Department of Health

Learning not blaming

The government response to the Freedom to Speak Up consultation, the Public Administration Select Committee report 'Investigating Clinical Incidents in the NHS', and the Morecambe Bay Investigation

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Ministerial Foreword

I was thrilled to return as Health Secretary, and I will continue to support the NHS on the journey it began after the publication of the Francis Inquiry into Mid Staffordshire NHS Foundation Trust.

A journey about facing up to hard truths when care falls short.

A journey about putting patients and their loved ones at the heart of care.

A journey about a culture of learning not blame; and of improving services for patients, not defending the system.

The three documents published today help to show why this journey matters so much.

The shocking evidence amassed by Sir Robert Francis QC in his *Freedom to Speak Up* review details the price paid by far too many NHS staff who spoke up with concerns about the quality of care. Those who should have listened to those concerns - and acted on them - responded instead in many cases with evasiveness and hostility.

The report of the Public Administration Select Committee into the investigation of clinical incidents also challenges the NHS to do far better at learning from mistakes and failures in care, and challenges those of us in positions of responsibility to do more to support the NHS to learn more effectively.

Finally, the heart-breaking stories of loss compounded by a callous lack of honesty on the part of the system set out in Dr Bill Kirkup's investigation of University Hospitals of Morecambe Bay NHS Foundation Trust show us all, whatever our role in delivering care or supporting those who do so, the importance of putting in place a culture that is truly honest and which learns from its mistakes.

I want to thank Sir Robert Francis QC, Dr Bill Kirkup CBE and the Public Administration Select Committee for their work; and I want to pay tribute to those members of staff, patients and their loved ones who stood up for a culture of truthfulness and compassion, and who would not give in to those who put what they thought were the interests of the system before what was right. The only way to honour their courage is to stand with them by continuing to build a culture that listens, learns and speaks the truth.

The Rt Hon Jeremy Hunt MP

Secretary of State for Health

Introduction

1. Since the publication of the Public Inquiry report into Mid Staffordshire NHS Foundation Trust in February 2013, the landscape of policy and legislation to ensure safe, effective, respectful and compassionate care has been transformed. The Care Quality Commission (CQC) inspection regime has been overhauled and a programme of robust, expert, thorough and independent inspection is now being rolled out across health and social care services in England. New sanctions, fundamental standards and tighter and tougher accountability have brought a harder edge to the assurance of good care. The beginning of a revolution in transparency about quality of care is bringing the power of open access to comparative data to bear on the priorities and consciousness of those who govern and lead in health and social care.

2. These changes are necessary, but they are insufficient on their own to secure the consistency of experience and reliability of care that patients should be able to take for granted and that staff are striving to provide. The remaining critical component is culture, in the context of financial sustainability. Since the publication of the Public Inquiry report, the NHS has undoubtedly made progress in strengthening its culture, but a great deal more remains to be done. Sir Robert Francis QC's "Freedom to Speak up" report in February and the investigation conducted by Dr Bill Kirkup into Morecambe Bay, published in March, illustrate this point powerfully, as does the excellent report of the Public Administration Select Committee (March 2015) into the investigation of clinical incidents.

3. In an organisation as large and as complex as the NHS – operating under pressure, under intense scrutiny and in which life or death decisions are made every day – no matter how strong the professional instinct to do the right thing, no matter how powerful the impulse to care, there are inevitably times when it might feel easier to conceal mistakes, to deny that things have gone wrong and to slide into postures of institutional defensiveness.

4. All large institutions operating in high risk environments are at risk of sliding into this behaviour, so it is vital that leaders are alert to the risks and actively work to promote the culture of openness, learning and professional and institutional humility which is the absolute bedrock of safe care. They also operate in a context in which financial health must go hand in hand with clinical quality – not one or the other but

both together, complementing each other. Trusts' efforts in efficiency will be recognised by the CQC in their assessment of financial sustainability.

5. The three reports that we are building on in developing our policy are distinct in their concerns, and this document addresses points raised in each of the three reports in turn. But there are also some common themes that run through them:

- openness, honesty and candour;
- listening to patients, families and staff;
- finding and facing the truth;
- learning from errors and failures in care;
- people and professionalism;
- the right culture from top to bottom.

Openness, honesty and candour

6. All three reports detail shocking examples of failures of honesty when things went wrong. Patients, staff and family members were entitled to expect to be listened to when they raised concerns or asked legitimate questions were blocked, their concerns dismissed. In some cases, those most in need of support and a fair hearing had their own motivations and integrity attacked.

7. Following the publication of the Public Inquiry into the Mid Staffordshire NHS Foundation Trust, there was a widespread recognition that the NHS needed to radically improve the way it responded to concerns from staff and the public. A defensive culture more concerned with reputation than with either the truth, or with treating those raising concerns well and fairly, had grown up over several years. A number of brave individuals and progressive organisations (including many front line providers) stood against this culture, and give us the confidence that a different and a better way is possible for all and not just some. The imperative now is to make sure that honesty and openness is not the heroic exception, but the normal expectation throughout the NHS.

8. We have put in place a number of measures to support a culture of honesty. The Duty of Candour, now in force, places a clear obligation on provider organisations to be honest with patients and their families when they experience

significant harm. This is now one of the Fundamental Standards, and the Care Quality Commission will take a close interest in how providers are meeting their duty. Developing a strong culture of honesty will require far more than duties and regulation, important as they are. As Prof Sir Norman Williams and Sir David Dalton argued in their report on candour[1], "What is needed is a culture of openness and honesty, stimulated by a duty of candour, which is wholeheartedly adapted by organisations and individuals. This will enable patients to be reassured that when things do go wrong, we will learn and we will improve".

Listening to patients, families and staff

9. Listening – really listening – to patients, families and staff goes hand in hand with a culture of candour. All too often the terms of the conversation people have with the NHS about a concern or complaint are set by the organisation; and all too often organisations can be too quick to dismiss or explain away concerns. As well as being the right thing to do, there is good evidence that paying close attention to what patients, families and staff have to say offers an invaluable source of insight and improvement for NHS organisations. Those organisations that are "problem sensing" such as Northumbria NHS Trust (which seeks the views of over 30,000 patients a year and works to act swiftly on the concerns and priorities of patients) can be far more confident that they are providing high quality care than organisations that do not take seriously what the people they serve and the people who provide care are telling them.

10. This is why we are endorsing the principle set out by Sir Robert Francis QC that there should be a "Freedom to Speak Up Guardian" in every NHS organisation. The Guardian will be appointed by the organisation's Chief Executive to act as a genuinely independent figure. As well as local leadership, we also accept the principle that there should be an Independent National Officer, which we have concluded should to be based in the Care Quality Commission to act as a key leader in a national renewal and reinvigoration of an open and learning NHS culture.

11. All feedback, whether positive or negative, should be thought of as a potential source of learning and improvement. This applies to complaints, but is, as both the report of the Public Administration Select Committee and that of the Morecambe Bay Investigation make clear, this is not universally put into practice. We strongly endorse the conclusion of the Public Administration Select Committee that "complainants need to feel heard, whether they are patients relatives or staff" and

[1] Building a culture of candour, Sir David Dalton, Prof. Norman Williams, Royal College of Surgeons, March 2014 - http://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf

the conclusion that we need to reform the Ombudsman system. The Government have signalled their intention to simplify and modernise the existing Ombudsman structures, as outlined in the draft Public Service Ombudsman Bill announced in the Queen's Speech on 27 May.

Finding and facing the Truth

12. One of the most important changes to the NHS in recent years has been the reform of the Care Quality Commission in order to clarify, and provide singular focus to, its overarching mission to deliver authoritative and independent judgements about quality. The system of robust, independent inspection that is now in place is both a source of clear information for the public and NHS organisations about the quality of services, and also sends a clear message that facing up to the truth about the quality of care is not negotiable.

13. The primary responsibility for the quality of care rests with clinicians. But the Board of their organisation also has a key role. They need to be "problem sensing" rather than "comfort seeking". This is why getting investigations right is so critical. We should not expect the CQC to be the primary source of improvement and learning for an organisation: it is for this very reason that the CQC is so interested in whether or not an organisation is well-led.

14. As both the Morecambe Bay Investigation and the report of the Public Administration Select Committee show, the NHS does not have a strong capability across the system in investigation. The Secretary of State for Health asked Dr Mike Durkin, National Director of Patient Safety at NHS England, to develop and publish clear standards and guidelines for incident reporting. Following this, NHS England published a revised Serious Incident Framework in March 2015 which seeks to simplify the incident management process and ensure that serious incidents are identified correctly, investigated thoroughly and, most importantly, learned from to prevent the likelihood of similar incidents happening again. On wider reporting, of both less serious safety incidents and other concerns that may be identified, work is underway to respond to the recommended action in the Freedom to Speak Up report that "NHS England, NHS TDA and Monitor should produce a standard integrated policy and procedure for reporting incidents and raising concerns". This work will continue over the summer.

15. The Government therefore can now therefore confirm that they accept the Public Administration Select Committee's recommendation to establish an independent patient safety investigation function for the NHS, and will be taking this

forward in the coming months. We agree that there should be a capability at national level in the NHS to offer support and guidance to NHS organisations on investigations, and to carry out certain investigations itself. We believe that through a combination of exemplary practice and structured support to others, such a capability could make a decisive difference to the NHS, promoting a culture of learning and a more supportive relationship with patients, families and staff. The new function will be called the Independent Patient Safety Investigation Service, and it will be brought under the single leadership of Monitor and the NHS Trust Development Authority (NHS TDA).

Learning from errors and failures in care

16. A culture that is honest, that listens and that finds and faces the truth is not enough. It must be accompanied by learning, and by change for the better. This is why the role of Boards is so critical. There are a number of things that can be done through national bodies and through policy and legislation to create the conditions in which learning from errors and failures is more likely, and we will continue to look for ways to do this; but the crucial step into a culture of learning and improvement has to be taken by the organisations providing care themselves. A number of NHS organisations have taken this step in recent years, and we must now make this the norm rather than, as it was in the past, the exception.

17. Commissioners and local people will want to hold their local providers to account for their progress on the journey to a culture of learning, and we will support them by making the NHS the most transparent health service in the world, building on the excellent start made by publishing outcomes data on the MyNHS website[2] that show individual surgeons' track records, and other critical information on the quality of care.

People and professionalism

18. The cultural change we need to see in the NHS depends on the people who work in it. This is an enormous source of hope and optimism. The overwhelming majority of the people working in the NHS came into it because they care, and because they want to make a difference to the lives of their patients - and this is what they do, day after day.

