The Francis Public Inquiry Report: a response

Policy response

This response by the Nuffield Trust to the findings of the Mid Staffordshire NHS Foundation Trust Public Inquiry, chaired by Robert Francis QC (the 'Francis Report'), offers an analysis of several of the key recommendations and themes. This paper is intended to inform the Government's response to the Francis Report. We have focused on those areas where the Nuffield Trust has particular expertise, such as funding, data, commissioning and regulation.

Key Points

- We support the Francis Report's main message that hearing and understanding patients must come first, at all levels of the system, from the individual interactions between staff, patients and families, to the hospital management and board, local and national regulatory and supervisory bodies, and the Department of Health.
- We welcome the Inquiry's proposal to introduce a statutory duty of candour in the NHS; to support the development of a culture of patient-focused care at the front line, and where the reporting of performance and concerns in an open and transparent manner is considered to be a necessary and usual way of working.
- We support the Inquiry's recommendations about the need to bring about culture change in the NHS. How the Government, the Department of Health and the NHS Commissioning Board intend to act in response to the Inquiry will be as important as what they suggest.
- We would encourage the Government to avoid the temptation to over-regulate, or be too punitive or over-critical, as this could undermine the readiness of staff and organisations to be open and honest when things go wrong.
- We support the principle of defining fundamental, enhanced and developmental standards of care, and suggest that these should be shaped by the voices of patients and the experience of staff, informed by the National Institute for Health and Clinical Excellence (NICE) and commissioners, and led by the Care Quality Commission as an independent body. The activity should not be led by the NHS Commissioning Board and clinical commissioning groups, who may be conflicted.
- We suggest that, in the setting of care standards, the care of vulnerable older people should be the first priority.
- Given the complexity of current regulatory arrangements for the NHS, we propose that the Department of Health further clarifies the ways in which health providers are to be monitored and held to account for quality of care and financial management, and which national organisations should take the lead responsibility in this respect. This clarification should go further than what is currently set out in the National Quality Board's paper *Quality in the New System*.
- While we would not support a major transfer of regulatory responsibilities from
 Monitor to the Care Quality Commission at this point, the effectiveness of the current
 regulation of governance of NHS providers should be reviewed, with a view to having
 more streamlined and less complicated arrangements. More generally, it will be
 important for both the Care Quality Commission and Monitor to work much more
 closely together and share information in the future.

- We consider the systematic sharing of existing real-time information about the quality of NHS care to be critical to the development of a more patient safety-focused service. This will need to be sensitive enough to detect the dispersed nature of small-scale failure in hospitals that are otherwise performing well, rather than aimed solely at identifying obvious outliers.
- The routine collection of data to enhance the ability to measure quality of care needs to be developed, informed by a range of organisations such as the Care Quality Commission (which we suggest should be responsible, as noted above, for leading the identification of fundamental, enhanced and developmental standards), the NHS Commissioning Board, NICE and other organisations such as Healthwatch England.
- We strongly endorse the Inquiry's comments and recommendations concerning developing peer review systems, and urge the Department of Health to consider in its response to the Inquiry how this might best be done.
- We support the recommendations to strengthen mechanisms for involving patients and the public in all levels of the NHS, including local representative bodies.

Nuffield Trust support for the Francis Inquiry

At the request of the Inquiry Chairman, the Nuffield Trust prepared a number of papers for the Mid Staffordshire NHS Foundation Trust Public Inquiry, covering matters including: the evidence on NHS commissioning; the regulation and training of NHS managers; the training and development of NHS boards; and the history and development of NHS organisation and management. Copies of these papers are available on the Inquiry website at www.midstaffspublicinquiry.com. In addition, Dr Judith Smith, Director of Policy, Nuffield Trust, provided expert evidence (oral and written), on NHS organisation and commissioning to the Inquiry and was appointed as an assessor of the final Inquiry recommendations. All our work on the Francis Inquiry is available on our website at www.nuffieldtrust.org.uk/francis-inquiry.

