Preparing for the Francis report

How to assure quality in the NHS

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Introduction

The national structures and systems designed to assure the quality of care delivered by the NHS are currently under intense scrutiny. The Care Quality Commission has been subject to both a parliamentary inquiry and a performance and capability review by the Department of Health. Both made strong criticisms of its past performance and made a series of recommendations that will lead to changes in its strategy and governance (House of Commons Committee of Public Accounts 2012b, Department of Health 2012a). The Nursing and Midwifery Council has also been subject to severe criticism of its performance by the Commission for Healthcare Regulatory Excellence (2012) and the House of Commons, Health Committee (2011).

It is widely expected that regulators will come in for further criticism in the autumn when the Public Inquiry into the serious failures of care at Mid Staffordshire NHS Foundation Trust reports (see www.midstaffspublicinquiry.com). This case is particularly significant, not only because of the scale of the failings identified, but also because the regulators were slow to identify those failings. The Inquiry's Chair, Robert Francis QC, is likely to propose far-reaching changes at all levels of the system, including to the external organisations that regulate quality. But will further changes to national structures and systems make such gross failings in quality less likely in future?

In this paper we set out our views on how the system of quality assurance, including regulation, needs to evolve, the principles on which it should be built and how it should operate. We argue that the system of quality assurance must support the actions and effectiveness of those working at the front line and of those who manage and lead organisations that deliver care. We hope it will help to shape the debate about how quality can be assured in future and inform how organisations at every level of the system including government, professional and other regulators, local providers and individual professionals will respond to the challenges that the events at Mid Staffordshire NHS Foundation Trust have highlighted so dramatically.

We begin the paper by defining what we mean by the quality assurance system and how this relates to individual professionals and providers of care. We do not try to set out in detail who does what or to interpret the statutes and legal duties that define what different organisations do. Rather we try to define at a high level the behaviours and principles that the system as a whole should follow.

What is the quality assurance system?

We use the term quality assurance system to refer to the organisations and processes for defining, assuring, maintaining and improving quality that are external to the organisations that deliver care (see box below). Our focus here is on the extent to which they provide assurance that essential standards of quality are being met, rather than on their ability to support continuous quality improvement. While both are crucial and interlinked, they raise distinct issues.

Some of the key organisations involved in quality assurance

The Care Quality Commission is the successor to the Commission for Health Improvement and the Healthcare Commission. It is responsible for licensing all providers of health and social care. It has the power to close services down if they are below standard.

The National Institute for Health and Clinical Excellence's main function in the present context is to produce clinical guidelines. It has recently been charged with defining quality standards for the treatment of a wide range of conditions.

The Commission for Healthcare Regulatory Excellence is responsible for overseeing all the professional regulators. It reports annually on their performance and in some circumstances can override their decisions.

The General Medical Council is responsible for registering doctors when they enter the profession, for making arrangements for dealing with poorly performing doctors, and, currently, for introducing a five-yearly system of revalidation.

The Nursing and Midwifery Council is responsible for registering nurses and midwives when they enter the profession and for dealing with poorly performing nurses and midwives.

Monitor is currently the regulator of foundation trusts. Following the Health and Social Care Act 2012 it will become the economic regulator of all providers of NHS services. In this role it is responsible for setting licensing conditions and for monitoring providers' systems of governance.

The National Patient Safety Agency works to improve patient safety in NHS providers but has no powers of intervention. It is being abolished and some of its functions taken over by the NHS Commissioning Board.

While the main focus is on those organisations, structures and processes external to care providers, we set out how these interact with other levels of the system. It is vital that these external organisations and structures reinforce and are aligned to the activities of those delivering care.

We suggest there are three lines of defence in the battle against serious quality failures in health care. The first line of defence is frontline professionals, both clinical and managerial, who deal directly with patients and carers and are responsible for their own professional conduct and competence and for the quality of the care they provide. They are first-hand witnesses when things go wrong and often have ideas about how the quality of care could be improved. It is vital that they are able to speak up and empowered to act to prevent failings in care.

The second line of defence is the boards and senior leaders of health care providers responsible for ensuring the quality of care delivered by their organisations. They are ultimately accountable when things go wrong and should be able to address problems that arise because

of a lack of systems and processes. It is vital that they are able to monitor the quality of care, take action to resolve issues, and create a culture of openness that supports staff to identify and solve problems.

The third line of defence is the structures and systems that are external, usually at national level, responsible for assuring the public about the quality of care. These national bodies can require organisations to be transparent and to give an account of their performance and actions. They can take action when local organisations fail to resolve issues.

A wide range of approaches and organisations are currently involved in quality assurance.

> **Licensing/registration**

All professionals require a licence in order to provide services legally. For example, doctors, nurses and other health care professionals must be registered with their respective regulators before they can practise. All providers of 'regulated activities' (as defined in in Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010) must be licensed by the Care Quality Commission.

