 The CQC will be monitoring compliance with this and other registration requirements as part of the new registration system (see Chapter 4).

3.8 Good engagement by all NHS bodies requires them to build and maintain sound working relationships with their local population. This means listening to and acting on what people say about their care. Real Involvement,14 the guidance for NHS organisations published in October 2008 on Section 242, explains what a high performing organisation looks like.

3.9 The accountability of the NHS to its local population is being strengthened further with the introduction in April 2010 of a duty to report on consultations in relation to commissioning decisions. This will apply to PCTs, requiring them to produce and publish reports once a year on any consultations that have influenced their commissioning decisions; and to SHAs in relation to their own consultations.

World Class Commissioning

3.10 World Class Commissioning, the three-year capability and capacity-building programme for commissioners, sets out how PCTs should fulfil their duty of involvement. Competency 3 (‘Engage with public and patients’) of the World Class Commissioning Assurance Framework explains that commissioners act on behalf of the public and patients. They are responsible for investing funds on behalf of their communities, and building local trust and legitimacy through the process of engagement with their local population. In order to make commissioning decisions that reflect the needs, priorities and aspirations of the local population, PCTs will engage with the public and actively seek the views of patients, carers and the wider community.

3.11 The relationship between commissioners and the public can therefore play a key role in terms of spotting and preventing serious failure at an early stage. As part of their dialogue with

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14 Real Involvement: working with people to improve services, Department of Health, 30 October 2008: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_089787
patients, PCTs should be taking account of concerns that are raised about providers and investigating them through the data they receive and routes open to them by way of their contracts with providers.

**Patient and public scrutiny**

**Local involvement networks (LINks)**

3.12 LINks are mostly made up of individuals and community groups who work together to improve local services. LINks have been set up to:

- cover all publicly funded health and adult social care services in the local authority area;
- provide the local population with a mechanism to monitor and review local care services;
- actively canvass people for their views and experiences of local care services; and
- encourage and support more people to get involved in shaping services in their local area.

3.13 In relation to supporting service changes, LINks have a role in:

- routinely asking local people what they think about local health and social care services and suggesting improvements directly to the service providers and commissioners;
- identifying specific issues, and making recommendations to commissioners and service providers;
- requesting information about local health and social care services when the community raises concerns;
- entering and viewing premises to see if services are working well; and
- referring issues to the local overview and scrutiny committee if it seems that action is not being taken; and

- providing assurance from April 2010 that providers’ Quality Accounts are representative of the services they provide.

3.14 **When LINks make recommendations for changes or improvements, services must respond.**

3.15 There are now 150 LINks and it is estimated that they involved around 30,000 local people and organisations in their work during 2008/09.

**LINks in action**

Since their introduction in 2008, communities have already seen the benefits of being involved with their LINk, with positive changes being made to the way their health and care services are run. For example:

- Norfolk LINk has put an extra level on consultation requirements around service changes to guarantee services for ME sufferers are not changed or removed without their go-ahead.
- Dorset LINk has facilitated a review of dementia services.
- Merton LINk has ensured that breast-screening services provide materials in Braille for the visually impaired.
- Sutton LINk has set up a language project for women to help give newly arrived communities better access to health services.

**Health overview and scrutiny committees (OSCs)**

3.16 Since January 2003, every local authority with social services responsibilities (150 in all) has had the power to scrutinise local health
services. Health OSCs provide a mechanism by which local authority members can scrutinise the NHS. The powers of overview and scrutiny of the NHS enable committees to review any matter relating to the planning, provision and operation of health services in the area. **OSCs bring democratic accountability into healthcare decisions and make the NHS more publicly accountable and responsive to local communities.**

3.17 Health OSCs have powers to:

- set their own priorities for scrutiny, reflecting the interests of their own communities;
- refer contested service changes to the Secretary of State for Health on the grounds of inadequate consultation or the merits of a proposal; and
- call NHS managers to give account and information about services and decisions.

3.18 There is strong evidence that since their introduction, OSCs have helped to improve both the quality of services and the experience of people who use them. From April 2010, both OSCs and LINks will also be given the opportunity to provide assurance that providers’ Quality Accounts are representative of the services they provide.

**Public involvement in regulation**

3.19 The Health and Social Care Act 2008 (the Act creating the CQC) sets out requirements on the CQC to involve patients and the public in its regulatory activities, including that it must:

- focus on the needs and experiences of people who use health and social care services;
- have regard to the views and experience of people who use services;
- have regard to the views and opinions of LINks;
- have regard to the need to protect and promote the rights of people who use services; and
- publish a statement on how it will engage with patients and the public.

3.20 The CQC’s **Voices into Action**\(^{15}\) gives details of how the CQC engages with and listens to people in exercising its regulatory functions. These include:

- having at least one member with experience as a service user on the CQC board;
- having service users represented on various working groups that steer day-to-day business or advise on special projects;
- conducting regular studies on patient experience of services and carrying out in-depth studies of different aspects of the services that matter to people;
- when assessing services, considering how they involve people, looking for best practice in involvement and evidence of what services have done differently as a result, and how involvement has improved services;
- ensuring that its communications are easily understood by people, are relevant to things that matter to them and make clear how people can be involved; and
- when consulting on specific policies or issues, consulting both formally (by publishing a consultation document to which anyone can respond) and informally (by engaging with interested parties).

\(^{15}\) **Voices into Action: how the Care Quality Commission is going to involve people**, Care Quality Commission, June 2009: www.cqc.org.uk/_db/_documents/A4_Report_2009_01.pdf
Public involvement in NHS foundation trusts

3.21 The legislation enabling the establishment of NHS foundation trusts provides them with independence from central government and sets out a governance structure that makes them accountable to the local communities that they serve through their members and governors.

Members

3.22 Anyone who lives in the area, works for an NHS foundation trust or has been a patient or service user may become a member of the trust. All NHS foundation trusts have a duty to engage with their local communities and encourage local people to become members of the organisation. NHS foundation trusts are required to take steps to ensure that their membership is representative of the communities they serve.

3.23 Members belong to various ‘constituencies’ as defined in each NHS foundation trust’s constitution. An NHS foundation trust must have a public constituency and a staff constituency, and may also have a patients’ (or service users’) constituency. There are approximately 1.6 million NHS foundation trust members in England.

Governors

3.24 Governors of NHS foundation trusts comprise elected and appointed individuals who represent members and stakeholder organisations on a board of governors. The board of governors should hold the trust’s board of directors collectively to account for the performance of the trust. This structure gives accountability both to taxpayers and to patients and their families. NHS foundation trust members can elect any of their number to be a governor. It is a legal requirement that the majority of members on the board of governors be elected by the public and patients’ (or service users’) constituencies.

3.25 In addition to the locally elected governors (public governors), NHS foundation trusts also have stakeholder governors and staff governors. The legislation requires that an NHS foundation trust appoint certain key stakeholders, such as representation from a PCT that commissions services from the trust and the local authority. The NHS foundation trust must also have at least three staff governors. The NHS foundation trust’s constitution will also set out key stakeholders who are entitled to appoint representatives to the board of governors. These distinct yet interrelated governor groups ensure that all relevant interests are represented and allow full participation in the overall governance process. The statutory powers of the board of governors include the appointment and, if appropriate, the removal of the non-executives (including the chair) of the NHS foundation trust board.

Strengthening engagement with patients and the public

3.26 This chapter has set out many ways in which patients, public and service users can get involved in, and hold to account, their local NHS organisations. However, we think it is important to gain a better understanding of whether the combined effect of these and other patient feedback mechanisms are providing a sufficient voice to patients and the public. We therefore recommend that we, as members of the NQB, conduct a review of these mechanisms with a view to understanding where they are working well, where more may need to be done and how their outputs are connecting with trust boards and the decision making process. As some of these mechanisms are still
relatively new or will shortly come into effect, we recommend waiting six months before starting this review.

3.27 We have also identified an emerging area which provides new opportunities for strengthening the accountability of healthcare providers to the patients and public they serve. Quality Accounts, annual reports to the public from local NHS organisations about the quality of healthcare services they provide, will ensure that the leadership of organisations is fully engaged in reviewing the quality of healthcare services and in setting priorities for improvement. We therefore believe that the introduction of Quality Accounts this year provides an important mechanism for patients and the public to hold providers to account and acknowledge the role that has already been given to LINks and OSCs in assuring a provider’s Quality Account.

3.28 The Department of Health will be evaluating the impact of the first Quality Accounts in summer 2010. As part of that evaluation, we recommend that the Department assesses how effectively users of services and wider stakeholders have been involved in determining the priorities for improvement set out in the Quality Accounts and in decisions affecting quality of healthcare services, and how effectively organisations act upon patient feedback. Where possible, this should also include exploring the potential for providers to account for improving the patient experience through respecting and involving service users.

3.29 Services should be designed following engagement with patients, making use of the formal mechanisms set out in this chapter. However, relying on patients alone to hold the system to account, even with the major increases in information being made available, cannot be sufficient. There will always be an asymmetry of information and understanding on the part of patients compared with others who work in or with the system. There must be a robust performance and regulatory framework in place to safeguard patients. This is described in the next chapter.
**Chapter 4: The performance and regulatory framework for safeguarding quality**

4.1 In the previous chapters, we emphasised the importance of all staff exhibiting the values and behaviours that put patients first. For individuals, within organisations and across the system as a whole this means embracing an open and learning culture and a constant willingness to listen to and hear what patients and the public are saying about services. These are vital elements of the early warning system for serious failure.