Background to this paper

The remit of the Inquiry was to find out why the 'commissioning, supervisory and regulatory' bodies failed to identify problems at the Mid Staffordshire NHS Foundation Trust and subsequently take action. While technically confined to the events at Mid Staffordshire, the wide scope of the Inquiry's recommendations is testament to the belief of the Inquiry Chairman, Robert Francis QC, that "Stafford was not an event of such rarity or improbability that it would be safe to assume that it has not or will not be repeated" (Francis, 2013: para 76). Certainly in the months and years following the issues at Mid Staffordshire coming to light there have been several other major cases that portray care in the NHS in a negative light. Francis draws attention to arguments used by some Inquiry witnesses that inaction over Stafford was justified because similar patterns of poor performance could be found elsewhere, i.e. Stafford was not exceptional, or if it was, it was so only because of the exceptionally large scale of the problems. Robert Francis concludes "it is an argument which evidences a culture of habituation and passivity in the face of issues which may indicate real suffering" (para 78).



From a patient and family perspective, just one incident of poor quality care in any hospital can potentially lead to a catastrophic loss

This encapsulates the uniquely difficult nature of the challenge facing providers, commissioners and regulators of health services. What happened at Stafford Hospital was particularly shocking because of its unprecedented scale and duration. But, from a patient and family perspective, just one incident of poor quality care in any hospital can potentially lead to a catastrophic loss, involving premature death or unnecessary suffering.

A fully patient-centred health system needs, therefore, to be able to detect and respond to individual failures that might be occurring within one ward or department of an otherwise high-performing hospital, as well as identify and respond to larger-scale, more systematic failures of individual institutions. This is the dual challenge facing health systems, particularly regulators and commissioners: creating a system that can detect (and prevent) individual failures at the same time as setting a threshold for when cumulative failures trigger a more resource-intensive, regulatory response.

The Inquiry's recommendations aim to address both dimensions of this challenge: first, a transformed culture at the hospital level of the system to ensure that individual failures in care are avoided and better ways are found for providers to understand the quality of care within their own organisations. Second, external bodies such as commissioners and regulators need to be watchful for signals of failure and able to act swiftly in a targeted and proportionate way when things start to go wrong. It is important that external bodies do not place too much confidence in the ability of risk ratings and/or early warning systems to give a complete picture, and that they use these alongside other sources of information such as patient complaints, staff survey data and 'soft' intelligence from NHS boards.

The thread linking both elements is a renewed focus on hearing and understanding what patients are saying, from the interactions between staff, patients and families on an individual ward, to the tiers of hospital management and the board, through all the local and national regulatory and supervisory bodies, to the Department of Health.



The reality is that more and more trusts will be treating larger numbers of sicker, older adults in an atmosphere of pay restraint and frozen budgets

Our analysis is necessarily influenced by extensive work at the Nuffield Trust on the financial challenge facing the NHS. The NHS faces a growing gap between demand – particularly meeting the needs of a growing cohort of older people with long-term conditions – and available resources. This gap is likely to persist over the next decade at least (Roberts and others, 2012). Since 2007/08, an increasing number of trusts have experienced financial deficits, and in 2011/12, 32 out of 250 trusts reported a deficit (Jones and Charlesworth, 2013). Although there is no straightforward causal connection between restricted resources and failures in care (Mid Staffordshire's failures did not happen simply because of staff shortages, although it has now been put into special financial measures), the reality is that more and more trusts will be treating larger numbers of sicker, older adults in an atmosphere of pay restraint and frozen budgets. Effective regulation, new forms of information and assessment, and informed patient and public involvement are also resource-intensive.

There are inevitably going to be difficult trade-offs for the Government to consider; between investing in developing and sustaining the right culture inside providers of care and ensuring sharper external scrutiny and regulation.

Changing clinical and managerial culture within provider organisations

NHS Constitution

The Francis Report recommends a renewed focus on the NHS Constitution as a reference point for the common values governing care in the NHS (para 1.121 onwards). While it makes sense to build on the NHS Constitution as an existing statement of values rather than replicate it, staff awareness of the Constitution is still low (45 per cent of staff were found to be aware of the Constitution in 2012) and only one in ten staff felt 'very or fairly well informed' about its contents (Department of Health, 2012). If the NHS Constitution is to guide behaviour across the NHS, it will need to be given a high profile amongst both staff and the public, with mechanisms put in place to ensure that its contents are both known and adhered to, perhaps through alignment with NHS recruitment, induction and appraisal processes.

