



Department
of Health

The Government Response to
the House of Commons Health
Committee Third Report of
Session 2013-14: *After Francis:
making a difference*



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making a difference*

Presented to Parliament
by the Secretary of State for Health
by Command of Her Majesty

November 2013

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Introduction

The Mid Staffordshire NHS Foundation Trust Public Inquiry, led by Robert Francis QC, reported in February 2013. It probed a culture where complacency pervaded, poor standards of care were allowed to persist, patients were harmed, and staff who tried to speak out were ignored or punished. It set a challenge not just for the Government, but for the whole health and care system.

Patients First and Foremost, published in March 2013, set out the initial response of England's health and social care system to Robert Francis's Inquiry report. It outlined a radical plan to end decades of complacency by detecting poor care quickly and ensuring that the system takes real responsibility for fixing problems urgently and effectively, while also recognising, and celebrating, the excellent care provided by much of the NHS.

In the eight months since publication of the initial response to the Inquiry a great deal has changed:

- The Care Quality Commission has appointed three Chief Inspectors of hospitals, adult social care and primary care.
- The Chief Inspector of Hospitals has begun a first wave of inspections of 18 Trusts.
- Expert inspections of hospitals with the highest mortality rates, led by the NHS Medical Director, revealed unacceptable standards of care. Eleven hospitals were placed into 'special measures' to put them back on a path to recovery and then excellence.
- The Care Quality Commission has consulted on a new system of ratings with patient care and safety at its heart.
- Legislation to introduce a responsive and effective failure regime which looks at quality as well as finance is progressing through Parliament.
- The Government is legislating to give greater independence to the Care Quality Commission
- The Care Quality Commission has conducted a major consultation on a new set of fundamental standards: the inviolable principles of safe, effective and compassionate care that must underpin all care in the future.
- The fundamental standards will enable prosecutions of providers to occur in serious cases where patients have been harmed because of unsafe or poor care, without the need for an advance warning notice.

- NHS England has published guidance to commissioners, Transforming Participation in Health and Care, on involving patients and the public in decisions about their care and their care services.
- For the first time, NHS England has published clinical outcomes by consultant for ten medical specialties and has also begun to publish data on the friends and family test.
- New nurse and midwifery leadership programmes have been developed from which 10,000 nurses and midwives will have benefitted by April 2015. Compassion in Practice has an action area dedicated to building and strengthening leadership.
- A new fast-track leadership programme to recruit clinicians and external talent to the top jobs in the NHS in England has been launched, including time spent at a world-leading academic institution.
- By the end of the year, 96% of senior leaders and all Ministers at the Department of Health will have gained frontline experience in health and care settings.

These national measures are important steps in making an irreversible change to the culture of England's health and care system so that the toleration of poor care can never again be a reality in the NHS. But perhaps more importantly, in the NHS itself the wind has changed. The leadership of the health and care system is embracing a culture of compassionate care and the overwhelming majority of staff want to deliver safe, effective and compassionate care. The stimulus of the Inquiry, combined with the national recognition of the reality of poor care and a collective determination to tackle it, has changed the weather in England's health and care system.

This response to the Health Select Committee answers the questions raised by the Committee, and seeks to describe how the Government intends to build on the rapid early progress. It is published alongside, and reflects, the Government's full response to the Inquiry which responds to all 290 of the Inquiry's recommendations. The overwhelming majority of these are accepted.

Government response to the Committee's conclusions and recommendations

The Francis Report and its significance

- 1. The importance of Robert Francis' report lies not only in its meticulous analysis of the system, identifying areas where misplaced assumptions, perverse incentives and the pursuit of natural human instincts inhibited the ability of the system to deliver high quality care, but also in its description of a culture where the most shocking and obvious deficiencies in care were apparently allowed to persist unchecked, with consequences for patients and relatives which were completely unacceptable. It is vital that the pervasiveness of this culture in many parts of the health and care system is recognised. (Paragraph 4)**
- 2. Robert Francis has described a healthcare system established for the public benefit and funded from public funds which now risks an undermining of public confidence in its guarantees of safety and quality. (Paragraph 5)**
- 3. The Committee is in no doubt as to the importance of the failures at Mid Staffs. It is vital to the interests of patients that the lessons from these failures are learned and acted upon, so that all patients can have confidence in the quality of care in the NHS. Without in any way detracting from the importance of this process, the Committee also believes that it is important to recognise that the experience of those patients at Mid Staffs who experienced poor care is not the day-to-day experience of millions of NHS patients treated each year by caring, experienced and committed staff. The purpose of highlighting the key lessons of the Francis Inquiry is not to undermine the NHS but to improve it. (Paragraph 6)**

No one joins the NHS to deliver anything other than exceptional care. But a system has been created that can sometimes make that difficult or even impossible. This response includes many measures to address that, but fundamentally it requires a deep-rooted change of culture that always puts patients first.

Nobody who reads Robert Francis's report of the Mid Staffordshire NHS Foundation Trust Public Inquiry can think that the terrible failings in professional conduct, leadership, safety and compassion at Mid Staffordshire were simply the result of one organisation losing its way. The wider system, a system whose primary purpose was to support the delivery of safe, effective care, and to act when that did not happen, failed as well. It did not see, or did not want to see, what was going on in Mid Staffordshire.

Traditionally, the response of the Government and of the central organisations of the NHS to failures in care has been to acknowledge the individual failing and then emphasise the very large number of positive experiences and excellent outcomes that people experience every

day in the NHS. This is an entirely understandable impulse: for one thing, it is true. But it would be wrong to use these facts to justify complacency. It is important for everyone that the system does not fall into a trap of ticking the policy boxes and losing its way in the complexity of multiple recommendations, yet missing the point of the simple messages of openness and putting patients first and foremost.

Many organisations in the NHS are already rejecting any such complacency, and are rising to this challenge. They are using the Francis report to ask searching questions about their own practice and ways of working. One of the key lessons that is emerging from this work is that even the most high-performing organisations can have areas of care that need improvement and sometimes fall below acceptable standards. It is important never to lose sight of the simple messages at the core of changing culture: hear the patient, speak the truth, and act with compassion.

The Committee's Inquiry

4. The Committee recommends that the Government should provide a response to the Committee's report in good time for it to be taken into account in the Second Reading debate in the Commons on the Care Bill [Lords]. (Paragraph 13)

Recommendation accepted.

The Government agrees with the Committee's recommendation and will schedule the debate accordingly.

Parliamentary oversight of professional regulation

5. The Committee agrees with Robert Francis' recommendation for its role in monitoring implementation of his recommendations. The Committee therefore proposes to enhance its scrutiny of regulation of healthcare professionals by taking public evidence each year from the Professional Standards Authority for Health and Social Care (the Professional Standards Authority, formerly the Council for Healthcare Regulatory Excellence) on the regulatory environment and the performance of each professional regulator, based on the Professional Standards Authority's own annual report. (Paragraph 14)

6. The Committee plans to draw on the views expressed by the Professional Standards Authority in its reports and in these sessions in preparing for its regular accountability hearings with the General Medical Council and the Nursing and Midwifery Council. It will also examine the case for inviting other professional regulators under the Professional Standards Authority's remit to appear before it from time to time, in the light of the views expressed about their performance by the Professional Standards Authority. (Paragraph 15)

7. The Francis Report demonstrated that failure of professional responsibility was a key factor which contributed to failures of care at the Mid Staffordshire NHS Trust. The Committee has also consistently emphasised the importance of an open and accountable professional culture in its own reports during this Parliament. It welcomes Robert Francis' recommendation that there should be enhanced parliamentary

oversight of the quality of professional regulation, and it intends to develop its relationship with the Professional Standards Authority to make this oversight as effective as possible. (Paragraph 16)

The Department of Health accepted Robert Francis's recommendation that there should be enhanced parliamentary oversight of the quality of professional regulation. The Department welcomes the Health Select Committee's proposal to continue its close scrutiny of the regulation of healthcare professionals, through annual select committees. The Professional Standards Authority's oversight of the healthcare regulatory bodies places it in the ideal position to provide the Health Select Committee with evidence to support this process.

Open culture and professional responsibility

8. The Committee believes that Trusts and other care providers have a fundamental duty to establish an environment where concerns about patient safety and care quality raised by clinicians or managers are addressed openly and directly. (Paragraph 18)

It is the central responsibility of the boards of provider organisations to pay close attention to the culture of their organisation, addressing cultural risks and seeking to improve the culture. They should establish an environment which encourages staff to raise concerns about patient safety and care quality. They must seek to eliminate any sign of a blame culture so that staff can raise concerns without fear of retribution, and opportunities to learn and improve are therefore available.

The Government is clear that any attempts to prevent individuals from speaking out in the public interest will not be tolerated. NHS guidance has been consistently clear that local policies should prohibit the inclusion of confidentiality clauses in contracts of employment and compromise agreements which seek to prevent an individual from making a disclosure in the public interest in accordance with the Public Interest Disclosure Act. The Government requires the inclusion of an explicit clause in any compromise agreement to make it absolutely clear to staff signing an agreement that they can make a protected disclosure in the public interest regardless of what other clauses may be included in the agreement.

Teams and organisations should develop ways to measure their cultural health, and act on these measures to improve. Cultural health is a matter for all staff groups; everybody who works in the health and care system is integral to improving and maintaining good cultural health. Many tools and methods are available and the Department of Health and its arm's length bodies are promoting these. The friends and family test for staff will also be rolled out from April 2014 which will help organisations to track how staff are feeling about organisational performance and culture.

It is important to ensure that there is a clear understanding of the cultural health of different parts of the NHS. Regular inspection will provide the basis for a new, clear, transparent system of ratings that will be accessible to the public. In June 2013, the Care Quality Commission (CQC) issued *A New Start: Consultation on changes to the way CQC regulates, inspects and monitors care*. In this, the Care Quality Commission suggested that a 'well-led' service is one where there is an open, fair and transparent culture that listens and learns from people's views and experiences to make improvements. It confirmed that its plan was to encompass an assessment of aspects of culture as part of its inspections to assess whether

a service is 'well led'. On 17 October 2013, the Care Quality Commission published the response to the consultation *A New Start: Responses to our consultation on changes to the way CQC regulates, inspects and monitors care services*, which showed that there is broad agreement with the new approach. All acute hospitals in England will have been inspected by the end of 2015.

