

Lessons Learned from the Francis Report (February 2013) – a summary of key messages

Purpose

The purpose of this report is to advise the Care Inspectorate's Strategy and Performance Committee on a series of key themes and issues to emerge from the final report of the public inquiry into Mid Staffordshire NHS Foundation Trust – 'The Francis Report'. Although this is an NHS based report, there is a strong focus on standards and regulation. Analysis of these findings will ensure that the Care Inspectorate can learn any lessons from concerns raised in relation to the NHS in England and, where relevant, take mitigative action to reduce risks and therefore improve the quality of care for people in Scotland.

Background

The Francis Report provides detailed analysis of what contributed to the failings in care at the Mid Staffordshire NHS Foundation Trust between January 2005 and March 2009. It identifies how the extensive regulatory system failed to detect and act effectively to address the Trust's problems for so long, even when the extent of the problems were known.

The report builds on the first independent inquiry, also chaired by Robert Francis QC. Its three volumes and an executive summary run to 1,782 pages detailing 290 recommendations.

The report recognises that what happened in Mid Staffs was a system failure, as well as a failure of the organisation itself. It suggests that a "fundamental culture change" is required, but rather than proposing a "root and branch reorganisation", instead recommends changes which can largely be implemented within the system that has now been created by the new reforms.

The report identifies numerous warning signs which could and should have alerted the system to the problems developing at the Trust. That they did not has a number of causes. These are noted as:

- A culture focused on doing the system's business – not that of the patients.
- An institutional culture which ascribed more weight to positive information about the service than to information capable of implying cause for concern.
- Standards and methods of measuring compliance which did not focus on the effect of a service on patients.
- Too great a degree of tolerance of poor standards and of risk to patients.
- A failure of communication between the many agencies to share their knowledge of concerns.

- Assumptions that monitoring, performance management or intervention was the responsibility of someone else.
- A failure to tackle challenges to the building up of a positive culture, in nursing in particular but also within the medical profession.
- A failure to appreciate until recently the risk of disruptive loss of corporate memory and focus resulting from repeated, multi-level reorganisation.

The report states that the essential aims of the recommendations are to:

- Foster a common culture shared by all in the service of putting the patient first.
- Develop a set of fundamental standards, easily understood and accepted by patients, the public and healthcare staff, the breach of which should not be tolerated.
- Provide professionally endorsed and evidence-based means of compliance with these fundamental standards which can be understood and adopted by the staff who have to provide the service.
- Ensure openness, transparency and candour throughout the system about matters of concern.
- Ensure that the relentless focus of the healthcare regulator is on policing compliance with these standards.
- Make all those who provide care for patients – individuals and organisations – properly accountable for what they do and to ensure that the public is protected from those not fit to provide such a service.

Introduction

Although the Inquiry concluded that the primary responsibility for allowing standards at an acute hospital trust to become unacceptable must lie with its Board, and the Trust's professional staff, it stresses that professional regulators have a responsibility to detect and redress deficiencies in local management and performance where these occur. Because of this, the report is particularly critical of the regulatory system that was in place and its failings.

This paper focuses on criticisms of the regulatory system, particularly the Healthcare Commission, as well as the current system under the Care Quality Commission (CQC).

Criticisms of the regulatory system can be split into a number of distinct areas:

- duplication in regulation
- self-evaluation and triangulation of information
- setting standards
- enforcement of compliance with standards
- commissioning
- information sharing

- complaints
- involvement
- CQC independence, strategy and culture
- openness, transparency and culture
- risk assessment and management
- registration of healthcare support workers

In each section the key messages and recommendations of relevance to the Care Inspectorate will be outlined. A table of the full recommendations of particular interest to the Care Inspectorate can be found at Appendix 2.

Duplication in regulation

The report makes a number of criticisms in relation to overlap and duplication in the regulatory system. It stresses that the responsibilities and accountabilities of external agencies were not well defined, often resulting in “regulatory gaps” or failure to follow up warning signs. In addition:

- Organisations worked in silos without consideration of the wider implications of their role, even “guarding their territories” on occasion.
- They were found to take “inappropriate comfort” from assurances, given either by the Trust itself or from action taken by other regulatory bodies.