[2] https://www.nhs.uk/Service-Search/performance/search

19. This is, of course, what makes the cases in all three reports of people and organisations falling short of the expectations of patients and the public so very shocking, and we must do all we can at national and local level to learn from these failings, never hesitating to act when fundamental standards of care or of professional conduct have been breached. This is why we legislated to make cases of wilful neglect a criminal offence, and why we asked Professor Sir Bruce Keogh to review the professional codes of both doctors and nurses to ensure that the right incentives are in place to prevent cover-ups and to promote learning.

20. The Morecambe Bay Investigation highlighted some important issues that were specific to maternity services. These issues will be addressed by the review of maternity services being led by Baroness Cumberlege. The Royal College of Obstetricians and Gynaecologists (RCOG) has instigated its own review, "Safer Women's Healthcare", due to be published in early 2016[3]. This review has multidisciplinary input and the RCOG anticipates that the working party report will complement the work of the National Maternity Review.

21. In addition, the Government committed in March to the removal of the Nursing and Midwifery Council (NMC)'s oversight of midwifery and the replacement with a more robust system. Our intention is to act as swiftly as possible to legislate, and we intend to do this by introducing an Order in Council made under section 60 of the Health Act 1999.

22. We ask a lot of the people who work in our NHS, but we should never put them in a position where they have to choose between telling the truth and keeping their job. Sir Robert Francis QC heard troubling accounts of whistleblowers who struggled to find alternative employment after raising their concerns. In line with Sir Robert's recommendation, we agree that NHS England, Monitor and the NHS Trust Development Authority (NHS TDA) should devise a support scheme to help whistleblowers who can demonstrate that they are having difficulty finding employment as a result of raising concerns to find alternative employment. Furthermore, a regulation-making power has been enacted to prohibit discrimination by a prospective NHS employer against a job applicant on the grounds that the applicant appears to have made a protected disclosure. We will be making regulations to implement this prohibition shortly.

23. The professional healthcare regulatory bodies in the UK are taking steps to review their standards and professional codes of conduct and ethics, and to strengthen these where necessary to ensure their registrants are clear what is

[3] http://www.england.nhs.uk/2015/03/26/chair-mr-announced/

expected of them in respect of the individual professional duty of candour. As part of this work, the General Medical Council (GMC) and Nursing and Midwifery Council (NMC) published joint duty of candour guidance for medical doctors, nurses and midwives on 29 June 2015. The professional duty of candour sits alongside the organisational duty of candour placed on providers of healthcare services since November 2014.

The right culture, from top to bottom

24. A healthy culture depends on the professionalism of individuals and on organisations that are committed to learning and to doing their best for patients and staff. The Morecambe Bay Investigation laid bare an organisation that failed this test. University Hospitals of Morecambe Bay NHS Foundation Trust became defensive, narrow and unsupportive to its staff, with tragic consequences for patients and their families. The terrible errors in care were compounded by a defensive and dismissive attitude to the families that had suffered so much, literally adding insult to injury.

25. The investigation led by Dr Bill Kirkup CBE contains a number of recommendations for the Trust, and we have asked the Trust to implement all 18 of them., and we have also asked Monitor to ensure this happens within the designated timescale. No time must be wasted in learning necessary lessons.

26. A clear message for the NHS emerges from the three reports. It must embrace a culture of learning rooted in the truth, a culture that listens to patients, families and staff and which takes responsibility for problems rather than seeking to avoid blame. This message applies to organisations throughout the NHS: to providers and commissioners of care, to regulators and inspectors; to individual staff; and to the Department of Health.

27. The remainder of this document focuses on next steps with each of the three reports. In the case of the Freedom To Speak Up report, we focus on the Government's response to its consultation on a package of measures to implement the principles and actions set out in the report at both a national and local level. The action being taken at both national and local levels in response to these reports builds on the NHS-wide movement for safety and compassion that followed the publication of the Inquiry into Mid Staffordshire NHS Foundation Trust. That report gave us reason enough to embrace a culture of listening and learning, and the further work of Sir Robert Francis QC, Dr Bill Kirkup CBE and of the Public

Administration Select Committee must strengthen our resolve to meet this important challenge.

28. Finally, these three reports highlight the need for NHS organisations to be less defensive and more welcoming of feedback in all of its forms, whether that is a complaint or an informal query. It is only by listening to users and carers that services can improve. And listening to these early warning signs – as the lessons of these reports clearly show – helps to prevent issues from becoming crises.

29. As the NHS becomes more integrated with social care, and the commissioning of services becomes more locally driven and locally accountable, the role of the local Healthwatch and of the Health and Wellbeing Board in speaking up for patients, users and carers should be welcomed as a positive contribution to service improvement.

Freedom to Speak Up review:

Consultation response on the implementation of the recommendations, principles and actions set out in the report of the Freedom to Speak Up review

Consultation Response: 16 July 2015

Introduction

1. In response to concerns around the reporting culture in the NHS, Sir Robert Francis QC was commissioned in June 2014 to carry out an independent policy review, called Freedom to Speak Up, to provide independent advice and recommendations on creating a more open and honest reporting culture in the NHS.

2. The Freedom to Speak Up (FTSU) report was published on 11 February 2015 and made two overarching recommendations:

Recommendation 1: All organisations which provide NHS healthcare and regulators should implement the Principles and Actions as set out in this report in line with the good practice described in this report.

Recommendation 2: The Secretary of State should review at least annually the progress made in the implementation of these Principles and Actions and the performance of the NHS in handling concerns and the treatment of those who raise them, and report to Parliament.

3. The Freedom to Speak Up report set out what needed to change to create an open and honest reporting culture and which organisations need to take this forward. While there is much good work across the NHS to be built on, it is clear from the findings of the report that a change in culture is needed across the board to ensure that staff feel safe to raise concerns without fear of reprisal, and that these concerns are dealt with appropriately.

4. The Department accepted the recommendations in principle and consulted on a package of measures to implement them, taking into account that the vast majority of the principles and actions require implementation by local NHS healthcare providers, regulators and oversight bodies. The Department's consultation sought views on the implementation of a package of measures resulting from the principles and actions set out in the Freedom to Speak Up report. The consultation document considered seven national level policy areas:

- the overall approach to local implementation of the principles and actions;
- the role of national bodies;

- the Freedom to Speak Up Guardian role;
- the title of the local Freedom to Speak Up Guardian;
- the Independent National Officer;
- standard practice in professional codes on how to raise concerns; and
- strengthening legislation.

5. The responses to the consultation have provided much material that can help to inform the local implementation of the principles and actions set out in the Freedom to Speak Up report and we intend to feed this material into the various national bodies that Sir Robert Francis QC has identified should prepare national guidance. In addition, NHS England will produce guidance by September 2015 on how to implement the principles and actions in the Freedom To Speak Up report in primary care. Having taken the responses into account, we intend to move ahead with the key actions that will give real momentum to the implementation of the principles in the Freedom to Speak Up report. So that national organisations, NHS Trusts and NHS Foundation Trusts ("Trusts") can move ahead without further delay, this consultation response sets out the analysis and conclusions by policy area. Also, NHS England will produce guidance by September 2015 on how to implement the principles and actions in the Freedom to Speak Up report in primary care.

6. This document does not provide details of how each and all of the principles and actions in the Freedom to Speak Up report will be implemented, as the vast majority require consideration by local NHS healthcare providers and regulators, and some require further consultation by national organisations. Many of the consultation responses covered issues that go beyond the scope of the consultation and, therefore, these views are not reflected in this report. However it is clear that many of those responses will be relevant to future consultations, such as on the guidance related to the Independent National Officer. We therefore propose to share the responses received with the relevant organisations to inform their development of guidance. However if individuals or organisations do not want their responses to be shared, they should notify the Department by emailing **hrdlistening@dh.gsi.gov.uk** before the end of July.

Consultation process

7. The consultation ran from 13 March 2015 to 4 June 2015 and was taken forward in accordance with the Cabinet Office Consultation Principles. The full text of

these principles is on the gov.uk website at www.gov.uk/government/publications/consultation-principles-guidance.

8. The consultation document was available on the gov.uk website.

9. We received 106 responses to the consultation in a number of formats including Citizen Space, by email and by post. The responses came from both individuals and on behalf of organisations. The Department would like to thank everyone who responded to this consultation and is grateful to them for their input.

Consultation responses and key themes

Overview

10. The seven policy areas set out in the consultation document focused on a package of measures to implement the principles and actions set out in the Freedom to Speak Up report. The majority of the consultation questions within the policy areas asked for general views and we therefore received wide-ranging comments. As a result, the analysis is largely qualitative and is presented accordingly. It should be noted that not all of the respondents answered all of the questions in the consultation.

11. For each policy area we have set out the key themes that emerged from all the responses where appropriate.

12. The Department received 106 responses; the respondents were identified as follows:

Category	**Number of respondents**	**percentage**
Individual not identified	24	23
An individual working in a Trust	3	3
Official response from a Trust	7	7
Individual working in a Trust (not known if official response)*	12	11
Official response from another organisation	48	45

Individual response from another organisation (not know if official response)*	7	7
Individual describing themselves as a whistleblower	5	5
Total	106	100**

*Not clear if the response is on behalf of the individual or an official response on behalf of the organisation

**percentages rounded

13. The majority of responses were supportive of the Freedom to Speak Up Guardian role and saw the role as being important. A number of respondents considered that the role should have national consistency and that it should be independent, reporting either to the Independent National Officer (INO) directly or having the option to refer to the INO even when reporting initially to the CEO/Board of the organisation.

14. There was support for training for the Freedom to Speak Up Guardian role to be of a national standard, although a number of respondents considered this training should allow for local needs to be incorporated into the training. There was also support for national networking between Guardians, which would allow information and best practice to be shared as well as provide a support network.

15. The majority of respondents supported the Independent National Officer role being hosted by the Care Quality Commission (CQC). There was also support for standardised practice in professional codes on how to raise concerns.

Analysis and implementation by policy area

Local implementation

Q1. Do you have any comments on how best the twenty principles and associated actions set out in the Freedom to Speak Up report should be implemented in an effective, proportionate and affordable way, within local NHS healthcare providers?

In considering this question, we would ask you to look at all the principles and actions and to take account of local circumstances and the progress that has already been made in areas highlighted by "Freedom to Speak Up".

16. We received 86 responses to this question. Key themes that emerged were:

- the twenty principles and associated actions are welcomed;
- there needs to be a cultural change;
- there should be local-level responsibility for implementing the measures; and
- there needs to be better accountability for the way in which organisations handle cases when a concern is raised.

