



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

Cm 9113

July 2015



Learning not blaming

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

July 2015



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Any enquiries regarding this publication should be sent to us at:
Department of Health, 79 Whitehall, London SW1A 2NS

Print ISBN 9781474123716
Web ISBN 9781474123723

ID 1307/1508 0715

Printed on paper containing 75% recycled fibre content minimum

Printed in the UK by the Williams Lea Group on behalf of the Controller of Her Majesty's Stationery Office

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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 candour¹, “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 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 website² 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 2016³. 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:

- “Having a consistent job description and person specification will ensure that the health providers are not wasting local time and resource creating bespoke roles”.

40. There were however a small number of respondents who felt that it should be a local level decision about the approach that should be adopted. **NHS Providers** commented that:

- “It is important that the approach to implementing the Freedom To Speak Up Guardian is workable for organisations and accessible and understandable for staff, providing support to raise concerns and mechanisms to resolve them, in line with the Trust’s culture of openness and engagement, rather than being something external to the Trust or overly cumbersome in process”.

41. **Health Education England** also suggested that it would be helpful to learn about how current local guardians had been introduced:

- “Excellent examples of “local guardians” have already been established and are functioning in at least four locations around England...it would be prudent to learn from the positive and negative aspects of their experience to date”.

42. Five responses were received from organisations which said they intended to appoint a Guardian at Director level.

43. While there was support for the role, there were differing views on how the role should be taken forward, whether the person should have a clinical background and what other skills were needed. In addition, as set out above, there was a view that the role should not be that of just one person, but that it could be shared due to the nature of the role and its impact on the individual. Points were also raised around the levels of support needed for Freedom to Speak Up Guardians.

Costs

44. There were some comments which stated that the role needed to be sufficiently resourced:

- “The Trust level role could potentially be full time or part-time, as part of a wider remit, but the costs of the arrangements will need to reflect the size, complexity and nature of organisations. It is also important that the funding of

the role and any administrative or other support required to underpin it are proportionate and do not divert resources away from front line services.”

- “There are inevitably costs associated with introducing a role such as this, particularly in terms of processing and responding to staff concerns promptly when arrangements are first put in place. Costs will to a large extent be determined by any national specification in terms of level of seniority and hours dedicated to the role. The costs of supporting the Guardian role and of administering the process and providing necessary external assurance will also need to be considered. IT information and feedback systems are critically important in enabling staff to raise concerns, especially where you have a large dispersed workforce as in Ambulance Trusts, and these inherent costs.”
- “Costs will to a large extent be determined by any national specification in terms of level of seniority and hours dedicated to the role. The costs of supporting the Guardian role and of administering the process and providing necessary external assurance will also need to be considered”. **The Association of Ambulance Chief Executives (AACE)**

Training

45. The majority of respondents felt there needed to be a national standard of training for Freedom to Speak Up Guardians, delivered at a national level. There was some support for the idea that this training should allow scope for a local element to the training.

46. A number of comments were made about the type of training that Guardians would require. This included training in:

- mediation;
- psychology;
- legal issues; and
- building trust and listening.

47. There were some suggestions as to who should deliver the training. Suggestions included:

- NHS England and Health Education England;
- National Clinical Assessment Service (NCAS);
- Independent National Officer.

48. A number of respondents also felt that it would be useful for there to be a training package available for Guardians and for there to be some form of IT-based learning.

49. A strong theme emerging was the need for national networking between Guardians, in order to ensure consistency between the various individuals undertaking the Freedom to Speak Up Guardian role and provide a support base.

Conclusion

50. While we want each organisation to have the flexibility to appoint the most suitable person to the role, it is clear that, given the wide ranging views on the skills the Guardians will need and the role's structure, some guidance on the recruitment process would be helpful. We propose that the Independent National Officer, once established, should produce guidance on factors that need to be taken into account when recruiting to the role. As some Trusts have already appointed their Freedom to Speak Up Guardians, we would expect that the Independent National Officer will take into account the existing good practice that is already taking place around this role when publishing its guidance. In addition, if Trusts feel confident to appoint their Guardian without this guidance, they should not wait for the guidance to be published. Any appointments should be made within the principles set out in the Freedom to Speak Up review.

51. We have considered whether the Freedom to Speak Up Guardian should report to the Board of the organisation that appointed them, or directly to the Independent National Officer. We are of the view that we would expect the Freedom to Speak Up Guardian, as recommended in the Freedom to Speak Up report, to be appointed by the Chief Executive of the organisation to act in a genuinely independent capacity. The Freedom to Speak Up Guardian would raise concerns with the Trust's Chief Executive or the Board. However, we recommend the Freedom to Speak Up Guardian should be able to raise concerns with the Independent National Officer if they have lost confidence, or consider good practice has not been followed, in how the organisation was handling concerns.

52. There was also support for standardised training for the role. It is important that there is guidance on what skills will be needed and the type of training that individuals undertaking the Freedom to Speak Up Guardian role might require. HEE will develop and publish guidance on training for this role working with the CQC and the Independent National Officer. We would expect HEE to take into account the work the INO will undertake around recruitment for this role.

Title of the local Freedom to Speak Up Guardian

Q7: What is your view on what the local Freedom to Speak Up Guardian should be called?

53. We received 74 responses to this question.

54. The largest number of responses received, 26 (35%), were in support of the title of “Freedom To Speak Up Guardian”, as those respondents felt it best described the role. A further 10 respondents (13%) supported Independent Staff Concerns Advocate, with only 2 (3%) in favour of Independent Patient Safety Champion. A significant number of responses, 36 (49%), suggested a different title, although there was little consistency within the alternative suggestions.

55. **The Royal College of Surgeons** supported the “Freedom to Speak Up Guardian” title:

- “We agree that a standardised name would help make this role more recognisable across NHS organisations and promote common responsibilities and cross-organisational sharing of information. We prefer the name “Freedom to Speak Up Guardian” as it is more explicit of the purpose of the role. An alternative option would be “Francis Guardian.”

56. **An individual from Rotherham NHS Foundation Trust** felt that the title of Freedom to Speak Up Guardian was very strong, stating:

- "Freedom to Speak Up Guardian" is a great title. It's already out there, it's self explanatory and its different to other descriptions. Every word is positive and it's plain English. It'll look good on posters and screens. Its measure of success is already described. If you felt free to speak up, the guardian did their job. You feel better when you've said it. The other titles don't have this. It is, most importantly in my view, staff orientated. This role is to facilitate and

support staff and by doing so support patients. We have too many champions and the word means different things as a verb and a noun. Advocacy feels like something strangers do in an emergency. I know we are all patient advocates but if we all worked for the patients in the first place we wouldn't need to add this title and it doesn't change anybody's job description.”

57. An individual in the University of Greenwich Business School commented on each title:

- “Independent Patient Safety Champion – this gives the impression that only concerns relating to patient safety can be raised. The Guardian should have the remit to receive all types of disclosure even non safety concerns such as financial misconduct incorrect information being publicised, especially those that would fall for protection under the Public Interest Disclosure Act 1998. Therefore the name needs to be open and non-restrictive.
- Independent Staff Concerns Advocate – within the NHS we have many different forms of workers from staff to agency to Students even volunteers. Whilst workers such as agency staff are protected under PIDA and student nurses are to be added to the list of protected people, the name doesn't highlight the fact they can make a disclosure and thus may put them off from doing so.
- Freedom to Speak Up Guardian – I would say this is as good as any other. Sir Robert Francis QC used this term and it is one that has been used in the media in discussions around the freedom to speak report. It therefore already has some building blocks upon which it can be developed and advertised.”