9. The Committee agrees with Robert Francis that the key requirement is for a culture change within the NHS which values openness and transparency in all care delivery – not just when things go wrong. The duty of candour does not simply arise in cases of service failure; the requirement for an open culture which encourages challenge is fundamental to the delivery of high quality care. (Paragraph 21)

The Government agrees with the Committee and Robert Francis that changing organisational culture is pivotal to achieving the meaningful change required in the NHS. A culture that puts patients first will ensure that care is both safe and compassionate.

The responsibility for an open culture within an organisation rightly sits with the board, but the Government and other arm's length bodies have also taken action to support this in the wider system. For example:

- staff contracts have been strengthened to include the right to raise concerns;
- the NHS Constitution has been amended to include explicit rights regarding whistleblowing and a pledge that employers will act upon concerns raised by staff;
- there is a national freephone confidential helpline for whistleblowers;
- the NHS staff survey has been strengthened to focus on openness;
- there is clear policy against compromise agreements prohibiting staff from speaking out; and
- in future, the Care Quality Commission will inspect Trusts' processes for encouraging staff to raise concerns and support whistleblowers.

The Government has introduced in the Care Bill a new statutory duty of candour which will apply to providers, rather than individuals and will be included as a new registration requirement for health and social care providers registered with the Care Quality Commission. There are a range of views on the threshold at which the duty of candour should be set: not so narrowly that important incidents are excluded, nor so broad that defensive behaviour and excessive bureaucracy grow to excess. The Government has therefore asked David Dalton and Professor Norman Williams to assess, by the end of 2013, the argument for extending the threshold for the duty of candour to cover moderate harm as well as death or serious injury, and the practical implications involved in such a threshold. The Department will consult on a draft set of regulations, which also provides the flexibility to be amended or varied over time as the new duty is established. The Government will consult on how best to reflect this in the NHS Constitution when it is next updated.

In addition to the statutory duty of candour on providers, there is also a professional duty of candour on individuals which will be strengthened through changes to professional guidance and codes. The professional values of individual doctors, nurses and other healthcare professionals are critical in ensuring an open culture in which mistakes are reported, whether or not they cause actual harm. The General Medical Council, Nursing and Midwifery Council and the other professional regulators will be working to agree consistent approaches to candour and reporting of errors, including a common responsibility across the professions to be candid with patients when mistakes occur, whether serious or not, and clear guidance that professionals who seek to obstruct others in raising concerns or being candid would be in breach of their professional responsibilities. The Government will ask the Professional Standards Authority to advise and report on progress with this work. The professional regulators will develop new guidance to make clear professionals' responsibility to report 'near misses' in relation to errors that could have led to death or serious injury, as well as actual harm, at the earliest available opportunity and will review their professional codes of conduct to bring them into line with this guidance. The Professional regulators will also review their guidance to panels taking decisions on professional misconduct to ensure they take proper account of whether or not professionals have raised concerns promptly.

An open culture is not limited to discussions about failure. Learning can also take place from sharing good practice and addressing near misses. It is important that Trusts embrace challenge and feedback from their patients. The Care Quality Commission will work closely with Healthwatch England and local Healthwatch to ensure that inspection and ratings processes take account of the views of service users and the public. Measures such as the friends and family test will promote improvement from within. Complaints should also be taken seriously by organisations as an insight into the quality of services. In June 2013, the Care Quality Commission issued *A New Start: Consultation on changes to the way CQC regulates, inspects and monitors care*. This made clear that information from individual members of the public who make complaints, raise concerns and provide feedback about the quality and safety of their care would be a vital source of information, and that a well-led service or organisation would have a good complaints procedure that drives improvement.

NHS England will review Quality Accounts before the 2014-15 cycle to ensure that they give patients appropriate information about the services they use, and that they add value to the quality assurance infrastructure used by Trusts and local and national organisations. The Quality Accounts are published nationally via the NHS Choices website to ensure that they are accessible and that the information they contain on quality is available to patients and the public.

The existing duty and practice of candour in the NHS

10. The principles now set out in the NHS standard contract with regard to candour with patients are sound, but experience in Mid Staffs and elsewhere makes it clear that such principles have in the past been too often honoured in the breach rather than in the observance. Whatever additional safeguards may be introduced, the Committee regards the enforcement of these principles on all providers of NHS services as a fundamental part of the role of NHS commissioners. Failure to apply to these principles

in practice should be seen as a failure of enforcement by commissioners as well as a failure of performance by service providers. (Paragraph 29)

The Government is clear that commissioners play a vital role in ensuring that providers are held to account for delivering safe and compassionate care, and this includes sharing knowledge and experience. In developing the new commissioning framework, NHS England, in its roles as both a direct commissioner of care and as a source of support and challenge to clinical commissioning groups (CCGs), has sought to apply the lessons of the Francis Inquiry at every opportunity. NHS England will hold clinical commissioning groups to account for quality and outcomes and for their financial performance, and will have the power to intervene where there is evidence that they are failing, or are likely to fail, in their functions. NHS England will also ensure that local commissioners of care are much more effectively linked to other local organisations with an interest in health and care so that information can be shared. This will help to address some of the issues of organisational isolation identified by the Francis Inquiry. Commissioners will be prominent members of local health and wellbeing boards, which will bring together local commissioners of health, care and other services to work in partnership to improve outcomes for the whole population.

In addition, NHS England has convened Quality Surveillance Groups in each area of the country which act as a virtual team across a health economy, bringing together organisations with information about and insight into the quality of care. These will include commissioners, system regulators and representatives of local authorities, local Healthwatch, public health and Local Education and Training Boards. If concerns are identified, action can be taken swiftly by the relevant organisation.

The authorisation process for clinical commission groups included scrutiny of their ability to commission safely and improve quality. Following authorisation, NHS England will continue to hold clinical commissioning groups to account for the quality outcomes that they achieve as well as for financial performance, through the clinical commission groups assurance framework. NHS England also has powers to intervene where there is evidence that clinical commission groups are failing or are likely to fail.

The Department of Health has also strengthened the focus on commissioning for outcomes through the outcomes frameworks for public health, the NHS and adult social care. This means that commissioners and providers of care are focusing on what matters most for patients and service users, including their experience of care.

11. Furthermore, the Committee believes that in the requirement for openness and transparency is too narrowly drawn in the NHS Standard Contract. The requirement for candour about mistakes should, in truth, be seen as part of a much wider commitment an open and accountable service. Challenge and debate about outcomes should occur at all levels of quality achievement and in all contexts of care, not just at the bottom. Indeed the Committee believes that if high quality service providers were to set the pace for openness and transparency by making properly anonymised information available on a dramatically improved basis, they would increase the pressure on less good providers to demonstrate that they were matching their standards to the best. Verbal commitments to high quality standards are virtually meaningless if no effective steps are taken to monitor performance. (Paragraph 30)

Robert Francis identified the principles of openness, transparency and candour as the 'cornerstone of healthcare'. He stated that 'every healthcare organisation and everyone working for them must be honest, open and truthful in all their dealings with patients and the public, and that organisational and personal interests must never be allowed to outweigh the duty to be honest, open and truthful'.

The definition of openness and transparency is necessarily wide. It must support Robert Francis's recommendations in relation to candour but also the open sharing of information which can support patients' care, and promote the identification of early warning signs locally and nationally, and further improvement and learning.

Patients and the public need easy access to reliable and accurate information about the safety of their hospital. The Care Quality Commission and NHS England will work with Monitor, the Trust Development Authority, the Information Centre and others to make patient safety data more accessible to all and provide clear guidance on what it means – and does not mean. This includes issuing a joint statement from Care Quality Commission and NHS England on their commitment to complete alignment of patient safety measurement and developing dedicated hospital safety website for the public which draw together up to date information on patient safety factors, for which robust data is available. This will include information on staffing, pressure sores, falls and other key indicators, where possible, at ward level. The website will begin publication from June 2014. It will, over time, become a key source of public information, putting the truth about care at the fingertips of patients and updated monthly.

Trusts will continue to be encouraged to use NHS Safety Thermometer data collection to help inform improvements in some key patient safety areas: pressure ulcers, falls resulting from harm, catheter-associated infections and venous thromboembolism.

Information is already shared in a number of ways. At a national level, for example, the Health and Social Care Information Centre publishes more than 130 statistical publications annually via its website (www.hscic.gov.uk). It also publishes a range of national indicators and metrics, many of which are available publicly through its indicator portal (www.hscic.gov.uk/indicatorportal). This includes the summary hospital-level mortality indicator, indicators from the Quality and Outcomes Framework and measures from the NHS Outcomes Framework. Data on individual hospital consultants, including mortality rates, are being provided to the public as a part of NHS England's drive for greater transparency and a commitment to providing patients with more information about their treatment.

At a local level, in April 2013 a network of local and regional Quality Surveillance Groups was established which brings together commissioners, regulators, local Healthwatch representatives and other bodies on a regular basis to share information and intelligence about quality across the system, including the views of patients and the public. Patient experience will be one of the key sources of intelligence for Quality Surveillance Groups.

In addition to this, the Department of Health asked Dame Fiona Caldicott to review information governance to ensure that there is an appropriate balance between the protection of confidential data and the use and sharing of information to improve people's health and social care and for the benefit of wider society. In its response to the Caldicott Review, *Information: To share or not to share* (2013), the Government agreed with Dame Fiona's statement that

every citizen should 'feel confident that information about their health is securely safeguarded and shared appropriately when that is in their interest'. This is supported by the Health and Social Care Information Centre's forthcoming Code of Practice for the Management of Confidential Information, which will outline principles that will apply to all NHS organisations. Individuals need the teams of professionals who are responsible for their care to share information reliably and effectively. Confidential information about an individual must not leak outside of the care team, but it must be shared within it in order to provide a seamless, integrated service.

A range of work has already been taken forward across the system to ensure that identifiable data is used appropriately, including within the research community. Anonymised data is used, for example, by the Clinical Practice Research Datalink, working with the Health and Social Care Information Centre to improve and safeguard public health. Aggregated data, such as that used within Hospital Episode Statistics, and the Health and Social Care Information Centre's data linking service also support performance management and early warning systems such as those used by the Care Quality Commission.

Accountability of commissioners

12. The Committee continues to believe that commissioners should be under an obligation to collect and publish full information about outcomes achieved for their communities, including a full account of failures to deliver acceptable standards of care. By failing to apply a duty of candour explicitly to commissioners, NHS England is losing an important opportunity to promote a more open and accountable culture throughout the NHS. (Paragraph 32)

The Government agrees that increased availability of information is one of the key mechanisms which can help to achieve Robert Francis's aspiration of an open, transparent health and care service. Commissioners should operate transparently, and that is why transparency is a key theme of the new commissioning system. The objective is to identify variation and unacceptable practice, and for the NHS to learn from this.