17. A high number of respondents welcomed the twenty principles in the Freedom to Speak Up report. A significant number felt that a change in culture was necessary to implement the principles.

18. A key theme of the responses was that the implementation of the principles and actions should be handled at a local level, rather than the NHS following a single set of nationally mandated procedures. National guidance and best practice was recognised as something that can help with consistency across the NHS, but local organisations should have flexibility to adapt practice into something which worked best for them.

- "These twenty principles will require a change of culture in many organisations. Some will be more ready than others to embrace this change. This must come from the Trust Board in hospital practice and the Board must be seen to embrace this within their routine work. It is absolutely correct that this needs to be driven from the Board downwards and the Board needs to demonstrate that they actively support the safe learning culture and a system of raising concerns." **- The Faculty of Pain Medicine, The Royal College of Anaesthetists.**

19. There were a number of comments relating to management of whistleblowing and how line managers should be trained or developed to handle whistleblowing matters. In addition the importance of managers changing their attitudes towards whistleblowing was highlighted, so that when a concern is raised it is not handled in a defensive manner, but dealt with in an open and transparent way. This would

allow the concern to be seen as part of a process by which improvements can be made and the person raising the concern would not be "blamed".

20. The need for specific training for managers was highlighted:

- **"**This must cover pro-active and positive, rather than defensive, handling of concerns. Managers need to ensure they do not see concerns, or the route used to raise them, as personal criticism. Organisations need to empower their managers and value those who are able to demonstrate that they preside over an open culture. The fact that staff feel able to raise concerns should be viewed as a positive reflection on the manager". **UNISON**

21. A number of respondents felt that better accountability was required and there should be suitably robust oversight of how local organisations handle whistleblowing concerns, ensuring that whistleblowers were properly protected by their employers and that concerns were handled in a satisfactory manner.

22. Another theme was that of training for all staff, both on how to raise a concern and on what action to take once a concern had been raised. The point was made that all members of the workforce should be aware of and understand their organisation's processes on how to raise a concern. There were also a number of comments stating that there should be a clear feedback process for staff once a concern has been raised. NHS Employers made the point that, based on research it has carried out, many staff are already aware of how to raise concerns but are not confident in doing so, because they have been affected by how other cases have been handled.

23. **NHS Employers** stated:

- "We know most people know how to raise concerns and that the area for focus is on building confidence so that everyone feels safe to raise a concern and that they have confidence action will be taken".

24. A number of respondents felt that it was important that the implementation of Freedom to Speak Up principles used existing structures in place in the NHS, or in professional regulatory bodies, rather than inventing new processes. The implementation of the principles should, therefore, be about the existing structures being aligned so that they work properly.

- **“**Implementation should be focused on Trusts enhancing local arrangements, building on existing good practice and tailored to their specific circumstances” – **Association of Ambulance Chief Executives**

- **“**The Key principles match to corporate and clinical governance structures and strategies within most NHS organisations. We believe that the principles contained within the Freedom to Speak Up review should not be divorced from initiatives already in place within NHS organisations if effective cultural change is to occur.” **- South Essex Partnership University NHS Foundation Trust**

- **“**In the RCS publication Duty of Candour: Guidance for Surgeons and Employers we have identified as common barriers to raising concerns and reporting incidents the lack of support, lack of feedback, uncertainty about what constitutes an incident and doubt that appropriate action follows reporting. Organisations should therefore ensure that they provide updates on progress to those who raise concerns, that they disseminate the findings of any investigations for learning purposes and that they demonstrate willingness to learn and apply lessons in practice through concrete action plans.” **- Royal College of Surgeons**

Conclusion

25. The responses received have set out robust ideas and clear views on how best to implement the twenty principles and associated actions set out in the Freedom to Speak Up report. However, given the wide scope, and drive towards local implementation and ownership of the principles in the report within a framework of national guidance, we will ask the Independent National Officer, once in post, to consider what national guidance might be appropriate on implementation, taking into account the consultation responses.

26. We therefore propose that:

- the CQC should consult in summer 2015 on how the Independent National Officer role will be implemented, taking into account principle 15 and its associated actions in the Freedom to Speak Up report;

- the Independent National Officer should be appointed by the CQC by December 2015. Once in place the Independent National Officer will produce guidance on local implementation of the Freedom to Speak Up Guardian role and how this role will develop; some Trusts have already taken this role

forward and have a guardian in place. We expect the Independent National Officer to take account of the good practice already taking place in many Trusts before publishing this guidance;

- Health Education England should produce guidance on what training will be needed for the Freedom to Speak Up Guardian role, along with a curriculum that NHS organisations can use to ensure that the training they are providing on raising concerns is of a sufficiently high standard; and

- the Department will share the responses to this consultation with the relevant organisations and the Independent National Officer to help inform the guidance they will develop.

27. We now expect local NHS organisations to take forward the actions that are for them in an effective, proportionate and affordable manner and that guidance will be published in due course by the Independent National Officer and the national regulators, as described in the Freedom to Speak Up report.

Primary Care

28. In addition, we have asked NHS England to produce guidance on how to implement the principles and actions in the Freedom to Speak Up report in primary care. This will follow a different timetable because NHS England will first need to engage stakeholders in their thinking. We expect this guidance to be published in September 2015.

Role of national bodies

29. Many of the principles and actions set out in the Freedom to Speak Up report are for the national regulators and bodies that oversee the NHS and healthcare provision in England to implement. These organisations will consult on their plans on the issues set out below:

- The CQC to consult on the approach to implementing the Independent National Officer role;

- NHS England, Monitor and the NHS Trust Development Authority to devise and establish a support scheme for NHS workers and former NHS workers, whose performance is sound and who can demonstrate that they are having difficulty finding employment in the NHS as a result of having made protected disclosures;

- NHS England, Monitor and the NHS Trust Development Authority will produce a standard integrated policy and procedure for reporting incidents and raising concerns.

30. In addition we expect Health Education England to work with the CQC and the Independent National Officer on guidance on training for the Freedom to Speak Up Guardian role. We expect the guidance to be published once the Independent National Officer is in post.

31. Recommendations will also be made by Health Education England in the autumn on ways in which education and training can be used to improve patient safety.

Freedom to Speak Up Guardian Role

Q2: Do you have any opinions on the appropriate approach to the new local Freedom to Speak Up Guardian role?

Q3: How should NHS organisations establish the local Freedom to Speak Up Guardian role in an effective, proportionate and affordable manner?

Q4: If you are responding on behalf of an NHS organisation, how will you implement the role of the Freedom to Speak Up Guardian in an affordable, effective and proportionate manner?

Q5: What are your views on how training of the local Freedom to Speak Up Guardian role should be taken forward to ensure consistency across NHS organisations?

Q6: Should the local Freedom to Speak Up Guardian report directly to the Independent National Officer or the Chief Executive of the NHS organisation that they work for?

32. The key themes that emerged were:

- the role is important and worthwhile;
- the role should be independent, with the authority to report concerns either directly to the Independent National Officer or directly to the CEO/Board, with the option in the latter case to refer matters to the Independent National Officer if this is deemed necessary;
- the role should be a team or a shared role;
- there should be a consistent/national approach;
- the role needs to be sufficiently resourced; and
- training should be of a national standard.

33. A large number of respondents felt that the role of the Freedom to Speak Up Guardian would be important and worthwhile and would have a positive impact on the whistleblowing process overall.

Independence

34. There was strong support for the role to be independent. There were mixed responses about whether the individual undertaking the Freedom to Speak Up Guardian role should have the authority to report a concern directly to the Independent National Officer, or they should report to the Board or Trust CEO. Respondents' support for reporting concerns directly to the Independent National Officer stemmed mainly from a lack of trust or confidence that the CEO or the Board of the Trust would take the correct action, or a feeling that he or she could be part of the problem, covering up concerns that had been raised, leading to whistleblowers' being unfairly treated.

35. The differing opinions on the chain of reporting can be seen in the comments below from two individuals:

- "That person should be completely independent of the Trust, and should report to the Independent National Officer (INO) or to the CQC. If the Freedom to Speak Up Guardian reports to the Chief Executive of a Trust or to the Medical Director, there are opportunities for all sorts of conscious and unconscious bias and influence".

- "I would have severe reservations to a guardian reporting to a national body; it could potentially create employee relation challenges and could be distrusted rather than trusted."

36. The support for the individual undertaking the Freedom to Speak Up Guardian role reporting directly to the CEO was highlighted by both Monitor and the CQC:

- "To ensure accountability and very senior oversight, the Local Guardians should report into the trust's CEO". **Monitor**

- "Local ownership will mean a degree of local flexibility is needed in how the roles should operate. However, we believe that they should be underpinned by a consistent framework, including person specifications clear job descriptions, and that post holders should receive standard training. We believe that the Local Guardians should report directly to the Chief Executive of the NHS Organisation that they work for rather than to the National Guardian (our preferred title for the Independent National Officer), thus ensuring that the emphasis remains on local ownership". **Care Quality Commission**

Shared role

37. There was significant support for the role to be either shared or to sit within a team. The reasons given were that the role could become overwhelming or stressful for just one person due to both volume of work and the nature of the concerns. It was felt that sharing the role could ensure that the responsibility of the role does not sit with one person.

38. It was also suggested that, given that some health organisations were spread across a large area with a disparate workforce, such as an ambulance service, having a higher number or team of Guardians would make the process practical and therefore more effective. **Lancashire Care NHS Foundation Trust** is already considering introducing a Guardian who has wider support in the Trust:

- "We fully support the appointment of such a post …we are considering one Guardian supported by a small network of Champions. We feel this flexibility is needed to ensure the role is meaningful".

Establishing the role

39. There was no particularly strong theme about how the Freedom to Speak Up Guardian should be established, although there was strong support that there should be a national approach to the role, such as having a standard job specification. This included **Hertfordshire Trust** who said:

widely. The Trust has admitted the extent of the problems within its maternity service, fully accepted the Kirkup Report as the definitive account of the problems, and offered apologies to those affected. Work programmes are being actioned to address the weaknesses identified including in education, training and development; clinical quality; workforce; governance and estates. There is a new leadership team in place at the Trust which is leading efforts to change the culture of the organisation to better support staff in providing excellent clinical care, and to support staff and patients or families in challenging any aspects of poor care and having those fairly reviewed and addressed where necessary. The Care Quality Commission were inspecting the Trust in July 2015, to assess whether they had gone far enough and fast enough in order to exit Special Measures. The report was scheduled to be published in the autumn.