As a result, regulators failed to carry out sufficient scrutiny of information, instead treating these assurances as fulfilling their own independent obligations. In order to address this, the Inquiry suggests that effective accountability to the public requires a simpler system of regulation. It recommends that there be a single regulator, dealing both with corporate governance, financial competence, viability and compliance with patient safety and quality standards for all trusts.

Self-evaluation and triangulation of information

The report stresses that at the “heart of the failure” to detect or prevent the events at Stafford sooner, was the concept of the core standards and the means of assessing compliance: the annual health check. It concludes that regulation “cannot be effective if it does not challenge claims of compliance made by the regulated organisations, and its prime purpose in protecting patients cannot be served by such a passive approach”.

In line with this, it warns that the assessment process “suffered a number of defects”, stressing that there was a reliance on self-assessment and self-declaration as the basis of regulation. The checks put in place by the Healthcare Commission to verify self-declarations were “inevitably a net with a wide mesh through which inaccurate self-assessment and deficiencies in practice could pass undetected”.

The focus was on examining providers' "apparent" performance in relation to the standards, most of which "focused on the presence of theoretical systems, not on real achievements and outcomes for patients."

Criticism was also made over the lack of proactive assurance or 'triangulation' of information. There were a number of warning signs which could have triggered a greater level of concern sooner. The report states that taken cumulatively, these areas of concern should have triggered an earlier regulatory response.

Setting standards

The report judges that the current structure of standards is better than what has gone before, although it "requires improvement."

It suggests that the standards are:

- Over-bureaucratic and "fail to separate clearly" what is absolutely essential from what is only desirable.
- Devised in a "top-down" system rather than a "bottoms-up" approach.

With this in mind the report recommends that standards should be divided into:

- **Fundamental standards of minimum safety and quality** – in respect of which non-compliance should not be tolerated.
- **Enhanced quality standards** – such standards should set requirements higher than the fundamental standards but be discretionary matters for commissioning and subject to availability of resources.
- **Developmental standards** – which set out longer term goals for providers – these would focus on improvements in effectiveness and are more likely to be the focus of commissioners and progressive provider leadership than the regulator.

The report calls for expectations towards providers to be set using an evidence-based methodology informed by professionals with a clinical background. It recommends that the National Institute for Clinical Excellence (NICE) be commissioned to formulate standard procedures and practice designed to provide the practical means of compliance, and indicators by which compliance with both fundamental and enhanced standards can be measured. These measures should include both outcome and process based measures, and should as far as possible build on information already available within the system or on readily observable behaviour.

The procedures and metrics produced by NICE should include evidence-based tools for establishing the staffing needs of each service. These measures need to be readily understood and accepted by the public and healthcare professionals.

In addition, it recommends that the NHS Commissioning Board, together with Clinical Commissioning Groups, should devise enhanced quality standards designed to drive improvement in the health service.

Enforcement of compliance with standards

The Inquiry advocates a “zero tolerance” approach in terms of non-compliance with fundamental standards. It recommends that a breach should result in regulatory consequences attributable to an organisation in the case of system failure, and to individual accountability where individual professionals are responsible.

Non-compliance with a fundamental standard leading to death or serious harm of a patient should be capable of being prosecuted as a criminal offence, unless the provider or individual concerned can show that it was not reasonably practical to avoid this.

The report states that the fundamental standards should be policed by the CQC as a single regulator, monitoring both compliance with fundamental standards, and the governance and financial sustainability which will enable a provider to deliver compliant services on a sustainable basis.

Also of note, the report states that “it should not be the role of the CQC to ensure improvement by the provider, but rather to ensure that compliance with the fundamental standards is such as to protect the safety of patients and the quality of the service provided”.

In terms of compliance with the enhanced quality standards, the report recommends that failure to comply should be a matter for performance management by commissioners rather than the regulator. However the regulator should be responsible for enforcing providers’ obligation to provide accurate information about compliance to the public.

Commissioning

The Inquiry found that Primary Care Trusts were not as effective as might have been expected in commissioning or monitoring delivery of quality.

Commissioners of services, as the paying party for services they contract from providers, must ensure that those services are well provided and are provided safely. The fundamental standards to be policed by the CQC form the minimum level of service that should be provided, but the report notes that the commissioner in its contracting arrangements will wish to set standards over and above that. It will also set out redress for non-compliance with those contracted standards.