Patients and the public need easy access to reliable and accurate information about the safety of their hospital. The Care Quality Commission and NHS England will work with Monitor, Trust Development Authority, the Information Centre and others to make patient safety data more accessible to all and provide clear guidance on what it means – and does not mean. This includes issuing a joint statement from Care Quality Commission and NHS England on their commitment to complete alignment of patient safety measurement and developing a dedicated hospital safety website for the public which will draw together up to date information on staffing, pressure sores, falls and other key indicators, where possible, at ward level. The website will begin publication from June 2014. It will, over time, become a key source of public information, putting the truth about care at the fingertips of patients and updated monthly.

At a national level, the Mandate sets out the Government's ambition for the NHS, and provides outcomes-focused objectives that NHS England must legally seek to achieve. The first Mandate between the Government and NHS England was published on 13 November 2012, and sets out objectives for NHS England over the period April 2013–March 2015. On

12 November, the refreshed mandate was published which includes a new objective about responding to the Inquiry's recommendations.

The NHS Outcomes Framework is contained within the Mandate; the first five sections of the Mandate align with the five domains of the Outcomes Framework. NHS England must produce an annual report which sets out how it has delivered the objectives set out in the Mandate, and this must be laid before Parliament. The Mandate is refreshed annually to ensure that it is still relevant and up to date.

In addition to the NHS Outcomes Framework, the clinical commissioning groups Outcomes Indicator Set (formerly known as the Commissioning Outcomes Framework) forms part of NHS England's systematic approach to promoting quality improvement. Its aim is to support clinical commissioning groups (CCGs) and health and wellbeing partners in improving health outcomes by providing comparative information on the quality of health services commissioned by clinical commissioning groups and the associated health outcomes – and to support transparency and accountability by making this information available to patients and the public.

Data on individual hospital consultants, including mortality rates, are being provided to the public as a part of NHS England's drive for greater transparency and a commitment to providing patients with more information about their treatment. The friends and family test can also be used as a catalyst for improvement activity within Trusts. The friends and family test will be rolled out across general practice and community and mental health services by the end of December 2014 and to the rest of NHS-funded services by the end of March 2015.

Although the Department of Health ultimately holds NHS England to account for its commissioning activity, the reforms are about ensuring that commissioning activity meets the requirements of the population. There are a number of ways in which this is achieved:

- health and wellbeing boards in each local authority bring together local government, the NHS and other partners to lead the planning and delivery of local services. This includes the development of a local Joint Strategic Needs Analysis to inform commissioning strategies.
- Local government health scrutiny functions provide an additional mechanism for locally elected leaders and the public to examine the effectiveness and quality of local services.
- Local Healthwatch also plays an important role in ensuring that the views of patients and users are fully taken account of throughout.

NHS England will review Quality Accounts before the 2014-15 cycle to ensure that they give patients appropriate information regarding the services they use, and that they add value to the quality assurance infrastructure used by Trusts and local and national organisations. The Quality Accounts are published nationally via the NHS Choices website to ensure that they are accessible and that the information they contain on quality is available to patients and the public.

The NHS Constitution

13. The Committee believes that the new formulation in the NHS Constitution explaining the duty of candour substantially understates the importance of a more open culture in the NHS. Commissioners and providers should be under a duty of openness about the full range of outcomes achieved, not just about examples of patient harm. More open accountability for outcomes achieved would be an important spur to improvements in the quality of care delivered across the full range of health and care facilities. It must be driven from NHS England, but it must permeate every aspect of care provision. It is the role of commissioners to ensure that the providers of NHS care provide timely, accurate and complete information to both individual patients and commissioners. (Paragraph 35)

Staff should be honest and open with patients and the NHS Constitution already emphasises this. In addition, wording was included in the March 2013 edition of the Constitution to reflect the contractual duty of candour.

While the Constitution focuses specifically on setting out the values of the NHS along with the rights and pledges to patients and staff and their responsibilities, achieving a truly open and transparent culture is a much wider endeavour. As noted in the response to point 12 above, the importance of increased availability and transparency of information about quality of services and care is embedded within the Mandate to NHS England. The Care Quality Commission and NHS England will additionally work with Monitor, Trust Development Authority, the Information Centre and others to make patient safety data more accessible to all and provide clear guidance on what it means.

When a new legal duty of candour is created, the Government will consult on how best to reflect this in the Constitution when it is next updated.

The case for a statutory duty

14. The Committee believes that a defensive and sometimes over-legalistic culture which attaches a higher priority to avoiding liability than improving outcomes represents a pervasive phenomenon which is not confined to the healthcare system. While legal accountability is important, it is even more important that legal advice based on such defensive considerations is not allowed to impede the proper relationship between clinical professional and patient, based on sound principles of professional responsibility. (Paragraph 44)

The Government agrees with the Committee that defensive legal considerations should not override open communication between clinician and patient. Prior to April 2009, where a complaint was received about which the complainant had indicated in writing that they were intending to take legal proceedings, the complaint was excluded from the NHS complaints arrangements. In 2009, the Department of Health removed this regulation because it considered that there should be no direct link between responding to a complaint and consideration of litigation. In some cases, it will be appropriate for the complaint to be put on hold, but that should be an exception.

It is important for patients, employers and professionals themselves that complaints and concerns about health professionals are investigated quickly. While some cases are legally complex or may have to await the completion of police investigations before they proceed, it is reasonable to expect that the overwhelming majority of cases are investigated and resolved or brought to a hearing within no more than 12 months, and the General Medical Council is already achieving this. The professional regulatory bodies are currently hampered by a cumbersome and complex inheritance of legislation, but the Government has asked the Law Commissions to review this and bring forward proposals to simplify and modernise professional regulation law. The Government will seek an early opportunity to legislate, enabling all the professional regulators to move rapidly to a maximum 12-month period for concerns raised about professionals to be resolved or brought to a hearing in all but a small minority of cases.

In addition to the statutory duty of candour on providers, there is also a professional duty of candour on individuals which will be strengthened through changes to professional guidance and codes. The professional values of individual doctors, nurses and other healthcare professionals are critical in ensuring an open culture in which mistakes are reported, whether or not they cause actual harm. The General Medical Council, Nursing and Midwifery Council and the other professional regulators will be working to agree consistent approaches to candour and reporting of errors, including a common responsibility across the professions to be candid with patients when mistakes occur, whether serious or not and clear guidance that professionals who seek to obstruct others in raising concerns or being candid would be in breach of their professional responsibilities. The Government will ask the Professional Standards Authority to advise and report on progress with this work. The professional regulators will develop new guidance to make clear professionals' responsibility to report 'near misses' in relation to errors that could have led to death or serious injury, as well as actual harm, at the earliest available opportunity and will review their professional codes of conduct to bring them into line with this guidance. The Professional regulators will also review their guidance to panels taking decisions on professional misconduct to ensure they take proper account of whether or not professionals have raised concerns promptly.

The Secretary of State for Health also legally required NHS England to insert a contractual duty of candour into the NHS Standard Contract for 2013-14. The Contract also refers organisations to the Being Open framework (www.nrls.npsa.nhs.uk/resources/all-settings-specialties/?p=2). This provides best practice for all healthcare organisations to create an environment where patients, their carers, healthcare professionals and managers all feel supported when things go wrong and have the confidence to act appropriately.

The Department of Health will now work with Action against Medical Accidents (AvMA) and NHS England to clarify that a threat of future litigation should not delay the handling of a complaint. As a further incentive for Trusts to promote a culture of openness across their organisation, the Government will consult on proposals about whether Trusts should reimburse a proportion or all of the NHS Litigation Authority's compensation costs when they have not been open about a safety incident. Where the NHS Litigation Authority finds that a Trust has not been open with patients or their families about a patient safety incident which turns into a claim, it could have the discretion to reduce or remove that Trust's indemnity cover

for that claim. The NHS Litigation Authority will continue to make compensation payments due to patients. Trusts who were not open with their patients could be required to reimburse the NHS Litigation Authority for a proportion or all of the payment.

15. Similarly, defensive and over-legalistic considerations of the best interests of Trusts should not be allowed to override the duty to be open and transparent with patients and relatives about adverse incidents, and to provide to them full explanations of the factors which led to such incidents. It is particularly important that NHS bodies provide full and candid explanations to relatives bereaved as a result of an adverse incident. (Paragraph 45)

The Government agrees that the open communication which should exist between clinician and patient unimpeded by legalistic concerns should also apply to organisations, including Trusts.

The NHS Litigation Authority actively promotes openness, transparency and candour and has long advocated that it is appropriate to apologise when things go wrong and to provide a full explanation in response to a concern. The NHS Litigation Authority is clear that providing an apology and an explanation in response to a concern, irrespective of whether this forms part of the complaints process, will not affect members' indemnity cover.

The Secretary of State for Health legally required NHS England to insert a contractual duty of candour into the NHS Standard Contract for 2013-14. The contract also refers organisations to the Being Open framework (www.nrls.npsa.nhs.uk/resources/all-settings-specialties/?p=2). The framework gives healthcare organisations guidance on how to develop and embed a Being Open policy that fits local organisational circumstances. Another key element of the framework is guidance on process on how to communicate with patients, their families and carers following harm.

The Government has introduced in the Care Bill a new statutory duty of candour which will apply to providers, rather than individuals, and will be included as a new registration requirement for health and social care providers registered with the Care Quality Commission. There are a range of views on the threshold at which the duty of candour should be set: not so narrowly that important incidents are excluded, nor so broad that defensive behaviour and excessive bureaucracy grow to excess. The Government has therefore asked David Dalton and Professor Norman Williams to assess, by the end of 2013, the argument for extending the threshold for the duty of candour to cover moderate harm as well as death or serious injury, and the practical implications involved in such a threshold. The Department will consult on a draft set of regulations, which also provides the flexibility to be amended or varied over time as the new duty is established.

The Department of Health will now work with Action against Medical Accidents and NHS England to clarify that a threat of future litigation should not delay the handling of a complaint. As a further incentive for Trusts to promote a culture of openness across their organisation, the Government will consult on proposals about whether Trusts should reimburse a proportion or all of the NHS Litigation Authority's compensation costs when they have not been open about a safety incident. Where the NHS Litigation Authority finds that a Trust has not been open with patients or their families about a patient safety incident which turns into

a claim, it could have the discretion to reduce or remove that Trust's indemnity cover for that claim. The NHS Litigation Authority will continue to make compensation payments due to patients. Trusts who were not open with their patients could be required to reimburse the NHS Litigation Authority for a proportion or all of the payment.