4.2 However, the provision of healthcare is complex. It is delivered by healthcare professionals working in clinical teams, within organisations that are part of a wider regional and national health economy. The delegated system of healthcare in England, and the scale of public investment in the NHS, make it necessary to have appropriate governance at local, regional and national levels to assure quality of care for patients and value for money for the taxpayer. The system should not rely solely on patients and the public to be the source of information on poor performance.

4.3 This chapter describes the performance and regulatory framework for both healthcare organisations and healthcare professionals to demonstrate their roles in safeguarding quality.

**Regulation and performance management of healthcare organisations**

4.4 From April 2010, the regulatory and performance frameworks will place three core requirements on NHS healthcare providers in relation to quality:

- A requirement, from April 2010, to meet the essential levels of safety and quality set by the new system of registration – this is a legal requirement set out in the Health and Social Care Act 2008. It will be built into the national standard contract between commissioners and providers of care and the NHS Performance Framework for NHS trusts (and, for foundation trusts, into their terms of authorisation). These essential levels of safety and quality are also known as registration requirements.

- A requirement to meet national priorities as set by the NHS Operating Framework for England – national priorities are determined by the Secretary of State and are published annually in the NHS Operating Framework. Performance against these is then built into:
  - the national standard contract;
  - the NHS Performance Framework for NHS trusts and Monitor’s Compliance Framework for foundation trusts; and
The performance and regulatory framework for safeguarding quality

- the CQC’s periodic review of all NHS organisations.

- A requirement to meet all other contractual obligations (over and above registration and national priorities) – these may be locally or regionally determined and will be built into contracts between commissioners and providers of care as appropriate.

4.5 Our review has principally focused on the roles and responsibilities of all players in the system in relation to the first core requirement (compliance with registration requirements). Through setting out the essential levels of quality and safety, the new system of registration, by definition, sets a bar for quality. This in turn helps to define what constitutes a serious failure, i.e. where there are significant and sustained breaches in compliance with registration requirements.

4.6 Any failure by a provider to meet the second core requirement (national priorities) will be routinely managed by PCTs and SHAs (and Monitor in the case of NHS foundation trusts). Any failure by a provider to meet the third core requirement (any contractual obligations over and above registration and national priorities) will routinely be managed by PCTs through contract management processes.

4.7 The system of registration, including its relationship with the NHS Performance Framework, Monitor’s Compliance Framework for NHS foundation trusts and the contract management function of PCTs, is explained in more detail in this chapter.

Figure 2: Essential levels of quality and safety – the new system of registration

<table>
<thead>
<tr>
<th>Registration Requirements</th>
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</thead>
<tbody>
<tr>
<td><strong>The Health and Social Care Act 2008 introduced registration requirements setting out essential levels of quality and safety in the following areas:</strong></td>
</tr>
<tr>
<td>• Care and welfare of service users</td>
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<tr>
<td>• Respecting and involving service users</td>
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<tr>
<td>• Assessing and monitoring quality</td>
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<tr>
<td>• Consent</td>
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<td>• Safeguarding</td>
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<td>• Complaints</td>
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<td>• Cleanliness and infection control</td>
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<td>• Records</td>
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<td>• Staffing</td>
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<tr>
<td>• Equipment</td>
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<tr>
<td>• Cooperating with other providers</td>
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</tbody>
</table>

Statutory guidance about compliance with registration requirements has been issued by the Care Quality Commission with more detail on the requirements under each area.16

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Registration

4.8 Subject to final Parliamentary approval, full registration of NHS providers by the CQC will come into effect from April 2010. Registration requirements have been set out in primary and secondary legislation and cover 16 areas in which providers will be expected to meet essential levels of quality and safety (see Figure 2). Independent healthcare providers will be registered against these requirements from October 2010, replacing the previous service-specific regulations and national minimum standards against which they are currently registered.

4.9 To provide more detail on what these essential levels of quality and safety entail, the CQC has published Guidance on Compliance.17

4.10 The new system of registration marks a significant shift for NHS providers and independent providers of healthcare. For the NHS, the previous system of compliance with core standards of care (known as Standards for Better Health) overseen by the Healthcare Commission had a strong component of self-declaration and was largely self-reported and retrospective. The new registration requirements and the guidance on compliance place a far greater focus on outcomes and people’s experience of care.

4.11 The new system will enable the CQC to provide dynamic, up-to-date assurance that essential standards are being met, based on the latest available information and intelligence, including from inspection. Providers are required to focus on positive outcomes for people who use services when assuring themselves of their standards of care.

Registration and serious failure

4.12 Where services fall below the essential levels of safety and quality, the CQC has a

Figure 3: Comparison of regulatory enforcement powers

| The Healthcare Commission could only issue an improvement notice where an NHS provider failed to comply with the code of practice on the prevention and control of healthcare-associated infections. In cases of serious service failings in any other area, the Commission could recommend that the Secretary of State place a provider in ‘special measures’. |
| From 1 April 2010, the CQC will be able to take direct enforcement action against any NHS provider that fails to meet any of the essential levels of safety and quality set by the system of registration. The CQC has a range of enforcement powers that it can use. It can: |
| • issue a warning notice; |
| • impose, vary or remove conditions on registration; |
| • issue a monetary penalty notice; |
| • suspend registration; |
| • prosecute for offences; and |
| • cancel registration. |

range of enforcement powers that it can use in relation to providers of care (described further in Chapter 5). Figure 3 shows how these powers compare with those held by the Healthcare Commission.

4.13 Most incidents of non-compliance with the registration requirements will not mean that a serious failure is occurring within the organisation concerned (i.e. that there are systemic failures within the organisation). For instance, a breach may be minor in terms of its impact on the people who use the service or only temporary where the organisation takes swift remedial action.

4.14 However, wherever a trust experiences significant and sustained breaches of one or more of the registration requirements, this will signal systemic problems within the organisation. An organisation that is fully and genuinely compliant with registration should, therefore, be able to minimise its risk of falling into serious systemic failure.

4.15 The system of registration is central to categorising serious failure within provider organisations and, as such, provides an anchor point for the early warning system we describe in this report.

4.16 Compliance with registration is the responsibility of the provider board. The board should routinely monitor the services it provides to ensure that its organisation remains compliant with registration requirements at all times and takes action where concerns about compliance are identified. To provide assurance around a provider's registration status, the CQC will monitor compliance on an ongoing, real-time basis. In doing so, the CQC will bring together a range of information from service users, other regulatory and external bodies, and national data sets through its Quality and Risk Profile System (QRPS); assess where risks lie; and prompt frontline regulatory activity, such as inspection, where risks may be heightened. While compliance should not be seen as an end in itself, it is a means for ensuring patient safety.

4.17 This report explains the CQC’s role more fully in Chapter 5 and the QRPS in Chapter 6.

Registration and performance management

4.18 So as to strengthen alignment across the system, the need to comply with registration requirements will become a core part of the following:

- **The NHS Performance Framework for NHS trusts** – this sets out the way in which NHS providers (excluding NHS foundation trusts) are performance managed. The framework identifies underperformance using a series of indicators from across the domains of finance, operational standards and targets, quality and safety, and user experience. Performance against the quality and safety domain of the framework will be informed by a trust’s registration status, as judged by the CQC. The framework is intended to ensure early intervention by describing when, but not how, SHAs and PCTs should intervene. This will become fully operational from April 2010.

- **Monitor’s Compliance Framework for NHS foundation trusts** – Monitor assures itself that NHS foundation trusts are adhering to their terms of authorisation (the conditions on which they are given NHS foundation trust status) through the Compliance Framework. It seeks to ensure that NHS foundation trusts are well led, financially robust and legally sound. The Compliance Framework will be amended for 2010/11 to reflect changes that will be in place from 1 April 2010, including registration. Registration requirements will be reflected in all NHS foundation trusts’ terms of authorisation and ongoing compliance.
monitored through the Compliance Framework. Monitor will look to the CQC for judgements on whether registration requirements are being met by NHS foundation trusts.

- **Contracts with providers** – PCTs use contracting to commission services from healthcare providers. Compliance with registration will form part of all contractual agreements made between commissioners and providers of NHS care through inclusion in the national standard contract. Although PCTs will look to the CQC for assurance about a provider’s registration status, their proximity to and relationship with the provider organisation will mean that they are well placed to spot the early signs of non-compliance with registration requirements.

**Regulation of healthcare professionals**

4.19 The first part of this chapter has set out the performance and regulatory frameworks in place for safeguarding quality at organisational level. However, the regulation of individual healthcare professionals is equally important in terms of safeguarding patients.

4.20 There are nine UK health professions regulators which are responsible for setting standards of competence, practice, conduct and ethics for all registered healthcare professionals. Although the codes of conduct for the different professional groups all vary to some extent, broadly speaking all registered healthcare professionals must:

- ensure that patient safety and patient interests are paramount;
- take action to protect patient safety, including reporting concerns about patient safety/the actions of colleagues where necessary; and
- protect confidentiality where any concerns are raised.