> **Standard-setting**

Standards are set for individuals and organisations, for the way that care should be provided and the outcomes that should be achieved, for specific conditions and for groups of patients such as children. For example, the General Medical Council (2012) sets out the standards it expects from doctors in 'Good Medical Practice'. The Care Quality Commission uses 16 essential standards of quality and safety to regulate providers of health and social care (Care Quality Commission 2012b). The National Institute for Health and Clinical Excellence (NICE) produce clinical guidelines setting out in detail the clinical evidence on how to manage and treat certain conditions (for example, Type 1 diabetes). They also produce more general quality standards, for example, on diabetes in adults (NICE 2012).

> **Inspection/ monitoring**

Regulators such as the Care Quality Commission can visit providers or use data to monitor the quality of care provided and spot problems. There has been little ongoing monitoring of health care professionals, but this will change with the introduction of revalidation for doctors.

> **Enforcement**

If regulators have concerns about the quality of care provided they can impose measures to deal with them. For example, the Care Quality Commission can require unsafe or low-quality services to be closed down. Professional regulators can remove from the register those who fall short of required standards.

> **Performance management**

Performance has been monitored on a regular basis against national targets and pressure has been exerted on senior management where providers have fallen short. Performance of NHS trusts has been managed by strategic health authorities (SHAs) and of foundation trusts by Monitor.

> **Contract management**

Commissioners can define the quality they want to be achieved when they agree contracts with providers. They can require information to enable them to monitor performance against these standards and to determine whether or not they have been achieved. If they are not satisfied with the performance of the provider they can re-tender the services, move the contract to an alternative provider, or withhold funding depending on the terms of the contract.

> **Incentives**

The methods of paying providers can be used to reward quality. Current examples include the use of Best Practice Tariffs for some hospital services and the clinical indicators in the Quality and Outcomes Framework for general practice.

➢ **Accountability and scrutiny**
Patients may seek redress through the courts or pursue complaints through the Health Ombudsman. At local level, local authority scrutiny committees can investigate and report on local issues. At national level, the National Audit Office or Care Quality Commission may assess the quality of specific services across the NHS as a whole.

➢ **Transparency/ disclosure**
Providers may face mandatory requirements to publish or disclose information. For example, all providers of NHS-funded care are required to publish a quality account annually.

The central issue is what balance to strike between these various instruments. We review briefly how the present system has evolved and the shift we see occurring as a result of the changes being introduced by the coalition government.

The development of quality assurance in the NHS in England

The Labour government's first White Paper (Department of Health 1997) put quality 'at the heart of the NHS'. The White Paper was followed up by *A First Class Service: quality in the new NHS* (Department of Health 1998), which set out a framework designed to realise that vision. It committed to produce national service frameworks (NSFs) for particular conditions which would set out the standards that patients can expect from the NHS. The government also established the National Institute for Clinical Excellence (now the National Institute for Health and Clinical Excellence – NICE) to appraise new technologies and set out clinical guidelines based on the evidence of what works. Implementation was to be delivered locally through a new system of clinical governance in which chief executives for the first time were made accountable on behalf of the board for clinical quality in the same way as for financial performance. Monitoring of local compliance with the NICE guidance and with the NSFs was to be carried out by a new national body, the Commission for Health Improvement. The Commission for Health Improvement carried out clinical governance reviews to assess how well trusts were implementing clinical governance and NICE guidelines. It also had powers to investigate failures in care and undertook studies of the implementation of NSFs (jointly with the Audit Commission) (Bevan 2011). The main justification for the creation of an independent statutory body was to give the public assurance by providing independent scrutiny of local clinical governance arrangements.

Although this broad framework of national standards, local implementation and external monitoring has endured, the means by which it is implemented has changed over time. NSFs have been abandoned; in their place the coalition government has extended the role of NICE, giving it responsibility for the development of standards, in addition to producing technology appraisals and clinical guidelines. The Commission for Health Improvement was replaced by the Healthcare Commission, which in turn has been succeeded by the Care Quality Commission. With each reorganisation the scope and approach to external monitoring of the quality of local services has changed. The Care Quality Commission registers all health and social care providers (public and private) against essential standards that are set out in regulations. Registration is based on a self declaration of compliance. The Care Quality Commission uses data (in its risk profiles) as well as routine and unannounced inspections to ensure organisations are compliant. The standards focus on the outcomes of care achieved whereas the Commission for Health Improvement was more focused on the internal processes for assuring clinical quality. Despite these successive changes there has been little improvement in the methods that regulators use to inspect and monitor (a theme to which we return).

The performance of NHS trusts has been monitored by SHAs, first using the Performance Assessment Framework, more recently against Vital Signs set out annually in the Operating Framework. Monitor through its compliance framework monitors foundation trusts against the national priorities set out in the Operating Framework. The Operating Framework 2012/13 (Department of Health 2011) set out a set of integrated performance measures including 15 measures on quality. In the future, commissioners will be held accountable using the NHS

Outcomes Framework (through the mandate for the NHS Commissioning Board and the Commissioning Outcomes Framework for clinical commissioning groups). It is not yet clear what quality measures Monitor will use to monitor the performance of providers over and above the registration requirements set by the Care Quality Commission.

The system set out in *A First Class Service* was established alongside long-established arrangements for the regulation of individual professionals. These too have been subject to radical change since 1997. The Bristol Inquiry and other investigations into individual doctors led to major changes in the governance of the General Medical Council and to a decision, only now being implemented, to introduce revalidation of all doctors every five years. Other professional regulators have also changed their governance, and a new body, the Commission for Healthcare Regulatory Excellence, was established to oversee their performance.

