



Department
of Health

Hard Truths

The Journey to Putting Patients First

Volume Two of the Government Response to the Mid Staffordshire
NHS Foundation Trust Public Inquiry: Response to the Inquiry's Recommendations

2 volumes not to be sold separately
Cm 8777-II



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NHS Foundation Trust Public Inquiry: Response to the Inquiry's Recommendations

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

January 2014

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You can download this publication from
<https://www.gov.uk/government/organisations/department-of-health>

ISBN: 9780101877725

Printed in the UK for The Stationery Office Limited on behalf of the Controller of Her Majesty's Stationery Office

01/14 34659 2593501

Printed on paper containing 75% recycled fibre content minimum.

Introduction

In June 2010, the Rt Hon Andrew Lansley MP, the Secretary of State for Health announced the establishment of a Public Inquiry into the serious failings in care and appalling suffering of many patients at the Mid Staffordshire NHS Foundation Trust between January 2005 and March 2009. The Inquiry was asked to make recommendations, drawn from its analysis of the role of the commissioning, supervisory and regulatory bodies in the monitoring of the Trust which could help identify early warning signs of potentially failing organisations sooner and ensure swift and appropriate action is taken.

The Report of the Inquiry was published on 6 February 2013.

Nobody who reads it can think that the terrible failings in professional conduct, leadership, safety and compassion at Mid Staffordshire were simply the result of one organisation losing its way. The wider system, a system whose primary purpose was to support the delivery of safe, effective care and to act when that did not happen failed as well. The Report from Robert Francis QC, Chairman of the Public Inquiry made 290 recommendations based on the role of the commissioning, supervisory and regulatory bodies in the monitoring of the Trust.

The Inquiry Report provides a powerful analysis of the flaws and failures of the organisation and culture, not only at the Trust in the years in question, but of the wider ‘*system as a whole [which] failed in its most essential duty – to protect patients from unacceptable risks of harm and from unacceptable, and in some cases inhumane, treatment that should never be tolerated in any hospital*’¹. It is only by getting things right across the system, from the ward and consulting room through to the boardroom and onto the organisations that provide external support and challenge that we can hope to change the culture for the better. Action is needed at every level to enable the excellent care that already exists in the health and care system to become the norm, and to become what every person can expect of the NHS.

The Government’s initial response to the Inquiry *Patients First and Foremost* set out a radical plan to prioritise care, improve transparency and ensure that where poor care is detected, there is clear action and clear accountability. We set out our vision, a shared statement of common purpose from the whole system and a range of measures designed to build a new culture, of trust not blame, within the NHS – a health service where there is greater partnership between patients and professionals; where lines of accountability are clear and where there is openness about mistakes; where services are designed from the patient’s point of view and where safety for patients always comes first.

Since the Inquiry reported, a great deal has already changed to improve inspection, increase transparency, place a clear emphasis on standards and safety, increase accountability for failure and build capability:

- the Government has introduced legislation to give **greater independence to the Care Quality Commission;**
- the Care Quality Commission has appointed three powerful **Chief Inspectors** of hospitals, adult social care and primary care;
- **expert inspections of hospitals with the highest mortality rates**, led by the NHS Medical Director, revealed unacceptable standards of care. Eleven hospitals were placed into 'special measures' **to put them back on a path to recovery and then to excellence;**
- the Care Quality Commission has conducted a major consultation on a new set of **fundamental standards:** the inviolable principles of safe, effective and compassionate care that must underpin all care in the future;
- NHS England has published guidance to commissioners, *Transforming Participation in Health and Care*, on **involving patients and the public** in decisions about their care and their services;
- the Care Quality Commission has consulted on a **new system of ratings** with patient care and safety at its heart;
- NHS England has for the first time **published clinical outcomes by consultant** for ten medical specialties and has also begun to publish data on the friends and family test;
- legislation to introduce a responsive and effective **failure regime** which looks at quality as well as finance is progressing through Parliament;
- the **Health and Safety Executive** has brought a prosecution against Mid Staffordshire Foundation Trust for the death of a patient during the period of the failings at the Trust. This case is awaiting sentence;
- **new nurse and midwifery leadership programmes** have been developed from which 10,000 nurses and midwives will have benefitted by April 2015. *Compassion in Practice* has an action area dedicated to building and strengthening leadership;
- a new fast-track **leadership** programme to recruit clinicians and external talent to the top jobs in the NHS in England has been launched, including time spent at a world leading academic institution;
- by the end of the year, over 90% of **senior leaders and all Ministers at the Department of Health will have gained experience in health and care settings.**

Patients First and Foremost also acknowledged a number of key issues identified by the Inquiry where further work was needed. Government commissioned six independent reviews to address these:

- *Review into the Quality of Care and Treatment Provided by 14 Hospital Trusts in England*, led by Professor Sir Bruce Keogh, the NHS Medical Director in NHS England.
- *The Cavendish Review: An Independent Review into Healthcare Assistants and Support Workers in the NHS and Social Care Settings*, by Camilla Cavendish.