4.21 Where healthcare professionals fail to observe the standards required of them, action may be taken against them by their regulatory body.

4.22 Professional standards and obligations will be strengthened by the new revalidation system for doctors, which will become operational in 2011/12. From October 2010, subject to Parliamentary approval, all licensed doctors who provide healthcare or set policy and standards for the delivery of healthcare will be linked with a named responsible officer. The remainder of this chapter explains these developments and how they will add to the early warning system for identifying serious failures in the NHS.

**Revalidation**

4.23 The purpose of revalidation is to ensure that licensed doctors are up to date and fit to practise, with the twin objectives of improving quality and increasing patient safety. It will help doctors to meet their personal and professional commitment to continually improve and update their skills.

4.24 Revalidation will comprise an annual appraisal of a doctor’s skills, over a five-year cycle, leading to a formal statement of suitability of revalidation, and subsequent relicensing by the GMC. Revalidation will normally be based on the evidence of five satisfactory annual appraisals. There will be a new, strengthened appraisal system, based on the requirements of the GMC’s *Good Medical Practice*,18 as well as the new role of responsible officer, a key contact who will liaise with the

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18 Good Medical Practice: www.gmc-uk.org/guidance/good_medical_practice.asp
GMC and make recommendations on the relicensing of individual doctors.

4.25 Revalidation will, therefore, provide an objective process for doctors to demonstrate that they remain up to date and fit to practise. It will include remediation and rehabilitation to provide help for those few who struggle to meet the standards required for revalidation and relicensing.

4.26 A key milestone on progress towards revalidation was the introduction of licences to practise by the GMC in November 2009. To practise medicine in the UK all doctors are now required by law both to be registered and to hold a licence to practise. The revalidation system will be in operation from 2011/12, building on learning from a set of pilots currently in progress.

**Responsible officers**

4.27 From October 2010, subject to Parliamentary approval, all licensed doctors who provide healthcare or set policy and standards for the delivery of healthcare will be linked with a named responsible officer, likely to be the medical director within an NHS trust or NHS foundation trust.

4.28 Responsible officers will have a key role in the oversight of doctors and improving the quality of care they provide. They will strengthen local clinical governance by taking on an important role in the evaluation and conduct of doctors. Responsible officers will be under a statutory duty to cooperate with the GMC to provide the fair and effective regulation of doctors.

4.29 The responsible officer will evaluate the fitness to practise of doctors and monitor the conduct and performance of doctors connected with their particular organisation. They will also be responsible for making a recommendation to the GMC on whether a doctor should be revalidated.
Chapter 5:
Roles and responsibilities throughout the system

5.1 Chapter 4 provided an overview of the performance and regulatory framework that will be in place for safeguarding quality from April 2010. This chapter now seeks to provide greater clarity around the roles and responsibilities of individuals and organisations throughout the system in relation to safeguarding quality.

5.2 Figure 4 sets out schematically how the organisational tiers within the NHS interact with each other in respect of safeguarding quality. This illustrates the checks and balances, reporting lines and complexity of the system. The diagram does not seek to provide a comprehensive account of all functions of the component organisations.

Figure 4: Structures and processes for safeguarding quality in the NHS

1 Performance management and SHA assurance framework
2 For example, overview and scrutiny committees
3 World Class Commissioning Assurance Framework
4 Performance Framework
5 Contract management
6 Foundation trust members
7 Terms of authorisation/Compliance Framework
8 Registration criteria
9 For example, local involvement networks
Providers

5.3 Healthcare professionals and clinical teams are the first line of defence and boards are ultimately responsible for safeguarding quality of care, whether the organisation is an NHS trust, NHS foundation trust, PCT provider arm, or independent sector organisation.

NHS staff and healthcare professionals

Healthcare professionals are the first line of defence. They have a key role in ensuring safe care through their own actions and in striving to improve the quality of care to patients.

- Professional standards require clinicians to make the care of their patients their first concern and to protect and promote the health of patients and the public in all that they do.
- The system of professional regulation places an obligation on healthcare professionals to raise concerns about patient and public safety.
- Professional standards and obligations will be strengthened by the new revalidation system.
- All staff working in the NHS have a responsibility to speak up should they have genuine concerns about patient safety.

5.4 Information about clinical performance is essential in order to safeguard quality of care to patients. Healthcare professionals have a professional obligation to know what they are doing and how well they are doing it. They need to ensure that the care they provide is safe and of a high quality through their own actions and, as part of a clinical team, by continuously striving to improve the quality of care in their pathway.

5.5 Healthcare professionals are subject to professional obligations in relation to quality and safety. All regulated healthcare professionals must abide by standards of professional practice, conduct and ethics set by their regulatory bodies. These professional standards require clinicians to make the care of their patients their first concern and to protect and promote the health of patients and the public in all that they do. This includes an obligation on registered healthcare professionals to raise concerns about patient and public safety.

5.6 Healthcare professionals, and all NHS staff, should raise any concerns they may have about the quality of care to patients with their team leader or manager in the first instance. Concerns should be addressed wherever possible by teams working to improve the quality of care they are providing. There may be instances where action cannot be or is not taken at team level. In which case, individuals or team leaders should look to the appropriate member of the trust senior management or board, and potentially the relevant professional body, for support and/or to take action.

5.7 Healthcare professionals and all NHS staff are also entitled to the protection of the ‘whistleblowing’ provisions of the Employment Rights Act 1996, as amended by the Public Interest Disclosure Act 1998. While the Act does not require organisations to have
‘whistleblowing’ policies in place, the Department of Health has made it clear that every NHS trust should do so. The NHS Constitution protects NHS staff should they raise concerns:

“Right: To protection from detriment in employment and the right not to be unfairly dismissed for ‘whistleblowing’ or reporting wrongdoing in the workplace.

“What this right means for staff: If staff follow procedures laid down in Public Interest Disclosure Act 1998, they will be protected against ‘whistleblowing’. There is also a confidential helpline that staff can use when considering ‘whistleblowing’, which is run by Public Concern at Work and staffed by legal experts. The helpline number is 020 7404 6609.”

5.8 Professional standards and obligations will be strengthened by the new revalidation system for doctors which will become operational from 2011/12, as explained in the previous chapter.

5.9 It is not just the responsibility of doctors, nurses and other healthcare professionals to safeguard the quality of care to patients. All staff working in the NHS have a responsibility to speak out should they have genuine concerns about patient safety, and the NHS organisations in which they work have a responsibility to listen to these concerns. There needs to be a constant awareness of the possibility of hazard and harm and a sensitivity to early signs of failure on the part of all staff. This includes following local and national guidance on identifying and reporting patient safety incidents to the National Patient Safety Agency (NPSA) and complying with national patient safety alerts.

5.10 In relation to managers of clinical care, the report of the Advisory Group on Assuring the Quality of Senior Managers, due to be published shortly, aims to provide more effective safeguards against poor performance in senior positions and much more robust measures to prevent managers who are perceived to have failed from moving to other NHS jobs. At the same time, it seeks to assure and enhance the quality of the overwhelming majority of senior NHS managers who perform well.

If you have a concern, who do you tell?

If a member of staff has a concern about the quality of care in their clinical area or elsewhere, they should tell:

- in the first instance, their manager or clinical manager;
- if necessary, the appropriate member of the trust board;
- if appropriate, their professional regulatory body.

They should also report the incident via their local incident reporting system.

Clinical teams

All clinical teams should measure and benchmark the quality of their services across the three dimensions of quality (safety, patient experience and effectiveness).

- Team leaders should encourage team members to be open about their concerns and to seek to improve quality of care.
- In measuring the quality of their services, teams should make use of clinical audit findings, robust indicators of quality such as those available on the menu of Indicators for Quality Improvement, feedback from patients and local incident reports.
- They should use this information to continuously review and improve quality of care, and to identify potential failings and raise any concerns with clinical management and the board.

5.11 Clinical teams are the guardians of the care pathway. High Quality Care for All rightly highlighted that a key characteristic of high performing clinical teams is their desire to measure their performance and use the information to make continuous improvements. Although measurement at the level of the clinical team should be focused on delivering continuous quality improvements, it has a key role to play in identifying potential failings in patient care.

5.12 Clinical teams should measure and benchmark the quality of their services across the three dimensions of quality (safety, patient experience and effectiveness) through:

- effective use of national and local clinical audit programmes;
- other locally and nationally available quality indicators such as those included on the menu of Indicators for Quality Improvement;
- reviewing the contributory factors to and learning from safety incidents; and
- examining patient feedback and complaints.

5.13 They should then use this information to continuously improve quality of care and to identify potential failings.

5.14 Within a clinical team, managers provide a link between the board and the clinical team. The clinical management role in respect of safeguarding quality includes:

- ensuring that a culture of open and honest cooperation is fostered within the team;
- leading the development and implementation of clinical standards;
- providing clinical advice to the board;
- providing professional leadership, including implementing professional regulation standards through key governance activities, e.g. appraisals, supervisions; and
- leading and implementing clinical governance and quality processes.

If you have a concern, who do you tell?