58. The title of Independent Staff Concerns Advocate was endorsed by the **Medical and Defence Union of Scotland** who commented that:

- “Independent Staff Concerns Advocate” is clear, makes appropriate and identifiable reference in the title to “Staff” and is rather less sensationalist in its description”.

59. Although there was little support for the title “Independent Patient Safety Champion”, one individual did consider that it had some merit, stating it:

- “presupposes, election by staff peers, power to report at chairman board and HWB levels, and powers of national association.”

60. There was concern that the name Independent Patient Safety Champion could be confusing given the role is around helping staff who wish to raise a concern, and ensuring these concerns are dealt with correctly.

61. The **Royal College of Nursing** endorsed the title of Freedom to Speak Up Guardian ahead of the alternatives, stating

- “the best title for the role of local Freedom to Speak Up Guardian is “Freedom to Speak Up Guardian”. We feel that the other two titles suggested in the consultation document; “Independent Patient Safety Champion” and “Independent Staff Concerns Advocate” are not fully reflective of the role itself. For example, not all of the concerns raised by individuals will be specifically associated with patient safety, and there may well be instances where concerns are raised by an individual who is not a staff member.”

62. Further comment as to why the title of Freedom to Speak Up Guardian was more suitable than Independent Patient Safety Champion and Independent Staff Concerns Advocate is set out below:

- “Freedom To Speak Up Guardian is recommended as this replicates the title of the Caldicott *Guardian* and lends more weight than titles such as independent patient safety champion which feels too similar to PALS worker / voluntary role and implies less authority.” **NHS Trust Development Authority**
- “I feel the title should remain Freedom to Speak Up Guardian. If you use Patient Safety Champion it may lead staff to feel it will be patient focussed or Independent Staff Concerns Advocate again may lead staff to feel they can only raise issues about staff/staffing matters.” **Individual**
- “Of the three options suggested in the consultation paper, the Freedom to Speak Up Guardian is UKPHR’s favoured title. A title of Independent Patient Safety Champion would rightly focus on the primary purpose of this role: patient safety. However, as a title it omits any mention of the workforce whose members will be a key audience of the Guardian. Conversely, the title Independent Staff Concerns Advocate omits from the title the necessary focus on patient safety. UKPHR therefore suggests Freedom to Speak Up Guardian should be the title with perhaps a nationally agreed strapline that reflects Sir Robert’s over-arching principle - to foster a culture of safety and learning in which all staff feel safe to raise a concern.” **UK Public Health Register**

- “We agree that a standardised name would help make this role more recognisable across NHS organisations and promote common responsibilities and cross-organisational sharing of information. We prefer the name “Freedom to Speak Up Guardian” as it is more explicit of the purpose of the role.” **Royal College of Surgeons**
- “The term “Freedom to Speak Up Guardian” is preferable but would need a formal definition and outline of responsibilities which should be made clear and available to all. The other titles suggested are too one-sided in relation to the all-encompassing nature of this role.” **British Dental Association**
- “The alternative suggestions of Independent Patient Safety Champion and Independent Staff Concerns Advocate imply a more limited scope than Freedom To Speak Up Guardian as not all concerns raised would be to do with patient safety, nor would those concerns always be raised through a staff route. The title Freedom to Speak Up Guardian has a positive connotation and helps move people away from the negative connotations associated with the word “whistleblowing”. **Colchester Hospital**

63. There was little consistency in the alternative suggestions put forward by respondents. Although the terms “champion”, “guardian” “patient”, “safety” and “speak-up” were included in a title on a number of occasions, only one full title, “Patient Safety Guardian”, was suggested more than once.

Conclusion

64. The proposal for a standard name is to ensure that, as healthcare staff move around the system, there are consistent messages and titles for the role, which allow the individual to identify immediately who in their organisation they should approach if they need support to raise a concern.

65. Taking into account the comments received, we have concluded that the role should be called the Freedom to Speak Up Guardian. We have arrived at this view due to the largest number of respondents favouring this title for the role, the concerns raised that having “patient” in the title could be misleading to staff, and given the lack of clear support for a different title.

Independent National Officer

Q8: Do you agree that the Care Quality Commission is the right national body to host the new role of Independent National Officer, whose functions are set out in principle 15 of the Freedom to Speak up report?

66. We received 75 responses to this question. The majority of respondents (56) were in full support of the Independent National Officer role being hosted by the CQC. A significant number of respondents (19) felt that the role should sit elsewhere, although there was no clear consensus on where this should be.

- “We should like to raise a specific point with regard to the Independent National Officer. To assist the clarity and accountability of this role, we think it important to be express about its reporting line. As the INO will be hosted at the Care Quality Commission, we consider that the role should most appropriately report directly into the CEO of the Care Quality Commission”.

Monitor

- “In order to be independent but yet have a position that allows intervention, HEE agrees that the role of the Independent National Officer should be best hosted within the Care Quality Commission”. **Health Education England**

Conclusion

67. The Independent National Officer is an important role and underpins the implementation of the principles and actions in the Freedom To Speak Up report. It will establish good practice across the NHS and provide a consistent independent person that staff in the NHS can turn to.

68. Principle 15 of the Freedom to Speak Up report sets out how the Independent National Officer will provide an independent role to review the handling of concerns raised by NHS workers and/or the treatment of the person or people who speak up where there is cause for concern. The person undertaking this role will:

- advise NHS organisations to take appropriate action where they have failed to follow good practice, or advise the relevant system regulator to make a direction to that effect;
- provide support to the Freedom to Speak Up Guardians;

- provide national leadership on issues relating to raising concerns by NHS workers;
- offer guidance on good practice about handling concerns; and
- publish reports on the office of the Independent National Officer.

69. Given the CQC's existing contact with staff raising concerns and its role in assessing providers' handling of staff concerns, we are of the view that the CQC is the most suitable national body to host the Independent National Officer role. We note the CQC's comment that the National Guardian role should be considered alongside the transfer of safety functions from NHS England and the potential creation of an independent investigations body (as recommended by the Public Administration Select Committee)⁴. The co-location of all safety functions could help to align all guidance for NHS organisations relating to investigations and as such, an independent investigations body could also be a suitable national body to host the National Guardian. However the work of the Independent National Officer needs establishing as soon as possible. Therefore, rather than delay implementation we have concluded that the role will sit within the CQC. We would expect the CQC to consult on how the role of the Independent National Officer will be implemented during summer 2015, given the urgent need to establish this position, and would expect the Independent National Officer to be appointed by the end of 2015.

Standards for Professionals

Q9: Do you agree that there should be standardised practice set out in professional codes on how to raise concerns?

70. We received 67 responses to this question, of which 47 agreed that there should be standardised practice on how to raise concerns set out in professional codes. 13 respondents disagreed, while a further 7 neither agreed nor disagreed with this measure. 38 respondents did not answer this question, a number of whom were unable to access the text for question 9 on a version of the consultation questionnaire held on GOV.UK. Of the answers received, the majority (70%) supported this measure, with 19% against.

⁴ In the response to the PASC report, below, the Government accept the need to establish a new Independent Patient Safety Investigation Service

71. There were two key themes that emerged from the comments of those who supported the proposal.

72. The first was that a standardised code should not just be limited to those in regulated professions, many of which already have detailed codes of conduct, but should be extended to all NHS staff and managers where similar codes of conduct are lacking.