The Committee's view on a statutory duty of candour

16. The Committee is mindful that NHS history is littered with examples of well-intentioned changes which have been superimposed on existing arrangements without sufficient attention being paid to the way in which it is proposed that the new arrangements will interact with existing processes. It is striking, for example, that the clauses in the Care Bill [Lords] which are intended to establish a criminal offence of providing false and misleading information – in effect criminalising a breach of the proposed statutory duty of candour – have specified neither the types of provider, nor the types of information to which the offence will apply, leaving both to be specified later in regulations. (Paragraph 59)

There are two new measures being introduced that are designed to improve openness among providers of care, but which focus on different things. The new duty of candour, overseen by the Care Quality Commission (CQC), is about the day-to-day interaction of provider organisations with patients and service users. It will require providers registered with the Care Quality Commission to ensure that patients are informed where there are failings in care. This new duty will be introduced in secondary legislation as a new Care Quality Commission registration requirement, and will be reviewed in the near future. The Care Quality Commission will be able to use its enforcement powers where providers do not meet this new duty of candour.

The false or misleading information clauses in the Care Bill are about the information that providers are required to supply or publish, which is distinct from the duty of candour owed to patients. The false or misleading clauses create a new 'stand-alone' criminal offence, prosecuted by the Crown Prosecution Service, where care providers supply or publish certain false or misleading performance and management information provided under a statutory or other legal obligation. Government is working with the Health and Social Care Information Centre and other bodies on draft regulations to specify the information requirements that are within the scope of the offence. The intention is that the draft regulations will:

- (a) limit the application of the offence to providers of NHS-funded secondary care;
- (b) focus specifically on information about outpatient, admitted patient and A&E activity that they are already required to provide to the Health and Social Care Information Centre in the form of Commissioning Data Sets;
- (c) specify data that is already used as the basis for calculating a variety of mortality indicators.

False or misleading information draft regulations will be reviewed in the near future.

Both the duty of candour and the false or misleading information offences allow directors and other senior individuals working for the provider ('the controlling mind') to be prosecuted in extreme cases. For a director or senior individual to be prosecuted, a successful

prosecution would have to have been brought against the provider and it would then have to be demonstrated that the offence was committed with those individuals' consent and connivance, or through their negligence.

Taken together, the two measures will increase provider accountability and promote openness to patients and service users (duty of candour) and reporting performance (false or misleading information).

17. The Committee remains to be persuaded of the case for the introduction of a statutory duty in addition to existing contractual duties and professional obligations. It is not clear that the proposed duty, the terms of which remain to be defined in secondary legislation, will constitute an effective means of achieving the fundamental culture change which is required within the NHS. (Paragraph 60)

Robert Francis identified the principles of openness, transparency and candour as the 'cornerstone of healthcare' and that 'every healthcare organisation and everyone working for them must be honest, open and truthful in all their dealings with patients and the public, and organisational and personal interests must never be allowed to outweigh the duty to be honest, open and truthful'.

The Care Quality Commission (CQC) consulted on the potential introduction of a duty of candour in its document *A New Start: Consultation on changes to the way CQC regulates, inspects and monitors care*. Its consultation response, published in October 2013, showed that respondents were strongly in favour of a statutory duty. The Department of Health will publish shortly draft regulations on a statutory duty of candour for further consultation. The aim is for the registration requirements to come into force during 2014 and 2015, subject to parliamentary approval. The duty of candour will be enforced using the Care Quality Commission's range of powers, which can include bringing a prosecution against a provider.

In addition, healthcare professionals are expected to abide by the principles set out in the codes of conduct of their respective professional bodies. In addition to the statutory duty of candour on providers, there is also a professional duty of candour on individuals which will be strengthened through changes to professional guidance and codes. The professional values of individual doctors, nurses and other healthcare professionals are critical in ensuring an open culture in which mistakes are reported, whether or not they cause actual harm. The General Medical Council and the Nursing and Midwifery Council will be working with the other regulators to agree consistent approaches to candour and reporting of errors, including a common responsibility across the professions to be candid with patients when mistakes occur, whether serious or not, and clear guidance that professionals who seek to obstruct others in raising concerns or being candid would be in breach of their professional responsibilities. The Government will ask the Professional Standards Authority to advise and report on progress with this work. The professional regulators will issue new guidance to make clear professionals' responsibility to report 'near misses' in relation to errors that could have led to death or serious injury, as well as actual harm, at the earliest available opportunity and will review their professional codes of conduct to bring them into line with this guidance. The Professional regulators will also review their guidance to panels taking decisions on professional misconduct to ensure they take proper account of whether or not professionals have raised concerns promptly.

However, the key to a true culture change lies in addressing all three of Robert Francis's principles of openness, transparency and candour. This includes operating a transparent culture where information is king and patients are aware of the outcomes achieved by their local health and care services. Measures including the friends and family test and publication of specialty outcomes data will help to achieve this. In addition, staff and patients should be able to operate in a culture of openness where, if they have concerns, they can be raised safely and taken seriously. It was made clear in *Patients First and Foremost* that NHS staff should feel free and able to raise their real concerns about patient care, and that the era of gagging staff must come to an end. The Government has acted to ensure that this becomes a reality by:

- All healthcare professionals will be protected by the provisions of the Public Interest Disclosure Act 1998;
- giving the new Chief Inspector of Hospitals an important role in ensuring that hospital inspections are not just seen as a 'tick box' exercise by judging whether the culture of the organisation actively promotes the benefits of openness and transparency;
- enabling staff to whistleblow to health and care professional regulatory bodies as of 1 October 2013; and
- backing the Whistleblowing Helpline's refresh of the Speak up for a Healthy NHS guidance, as recommended in its Bridging the Gap campaign report of July 2013.

Ensuring that the way in which the NHS manages and responds to complaints will also be critical in shaping a culture that hears and learns from patients and ends a culture of defensiveness or, at worst, denial about poor care and harm to patients. The Rt Hon Ann Clwyd MP and Professor Tricia Hart reviewed the system of complaints handling in NHS hospitals and made a number of key findings:

- Vulnerable people find the complaints system complicated and hard to navigate.
- There is a low level of public awareness of the NHS Complaints Advocacy Service.
- People are reluctant to complain and staff can be defensive and reluctant to listen to or address concerns.
- Organisations do not always deliver their legislative responsibilities on complaints handling.
- There is a need for quality, trained staff to deal with complaints effectively and appropriately.

The Government welcomes the review and accepts the principles behind the recommendations, although many are for action at individual Trust level.

Trust Chief Executives and Boards should promote a culture of openness and encourage feedback and welcome complaints. Staff must be trained and encouraged to seek feedback, and act on it.

The Government wants to see every Trust make clear to every patient from their first encounter with the hospital:

- how they can complain to the hospital when things go wrong;

- who they can turn to for independent local support if they want and where to contact them;
- that they retain the right to complain to the Ombudsman if they remain dissatisfied and how to contact them; and
- details of how to contact their local Healthwatch.

Government wants to see Trust Chief Executives and Boards taking personal responsibility for complaints handling and ensuring there is effective clinical involvement. This includes signing-off letters to patients, ensuring every patient is offered a conversation at the start of the complaints process, and that they are clear that if they are not happy with the way the complaint has been handled they can get an independent view from the Health Service Ombudsman. Government also want to see directors with responsibility for patient safety being required to give an update on complaints at each Board meeting and will work with NHS England to determine the most effective mechanism through which to achieve this. Boards need to see regular data about complaints which means the 'narrative and not just the numbers', so they can identify themes and recurring problems, and take action. All Trusts, not just the good ones, should see complaints as an opportunity to learn and improve the care they provide.

Detailed information on complaints and the lessons learned will be published quarterly. This will include the number of complaints received as a percentage of patient interventions; the number of complaints the hospital has been informed have subsequently been referred to the Ombudsman and the lessons learned and improvements made as a result of complaints.

18. The Committee continues to believe that it is a mistake to think of the requirement for a more open culture specifically in the context of failures of care. The culture change which is required within the NHS requires greater openness across the full range of its activities – including examples of care that do not match current best practice, as well as overt failure. (Paragraph 61)

The Government fully supports an open culture that is not limited only to sharing the most overt failures. A true 'learning organisation', as Professor Don Berwick advocates in his review, should operate a consistently transparent culture where staff share information on errors, mistakes, near misses and good practice. Provider organisations should aspire to excellence in care standards, not just what is acceptable; to do this they must learn from any occasion where care falls below excellent standards.

Patients and the public need easy access to reliable and accurate information about the safety of their hospital. The Care Quality Commission and NHS England will work with Monitor, the Trust Development Authority, the Information Centre and others to make patient safety data more accessible to all and provide clear guidance on what it means – and does not mean. This includes issuing a joint statement from Care Quality Commission and NHS England on their commitment to complete alignment of patient safety measurement and developing a dedicated hospital safety website for the public which will draw together up to date information on patient safety factors, for which robust data is available. This will include information on staffing, pressure sores, falls and other key indicators, where possible, at ward level. The website will begin publication from June 2014. It will, over time, become a

key source of public information, putting the truth about care at the fingertips of patients and updated monthly.

NHS England has commissioned the National Institute for Health and Care Excellence (NICE) to produce quality standards. These are not mandatory, like the fundamental standards of care, but NHS England's guidance to commissioners makes clear that they must have regard to quality standards as the benchmark for specifying high-quality, enhanced care. These quality standards can be used to drive improvement in Trusts and for Trusts to recognise that, where care falls below these standards, there is an opportunity to share, learn and improve.

Expert inspection against standards, informed by hard data and soft intelligence, will enable the Care Quality Commission through its Chief Inspectors to make judgements about whether providers are:

- **Outstanding:** sustained high-quality care over time across most services, together with good evidence of innovation and shared learning.
- **Good:** the majority of services meet expected and high-quality standards and deliver care which is person centred and meet the needs of vulnerable users.
- **Requires improvement:** significant action is required by the provider to address concerns.
- **Inadequate:** serious and/or systematic failings in relation to quality.

The Chief Inspector of Hospitals will take NICE's quality standards into account when judging whether to award a rating of good or outstanding. These ratings will be publicly available and will allow patients to make informed decisions about their care.