- *A Promise to Learn – A Commitment to Act: Improving the Safety of Patients in England*,² by Professor Don Berwick.
- *A Review of the NHS Hospitals Complaints System: Putting Patients Back in the Picture* by Rt Hon Ann Clwyd MP and Professor Tricia Hart.
- *Challenging Bureaucracy*, led by the NHS Confederation.
- The report by the Children and Young People's Health Outcomes Forum, co-chaired by Professor Ian Lewis and Christine Lenehan.

Hard Truths: The Journey to Putting Patients First builds on *Patients First and Foremost* and describes the changes we are making to the way the NHS and wider health and care system work to build a culture centred on openness, trust and compassion. It is an integrated system wide response coordinated by Government on behalf of national organisations working in partnership across the wider health and care system. It applies equally to mental and physical health services. The Government has also carefully considered the extent to which the reform programme set out in *Caring for Our Future: reforming care and support* and the Care Bill address the Inquiry's key themes in social care.

This accompanying *Volume two: Response to the Inquiry recommendations* should be read alongside *Hard Truths*. It provides a detailed response to each of the 290 recommendations made by the Inquiry across every level of the system. Throughout the document the term 'we' has been used to represent the Government and national organisations across the health and care system. Where a specific recommendation is directed to a single organisation, the response clearly states which one. The overwhelming majority of the 290 recommendations made by the Inquiry are accepted either in full or in principle and work is already underway to implement them. In some cases, for example where a recommendation has been explicitly rejected, we are taking an alternative approach that we believe is more likely to be effective in reaching the desired outcome. Others will continue to shape the direction of thinking in key areas for the coming months and years.

This is only a step on the journey – there is much more to do. Transforming the culture of the NHS is a complex challenge.

'While the theme of the recommendations will be a need for greater cohesion and unity of culture throughout the healthcare system, this will not be brought about by yet further 'top down' pronouncements but by engagement of every single person serving patients in contributing to a safer, committed and compassionate and caring service' – Robert Francis

This further Government response to the Inquiry reflects a call to action for every part of the health and care system. Every individual, every team and every organisation needs to reflect with openness and humility on how they use the lessons from Mid Staffordshire to make a meaningful difference for people who use services and their staff. As part of strengthening the system and a continuous drive for further improvement, the Department of Health will lead the system in reporting annually each Autumn on progress to implement the measures set out in this document.

2 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf

Accountability for implementation of the recommendations

The Inquiry made clear:

the suffering of the patients and those close to them described in the first inquiry report requires a fully effective response and not merely expressions of regret, apology and promises of remedial action. They have already been at the receiving end of too many unfulfilled assurances for that to be acceptable Therefore the first recommendation of the report relates to the potential oversight of and accountability for implementation of its recommendations.

Hard Truths: the Journey to Putting Patients First builds on the shared statement of common purpose from across the health and care system set out in the Government's initial response to the Inquiry *Patients First and Foremost*. This accompanying document, *Volume Two of the Government Response to the Mid Staffordshire NHS Foundation Trust Public Inquiry: Response to the Inquiry's Recommendations* is an integrated and detailed response to the Inquiry's 290 recommendations from each and every part of the wider system coordinated by the Department of Health in its role as system steward. The document makes clear which recommendations have been accepted, by whom and what progress is being made towards their implementation. The Department of Health will lead the system in providing an annual report on progress across the system each Autumn.

IMPLEMENTING THE RECOMMENDATIONS

Recommendation 1

It is recommended that:

- All commissioning, service provision regulatory and ancillary organisations in healthcare should consider the findings and recommendations of this report and decide how to apply them to their own work;
- Each such organisation should announce at the earliest practicable time its decision on the extent to which it accepts the recommendations and what it intends to do to implement those accepted, and thereafter, on a regular basis but not less than once a year, publish in a report information regarding its progress in relation to its planned actions;
- In addition to taking such steps for itself, the Department of Health should collate information about the decisions and actions generally and publish on a regular basis but not less than once a year the progress reported by other organisations;

- **The House of Commons Select Committee on Health should be invited to consider incorporating into its reviews of the performance of organisations accountable to Parliament a review of the decisions and actions they have taken with regard to the recommendations in this report.**

Accepted.

