Making it better?
Assuring high-quality care in the NHS

Key points
• The NHS must confront the fundamental issue of poor quality care and develop practical solutions and ensure their consistent implementation.
• Creating a positive culture is vital to ensuring patients receive good quality care.
• Existing oversight mechanisms could be strengthened and used to better effect to provide improved assurance of management and care quality.
• A balance is needed between national ‘external’ regulation and effective ‘internal’ governance and scrutiny by both individuals and organisations.
• Strengthened employment practices, consistently applied, could improve the accountability of individual and organisations for quality.

The public inquiry into events at Mid Staffordshire NHS Foundation Trust between 2005 and 2009 (the Francis Inquiry) painted a shocking picture of appalling standards of patient care, with both institutional and individual failures to tackle these issues. It highlighted poor management practices, and an organisational focus on national financial and performance imperatives to the detriment of the quality of patient care. It also challenged the effectiveness of the regulatory and oversight mechanisms in identifying and tackling poor quality patient care proactively and systematically.

This has focused attention on who is responsible for ensuring patients receive high-quality care, and for acting if appropriate standards are not met. It has particularly highlighted how the decisions and actions of managers at all levels can affect the quality of care patients receive. This has fuelled calls to make NHS organisations, their boards and individual staff, including managers, more accountable for the quality of care.

There is a danger in extrapolating from events at Mid Staffs to develop system-wide solutions. We know that the standards of patient care documented at Mid Staffs are not universal across the NHS, but the potential for poor quality care lies everywhere. The NHS must confront these fundamental issues.

This paper aims to start a constructive debate, leading to concrete proposals about how to tackle these issues and find ways of reinforcing both organisational and individual accountability for delivering and improving the quality of NHS patient care. It draws on a recent NHS Confederation seminar, attended by senior representatives from NHS providers and commissioners, existing regulatory and oversight bodies, and the Department of
A prerequisite for ensuring that any steps taken following the Francis Inquiry are successful in securing greater public confidence in the NHS must be asking what questions we are trying to answer. Then we must focus forensically on those areas where changes can be made, without creating more bureaucracy or giving the public a false sense of assurance. In summary, we need to do the things that genuinely make a difference.

We have structured this paper to assess the current position and take account of some of the main recommendations of the Francis Inquiry. It presents for consideration some of the options for improvements. We welcome your feedback on this paper and the questions it asks.

Please send your feedback to ManagerRegulation@nhsconfed.org by 29 March 2013.

High performing organisations:

- create a positive, open and transparent culture
- embed desired values and behaviours across the organisation
- prioritise delivery of high-quality patient care, setting quality objectives
- have appropriate, integrated governance systems, processes and procedures, including robust clinical and financial governance arrangements, and implement them
- identify key risks early and work to mitigate them
- encourage, value and act on feedback from patients and staff
- understand and track performance, including learning from complaints, concerns and serious incidents to improve the quality of care
- know their limitations and understand other organisations may be better equipped to provide some services.
positive organisational culture, they create the right environment to support and enable individual staff (clinical, managerial and support) to do the ‘right’ thing for patients. However, not all parts of all NHS organisations do this all the time.

Evidence from the Francis Inquiry and other NHS organisations demonstrates the negative impact culture can have on the quality of care. Particular concerns include where financial considerations are prioritised over quality and patient care, where a blame and bullying culture pervades, and where there is a failure to recognise the potential to compromise quality in some circumstances without changing the organisation’s operating model.

Existing regulatory and oversight mechanisms clearly struggle to address some of the underlying issues. Current systems do little to assess organisational culture or to provide adequate support or incentives to assist organisations to achieve the necessary improvements, particularly where problems have deep-rooted or health system-wide causes, or where the scale of improvement required is significant in terms of the length of time and new resource needed.

Trusts that struggle with quality often struggle financially. Concerns that the NHS focuses on finances rather than quality are not unique to Mid Staffs. But it is impossible to divorce the delivery of safe, high-quality care from the level and effective stewardship of the resources available. And local management is required to deliver both. Indeed, NHS organisations that overspend are operating within a cash-limited national budget, and therefore require other organisations to underspend in order to cover their debts, potentially undermining the resources that they hold to deliver high-quality care.