Openness, transparency and candour

We support the recommendation to create a statutory duty of candour in relation to harm to patients and reporting of concerns. This has the potential to empower staff, particularly junior personnel, to speak up when things go wrong or if they feel their team or department is not taking appropriate action. On its own, the duty of candour is unlikely to be enough to change the internal culture of hospitals. The manner and timing of its implementation will be critical, as will the provision of training and development in support of the change, in order to avoid an exacerbation of the defensiveness identified in the Francis Report.

It will be important to accompany any such new statutory duty with an acknowledgement of the pressures faced by staff on a daily basis, particularly as the severity of illness and age of patients has increased and will continue to increase. Trusts may need to more urgently investigate innovative responses to this change in the patient population, which might include the use of new forms of ward management, review of the approach to patient care, and monitoring of quality and patient experience in real-time. Schwarz Rounds, pioneered in the United States, are an example of an initiative designed to change hospital culture by providing a safe environment for staff (of all disciplines) to discuss their responses to stressful or difficult situations, and are now being piloted in NHS hospitals (Goodrich, 2011). Other peer-led examples of health care practice include Balint groups for general practitioners, an initiative originally led by the Tavistock clinic designed to improve the therapeutic alliance between doctor and patient (Launer, 2007).

Skill mix in nursing: the role of health care support workers

The Francis Report calls for a renewed focus on compassionate caring in the training
and performance management of nursing. It also recommends the registration of health
care support workers. We support these recommendations and also argue for the
inclusion of a similar focus on compassionate care in the training and definition of
professionalism for doctors.

The regulation of support workers is to be welcomed. There is currently an absence of systematic information about their numbers, training and development, and how they are being used in hospitals, community health services and social care. Studies in the United States have found that higher proportions of registered nursing staff are associated with higher-quality care as measured by, for example, lower mortality, reduced adverse events and hospital-acquired pneumonia (Hurst and Williams, 2012). Not enough is known about the impact of a change in skill mix within the UK: registration will allow information about skill mix to be publicly available and facilitate research in this area.

Managerial culture

The system of values and beliefs underpinning NHS management is a critical factor in shaping what managers do, how others perceive them, and how they respond to pressure and challenge. Academic research confirms the importance of healthy organisational culture for the performance and safety of health services (Shipton and others, 2008). Commentary on the NHS frequently highlights its centrally directed approach, distinctive in the international context (Newdick and Smith, 2010). Research undertaken by the NHS Confederation cited the 'top-down and directive style' of NHS management as a particular challenge and reported interviewees describing the environment in the NHS as 'brutal, arbitrary, prone to favouritism and intolerant of risk-taking that isn't successful' (NHS Confederation, 2009: p4).



We support the proposal in the Francis Report to introduce a formal code of ethics, standards and conduct for NHS boards, leaders and managers

We support the proposal in the Francis Report to introduce a formal code of ethics, standards and conduct for NHS boards, leaders and managers. This needs to have 'teeth' in order that it does not meet the same fate as the current code of conduct for NHS managers which appears to have been unevenly applied, and rarely, if ever, used as a tool for accountability and development (Newdick and Smith, 2010). We support the use of a formal code alongside a 'fit and proper person' test for NHS boards and managers. We also support the development of a system of accreditation for NHS managers, to enable a stronger sense of profession, status and belonging for leaders in the NHS; something that is needed as a way of rebuilding public and professional trust in health management following recent attacks on 'bureaucracy' and management (Smith and Chambers, 2011).

Promoting broader culture change

Some of the organisational failings referred to in the Francis Report, for example the 'culture of self-promotion', the tendency to emphasise success rather than failure, and the focus on financial issues above all else by the leadership of the trust, are identified in the Francis Report as having existed more widely across the NHS, including in the behaviour of strategic health authorities, the Department of Health and Monitor. The Francis Report rightly calls for all levels of the NHS to adopt a more questioning attitude towards the quality of care experienced by patients, and to keep this in balance with a concern for financial and other measured outcomes of care. In practice, this has been difficult to do, because of the uniquely political nature of the NHS in England. Much of the pressure to meet financial and other process targets can be traced back to ministers, whose political reputations rest on their ability to demonstrate to the electorate that the NHS has improved under their watch.