- “As a union representing members across most of the regulated professions we believe this would be helpful, and would be of particular benefit to staff working in multi-disciplinary teams. Registrants who raise concerns often experience reprisals from their organisation and “trumped up” referrals to regulators are a common form of this. We would therefore call on the professional regulators to develop awareness of this among their investigators and panel members and procedures for them to raise concerns about this to the INO and CQC as appropriate.” – **Unison**
- “There is already good guidance produced by professional bodies such as the GMC and NMC which covers the expectations on staff to raise concerns in a particular way as part of the Duty of Candour. This could be adapted and implemented across the sector in a way that takes into consideration the nuances of different professions.” – **Public Concern At Work**
- “Yes, the more embedded into professional codes the better as national bodies can then hold organisations and their staff to account in a more appropriate way. This should also be included in the NHS manager’s code of conduct.” – **Trust Development Agency**
- “Yes, but not confined to “professionals”. Safety is everybody’s business. “-
Individual

73. The second key theme was that individuals should still be able to deviate from standardised practice if the circumstances warrant doing so. A few responses cited the situation where an individual lacked confidence in their line manager’s ability to handle any concerns they raised. The individual should be allowed to deviate from the process of first raising the concern with their line manager and proceed either further up the management chain or go directly to a whistleblowing officer, without risk of being penalised for deviating from standardised practice.

- “We would welcome consistent principles amongst professional regulators in respect of raising concerns in line with the model we have adopted, but

standardisation of content may not be appropriate.” – **Nursing and Midwifery Council**

- “We believe that professional codes should be based on principles and should focus on the outcomes that need to be achieved. This allows professionals to apply principles sensibly to the many varied and changing circumstances they face. To descend into the level of detail proposed in paragraph 13 in a professional code is counter to that approach and would necessitate frequent revisions.” – **Professional Standards Authority**

74. The majority of the concerns with this proposal were about how it duplicated the existing codes of practice for professionals and that standardised practice would have varying degrees of applicability to different sectors. Many respondents also felt that best practice in raising concerns was something that should be determined at a local level, taking into consideration the configuration of local services.

Conclusion

75. Professional codes are guidance on behaviour and how to deal with particular situations such as communication with patients, delegation, seeking consent, treating people with dignity; and what to do if a professional has witnessed something about which they have concerns. Professor Sir Bruce Keogh is currently considering the professional codes, including how they cover the issue of raising concerns, and will report back shortly.

Strengthening legislation

76. The Freedom To Speak Up report proposed legislative change in Principle 20 - Legal protection. Since the publication of the report, a regulation making power was added to the Small Business, Enterprise and Employment Act 2015 (the SBEEA) to prohibit discrimination against whistleblowers (or applicants believed by the prospective employer to have been whistleblowers) when they apply for jobs with prescribed NHS employers.

77. The SBEEA also introduced a regulation making power to impose a duty on prescribed persons (such as the CQC, Monitor and the professional regulatory bodies) to report annually on whistleblowing disclosures made to them. Going forward, taking account of the Freedom To Speak Up report’s proposal, we intend to add further organisations to the Prescribed Persons Order.

78. In addition, the Government have previously extended the definition of “worker” within the whistleblowing statutory framework in the Employment Rights Act 1996 to include student nurses and student midwives; the intention is to extend the definition to all students studying for a career in healthcare when Parliamentary time allows.

Equality Analysis

79. The Equality Analysis for this consultation response will be published separately.

PASC report

The Government's Response to the Public Administration Select Committee's Report on Investigating Clinical Incidents in the NHS

Executive Summary

1. Healthcare is complex and there is always the potential to do harm, even in the best organisations. Organisational resilience to error is therefore incredibly important. A healthcare organisation with a strong safety culture embraces a willingness to be open and transparent about errors and harm, and seeks out opportunities for learning and improvement.

2. However, we are not there yet. Annually, there are 30,000 reports of serious incidents in the NHS to the Strategic Executive Information System (STEIS), around 10,000 reports of patient safety incidents resulting in severe harm or death to the National Reporting and Learning System (NRLS) and over 300 Never Events reports. The cost of clinical negligence liabilities now stands at £1.4 billion per year. The most recent research estimates that around 9,000 deaths in hospital each year are more likely than not to have been caused by problems in care. The scale of the problem is not unique to the English healthcare system. Nevertheless, the failings uncovered in settings such as Mid Staffordshire NHS Foundation Trust and the University Hospitals of Morecambe Bay NHS Foundation Trust have led to a strong determination to ensure high standards of safe clinical care for all – wherever and whenever it is delivered.

3. One area for improvement is the quality of NHS Trusts' investigations into serious incidents. There is significant variation in the way NHS providers handle serious incidents, including what prompts a decision to investigate, the way the investigation is conducted, the timeliness of the investigation, the way patients and families are engaged in the process and how actions or learning are taken forward.

4. The Public Administration Select Committee recommended in March 2015 the establishment of a new independent patient safety investigation body to conduct investigations in the NHS. The Government concur that there should be a capability at national level to offer support and guidance to NHS organisations on investigations, and to carry out certain investigations itself. The Government 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.

5. A new **Independent Patient Safety Investigation Service (IPSIS)** will conduct independent, expert-led investigations into patient safety incidents. It will be selective about the incidents it investigates to ensure optimum effectiveness, and it will focus on incident types that signal systemic or apparently intractable risks within the local

health care system. Examples include incidents that lead to high cost litigation claims, certain never events, and incident types such as medication errors. There will be some capacity to examine cross cutting themes from these investigations.

6. The Service will have the capacity to investigate only a small proportion of the many safety incidents that occur each year, and therefore a key part of its role will be to champion the need for good quality local investigations and lead on approaches that will enhance the capabilities of providers to conduct their own investigations.

7. The operation of the new function will be based on the following principles:

- **Objectivity:** will take a non-punitive approach and its practices and recommendations will be intended for learning and improvement, not to find fault, attribute blame or hold people to account.
- **Transparency:** act as an exemplary model of openness and transparency including genuine engagement with patients and their families throughout the investigation process, from start to completion.
- **Independent in action, thought and judgement:** able to operate without fear or favour irrespective of its location. The Service will exercise its independence to get to the bottom of any patient safety incident that it examines; its findings will apply to any organisation or individual as it sees fit; and its processes, practices and outputs will be transparent and subject to external scrutiny.
- **Expertise:** staffed by experts in patient safety, investigations, human factors and healthcare provision.
- **Learning for improvement:** produce findings from investigations that will help deliver practical, proportionate solutions that address the root cause of the problem under investigation. It will also provide support to local investigators and commissioners in order to transfer skills and systematically increase the capability in a particular local NHS system.

8. The Independent Patient Safety Investigation Service will be in place from 1 April 2016. There will be some central funding in the first instance, but we would expect the Service to demonstrate its value to the wider NHS quickly, and to move towards a mixed-funding model with a significant proportion of its income being derived from NHS Trusts themselves. We expect that having in place a credible and standardised process for investigation should also alleviate the need for very lengthy and often quite costly public inquiries and national investigations. The Service should

also drive greater efficiency in the system through more timely investigations, help to achieve better outcomes for patients, their families and NHS organisations, and potentially reduce the system-wide costs associated with healthcare harm.

9. We anticipate that healthcare providers will benefit greatly from a high-quality Independent Patient Safety Investigation Service, and from its expert insight, which will lead to safety improvements. It should mean timely investigations, with a genuine commitment to openness, transparency and engagement with staff and patients and their families/carers, championing an ethic of learning and continuous improvement. Fundamentally, it will be a catalyst for change, and will contribute strongly to the culture change that we need in the NHS.