7. This response also reflects progress against the system-wide recommendations where, for example, NHS England has begun a national review of maternity care chaired by Baroness Cumberlege, which will identify sustainable care models; where Health Education England will review how best to use smaller units in training programmes for staff to ensure the flow of latest learning and new ideas into otherwise potentially isolated units; and where the General Medical Council and Nursing and Midwifery Council have launched joint guidance on the professional duty of candour, including giving advice to professionals on apologising to patients when things go wrong.

8. Our ambition for the NHS is that we can learn the significant lessons from the horrific examples of failed care that we have seen at Mid Staffordshire and Morecambe Bay and instil an openness and willingness to learn from clinical mistakes; and that we actively listen to families' concerns and address them appropriately. This report and today's announcements provide a road map to ensure safer care, and a more responsive system when things go wrong.

[A] Recommendations for the Trust

Recommendations for the Trust: 1-18

1. The Morecambe Bay Investigation found that there were serious failures in clinical care at University Hospitals Morecambe Bay NHS Foundation Trust, causing avoidable harm to mothers and babies including unnecessary deaths, and found that there was a pattern of Trust failure to recognise the severity and nature of the problem, compounded by denial. The Trust failed to look into serious incidents and sought to diminish the seriousness of the situation to others. At the Trust level there were failures in risk assessment and care planning; a deficient response to adverse incidents; and failure to investigate and improve. The Investigation Report, published on 3 March 2015, challenged the Trust to make a number of improvements quickly.

2. The Trust had earlier been placed into special measures in July 2014 following the Care Quality Commission inspection of February 2014. This means that they have to have made real improvements by the next Care Quality Commission inspection in July 2015. An Improvement Director appointed by Monitor provides constructive challenge as part of the process. The Care Quality Commission will publish their judgment of the Trust in the autumn.

3. To address both the requirements of special measures and the Morecambe Bay Investigation recommendations, the Trust has put substantial plans in place to make improvements. Delivery of these plans is overseen by several groups including a "Kirkup Recommendations Implementation Group". The Group reports to the Morecambe Bay Investigation sub-committee, which is a sub-committee of the Trust Board and the local Quality Surveillance Group (QSG), chaired by local NHS England representatives and ensuring that the Trust, clinical commissioning groups (CCGs), regulators and others are working together in the best interests of the local population. Progress reports are publicly available[10]. The Trust has taken care to involve affected families in groups looking at how their services can be made more effective and patient-centred.

4. The Trust is being inspected by the Care Quality Commission in July 2015 and it would be wrong to speculate whether sufficient progress will have been made by then. However the Trust reports that they have so far:

[10] http://www.uhmb.nhs.uk/morecambe-bay-investigation/implementing-the-recommendations/

- Formally admitted the extent and nature of the problems that occurred and apologised individually to families (recommendation 1);

- Started to strengthen multi-disciplinary working - in particular between paediatricians, midwives, obstetricians and neonatal staff – as part of a broader, ongoing programme of work (recommendation 5);

- With maternity staff, begun to review how investigations into incidents are carried out and started a programme to raise awareness of incident reporting, (recommendations 11 & 12);

- Reviewed clinical leadership in terms of individuals and structures in obstetrics, paediatrics and midwifery (recommendation 14); and

- Ensured that in carrying out all of these, the Trust is working closely with the Care Quality Commission, Monitor, NHS England and others (recommendation 18).

[B] Recommendations for the wider NHS

Reviews: 19-22

Recommendation 19:

In light of the evidence we have heard during the Investigation, we consider that the professional regulatory bodies should review the findings of this Report in detail with a view to investigating further the conduct of registrants involved in the care of patients during the time period of this Investigation. Action: the General Medical Council, the Nursing and Midwifery Council.

5. We accept this recommendation. Action is under way.

6. The General Medical Council and the Nursing and Midwifery Council have emphasised that they have reviewed the findings of the Morecambe Bay Investigation Report and are acting on relevant recommendations. They have both met with Dr Kirkup to discuss his findings. The Department understands these organisations have paid particular attention to findings concerning the professional conduct of registrants involved in the care of patients at the University Hospitals of Morecambe Bay NHS Foundation Trust, so that they can take appropriate action against anyone who they suspect has broken their professional code.

Recommendation 20:

There should be a national review of the provisions of maternity care and paediatrics in challenging circumstances, including areas that are rural, difficult to recruit to, or isolated. This should identify the requirements to sustain safe services under these conditions. In conjunction, a national protocol should be drawn up that defines the types of unit required in different settings and the levels of care that it is appropriate to offer in them. Action: NHS England, the Care Quality Commission, the Royal College of Obstetricians and Gynaecologists, the Royal College of Midwives, the Royal College of Paediatrics and Child Health, the National Institute for Health and Care Excellence.

7. We accept this recommendation. A review of maternity care, which will also consider neonatal care and paediatrics in the context of maternity care, is underway.

8. In its report to Cumbria Clinical Commissioning Group, the Royal College of Obstetricians and Gynaecologists highlighted the association between frequent exposure to complex cases and more favourable outcomes for patients across all aspects of clinical care. The report suggests that some units, particularly rural and isolated units, need to develop innovative models of care that enable clinicians to maintain their skills and competencies and staffing structures to ensure safe levels of expert clinical coverage.

9. NHS England announced a review of maternity services on 3 March 2015. Baroness Cumberlege is the independent Chair leading the review and is being supported by a core team of experts, including Catherine Calderwood, the Chief Medical Officer for Scotland, who worked on the Morecambe Bay Investigation and James Titcombe OBE, one of the family members affected by the failings at Morecambe Bay. The Review will develop proposals for the future shape of modern, high quality and sustainable maternity services across England. The terms of reference set out three complementary objectives:

- review the UK and international evidence and make recommendations on safe and efficient models of maternity services, including midwife-led units
- ensure that the NHS supports and enables women to make safe and appropriate choices of maternity care for them and their babies
- support NHS staff including midwives to provide responsive care.

10. The review will pay particular attention to the challenges of achieving the objectives in more geographically isolated areas. It will also consider the links between the different models of maternity care and neonatal units, ensuring access to appropriate levels of more intensive care following birth, if they are needed. It is expected to conclude and publish proposals by the end of the year.

Recommendation 21:

The challenge of providing healthcare in areas that are rural, difficult to recruit to or isolated is not restricted to maternity care and paediatrics. We recommend that NHS England consider the wisdom of extending the review of

requirements to sustain safe provision to other services. This is an area lacking in good-quality research yet it affects many regions of England, as well as Wales and Scotland. This should be seen as providing an opportunity to develop and promote a positive way of working in remote and rural environments. Action: NHS England.

11. We accept this recommendation in principle. NHS England are establishing Vanguard sites to explore how new models of care can address the challenges faced by services that are rural, geographically isolated or difficult to recruit to.

12. The Investigation highlighted some of the problems that can affect services provided in remote or isolated areas, where poor practice becomes entrenched and low staff turnover and low numbers of procedures can lead to a lack of clinical experience and reduced opportunities for learning.

13. The NHS Five Year Forward View[11] set out a way forward for the NHS that includes new and different care models to meet the health needs of the population in the future. Through these new care models, care will often be focused more in community settings than in hospitals, will be more joined up to recognise the need of people with multiple conditions, and will be more patient-focussed. For example, integrated community teams will be community based (including in rural districts) and where clinically appropriate will utilise tele-health to support effective, safe and quality care.

14. One of the main areas of focus for the new model of acute care collaboration will be on the question of how to maintain local access to a range of safe, clinically and financially sustainable acute services - in particular for services with low volumes of patients or where there are national or local staff shortages.

15. Changing how care is provided is an ambitious and lengthy task. To start this process NHS England has established some Vanguard sites which will test whether these models work for patients. NHS England has selected areas that address these challenges in both rural and urban settings. Lancashire North, which covers the population of Morecambe Bay, is one of the nine Primary and Acute Care Systems Vanguard sites that will receive national, regional and local support to develop new care models joining up GPs, hospitals, community and mental health services.

[11] NHS Five year Forward View (October 2014)

16. Examples of best practice and shared learning from these Vanguard sites will be made available to the wider NHS as soon as possible.

17. NHS England, Monitor and the NHS Trust Development Authority have also recently announced the first locations to enter into the Success Regime, in which the tripartite partners will jointly oversee a package of challenge and support for some of the most challenged health economies. The regime will be tailored to local circumstances, building upon existing interventions and working with providers, commissioners and other local stakeholders to diagnose key underlying issues and develop and implement the solutions to address both short-term performance and long-term strategic issues.

18. The aim of the Success Regime is to create the conditions within health economies to enable them to become high performing in the future. It will differ from other interventions in that it will focus on identifying and addressing issues across whole health systems as opposed to simply dealing with individual providers or commissioners

Recommendation 22:

We believe that the educational opportunities afforded by smaller units, particularly in developing a broad range of care with a high personal level of responsibility, have been insufficiently recognised and exploited. We recommend that a review be carried out of the opportunities and challenges to assist such units in promoting services and the benefits to larger units of linking with them. Action: Health Education England, the Royal College of Obstetricians and Gynaecologists, the Royal College of Paediatrics and Child Heath, the Royal College of Midwives.

19. We accept this recommendation in principle. Work already underway by Health Education England addresses this recommendation. Health Education England is committed to supporting efforts to improve the quality of patient care by ensuring that its quality management infrastructure ensures the delivery of high quality training in sites where safe services are provided.

20. Health Education England recognises that there are particular challenges in attracting and retaining students, trainees and learners to work in smaller and/or

isolated hospitals and that this can exacerbate problems such as those described at Furness General Hospital.

21. They have established a Working Group to consider the issues raised by the Investigation in relation to making best use of smaller units in the provision of training. While focussing on maternity services this group will look at the broader issues for trainees from other professions. Health Education England intends to complete its initial review by the spring of 2016.

22. Health Education England will also use its wider work on quality management of placements and training posts to explore opportunities to improve training provision and take-up in hospitals such as Furness General.

Investigations: 23

Recommendation 23:

Clear standards should be drawn up for incident reporting and investigations in maternity services. These should include the mandatory reporting and investigation of serious incidents of maternal deaths, late and intrapartum stillbirths and unexpected neonatal deaths. We believe that there is a strong case to include a requirement that investigation of these incidents be subject to a standardised process, which includes input from and feedback to families and independent, multidisciplinary peer review, and should certainly be framed to exclude conflicts of interest between staff. We recommend that this build on the national work already begun on how such a process would work. Action; the Care Quality Commission, NHS England, the Department of Health.

23. We accept this recommendation in principle. A new national, Independent Patient Safety Investigation Service will supplement existing practice.