19. The Berwick Review recommends the commissioning of research into how best to support the proactive disclosure of serious incidents and the process of engaging with patients in relation to less serious incidents. While further research into these matters is necessary, and is likely in the medium term to make a positive contribution to candid dialogue between providers and patients, it should not delay the implementation of measures designed to entrench a culture of openness and candour across the full range of NHS activities. (Paragraph 62)

The Government believes that fully embedding the recommendations of Robert Francis is a process that will and must take time to get right, but it is important to start now. As outlined in the rest of this response, actions have already been taken to promote openness and candour in the health and care system. This includes taking steps to embed a duty of candour both at a provider and individual level, as well as promoting transparency through reviewed Quality Accounts and increased information for patients. Professional regulators have also made their commitment known – for example, the General Medical Council has included a question on patient safety in the National Training Survey, developed new guidance on raising concerns and introduced a new confidential helpline for doctors. In addition to this work, staff contracts have been strengthened to include the right to raise concerns, the NHS Constitution has been amended to include explicit rights regarding whistleblowing and the NHS staff survey has been strengthened to focus on openness. There is clear policy against compromise agreements prohibiting staff from speaking out, and the Care Quality Commission has

confirmed that it will inspect Trusts against their processes for encouraging staff to raise concerns.

The Government has welcomed the Berwick report and accepts all its overarching recommendations. It does not agree with implementation of every one of the actions, but does agree with the vast majority. Working with its partners, the Department of Health is considering how the recommendations will now be implemented. The Government accepts Professor Don Berwick's recommendation that we should avoid an automatic duty of candour where patients are told of every error or near miss.

There are a range of views on the threshold at which the duty of candour should be set: not so narrowly that important incidents are excluded, nor so broad that defensive behaviour and excessive bureaucracy grow to excess. The Government has therefore asked David Dalton and Professor Norman Williams to assess, by the end of 2013, the argument for extending the threshold for the duty of candour to cover moderate harm as well as death or serious injury, and the practical implications involved in such a threshold. The Department will consult on a draft set of regulations, which also provides the flexibility to be amended or varied over time as the new duty is established.

It is important for patients, employers and professionals themselves that complaints and concerns about health professionals are investigated quickly. While some cases are legally complex or may have to await the completion of police investigations before they proceed, it is reasonable to expect that the overwhelming majority of cases are investigated and resolved or brought to a hearing within no more than 12 months, and the General Medical Council is already achieving this. The professional regulatory bodies are currently hampered by a cumbersome and complex inheritance of legislation, but the Government has asked the Law Commission to review this and bring forward proposals to simplify and modernise professional regulation law. The Government will seek an early opportunity to legislate, enabling all the professional regulators to move rapidly to a maximum 12-month period for concerns raised about professionals to be resolved or brought to a hearing in all but a small minority of cases.

The Francis report and whistleblowers

20. Robert Francis has recommended a change in the culture whereby it is easier, and more palatable, to raise a genuine concern than it is not to do so. The Committee agrees with this approach, although it recognises that there can be serious consequences for individuals who do raise their concerns. The management of each provider of NHS care has an unequivocal obligation to establish a culture in the organisation within which issues of genuine concern can be raised freely. Disciplinary procedures, professional standards hearings and employment tribunals are not appropriate forums for constructive airings of honestly-held concerns about patient safety and care quality. (Paragraph 69)

Fostering and sustaining an open culture in which concerns about care can be raised, investigated and acted upon without fear of retribution is critically important. It is for local organisations to establish a culture that promotes openness, removes blame and provides

appropriate opportunities for staff to raise concerns. Those who do raise concerns should be supported to do so and should not face retribution.

The Care Quality Commission will judge whether an organisation's culture actively promotes the benefits of openness and transparency as part of its inspection. There is also a national freephone confidential helpline for whistleblowers.

Government policy is clear that any attempts to prevent individuals from speaking out in the public interest will not be tolerated. NHS guidance has been consistently clear that local policies should prohibit the inclusion of confidentiality clauses in contracts of employment and compromise agreements which seek to prevent an individual from making a disclosure in the public interest in accordance with the Public Interest Disclosure provisions of the Employment Rights Act 1996.

21. The Committee agrees with Robert Francis that providers of health and care, as well as their regulators, should be required to be open and transparent. Non-disparagement or 'gagging' clauses which inhibit free discussion of issues of care quality and patient safety are unlawful. No NHS body should be party to such an agreement or should seek to enforce an agreement in a way which inhibits free discussion of such issues. (Paragraph 76)

'Gagging' clauses are unacceptable. The Government is clear that any attempts to prevent individuals from speaking out in the public interest will not be tolerated. Guidance from NHS Employers has been consistently clear that local policies should prohibit the inclusion of confidentiality clauses in contracts of employment and compromise agreements which seek to prevent an individual from making a disclosure in the public interest in accordance with the Public Interest Disclosure provisions of the Employment Rights Act 1996.

The Government, however, is also aware that some confidentiality clauses may make people feel as though they are being 'gagged' even though they are not. Such clauses, although not illegal, may have what is known as a 'chilling effect' on some people. The Government will now therefore require the inclusion of an explicit clause in the compromise agreement to make it absolutely clear to staff signing an agreement that they can make a protected disclosure in the public interest regardless of what other clauses may be included in the agreement.

Compromise agreements at the Care Quality Commission

22. The Committee welcomes the assurance from the Chair of the Care Quality Commission that its standard compromise agreement now includes a clause making it clear to employees that such agreements do not prevent them from raising legitimate concerns through protected disclosures. The Committee recommends that the Care Quality Commission should write to each employee or former employee with which it has an existing compromise agreement to confirm that any non-disparagement terms of such agreements will not be enforced in cases where such persons wish to raise concerns which they believe to be in the public interest. (Paragraph 79)

The Care Quality Commission accepts this recommendation.

The Chief Executive of the Care Quality Commission has committed to write to all former employees in line with this recommendation. This will be completed by the end of November 2013.

The Care Quality Commission has issued 23 compromise agreements since its inception. The most recent of these was in 2012-13. The wording of compromise agreements was amended in 2011-12 to include a statement highlighting that signatories are able to make protected disclosures where they have genuine concerns.

The Care Quality Commission has publicly stated that it does not intend to enter into further compromise agreements with members of staff. The Care Quality Commission's standard contract of employment contains a standard confidentiality wording by which the employee remains bound after leaving the organisation. This does not prevent individuals from making protected disclosures where they have grounds for concern.

Compromise agreements and severance payments

23. It is unacceptable that in several cases the payment of public money in settlement of claims against NHS bodies has not been subject to normal approval procedures by the Department of Health and the Treasury. The Committee welcomes the fact that Departmental and Treasury approval will be required before such payments are made in future. (Paragraph 84)

Prior to 11 March 2013, HM Treasury approval for settlement payments being proposed through judicial mediation was not a requirement.

With effect from 11 March 2013, all non-contractual payments, including those being proposed through judicial mediation, require Treasury approval. The Department has complied and will continue to comply with Treasury approval processes.

Following the change in Treasury rules, Monitor, the NHS Trust Development Authority, NHS England and the Department of Health informed Foundation Trusts, NHS Trusts, clinical commissioning groups and departmental arm's length bodies respectively of the new requirement.

The case of Gary Walker

24. The Committee is concerned by the insensitivity and lack of discretion shown by United Lincolnshire Hospitals Trust and its legal representatives in seeking to restrain Gary Walker from discussing legitimate patient safety concerns. If this reaction is an indication of the prevailing culture in Trusts confronting those who seek genuinely to raise patient safety issues, then that culture must change. (Paragraph 89)

The Government is committed to ensuring that whistleblowers are supported. Policy is clear that any attempts to prevent individuals from speaking out in the public interest will not be tolerated. NHS guidance has been consistently clear that local policies should prohibit the inclusion of confidentiality clauses in contracts of employment and compromise agreements which seek to prevent an individual from making a disclosure in the public interest in accordance with the Public Interest Disclosure provision of the Employment Rights Act 1996. Government is, however, also aware that some confidentiality clauses may make people feel as though they are being 'gagged' even though they are not. Such clauses, although

not illegal, may have what is known as a 'chilling effect' on some people. Government now therefore requires the inclusion of an explicit clause in the compromise agreement to make it absolutely clear to staff signing an agreement that they can make a protected disclosure in the public interest regardless of what other clauses may be included in the agreement.

The role of the Care Quality Commission in establishing a culture comfortable with challenge

25. The Committee recommends that the Care Quality Commission should, in all its inspections of providers, satisfy itself that arrangements are in place to facilitate and protect the position of any member of staff who wishes to raise concerns about the quality of care provided to patients. As part of this process, the Care Quality Commission should satisfy itself that proper safeguards are in place for whistleblowers who may provide an additional safeguard for patient interests. (Paragraph 96)

Recommendation accepted.

The Chief Inspector of Hospitals plays an important role in ensuring that hospital inspections are not just seen as a 'tick box' exercise by judging whether the culture of the organisation actively promotes the benefits of openness and transparency. This judgement will be achieved by applying a rigorously objective and searching approach to assessing the quality of care. The Chief Inspector and his expert teams will focus on the importance of an organisation being 'well led', looking closely at the culture and leadership of hospital Trusts. In making this assessment, the Chief Inspector will draw on a wide range of evidence, including the views of patients and staff.

Fundamental standards of healthcare

26. The Committee agrees in principle with the proposal to establish a set of clear and unambiguous fundamental standards in such a way that patients, their relatives, clinical and auxiliary staff and NHS managers can immediately recognise unacceptable care and take appropriate action. (Paragraph 109)

The Department of Health has been working with the Care Quality Commission (CQC) to develop a set of fundamental standards. These fundamental standards will set a clear bar below which standards of care should not fall. There will be immediate and serious consequences for services where care falls below these levels, including the possibility of prosecution. The Care Quality Commission published the responses to its public consultation on 17 October 2013, which showed that there is agreement with the new approach. The Department will consult shortly on the draft regulations which will set in legislation the fundamental standards of care that providers must meet. The new regulations will come into effect during 2014 and 2015 and will apply to all providers of health and social care that are required to register with Care Quality Commission.