10. We also recognise that as in other industries, it will be possible to investigate only a proportion of serious incidents each year in this way. While part of the role of the new patient safety investigation function will be to support trusts to develop their own capabilities there may be further actions needed to strengthen the quality of locally conducted investigations.

11. In their report, the Committee put forward a comprehensive range of proposals for the formation and operation of this new national patient safety investigation function. We are grateful to the Committee for these detailed recommendations. We will establish an expert group who will advise the Department of Health and the Secretary State for Health on the purpose and role of a new investigation function over the coming months. The group will be relied upon for its expertise in patient safety, healthcare and investigation and use the available evidence to reach its conclusions.

12. The Committee's report also makes several recommendations about the Ombudsman. It notes that "there are serious questions about the capacity and capability of the Ombudsman's office, in particular in relation to complaints involving clinical matters" and that they are "aware of considerable anguish and disquiet where Parliamentary and Health Service Ombudsman investigations fail to uncover the truth, and of pain inflicted by the Ombudsman's defensiveness and reluctance to admit mistakes".

13. The Parliamentary and Health Service Ombudsman is accountable to Parliament, through the Public Administration and Constitutional Affairs Committee (previously the Public Administration Select Committee) rather than the Government or the Secretary of State for Health. The Ombudsman's aim is to improve the quality and accessibility of its services, and the steps it has taken to increase the number of

cases that it considers is to be welcomed. However, there is still some way to go. We would like to see improvements in the pace and responsiveness of the Parliamentary and Health Service Ombudsman, and – crucially – much greater patient and public confidence in its work. We agree with the Committee that fundamental reform of the Ombudsman system is needed. 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.

14. The Committee made a number of other recommendations, which are addressed as part of our full response.

Response to recommendations

1. This Government response addresses, in turn, the individual conclusions and recommendations of the Committee's report set out in bold below. The response is in normal type.

Complainants need to feel heard, whether they are patients, relatives or staff. They deserve the opportunity to contribute to learning in the system that will prevent a repeat of the same failure. Instead, they too often feel their issue is managed or avoided, to minimise reputational damage to individuals and organisations, or to avoid financial liability. The system is unacceptably complicated, with an unresolved tension between the desire for an open “no blame” culture and the demand for the clear accountability the public is entitled to expect from a public service. There is a clear requirement for a single body to provide a single focus for accountability for driving local improvement. (Paragraph 74)

2. Complaints handling has been an important part of the Government's programme of work, particularly following Sir Robert Francis QC's Public Inquiry 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.

3. Over the last two years action has been taken 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 there will be more granular detail on the issues being complained about. We have sought to build an enduring national partnership of organisations committed to working together to improve complaints handling, and looking at complaints within a wider context.

4. 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.

5. 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.

6. 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.

7. 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 health watch is also very important as a means to ensuring the local NHS is handling complaints well.

8. 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; the tracking survey capturing public perceptions of the NHS, including how people feel about complaining - the results of the winter 2014 tracking survey were recently published. 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 the PHSO/Healthwatch document "My expectations for raising concerns and complaints"⁵. 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.

9. The Parliamentary and Health Service Ombudsman remains an important element of the complaints process and provides an independent view for individuals

⁵ http://www.healthwatch.co.uk/sites/healthwatch.co.uk/files/vision_report_0.pdf

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 Parliamentary and Health Service Ombudsman.

10. The Government are leading work to reform the Ombudsman landscape following on from the proposals set out in Robert Gordon's report⁶. 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 supporting infrastructure is as effective as possible and easy for people to use.

11. We continue to believe it is 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, high quality services. Delivering this requires the whole care system to play its part. 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"⁷, and considering how to improve the culture around patient feedback, including complaints.

12. To enhance transparency, hospital complaints data is now being collected quarterly, as opposed to annually, with the first publication of data under these arrangements being expected in late summer 2015.

Complainants deserve an Ombudsman they can have confidence in. There are serious questions about the capacity and capability of the Ombudsman's office, in particular in relation to complaints involving clinical matters. We are aware of considerable anguish and disquiet where Parliamentary and Health Service Ombudsman investigations fail to uncover the truth, and of pain inflicted by the Ombudsman's defensiveness and reluctance to admit

⁶ "Better to Serve the Public: Proposals to restructure, reform, renew and reinvigorate public services ombudsmen", Robert Gordon CB, October 2014 - https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/416656/Robert_Gordon_Review.pdf

⁷ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/270368/34658_Cm_8777_Vol_1_accessible.pdf

mistakes. This underlines the need for improved competence and culture change throughout the system, including in the PHSO. PHSO leadership is aware of the need for this change, but it is proving more challenging than expected. We welcome the PHSO's aim to improve the quality and accessibility of its services. However, the Ombudsman's office is under considerable strain. Fundamental reform of the Ombudsman system is needed. (Paragraph 75)

Much external criticism of PHSO concentrates on its handling of past cases, which has encouraged the organisation to devote considerable resource to reviewing these cases. Poor adjudications based upon inadequate evidence underline that PHSO was not established to conduct clinical investigations, but to adjudicate on maladministration and service failure based on evidence provided to it by others. We therefore recommend that PHSO should concentrate its energy on improving its internal culture and competence in respect of its current adjudications, rather than on reviewing or justifying past adjudications. PHSO needs to reflect upon how it wishes the public to perceive its role: how it balances the independence of its adjudications with the wish to support complainants and to respond to public criticism. We expect the PHSO to make its internal change programme its main effort. The PHSO's leadership must avoid becoming distracted by other issues, such as the proposed review in its legislative framework, which will take some years to complete. The internal change programme is essential and urgent, with or without legislative change. We expect to see clear signs of significant progress early in the next Parliament. (Paragraph 77)

13. The Parliamentary and Health Service Ombudsman is not accountable to the Government or the Department of Health - and the Department is not responsible for the performance of the Ombudsman. However, the Department *is* responsible for improving the experience of patients, and it is important that those patients have confidence in the NHS complaints arrangements and in the Ombudsman as the independent, final stage of those arrangements. The concerns that patients and their families have expressed about the Parliamentary and Health Service Ombudsman often relate to issues of openness and transparency. We therefore agree with the views expressed by the Committee. As we seek to improve the culture of the NHS going forward, it would clearly provide reassurance to patients and their families if

they felt the Ombudsman was more open, and we believe there is much more for the Parliamentary and Health Service Ombudsman to do to rebuild the levels of public confidence necessary to discharge its role effectively.

We reiterate our conclusion, in *Time for a People's Ombudsman Service*, that change is urgently needed. Some of the PHSO's shortcomings are systemic and can only be addressed through legislation, which is needed early in the next Parliament. However, unhappiness with the Ombudsman also underlines the need for improved capacity for clinical incident investigations in response to complaints, long before they reach the Ombudsman. The Ombudsman must acknowledge current concerns, and the need for larger reforms must not delay necessary practical improvement. (Paragraph 76)

14. The Committee will be aware that an aim that the Government have set out previously has been the need to ensure that people using public services find it simple and straightforward to complain, and that public sector organisations respond quickly and effectively to complaints. Public organisations should also use the information that they receive from complaints to improve their services.