In addition to these structural changes, new policies have been introduced. In 2007 Lord Darzi was commissioned to carry out what was termed a 'next stage review' of the NHS, with particular emphasis on what steps were required to raise the quality of care the NHS provided (Department of Health 2008).

A number of independent reports were commissioned as part of Lord Darzi's review. These identified a number of significant weaknesses in the existing quality assurance system. Instead of a single set of national standards, a number of different sources of standards were identified, defined in different ways and by different organisations (McGlynn *et al* 2008). Reports from the US Institute for Healthcare Improvement (2008) and the Joint Commission International (2008) identified a series of obstacles to quality improvement including the lack of a coherent framework for quality improvement and oversight and a lack of clarity about the meaning of quality and how it should be measured.

Following publication of Lord Darzi's final report (Department of Health 2008), a number of new policies were introduced, including changes to hospital payments, requirements on trusts to publish quality accounts and the creation of Academic Health Science Centres. The Commissioning for Quality and Innovation plan linked a proportion of a hospital's income to the attainment of specific quality objectives. These policies were part of a wider strategy that emphasised the importance of measurement and publication of quality data to ensure that the goal of high-quality care was realised everywhere. This period also saw refinement of the financial incentives in the system to ensure that they were more aligned to the objectives of quality improvement.

Leatherman and Sutherland (2003) produced an assessment of progress with implementing the quality agenda set out by the Labour government in 1997. Although the aim was to create a blame-free culture, this appeared to be at odds with the practice at the time of naming and shaming poor-performing hospitals. They also criticised the government for being slow in publishing unfavourable data. The goal of greater openness remained elusive. Despite commitments to decentralise and to give local organisations greater autonomy, central direction and target-setting continued and action on patient engagement did not match the rhetoric. Another later study concluded that as a result of these developments, England had the most extensive top-down quality assurance system in Europe (Legido-Quigley *et al* 2008).

Since the first steps were taken at the end of the 1990s towards developing an explicit policy on quality, the balance between the various approaches (outlined above) has shifted. Initially, for example, when the Commission for Health Improvement was established, inspection and monitoring focused on ensuring that effective systems of clinical governance were in place in all NHS providers. Under the Care Quality Commission and Monitor the emphasis is on licensing and registration against minimum standards.

From 2000 onwards, the Labour government relied heavily on centrally driven performance management. In contrast, the coalition government expects the publication of more information about the performance of providers to drive up quality through patients' choice of

provider as well as local people demanding better services. The so-called 'information revolution' is part of a wider commitment to transparency across public services.

The role of commissioners in assuming quality has also been given renewed emphasis through the creation of clinical commissioning groups, which are supposed to improve outcomes. Up to now, however, there is little evidence that local commissioners have had much influence on quality through their contracts with providers (Smith and Curry 2011). The hope is that greater clinical engagement in commissioning will align clinical and financial decisions and engender a greater focus on quality rather than on volumes and costs.

The government's reforms will make the CHRE a statutory body accountable to parliament and renamed the Professional Standards Authority for Health and Social Care. The government has signalled a preference for voluntary regulation for new professional roles, and the new body has been given powers to set standards for voluntary registers. The government have not yet taken a view on whether there should be regulation of health care managers and if so what form this should take.

There has been a gradual extension of the use of nationally determined financial incentives to improve quality, and there appears to be support for this to continue through the Quality and Outcomes Framework as well as through the development of further Best Practice Tariffs.

Finally, the systems of accountability and scrutiny are changing, with a greater emphasis on local accountability through a stronger role for local government in relation to commissioners and on the provider side through an enhanced role for governors in foundation trusts. This is expected over time to replace the national oversight and performance management by Monitor and SHAs. However, it is not clear that governors currently have the capabilities or information to provide effective challenge to boards (Maybin *et al* 2011), which they will need to develop before national oversight is removed.

In summary, the current system is complex and lacks coherence. There are many players in the system, who have overlapping roles and responsibilities. As well as creating duplication and placing an excessive regulatory burden on providers, this poses a risk that no one takes responsibility to address failures in the quality of care. The different approaches to quality assurance have been layered on top of each other. The requirements of licensing and the associated powers of inspection and enforcement are used alongside commissioning and incentives. National oversight from regulators and performance management continues alongside greater scrutiny and local accountability. Information and data are required to support all of these functions. Data on quality is increasingly made public. Louis D Brandeis, a US supreme court justice in the early 20th century, speaking in praise of transparency said 'Publicity is justly commended as a remedy for social and industrial diseases. Sunlight is said to be the best of disinfectants; electric light the most efficient policeman.' Transparency is critical but it needs to be made available in a spirit of openness rather than one of judgement. There is a risk that these external systems and processes actually hamper rather than enhance the ability of providers of care to deliver high-quality care.

Principles for effective design

In this section we set out four principles which we believe should guide any redesign of the system as a whole. We draw on research into the processes involved in quality assurance (Schiff and Rucker 2001) and ensuring patient safety (Walshe and Shortell 2004) and also into assessing the effectiveness of regulation (Bevan 2011).