27. The Committee believes that once it has been established that a breach of a fundamental standard has occurred, it is axiomatic that it is treated seriously, reported accordingly and investigated thoroughly. Regulatory consequences – including unannounced Care Quality Commission inspections – may follow from breaches, but it

is important that any regulatory action should be proportionate to the breach that has occurred, and that it concentrates on analysis and remedy of the circumstances which have led to the breach. (Paragraph 112)

The Government agrees that decisive action must be taken in response to a failure of quality of care. Just as there is a clearly defined end point for hospitals that are financially unsustainable, the same principle must apply for those that are clinically unsustainable. The process must ensure that problems can be rectified quickly while allowing essential services to continue and without compromising patient safety.

The Care Quality Commission (CQC) has carried out a significant review of how it uses information to identify potential failures in the quality of care in hospitals in relation to five key questions – is a service safe, effective, caring, responsive and well led? ‘Well led’ means that there is effective leadership, governance (clinical and corporate) and clinical involvement at all levels of the organisation, and an open, fair and transparent culture that listens and learns from people’s views and experiences to make improvements.

In instances where, but not limited to these, the Chief Inspector of Hospitals considers that standards of the quality of care are inadequate, the Care Quality Commission may recommend that the NHS Trust Development Authority or Monitor place the Trust into special measures. Special measures provide a framework for action where it is not thought probable that the Trust leadership can secure the necessary improvements in quality without intensive intervention. Such interventions would be led by Monitor or the NHS Trust Development Authority and include formal partnering with a high-performing Trust to share best practice and guidance, a full leadership capability review including the ability to replace directors, the creation of a public Improvement Plan, and the appointment of an improvement director to oversee progress. Typically the Chief Inspector will re-inspect the Trust after a year to ascertain whether the required improvements are being made.

Ultimately, if it proves impossible for an NHS Trust or an NHS Foundation Trust to turn their performance around, Monitor, or the NHS Trust Development Authority, will be able to place the organisation into special administration on quality grounds. Special administration will provide a framework for determining how best to secure a comprehensive range of high-quality services that are both financially and clinically sustainable. As a backstop, if the Care Quality Commission considers that Monitor or the NHS Trust Development Authority has erred in not placing a Trust into special administration, it will be able to compel them to initiate the process.

28. The Committee expects to examine the Care Quality Commission’s progress in developing the full range of standards identified in paragraph 104 of this report in the course of its regular programme of accountability hearings. (Paragraph 113)

The Care Quality Commission welcomes the Committee’s interest in this area, and also the opportunity to update the Committee on progress in developing these standards.

Criminally negligent practice

29. The Committee agrees that serious breaches of fundamental standards which risk harming patients, or which are directly responsible for the death or serious injury of patients, should be treated as criminal matters. (Paragraph 116)

The fundamental standards will be included in Care Quality Commission (CQC) registration requirements in such a way as to make sure that providers can be prosecuted for serious breaches. The Care Quality Commission's guidance will set out how it will enforce the fundamental standards and explain the thresholds for the various enforcement measures that it will use in response to breaches.

30. The Committee notes the recommendation of the Berwick Review that an offence of wilful or reckless neglect or mistreatment, applicable both to organisations and individuals, should be introduced. It considers that the proposal should be examined to determine whether egregious acts or omissions on the part of individuals or providers that cause death or serious injury to patients can be prosecuted as offences under existing criminal statutes. (Paragraph 117)

The Government will act to tackle wilful neglect. The Government agrees with Professor Don Berwick's recommendation that there should be legal sanctions where individuals or organisations are unequivocally guilty of wilful or reckless neglect or mistreatment of patients. This will help to ensure that there is ultimate accountability for those guilty of the most extreme types of poor care. The Government will seek to legislate on this, and will work with stakeholders beforehand to determine the details of this measure, and will consult on proposals for legislation as soon as possible.

Standards on care at the end of life

31. The evidence of poor care at end of life in the NHS which has emerged from the Mid Staffs inquiries, the review of the Liverpool Care Pathway and other press and broadcast media coverage is deeply disturbing. The Committee recommends that the National Institute for Health and Care Excellence should establish specific standards for end of life care designed to ensure that dying patients receive all the care they require to minimise their suffering. (Paragraph 125)

Recommendation accepted.

A National Institute for Health and Care Excellence (NICE) Quality Standard – *End of Life Care for Adults* – has already been published by NICE. A NICE Quality Standard – *End of Life Care for Infants, Children and Young People* – has also been referred to NICE by NHS England. In addition, NHS England has recently been asked to consider referring to NICE the development of a Clinical Guideline focusing on care of the dying and including guidance on the organisation and delivery of care. NHS England is supportive of this proposed referral. The aim is to have this Clinical Guideline prioritised for publication by autumn 2016 at the latest.

The National Patient Safety Agency

32. The Committee has recommended before that prime responsibility for monitoring of patient safety practice and data should be a core responsibility of the Care Quality Commission. It repeats this recommendation in this report in order to re-establish the principle that this responsibility should be demonstrably at arm's length from both the Department and from NHS England. The Committee further notes that the definitions of patient safety incidents used by the National Reporting and Learning System focus only on incidents in taxpayer-funded healthcare. The definitions should be amended to cover patient safety incidents in private healthcare and taxpayer-funded social care services, both of which fall within the Care Quality Commission's responsibility. (Paragraph 133)

Patient safety is a critical component of what an effective regulator seeks to secure, maintain and improve, which is why patient safety is rightly placed at the heart of the Care Quality Commission's (CQC's) new inspection regime. But improving patient safety is everyone's business, not just the regulator's.

As Professor Don Berwick recently highlighted, we require an active commitment to learning and improvement by everyone who works in the system to continuously reduce the risk of harm. While regulation is a crucial component of patient safety, it is not sufficient alone to secure patient safety. Ensuring the continuous reduction of harm to patients requires the underlying culture of the entire NHS to be devoted to learning, improvement and innovation, and delivering that is a role that goes much wider than the system regulator's remit and more appropriately sits with NHS England alongside its responsibility for the other aspects of quality.

The core functions of the National Patient Safety Agency (NPSA) that moved to NHS England in relation to the National Reporting and Learning System (NRLS) are to collect patient safety incident reports from all healthcare organisations, so that those reports could be analysed by patient safety experts in order to learn from what had gone wrong, and then to use that knowledge to encourage improvement across the system. This means that the National Reporting and Learning System function is focused on learning, improvement and innovation, and not regulation or assurance. The National Reporting and Learning System data does not tell you how safe the system is; it tells you about the kinds of things that are being reported as going wrong and allows you to learn from them.

To look at it another way, the Care Quality Commission, through its new inspection process, can provide a deep understanding of what needs to improve, and where, to make care more safe. However, it is not the Care Quality Commission's role to determine *how* to make care more safe. Determining how to improve care is the job of every organisation in the NHS itself, and the NHS relies in part on using the National Reporting and Learning System to provide this insight. It is therefore most appropriate that this function sits in the NHS.

The 2010 Arm's Length Bodies Review and Health and Social Care Act 2012 moved the functions of the National Patient Safety Agency to NHS England, including ownership of the National Reporting and Learning System. This placed responsibility for patient safety improvement with the leadership of the NHS, a crucial step in ensuring that the whole culture of the NHS is devoted to continuous learning and improvement. By making NHS England

responsible for patient safety improvement, the Government can hold NHS England and therefore the NHS more widely to account for improving patient safety, via the NHS Outcomes Framework. Equally, NHS England is able to work through all its activities, both in support of the wider commissioning system and when commissioning services itself, to improve safety alongside the other aspects of quality for which it has responsibility (clinical effectiveness and patient experience). It would not make sense to separate patient safety from the other aspects of quality.

The Care Quality Commission and NHS England will continue to collaborate seamlessly on the use and sharing of information, including reported incidents from the National Reporting and Learning System, to support the Care Quality Commission's surveillance and inspection. It is not necessary for the Care Quality Commission to run the National Reporting and Learning System in order to use some of the information that it generates in its regulation and inspection activities.

Feedback and complaints

33. The Committee agrees with Robert Francis that proper complaints handling is vital if organisations are to ensure that services are changed for the better.

(Paragraph 138)

Complaints often contain hard truths, but, looked at in the right way, they can provide tremendously valuable nuggets of insight and be the source of improvements in patient care. A number of NHS organisations have shown how to use complaints effectively as a catalyst for improvement and as a warning light in relation to poor practice. The Government agrees that effective complaints handling is one of the key measures in attaining a truly open and transparent health and care system. In recognising this, the Government commissioned a review into the handling of complaints in NHS hospitals, led by Rt Hon Ann Clwyd MP and Professor Tricia Hart. The review reported on 28 October 2013 and concluded that:

- vulnerable people find the NHS complaints system complicated and hard to navigate;
- there is a low level of public awareness of the NHS Complaints Advocacy Service;
- people are reluctant to complain and staff can be defensive and reluctant to listen to or address concerns;
- organisations do not always deliver their legislative responsibilities on complaints handling; and
- there is a need for quality, trained staff to deal with complaints effectively and appropriately.

The key recommendations included that:

- every Chief Executive should take personal responsibility for the complaints procedure;
- there should be Board-led scrutiny of complaints;
- there should be a new duty on all Trusts to publicise an annual complaints report, in plain English, which should state what complaints have been made and what changes have taken place;

- Trusts should provide patients with a way of feeding back comments and concerns about their care on the ward including simple steps such as putting pen and paper by the bedside and making sure that patients know who to speak to if they have a concern – it could be a nurse or a doctor, or a volunteer on the ward to help people;
- Patient Advice and Liaison Services (PALS) should be re-branded and reviewed so that it is clearer what the service offers to patients and it should be adequately resourced in every hospital;
- the Care Quality Commission should include complaints in its hospital inspection process and analyse evidence about what the Trust has done to learn from its mistakes; and
- Trusts should actively encourage both positive and negative feedback about their services.

The Government welcomes the review and accepts the principles behind the recommendations, although many are for action at individual Trust level. The Department welcomes the Ombudsman's ambition to increase the number of cases she takes on, and her valuable role in helping the health system to interrogate and learn lessons from complaints.

The Committee also refers (at paragraph 134) to its expectation that the Government will, in its full response to the Francis report, consider the progress on relevant recommendations made in its 2011 report on *Complaints and Litigation*, as well as the recommendations relevant to the NHS which emerge from the present inquiry into complaint handling being undertaken by the Public Administration Select Committee. The majority of issues raised in recommendations by the Health Select Committee have been picked up by the Francis report and/or the Review of NHS Complaints System. Where there is such synergy, they will be addressed in our response to the Francis report. The Government will work to address any remaining recommendations by the Health Select Committee in the next year.