15. The Minister for Government Policy commissioned the Gordon Report in 2014. This examined whether the current public sector Ombudsman is best for citizens and Parliament, and whether it provides value for money. A primary reason for this was that the provision of public service has become more complex with a greater number of Ombudsman cases crossing boundaries, for example, across social care and health care. A single organisation may be able to provide a clearer and simpler path for complainants, and help to improve services across the care sector. The Gordon Report recommends creating a new Public Service Ombudsman, bringing together the existing jurisdictions of the Parliamentary and Health Service Ombudsman, the Local Government Ombudsman and the Housing Ombudsman. The public consultation on this report closed in June and a response will be published in due course.

16. We agree that the report highlights the opportunity for an improved customer experience (through an integrated service), with more effective handling of complaints that are not resolved at local level. The Government have indicated that they will publish a draft Public Service Ombudsman Bill in the first session of this Parliament to merge into one service the Parliamentary and Health Service Ombudsman, the Local Government Ombudsman and the Housing Ombudsman.

Responses to the consultation on the Gordon Report, to be published in due course, will inform the policy development process and plans for this future legislation.

It is time for PASC to take another look at our role in relation to the Ombudsman. Parliament expects PASC to pay close attention to the effectiveness of the service provided by the Ombudsman, so we have the authority to set out our expectations for its performance. Our successor Committee in the next Parliament should examine PHSO's internal change programme and make recommendations about how to reinforce and to accelerate much needed change in the behaviour, attitudes and competence of PHSO staff. This scrutiny should be forward-looking. This Committee cannot be a court of appeal in respect of PHSO's adjudications nor can it seek in any way to influence decisions in individual cases because this would compromise the independent quasi-judicial role of PHSO. However, our scrutiny role in this Parliament has been enhanced by understanding previous cases and this learning should continue in future. We reiterate our previous recommendation in *Time for a People's Ombudsman Service* that the Public Accounts Commission or a similar body should take primary responsibility for scrutiny of PHSO, including examining corporate plans, budget and resources. But this does not absolve us from looking at the Ombudsman's:

- **quality of adjudications;**
- **their competence in respect of evidence, investigation and legal interpretation; and**
- **the leadership and development of the service. (Paragraph 78)**

We hope that our successor Committee will return to the question of the boundaries between the Ombudsman and other regulatory and investigatory bodies, including the proposed new central investigative body. (Paragraph 79)

We recommend that our successor Committee should ask the National Audit Office to assist with an inquiry on the value for money of the Parliamentary and Health Service Ombudsman. (Paragraph 80)

17. These are issues for Parliament and the Public Administration and Constitutional Affairs Committee to consider.

We welcome the call for a “whole-system” approach. Too many recent reforms of patient safety arrangements in the NHS, while reasonable in themselves, have not taken account of the impact on other parts of the system. Reliance upon a single method of investigation such as root cause analysis is not enough to get to the heart of a case. Investigative staff must be competent and confident if local investigation is to be effective. We wish to see a clarification of the current processes for complaints and investigations of clinical incidents. This must make it easier for patients and families to complain and understand what is happening to their complaint. (Paragraph 132)

18. We know from the work led by Dr Mike Durkin, National Director of Patient Safety at NHS England, that the quality of investigations at a local level are variable, and too often are conducted poorly. The potential for learning and improvement is also compromised.

19. We welcome the Committee’s support for a whole-system approach and the need to promote better cross-system learning. In “Culture Change in the NHS. Applying the Lessons of the Francis Inquiries”, we said that there was a need to concentrate and consolidate national expertise and capability on safety within a single organisation that can provide strategic leadership across the whole healthcare system.

20. 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. The new Independent Patient Safety Investigation Service will also be located under Monitor and the NHS Trust Development Authority. This move will build on the post-Francis reforms that have been designed to ensure that there is greater clarity about the standards for safe care, and about the roles and responsibilities of organisations in the system for safety.

We welcome the proposal for “Freedom to Speak Up Guardians” recently accepted by the Government, but in order for them to be effective, the information given to Guardians must be protected from disclosure, so that information cannot be used to publish or penalise those making whistleblowing reports to Guardians; that will require legislation. (Paragraph 133)

21. The Government have accepted in principle the recommendations made by Sir Robert Francis QC in his Freedom to Speak Up report. The Department of Health has consulted on a package of measures on how to implement these recommendations. The consultation focused on how measures can be implemented locally, the role of national bodies, the title of the Freedom to Speak Up Guardian role and standards for professionals. The Freedom to Speak Up report recommends that Freedom to Speak Up Guardians are appointed by all NHS organisations. As employees of their organisation, existing legislation would apply to them. When a whistleblower makes a protected disclosure to a Freedom to Speak Up Guardian who is also an employee of the whistleblower’s employer, they would potentially be making a protected disclosure to their employer under existing legislation. Therefore the whistleblower has a statutory right not be subjected to any detriment by their employer. Therefore, there is no intention to make new legislation or amend existing legislation.

22. The Government expect all NHS organisations to have in place whistleblowing policies that are compliant with the Employment Rights Act 1996, as amended by the Public Interest Disclosure Act 1998, and with best practice. In addition, we support a free helpline, run by Mencap. The helpline provides independent and confidential advice to staff in the NHS and social care wanting to raise a concern but unsure how to do so or what protections they have in law if they do so. The Whistleblowing Helpline also gives employers advice on best practice in implementing whistleblowing policies that are compliant with the Employment Rights Act 1996. In March 2014, refreshed NHS and Social Care Whistleblowing Guidance was published, aimed at staff and employers. It can be located at:

<http://www.wbhelpline.org.uk/resources/raising-concerns-at-work/>

23. This guidance provides employers with information about what to consider when developing their policies and procedures on how disclosures should be handled, and considers the issue of confidentiality. The information shared with a Freedom to Speak Up Guardian may on occasions need to be shared with others to

ensure that patient safety, fraud and other serious issues can be addressed. However existing data protection law and the law of confidence will protect personal data and confidential information from unlawful disclosure.

24. The Freedom to Speak Up report emphasised the importance of listening to staff and the need to create an open and transparent culture in the NHS, in which staff feel supported to speak up if they have concerns and know they will be listened to and supported if they do.

25. In February 2015, the Secretary of State for Health wrote to the Chairs of NHS Trusts seeking their support to work with the Government to eradicate bullying, intimidation and victimisation. The Government have already taken a number of steps to protect NHS staff and fully supports the right of staff, working in the NHS to raise concerns and expect all NHS organisations to support staff that wish to do so.

We welcome the decision of the Secretary of State for Health, who has followed our inquiry closely, to invite Dr Mike Durkin of NHS England to look at the possibility of setting up a new independent patient safety investigation body in order to conduct clinical investigations. This will not solve all the problems we have identified, but is an essential step. (Paragraph 134)

26. While giving evidence to the inquiry on 25 February 2015, the Secretary of State for Health advised the Committee that serious incidents should continue to be investigated at a local level, but that it would be worthwhile to consider whether the NHS could benefit from a service similar to the Air Accidents Investigation Branch at the Department for Transport.

27. The Secretary of State informed the Committee that Dr Mike Durkin, National Director of Patient Safety at NHS England, was looking into the possibility of setting up such a function for the NHS. Dr Durkin and his colleagues at NHS England were already exploring the benefits that a national investigation capability could bring and had undertaken a small number of exemplar investigations in order to provide insights into the role of investigation in safety improvement. They have informed us that their key observations and conclusions were as follows:

- variable, and too often poor, quality of investigations at a local level;

- the potential to identify key learning points and design strong systemic solutions via exemplar investigations – with a higher likelihood of faster learning, resolution and eradication of narrow focus incident types;
- the value of involving patients and their families in the investigation and draft investigation report;
- staff should not be blamed or punished for making an honest mistake or for speaking up;
- the NHS needs to do fewer, but higher quality, investigations;
- complaints involving patient safety issues should be included in the patient safety investigation process; and
- reports should be published within a consistent, transparent and systematic model.