The Inquiry made recommendations aimed at national organisations both by name and by implication because of the nature of their responsibilities within the newly reformed system. This document includes a detailed account from each of these organisations on what they have already done to implement recommendations directed to them and what further action they plan to take. Many organisations have published updates separately on their own websites.

In addition, a number of recommendations were aimed at NHS Trusts and NHS Foundation Trusts.

The Secretary of State wrote to all Trust Chairs in February 2013 asking them to hold listening events with their staff to hear what they have learnt from the Inquiry findings, and how they best think safe, effective and compassionate care can be delivered in an NHS managing a growing workload within a tight financial context. He followed this up with a letter on 26 March asking them to set out how they intend to respond to the Inquiry's conclusions before the end of 2013. Some Trusts have already issued a response. We would expect these responses to be placed on Trust websites. To maintain momentum, we would encourage all NHS trusts and NHS Foundation Trusts to use the opportunity this further response to the Inquiry presents to continue these local conversations. Leadership teams that put patients first recognise their organisations rely on the skill, motivation and behaviour of the people providing care to patients to drive improvements in safety, quality and compassionate care.

The Government's initial response to the Inquiry, *Patients First and Foremost* published in March 2013, set out a radical programme to prioritise care, improve transparency and ensure that where poor care is detected there is clear action and clear accountability. Informed by the six independent reviews and more detailed work over the summer, *Hard Truths: the Journey to Putting Patients First* builds on this to provide a detailed response to each of the 290 recommendations made by the Inquiry. The Department of Health will lead the system in providing an annual report on progress each Autumn.

The Health Select Committee confirmed in its *3rd Report After Francis – making a difference*, published in September 2013, that it agrees with the Inquiry's recommendation that it should monitor implementation of all his recommendations. Specifically, the Committee proposes to enhance its scrutiny of regulation of healthcare professionals by taking public evidence each year from the Professional Standards Authority for Health and Social Care on the regulatory environment and the performance of each professional regulator, based on the Professional Standards Authority's own performance reviews. The Government is publishing its response to the Health Select Committee's report in parallel with *Hard Truths*.

Recommendation 2

The NHS and all who work for it must adopt and demonstrate a shared culture in which the patient is the priority in everything done. This requires:

- **A common set of shared core values and standards shared throughout the system.**
- **Leadership at all levels from ward to the top of the Department of Health, committed to and capable of involving all staff with those values and standards;**
- **A system which recognises and applies the values of transparency, honesty and candour;**
- **Freely available, useful, reliable and full information on attainment of the values and standards;**
- **A tool or methodology such as a cultural barometer to measure the cultural health of all parts of the system.**

Accepted.

Shared core values and standards:

- We will continue to use and promote the core values and expectations for the NHS set out in the NHS Constitution.
- The development of values based recruitment by Health Education England will reinforce the importance of values as the driving force of the NHS.
- The Care Quality Commission has conducted a major consultation on a new set of fundamental standards of care which will set out the inviolable principles of safe, effective and compassionate care that must underpin all care in the future.
- The introduction of a new and robust inspection regime is an important shift in the way nationally the system will ensure poor care is identified and tackled.

Leadership at all levels

- We recognise the importance of leadership at all levels in ensuring that we prevent terrible failures of care of the kind we saw at Mid Staffordshire NHS Foundation Trust, and welcome the connection made in this recommendation between effective leadership and the engagement of staff.
- The NHS Leadership Academy is developing and implementing a wide ranging programme of leadership support at all levels of the NHS, with a strong emphasis on values.

Information on the attainment of the values and standards

- We agree that the NHS needs to do much more to put in place a transparent approach to providing care and to working with patients. The shift to greater transparency is the foundation for the culture of honesty and candour that this recommendation calls for.
- We are putting in place legal changes that place a statutory duty of candour on healthcare providers and which create a new offence of providing false or misleading information.

We believe that the combination of positive reinforcement of the value of openness with sanctions for the most serious failings in candour and honesty will support the NHS to become a far more open culture than the one examined by the Inquiry's report.