34. The Committee recommends that NHS providers should promote a culture of openness to complaints and receptiveness to feedback throughout their organisations, and they should also develop channels which allow patients and their families to make observations about poor standards of care in the confidence that there will be no detriment to the patient and will be taken seriously by the organisation. Any staff who deliberately treat patients poorly as a consequence of complaints being made should be held to be in breach of a fundamental standard of NHS care, and liable for the consequences. (Paragraph 140)

Recommendation accepted in principle.

NHS providers need to promote a culture that is open and receptive to feedback, and one in which such feedback should be given without fear of reprisal. It is for local organisations to ensure that staff are fully aware that poor treatment of a patient following a complaint is not acceptable.

The value of patients' complaints and feedback is now widely recognised. The Francis Inquiry, the Keogh review, the Berwick review and, most recently, the Rt Hon Ann Clwyd MP and Professor Tricia Hart's review into complaints handling in hospitals all highlight the importance of seeking feedback from patients and their families and actively learning as a result.

The Government wants to see Trust Chief Executives and Boards taking personal responsibility for complaints handling. This includes signing off letters to patients and ensuring that every patient is offered a conversation at the start of the complaints process, and that they are clear that if they are not happy with the way the complaint has been handled they can get an independent view from the Health Service Ombudsman.

The Government wants to see every Trust make clear to every patient from their first encounter with the hospital:

- how they can complain to the hospital when things go wrong;
- who they can turn to for independent local support if they want it and where to contact them;
- that they retain the right to complain to the Ombudsman if they remain dissatisfied and how to contact them; and
- details of how to contact their local Healthwatch.

A sign in every ward and patient area would be a simple means of achieving this and the Department will be discussing with Healthwatch England, the Care Quality Commission and NHS England the best means of ensuring that this becomes standard practice in all NHS hospitals in England. The Government would expect these posters to set out how to complain about the hospital, how to seek support from their local Healthwatch and how to refer their complaint to the Ombudsman.

Trust Boards should see regular data about complaints which means 'the narrative and not just the numbers', so that they can identify themes and recurring problems, and take action. All Trusts, not just the good ones, should see complaints as an opportunity to learn and improve the care they provide.

To increase transparency, detailed information on complaints and the lessons learned will be published quarterly. This will include the number of complaints received as a percentage of patient interventions; the number of complaints that the hospital has been informed have subsequently been referred to the Ombudsman; and the lessons learned and improvements made as a result of complaints. The Government will also explore with NHS England and other key partners the introduction of a regular and standard way of surveying people who have made a complaint to find out whether they were satisfied with the way it was handled, and to enable comparison across hospitals.

Staffing ratios and patient care

35. The Committee recommends that commissioners should, via the NHS standard contract, require all care providers to collect information on the deployment of registered nurses and other healthcare staff at ward level on a daily basis, and make it available immediately to commissioners for publication in a standard format which will enable ready monitoring, analysis and comparison by all stakeholders. This should include making the information available in individual health and care settings. (Paragraph 152)

Recommendation accepted in principle.

The boards and leaders of providers need to have a detailed understanding of the workforce in their organisations. This means having systems and processes in place to provide assurance that the right number of staff are in place at the right time. As the Keogh review showed, staffing levels can vary greatly from shift to shift and ward to ward. Boards need both to understand the realities of staffing in their organisations and to be able to set that against the best available evidence-based guidance. Transparently and openly publishing data about staffing levels is an important part of providing assurance to the public and to staff themselves about safety.

NHS England is currently considering the feasibility of including requirements relating to staffing level transparency in the Standard Contract. From next April and by June at the latest, NHS Trusts will publish ward level information on whether they are meeting their staffing requirements. Actual versus planned nursing and midwifery staffing will be published every month; and every six months Trust boards will be required to undertake a detailed review of staffing using evidence based tools. The first of these will take place by June 2014 and Trusts will be required to set out what evidence they have used to reach their accredited tools. A review every six months will allow for the collection of several data points to inform appropriate staffing. Commissioners will use staffing data as a basis for further questions and discussions with providers. Commissioners will also use staffing data as a basis for further questions and discussions with providers. Where concerns are highlighted, Trusts will be expected to provide an explanation for their commissioners and the Care Quality Commission and to work with their commissioners to develop an action plan to address those concerns. A joint statement between NHS England and the Care Quality Commission is being published setting out how the two organisations will align their work to support inspection and surveillance work for safety.

It is imperative that healthcare organisations are supported by independent, well-evidenced, clear and authoritative guidance to ensure that they are able to provide the right numbers and mix of staff to meet the needs of patients and service users. To this end, the Chief Nursing Officer has led the development of staffing guidance and, as a result, the National Quality Board is publishing a guidance document that sets out the current evidence on safe staffing and includes a set of expectations for NHS organisations. This document sets out the current shared understanding of key national NHS organisations of what the current evidence means for decisions about staffing.

To build on this guidance, and the Department of Health has therefore asked NICE to set out authoritative, evidence-based guidance on safe staffing. By summer 2014, NICE will have produced guidance on safe staffing in acute settings, including a review and endorsement of existing staffing tools. This initial phase will be followed by further work to develop similar tools and endorsement in non-acute settings, including mental health, community services and learning disability. The focus of the work will be nursing and maternity staffing levels, but it will also take into account the importance of getting the skill mix right and the wider context of other workforce groups, along with the importance of multi-disciplinary working in modern healthcare. The work led by NICE will be overseen by an independent advisory committee for staffing. This will consider the evidence and draft the guidance, but it will also be able to signal the need for changes to existing tools where the evidence clearly indicates that there is an urgent need for them to be updated.

36. The Committee has not undertaken an in-depth review of safe staffing issues, but has been impressed by the approach of Salford Royal NHS Foundation Trust to the development of a staffing management tool. This appears to the Committee to be good practice, and the Committee recommends the adoption of this or similar systems across the NHS. (Paragraph 153)

Recommendation accepted.

The Government agrees that transparency is critical to ensuring safe staffing: it provides those with a legitimate interest in staffing levels (the public, patients, commissioners, regulators and staff) with clear information as a basis for assurance or further action, and makes it much more difficult to disguise staffing problems. In some Trusts, such as Salford Royal NHS Foundation Trust and Wrightington, Wigan and Leigh NHS Foundation Trust, transparency is being taken even further, with actual versus expected staffing levels being published on a shift-by-shift basis in some clinical areas. Central Manchester University Hospitals NHS Foundation Trust plans to do the same. All Trusts should put in place measures to increase transparency on staffing at ward and service level as quickly as possible. As outlined above, from next April and by June at the latest, NHS Trusts will publish ward level information on whether they are meeting their staffing requirements. Actual versus planned nursing and midwifery staffing will be published every month; and every six months Trust boards will be required to undertake a detailed review of staffing using evidence based tools.

Training and status of nurses

37. The Committee recommends that any proposal to require those seeking NHS funding for a nursing degree to first serve a period as a healthcare assistant should be fully piloted and carefully evaluated before full implementation in order to establish evidence about the value of the proposal and to determine the optimum length of time for such placements. The Committee also believes that it is important that such a system takes account of other lifetime experiences of potential trainees, including lived experience and voluntary work. (Paragraph 159)

Recommendation accepted.

In *Patients First and Foremost*, the Government committed to a pilot programme whereby every student who seeks NHS funding for nursing degrees will serve up to a year as a healthcare assistant.

The pilot is an opportunity for aspiring nurse students to get real, paid caring experience for up to one year as a healthcare assistants before entering undergraduate nursing education, and to see whether nursing is right for them and they are right for nursing.

In September 2013, Health Education England (HEE) established the first set of pilots, and 150 to 200 aspiring student nurses began working as healthcare assistants. Health Education England is looking to introduce further pilots in February/March of next year. On completion, the pilot will be evaluated to see how pre-degree care experience could be rolled out in an affordable and cost-neutral way, so that everybody who wants to train to be a nurse is able to get caring experience before they start their studies. The evaluation results of the pilot scheme will need to be considered in the context of the Nursing and Midwifery Council's

pre-registration nursing standards 2010 and their application across the four countries of the United Kingdom.

Nursing care for the elderly: the registered older person's nurse

38. The Committee sees no reason why registered nurses should not concurrently hold the status of registered older people's nurse, and we recommend that those nurses and care assistants who have successfully completed training in the skills required to care for older people should have those skills formally recognised and certified. (Paragraph 162)

Recommendation accepted in principle

In *Patients First and Foremost*, the Government stated that it would not be pursuing Robert Francis's recommendation for the creation of a registered older people's nurse, as many older people in hospitals are under the care of specialist teams (for example, orthopaedics or cancer services) and require nurses to have those specialist skills. Additionally, care of older people with many conditions and frailty can take place in their own home and care homes as well as in hospitals.

However, the Government recognises that it is essential those nursing caring for older people, be that in hospital, care homes or the community, have the right compassion, skills and values to look after what can often be some of the most vulnerable people in our society. Alongside this, nurses need to continually have the most up to date knowledge and skills required to provide high quality care.

The Government has asked Health Education England, as part of its Mandate for 2013–15, to work with Higher Education Institutions to review the content of pre-registration nurse education in order to ensure that all new nurses have the skills to work with the large numbers of older people being treated in the healthcare system. Furthermore, Health Education England, working with the Chief Nursing Officer, the Director of Nursing at the Department of Health and Public Health England and the nursing profession, will develop a bespoke older persons nurse post-graduate qualification training programme. Completion of this training programme and demonstrable expertise in working with older people will allow nurses the opportunity to become part of an Older Persons Nurse Fellowship programme which will enable nurses in this field to access a clinical academic pathway. The first cohort of students will commence the post-graduate programme in September 2014.

Training and regulation of healthcare assistants

39. The Committee agrees that the issue of induction, training and performance management of healthcare assistants should be reviewed again in the light of the recommendations of the Cavendish Review of training and support for healthcare assistants. (Paragraph 171)

The Cavendish review recognised 'unacceptable variations in the competence' of the support workforce. Though there are undoubtedly pockets of excellent practice in relation to support for healthcare assistants, overall, training is neither sufficiently consistent nor sufficiently well supervised to guarantee the safety of all patients and users in health and social care.

Cavendish made the following recommendations around recruitment, training and education:

Recommendation 1: Health Education England should develop a 'Certificate of Fundamental Care', in conjunction with the Nursing and Midwifery Council, employers, and sector skills bodies. This should be written in language which is meaningful to the public, link to the framework of National Occupational Standards, and build on work done by Skills for Health and Skills for Care on minimum training standards.