28. In conclusion, Dr Durkin informed the Secretary of State that the NHS would have much to gain from a central investigative resource – which could promote good investigatory practice and also have its own investigative capacity.

29. The Care Quality Commission have also told us that they have discovered, during their inspections of hospital trusts, that the quality of local investigations – including the use of good practice guidance – is variable. They have informed us that they find variable quality in reports and that, too often, investigations do not lead to significant learning.

30. It is clear that strong and urgent action needs to be taken to dramatically improve the quality of local NHS investigations into serious incidents. This is why the Government have decided to establish a new Independent Patient Safety Investigation Service which through a combination of exemplary practice and structured support to others, could make a decisive difference to the NHS, promoting a culture of learning and a more supportive relationship with patients, families and staff.

We are struck by the fact that no public inquiry has taken place into an aviation accident since the 1970s, where just such a body exists in the form of the Air Accidents Investigation Branch of the Department for Transport. The present situation in the NHS, where investigations of clinical incidents and complaints are tangled together and often prove hard for the patient and their

family to navigate, needs to be replaced by a more rational and easy-to-understand system. (Paragraph 135)

31. We believe that there is an enormous amount that the NHS can learn from the airline industry when it comes to safety – as well as other safety-conscious sectors such as the nuclear and oil industries. Indeed, when giving evidence to the Committee on 25 February 2015, the Secretary of State for Health noted that the processes that the Government have been developing to make the NHS the safest healthcare system in the world “...have been modelled on those in the airline industry, which are designed to make it incredibly easy for pilots to speak up”.

32. The Secretary of State has met with the Chief Inspector of Air Accidents, Keith Conradi, to learn more about how the airline industry has a culture that is open, transparent and encourages learning. We have also been struck by the reduction in the number of accidents and casualties in the aviation world in recent decades – data from the Aviation Safety Network shows that there were 20 accidents and 692 casualties in 2014, compared with 78 accidents and 1,475 casualties in 1970.

33. We agree that more needs to be done to improve the investigation of clinical incidents in the NHS, and to make the system easier to understand. Whether a serious incident is identified from a complaint, a staff concern or from a patient safety incident report, the principal outcomes of an investigation should irrespectively be the same – to establish the root causes of the incident and make recommendations that lead to learning and improvement, and better outcomes for patients, their families, staff and the service. The NHS England Serious Incident Framework (2015) makes it clear that serious incidents identified (or alleged) through the complaints route, or any other mechanism, must be treated in line with the principles in the Framework to ensure they are investigated and responded to appropriately. If the investigation reveals that there were no weaknesses/problems within a provider’s intervention that either caused or contributed to the incident in question, the incident can be downgraded.

34. As part of the establishment of a new Independent Patient Safety Investigations Service we will also seek further expert advice on how local organisations can align their processes for handling complaints and investigations into serious incidents.

We therefore conclude there is a need for a new, permanent, simplified, functioning, trusted system for swift and effective local clinical incident

investigation conducted by trained staff, so that facts and evidence are established early, without the need to find blame, and regardless of whether a complaint has been raised. This would greatly reduce or remove the need for costly major inquiries into clinical failure. (Paragraph 136).

Such a single, independent, investigative body would provide national leadership and support of local capability and act as a catalyst to promote a just and open culture across the whole health system. It would proactively investigate the most serious patient safety issues, encourage improvement in the quality of local investigations, better capture and disseminate learning from them and serve as a resource of skills, expertise and experience for the conduct of clinical incident investigations. (Paragraph 137)

35. The Government concur that there should be a capability at national level to offer support and guidance to NHS organisations on investigations, and to carry out certain investigations itself. The Government 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.

36. A new **Independent Patient Safety Investigation Service** will conduct independent, expert-led investigations into patient safety incidents. It will be selective about the incidents it investigates to ensure optimum effectiveness, and it will focus on incident types that signal systemic or apparently intractable risks within the health care system. The selection of the incident types for investigation will be guided by our knowledge of which incidents represent the most significant burden on the system and patients, for example incidents that lead to high cost litigation claims. It will also seek to proactively investigate priority areas that would benefit from an in-depth investigatory approach in order to support the development of potential solutions to significant problems. Examples include incident types like medication errors, avoidable deterioration of patients, or pressure ulcers, or features of incidents including problems with communication during handover or discharge, or incidents that affect key patient groups such as the acutely ill elderly, those with mental health care needs or expectant mothers.

37. The Service will respond to the concerns that had been previously subject to public inquiries, or national investigations, such as Mid-Staffordshire NHS Foundation, and the University Hospitals of Morecambe Bay NHS Foundation Trust.

38. The Service will have the capacity to investigate only a small proportion of the many safety incidents that occur each year, and therefore a key part of its wider role will be to lead various approaches designed to enhance the capabilities of providers to conduct their own investigations.

39. The operation of the new function will be based on the following principles:

- **Objectivity:** It will take a non-punitive approach and its practices and recommendations will be intended for learning and improvement, not to find fault, attribute blame or hold people to account.
- **Transparency:** act as an exemplary model of openness and transparency including genuine engagement with patients and their families throughout the investigation process, from start to completion.
- **Independent in action, thought and judgement:** able to operate without fear or favour irrespective of its location. The Service will exercise its independence to get to the bottom of any patient safety incident that it examines, its findings will apply to any organisation or individual as it sees fit and its processes, practices and outputs will be transparent and subject to external scrutiny.
- **Expertise:** staffed by experts in patient safety, investigations, human factors and healthcare provision.
- **Learning for improvement:** produce findings from investigations that will help deliver practical, proportionate solutions that address the root cause(s) of the problem under investigation. It will also provide support to local investigators and commissioners in order to transfer skills and systematically increase the capability in a particular local NHS system.

40. The Independent Patient Safety Investigation Service will be in place from 1 April 2016. There will be some central support in the first instance, but we would expect the Unit to demonstrate its value to the wider NHS quickly, and to move towards a mixed-funding model with a significant proportion of its income being derived from Trusts themselves. Having in place a credible and standardised process for investigation should also alleviate the need for very expensive public inquiries and national investigations. The Unit should also drive greater efficiency in the system

through more timely investigations, better outcomes for patients, their families and NHS organisations, and potentially reduce the system-wide costs associated with healthcare harm.

41. We anticipate that providers will benefit greatly from the new Independent Patient Safety Investigation Service, and their expert advice on safety improvement. It should mean timely investigations, with a genuine commitment to openness, transparency and engagement with staff and patients and their families/carers; that adopts an ethic of learning and continuous improvement. Fundamentally, it will be a catalyst for change, and will contribute strongly to the culture change that we need in the NHS.