If a clinical team or manager is concerned about their performance or the outcomes of care provided and is unable to address the issue quickly and effectively, they should tell:

- the medical/clinical director or director of nursing, who is ultimately responsible for taking leadership of the situation;
- the chief executive, who should work with the board and the clinical team to tackle performance issues; and/or
- the trust board, who is ultimately responsible for safeguarding patient safety within their organisation. They will work with the clinical team to tackle the issue and will need to take a view as to whether to involve others.

Indicators for Quality Improvement can be found on the NHS Information Centre’s website at https://mqi.ic.nhs.uk/
Boards of NHS provider organisations

Boards are ultimately responsible for the provision of high quality care in their organisation.

In safeguarding quality and safety, boards should be:

- ensuring that the essential levels of quality and safety are met through having appropriate systems and processes for monitoring quality in place; and
- driving continuous quality improvement across the full range of services through systematic measurement of quality.

Boards should also:

- foster a culture of openness and transparency around quality and incentivise quality improvement in every service line;
- engage in continuous dialogue with patients and the public including reporting publicly on quality of care through Quality Accounts;
- ensure mandatory reporting of serious incidents to the NPSA from 2010; and
- ensure that effective revalidation systems are in place within trusts for doctors from April 2010 through ‘responsible officers’.

5.15 Provider boards are ultimately responsible for the provision of high quality care in their organisations.

5.16 Every NHS trust in England will need to be registered by the CQC against the essential levels of quality and safety by April 2010. Some trusts may be registered with conditions, performance against which will be monitored by the CQC. Other types of provider organisation will need to be registered with the CQC in coming years. In any provider organisation (NHS trust, NHS foundation trust, independent provider, PCT provider arm), it is the board’s responsibility to ensure that its organisation is registered, and then that it continues to comply with registration requirements. As explained in Chapter 4, an organisation that is fully and genuinely compliant with registration requirements is less likely to experience a serious failure. In order to ensure compliance with registration requirements, an organisation will need to have effective information systems that allow them regularly to monitor and scrutinise performance against the essential levels of quality and safety across all clinical areas.

5.17 However, as is already the case in the best trusts, boards will need to do more than just monitor their achievement of these essential levels of quality and safety. The board must continuously drive for quality improvement throughout its organisation. If the board is setting clear objectives for improving quality and safety, and routinely paying attention to quality across the spectrum of care provided to patients, it will be able to identify irregularities, dips in performance or potential concerns at an early stage and take remedial action. This continuous drive for improvement is at the heart of the early warning system for serious failure.

5.18 It will also be the responsibility of the board, through its responsible officer (the medical director in most cases), to ensure that effective revalidation systems are in place for doctors within the trust. This was explained in Chapter 4.
5.19 Processes are essential, but it is the values and behaviour displayed throughout the NHS that are critical to identifying and preventing potential serious failures. Boards of NHS provider organisations must lead and foster a culture of openness and transparency. They should:

- motivate and incentivise staff to strive for quality improvements in the care they are providing;
- encourage healthcare professionals and other staff to come forward with any concerns they may have;
- be open with patients and their families when mistakes have been made;
- take account of staff satisfaction and staff survey information, as these may provide insight into areas of concern;
- facilitate mature discussions should concerns be raised; and
- take proportionate action as a result.

5.20 Patients, service users and the public should be at the centre of all that NHS organisations do. Patient experience is often an excellent indicator of the quality of a service. It is essential that provider boards take regular and conscious account of what patients are saying about the provision of care in their organisations. As was the case in Mid Staffordshire, patient concerns about safety are often a timely and accurate indicator of where things are going wrong. Chapters 2 and 3 explained how patients and the public can be involved in the NHS, and how the NHS must engage with and listen to them.

5.21 From April 2010, all acute trusts in England will be required to publish a Quality Account at the same time as their financial accounts. The process of developing this Quality Account should include consultation with patients and the local public, and will reinforce the need for dialogue between trusts and the people who use their services. It will focus boards’ attention on a regular basis on quality of care in every service line.

5.22 The National Leadership Council will shortly be publishing a set of guiding principles on good governance for all NHS boards. It will emphasise that NHS boards have a key role in safeguarding quality and that their purpose is to govern effectively in such a way that the public can be confident.

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<thead>
<tr>
<th>If you have a concern, who do you tell?</th>
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<tr>
<td>Boards of NHS provider organisations are expected to and should be able to address and to rectify most concerns, notifying regulators and system managers as appropriate to the level of concern.</td>
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If a provider board is concerned about the organisation’s performance (including its ability to meet registration requirements) and is unable to address issues quickly and effectively, it should tell:

- **the PCT**, as the provider may be in breach of its contract. The PCT will be able to advise on how concerns can be addressed and will need to consider whether to involve others;
- **the SHA**, in the case of an NHS trust. The SHA is responsible for the operation of the NHS in the region and will need to ensure continuity of care for the population;
- **Monitor**, in the case of NHS foundation trusts. Monitor is responsible for ensuring that foundation trusts remain compliant with their terms of authorisation;
- **the CQC**, if it is concerned the trust is in breach of or likely to breach registration requirements, as the CQC is responsible for registering all providers.
5.23 **Commissioners and system managers (PCTs, SHAs and the Department of Health)** are responsible for securing the provision of high quality care at the local, regional and national levels.

**Primary care trusts**

PCTs commission services from registered providers to meet the needs of their populations.

- From April 2010 they will be under a new legal duty to secure continuous improvement in the quality of healthcare.

- They are responsible for managing contracts – having robust contract monitoring arrangements in place to assure themselves that providers are meeting their contractual obligations, including complying with registration requirements.

- They should perform as world class commissioners by striving to commission innovative, effective, high quality services that meet the needs of local populations.

- They should consult with the public on delivery and quality of care.

- They should develop and lead a culture of information sharing.

- They must work collaboratively with SHAs and regulatory bodies to understand and share information through informal and formal mechanisms.

5.24 **PCTs commission services from registered providers to meet the needs of their populations.** This involves assessing the needs of the local population and contracting with providers to meet these needs. From April 2010, PCTs will have a duty to make arrangements to secure continuous improvement in the quality of healthcare they provide themselves and in the quality of healthcare that is provided by the organisations they contract with (set out in Section 139 of the Health and Social Care Act 2008).

5.25 PCTs are responsible for managing contracts. To do this effectively, they must ensure that they have robust contract monitoring arrangements in place. These should include agreeing clear performance measures and reporting cycles; having fit-for-purpose data monitoring systems; and holding regular contract performance meetings with providers.

5.26 Through robust contract monitoring and the appropriate use of soft intelligence, for example of changes in management or recent reorganisations, PCTs will have access to the most up-to-date information and intelligence about providers and therefore play a vital role in detecting and preventing serious failures at an early stage. While it is for the CQC to make judgements on whether a provider is compliant with registration requirements, the PCT should be able to spot signs of non-compliance at an early stage and should inform the provider and the CQC as appropriate.
Roles and responsibilities throughout the system

5.27 PCTs should be striving to perform as world class commissioners by commissioning innovative, effective, high quality services that meet the needs of their local populations. They should strive to achieve the highest level of World Class Commissioning competencies: in relation to safeguarding quality, competencies 3, 4, 8 and 10 are particularly relevant.  

5.28 Again, it is important to recognise that systems and processes alone are not enough to safeguard quality. PCTs should be developing a culture of open and honest cooperation within and between the organisations that provide services to their populations. They also need to work collaboratively with SHAs and regulatory bodies to understand and share information on risk through informal and formal mechanisms. This may include the sharing of information for use in Planned Collaborative Reviews and Triggered Risk Summits as explained in Chapter 6.

5.29 Every PCT should have a process for reporting all serious incidents, including ‘Never Events’, to the PCT board, and have plans for recording ‘Never Events’ in its annual reporting arrangements. It also has a role in working with providers to commission independent investigations if there is a need to do so. The PCT should carry out regular thematic reviews of serious incidents to identify trends and patterns across the PCT.

If you have a concern, who do you tell?

If a PCT has a concern that a provider may be in breach of its registration requirements, it should inform:

- the **CQC**, as the organisation that makes judgements as to whether registration requirements are being met and whether enforcement action should be taken;
- the **SHA**, as the body responsible for the operation of the health service in its region, for holding PCTs to account for the quality of services that they commission and for managing the performance of NHS trusts;
- **Monitor**, in the case of NHS foundation trusts, as the organisation responsible for ensuring that NHS foundation trusts remain compliant with their terms of authorisation.

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22 Competency 3 – Proactively seek and build continuous and meaningful engagement with the public and patients, to shape services and improve health.
Competency 4 – Lead continuous and meaningful engagement with clinicians to inform strategy, and drive quality, service design and resource utilisation.
Competency 8 – Promote and specify continuous improvements in quality and outcomes through clinical and provider innovation and configuration.
Competency 10 – Effectively manage systems and work in partnership with providers to ensure contract compliance and continuous improvements in quality and outcomes.
Strategic health authorities

SHAs are accountable to the Secretary of State for Health for the effective operation of the NHS in their regions.

- They do this by holding PCTs to account for commissioning appropriate services and ensuring that all providers perform against their contracts.
- They also hold NHS providers that are not NHS foundation trusts to account through the NHS Performance Framework.
- SHAs are responsible for improving PCT capability through the World Class Commissioning assurance process.
- They should be working collaboratively with the CQC and Monitor to understand and share information on risk through informal and formal mechanisms.
- In the event of a serious failure, SHAs have a vital role to play in ensuring continuity of care to patients.