The report states that responsibility for driving improvement in the quality of service should therefore rest with the commissioners through their commissioning arrangements. Commissioners should promote improvement by requiring compliance with enhanced standards that demand more of the provider than the fundamental standards.

Information sharing

Criticism was made of the lack of effective communication across the healthcare system in sharing information, and how that information is used for effective regulation. The Inquiry found that:

- Organisations relied on others to keep them informed, rather than actively seeking and sharing intelligence.
- There was a lack of openness, transparency and candour in the information emanating from the Trust and over-reliance on that information by others.
- Too many assumptions were made that others would be aware of important information.

The report is explicit that the safety of patients should take precedence over any claims of confidentiality surrounding risk reports. It states that an integrated system with common information practices and shared databases, where possible, is necessary. This would serve to improve accountability, provide clearer information for the public, as well as highlighting inadequate performance of services.

It is also recommended that sharing of intelligence between regulators needs to go further than sharing existing concerns identified as risks, and should extend to all intelligence which combined with that held by partner organisations may raise the level of concern. The report recommends that work is done on a template of the sort of information each organisation would find helpful.

In addition the report recommends that the Health and Social Care Information Centre be tasked with the independent collection, analysis, publication and oversight of healthcare information in England, or, with the agreement of the devolved governments, the United Kingdom. It should publish detailed breakdowns of clinically related complaints and other quality related information.

Complaints

In-keeping with the patient focus advocated throughout the report, the way in which patients may raise concerns and how these are handled is given particular attention. The report stresses that:

- A uniform process of complaints handling should be applied.
- Methods of registering a comment or complaint must be readily accessible and easily understood.
- Any expression of concern made by a patient should be treated as a complaint, unless the patient's permission is refused.

- Multiple gateways should be provided to patients, both during their treatment and after its conclusion.
- Comments or complaints which describe events amounting to an adverse or serious untoward incident should trigger an investigation.
- While a complaints system should be consistent, it must never be applied in a formulaic or insensitive manner.
- Complaints relating to possible breaches of fundamental standards and serious complaints should be accessible to the CQC, relevant commissioners and other scrutiny partners.
- Learning from complaints must be effectively identified, disseminated and implemented, and it must be made known to the complainant and the public, subject to suitable anonymisation.

In addition, the report highlights that complaints, their source, handling and outcome provide an insight into the effectiveness of an organisation's ability to uphold both the fundamental standards and the culture of caring. It claims that they are a source of information that has so far been undervalued by the CQC, noting that the substance of complaints is not routinely fed into the Quality and Risk Profile.

With this in mind the Inquiry recommends that the CQC introduce a mandated return from providers about patterns of complaints, how they were dealt with and outcomes. The CQC should also pay greater attention to the narrative contained in, for example, complaints data, as well as to the numbers.

Involvement

The report highlights the importance of involvement, noting the need to involve patients both in commissioning and in regulation.

The Inquiry recommends that patients, through their user group representatives, should be integrated into the structure of the CQC and/or through liaison with the patient's consultative council. Consideration should also be given to inviting nominated members from representative bodies such as Nursing and Allied Healthcare Professionals.

In addition the report stresses that commissioners need to recognise their accountability to the public they serve by measures designed to involve the public in commissioning and enable their views to be taken into account.

CQC independence, strategy and culture

The Inquiry report makes a number of general observations on the culture, strategy and workings of the CQC that have previously been highlighted in other critical reports. For example:

- The CQC's strategy has been constrained by its resources and lacks the time to carry out properly the responsibilities it has been given in statute by the Department of Health.
- There has been a focus on registration at the expense of monitoring and inspections.
- The skills base and effectiveness of CQC inspectors may have been diluted by converting them to general roles, by staff perception of the quality of training and by concerns about changes in the frequency of required inspections.
- Patient user groups have not to date been embedded in the CQC itself or in its culture and an opportunity has been missed to obtain the patient perspective.

In addition, although the report welcomes the strategic direction of the new regulatory model being developed by the CQC, it criticises the organisation for not communicating this clearly to both the public and its staff. It also warns that the CQC has an unhealthy culture, in which senior managers are more concerned about public image than delivery, which is "hostile to internal and external criticism" and in which staff feel under pressure and unsupported.