- We also agree that NHS organisations need to be accountable to the people they serve for the ways in which they have lived up to the values and standards expected of them. This will be in part achieved through the use of fundamental standards of care by the Chief Inspector of Hospitals.

Measuring cultural health

- We agree that it is important to ensure there is a clear understanding of the cultural health of different parts of the NHS. Regular inspection will provide the basis for a new, clear, transparent system of ratings that will be accessible to the public. All acute hospitals in England will have been inspected by the end of 2015.
- The Care Quality Commission is developing a set of indicators for inspecting all providers of NHS care, and this will permit judgements to be made about the culture of the organisation in question as well as other elements of its performance.
- In June 2013, the Care Quality Commission issued 'A new start – Consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care'. In this, the Care Quality Commission suggested that a 'well-led' service is one where there is effective leadership, governance (clinical and corporate) and clinical involvement at all levels of the organisation, and an open, fair and transparent culture that listens and learns from people's views and experiences to make improvements. They confirmed their plan was to encompass an assessment of aspects of governance, leadership and culture as part of its inspections to assess whether a service is 'well-led'.
- The boards of NHS organisations at all levels have a central responsibility to pay close attention to the culture of their organisation, actively dealing with cultural risks and seeking improvements in their organisation's culture, drawing on support mechanisms such as the cultural barometer that is being developed by the National Nursing Research Unit at King's College London along with other organisations. We would expect boards to be transparent about this with patients and the public.

Putting the patient first

The Inquiry highlighted the need for patients to be the first priority in all of what the NHS does and that they should receive effective care from caring, compassionate and committed staff working within a common culture. The Inquiry emphasised the significant role of the NHS Constitution in setting out the health system's common values, along with the rights, expectations and responsibilities of patients. It also highlighted the need for the Constitution to be an important reference point for staff and patients and staff to be committed to its values.

The updated Constitution published in March 2013 placed a renewed emphasis on the values of the NHS. The Department of Health, NHS England, Health Education England and clinical commissioning groups are working to embed and promote the Constitution across the system to raise awareness among patients, the public and staff.

CLARITY OF VALUES AND PRINCIPLES

Recommendation 3

The NHS Constitution should be the first reference point for all NHS patients and staff and should set out the system's common values, as well as the respective rights, legitimate expectation and obligations of patients.

Accepted.

We agree that the *NHS Constitution*³ should be the central reference point for all NHS patients and staff. The Constitution sets out principles and values to guide the NHS, as well as rights, pledges and responsibilities for patients and staff, and it has a powerful role to play in shaping the culture of the NHS. The Secretary of State for Health, all NHS bodies, private and voluntary sector providers supplying NHS services, and local authorities (in the exercise of their public health functions) are required by law to take account of the NHS Constitution in their decisions and actions. NHS England and clinical commissioning groups and Health Education England also have a legal duty to promote the Constitution.

We recognise that levels of awareness of the Constitution are low among patients, the public and staff, and that we must raise the profile of the Constitution if it is to genuinely become the first reference point for patients and staff. To achieve this, the Department of Health, NHS England, Health Education England and clinical commissioning groups are working with relevant partners to embed and promote the Constitution across the system. The Department of Health is also developing options to increase the impact of the Constitution so that patients

3 <http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/2013/the-nhs-constitution-for-england-2013.pdf>

and the public understand their rights and responsibilities and are clear about what to do when their expectations are not met.

Recommendation 4

The core values expressed in the NHS Constitution should be given priority of place and the overriding value should be that patients are put first, and everything done by the NHS and everyone associated with it should be informed by this ethos.

Accepted.

In the *Statement of Common Purpose*, all the leaders of the health and care system have personally committed to the values of the Constitution.

The Constitution sets out the following values for the NHS:

- Working together for patients
- Respect and dignity
- Commitment to quality of care
- Compassion
- Improving lives
- Everyone counts.

The Constitution notes that these values should underpin everything the NHS does and ‘provide common ground for co-operation to achieve shared aspirations, at all levels of the NHS’.

In response to this recommendation, the Department brought forward the values section so that it appears early in the document (directly following the principles section) and re-ordered the values so that they start with ‘*working together for patients*,’ in the updated Constitution published on 26 March 2013. The text of this value explicitly states that ‘patients come first in everything we do.’ The work we are currently undertaking with stakeholders to increase awareness levels of the Constitution, as well as increase its impact, seeks to ensure that everyone is informed by the ethos that patients come first.