5.30 SHAs are accountable to the Secretary of State for Health for the effective operation of the NHS in their region. They do this by holding PCTs to account for commissioning appropriate services and by assuring themselves that they are effectively managing the contracts they have with all providers. They also manage the performance of NHS providers that are not NHS foundation trusts through the NHS Performance Framework.

5.31 The NHS Performance Framework will be extended to PCT commissioners from April 2010 and will become part of the formal process through which SHAs manage the performance of PCTs as commissioners.

5.32 SHAs also have a role in driving up the capability of PCTs through the World Class Commissioning assurance process. By supporting PCTs in their efforts to improve, particularly in those competencies related to quality, SHAs will be strengthening the NHS’s ability to safeguard quality.

5.33 There may be times when an SHA will receive information concerning a provider which the PCT may not have or may not recognise as significant. They may also have intelligence that points to more systemic failures within a PCT area or the PCT itself. SHAs are therefore a vital part of the information landscape. They need to be working collaboratively with the CQC and Monitor to understand and share information on risk through informal and formal mechanisms, for example as part of Planned Collaborative Reviews, and can contribute to the CQC’s quality and risk profiles on provider organisations as appropriate (as described in Chapter 6).

5.34 As stated throughout this report, values and behaviours that put patients first are essential at every level in safeguarding quality. Strong leadership is needed to make these a reality. The SHA has a role in:

- providing leadership across the region to create a culture of open and honest cooperation between and within PCTs and providers;
- engaging in mature dialogue with their providers and PCTs about concerns either party may have; and
- demonstrating constructive relationships with the regulators through collaborative action to address areas of concern.
5.35 SHAs have a vital role in the event of a serious failure as they are accountable to the Secretary of State for the effective operation of the NHS in their regions. This is described further in Chapter 6.

If you have a concern, who do you tell?
If the SHA has a concern that a provider may be in breach of its registration requirements, it should inform:

- the PCT, if the concern is about an individual NHS trust or NHS foundation trust;
- the CQC, to warn that a provider may be in breach of registration requirements;
- Monitor, in the case of an NHS foundation trust, to warn that the provider may be in breach of its terms of authorisation;
- the Department of Health, as part of the performance management process for SHAs.

Department of Health

The Department of Health, through the Secretary of State for Health, is accountable to Parliament for the provision of care by the NHS.

- The Department of Health designs the health system. This includes setting:
  - registration requirements;
  - the NHS Performance Framework; and
  - national priorities and system levers, through the NHS Operating Framework.
- The Department devolves responsibility for the provision of healthcare to regional and local levels.
- The Department directly manages the performance of SHAs through formal accountability meetings and informal processes.
- The Department should work collaboratively with SHAs and regulatory bodies to understand and share information on risk through informal and formal mechanisms.

5.36 The Department of Health is the department of state for the NHS and adult social care. It supports Ministers in their accountability to Parliament for the NHS and its provision of high quality care to the population. It designs the health system and sets the strategic direction for the NHS. It achieves this by a number of means, including:

- setting national priorities, system levers and enablers through the NHS Operating Framework;
- setting the regulatory framework, including registration requirements which are regulated by the CQC;
Review of early warning systems in the NHS

- setting the performance criteria for the NHS Performance Framework, which exists to monitor and challenge the performance of NHS trusts and PCTs; and
- directly managing the performance of SHAs and working with them to improve their capability through the SHA assurance process.

5.37 Its role in the early warning system is to ensure that there are effective flows of information on emerging concerns and risks throughout the system and to provide national leadership for a culture of open and honest cooperation. It works collaboratively with SHAs and regulatory bodies to understand and share information on risk through informal and formal mechanisms.

5.38 The Department has statutory powers which it can use in the event of a failure. Under the National Health Service Act 2006, the Secretary of State can:

- direct NHS trusts (not NHS foundation trusts);
- remove the chair and/or non-executive director of the trust board (not NHS foundation trusts); and
- make an intervention order in relation to a PCT, SHA or NHS trust where they consider the body is not performing its functions adequately, or where there are significant failings in the way the body is being run. Such an order might include removing or suspending some or all board members, and/or requiring the body to delegate functions to a third party.

Regulators

5.39 The regulators ensure that providers are adhering to their statutory obligations.

Care Quality Commission

The CQC is the regulator for health and adult social care in England.

- The CQC registers all providers of health and adult social care against registration requirements, and attaches conditions to registration where appropriate.
- It monitors ongoing compliance with the registration requirements and takes enforcement action if providers fail to meet these requirements.
- The CQC undertakes periodic reviews of NHS and adult social care organisations.
- The CQC makes information about the quality of services publicly available.
- It works collaboratively with other regulatory bodies and partners to understand and share information on risk through informal and formal mechanisms, and to avoid duplication in regulatory activity.

5.40 The CQC is the regulator for health and adult social care in England. It promotes the rights and interests of people who use these services, and has a wide range of powers to take action on their behalf. The CQC’s overall purpose is to encourage: improvement in the quality of care; the provision of services according to the needs and experiences of people using those services; and, the efficient
and effective use of resources. It does this through a range of activities, including:

- registering health and adult social care services, ensuring that essential levels of quality and safety are being met wherever care is provided;
- ongoing monitoring of providers, to check that they are meeting essential levels of quality and safety, using planned and responsive reviews of compliance, including site visits;
- using a range of enforcement powers to take swift, effective action where services are failing people;
- carrying out reviews of services to assess how well those providing and arranging services locally are performing, and to help them improve;
- where necessary, carrying out in-depth reviews of particular services, pathways of care, or areas where there are particular concerns about quality; and
- visiting patients whose rights are restricted under mental health legislation, to ensure that their rights are being protected.

5.41 The CQC’s regulatory activities are targeted and based on an assessment of risk. This means that the CQC will be most active in areas where the risks of harm are greatest, where people are less able to assert their rights, where information on the quality of care is poor, or where providers of services are failing to improve.

5.42 The CQC has a range of enforcement powers in relation to providers of care. These include statutory warning notices, penalty notices, suspension and cancellation of registration, and prosecution for specified offences. The primary concern is to protect the people who use services. Any enforcement action will be proportionate to the risk posed to people and the seriousness of any breach of the law.

5.43 The CQC aims to work closely with SHAs as the performance managers of PCTs and NHS trusts (not NHS foundation trusts), and with Monitor as the independent regulator of NHS foundation trusts, so that there is agreement on who is best placed to take any action in response to specific concerns.
Monitor

Monitor sets the regulatory and reporting framework, including terms of authorisation, for NHS foundation trusts.

- Monitor authorises NHS trusts as NHS foundation trusts and will be able to effect de-authorisation in cases of serious failure.
- It sets out requirements placed on NHS foundation trusts in its Compliance Framework (which includes compliance with registration requirements) and other regulatory documents and monitors compliance.
- Monitor can intervene as appropriate to ensure timely and successful rectification of significant breaches of terms of authorisation. Monitor will look to the CQC for judgements as to whether registration requirements are being met.
- Monitor ensures that NHS foundation trust boards are governing the trust effectively, including on matters of clinical quality.
- It works collaboratively with other regulatory bodies and partners to understand and share information on risk through informal and formal mechanisms.

5.44 Monitor is the independent regulator of NHS foundation trusts. Its role is to make sure that NHS foundation trusts are well led, are legally set up and run, and have their finances in good order. It approaches this task by regulating NHS foundation trusts in proportion to the risks they face, and by placing responsibility for performance and resolution of problems firmly on trust boards.

5.45 There are three main strands to Monitor’s role:
- determining whether a trust is ready to become an NHS foundation trust;
- ensuring that NHS foundation trusts comply with the terms and conditions of their authorisation and, where they are not, taking regulatory action to achieve compliance; and
- supporting the development of NHS foundation trusts.

5.46 As Monitor’s regulatory approach is proportionate to risk, successful well-governed trusts that demonstrate a low risk of breaching terms of authorisation are required to provide limited information and so will expect to have less contact with Monitor. Where the reverse is true, the intensity of regulatory review and the potential for action will increase proportionately to the risk of non-compliance.

5.47 Governance of clinical quality and patient safety are included as one of the seven elements of Monitor Compliance Framework. Specifically, boards of NHS foundation trusts are asked to certify that they have and will keep in place effective arrangements to monitor and improve the quality of healthcare provided to patients; and that they are currently, and have sufficient plans in place to continue to be, registered with the CQC. Additionally, Monitor:
- may require additional assurance, with the potential for further regulatory action, where third-party reports and intelligence (e.g. from the CQC or PCTs) indicate that the basis for self-certification may be incorrect; and
- regards risk of a failure to maintain the legal requirements of registration with the CQC as a potential significant breach of an NHS foundation trust’s terms of authorisation.
5.48 Where Monitor sees evidence of material service underperformance, or wider governance or financial problems, it will act swiftly to identify the underlying cause and ensure that action is taken effectively and promptly. If Monitor is concerned that a trust is not taking appropriate action to address significant concerns, it can use its formal powers to safeguard patients. Monitor works with a network of organisations to access a broad range of information on NHS foundation trust performance. Monitor looks to the CQC for advice in respect of NHS foundation trusts’ compliance with registration requirements.