➢ **The system should be patient-centred**

First, the quality assurance system must support health care providers to be patient centred and monitor their success in achieving this. A focus on the patient not only creates a positive experience of care for patients and their families but also supports clinical effectiveness and

patient safety. Organisations and staff must be encouraged to focus on the needs of patients rather than on satisfying the requirements of regulators or other external bodies.

This has been a recurring theme in documents on quality in the NHS: 'Effective involvement of patients and carers is essential to ensuring that everyone is fully engaged in the drive for quality, and that this focuses on what really matters' (Department of Health 1998, para 3.10). More recently in the National Quality Board report in 2010: 'Patients, users and carers are the reason for the NHS existing… and as such must be at the centre of all that the NHS and its staff do' (National Quality Board 2010, p 15). All providers of NHS-funded care are governed by the NHS Constitution. One of the seven principles of the Constitution is 'NHS services must reflect the needs and preferences of patients, their families and their carers. Patients, with their families and carers, where appropriate, will be involved in and consulted on all decisions about their care and treatment' (Department of Health 2012b, para 4).

While there are examples of excellent practice and many important initiatives under way, overall, providers remain insufficiently focused on listening to and learning from patients about their experiences. The collection and use of feedback from patients, including complaints and survey data, needs to become more firmly embedded in the day-to-day organisation of care. Board members, including non-executive directors, need to regularly hear direct from patients, either during board meetings, walk-arounds or through other informal contact. They need to be monitoring not only the volume of complaints but also the content of those complaints. Currently, the only mandatory requirement is for organisations to participate in annual national patient surveys, but these do not produce data that is sufficiently timely or detailed to enable a provider to understand and act on what it tells them about the quality of care in different parts of their organisation. We have recommended that patient-reported experience measures are developed that can be routinely collected alongside other data such as patient-reported outcome measures (Robert and Cornwell 2011).

External bodies need to assure the public that the internal clinical governance arrangements enable the board to know about the quality of the care experienced by patients in their care. But they should also support providers in this, for example, by sharing data collected for regulatory purposes with providers and feeding back to staff the findings of inspections. Requirements to be patient centred are also found in guidance issued by professional regulators. For example, the General Medical Council's guidance to doctors – 'Good Medical Practice' – makes clear that doctors must be patient-centred and that patients must always be their first concern (General Medical Council 2012). Although compliance with this guidance is mandatory, the key challenge is embedding this approach in every aspect of practice. As part of revalidation every doctor will be required to collect and reflect upon patient feedback. However, a more systematic approach to the collection of patient feedback will be required if the public are to have confidence in the process of revalidation (Ipsos MORI/ The King's Fund forthcoming). The Society for Cardiothoracic Surgery has piloted a method for doing this that could be the basis for collecting feedback in other specialties. All clinicians and clinical teams – not only doctors – should have access to and use information from patients about their care. The increasing availability of patient-reported outcome measures provides further opportunities for clinicians to understand the impact of their care on patients, though currently these data remain underused (Devlin and Appleby 2010).

The regulators themselves must also be focused on patients and users. The Care Quality Commission tries to ensure the standards reflect the outcomes of care valued by patients and users. The Care Quality Commission also listens to patients in carrying out its regulatory functions: inspectors talk to patients and carers during visits; analysis of data from patient surveys is included in the risk profiles as well as qualitative data from other user forums on websites; patients are invited to 'share their experience' and report concerns about specific providers via their website and phone line. In future, Care Quality Commission plans to involve more users in inspection teams. Healthwatch England could play an important role as a consumer champion, ensuring the voice of patients, users and carers is heard more directly at national level. However, the fact that it is part of Care Quality Commission and that limited resources are available to local Healthwatch suggest these new bodies will find it difficult to

fulfil their role and should not be relied on to ensure providers hear about the concerns of patients. Despite changes to the governance of professional regulators to increase lay membership of councils, it is not clear how much the voice of patients informs regulators' activities.

The quality assurance system needs to ensure that staff and providers are patient centred and are listening to and responding to the experiences and concerns of patients, carers and families. They also need to ensure that their own activities are informed by the views and experiences of patients, carers and families.

> ➤ **The system should engage staff**

Staff engagement is critical to achieving high-quality care. There is evidence that the environments in which staff work often depersonalise and dehumanise care-giving and that the wellbeing, morale and values of staff are a key factor in shaping patients' experiences and whether they are treated with compassion and empathy (Goodrich and Cornwell 2008). As with patient engagement, the role of the quality assurance system is to support the NHS in promoting staff engagement and monitoring its success in doing so. This will require a shift away from monitoring staff numbers and other inputs to focusing on the environment and context within which staff work and on their experience of work.

The King's Fund has recently argued that leaders of health care organisations need to cultivate a culture of engagement with patients and staff. We also reviewed evidence that suggests organisations whose staff are engaged deliver a better patient experience, fewer errors and higher staff morale (The King's Fund Leadership Review 2012). There is also evidence that staff want to work in organisations that treat patients as they would want members of their family to be treated and that having good relationships with patients can positively influence job satisfaction (Goodrich and Cornwell 2008). External bodies should consider using data on the experience of staff as an indicator of the 'health' of an organisation's culture.