It recommends that the CQC review its processes to ensure that it is capable of delivering effective regulatory oversight in accordance with the recommendations and principles outlined within the report. It should also undertake a formal evaluation of how it would detect and take action on the warning signs and other events giving cause for concern at the Trust described in the Francis report, and its previous Inquiry, and open that evaluation for public scrutiny.

Openness, transparency and culture

Strong criticism was made in relation to the culture of care at the Trust. The report suggests that a culture existed that focused on "doing the system's business – not that of the patients." In order to resolve this, the Inquiry calls for a "relentless focus" on the patient's interests and an obligation to keep patients safe and protected from substandard care.

For a common culture to be shared throughout the system, the report states that three characteristics are required:

- **Openness:** enabling concerns to be raised and disclosed freely without fear, and for questions to be answered;
- **Transparency:** allowing true information about performance and outcomes to be shared with staff, patients and the public;
- **Candour:** ensuring that patients harmed by a healthcare service are informed of the fact and that an appropriate remedy is offered, whether or not a complaint has been made or a question asked about it.

This requires all organisations and those working in them to be honest, open and truthful in all their dealings with patients and the public. The report states that a statutory obligation should be imposed with enforcement of these duties lying with the CQC.

The CQC should also keep on constant review its ability to deliver the necessary regulatory oversight and enforcement, taking into account its duties of openness, honesty and candour, and ensure that its strategy and performance are communicated effectively to its staff.

Risk assessment and management

The report notes the change of direction in regulation from an emphasis on planned, routine reviews to more focused responsive reviews based on assessment of risk. Although commending the CQC for this, the report recommends that inspection remain the central method for monitoring compliance with fundamental standards. A “specialist cadre” of hospital inspectors should be established, with consideration given to collaborative inspections with other agencies and a greater exploitation of peer review techniques.

In addition, direct observations with practice, direct interaction with patients, carers and staff, and audit of records should take priority over monitoring and audit of policies and protocols.

Furthermore, the report warns that routine and risk-related monitoring, rather than acceptance of self-assessment, is “essential”.

In relation to this, the report recommends that:

- Information behind the quality and risk profile – as well as the ratings and methodology – should be made publicly available, as far as confidentiality allows. This would enable the public to understand the limitations of this tool.
- The CQC draw on a wider range of information to assess risk (for example, complaints information, quality accounts, peer review etc.)

The report also notes that patient information and feedback do not appear to be priorities when obtaining relevant information about an organisation or generally when the CQC is considering its regulatory approach. It stresses that it is service users, including visitors and families, who are likely to be the first to witness poor outcomes or the warning signs that standards are slipping.

In addition the report sets out a role for the regulator in terms of media monitoring. It recommends that those charged with oversight and regulatory roles in healthcare should monitor media reports about the organisations for which they have responsibility. An example of a serious incident or avoidable harm should trigger an examination by the CQC on how that was addressed by the provider.

Registration of healthcare support workers

Noting that healthcare support workers are not subject to any system of registration, the report recommends the creation of a system under which no unregistered person would be permitted to provide direct physical care to patients for payment in a hospital or care home setting. It notes that exemptions will be required for persons caring for members of their own family or those with whom they have a genuine social relationship.

It suggests that there should be a uniform code of conduct that would apply to all healthcare support workers, who should receive training and education in accordance with common national standards. These should be prepared and maintained by the Nursing and Midwifery Council (NMC) following consultation.

Other

In addition to the key areas outlined above there were a number of points and suggestions made in the report that were not formally recommended. Of note, the Inquiry report stresses that as inspection reports form the basis on which regulatory intervention may be taken, it is important that they include the facts on which they are based, and that “conclusions are rational and clearly expressed”. It further states that: “Quite what language is used is a matter of style rather than of substance.... What is important is whether the extent of the findings made is sufficiently described to be understood by a member of the public.”

Key points for further discussion/action within Care Inspectorate

A number of criticisms of the regulatory system in England and recommendations to the CQC in terms of the Mid-Staffs Inquiry are in line with those made in previous reports into the operation and governance of the CQC. In August 2012 the Care Inspectorate’s policy team, in collaboration with Healthcare Improvement Scotland (HIS), produced a ‘Lessons Learned’ report for both Boards, synthesising the key messages, issues and recommendations from nine separate reports into the scrutiny experience in England, including four specifically into aspects of the performance of the CQC. An action plan is now being developed to address the recommendations from this report.