**Individual responsibility for high-quality care**

Everyone involved in the management or delivery of NHS services has a personal responsibility for the quality of care provided. A positive organisational culture reinforces this and increases the likelihood that unacceptable behaviour or practices are identified quickly and action taken.

A combination of mechanisms helps to reinforce individuals’ responsibilities for their conduct and practice in caring for patients and to safeguard patients and the public. Some apply to all staff, such as employment practices, others to clinical staff, such as professional regulation, and others primarily to senior managers and board members, such as codes of conduct and governance and scrutiny by non-executive directors (NEDs) and foundation trust governors.

With over half of NHS managers (58 per cent) and 26 per cent of board members clinically qualified and registered with a professional body, professional regulation is an important tool in safeguarding standards of patient care. Integral to this is a code of conduct which reinforces individual clinicians’ responsibilities. Healthcare regulators, such as the General Medical Council and Nursing and Midwifery Council, are clear these responsibilities extend to clinicians’ behaviour as managers.

However, existing mechanisms do not appear (and most importantly are not believed by the public, patients and many clinicians and managers) to be sufficiently robust in holding management to account.

Despite codes of conduct and good governance, there are no equivalent accountability mechanisms governing NHS managers to those for registered healthcare professionals. The Francis Inquiry concludes that there is no system of accountability for managers and leaders of NHS organisations other than by reference to their contracts of employment.

Employment practices could be strengthened and applied more systematically, including ongoing assurance of the competency and capability of staff through effective appraisal.

Mechanisms to hold NEDs and senior NHS managers accountable appear weak or only come into force when there is significant financial or quality failure (such as Monitor’s current powers).
Concerns exist about the recruitment, training and induction for NEDs, and the apparent lack of challenge they provide to the executive team. Distinguishing between the theory and practice of how these mechanisms operate is also important.

The Professional Standards Authority (PSA) recently published standards for members of NHS boards and clinical commissioning group (CCG) governing bodies. These cover personal behaviours, technical competence and business practices, and identify values to be applied in work and relationships with others. They include a requirement for board members to act in the interests of patients, service users and their local community. While development of these standards is welcome, the PSA’s remit did not include implementation and there is no indication of how this will be monitored or assessed.

Are existing mechanisms adequate?

Is a new regulatory approach for organisations required?
The table at the end of this paper outlines the existing regulatory and oversight processes designed to assure the quality of NHS patient care and its management.

Rather than needing new processes or a wholesale reorganisation of regulation, attention should focus on using existing powers more effectively and adjusting approaches to address some of their limitations.

Regulators in other sectors are more proactive in assessing organisational culture and the board’s commitment and capability to deliver their responsibilities. This can include interviewing NEDs before their appointment. The Financial Services Authority (FSA) designates certain senior organisational roles as requiring their prior approval for any appointments, based on the individual’s skills, behaviour and experience and their suitability for the role. The FSA can also apply sanctions if an individual fails to meet required standards in practice.

Significant changes to existing mechanisms are imminent, including the new Monitor license, introducing a ‘fit and proper persons’ test for board members. Monitor also proposes strengthening its assessment and oversight of governance, including three-yearly external assessments of boards’ governance. The implications of the recommendation from the Francis Inquiry to transfer responsibility for all types of governance to the Care Quality Commission (CQC) will need to be assessed carefully.

Foundation trust governors have new responsibilities and powers to hold NEDs, individually and collectively, to account for the performance of the board. They need to be better supported and prepared to fulfil this role effectively.

These changes offer opportunities to tackle quality issues in a more coordinated way, working with the CQC. For example, the PSA’s newly developed standards could provide the basis for Monitor’s fit and proper persons test. Similarly, the NHS Trust Development Authority and the CQC could use adherence to this code as part of their assessment of trusts.