Supporting staff to take ownership of quality crucially means supporting them to raise concerns when they witness substandard care. The culture in many health care providers remains closed and deferential. Along with patients, staff are in a good position to detect when quality standards are slipping. There is considerable anecdotal evidence that many staff are reluctant to raise concerns. A better understanding of why this is the case and of how to engender a more open culture is urgently needed. One suggestion would be to give staff the ability to go 'outside the line' of direct line management to a member of the executive or non-executive to report concerns that they felt were not being taken seriously by their direct superiors. Such a system exists in the nuclear industry and is an important safeguard to make sure safety risks are escalated.

Whistleblowers (that is, staff who want to raise a concern about the organisation they work for) must also be given adequate support and protection. Providers are expected to have whistleblowing policies in place. The Care Quality Commission was criticised by the Public Accounts Committee for scrapping its 'dedicated whistleblower line' and, in the case of Winterbourne View, for not acting on concerns reported to them (House of Commons, Committee of Public Accounts 2012a). It does have processes for whistleblowers to contact the organisation and raise concerns. It is vital that all staff working in health care are aware of how to raise concerns about the quality and safety of care. Concerns about individual professionals may also be raised with the relevant professional regulator. It is it vital that the regulators share information and investigate whether problems are the result of individual conduct or competence, or whether the issues are more widespread and systemic. The Memoranda of Understanding that the Care Quality Commission has with professional regulators includes provisions on the cross-referral of concerns (see Care Quality Commission 2012a).

More generally, employers and managers need to take appraisal – which forms a mandatory part of the process for revalidating doctors – more seriously. The quality of appraisal in the NHS as a whole is varied and too often substandard performance goes unchallenged. There is

evidence that there is a strong link between well-structured appraisal and staff engagement and between engagement and better clinical performance (The King's Fund Leadership Review 2012). Effective appraisal of all clinicians would contribute to ensuring the delivery of high-quality care. Beyond this, employers and managers need to align recruitment, appraisal and other staff development and engagement to support of the goal of assuring quality of care for patients.

The quality assurance system needs to ensure that all staff working in health care are aware of how to raise concerns about the quality and safety of care and that concerns are heard and acted on. The quality assurance system needs to monitor staff experience and other indicators of staff engagement and, where concerns are raised, regulators must share information and jointly investigate the matter.

> ➤ **The system should promote good governance and effective leadership**

The primary responsibility for quality rests with the boards of organisations. An external quality assurance system that is too heavy handed, duplicative or bureaucratic risks failing to motivate boards to take real ownership of their responsibility for the quality of care they deliver. The quality assurance system needs to explicitly encourage the leaders and boards of organisations to recognise their responsibility for internal governance of quality.

As noted above, quality regulation has shifted over time from observing whether internal governance processes for quality assurance were in place under the Commission for Healthcare Improvement to the Care Quality Commission's focus on measuring whether standards of care are actually being met. As part of a broader shift that places the main responsibility for quality on local providers, there again needs to be a greater emphasis on good governance. Providers need to demonstrate that the governance processes for ensuring quality both at board level and also within each organisation – eg, at specialty or service level – are effective.

Monitor produced a quality governance framework in July 2010 (see box below). It defines quality governance as the 'combination of structures and processes in place, both at and below board level, that enable a trust board to assure the quality of care it provides' (Monitor 2010).

Monitor's quality governance framework

Strategy
- Does quality drive the trust's strategy?
- Is the board sufficiently aware of potential risks to quality?

Capabilities and culture
- Does the board have the necessary leadership, skills and knowledge to ensure delivery of the quality agenda?
- Does the board promote a quality-focused culture throughout the trust?

Processes and structure
- Are there clear roles and accountabilities in relation to quality governance?
- Are there clearly defined, well-understood processes for escalating and resolving issues and managing quality performance?
- Does the board actively engage patients, staff and other key stakeholders on quality?

Measurement
- Is appropriate quality information being analysed and challenged?
- Is the board assured of the robustness of the quality information?
- Is quality information used effectively?

Source: Monitor (2010)

The framework now forms part of the assessment process for trusts applying to become foundation trusts (Monitor 2012) and the compliance framework that is used to ensure that foundation trusts are meeting the terms of their authorisation (Monitor 2011). Boards are required to declare that they have in place effective arrangements to monitor and improve the quality of care (see box below). These arrangements are still very new and it is too early to judge whether they support the principle of good governance and effective leadership. The experience of the Commission for Health Improvement was that the impact of clinical governance reviews diminished over time and the process of assessment was onerous.

Monitor's compliance criteria for boards

Boards should:
- describe their own objectives for improving quality
- identify metrics to monitor quality in terms of clinical outcomes, patient or service user safety and experience, and expected levels of performance
- ensure they have in place systems, processes and procedures to monitor, audit and improve quality, including meeting their own objectives, health care targets and indicators and complying with all relevant legislation, and that relevant risks or shortfalls are identified, understood and mitigated
- maintain effective governance systems to monitor and report on cleanliness, patient safety and experience in a timely fashion
- consider serious incidents and patterns of complaints
- maintain a programme of internal audit review and independent assurance that supports the certification process.