The creation of an arm's length body to run the NHS (the NHS Commissioning Board) was in part designed to break the link between ministers and the operational management of the NHS, but it would be naïve to expect that ministerial pressure on senior NHS managers will disappear from April 2013 (when the NHS Commissioning Board formally takes over), just as it was to suppose that semi-autonomous foundation trusts would be immune to outside managerial and political pressure.

Politicians from all parties have struck a contrite tone in the wake of the Francis Report, and ministers have avoided being defensive about the state of quality of NHS services: both these stances are likely to come under pressure as the next election approaches and the Government is inevitably judged on its stewardship of the NHS.

Defining and measuring standards of care

The Inquiry recommends the definition of 'fundamental standards' that must be adhered to by NHS providers, and a shift in the burden of proof, where all those in a position of oversight or performance management need to have "convincing evidence [to be] available before accepting that such standards are being complied with" (para 139).

Although many patients and families will now be justifiably anxious about the real standards of care in their local trust, we would encourage the Government to avoid the temptation to over-regulate or be too punitive – a 'big stick approach' will not work and will serve only to further alienate staff and reproduce the distortions created over the past decade by targets. Indeed, the way in which the Government approaches an issue such as the development and assessment of fundamental standards will in itself be an indication of the way in which NHS culture is changing, or not.

Setting fundamental standards is not straightforward. There should be a clear, transparent and inclusive approach to developing these standards and how they are to be assessed, involving a range of stakeholders. The organisation to lead this is the Care Quality Commission.

A priority will be to devise a way to assess when a failure of care exists amongst the millions of care interactions up and down the country. It will also be important that fundamental standards are defined bottom-up by staff in collaboration with users, and building on the extensive work to date by the Care Quality Commission and its predecessors the Healthcare Commission and Commission for Health Improvement. Moreover, any assessment needs to be robust, reproducible and ideally be made in a way that is efficient and does not hinder the delivery of clinical care. We endorse the Inquiry's recommendation that NICE plays a core role in the development of these standards, which can evolve as data improve.

We would recommend that the highest priority for initial development of fundamental standards be given to care of the frail older people on acute wards (for example Ontario's Senior Friendly Hospital Initiative (Wong and Liu, 2011)) and that this priority should shape any new requirements for data collection in NHS trusts set by the NHS Commissioning Board or the Care Quality Commission. Any assessment of standards developed for older patients will need to consider how best to capture the experience of the most vulnerable and their families. The witness statements to the Inquiry revealed how those with dementia, often with no relatives to advocate on their behalf, were particularly vulnerable to poor standards of care and least able to report it.

If fundamental standards are to be defined, one of the most difficult issues will be setting a threshold for compliance. It will be important to identify absolute standards that are well understood in advance of any assessment.



A fundamental standards approach, if sufficiently sensitive, would also allow the identification of isolated poor performance within wards and departments

A fundamental standards approach, if sufficiently sensitive, would also allow the identification of isolated poor performance within wards and departments of trusts. In practice, however, it might be difficult to reach a consensus about where this 'fundamental' threshold should be set, especially if regulatory sanctions or even a failure regime were triggered when it was breached. For example, should all cases of pressure sores or dehydration/malnutrition amongst elderly patients be considered evidence of compassionate neglect?

If the definition of fundamental standards is a bottom-up exercise led by the independent quality regulator, the Care Quality Commission, and based on evidence supplied by NICE, then we suggest a similar process is appropriate for the definition of enhanced or developmental standards which would again be led by the Care Quality Commission but which would clearly involve commissioners. This also hinges on whether 'fundamental', 'enhanced' and 'developmental' standards become part of a system of aggregate ratings of providers (Nuffield Trust, 2013).

Rating hospitals¹

If fundamental, enhanced and developmental standards can be defined, the Government would need to consider whether and how they should be incorporated into any ratings system that might be designed in the future. Though relative measurement is often used, it is not always clear whether being in the top or bottom 20 per cent is necessarily good or bad. As the Inquiry noted, the presence of peers among the bottom 20 per cent of mortality rates was used sometimes as an excuse for inaction. There may also be a tension

^{1.} The Nuffield Trust has been commissioned by the Secretary of State for Health to review whether aggregate ratings of provider performance should be used in health and social care. The report is due for publication in late March 2013.

between summative information on the performance of a hospital that might be produced in the style of annual OFSTED ratings that guide parents' choices, and the information on compliance with fundamental standards intended to guide boards, commissioners and regulators: this would need to be provided closer to real time, and be sensitive enough to identify very dispersed incidents of failure.