24. The Investigation found that there were a substantial number of missed opportunities to uncover and address the problems at Morecambe Bay. The quality of investigations carried out into serious incidents was found to be poor, and this contributed to the ongoing failures to learn and improve, and also resulted in the system having an overly optimistic view of performance in the midwifery unit.

Recommendation 42:

We further recommend that all external reviews of suspected service failures be registered with the Care Quality Commission and Monitor, and that the Care Quality Commission develops a system to collate learning from reviews and disseminate it to other Trusts. Action: the Care Quality Commission, Monitor.

43. We accept these recommendations. A new national, Independent Patient Safety Investigation Service will improve local standards of investigation and openness.

44. During the 10-year period in which serious incidents were occurring at Morecambe Bay, the Investigation found that there had been external reviews conducted into operational aspects of the Trust, that were not brought to light in a timely or transparent way and that had regulators been sighted on the Fielding report earlier, action might have been taken sooner to address concerns.

45. NHS Trusts and Foundation Trusts are already required to notify the Care Quality Commission and Monitor and the NHS Trust Development Authority of certain events, such as serious incidents or third party investigations or reports. However we also believe that there is a strong case for requiring providers to notify regulators - both the Care Quality Commission and Monitor or the NHS Trust Development Authority - when they commission external investigations. The Government will consult on proposals to extend the regulations that set out requirements for notifications to cover the commissioning of external investigations.

46. In the meantime, Monitor and the Care Quality Commission will continue to use their respective statutory information-gathering powers to require NHS Trusts and Foundation Trusts to notify them of both the commissioning and the conclusions of relevant external investigations.

47. Trusts also have to report in their Quality Account on the number and where available, the rate of patient safety incidents reported within the reporting period, and the number and percentage of such patient safety incidents that resulted in severe harm or death. There is also a requirement to report on whether they have taken part in any reviews or investigations by the Care Quality Commission under section 48 of Health and Social Care Act 2008. We will consider what more can be done to improve awareness and accessibility of this information.

48. There are several existing mechanisms for reporting and sharing learning from serious incidents:

- NHS bodies are already required to notify the Care Quality Commission and the National Reporting and Learning System, currently overseen by NHS England, where serious incidents have happened, including those which prompt investigations. Reports to the National Reporting and Learning System are analysed by expert clinicians to identify common hazards, and can result in recommendations being made to local NHS organisations to mitigate these risks and improve the safety of patient care.

- The NHS England Serious Incident Framework recommends that providers collaborate with external scrutiny and investigations, including the full and open exchange of information with other investigatory agencies (such as the police, the Health and Safety Executive, Coroner and local safeguarding boards). It also recommends publishing information about serious incidents including data on the numbers and types of incidents, excluding material that would compromise patient confidentiality, within annual reports, board reports and other public facing documents.

49. The Government have accepted the recommendation of Sir Robert Francis QC that national expertise on patient safety should be based within a single organisation that can provide strategic leadership across the whole healthcare system. The Government intend to bring under the single leadership of Monitor and the NHS Trust Development Authority responsibility for leading the patient safety functions that currently sit with NHS England. The new Independent Patient Safety Investigation Service will also be brought under the single leadership of Monitor and the NHS Trust Development Authority. A core element of that role would be supporting the NHS to learn from service failures. Responsibility for disseminating learning from external investigations would best sit with the body that has the lead role on patient safety.

Recommendation 26:

We commend the introduction of a clear national policy on whistleblowing. As well as protecting the interests of whistle-blowers, we recommend that this is implemented in such a way that ensures that systematic and proportionate response is made by Trusts to concerns identified. Action: the Department of Health.

50. We accept this recommendation. The Department has accepted in principle the recommendations made by Sir Robert Francis QC in his Freedom to Speak Up report; and has consulted on a package of measures to support implementation of the principles and actions that he set out in that report.

51. The consultation, which closed on 4 June 2015, focused on how measures can be implemented locally, the role of national bodies, the role and title of the Freedom to Speak Up Guardian, and standards for professionals on how to raise concerns. The Department's response to the consultation, including measures to better support whistleblowers in future, are described earlier in this document.

52. In particular, a new Independent National Officer for whistleblowing will be hosted by the Care Quality Commission. This role will provide national leadership not just on the treatment of whistleblowers but on how providers respond to the concerns raised by staff. The Care Quality Commission already look at how providers respond to complaints, other forms of patient feedback and how well the provider engages its staff; in the future the Care Quality Commission will also consider in its inspection programme whether providers respond receptively to issues raised by staff. The Department's response also sets out measures to facilitate a Freedom to Speak Up Guardian in every Trust.

Recommendation 27:

Professional regulatory bodies should clarify and reinforce the duty of professional staff to report concerns about clinical services, particularly where these relate to patient safety, and the mechanism to do so. Failure to report concerns should be regarded as a lapse from professional standards. Action: the General Medical Council, the Nursing and Midwifery Council, the Professional Standards Authority for Health and Social Care.

53. We accept this recommendation. A review of professional codes is under way.

54. Dr Kirkup found that many staff did not raise any concerns about standards of care in the maternity units across Morecambe Bay, but perhaps even more troubling is that where concerns were raised there was no evidence that they were properly addressed or followed up.

55. The Professional codes of conduct for both the General Medical Council[13] and the Nursing and Midwifery Council[14] require registrants to raise concerns and take action where patient safety is at risk.

56. In addition, Professor Sir Bruce Keogh has been asked to review the professional codes of practice of doctors, nurses and midwives and to ensure that the right incentives are in place to prevent people from covering up, instead of reporting and learning from mistakes. This work is being conducted in collaboration with key stakeholders, including the Professional Standards Authority, the General Medical Council, the Nursing and Midwifery Council and Health Education England. The final report is expected later this year.

National standards: 28-29

Recommendation 28:

Clear national standards should be drawn up setting the professional duties and expectations of clinical leads at all levels, including, but not limited to, clinical directors, clinical leads, heads of service, medical directors, nurse directors. Trusts should provide evidence to the Care Quality Commission, as part of their processes, of appropriate policies and training to ensure that standards are met. Action: NHS England, the Care Quality Commission, the General Medical Council, the Nursing and Midwifery Council, all Trusts.

Recommendation 29:

Clear national standards should be drawn up setting out the responsibilities for clinical quality of other managers, including executive directors, middle-managers and non-executives. All Trusts should provide evidence to the Care Quality Commission, as part of their processes, of appropriate policies and training to ensure that standards are met. Action: NHS England, the Care Quality Commission, all Trusts.

57. We accept these recommendations in principle.

[13] http://www.gmc-uk.org/guidance/good_medical_practice/respond_to_risks.asp
[14] http://www.nmc.org.uk/standards/code/read-the-code-online/

58. Following the tragedies at Mid Staffordshire NHS Foundation Trust and University Hospitals of Morecambe Bay NHS Foundation Trust there has been a renewed focus on leadership and quality across the NHS, particularly for those in senior and executive clinical and management positions. It is helpful to see these two elements as equally important, and the most significant changes are likely to be made where these staff are brought together to provide input and challenge to each other's perceptions and roles.

59. Discussions are underway between the Department of Health, NHS England, the Care Quality Commission, the General Medical Council, the Faculty of Medical Leadership and others to address the professional duties of clinical leaders and clinical accountability. The General Medical Council and the Nursing and Midwifery Council already have guidance on leadership and management.[15]

60. The Faculty of Medical Leadership and Management has published the first UK standards of medical leadership[16], explaining further how effective leadership is essential to good quality care. The Faculty is planning further work to make the links between the standards and appraisal and revalidation; to design a system of credentialing; to issue guidance for organisations as to the optimal resources required for medical leaders to be most effective.

61. An alliance of medical colleges, other health professional colleges and associations in partnership with the British Standards Institute are also working to create standards for accreditation of clinical services by June 2016. The prime purpose of these standards is to provide clinical services with a framework on which to base quality improvement. The standard on leadership will apply to all clinical leaders, not just doctors.

62. Good leadership by boards - setting and upholding values, holding the organisation to account and knowing where and when to challenge, is an essential prerequisite for quality and safety. The Professional Standards Authority updated

http://www.gmc-uk.org/guidance/ethical_guidance/management_for_doctors.asp; http://www.nmc.org.uk/news/news-and-updates/new-code-comes-into-force-for-every-nurse-and-midwife/

[15] https://www.fmlm.ac.uk/professional-development/accreditation-and-standards/the-leadership-and-management-standards-fo

[16] https://www.fmlm.ac.uk/professional-development/accreditation-and-standards/the-leadership-and-management-standards-fo

their standards for members of NHS Boards and Clinical Commissioning Group Governing bodies in England in November 2013[17].

63. The NHS Leadership Academy's Healthcare Leadership Model, which is based on comprehensive research about what behaviours lead to effective healthcare, is also focused on improving the quality of leadership to ensure a culture based on openness and transparency.

64. In addition, the Secretary of State asked Professor Sir Bruce Keogh to review the Professional Codes for doctors and nurses. As part of this, Sir Bruce will work with regulators to develop a strengthened professionalism that always favours openness ahead of defensiveness.

65. As well as the work to improve and raise awareness of clinical and managerial staff's awareness of their responsibilities and behaviours in relation to clinical quality as part of the Care Quality Commission's new inspection regime, they ask five key questions of all health and care services: is the service safe, effective, caring, responsive and well-led.

66. Inspection teams use key lines of enquiry to organise evidence and inform judgements about these five questions. These key lines of inquiry include a focus on staff having the right skills and training to perform their role effectively. The approach means that the inspection team can assess how effectively an organisation monitors, investigates and addresses patient safety concerns and how it ensures staff, including key clinicians and managers, are able to perform their role effectively.

Approach to investigations: 30 + 44

Recommendation 30:

A national protocol should be drawn up setting out the duties of all Trusts and their staff in relation to inquests. This should include, but not be limited to, the avoidance of attempts to "fend off" inquests, a mandatory requirement not to coach staff or provide "model answers", the need to avoid collusion between staff on lines to take, and the inappropriateness of relying on coronial

[17] http://www.professionalstandards.org.uk/docs/default-source/psa-library/131120-standards-for-nhs-bms-v-2-0-final.pdf?sfvrsn=0

processes or expert opinions provided to coroners to substitute for incident investigation. Action: NHS England, the Care Quality Commission.

67. We accept this recommendation in principle. We will give further thought, with the Ministry of Justice and Chief Coroner's Office, to whether an additional protocol would be helpful in guiding appropriate behaviour in relation to coroner investigations and inquests. In the meantime, we will ask Monitor and the NHS Trust Development Authority to remind Foundation Trusts and NHS Trusts of the existing legislation and guidance setting out their duties in relation to inquests.