Recommendation 2: A 'Higher Certificate of Fundamental Care' should also be developed, linked to more advanced competences developed and agreed by employers. The Department of Health should hold Health Education England and Skills for Care to account for ensuring that there is step-change in the involvement of best care employers.

Recommendation 3: The Care Quality Commission should require healthcare assistants in health and support workers in care to have completed the Certificate of Fundamental Care before they can work unsupervised.

Recommendation 4: The Nursing and Midwifery Council should recommend how best to draw elements of the practical nursing degree curriculum into the Certificate; Health Education England, LETBs and employers should seek to have nursing students and HCAs completing the Certificate together.

Recommendation 5: Health Education England, with Skills for Health and Skills for Care, should develop proposals for a rigorous system of quality assurance for training, which links funding to outcomes, so that money is not wasted on ineffective courses.

Recommendation 6: Employers should be supported to test values, attitudes and aptitude for caring at recruitment stage. NHS Employers, Health Education England and the National Skills Academy for social care should report on progress, best practice and further action on their recruitment tool by summer 2014.

As set out above, the Cavendish Review made a number of recommendations to improve the national standards on education and training, including a Certificate of Fundamental Care. The Government has asked Health Education England to lead work with Skills Councils, other delivery partners and health and care providers to develop a 'Care Certificate'. This will provide assurance that healthcare assistants and social care support workers receive high quality training and the consistent training and support they need to do their jobs. This should ensure that they understand the skills required and demonstrate the behaviours needed to deliver compassionate care across health and social care and help raise the status of caring. Health Education England are leading the work in close partnership with Skills for Care, Skills for Health and other relevant partners. The objective would be to ensure that training is consistent and of high quality across both health and social care.

Health Education England is already supporting employers to test values, attitudes and aptitude for caring at recruitment stage under its mandate. For social care, the project on value based recruitment was launched by Norman Lamb MP in July, and will be piloted for 12 months.

40. Healthcare assistants have an important and valued role, especially in caring for older people in their own homes and in formal care settings. The Committee believes that they should be encouraged and supported in undertaking continued

professional development. The Committee does not believe the current unregulated status of healthcare assistants should endure, but it remains mindful of the need to ensure the Nursing and Midwifery Council performance improves before additional responsibilities are laid at its door. (Paragraph 172)

The Nursing and Midwifery Council (NMC) should focus on delivering its core functions relating to the regulation of nurses and midwives, and therefore it is agreed that it should not be charged with additional regulatory responsibilities.

Healthcare assistants should, however, engage with valuable, well-supported continued professional development. In March 2013, Skills for Care and Skills for Health published the National Minimum Training Standards for Healthcare Support Workers and Adult Social Care Workers in England. The standards define the minimum knowledge that workers must have, irrespective of individual job role, and include a focus on personal development.

Regulating the system: the future of the Care Quality Commission and Monitor

41. The Committee does not support further major institutional change to the relationship between Monitor and the Care Quality Commission. The Committee recommends that the two organisations continue to develop closer working arrangements to deal with cases of provider failure and shall seek evidence about the effectiveness of these arrangements from both organisations through its programme of annual accountability hearings with them. (Paragraph 179)

Recommendation accepted.

In Patients First and Foremost (2013), the Government agreed that ‘... regulators and commissioners should ensure that they have a shared picture of provider performance and that there should be ... better communication and greater coordination ... between the Care Quality Commission and Monitor’. Patients First and Foremost also announced that the Care Bill would lay the framework for a single failure regime, under which the Care Quality Commission will be able to prompt intervention from Monitor for NHS Foundation Trusts (or the NHS Trust Development Authority for NHS Trusts) to address failures of quality if providers are unable to resolve problems on their own. In advance of the underpinning legislation that the Care Bill will provide, the Care Quality Commission plans to introduce this programme in November 2013 through a protocol setting out how it, Monitor and the NHS Trust Development Authority will co-ordinate their respective powers of intervention.

42. The Committee recommends that the Government publish for comment, prior to its formal introduction to Parliament, a draft of the legislation under which it is proposed to alter the inspection regime of the Care Quality Commission and the functioning of the single failure regime for Trusts and Foundation Trusts. (Paragraph 180)

Recommendation accepted.

The majority of the legislation relating to the functioning of the single failure regime is set out in the Care Bill, and the wider policy context of how it will operate has been set out in a joint policy statement published by the Department of Health, NHS England, the Care Quality

Commission, Monitor and the NHS Trust Development Authority. Implementing the new regime will require revised directions to the NHS Trust Development Authority. These will be published in draft in advance of formal introduction to Parliament.

The Government will make a number of regulations to support the Care Quality Commission's new inspection model, in particular to revise the requirements for registration with the Care Quality Commission to include new fundamental standards. These standards will set the basic standard below which it is unacceptable for care to fall. Together, the Government and the Care Quality Commission will consult on draft regulations setting the revised registration requirements later this year. In addition, subject to the passage of the Care Bill, regulations will set out which registered providers will be rated by the Care Quality Commission. The Care Quality Commission has set out its intention to begin producing ratings of all NHS Acute Trusts by 2015. The Government will draw up regulations to enable the Care Quality Commission to meet this timetable. The Care Quality Commission is required to consult on its ratings methodology.

43. The Committee welcomes the principle of ensuring that inspections are targeted and based on risk assessment, but believes that the Care Quality Commission will need to continue to develop its thinking about the application of these principles based on evidence and experience. It has not been demonstrated to the Committee that proposals for the frequency of inspections have been based on such evidence. The Committee therefore recommends that these proposals should be supported by effective monitoring arrangements which will trigger an immediate inspection in cases where standards are alleged to be falling. (Paragraph 183)

Recommendation accepted in principle.

The Government agrees that the targeting of inspections should be evidence based, and should take place swiftly as soon as concerns are raised.

In June 2013, the Care Quality Commission (CQC) issued *A New Start: Consultation on changes to the way CQC regulates, inspects and monitors care*. The Care Quality Commission set out in this consultation that, in future, inspections would be risk based and guided by evidence from data and intelligence. To achieve this, the Care Quality Commission monitors more than 150 different indicators developed by analysts to give inspectors a clear picture of the areas of care that need to be followed up within an NHS Acute Trust. Together with local information from partners and the public, this monitoring helps the Care Quality Commission to decide when, where and what to inspect. The indicators on their own will not be used to draw definitive conclusions or judge the quality of care – that will be a matter for inspection. Instead, the indicators will be used as 'smoke detectors', which will start to sound if a hospital is outside the expected range of performance for one or more indicators. The Care Quality Commission will then assess what the most appropriate response should be. A number of these indicators are 'tier one indicators', which always trigger action to obtain assurance. Tier one indicators include serious incidents such as 'never events'. Subject to the passage of new regulations, in 2014 the Care Quality Commission will have new powers to act immediately if it considers that patients and service users are at immediate risk of harm, without first having to issue a formal warning.

In October 2013, the Care Quality Commission published the results of its Intelligent Monitoring work to group the 161 NHS Acute Trusts into six bands based on the risk that people may not be receiving safe, effective, high-quality care, with band 1 being the highest risk and band 6 the lowest. The Care Quality Commission also published on its website the methodology that it used.

In addition to this, the National Quality Board is supporting the development of a network of Quality Surveillance Groups (QSGs). The local Quality Surveillance Groups will act as a virtual team across a health economy, bringing together organisations with information about and insight into the quality of care. This will include commissioners, system regulators, representatives of local authorities, Healthwatch, Local Education and Training Boards and public health. At regional level, Quality Surveillance Groups will also include representatives of professional regulators, Health Education England and the Health Service Ombudsman. If concerns about the quality of care are identified, action can be taken swiftly by the relevant organisation.

Inspecting the system: a Chief Inspector of Hospitals

44. The Committee notes that the Chief Inspector of Hospitals is an official of the Care Quality Commission, leading the hospital inspection function of that organisation: although new methods of hospital inspection may be introduced, the Care Quality Commission retains overall responsibility for hospital inspection. The Committee hopes that the substance of the role and the way it is exercised by its first incumbent justifies the rhetoric with which it has been introduced. (Paragraph 188)

Professor Sir Mike Richards has been appointed as the first Chief Inspector of Hospitals. The Chief Inspectors of Hospitals, Adult Social Care and General Practice are Executive Directors of the Care Quality Commission (CQC), reporting to the Chief Executive, and are members of the Care Quality Commission's Board. Subject to parliamentary approval, legislation set out in the Care Bill will ensure that these three positions become statutory members of the Care Quality Commission's Board, while highlighting their, and the Care Quality Commission's Board's, independence from Government in making decisions about the performance of health and social care providers.

Their role is to lead inspection activities in their respective sectors, and to ensure that appropriate and relevant standards and methodologies are applied to inspections and assessment of performance leading to a rating, and that appropriate enforcement action is taken where necessary.

Death certification reform

45. The Committee regrets the continued delay to implementation of the reform of death certification – a necessary reform to protect the public. The Committee notes the commitment of the Government to implementation of the new system in October 2014, and urges the Government to ensure that the timetable does not slip further. (Paragraph 198)

The Government shares the Committee's views on the importance of reform to the death certification system and remains firmly committed to it. Government will continue to work with our partners in delivery, and be advised by them about implementation.

46. The Committee recommends that the Government give early effect to the recommendations of Robert Francis in respect to coroners and death certification which do not depend on the introduction of the independent medical examiner system. (Paragraph 200)

Recommendation accepted.

The Government is committed to taking important action on death certification and the system has already taken robust action in this area, as outlined below.

The Judicial College has taken responsibility for training all coroners and coroners' officers under the remit of the Chief Coroner's Office from July 2013.

The college has also already supplied training to coroners on the Coroners and Justice Act 2009 and will develop further training for all coroners' officers on their roles, anticipated to be available in 2014.

In September 2013 the Chief Coroner's Office sent out additional guidance, *Reports to Prevent Future Deaths*, to support the sharing of relevant information with other organisations such as the Care Quality Commission.

The Ministry of Justice and the Chief Coroner have also developed guidance, *The Appointment of Coroners* (July 2013), for local authorities on coronial appointments. This includes guidance on the qualifications and process for coroner appointment.

It remains an offence to intentionally suppress, conceal, alter or destroy relevant documentation, except under specific circumstances in line with the Coroners and Justice Act 2009.



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