Although there is a current interest in ratings as an aid to identify and encourage better quality services, we would observe that high-level organisational ratings have two important limitations in this context. First, they may not necessarily predict future lapses in quality (and thus might lead to a false sense of security); second, they have limited sensitivity to identify failings within organisations, clinical units or individual wards. We believe that the ability to identify failings at this intra-organisational level is critical for regulatory agencies, and also for trust boards and management teams as they seek to take action to address any local failings in care. The key to doing this is to have systems that are alert to failure – scanning information and intelligence for possible problems. These might include:

- reports from staff (including whistleblowers)
- reports from patients, including individual complaints to complement surveys
- the frequency of intermediate adverse events captured within certain clinical indicators (for example 'never events', readmission rates, in-hospital mortality or treatment complications in low-risk cases).

This activity could be classified as 'surveillance' which takes in a wider set of intelligence than a 'rating'.

Tracking mortality rates has a place in the wider monitoring system, but as a surveillance method it is limited because the rates are often ambiguous, and it is difficult to unpick cause and effect. More substantively, by the time people are dying in sufficient numbers to detect on a mortality alert, it is too late.

Acting on information

The Inquiry gives an account of how multiple organisations either failed to notice that care standards had collapsed at Mid Staffordshire NHS Foundation Trust or, more pertinently, failed to act on the information that they had. It was striking from the early warning signs section of the Francis Report how many external organisations had concerns about the trust, but did not share information effectively, or act upon such information.

Since that time, more open channels of discussing concerns have been developed (National Quality Board, 2013), but it is not clear that there are robust methods of sharing real-time information in place within the NHS. Quality Surveillance Groups have been designed by the National Quality Board to bring together local commissioners, regulators and local authority representatives to scrutinise quality across a health economy, but their design does not yet look sufficiently fail-safe. We would like to see absolutely reliable ways of routine information-sharing being established, possibly through an online facility. The Quality Risk Profiles designed by the Care Quality Commission are an important start, drawing on information from a range of sources.

Quality Accounts produced by hospitals also have potential to become documents of equal importance to financial accounts, and to inform the public about the state of quality within an NHS organisation. These Quality Accounts have not, however, always been comparable or consistent in their contents (Foot and others, 2011). We support the recommendations to improve and validate Quality Accounts.

The Francis Report recommends that commissioners – from 1 April 2013, the clinical commissioning groups and their constituent GPs – take a much more active role in the scrutiny of information about quality, as part of an overall commitment to better commissioning. The local GPs in particular were singled out by Francis as having failed to notice that things were awry at Mid Staffordshire or, if they did, for only having communicated this to individual consultants in the hospital, and not airing concerns in any collective forum such as the primary care trust, local medical committee or practice-based commissioning consortium.

Individual practices and clinical commissioners will need to be much more proactive in future. GPs might be encouraged to follow up patients who have recently had time in hospital, given their role as coordinators of patients' care, which is a far cry from routine practice at present. Commissioners will need to have access to timely and robust quality data about services they commission, as well as sources of informal data received directly from patients, and complaints. We support the Inquiry recommendation to find ways of making the content and themes from complaints available to commissioners in a way that does not compromise confidentiality or interfere in any (potential) legal processes.



Direct inspection and investigation are important regulatory tools, though their power should not be over-estimated

The Inquiry recommendations rightly endorse the role of professional investigators at the quality regulator, the Care Quality Commission, as long as they are sufficiently well trained and with adequate clinical experience to understand the reality of complex organisations such as hospitals, which might be missed by other sorts of inspections. Direct inspection and investigation are important regulatory tools, though their power should not be over-estimated. Although there may be calls for more on-site inspection, by themselves these are not sufficient to ensure high-quality care. Even when direct observation is involved, an inspector cannot see all wards all days, and cannot assess the efficacy of individual treatments.