Different approaches may be needed, particularly to intervene earlier to prevent failure or tackle the most intractable quality problems. The CQC could be more proactive in assessing organisational culture and its impact on quality as part of its routine inspections. The CQC and Monitor are already exploring development of a ‘cultural barometer’ to assess organisations. Although there may be significant challenges, particularly in assessing large, multi-site trusts, it is not impossible.

Strengthening organisational governance and processes
Organisational governance and processes, and their systematic operation by staff, provide the first line of defence against poor quality care. Organisations should identify and systematically monitor key quality indicators throughout the organisation, which can provide clear early warning signals of any problems.
Possible indicators include serious untoward incidents and data from the patient and staff surveys.

Effective clinical governance provides clear lines of accountability for clinical quality, and systems to identify and manage risk and address poor performance. Boards should afford the same priority to clinical and quality governance as they do to financial governance, with regular reporting and oversight.

The operation of clinical governance could be strengthened to provide more consistent and rigorous assurance to safeguard standards of care and improve quality. The CQC’s inspection processes could provide better assurance that clinical governance processes are properly embedded throughout the organisation and the delivery of care.

Strengthening and standardising the content of quality accounts could improve local scrutiny and assurance of quality standards, and focus attention on progress in improving care. Boards could be required to set out their commitments on quality and report on progress in achieving these.

Mandatory reporting of certain quality indicators, such as the early warning signals mentioned above, and benchmarking of performance against other providers, would make quality accounts a much more useful tool and a better indicator of quality within an organisation. NEDs and foundation trust governors could then use quality accounts to hold senior NHS staff to account, and patients and the public could use them to compare performance between providers.

External assurance of quality accounts, similar to the way in which financial accounts are audited, could add further value and secure greater public confidence in their content and accuracy. This approach is supported by recommendations from the Francis Inquiry. However, it will be important to avoid duplicating Monitor’s current proposals for external assurance of governance arrangements.

**Improving employment practice**

Despite the good practice of NHS employers in applying systematic employment checks, there is still scope to strengthen practices to secure high standards of staff behaviour. Translating the board’s quality objectives into recruitment and performance frameworks can help guide the everyday actions of individual managers and other staff. Increasingly, NHS organisations have their own values framework and recruit for values.

The Dalton report in 2010 highlighted changes to employment practice to improve senior NHS staff and NEDs’ accountability for quality. These included embedding a statement of professional ethics into contracts and improved appraisal for all NEDs and senior NHS staff. As yet, these have not been adopted, but Government and individual NHS organisations could consider how these recommendations could be translated into practice.

**Is formal regulation of managers an answer?**

Events at Mid Staffs have renewed demands for formal regulation of managers in much the same way that healthcare professionals are regulated. This was recommended by the public inquiry into children’s heart surgery at the Bristol Royal Infirmary 1984–1995 (the Bristol Inquiry), although it was rejected by government as impractical.

The NHS Next Stage Review highlighted the need for more effective arrangements to assure the quality of NHS senior managers and their suitability for the role, although it stopped short of recommending formal regulation. Particular concerns were raised about the need to address the performance and conduct of the very small number of senior leaders who fail to meet expected standards. The review concluded that improved recruitment procedures or formal systems of assuring suitability for future employment would be more effective and proportionate safeguards of patients’ interests.

The Francis Inquiry does not directly recommend formal regulation of managers,
concluding that there is no consensus in favour of regulating NHS managers. However, it suggests that the issue is kept under review depending on whether it is thought that a wide range of managers and leaders should be under regulatory oversight and using experience of operating the fit and proper persons test. It proposes several changes to enhance the effectiveness of leaders in healthcare organisations and to ensure greater consistency in how NHS managers and other regulated and healthcare professionals are held to account for their practice and behaviour.

For many, statutory regulation of managers remains an attractive option. They see it as a tried and tested method of public protection.