68. Dr Kirkup's assessment of the behaviour of certain staff in relation to the inquest process is particularly concerning. There is existing legislation in relation to how public bodies and professionals should behave with respect to coronial processes, and expectations within existing professional codes. All relevant information must be shared with coroners to ensure that they are able to carry out their statutory duties to investigate relevant deaths, to ascertain who has died, where, when and how:

- The *Coroners and Justice Act 2009* gives coroners powers to require a person or organisation in England and Wales to provide evidence and to require a witness in England and Wales to give evidence at an inquest. The 2009 Act makes it, "*an offence for a person to do anything that is intended to have the effect of (a) distorting or otherwise altering any evidence, document or other things that is given, produced or provided for the purpose of an investigation… (b) preventing any evidence, document or other thing from being given produced or provided for the purposes of such an investigation or to do anything that the person knows or believes is likely to have that effect".* This offence is limited to actions where there is "intention" to distort or alter evidence, and is punishable by a fine and / or imprisonment.

- The new Nursing and Midwifery Council Code requires nurses and midwives to cooperate with all investigations and audits and to be open and candid with service users about all aspects of care and treatment, including when any mistake or harm has taken place.

- The General Medical Council's publication *Good Medical Practice* and supporting guidance includes clear requirements for medical doctors to cooperate with formal inquiries, including inquests, to be honest and trustworthy when giving evidence, and to make sure any information they give is not false or misleading.

Recommendation 44:

This Investigation was hampered at the outset by the lack of an established framework covering such matters as access to documents, the duty of staff and former staff to cooperate, and the legal basis for handling evidence. These obstacles were overcome, but the need to do this from scratch each time an investigation of this format is set up is unnecessarily time-consuming. We believe that this is an effective investigation format that is capable of getting to the bottom of significant service and organisational problems without the need for a much more expensive, time-consuming and disruptive public inquiry. This being so, we believe that there is considerable merit in establishing a proper framework, if necessary statutory, on which future investigations could be promptly established. This would include setting out the arrangements necessary to maintain independence and work effectively and efficiently, as well as clarifying responsibilities of current and former health service staff to co-operate. Action: the Department of Health.

69. We accept this recommendation in principle. A new Independent Patient Safety Investigation Service will conduct independent, expert-led investigations into patient safety incidents. The Service will also respond to the concerns that had been previously subject to public inquiries or national investigations, such as Mid-Staffordshire NHS Foundation and University Hospitals Morecambe Bay NHS Foundation Trust. We intend to establish an expert advisory group who, over the coming months, will advise on the purpose and function of the new Independent Patient Safety Investigation Service. As part of this work, we will build on the useful insights that participants in this Investigation have shared.

70. We agree that independent non-statutory investigations provide a useful, more rapid and potentially more efficient alternative to statutory public inquiries as a last resort for investigating failings in care. This route has now been well tested and has the benefit of being able to engage with affected families, ensuring their key concerns are built into the Terms of Reference and can therefore be addressed by the investigation/ panel; and of not being a legal process which can inhibit people's willingness to engage openly and candidly.

71. We are considering whether we can use, or build on, the central Cabinet Office support provided to inquiries, including guidance for each stage of the inquiry, useful

documents and access to a Whitehall officials' and former inquiry secretaries' network, and which is currently being updated and considered by a cross-Government group.

Complaints: 31

Recommendation 31:

The NHS complaints system in the University Hospitals of Morecambe Bay NHS Foundation Trust failed relatives at almost every turn. Although it was not within our remit to examine the operation of the NHS complaints system nationally, both the nature of the failures and persistent comment from elsewhere lead us to suppose that this is not unique to this Trust. We believe that a fundamental review of the NHS complains system is required, with particular reference to strengthening local resolution and improving its timeliness, introducing external scrutiny of local resolution and reducing reliance on the Parliamentary and Health Service Ombudsman to intervene in unresolved complaints. Action: the Department of Health, NHS England, the Care Quality Commission, the Parliamentary and Health Service Ombudsman.

72. We accept this recommendation in principle and recognise that there are still challenges to overcome if we are to see improvements in the way complaints are handled in the NHS. However, we do not believe that another fundamental review will help. The issues are already well documented.

73. Complaints handling has been an important part of the Government's programme of work, particularly following the Inquiries into Mid Staffordshire NHS Foundation Trust. We are working to put in place a more open and transparent culture in which all forms of feedback – comments, concerns, compliments and complaints – are welcomed and acted upon. Over the last two years we have sought to achieve this by focusing on action in a number of areas. We have increased transparency by improving the quality and frequency of national complaints data in secondary care. The first quarterly data returns will be published in the summer and for the first time will have more granular detail on the issues being complained about.

74. We have sought to improve the information available locally for patients on how to complain, including by publishing a national advice guide, providing templates for

posters on every hospital ward and, through Healthwatch England working with Citizen's Advice, ensured there is accurate information online about how to complain.

75. The Parliamentary and Health Service Ombudsman and Healthwatch developed a set of expectations which define what a "good" complaints experience feels like from the patient perspective. This provides a clear guide for Boards and Chief Executives to refer to when considering how to improve their complaint handling locally. We have added new commitments to the NHS Standard Contract on the importance of promoting information about how to complain and where to get advocacy support. New education and training tools have been produced by Health Education England and the Royal College of Nursing. The right to complain remains enshrined in the NHS Constitution.

76. To reinforce all of this, the Care Quality Commission inspection process now considers complaints as part of every inspection in primary, secondary and social care and takes a sample of complaints to look at how they have been handled in practice. The local scrutiny function performed by local Healthwatch is also very important as a check and balance on the action taken by the local NHS to handle complaints.

77. We also have ways to benchmark progress, using the annual Care Quality Commission inpatient survey to track whether information is available to people about how to complain, and the tracking survey capturing public perceptions of the NHS, including how people feel about complaining; the results of the winter 2014 tracking survey were published in January and showed around seven in ten people say they would feel comfortable making a complaint about a poor experience at an NHS hospital (71%)[18]. A full summary of the Government's work and progress to improve complaints handling across the board was set out in our "Culture Change in the NHS"[19] progress report in February.

78. However, there is more to do. NHS England is taking forward a number of actions to improve complaints handling over the coming months. This includes developing a toolkit for commissioners to help commissioners deal with complaints more effectively and hold providers to account. NHS England are also working with the Parliamentary and Health Service Ombudsman to pilot ways of surveying patients about their experience of complaining, based on the statements set out in

[18] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/439487/14-05840601_NHS_Tracker_Report_Winter_2014__new.pdf
[19] https://www.gov.uk/government/publications/culture-change-in-the-nhs

the Ombudsman/Healthwatch document *My expectations for raising concerns and complaints*[20]. We will consider what additional action could be taken to improve complaint handling; this includes looking at ways to improve collaboration across organisational boundaries and create a culture where lessons are learnt.

79. The Parliamentary and Health Service Ombudsman remains an important element of the complaints process and provides an independent view for individuals who are dissatisfied with the outcome of their complaint locally. However, we agree that improved local handling of complaints would reduce the proportion of complainants who remain dissatisfied and take their cases to the Ombudsman.

80. The Government are leading work to reform the Ombudsman landscape following on from the proposals set out in Robert Gordon's report. A consultation on these proposals, including the option of creating a single Public Services Ombudsman has just closed. Plans for a draft Bill were announced in the Queen's Speech and the Cabinet Office is working on the Bill which is due to be published later on in this Parliamentary session. As the Ombudsman is the final stage of the complaints process it is important that the infrastructure which surrounds them is as effective as possible and easy for people to use.

81. We continue to believe it important that improvement in the handling of complaints is linked to wider issues around hearing the patient voice, learning lessons and focussing on providing safe quality services. Delivering this requires the whole care system to play its part. In its role as steward of the system the Department will convene a new national partnership of organisations which looks at complaints improvement within a wider context, building on the work done to deliver commitments set out in "Hard Truths", and considering how to improve the culture around patient feedback, including complaints.

82. Finally, as discussed earlier in this document, the Government can now confirm that they accept the Public Administration Select Committee's recommendation to establish an independent patient safety investigation function (the Independent Patient Safety Investigation Service) for the NHS, and will be taking this forward in the coming months. As part of the work that is done to improve the investigation of patient safety incidents in the NHS, there will be consideration given to how local organisations can align their processes for handling complaints and investigations into serious incidents.

[20] http://www.ombudsman.org.uk/__data/assets/pdf_file/0010/28774/Vision_report.pdf

Midwifery Supervision: 32

Recommendation 32:

The Local Supervising Authority system for midwives was ineffectual at detecting manifest problems at the University Hospitals of Morecambe Bay NHS Foundation Trust, not only in individual failures of care but also with the systems to investigate them. As with complaints, our remit was not to examine the operation of the system nationally; however the nature of the failures and the recent King's Fund Review (*Midwifery regulation in the United Kingdom*) leads us to suppose that this is not unique to this Trust, although there were specific problems there that exacerbated the more systematic concern. We believe that an urgent response is required to the King's Fund findings, with effective reform of the system. Action: the Department of Health, NHS England, the Nursing and Midwifery Council.

83. We accept this recommendation. We will therefore modernise the regulatory regime for midwifery.

84. The statutory supervision of midwives was designed in 1902 to protect the public. It no longer meets the needs of current midwifery practice. Reports and recommendations by the Parliamentary and Health Service Ombudsman and Kings Fund found that midwifery regulation was structurally flawed as a framework for public protection, and highlighted that statutory supervisory structures encourage confidentiality in a way that does not always contribute to improving practice or systems and can be perceived as protecting the midwife rather than women or babies. This is borne out by the findings of the Morecambe Bay Investigation where the process of statutory supervision was ineffective at identifying the root causes for the many distressing incidents; at identifying and addressing poor practice amongst midwifery staff; and most importantly in addressing the families concerns.

85. In addition, the Government committed in March to the removal of the Nursing and Midwifery Council's oversight of midwifery supervision, and will work with the UK chief nursing officers to design a new system of supervision that is proportionate and recognises the importance of managing risks and promoting safety, as well as the professional development of midwives. Our intention is to act as swiftly as possible

to legislate, and we intend to do this by introducing an Order in Council made under s60 of the 1999 Health Act.