42. We have noted the Committee's detailed recommendations for the proposed investigative body:

- **It must offer a safe space: strong protections to patients, their families, clinicians and staff, so they can talk freely about what has gone wrong without fear of punitive reprisals (Paragraph 136);**
- **It must be independent of providers, commissioners and regulators (Paragraph 136);**
- **It must be free to investigate non-NHS funded healthcare as well as the NHS (Paragraph 136);**
- **It must have the power to publish its reports and to disseminate its findings and recommendations (Paragraph 136);**
- **It would provide national leadership and support of local capability...it would proactively investigate the most serious patient safety issues, encourage improvement in the quality of local investigations, better capture and disseminate learning from them and serve as a resource of skills, expertise and experience (Paragraph 137);**
- **The new body's reports should be received by the Secretary of State for Health, who should be accountable for the implementation of their recommendations through such bodies as NHS England and the Care Quality Commission. The new body should be accountable to a Select Committee such as PASC (Paragraph 138);**

- **The new body should be permanent and independent. Witnesses should be given legal immunity for what they say and evidence should be exempt from the Freedom of Information Act (Paragraph 139);**
- **The new body must have its own substantial investigative capacity. A clear mandate and set of clear criteria would need to be established regarding when it should undertake an investigation. Each investigation should be conducted by trained and expert investigators. Each investigation should publish safety recommendations that are intended to prevent recurrence and improve patient care (Paragraph 140);**
- **The new body should establish a single set of incontestable evidence. There must be a duty to provide relevant information to its investigators in a timely fashion (Paragraph 141);**
- **The new body should complement existing NHS bodies, so the Department of Health should work with NHS England, the Care Quality Commission and others to draw up Memoranda of Understanding between the new body and existing bodies (Paragraph 142);**
- **The new body should be funded by the Department of Health, not by trusts and Clinical Commissioning Groups. In order to fund its investigation of non-NHS funded health provision, a levy on the independent sector could be considered, but not any kind of direct charge (Paragraph 143).**

43. We are grateful to the Committee for these comprehensive proposals. We will establish an expert group who will advise the Department of Health and Secretary of State for Health on the purpose and role of a new investigation function for the NHS over the coming months. The group will be relied upon to make use of its expertise in patient safety, healthcare and investigation and the available evidence to reach its conclusions. We will ask the expert group to consider carefully the Committee's proposals.

We therefore recommend that the Secretary of State for Health should start consulting on this proposal immediately. To establish this new investigative body as independent and system-wide, ensuring it can work across the NHS, the Government should set up a cross-organisation working group including safety experts and representatives of key NHS organisations including the

Care Quality Commission, NHS England, the Department of Health, and representatives of providers, commissioners, and patients and their families, with an independent chair. This group should be charged with making rapid progress in refining the working model, investigative criteria and protections provided by this body. Precursor bodies should be set up to start work as soon as possible and draft legislation should be published for scrutiny early in the next Parliament. (Paragraph 144)

44. The Government concur that there should be a capability at national level to offer support and guidance to NHS organisations on investigations, and to carry out certain investigations itself. The Government 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.

45. A new Independent Patient Safety Investigation Service outlined above will conduct independent, expert-led investigations into patient safety incidents.

We also recommend that Independent Medical Examiners, as provided for in the Coroners and Justice Act 2009, should be appointed for every Clinical Commissioning Group, to examine hospital deaths, to keep families of deceased relatives informed, and to alert the coroner to cases of concern. In time, such Examiners should refer cases for investigation to our proposed new body. (Paragraph 145)

46. The Coroners and Justice Act 2009 (as amended by the Health and Social Care Act 2012) places responsibility for appointing medical examiners on local authorities in England and on local health boards in Wales. The Act provides the framework for a new system of medical examiner scrutiny of the cause(s) of death proposed by a certifying doctor soon after a death occurs; and a medical examiner's confirmation would enable a death to be registered. The primary role of medical examiners is therefore to confirm cause(s) of death, and in doing so, medical examiners must offer the bereaved family an opportunity to raise any concerns and to act on those concerns. Where the concerns may warrant an investigation by a coroner, the medical examiner must notify a death to the coroner.

47. The medical examiners system has been trialled successfully in a number of areas across the country. The work of the two flagship sites in Gloucestershire and Sheffield has been extended to operate a medical examiner service on a city and countywide basis at a scale that will be required for implementation by local authorities when legislation is introduced. We will soon be publishing a report from the interim National Medical Examiner setting out the lessons learned from the pilot sites.

48. The Government remain committed to the planned reform of the death certification system. 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.

Finally, we recommend that educators, professional bodies and Royal Colleges should ensure that Human Factors and incident analysis modules are introduced as part of the training of healthcare professionals, with regular tutorials involving role play to increase understanding of how human factors can affect patient safety. We also recommend the development of a body of professionally qualified administrative and investigative staff, who, over time will be able to provide a substantial infrastructure in support of all investigation of clinical incidents. There should be formal examinations and qualifications similar to those formerly made by the Institute of Health Service Administration and the Association of Medical Records Officers. (Paragraph 146)

49. We agree that an understanding of the application of human factors to investigations of patient safety incidents offers an important opportunity to address and correct any underlying environmental and organisational issues that may have contributed to the incident. The Berwick Review⁸ recommended that all healthcare professionals should “receive initial and ongoing education on the principles and practices of patient safety....”.

⁸ *A promise to learn – a commitment to act: Improving the Safety of Patients in England*, National Advisory group on the safety of Patients in England, 2013

50. Health Education England launched a campaign in February of this year, in association with Patient Safety Collaboratives and academic health science networks, to promote the role of human factors in improving safety.

51. The Health Education England Commission on Education and Training for Patient Safety, jointly chaired by Professor Sir Norman Williams and Sir Keith Pearson, Chair of Health Education England, will set out comprehensive proposals for enhancing safety training for all health and care professionals. The Board will report in autumn 2015 and will set out recommendations against four themes including Education and training in human factors for patient safety. There will be a two to five year programme to take forward the recommendations from the Commission. Groups will be established to identify the best way to implement these recommendations, and to ensure that outcomes are achieved.

52. The Committee also recommended the development of a body of professionally qualified administrative and investigative staff who, over time, will be able to provide a substantial infrastructure in support of all investigation of clinical incidents. The NHS England Serious Incident Framework⁹ calls for providers to maintain clear procedures to support robust serious incident investigations, including a process to ensure that investigations are undertaken by appropriately trained and resourced staff and/or investigation teams that are sufficiently removed from the incident to be able to provide an objective view.

53. We expect that the most appropriate administrative and investigative staff will be part of the new Independent Patient Safety Investigation Service. Part of the role of this Service will be to help enhance the capability for local providers to conduct investigations well.

⁹ *Serious Incident Framework: Supporting learning to prevent recurrence* NHS England 2015

Morecambe Bay Investigation

The Government's response to the Report of the Morecambe Bay Investigation

Executive Summary

1. The Morecambe Bay Investigation Report, published by Dr Bill Kirkup CBE on 3 March 2015 contained a series of shocking revelations - of parents and families raising concerns that were not listened to or properly investigated, and where there was a systemic failure to learn lessons. Of staff closing ranks, behaving inappropriately and not recognising where their standards fell well below what was expected of them. Where there were multiple missed opportunities to address problems across large parts of the health system.

2. The Government previously forged an opportunity for the NHS to be more open about poor care. Inevitably, in a system as large and complex as the NHS things will sometimes go wrong. But we now have an historic opportunity to put this right.

3. Wherever it is possible to minimise errors, we should of course do so. But where a mistake is made we must do more to ensure that the NHS is able to properly investigate those errors locally, and to learn from them. In this way we engender an open, learning culture which is in the best interests of both staff and patients - an NHS which is an organisation ready to listen and willing to learn.