The Francis Report also notes that Monitor was in a weak position (and somewhat disinclined) to detect quality failings in Mid Staffordshire. The report recommends that the Government should consider transferring the regulation of governance of health care providers from Monitor to the Care Quality Commission. While we would not support more reorganisation at this point, the effectiveness of the current regulation of governance of NHS providers should indeed be reviewed, with a view to having more streamlined and less complicated arrangements. More generally, it will be important for both the Care Quality Commission and Monitor to work much more closely together and share information in the future.

The Government has indicated that it will consider creating an inspector of hospitals, who would appropriately be working in the Care Quality Commission. An inspector could help to lead the development of standards with relevant groups including the public, lead the response to apparent clinical failure, and champion and encourage the development of peer review (see below). It will be important for such a figure to be able to command the confidence of clinical staff at the same time as empathising with patients. But there is also a risk of adding another layer of regulation and complexity into the system.

Peer review is another valuable method of responding to concerns about quality that focuses on improvement rather than punitive action. Examples include the West Midlands Quality Review Service (which uses specialist review teams funded by commissioners and providers) and the National Cancer Peer Review programme, which combines self-assessment with targeted peer review visits by multidisciplinary teams. These peer review systems are critical in the defence against poor quality and precisely how they should be developed and funded deserves much further thought.

Clarification of roles in assessing and improving quality of care It would be useful if, given the Department of Health's response to the Francis Inquiry, there might be further clarification as to the roles of national bodies in assessing and monitoring quality of care (including but not limited to failure). In particular, this could include the relationships between the Care Quality Commission and the NHS Commissioning Board, and the Care Quality Commission and Monitor; and the role and membership of the National Quality Board. At present, and despite the recent document published by the National Quality Board (2013), there is some overlap that may not be helpful.



Effective patient and public scrutiny requires training, resources and a clear sense of mission

Public involvement

One of the most notable failures highlighted in the Francis Report relates to patient and public engagement and scrutiny bodies. The Francis Report is critical of the local Patient and Public Involvement Forum and its successor the Local Involvement Network (LINk), and raises serious concerns about the likely efficacy of Healthwatch in future. The local overview and scrutiny committee was also judged to have failed either to have noticed or acted on concerns about quality. The Francis Report noted that both bodies were inclined to be deferential towards their local trust, which raises an important challenge for the role of lay scrutiny in the future. Effective patient and public scrutiny requires training, resources and a clear sense of mission in relation to understanding and challenging the quality of local NHS services. Achieving the latter is not straightforward, particularly when many local people feel that their NHS services are under threat. A mature approach to local patient and public involvement will need to enable multiple channels of engagement; these will involve the public in a range of roles, from support to challenge.

Conclusion: is the system set up to enable genuine culture change?

The Francis Report alludes to, but does not develop, some important underlying tensions in the current system that might need some further consideration. It notes that the trust board was overly focused on meeting financial and access targets, and that a mismatch between funding and the needs of the service was allowed to happen "without protest" (para 1.16). It is not clear from the report where the responsibility should lie for bringing resources and need into alignment. In other words, there is a question about who should make difficult decisions about rationing and the viability of hospital services when resources are frozen. A candid and honest approach to the quality of services, where patients are put first, will require trust boards to be able to signal to commissioners when services are reaching breaking point. This will require commissioners to take difficult collective decisions on behalf of their local populations.



A candid and honest approach to the quality of services... will require trust boards to signal to commissioners when services are reaching breaking point

This sort of candour may not sit easily with a more market-oriented approach to health service improvement, where trusts are expected to compete to attract patients, and success and failure are driven by patients' informed choices. Many of the patients who suffered in Mid Staffordshire may not have had a viable alternative in terms of hospital provision, or were unable to access information to make an informed choice.

This raises once again the unresolved issue of how best to define and handle failure in the NHS. Defining and assessing fundamental patient-centred standards of care in the wake of the Francis Inquiry may well improve the quality of care in the NHS but, if defined too tightly, it may also increase the number of NHS organisations that are at risk of failing. This will only intensify the need to make difficult and controversial decisions about the volume and location of NHS services.

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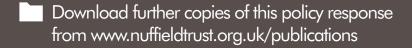
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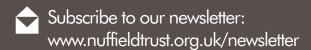


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