86. Midwifery supervision is important for providing clinical supervision and professional development for midwives resulting in high standards of safe care for mothers and babies. Removing midwifery supervision from statute provides an opportunity to design a new system that enables a clear separation between the regulation of midwives (the role of the Nursing and Midwifery Council) and the supervision of midwives. England, Scotland, Wales and Northern Ireland are already working together to design this new system, which will include how the system will operate in future and where responsibility for its oversight will go. However, statutory supervision must continue until the law changes and a new system is in place and so as the Nursing and Midwifery Council and Government nurse leaders in the four countries have made clear, Trusts must not disestablish supervisor posts or other structures until that time.

National protocols: 33-35

Recommendation 33:

We considered carefully the effectiveness of separating organisationally the regulation of the quality by the Care Quality Commission from the regulation of finance and performance by Monitor, given the close inter-relationship between Trust decisions in each area. However, we were persuaded that there is more to be gained than lost by keeping regulation separated in this way, not least that decisions on safety are not perceived to be biased by their financial implications. The close links, however, require a carefully co-ordinated approach, and we recommend that the organisations draw up a memorandum of understanding specifying roles, responsibilities, communication and follow-up, including explicitly agreed actions where issues overlap. Action: Monitor, the Care Quality Commission, the Department of Health.

87. We accept this recommendation. Closer working links have been established and will be developed further.

88. An updated Memorandum of Understanding between Monitor and the Care Quality Commission was published on 26 February 2015. It describes what they

intend to achieve and their continued commitment to working together. Both organisations have improved how they work together in areas including: Monitor's assessment process and significant transaction reviews, management of Care Quality Commission registration requirements, management of risk, and joint escalation and enforcement of the new licensing regime. The Care Quality Commission and Monitor have clarified their roles in the Single Failure Regime, including Special Measures. Work is ongoing to further improve joint working and the sharing of information. In addition, the Care Quality Commission will work jointly with Monitor and the NHS Trust Development Authority to develop proposals to assess the efficiency of providers as part of its inspection and rating process.

89. The Care Quality Commission and Monitor will keep this Memorandum of Understanding under regular review and will update it as relevant to reflect the Care Quality Commission's new role in assessing Foundation Trusts' use of resources and any other changes to the functions of the two organisations.

Recommendation 34:

The relationship between the investigation of individual complaints and the investigation of the systemic problems that they exemplify gave us a cause for concern, in particular the breakdown in communication between the Care Quality Commission and the Parliamentary and Health Service Ombudsman over necessary action and follow-up. We recommend that a memorandum of understanding be drawn up clearly specifying roles, responsibilities, communication and follow up, including explicitly agreed actions where issues overlap. Action: the Care Quality Commission, the Parliamentary and Health Service Ombudsman.

90. We accept this recommendation. The Investigation found that the lack of co-ordination between the Care Quality Commission and the Parliamentary and Health Service Ombudsman was a contributory factor to the ongoing inability of the wider system to identify and act on failings at the Trust. A new Memorandum of Understanding between the Care Quality Commission and the Parliamentary and Health Service Ombudsman was signed in September 2013 which outlined how the two organisations will collaborate, co-operate and share information relating to their respective roles.

91. We have asked the Care Quality Commission and the Ombudsman to keep this Memorandum of Understanding under regular review and to keep it up to date.

Recommendation 35:

The division of responsibilities between the Care Quality Commission and other parts of the NHS for oversight of service quality and the implementation of measures to correct patient safety failures was not clear, and we are concerned that potential ambiguity persists. We recommend that NHS England draw up a protocol that clearly set out the responsibilities for all parts of the oversight system, including itself, in conjunction with the other relevant bodies; the starting point should be that one body, the Care Quality Commission, take prime responsibility. Action; the Care Quality Commission, NHS England, Monitor, the Department of Health

92. We accept this recommendation in principle. Patient safety is a critical element of an effective, patient-focused health system and we agree that it is important to be clear about who is responsible for patient safety. The onus on ensuring quality sits primarily with provider Trusts themselves; although commissioners and regulators also have an important role.

93. In "Culture Change in the NHS"[21] the Government agreed that it would be sensible to concentrate and consolidate national expertise and capability on safety within a single organisation that can provide strategic leadership across the whole healthcare system. The Government intend to bring under the single leadership of Monitor and the NHS Trust Development Authority the responsibility for leading the patient safety functions that currently sit with NHS England.

94. Through the newly re-established National Quality Board we will continue to improve both the operation of the oversight arrangements in place at present and the understanding of those arrangements by NHS organisations and the public. A network of regional and local Quality Surveillance Groups has been in place since April 2013 to ensure effective intelligence sharing and action on quality concerns between all partners.

[21] https://www.gov.uk/government/publications/culture-change-in-the-nhs

95. Where Trusts, for whatever reason, are not able to provide the quality of care required, other parts of the system have a role to play in helping them improve. The Care Quality Commission has been established as the independent inspector of quality and has clear processes in place to identify issues that are brought to light through the inspection process. Where Trusts are unable to rectify identified problems themselves Monitor or the NHS Trust Development Authority provides support to enable the provider Trusts to improve – in UHMB's case through the special measures regime.

96. The Care Quality Commission is inspecting University Hospitals of Morecambe Bay NHS Foundation Trust in July this year to assess its progress against the agreed action plan, and its report will be published in the autumn.

Organisational change: 36-37

Recommendation 36:

The cumulative impact of new policy and processes, particularly the perceived pressure to achieve Foundation Trust status, together with organisational reconfiguration, placed significant pressure on the management capacity of the University Hospitals of Morecambe Bay NHS Foundation Trust to deliver against changing requirements whilst maintaining day-to-day needs, including safeguarding patient safety. Whilst we do not absolve Trusts from responsibility for prioritising limited capability safely and effectively, we recommend that the Department of Health should review how it carries out impact assessments of new policies to identify the risks as well as the resources and time required. Action: the Department of Health.

97. We accept this recommendation in principle. We acknowledge the Investigation's findings that the pursuit of Foundation Trust status distorted management capacity and priorities at Morecambe Bay.

98. In response to the failings at both Mid Staffordshire NHS Foundation Trust and University Hospitals of Morecambe Bay NHS Foundation Trust:

- the Foundation Trust application process has now been significantly improved, requiring a strong focus on quality of care as well as on governance and good financial control.

- The Care Quality Commission now works closely with Monitor and the NHS Trust Development Authority to share intelligence about the Trusts' performance capacity and capability.

- Under the Care Quality Commission's new ratings system, NHS Trusts need an overall rating of "good" or "outstanding" to progress to the next stage of the Foundation Trust assessment process

- The Care Quality Commission's new inspection model, including the development of its intelligent monitoring tool, ensures that issues of concern are picked up earlier and can be addressed.

99. The Department of Health will continue work with its Arms' Length Bodies to develop policy in partnership, and ensure that oversight and regulatory mechanisms are as effective as possible in ensuring sustainable high quality care. Formal impact assessments are and will continue to be an important part of how new policies are considered and implemented.

Recommendation 37:

Organisational change that alters or transfers responsibilities and accountability carries significant risk, which can be mitigated only if well managed. We recommend that an explicit protocol be drawn up setting out how such processes will be managed in future. This must include systems to secure retention of both electronic and paper documents against future needs as well as ensuring a clearly defined transition of responsibilities and accountability. Action: the Department of Health.

100. We accept this recommendation. We agree that these are important concepts, and indeed a number of protocols were drawn up and widely communicated in managing changes to the health system in 2012. The Department of Health issued

guidance to NHS bodies in transition in September 2011 setting out the effective management of records during organisational change[22].

101. In its report of 10 July 2013, "Managing the transition to the reformed health system"[23] the National Audit Office noted the "considerable planning and preparatory work" that was done ahead of the Health and Social Care Act being passed and highlighted that the "Department's programme management demonstrated many elements of good practice"[24], including comprehensive governance structures, ongoing monitoring arrangements for key aspects of the transition, and a variety of mechanisms to assess and gain assurance about the new system's state of readiness.

102. The National Archives has oversight of records management within Government departments, and publishes guidance on best practice. They have recently revised the guidance on "Machinery of Government Changes"[25] which the Department follows when transferring information assets between owners. The National Archives have considered the Department's records management compliance as part of their Information Management Assessment in October 2014, the report of which will be published shortly.

Perinatal deaths and recording: 38-40

Recommendation 38:

Mortality recording of perinatal deaths is not sufficiently systematic, with failures to record properly at individual unit level and to account routinely for neonatal deaths of transferred babies by place of birth. This is of added significance when maternity units rely inappropriately on headline mortality figures to reassure others that all is well. We recommend that recording systems are reviewed and plans brought forward to improve systematic recording and tracking of perinatal deaths. This should build on the work of

[22] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216477/dh_130584.pdf
[23] http://www.nao.org.uk/report/managing-the-transition-to-the-reformed-health-system-2/
[24] http://www.nao.org.uk/wp-content/uploads/2013/07/10175-001-Managing-the-transition-to-the-reformed-health-system.pdf
[25] http://www.nationalarchives.gov.uk/information-management/manage-information/managing-risk/machinery-government-change/

national audits such as MBRRACE-UK, and include the provision of comparative information to Trusts. Action: NHS England

103. We accept this recommendation. We will explore the feasibility of publishing data about the safety and quality of maternity services at individual Trust level.

104. As recommended by the Morecambe Bay Report, MBRRACE-UK has established a system to systematically collect and report surveillance information on all stillbirths and neonatal deaths nationally. MBRRACE-UK published its first Perinatal Mortality Surveillance Report on the 10th June 2015. It provides crude and also stabilised and adjusted neonatal mortality rates in 2013 by service delivery organisation (operational delivery network in England), by place of birth, and by commissioning area (Clinical Commissioning Group in England). In autumn they will provide Trusts with individual Trust-level reports to enable them to more closely scrutinise their own rates in comparison with Trusts providing similar types of care (for high versus low risk women) and to better understand where deaths occur to babies born in the Trust and those who die having transferred into the Trust for higher level neonatal care.

105. Any Care Quality Commission maternity outlier is alerted to Trusts where there is a cause for concern. In addition the Care Quality Commission and MBRRACE are establishing pursuing a data-sharing agreement which would allow inspectors to receive a regular update of all maternal deaths.

Recommendation 39:

There is no mechanism to scrutinise perinatal deaths or maternal deaths independently, to identify patient safety concerns and to provide early warning of adverse trends. This shortcoming has been clearly identified in relation to adult deaths by Dame Janet Smith in her review of the Shipman deaths, but is in our view no less applicable to maternal and perinatal deaths, and should have raised concerns in the University Hospitals of Morecambe Bay NHS Foundation Trust before they eventually became evident. Legislative preparations have already been made to implement a system based on medical examiners, as effectively used in other countries, and pilot schemes have apparently proved effective. We cannot understand why this has not

already been implemented in full, and recommend that steps are taken to do so without delay. Action: the Department of Health.