Francis proposals to improve assurance of management and quality include:

- an offence of causing death or serious injury to a patient through the breach of regulatory requirements
- a statutory duty of candour on all healthcare providers and all registered professionals
- a criminal offence for any registered healthcare professional or director of an organisation to fail to provide honest information or obstruct that process
- a common code of ethics, standards and conduct for all senior NHS managers and leaders to form part of their contractual obligations and enforced by employers
- support for a ‘fit and proper persons’ test, which should include examination of a director’s fitness to be in post and a requirement to comply with a common code of conduct
- organisations must notify the regulator of all cases of non-compliance that result in dismissal or termination of appointment
- disqualification of anyone found to be in serious non-compliance with the code from holding another senior post
- creation of a leadership college to provide standardised training to potential managers, which could form the basis of an accreditation scheme
- strengthening oversight of governance in non-foundation trusts to similar standards as those for foundation trusts.

Importantly, regulation would reinforce the need for demonstrable competence on entry into management roles, and would offer a system to remove individuals who fail. However, it may do little to tackle the ongoing performance issues that ultimately are the key to preventing quality failures.

The Government has already indicated its reluctance to extend statutory regulation to currently unregulated professional or occupational groups unless:

- there is a compelling case based on the risks to patient safety, and
- assured voluntary registers are not sufficient to manage this risk.

This makes formal statutory regulation of managers unlikely, but there are alternative approaches, including enhanced employer responsibilities, voluntary registration and negative licensing.
Is voluntary regulation an answer?
Voluntary regulation or accreditation could increase public confidence in the quality of NHS management and improve standards of competence, and is an approach commonly used in other countries. Employers could reinforce the value of any recognised self-regulation or accreditation scheme by specifying it as a requirement when recruiting new staff. This could then link to CQC requirements.

For voluntary regulation to succeed, a respected body must establish any scheme and ‘own’ the voluntary register. The Institute of Healthcare Management could take on this role, which could be supported by a common code of conduct for all NHS staff. Adopting the Francis recommendations for a leadership college would also provide the basis for effective, voluntary regulation and a respected accreditation scheme.

However, a voluntary approach could lead to development of differing schemes, which would fail to ensure a coherent view of required education and training standards. A lack of legal powers can also undermine voluntary regulation as there is:

- no requirement on anyone undertaking certain roles to be registered
- no powers to prevent unregistered people from undertaking designated roles
- no powers to compel the disclosure of information or witnesses to participate in fitness to practise cases.

Is negative licensing an answer?
A system of negative licensing, underpinned by legal powers, could increase individual accountability for conduct and behaviour. This would address some concerns and deal with the very small number of criminal or incompetent managers, preventing them from moving to other jobs in health and social care. However, it would require legislative change.

This approach applies to the teaching profession in England, with the Department of Education holding a list of teachers prohibited from working in any school, children’s home or youth accommodation. This only covers cases of serious misconduct. Headteachers and governing bodies deal with less serious cases of misconduct and cases of incompetence or underperformance.

Negative licensing is used in New South Wales, Australia, for all healthcare professionals not subject to statutory regulation. Key features of this scheme include:

- staff in identified roles do not have to register as the scheme applies automatically
- a statutory code of conduct covering standards of conduct, performance and ethics
- formal, independent complaints adjudication processes
- a range of potential sanctions if complaints are proven, including warnings, prohibition orders preventing individuals from providing health services (either for a limited period or indefinitely); and conditions on an individual’s practice
- prosecution of breaches of any orders through the courts.

Any system of negative licensing would require a universal code of conduct that applied to all currently unregulated NHS managers. It could be a relatively low cost way of dealing with serious cases of misconduct and prevent or restrict the employment of anyone found in breach. Questions would still exist about who the scheme should cover, its administration, including dealing with complaints or referrals and holding the list of prohibited individuals, and who should pay for it.

However, any scheme of negative licensing is likely to deal with only the most serious cases, relying on more robust employer processes to deal with poor performance and less serious cases of misconduct. It would need to be compliant with the Human Rights Act, which could add complexity and costs.

Potentially, the PSA or the Health and Care Professions Council could operate such a scheme. Whoever has responsibility for operating the scheme, it will need...
to cover the growing number of people that move employment between the NHS and independent sector.