4. This response echoes many of the themes of the Public Administration Select Committee's report in March 2015, "Investigating clinical investigations in the NHS" – namely that investigations should be timely, focused and deliver answers to patients faster which is why we will establish a new Independent Patient Safety Investigation Service (IPSIS) that will conduct independent, expert-led investigations into patient safety incidents. It will also facilitate support and guidance to NHS organisations to help enhance local capacity and capability in relation to investigations, ensuring closer links to complaints involving serious incidents and with a particular focus on ensuring families are both involved in the investigation handling and informed of the outcome and learning from events.

5. A culture of openness, not reticence, will support those people who need to speak up about poor care - the proposals today to introduce a Freedom to Speak Up Guardian in every NHS Trust appointed by the Chief Executive to act in a genuinely independent capacity, will provide additional support to staff who wish to raise a concern meaning that families do not have to suffer the delay and obfuscation that people experienced in Morecambe Bay.

6. This Government response reflects the actions being taken locally at the Trust to address the critical and underlying issues within the maternity service and more

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 available¹⁰. 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 View¹¹ 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 Health, 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.

25. On mandatory reporting and standardised reviews of perinatal deaths, the Department is working with NHS England, the Scottish, Welsh and Northern Irish health departments along with the Royal College of Midwives and the Royal College of Obstetricians and Gynaecologists and Sands (the leading stillbirth charity) to consider how standardised reviews for all perinatal deaths might be introduced. We will keep in mind this recommendation when developing this work.

26. MBRRACE-UK (Mothers and Babies – Reducing Risk through Audits and Confidential Enquiries across the UK) currently collects information on:

- all late fetal losses, stillbirths and neonatal deaths;
- characteristics of mothers whose babies are stillborn or die in the first 28 days after birth;
- all mothers in the UK who die during pregnancy or in the 12 months after giving birth.

27. They conduct confidential enquiries on topics related to aspects of stillbirth, infant deaths, and neonatal deaths. They also conduct confidential enquiries into all maternal deaths and topic specific serious maternal morbidity.

28. Data is anonymised and the confidential enquiry expert assessors review the care provided and compare the quality of care with national agreed “best practice” standards to identify where improvements could be made. Based on their findings, MBRRACE-UK makes national recommendations about how care for mothers and babies across the UK can be improved in future.

29. While reporting is not mandatory, MBRRACE-UK collects surveillance information about mothers and babies that die directly from hospital trusts via hospital medical records, including reports and test results; letters and medical records from other doctors (ie GPs); a description from local staff about the care provided to the woman and her baby in the form of written statements. MBRRACE-UK is confident that they identify all maternal deaths and compliance with the confidential enquiry is mandated in England through “Quality Accounts” and for doctors through General Medical Council best practice requirements.

30. As well as acknowledging the importance of using data and standardised reviews to improve maternity services specifically, the Government believe that clear

standards should be drawn up for incident reporting and investigations in relation to all serious incidents, not just maternity.

31. in line with this recommendation, the Secretary of State for Health asked Mike Durkin, 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 2015¹². This requires all unexpected or avoidable deaths, including those of mothers or babies, which may have been or were the result of failings in health care, to be reported to the relevant commissioner(s) and to be investigated as serious incidents. It is not always initially clear if a failure in health care has occurred and has directly led to a death. In these circumstances, providers and commissioners are expected to discuss the incident, to investigate it appropriately and to let the investigation decide. If a serious incident is initially declared but further investigation reveals no serious incident occurred, the incident can be downgraded.

32. In addition, the Care Quality Commission is conducting a thematic review into the quality of investigations in a sample of NHS Trusts and Foundation Trusts. This review will seek to understand the quality of investigations and to identify areas for improvement. This work will report later in 2015.

33. There is further scope to improve the quality of investigations into serious incidents in the NHS and there is much to be learned from other safety-conscious sectors such as the airline industry.

34. We will therefore, as indicated elsewhere in this document, establish a new, Independent Patient Safety Investigation Service that will conduct independent, expert-led investigations into patient safety incidents from 1 April 2016. It will be selective about the incidents it investigates to ensure optimum effectiveness, and it will focus on incident types that signal systemic or apparently intractable risks within the local health care system. For example, incidents that lead to high cost litigation claims, certain never events and incident types such as medication errors. There may be some capacity to examine cross cutting themes from these investigations.

35. The Service will have the capacity to investigate only a small proportion of the many safety incidents that occur each year, and therefore a key part of its wider role will be to champion the need for good quality local investigations and lead on

¹² <http://www.england.nhs.uk/ourwork/patientsafety/serious-incident/>

approaches that will enhance the capabilities of providers to conduct their own investigations.

36. We have said that an important principle of this new Service will be its ability to exercise independence and operate without fear or favour irrespective of its location in order to get to the bottom of any patient safety incident that it examines. To ensure that its processes, practices and outputs are transparent and subject to external scrutiny.

Openness and transparency: 24-27

Recommendation 24:

We commend the introduction of the duty of candour for all NHS professionals. This should be extended to include the involvement of patients and relatives in the investigation of serious incidents, both to provide evidence that may otherwise be lacking and to receive personal feedback on the results. Action: the Care Quality Commission, NHS England.

37. We accept this recommendation. A duty of candour has been introduced.

38. A lack of openness and honesty at Morecambe Bay was a fundamental cause of both the distress of the families, and of the inability of the Trust to learn from serious incidents. At a regulatory, provider and professional level action is being taken to increase the involvement of patients/relatives in investigation of serious incidents.

39. All providers must now comply with a new legal requirement for openness – the duty of candour – as a condition of their registration with the Care Quality Commission and hence a condition of their providing care. Providers must now inform patients where there has been a significant failure in their care or treatment and set out what further enquiries will be undertaken into the incident and to inform patients of the outcome of such enquiries. Registered providers must also seek and act on feedback from patients in order to improve services. We believe that these requirements address the recommendation. However, we will keep the effectiveness of the duty of candour under review and will consider whether further changes are needed in due course.

40. The new NHS England Serious Incident Framework, published on 27 March 2015, also requires providers to: comply with national requirements and guidance in relation to being open with patients or their representatives when things have gone wrong; support and enable staff in disclosing incidents to patients and their representatives; and involve patients and families/carers in investigations, sharing findings and facilitating specialist support where appropriate.

41. In addition, all healthcare professionals including doctors, nurses and midwives have an individual professional duty of candour, which is a responsibility to be open and honest. This responsibility is set out in their respective professional codes of conduct. In October 2014, the Department welcomed a joint statement by eight of the statutory regulators of healthcare professionals, including the General Medical Council and the Nursing and Midwifery Council, reaffirming that every healthcare professional must be open and honest with patients when something goes wrong with their treatment or care. Similarly, the Department is pleased to note that the General Medical Council and the Nursing and Midwifery Council launched their new joint guidance on the professional duty of candour on 29 June 2015, which includes advice on apologising to patients when things go wrong.

42. The Government fully expect both individuals and organisations to comply with these processes; and will also seek further advice from the expert group considering the national investigations capability on:

- how any new investigation function can ensure a genuine commitment to openness, transparency and engagement with patients and their families/carers throughout the investigation process; and,
- whether this can be made an integral objective of any investigative process.

Recommendation 25:

We recommend that a duty should be placed on all NHS Boards to report openly the findings of any external investigation into clinical services, governance or other aspects of the operation of the Trust, including prompt notification of relevant external bodies such as the Care Quality Commission and Monitor. The Care Quality Commission should develop a system to disseminate learning from investigations to other Trusts. Action: the Department of Health, the Care Quality Commission.

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 Council¹³ and the Nursing and Midwifery Council¹⁴ 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 leadership¹⁶, 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 2013¹⁷.

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 change²².

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 at 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.