Source: Monitor (2011)

There remains little public assurance about the effectiveness of clinical and quality governance in primary care and other organisations that are not foundation trusts; furthermore they differ from the requirements for charities, other non-profit organisations and private sector companies. Could the framework for quality governance be extended to all providers of NHS-funded services, potentially through Monitor's licensing powers?

Culture – that is, 'how we do things round here' – is both a function of governance and a reflection of the leadership, values and drive of those in senior positions throughout the organisation. The National Quality Board has recently brought out a guide for provider boards with advice and information on the sort of things they should be doing in order to govern effectively for quality (National Quality Board 2011b). It underlines the important role of the board in creating the right organisational culture (p 7):

> it is the responsibility of the board to create a culture within the organisation that enables clinicians and clinical teams to work at their best, and to have in place arrangements for measuring and monitoring quality and for escalating issues, including, where needed, to the board. Boards should encourage a culture where services are improved by learning from mistakes, and staff and patients are encouraged to identify areas for improvement, and not afraid to speak out.

A frequent complaint from trusts, and one often echoed in government documents, is about the number of different information requests and reporting requirements, referred to as 'red tape' or regulatory burden (NHS Confederation 2009). Yet analysis of high-performing organisations finds that one 'habit' they have in common is measurement and oversight (Bohmer 2011). While for many organisations measurement is driven by external audiences such as regulators and payers, among these high-performing organisations measurement is for purposes such as internal accountability and performance management. Those organisations go beyond the measures required for external reporting. Quality assurance systems must support such activity and be built on the foundations of good governance within organisations.

There is a risk that the regulatory requirements of external bodies crowd out a focus on the effectiveness of internal quality governance arrangements and that the activities related to fulfilment of these requirements run counter to an organisational culture that promotes learning and improvement. The quality assurance system must support good governance and effective leadership within providers.

> ### The system should ensure the roles of organisations are clear

One challenge is that the various elements that make up the quality assurance system were not designed as part of a coherent whole. In 2009 the National Quality Board was established to 'bring about greater alignment for quality between the national bodies responsible for the overall health system' (National Quality Board 2011a, p 6). A review of early warning systems (National Quality Board 2010) was commissioned in response to an earlier review by the Healthcare Commission into Mid Staffordshire NHS Foundation Trust (Healthcare Commission 2009). That report provided a comprehensive overview of the structures and processes in place at the time to assure quality and to ensure early signs of quality failures were identified and addressed (see figure below). It made a series of recommendations of further steps that could be taken to enhance the mechanisms for safeguarding the quality of care. However, as a result of the Health and Social Care Act 2012 many of the organisations who played a key role in that system of assurance are being abolished and new organisations with different responsibilities are being created. The National Quality Board will shortly be publishing further guidance on how quality can be assured in the reformed NHS.

Structures and processes for safeguarding quality in the NHS
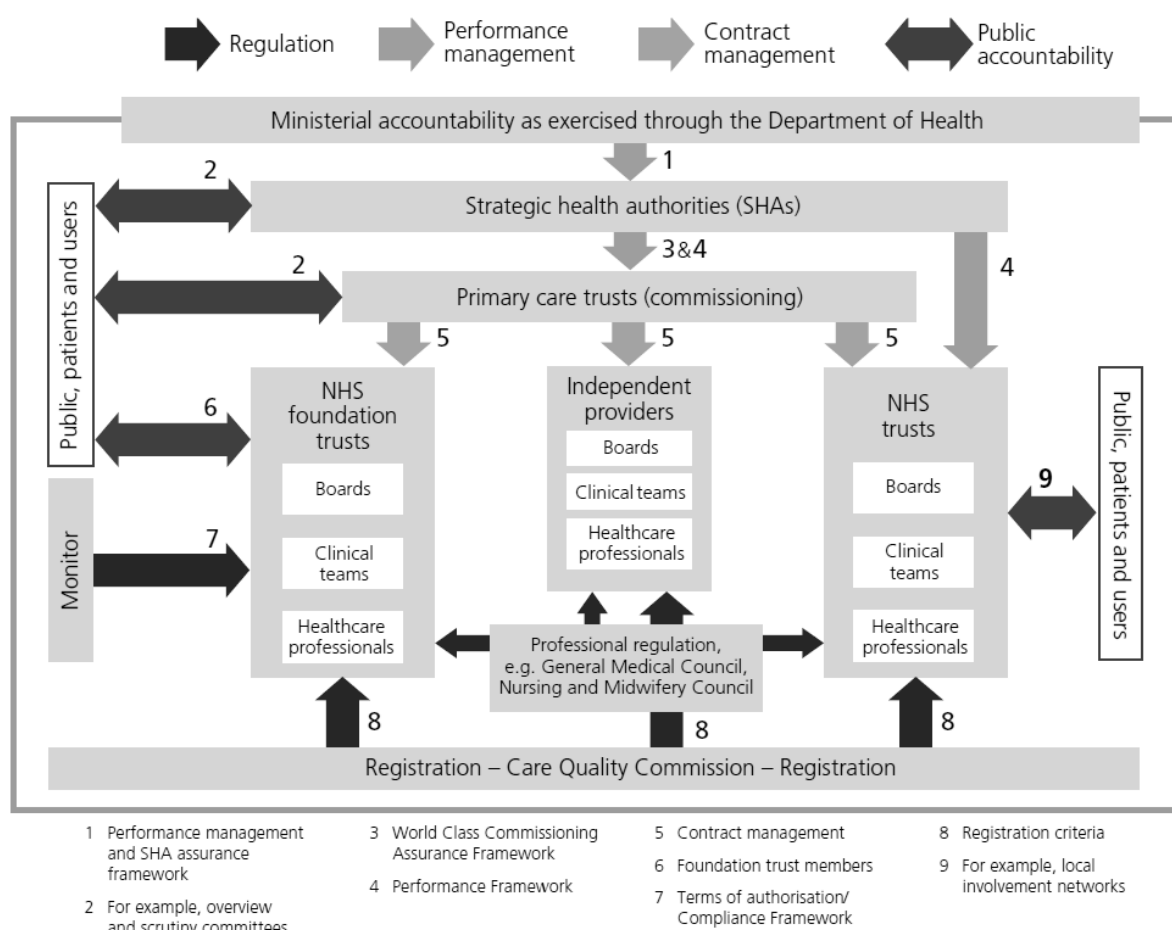
Source: National Quality Board 2010