Confederation viewpoint

In the aftermath of the Francis Inquiry, there is a danger of just looking to regulation to provide improved assurance of NHS managers and management to safeguard standards of patient care. But as the inquiry clearly concludes, a fundamental change in culture is required to prevent similar failures from happening again. It suggests that many of the changes can be implemented within the current system.

Regulation can act as one safeguard, but there is no evidence or guarantee that it will prevent poor performance or improve quality. Indeed, over-reliance on national systems of regulation may weaken individual and employer responsibilities for addressing problems effectively and promptly. A balance is needed between national ‘external’ regulation and effective ‘internal’ local governance and scrutiny.

Introducing regulation for individual NHS managers is unlikely to achieve the intended benefits and may generate significant costs. Although a system of negative licensing may seem to provide a solution, particularly preventing any manager found guilty of serious misconduct from taking on other NHS management roles, it is not without significant practical questions about its operation and costs.

We should be extremely cautious about introducing significant new regulation to address issues with the quality of NHS management. Doing this risks distracting NHS leaders and managers from the task in hand, without delivering any tangible benefits.

Much could be done to strengthen existing quality assurance arrangements for organisations and individual staff to support high-quality, patient-centred care, and this paper considers several ways in which this could be done. Particular attention should focus on how the CQC and Monitor could work together to do more to assess culture and the operation of effective organisational governance processes to secure standards of high-quality care.

Like the Francis Inquiry, this paper highlights the central importance of organisational culture and robust employment practices to ensuring high standards of patient care and embedding desired values into all staff’s practice. Finding ways to reinforce and embed positive organisational cultures across the NHS is vital.

In part, this needs better alignment of the whole system around quality objectives, including the positive and open culture required to deliver them alongside appropriate incentives and rewards. Conversely, it requires challenging the punitive, ‘name and blame’ culture that can characterise the NHS at all levels, including its regulatory systems. This requires coordinated leadership from national bodies to align systems and processes around quality, including regulation, performance frameworks, contracts and payment systems etc.

Without this, we will not create the right environment and structures to support local commissioners and providers in delivering high-quality, patient-centred care. It will be difficult to have the vital, honest conversations about the challenges and risks facing organisations (and how to solve them), particularly in the increasingly competitive NHS environment. Senior leaders will be increasingly reluctant to take on the management or leadership of struggling NHS organisations, particularly where the causes of problems are outside their control. As a result, patients will continue to suffer.

The Francis Inquiry reports at a time of significant change and challenge for the NHS. A new system architecture comes into force from April 2013, and resources are increasingly under pressure, particularly from rising demand and limits on health spending. Significant numbers of management posts have been cut.
The new system presents opportunities to improve the quality of NHS management and strengthen accountability. For example, the NHS Leadership Academy is well placed to strengthen the quality of NHS management and leadership, including foundation trust governors. Similarly, Monitor licensing, particularly in conjunction with enhanced CQC mechanisms, could deliver real benefits without significant disruption.

Questions for consultation

We welcome your feedback on this paper and the questions it poses, in particular the following:

- Are existing assurance mechanisms effective in ensuring organisations and individuals provide high-quality care? If not, how could they be strengthened and, particularly, become more proactive in addressing the issues of poor quality care?
- Do existing assurance mechanisms provide appropriate accountability for organisations or individuals that fail to provide high-quality care? If not, how could they be strengthened?
- What sanctions, if any, should apply to the organisation or individual members of the board if their organisations fail to provide quality of care? If so, who should enforce them?
- How could the accountability of boards for quality and achieving regular improvements for patient care be strengthened?
- How could organisations be encouraged to develop a positive culture of leadership, learning and improvement? Who should lead this?
- Would proposals to strengthen quality accounts improve local accountability for quality?
- Should the CQC and Monitor actively assess organisational culture, effective use of clinical governance and employment practices to assure the quality of NHS management? If so, how should it assess this?
- Are new mechanisms needed to improve individual accountability for quality? If so, who should they apply to? Should it be just senior NHS managers and NEDs or all managers?
- Would a common code of conduct for all NHS staff guarantee the quality of patient care? If so, who should develop and own it and how could it be embedded in standard employment contracts and performance frameworks?
- Would a voluntary system of regulation provide sufficient assurance? If so, who should lead it?
- Would negative licensing provide adequate safeguards to prevent poor quality managers from practising?
- Would the Francis proposals for a statutory duty of candour and a criminal offence of causing death or serious injury to patients help assure quality and provide sufficient deterrent to change the behaviour of both organisations and individuals?
- Is statutory regulation of managers the only answer to assuring the quality of NHS managers and actions? If so, who should lead it?