5.49 In describing the roles and responsibilities of individuals and organisations throughout the system, this chapter has highlighted the importance of working together to share information and intelligence on risk. Both formal and informal mechanisms are needed to facilitate this, and the next chapter sets out some of the important developments under way that will strengthen the system’s ability to detect and act on emergent problems.
Chapter 6:
Practical arrangements for cooperation to prevent and mitigate failure

6.1 The previous chapter set out the detailed roles and responsibilities of each part of the system in relation to spotting and preventing serious failure in the quality and safety of care provided to patients. Common to all organisations is a need to work collaboratively with other bodies and partners to understand and share information on risk through informal and formal mechanisms. As well as those bodies considered in detail in Chapter 5, other bodies involved in this enterprise will include, for example, the National Patient Safety Agency (NPSA), the NHS Litigation Authority and local authorities (in relation to social care).

6.2 This chapter sets out some of the formal mechanisms that have been introduced to facilitate joint working between organisations and the sharing of information and intelligence on risk. It also recognises that no system can be 100% failsafe, and that, in the event of serious failure, it is essential that the different organisations within the system work together to take the necessary action.

Formal mechanisms for sharing information on risk

6.3 The formal mechanisms described here will not be the only ones that exist across the system and should not be seen as a substitute for organisations routinely working together, both formally and informally. That said, there are some important developments under way that will strengthen the system’s ability to detect and act on emergent problems.

Quality and risk profiles

6.4 To support registration, the CQC is developing a Quality and Risk Profile System (QRPS) to provide a picture of the quality of care provided by an organisation and the level of risk attached to it. This system is in the early stages of development and will be built on and strengthened over time. It recognises that assessing the risks to quality of care is not just a matter of data and indicators but needs to take into account wider intelligence such as information about recent changes in management or the reorganisation of services.

6.5 The QRPS will provide a more up-to-date system than previous national systems for collating information on risks to quality of care, and will include local intelligence. The information gathered through the QRPS will then be used to generate quality and risk profiles for provider organisations. These profiles will incorporate information from various sources across the NHS system to facilitate collaboration and intervention. Sources may include:

- information from people who use services, carers, the public and representative groups;
Practical arrangements for cooperation to prevent and mitigate failure

- information on specific conditions and treatments derived from national data sets, such as Hospital Episode Statistics, and, where available, from clinical audit data;
- information from the CQC’s inspection activity;
- notifications about safety incidents submitted via the NPSA or directly to the CQC;
- relevant information from other CQC assessments of quality, such as special reviews;
- judgements from other regulators and system managers;
- soft intelligence, such as changes in the top management of a provider or significant restructuring of services; and
- aggregate data on provider performance supplied for national purposes.

6.6 The QRPS will enable the CQC to share information and judgements on provider risk across the NHS system (between regulatory partners, SHAs, commissioners and trusts themselves) and, in time, with the public, in a more flexible and dynamic way. It will be possible to use it to develop different views of an organisation’s quality and risk status; to help risks to be rapidly identified; and to determine appropriate action in cases of serious lapses in quality and safety.

Ongoing monitoring of mortality and other data

6.7 The CQC inherited from the Healthcare Commission a process for identifying and monitoring mortality for specified conditions. It is via this system that the CQC issues ‘alerts’ to trusts on potential concerns regarding deaths in hospital. The CQC is continuing to develop this programme of surveillance on particular aspects of care. In time, such analyses will feed into the quality and risk profile of individual organisations.

6.8 The alerts are used to prompt interaction between the CQC and trusts with a view to understanding the issues in each case and, where quality of care is deficient, ensuring that action is taken to address the causes of the high mortality rate.

6.9 Once cases are closed, the results of mortality monitoring and other alerts are published quarterly. In about one third of cases some action is taken with a view to promoting improvement, and results suggest that this is effective.

Memorandum of understanding between Monitor and the CQC

6.10 Monitor and the CQC signed a memorandum of understanding in September 2009. It sets out how the two organisations will work together:

- In carrying out their regulatory functions, each will inform the other as soon as reasonably possible of any matters that may require action or a response.
- Each will keep the other fully informed about developments in its approach and methodologies in which the other may have an interest.

6.11 The memorandum seeks to ensure that Monitor is informed about concerns that the CQC may have about the quality of care delivered by trusts applying for NHS foundation status, and that these concerns are resolved before a decision is taken to authorise the applicant. Arrangements have also been agreed as part of the memorandum to share information about underperforming NHS foundation trusts and to coordinate any action.
6.12 The memorandum similarly seeks to ensure that Monitor refers to the CQC any serious concerns or risks in respect of performance against registration requirements that it identifies during assessment.

Collaboration between system regulators and professional regulators

6.13 It is important for system regulators and professional regulators to develop positive working relationships as both have a statutory duty to protect the public. In particular, the CQC and professional regulators are developing agreements on how they can work together so that information that raises concerns about the performance of individual practitioners or the delivery of care can be shared confidentially and quickly, allowing appropriate and swift action to be taken.

6.14 Professional regulators may also hold information indicating more systemic risks and issues within organisations, which will be useful to system regulators.

6.15 Information from the CQC about general care delivery can help professional regulators identify where there might be specific issues of governance, leadership or training, and decide whether organisations are appropriate to provide training.

Planned Collaborative Reviews and Triggered Risk Summits

6.16 The CQC will lead two formal mechanisms for bringing key partners together to share information and intelligence on risk. The primary purpose of both mechanisms will be to protect patients by enabling the CQC to develop richer quality and risk profiles for provider organisations and to make more fully informed judgements on compliance with registration requirements.

6.17 Planned Collaborative Reviews will take place on an annual basis and will look at provider risk across a whole strategic health authority (SHA) region. They will bring together a wide range of organisations that hold information and intelligence on safety and quality, e.g. other regulators, the SHA, PCTs, the NPSA, the NHS Litigation Authority and the Audit Commission. These reviews will ensure that risk is assessed consistently across England.

6.18 Triggered Risk Summits provide a responsive mechanism for a detailed discussion and assessment of risk in the event of a specific serious concern emerging about an organisation or group of organisations. They are run by the CQC as and when required but can be triggered by any of the performance management or regulatory bodies (principally the CQC, Monitor and the SHA).

In the event of a potential or actual serious failure

6.19 This report has explained how the system should function to identify risks at an early stage and thereby prevent a serious failure from occurring. If organisations and individuals adopt the values and behaviour that we have described, and if the systems and processes operate as designed, serious failures should be kept to a minimum, with risks identified early and tackled quickly and effectively.

6.20 However, no system can be 100% failsafe, particularly one as complex and vast as the NHS. Not every serious failure is predictable, and therefore not every serious failure can be entirely prevented. There will be instances where a failure occurs as a result of several unforeseen circumstances happening simultaneously. In such circumstances, it is crucial that the overall system is able to respond in a coordinated and aligned way. This response will need to achieve three things:
• **safeguard patients** – the responsibility for this primarily rests with the organisation that provides the care, but the CQC has a wide range of enforcement powers where there are concerns that a provider may not be taking appropriate action to achieve this;

• **ensure continued provision of services to the population** – the responsibility for this rests firmly with the SHA and the PCT; and

• **secure rapid improvements in the quality of care at the failing organisation** – the responsibility for this rests with the PCT and the SHA and, in relation to foundation trusts, with Monitor.

6.21 However, there is currently no formal mechanism in place for ensuring that, in the event of a serious failure, the management and regulatory responses are aligned and remain coordinated at all times. **We therefore recommend that such a mechanism is introduced in order to provide clear leadership and the ongoing coordination and pace of action by all organisations with an accountability for remedying the failure.**

6.22 **Given that the SHA is responsible for the overall operation of the NHS in the region and for ensuring the provision of services to the population, we recommend that it take on this role.** In doing so, it should align the management response, the need to maintain provision of safe services to the local population at all times and any enforcement action proposed by the regulators. In this role, the SHA does not direct the regulators, who are free to act within their statutory frameworks, but works alongside them to ensure an efficient and effective system-wide response.
Chapter 7: Conclusion and recommendations

7.1 The previous chapters have looked at the various component parts that make up the overall early warning system in the NHS for preventing serious failures in the quality of care provided to patients. Recognising that no system can ever be 100% failsafe, Chapter 6 then described how the system should respond in the event of a serious failure emerging or being identified.

7.2 This early warning system is not the responsibility of a single organisation or reliant on a single process. Its success is dependent on the culture within and between organisations which, in turn, needs to be underpinned by robust systems and processes and clarity around roles and responsibilities. It is a collective endeavour and a collective responsibility.