Although the Francis Report does not specifically address how the lessons from Stafford might be applied to different parts of the system, it states that there are “likely to be implications” in the lessons learned and recommendations for other sectors.

A number of the recommendations made within the Francis Report are either already included in the scope of our original Lessons Learned report or should be considered for further discussion/action within the Care Inspectorate.

The key points/recommendations for further discussion/action can be summarised as follows:

Duplication in regulation

- Single regulator for financial and care quality. (recommendation 19)

Setting standards

- Standards should be divided up into: fundamental standards of minimum quality and safety; enhanced quality standards; and developmental standards. (recommendation 13)
- NICE should be commissioned to formulate standard procedures and practice designed to provide the practical means of compliance, and indicators by which compliance with both fundamental and enhanced standards can be measured. (recommendation 22)
- These measures should include clinical outcomes, suitability and competence of staff and the culture of organisations. The standard procedures and practice should include evidence-based staffing tools for staff numbers and skill mix. (recommendation 23)

Enforcement of compliance with standards

- Zero tolerance approach in terms of non-compliance with fundamental standards: a service incapable of meeting fundamental standards should not be permitted to continue. Where serious harm or death has resulted to a patient as a result of a breach of the fundamental standards, criminal liability should follow. (recommendation 28)
- The CQC should be responsible for policing the fundamental standards. It should not be responsible for directly policing compliance with any enhanced standards but for regulating the accuracy of information about compliance with them. (recommendation 20)
- Compliance with enhanced quality standards should be the responsibility of commissioners. (recommendation 17)

Commissioning

- Commissioners should be enabled to promote improvement by requiring compliance with enhanced standards or development towards higher standards. They can incentivise such improvements. (recommendation 125)

Information sharing

- Sharing of intelligence between regulators needs to go further than sharing of existing concerns identified as risks. Work should be done on a template of the sort of information each organisation would find helpful. (recommendation 35)
- A coordinated collection of accurate information about the performance of organisations must be available to providers, commissioners, regulators and

the public, in as near time as possible, and should be capable of use by regulators in assessing the risk of non-compliance. (recommendation 36)

- The Health and Social Care Information Centre should be tasked with the independent collection, analysis, publication and oversight of healthcare information in England, or, with the agreement of the devolved governments, the United Kingdom. (recommendation 257)

Complaints

- A mandated return from providers, about patterns of complaints, how they were dealt with and outcomes should be introduced. (recommendation 39)
- Methods of registering a comment or complaint must be readily accessible and easily understood. Multiple gateways need to be provided to patients, although all such methods should trigger a uniform process. (recommendation 109)
- Patient feedback which is not in the form of a complaint, but which suggests cause for concern should be the subject of investigation and response of the same quality as a formal complaint, whether or not the informant has indicated a desire to have the matter dealt with as such. (recommendation 112)

Involvement

- Patients through their user group representatives should be integrated into the structure of the CQC. It should consider whether there is a place for a patients' consultative council with which issues could be discussed to obtain a patient perspective directly. (recommendation 58)
- Consideration should be given to the introduction of a category of nominated board members from representatives of the professions. (recommendation 59)

Risk assessment and management

- Routine and risk-related monitoring, as opposed to acceptance of self-declaration of compliance, is essential. The CQC should draw on a wider range of information to assess risk. (recommendation 49)
- An emphasis on inspection as a central method of monitoring non-compliance should be retained. (recommendation 50)
- Development of a "specialist cadre" of inspectors by thorough training in the principles of hospital care. (recommendation 51)
- The information behind the quality and risk profile – as well as the ratings and methodology – should be placed in the public domain where possible. (recommendation 253)
- Regulators should monitor media reports about organisations for which they have responsibility. Any example of serious incident or avoidable harm should trigger an examination by the CQC of how that was addressed by the provider. (recommendations 43 & 44)

Registration of healthcare support workers

- Registration system should be created under which no unregistered person would be permitted to provide direct physical care to patients for payment in a hospital or care home setting. (recommendation 209)