Please send your feedback to ManagerRegulation@nhsconfed.org by 29 March 2013.
1. Centre for Innovation and Health Management (2012).
2. These include the Standards of Business Conduct for NHS staff (1993); the Code of Conduct for NHS managers (2002) which sets the core standards of conduct expected of NHS managers, and should be incorporated in the employment contracts of chief executives and other directors; and Monitor’s NHS Foundation Trust Code of Governance (2006), which outlines principles of good governance for foundation trusts.

Our work
This paper forms part of our work programme on Supporting a new style of NHS leadership. To read more about our work in this area, see www.nhsconfed.org/leadership

The NHS Confederation
The NHS Confederation represents all organisations that commission and provide NHS services. It is the only membership body to bring together and speak on behalf of the whole of the NHS. We help the NHS to guarantee high standards of care for patients and best value for taxpayers by representing our members and working together with our health and social care partners. We make sense of the whole health system, influence health policy and deliver industry-wide support functions for the NHS.
## Current mechanisms for assuring NHS quality and management

<table>
<thead>
<tr>
<th>CQC</th>
<th>Monitor licence/ NHS Trust Development Authority for NHS trusts</th>
<th>Council for Healthcare Regulatory Excellence (CHRE) code</th>
<th>Commissioning</th>
<th>Professional regulation</th>
<th>Board challenge</th>
<th>Employment practices</th>
<th>Other</th>
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<tr>
<td><strong>Non-executive directors (NEDs)</strong></td>
<td>Powers to remove Monitor licence. Conditions include a fit and proper persons test for board members and cover governance of foundation trusts.</td>
<td>Will apply to all NEDs but unclear who will monitor implementation.</td>
<td></td>
<td>Chair of council of governors also chairs board. Senior independent director.</td>
<td>Loss of Appointments Commission: no longer central mechanisms to support board development.</td>
<td>Foundation Trust Council of Governors: New power to hold NEDs to account for performance of the board of directors. Appoint and remove chair and NEDs.</td>
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<td><strong>Executive directors</strong></td>
<td>Nominated individual: employed director, manager or secretary responsible for supervising the management of the regulated activities. Requirements include CRB checks, good character and appropriately skilled.</td>
<td>Powers to remove. Monitor licence conditions include a fit and proper persons test for board members and cover governance of foundation trusts.</td>
<td>Will apply to all but unclear who monitors implementation.</td>
<td>Applies to most healthcare professionals plus other professions, e.g. accountants, lawyers, HR professionals. Can be prevented from practising.</td>
<td></td>
<td>NHS Code of Conduct as part of employment contracts. Recruitment, training, appraisal and disciplinary processes.</td>
<td>Foundation Trust Council of Governors: Approve appointment of CEO. NHS Leadership Academy: support and development for leaders.</td>
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<td><strong>Foundation trusts governors</strong></td>
<td>Powers to remove. Monitor licence conditions regarding fit and proper persons test apply to governors.</td>
<td>Will apply to all but unclear who monitors implementation.</td>
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<td>Code of conduct/Nolan principles: Powers to remove governors. Governors Council or the trust can remove in certain circumstances.</td>
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<td><strong>Senior NHS Managers</strong></td>
<td>Organisational assessment of effectiveness/appropriateness. Registered manager: • does not apply automatically to NHS • CQC approves • responsible for the day-to-day running of each regulated activity/location • shares legal responsibility for compliance with the provider.</td>
<td></td>
<td>Revalidation/CPD. Fitness to practise: can mean struck off register.</td>
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<td>NHS Leadership Academy: support and development for leaders.</td>
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