Figure 5: The NHS early warning system

A PROVIDERS

Board

Clinical teams

Healthcare professionals

B WORKING TOGETHER TO MANAGE RISK

PCT

SHA

Monitor

CQC

NPSA

DH

C SERIOUS POTENTIAL FAILURE IDENTIFIED

Judgement that serious breaches in compliance with registration requirements have occurred/may occur

D SYSTEM-WIDE RESPONSE Coordinated by SHA

SHA

Responsible for the operation of the NHS in the region

CQC

Power to take enforcement action due to breach of registration requirements

Monitor

Power to take compliance action where there is a breach of terms of authorisation by a foundation trust

PCT

Support improvement response/secure continued provision of services

E AGREED COORDINATED ACTION

The management and regulatory responses are aligned and coordinated in order to:

- safeguard patients
- ensure continued provision of services to population
- secure rapid improvements at the failing organisation
Conclusion and recommendations

7.3 Through Figure 5 and the accompanying commentary, this concluding chapter seeks to present the overall system. In doing so, it:

- highlights some of the key enhancements that have been made to the system since the failures at Mid Staffordshire NHS Foundation Trust occurred, as well as those in the pipeline; and
- makes a small number of recommendations for how the system could be further strengthened in order to enhance our collective ability and responsibility to safeguard the quality of care provided to patients.

A. Providers

7.4 The early warning system starts within the organisation providing care. Healthcare professionals and clinical teams are the first line of defence, and the provider board is ultimately responsible for the quality of care provided to patients across all of its services.

7.5 The effectiveness of this part of the early warning system depends on a culture of open and honest cooperation being in place within the provider organisation, such that:

- healthcare professionals are able to fulfil their professional duty to make the care of patients their first priority, confident in the knowledge that if they raise any concerns they will be listened to;
- clinical teams are constantly measuring and benchmarking the quality of services they are providing and, in doing so, are open and honest about where improvement is needed;
- the board is scrutinising quality across the full range of services provided and fosters an open and learning culture throughout the organisation, raising any concerns with the relevant parts of the wider system; and
- the organisation as a whole is listening to and acting upon feedback and complaints from patients and the public.

7.6 Since the events at Mid Staffordshire occurred, High Quality Care for All has firmly anchored quality as the organising principle of the NHS. While progress is by no means universal, its impact in bringing about a greater focus on quality within provider organisations should not be underestimated. Clinical teams are beginning routinely to measure, monitor and improve services, supported by clinical dashboards and other resources such as the assured menu of Indicators for Quality Improvement. In June 2010, all acute, mental health and ambulance trusts will produce, for the first time, Quality Accounts, focusing provider boards on quality issues right across their organisations. At the level of individual healthcare professionals, the introduction of revalidation for doctors will further strengthen the system of professional regulation.

7.7 However, we take the view that there are areas where more could be done to strengthen the focus on quality within provider organisations.

Recommendation 1: We recommend that trust boards be given further guidance on how best to govern for quality. In carrying out this review, we consistently heard that boards would welcome this. This report talks about what boards should be doing at a high level, but it has not looked at the next level of detail. We, the NQB, have already agreed to lead a piece of work in 2010 designed to help all boards providing NHS services to develop robust governance for quality. We will build on the work of the National Leadership Council in this area, on the CQC’s guidance on compliance with registration requirements and its development of quality and risk profiles, and on work by Monitor to develop
a quality governance framework for NHS foundation trusts. The aim of our work will be to ensure that NHS provider boards have access to a coherent and aligned package of support which enables them confidently and competently to ask the right questions about the quality of care being provided in their organisations.

**Recommendation 2:** We need to create an environment in which healthcare professionals, as the first line of defence, feel able to be open about the quality of care they are providing and to raise concerns. We recommend that the Department of Health works with the Royal Colleges, including the Academy of Medical Royal Colleges, and the Specialist Associations, to look into how professional bodies can encourage a culture of openness and transparency among all healthcare professionals, including supporting them in raising concerns early.

**Recommendation 3:** In carrying out this review, we identified the importance of patients and the public being able to hold NHS providers to account for the quality of their services. Quality Accounts will ensure that the leadership of organisations is fully engaged in reviewing the quality of healthcare services they provide and in setting priorities for improvement. We believe that the introduction of Quality Accounts in 2010 represents a good opportunity for patients and the public to hold providers to account and acknowledge the role that has already been given to local involvement networks and overview and scrutiny committees in assuring a provider’s Quality Account. The Department of Health will be evaluating the impact of the first Quality Accounts in summer 2010. As part of that evaluation, we recommend that the Department assesses how effectively users of services and wider stakeholders have been involved in determining the priorities for improvement set out in the Quality Accounts and in decisions affecting quality of healthcare services, and how effectively organisations act upon patient feedback. Where possible, this should also include exploring the potential for providers to account for improving the patient experience through respecting and involving service users.

**B. Working together to manage risk**

7.8 Every part of the NHS system has a role to play in the early warning system in respect of safeguarding quality, both in fulfilling its particular responsibilities and in working together with other parts to safeguard quality of care to patients.

7.9 Through this report we have:

- set out clear roles and responsibilities for each part of the system in respect of safeguarding quality, from individual healthcare professionals, clinical teams and the boards of provider organisations through to the commissioners and the regulators;
- described a culture of open and honest cooperation where every part of the system has a responsibility to share information and concerns with others; and
- emphasised the importance of all parts of the system listening to and engaging with patients about the quality and design of services.

7.10 Although different organisations have different roles to play, they all have a responsibility to work together for the good of patients. This means sharing the information that they may uniquely hold within their organisations. For example, PCTs, through their contract monitoring role and their proximity to
the organisations providing care, will have access to the most up-to-date information and intelligence about individual providers. They can therefore play a vital role in detecting and preventing serious failures at an early stage and should share any concerns they have with the relevant parts of the wider system. Similarly, the CQC’s Quality and Risk Profile System (QRPS) will support the drawing together of many strands of information in real time, and will allow this information to be shared with the rest of the system in the form of a quality and risk profile for each organisation. Planned Collaborative Reviews will also provide a forum in which the different parts of the system can openly discuss the information they have in relation to a regional health economy.

7.11 It is essential that the correct steps are taken to embed these roles and responsibilities, and the culture we have described, within all NHS organisations in order to promote high quality care. To further strengthen the wider system’s ability to safeguard quality, we make the following recommendations.

**Recommendation 4:** Currently there are separate compliance frameworks for different types of provider (e.g. Monitor’s Compliance Framework for NHS foundation trusts and the NHS Performance Framework for NHS trusts). They are broadly similar, and we recommend that they should continue to be moved into closer alignment as set out in the NHS Operating Framework. However, we recommend that they are revised in order to make them more sensitive to quality issues so that underperformance in quality can be spotted and tackled through performance management before it becomes a serious failure and requires a regulatory response.

**Recommendation 5:** The role of commissioners is vitally important in safeguarding quality. They are the next line of defence against serious failure after the provider board as, through contract management, they will have access to the most up-to-date information in relation to quality of care. We welcome the extension of the NHS Performance Framework to PCT commissioners from April 2010 and recommend that its future development ensures that the responsibility of PCTs for commissioning high quality services is adequately covered.

**Recommendation 6:** This report has emphasised the importance of all parts of the system actively engaging and listening to patients and service users about the quality and design of services – providers, commissioners, system managers and regulators. Chapter 3 set out many of the formal mechanisms and requirements that have been introduced to support this. However, we are keen to gain a better understanding of whether the combined effect of these and other patient feedback mechanisms are providing a sufficient voice to patients and the public. We therefore recommend that we, as members of the NQB, conduct a review of patient engagement and feedback mechanisms with a view to understanding where they are working well, where more may need to be done and how their outputs are connecting with trust boards and the decision making process. As some of these mechanisms are still relatively new or will shortly come into effect, we recommend waiting six months before starting this review.
C. Serious potential failure identified

7.12 By sharing information within organisations providing care, and between providers, PCTs, SHAs and regulators, regularly and routinely, the early signs of potential serious failures can be spotted.

7.13 The new system of registration, which will come into effect from 1 April 2010, sets out the essential levels of quality and safety that NHS trusts must meet if they are to be permitted to provide care to patients. These minimum requirements provide the NHS with a bar against which it can look for signs that a provider is at risk of a serious failure. Not all breaches of registration requirements will indicate a serious failure; however, where a serious failure does occur there will be significant and sustained breaches indicating a systemic failure across an organisation. The new system of registration will therefore help to identify when a serious failure is occurring and when there will be a need for a system-wide response.

D. and E. System-wide response and agreed coordinated action

7.14 If and when a potential or actual serious failure has been identified, there needs to be a system-wide response. The management and regulatory responses need to be aligned and remain coordinated at all times in order to achieve three key objectives:

- immediately safeguard patients;
- ensure continued provision of services to the population; and
- secure rapid improvements to the quality of care at the failing organisation.

Recommendation 7: There needs to be a single organisation responsible for making sure that all the action being taken, whether regulatory or management, is aligned and coordinated, and achieves the three objectives listed above. We recommend that the SHA takes on this role. The SHA is well placed, given its responsibility for the operation of the NHS in the region. The SHA should not direct the regulators, who must operate within their statutory powers, but should ensure that the NHS takes the action it needs to.