Recommendation 40:

Given that the systematic review of deaths by medical examiners should be in place, as above, we recommend that this system be extended to stillbirths as well as neonatal deaths, thereby ensuring that appropriate recommendations are made to coroners concerning the occasional need for inquests in individual cases, including deaths following neonatal transfer. Action: the Department of Health.

106. We accept these recommendations in principle. The medical examiners system has been trialled successfully in a number of areas across the country. We will soon be publishing a report from the interim National Medical Examiner setting out the lessons learned from the pilot sites.

107. The Government remain committed to the principle of these reforms. Further progress will be informed by a reconsideration of the operation of the new system in the light of other positive developments on patient safety since 2010 and by a subsequent public consultation exercise on regulations required to introduce a medical examiner system nationally in England.

108. Medical examiners would scrutinise all deaths except for stillbirths (for legal reasons) and any death that requires a coroner investigation. However, the MBRRACE confidential enquiries provide independent scrutiny of all maternal deaths and topics related to stillbirths and neonatal deaths, which is sufficient to learn national lessons for improvement of care.

Handling external reviews: 41-42

Recommendation 41:

We were concerned by the ad hoc nature and variable quality of the numerous external reviews of services that were carried out at the University Hospitals of Morecambe Bay NHS Foundation Trust. We recommend that systematic

guidance be drawn up setting out an appropriate framework for external reviews and professional responsibilities in undertaking them. Action: the Academy of Medical Royal Colleges, the Royal College of Nursing, the Royal College of Midwives.

109. We accept this recommendation, and there are actions in train, which go some way to meeting it. For example, the Serious Incident Framework published by NHS England and updated in March 2015, sets out details of when and how investigations – including independent investigations - should be undertaken.

110. As noted earlier, the Government are accepting the Public Administration Select Committee's recommendation to establish an independent patient safety investigation function for the NHS, and will be taking this forward in the coming months (the Independent Patient Safety Investigation Service). One of the tasks will be to work with stakeholders to consider how the new function will operate alongside and complement existing bodies that relate to NHS organisations and this will include organisations that may be carrying out other reviews (including professional and external reviews).

Focus on quality: 43

Recommendation 43:

We strongly endorse the emphasis placed on the quality of NHS services that began with the Darzi review, *High Quality Care for All,* and gathered importance with the response to the events at the Mid Staffordshire NHS Foundation Trust. Our findings confirm that this was necessary and must not be lost. We are concerned that the scale of recent NHS reconfiguration could result in new organisations and post holders losing the focus on this priority. We recommend that that importance of putting quality first is re-emphasised and local arrangements reviewed to identify any need for personal or organisational development, including amongst clinical leadership in commissioning organisations. Action: NHS England, the Department of Health.

111. We accept this recommendation, and strongly agree that the emphasis on quality of care must be maintained, and that service changes should put the safety and quality of patient care as central objectives. Indeed the recent NHS reforms to the structure and assessment of the health service, including GP-led commissioning and an expert-led inspection system have put clinical priorities and patient care at its heart. The Government will continue to prioritise the quality of care, and will hold its arms-length bodies to account on their commitments to reinforce and improve the quality of care. This will be a key focus of the newly re-established National Quality Board, in providing leadership for quality across the NHS.

Annex: Recommendations 1-18

[A] Recommendations for the Trust

1. The University Hospitals of Morecambe Bay NHS Foundation Trust should formally admit the extent and nature of the problems that have previously occurred, and should apologise to those patients and relatives affected, not only for the avoidable damage caused but also for the length of time it has taken to bring them to light and the previous failures to act. This should begin immediately with the response to the Report.

2. The University Hospitals of Morecambe Bay NHS Foundation Trust should review the skills, knowledge, competencies and professional duties of care of all obstetric, paediatric, midwifery and neonatal nursing staff, and other staff caring for critically ill patients in anaesthetics and intensive and high-dependency care, against all relevant guidance from professional and regulatory bodies. This review should be completed by June 2015, and identify requirements for additional training, development, and where necessary, a period of experience elsewhere.

3. The University Hospitals of Morecambe Bay NHS Foundation Trust should draw up plans to deliver the training and development of staff identified as a result of the review to maternity, neonatal and other staff, and should identify opportunities to broaden staff experience in other units, including by secondment and by supernumerary practice. These should be in place in time for June 2015.

4. Following completion of additional training or experience where necessary, the University Hospitals of Morecambe Bay NHS Foundation Trust should identify requirements for continuing professional development of staff and link this explicitly with professional requirements including revalidation. This should be completed by September 2015.

5. The University Hospitals of Morecambe Bay NHS Foundation Trust should identify and develop measures that will promote effective multi-disciplinary team-working, in particular between paediatricians, obstetricians , midwives and neonatal staff. These measures should include, but not be limited to, joint training sessions, clinical policy and management meetings and staff development activities. Attendance at designated events must be compulsory within terms of employment. These measures should be identified by April 2015 and begun by June 2015.

6. The University Hospitals of Morecambe Bay NHS Foundation Trust should draw up a protocol for risk assessment in maternity services, setting out clearly: who should be offered the option of delivery at Furness General Hospital and who should not: who will carry out this assessment against which criteria; and how this will be discussed with pregnant women and families. The protocol should involve all relevant staff groups, including midwives, paediatricians, obstetricians and those in the receiving units within the region. The Trust should ensure that individual decisions on delivery are clearly recorded as part of the plan of care, including what risk factors may trigger escalation of care, and that all Trust staff are aware that they should not vary decisions without a documented risk assessment. This should be completed by June 2015.

7. The University Hospitals of Morecambe Bay NHS Foundation Trust should audit the operation of maternity and paediatric services, to ensure that they follow risk assessment protocols on place of delivery, transfers and management of care, and that effective multidisciplinary care operates without inflexible demarcations between professional groups. This should be in place by September 2015.

8. The University Hospitals of Morecambe Bay NHS Foundation Trust should identify a recruitment and retention strategy aimed at achieving a balanced and sustainable workforce with the requisite skills and experience. This should include, but not be limited to, seeking links with one or more centre (s) to encourage development of specialist and/or academic practice whilst offering opportunities in generalist practice in the Trust; in addition, opportunities for flexible working to maximise the advantages of close proximity to South Lakeland should be sought. Development of the strategy should be completed by January 2016.

9. The University of Hospitals of Morecambe Bay NHS Foundation Trust should identify an approach to developing better joint working between its main hospital sites, including the development and operations of common policies, systems and standards. Whilst we do not believe that the introduction of extensive split-site responsibilities for clinical staff will do much other than lead to time wasted in travelling, we do consider that, as part of this approach, flexibility should be built into working responsibilities to provide temporary solutions to short-term staffing problems. This approach should be begun by September 2015.

10. The University Hospitals of Morecambe Bay NHS Foundation Trust should seek to forge links with a partner Trust, so that both can benefit from opportunities for learning, mentoring, secondment, staff development and sharing approaches to problems. This arrangement is promoted and sometimes facilitated by Monitor as

"buddying" and we endorse the approach under these circumstances. This could involve the same centre as part of the recruitment and retention strategy. If a suitable partner is forthcoming, this arrangement should be begun by September 2015.

11. The University Hospitals of Morecambe Bay NHS Foundation Trust should identify and implement a programme to raise awareness of incident reporting, including requirements, benefits and processes. The Trust should also review its policy of openness and honesty in line with the duty of candour of professional staff, and incorporate into the programme compliance with the refreshed policy. This should be begun with maternity staff by April 2015 and rolled out to other staff by April 2016.

12. The University Hospitals of Morecambe Bay NHS Foundation Trust should review the structures, processes and staff involved in investigating incidents, carrying out root cause analyses, reporting results and disseminating learning from incidents, identifying and residual conflicts of interests and requirements for additional training. The Trust should ensure that robust documentation is used, based on a recognised system, and that Board reports include details of how services have been improved in response. The review should include the provision of appropriate arrangements for staff debriefing and support followed by a serious incident. This should be begun with maternity units by April 2015 and rolled out across the Trust by April 2016.

13. The University Hospitals of Morecambe Bay NHS Foundation Trust should review the structures, processes and staff involved in responding to complaints, and introduce measures to promote the use of complaints as a source of improvement and reduce defensive "closed" responses to complainants. The Trust should increase public and patient involvement in resolving complaints, in the case of maternity services through the Maternity Services Liaison Committee. This should be completed, and the improvements demonstrated at an open Board meeting, by December 2015.

14. The University Hospitals of Morecambe Bay NHS Foundation Trust should review arrangements for clinical leadership in obstetrics, paediatrics and midwifery, to ensure that the right people are in place with appropriate skills and support. The Trust has implemented change at executive level, but this needs to be carried through to the levels below. All staff with defined responsibilities for clinical leadership should show evidence of attendance at appropriate training and development events. This review should be commenced by April 2015.

15. The University Hospitals of Morecambe Bay NHS Foundation Trust should continue to prioritise the work commenced in response to the review of governance systems already carried out, including clinical governance, so that the Board has adequate assurance of the quality of care provided by the Trust's services. This work is already underway with the facilitation of Monitor, and we would not seek to vary or add to it, which would serve only to detract from implementation. We do, however, recommend that a full audit of implementation be undertaken before this is signed off as completed.

16. As part of the governance systems work, we consider that the University Hospitals of Morecambe Bay NHS Foundation Trust should ensure that middle manager, senior managers and non-executives have the requisite clarity over roles and responsibilities in relation to quality, and it should provide appropriate guidance and where necessary training. This should be completed by December 2015.

17. The University Hospitals of Morecambe Bay NHS Foundation Trust should identify options, with a view to implementation as soon as practicable, to improve the physical environment of the delivery suite a Furness General Hospital, including particularly access to operating theatres, an improved ability to observe and respond to all women in labour and en suite facilities; arrangements for post-operative care of women also need to be reviewed. Plans should be in place by December 2015 and completed by December 2017.

18. All of the previous recommendations should be implemented with the involvement of Clinical Commissioning Groups, and where necessary, the Care Quality Commission and Monitor. In the particular circumstances surrounding the University Hospitals of Morecambe Bay NHS Foundation Trust, NHS England should oversee the process, provide the necessary support, and ensure that all parties remain committed to the outcome, through an agreed plan with the Care Quality Commission, Monitor and the Clinical Commissioning Groups.