Interdependencies and connections between organisations within the quality assurance system need to be identified and agreements formed about how they will work together to avoid unnecessary duplication – eg, data collection. The respective roles of the Care Quality Commission, Monitor and commissioners in acting on quality failures need to be aligned. Where they overlap because, for example, financial and quality failures are closely linked, their activities need to be effectively co-ordinated. Care Quality Commission has no fewer than 17 Memoranda of Understanding. The Health and Social Care Act has created a number of new bodies such as the NHS Commissioning Board, the Provider Development Authority and Public Health England, which all have a role to play in ensuring the quality of care. It is vital that the Department of Health, through the National Quality Board, retains responsibility for ensuring a coherent national strategy for quality that co-ordinates all the relevant organisations

There is some confusion in the existing system about how different organisational and service quality standards relate to each other. There is a need for a clearer narrative to explain the role of NICE quality standards in the new system. This should make clear how they relate to the registration standards used by the Care Quality Commission and the levels of ambition which will be set under the Outcomes Framework and Commissioning Outcomes Framework. Likewise, there is confusion about the role of commissioners in setting their own standards and monitoring compliance as opposed to that of regulators, who have statutory responsibility for doing so.

People working in the NHS, as well as patients and the public, need to understand who does what and who is responsible for what. NHS staff are still confused about where and how to raise concerns about performance and quality and believe that they remain at risk if they do. Similarly, the complaints procedure remains opaque and difficult for patients to navigate. There needs to be a single portal for making complaints that is clearly signposted for patients and their carers.

The various components of the quality assurance system must have clearly defined roles, so that their activities do not overlap unnecessarily or interfere with each other. Their roles and responsibilities within the quality assurance system need to be understood by all those working within and for the NHS.

Operational requirements

However the quality assurance system is designed, it must meet a number of operational requirements if it is to work effectively. The main ones are outlined below.

> ➤ **Ensure action is taken when problems are identified**

The quality assurance system fails when it identifies problems which are not then adequately addressed by those responsible. Quality assurance must not stop at the identification of problems or risks – it must ensure that they are dealt with swiftly and effectively. There is evidence that investigation and inquiry reports are insufficiently acted on or followed up. In the immediate future, clinical commissioning groups will find it hard, particularly in view of their limited resources, to carry out these tasks. So there is a risk that this gap in the current system will be perpetuated.

> ➤ **Create a learning system**

The quality assurance system needs to be dynamic and have the capacity for learning. Evidence on the right balance of different elements of the system is scarce. The system needs to build evidence about what methods and processes offer best value for money, and what risks of negative effects different approaches have. Importantly, learning and dynamic systems can best develop when there is a basic level of organisational stability, so that organisations and the staff within them can build experience and expertise. Regulation in the health sector

has been much more prone to reorganisations than other sectors. The loss of some organisations (such as the National Patient Safety Agency) and the frequent reorganisation of system regulators such as the Care Quality Commission and its predecessors has weakened the system's ability to learn and improve.

> ## Subject standards to regular review

The standards that underpin the quality assurance system, both for individuals and for organisations and services, need to be dynamic. They need to be subject to wide consultation and regular review to ensure that they remain up to date and comprehensive. Standards must keep pace with new models of care and with public expectations about quality of care change. For example, standards for individual professionals increasingly need to reflect skills such as teamworking, communication and shared decision-making as well as clinical skills, on which quality assurance has largely focused in the past.

> ## Be proportionate to risk

If resources are to be used effectively, the quality assurance system must take account of different levels of risk. Low-risk and small-scale problems should be addressed locally. National monitoring and assurance of quality should focus on higher risk services and on organisations and quality issues that appear to be endemic across the NHS.