Making this happen

7.15 As a Board, we recognise that one document will not ensure that the system operates as it should – namely, as we have described in this report. That is why it will be critical for the Department of Health, together with regulatory partners and the wider NHS, to work hard at making the system described in this report a reality. This might include:

- communicating this report and the early warning system it describes to the chief executive of every NHS trust, NHS foundation trust, PCT and SHA in England;
- working with the SHA chief executives, through the NHS Management Board, to ensure that each SHA understands its role and that of the other elements of the system in safeguarding against failure;
- SHAs working with their PCTs, and in turn their providers, so that each regional health economy understands the respective responsibilities of the different parts of the system and who does what when. Monitor could take on a similar role with NHS foundation trusts;
- the CQC working with a range of stakeholders to improve the information shared across the system in quality and risk
profiles to help risks to be identified earlier and to trigger follow-up action;

• the Department of Health and the NQB working with professional bodies to better understand how to realise the culture described in this report across the healthcare professions; and

• deploying the NQB’s forthcoming work on what good governance for quality looks like at the level of the trust board.

7.16 The NQB, as part of our role in providing strategic oversight and leadership for quality in the NHS, is strongly committed to seeing the system described in this report implemented throughout the country. We will work with the Department of Health, the regulators and the wider NHS system to support them in making this happen during 2010 and beyond.
Glossary of terms and abbreviations

Alberti Review
Professor Sir George Alberti, former National Clinical Director for Emergency Care, conducted a review for the Secretary of State for Health into Mid Staffordshire NHS Foundation Trust’s procedures for emergency admissions and treatment and its progress against the recommendations in the Healthcare Commission’s report. In addition, he looked at other related areas of work, including the quality of care issues highlighted in the report in relation to the medical admission wards.

Care pathway/pathway of care
A pre-determined plan of care for patients with a specific condition.

Care Quality Commission (CQC)
The regulator for health and adult social care in England. It merged three existing regulators and took over their responsibilities from 1 April 2009: the Healthcare Commission, the Mental Health Act Commission, and the Commission for Social Care Inspection.

Colin-Thomé Review
Dr David Colin-Thomé, National Clinical Director for Primary Care, conducted a review for the Secretary of State for Health into the circumstances surrounding the Mid Staffordshire NHS Foundation Trust prior to the Healthcare Commission’s investigation to learn lessons about how the PCT and SHA failed to expose what was happening in this hospital.

Commissioning
The process by which PCTs secure best value and deliver improvements in health and care services to meet the needs of the populations they serve. The commissioning cycle includes designing, procuring and ensuring delivery of those services.

Compliance Framework
Monitor’s framework describing how it monitors NHS foundation trusts’ compliance with their terms of authorisation.

Department of Health
The department of state for the NHS and adult social care. It supports Ministers in their accountability to Parliament for the provision of high quality care by the NHS. It designs the health system and sets the strategic direction for the NHS.
Essential levels of quality and safety

The minimum requirements NHS providers must meet if they are to be permitted to offer care to patients. They were determined by Parliament and are set out in legislation. The CQC assesses compliance against them, monitors ongoing compliance and takes enforcement action where they are breached. (See also registration requirements.)

Guidance on Compliance

The CQC’s guidance to providers on what they need to do to meet the essential levels of quality and safety/registration requirements. This guidance is made binding by being set out in statute.

Healthcare Commission

Former regulator of health services in England. The CQC superseded it when it took over responsibility for regulation from 1 April 2009.

High Quality Care for All

The final report of the NHS Next Stage Review, published in July 2008. It sets out how the NHS should support the delivery of high quality care by frontline staff to make the NHS fit for purpose for the next decade.

Indicators for Quality Improvement

A resource for local clinical teams providing a growing set of robust indicators which they can use to monitor the quality of the services they provide and to drive quality improvement. They also provide a tool for local, regional and national benchmarking.

Local involvement networks (LINks)

Groups of patients and public representatives whose role is to find out what the public like and dislike about local health and social care, and to work with commissioners and providers to improve services.

Memorandum of understanding

An agreement between two parties, setting out how they will work together on a specific issue, or in general. It is not legally enforceable.

Monitor

Monitor is the independent regulator of NHS foundation trusts in England. Its role is to make sure that NHS foundation trusts are well led, are legally set up and run, and have their finances in good order.

National minimum standards

Standards set by the Department of Health for a range of services, including care homes, domiciliary care agencies and adult placement schemes. These will be incorporated into the registration requirements/essential levels of quality and safety from 1 April 2010.

National Patient Safety Agency (NPSA)

An arm’s length body of the Department of Health that leads and contributes to improved, safe patient care by informing, supporting and influencing the health sector.
National Quality Board (NQB)

Established by High Quality Care for All to provide strategic oversight and leadership for quality in the NHS. It is chaired by the chief executive of the NHS, and includes representatives from the organisations which run the NHS, experts and professionals in healthcare, and lay members.

National standard contract

The basis for agreements between PCTs and all types of provider delivering NHS-funded services. It is updated each year to support the NHS Operating Framework.

Never Events

Serious, largely preventable patient safety incidents that should not occur if the available preventive measures have been implemented.

NHS foundation trust

A type of NHS organisation (usually a hospital or group of hospitals, or a mental health trust). They are established as independent, public benefit corporations with accountability to their local communities. They are given greater freedoms and flexibility to manage their affairs, as a result of excellent sustained performance. They are accountable to Monitor, Parliament and their governors and members, and to commissioners through their contracts.

NHS foundation trust governors

Representatives of the public or other stakeholders with a statutory responsibility to provide challenge to NHS foundation trust boards in relation to financial and quality-related performance matters. They are elected by the NHS foundation trust’s members.

NHS foundation trust members

Any member of the public or stakeholder organisation can become a member of their local NHS foundation trust. Their role is to inform the trust as to the needs and concerns of the local community.

NHS Operating Framework

Sets out a brief overview of the priorities, system levers and enablers for the NHS for the coming year (e.g. 2010/11). It is accompanied by annexes which provide more detail on the priorities, how they are measured and how the new arrangements for managing the system will work. The performance of NHS organisations is then managed against delivery of these priorities through the NHS Performance Framework and assessed against them as part of the CQC’s periodic reviews.

NHS Performance Framework

Sets out the approach to identifying underperforming NHS organisations and stipulates when intervention in such organisations should occur. It is used by PCT commissioners to manage the performance of NHS trusts (not NHS foundation trusts) and will be used by SHAs to manage the performance of PCT commissioners from April 2010. It will also be extended to include mental health trusts from April 2010.

Overview and scrutiny committees

Committees made up of locally elected lay members which provide a mechanism by which the local authority or population can scrutinise the NHS.
Planned Collaborative Reviews

Annual reviews to look at provider risk across a whole SHA region, bringing together the organisations that hold information and intelligence on safety and quality, e.g. the CQC, Monitor, SHA, PCTs, NPSA, NHS Litigation Authority and the Audit Commission.

Primary care trust (PCT)

NHS body with responsibility for delivering healthcare services and health improvements to a local area by commissioning services from providers to meet local needs. PCTs are accountable to the regional SHA.

Quality and Risk Profile System (QRPS)

The CQC’s system for providing a picture of the quality of care provided by, and risk associated with, an organisation. This pools information from a variety of sources to inform the CQC’s judgements on providers’ compliance with registration requirements.

Regulation

The process by which the CQC assesses whether providers of NHS services (e.g. GP practices, hospitals, mental health trusts) are meeting the essential levels of quality and safety (registration requirements). The CQC will either register a provider, register a provider with conditions, or refuse to register a provider. Subject to Parliamentary approval, all acute trusts will be registered by 1 April 2010.

Registration requirements

The essential levels of quality and safety which providers of NHS services must meet in order to be registered. (See also ‘essential levels of quality and safety’.)

Regulated activities

A statutory list of activities, which determine whether an organisation needs to be registered by the CQC.

Revalidation

A new system for doctors requiring them to demonstrate to the General Medical Council that they are up to date and fit to practise medicine. Doctors who take part in revalidation will be granted a licence to practise, and will be reassessed every five years. Revalidation will come into force for all doctors by 2011/12.

Serious untoward incidents

An incident involving NHS care or on NHS property which leads to a number of defined serious consequences, including causing death, serious or life-threatening injury; involving a hazard to public health; or contributing to an unacceptable, sustained reduction in the standard of care.

SHA assurance framework

Framework for assessing the capability of SHAs. It aims to provide greater consistency and transparency on how the Department of Health holds SHAs to account as the local headquarters of the NHS.

Standards for Better Health

Describe the level of quality that healthcare organisations, including NHS foundation trusts, and private and voluntary providers of NHS care, will be expected to meet in terms of safety; clinical and cost effectiveness; governance; patient focus; accessible and responsive care; care environment and amenities; and public health. They expire on 31 March 2010, when they will be replaced by registration requirements.
Terms of authorisation

A set of detailed requirements covering how trusts must operate once they are authorised as NHS foundation trusts. They include the general requirement to operate effectively, efficiently and economically; requirements to meet healthcare targets and national standards; and the requirement to cooperate with other NHS organisations.

Triggered Risk Summit

Detailed discussion and assessment of risk in the event of a specific serious concern emerging about an organisation or group of organisations. Run by the CQC as and when required but can be triggered by any of the performance management or regulatory bodies (principally the CQC, Monitor and SHAs).

World Class Commissioning

A three-year capability-building programme for commissioners (in PCTs and practice-based commissioners) which aims to transform dramatically the way health and care services are commissioned in England. It sets out 11 competencies which commissioners are expected to exhibit and provides support to help them improve performance in each area. An assurance process assesses PCT performance against the competencies annually and identifies areas for improvement.
Notes