However, it is difficult to determine what risk rating to give different organisations, in part because the services they provide are heterogeneous but also because very few providers are consistently either substandard or excellent across all their services. The assurance and monitoring of quality therefore needs to reflect this. Currently, risk profiling and risk rating is based on overall organisational risk. It is important that quality assurance can pick up emerging quality problems in particular service lines where risks are known to be higher. Regulators must pay particular attention to settings where patients are more vulnerable – for example, detained patients or those in secure facilities. In such closed environments patients may be isolated from family and carers and be more fearful to speak up about failings in their care or that of others they might witness.

The National Quality Board could usefully work with the Care Quality Commission, Monitor and the professional regulators to identify where any major national issues emerge as high risk across the system. For example, serious issues have been well documented in the care of people with dementia across care settings, but the regulatory response to this has arguably not been adequate.

> ## Recognise that different settings and services will need different approaches

Organisational structures vary significantly between primary care, community services, acute hospitals, and mental health providers. How the quality assurance system applies these principles therefore will need to vary accordingly. While boards play a significant role in quality assurance within acute providers, there is no direct equivalent for primary care providers. Internal quality governance in primary care is therefore weaker. As primary care providers increasingly come together in federations of practices, there is potential for better internal governance of quality. There are also differences in the governance of organisations depending on their legal form – eg, limited companies, charities or partnerships. Given the diversity of providers of health care, the quality assurance system will need to adapt to ensure patients and the public can be equally confident of the quality of care wherever they are treated.

Many of the current approaches focus on either individual organisations or individual professionals and yet the delivery of modern health care is increasingly team based and inter-organisational. The quality assurance system needs to reflect this move to greater multidisciplinary and cross-boundary working. Currently no part of the quality system deals adequately with these areas but they will become more important as and when systems of

integrated care develop across current organisational and professional boundaries.

Discussion

In its review of early warning systems published in 2010, the National Quality Board stated:

> *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.*
>
> (National Quality Board 2010, p 9)

We agree.

The forthcoming report of the Francis Inquiry will no doubt question again whether the national systems and processes in place are adequate to prevent such gross failures in the quality of care provided to patients. There is a risk that the response will focus on national regulators and will single out particular organisations for attention. As recent events in financial markets have shown, not all major risks can be foreseen and some apparently low-risk areas can give rise to serious failure.

Inevitably there will be other providers in future that will fail in whole or part to maintain standards. When this occurs it must not automatically be attributed to a failure in regulation. It would be wrong to respond by imposing ever more rigorous monitoring and inspection, with the risk of discouraging frontline staff and provider organisations from taking responsibility for the quality of care they provide.

It is vital that any response to the Francis Inquiry recognises the importance of supporting frontline clinicians to identify and tackle poor-quality care and of boards to change the organisational culture in the NHS. We must move away from a culture that too often encourages complicity with poor care.

As we have shown, the different approaches to quality assurance have been layered on top of each other. There is a risk that these external systems and processes actually hamper rather than enhance providers' ability to deliver high-quality care. There is little evidence to demonstrate their effectiveness. In the current financial climate it is important that regulatory activities are also cost effective, but this has proved challenging to establish (Sutherland and Leatherman 2006). While the direct costs of regulation are calculable, the indirect costs – ie, the costs falling on the regulated organisation – are not. Without such evidence it is not safe to assume that additional regulation will be beneficial.

There is some evidence that public reporting of data on quality (when benchmarked) can have a powerful effect on the reputation of organisations and individuals (Shekelle *et al* 2008). But recent evidence suggests that aligning these to financial incentives does not increase the impact on quality improvement (Jha *et al* 2012). Further research is needed to understand how these different approaches to quality assurance interact and which combination is the most cost effective.

We believe, however, that a number of principles should guide the design of the quality assurance system. It should be patient centred, engage staff, promote good governance and effective leadership, and all those who are part of it must be clear about their roles. At each level we have made a number of recommendations for how those organisations that make up the quality assurance system need to act.

- They need to ensure that staff and providers are patient centred and are listening to and responding to the experiences and concerns of patients, their families and carers.

They also need to ensure that their own activities are informed by the views and experiences of patients, carers and families.

- They need to ensure that all staff working in health care are aware of how to raise concerns about the quality and safety of care and that those concerns are heard and acted upon. They need to monitor staff experience and other indicators of staff engagement and, where concerns are raised, regulators need to share information with the relevant organisations and jointly investigate the matter.

- There is a risk that the regulatory requirements of external bodies crowd out a focus on the effectiveness of internal quality governance arrangements and that the activities related to fulfilment of these requirements run counter to an organisational culture which promotes learning and improvement. The quality assurance system must support good governance and effective leadership within providers.

- The various organisations within the quality assurance system must have clearly defined roles, so that their activities do not overlap unnecessarily or interfere with each other. Their roles and responsibilities within the quality assurance system need to be understood by all those working within and for the NHS.

As we have shown here, it is important that the quality assurance system – that is, the processes and systems external to providers – is effective as a third line of defence against serious quality failures. The period in the run-up to the Francis Inquiry report gives organisations, both national and local, the opportunity to identify the main barriers to effective quality assurance and to agree strategies to tackle them. We hope these principles and suggestions are a useful guide as we work to design a more effective system that can win back the confidence of patients and the public.

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