We note that Principle 4 of the Constitution currently states that ‘the NHS *aspires* to put patients at the heart of everything it does.’ The Department of Health will consult on how this statement might be strengthened when we next update the Constitution.

Recommendation 5

In reaching out to patients, consideration should be given to including expectations in the NHS Constitution that:

- **Staff put patients before themselves;**
- **They will do everything in their power to protect patients from avoidable harm;**
- **They will be honest and open with patients regardless of the consequences for themselves;**

- **Where they are unable to provide the assistance a patient needs, they will direct them where possible to those who can do so;**
- **They will apply the NHS values in all their work.**

Accepted.

The *NHS Constitution*⁴ already addresses some of the issues highlighted in this recommendation, and when it is next updated the Department of Health will consult with stakeholders on how to best reflect other issues.

We agree that staff should be honest and open with patients, and the Constitution already makes clear that these are staff responsibilities. The Constitution also includes an expectation that staff will raise concerns early, in the public interest about risk, malpractice or wrongdoing (such as a risk to patient safety, fraud, or breaches of patient confidentiality) and a pledge that their employer will support staff to raise these concerns and act upon them. In addition, we are introducing a statutory duty of candour on all health providers, making it a requirement for them to be open and honest where there have been failings in care (see recommendations 174 and 181 for more on our response about openness and candour).

We agree with the principle that patients should come first in everything the NHS does, and this is explicitly stated in the Constitution. We do not propose to include the more explicit wording '*staff put patients before themselves*' suggested by the Inquiry, as we have heard concerns from stakeholders that such an expectation may also have a negative impact on staff safety and wellbeing.

The Constitution also already states that its values should underpin everything the NHS does.

We agree with the importance of protecting patients from avoidable harm. The Constitution already includes an expectation that staff will raise concerns early, such as a risk to patient safety; however, there is scope to further reflect the issue of staff protecting patients from avoidable harm. More broadly, as part of their code of conduct, regulated healthcare professionals already have a duty to comply with standardised procedures that protect patients from avoidable harm. Other work to help protect patients from avoidable harm includes introducing the new fundamental standards of care which will set out the level below which care should not fall (refer to the responses to recommendations 13-18 for more information), and ensuring that the NHS takes a zero tolerance approach to all healthcare associated infections (refer to the response to recommendation 107 for more information).

When the Constitution and the *Handbook to the NHS Constitution*⁵ are next updated, the Department of Health will consider, in consultation with stakeholders, how best to further reflect the importance of staff:

- protecting patients from avoidable harm
- directing patients to other sources of assistance, in situations where they themselves are unable to help.

4 <http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/2013/the-nhs-constitution-for-england-2013.pdf>

5 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170649/Handbook_to_the_NHS_Constitution.pdf

Recommendation 6

The handbook of the NHS Constitution should be revised to include a much more prominent reference to the NHS values and their significance.

Accepted.

The Department of Health has already taken action to reflect this recommendation in the *Handbook to the NHS Constitution*.⁶

As noted in the response to recommendation 4, the *NHS Constitution*⁷ sets out the following values for the NHS:

Working together for patients

- Respect and dignity
- Commitment to quality of care
- Compassion
- Improving lives
- Everyone counts

The Constitution provides more information about these values, and the Department included an explanation of these values in the handbook when it was updated in March 2013.

Recommendation 7

All NHS staff should be required to enter into an express commitment to abide by the NHS values and the Constitution, both of which should be incorporated into the contracts of employment.

Accepted in principle.

It is important that employers are able to recruit and retain the caring and compassionate staff the NHS needs. NHS Employers will support NHS organisations in developing and strengthening local policies and guidance so that there is a clear link between the values in the NHS Constitution and their own local values.

The Department of Health will commission NHS Employers to support NHS organisations in strengthening local policies on appraisal and performance management are strengthened so that there is a clear line of sight between the NHS values, the Constitution and performance and appraisal systems.

Steps have already been taken to improve performance and appraisal systems and agreement has been reached that, with effect from March 2013, pay progression will be linked more strongly to performance for the 1.1 million staff on Agenda for Change pay, terms and conditions. The agreement makes clear that:

- Employers must reference the NHS Constitution in local performance arrangements;

6 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170649/Handbook_to_the_NHS_Constitution.pdf

7 <http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/2013/the-nhs-constitution-for-england-2013.pdf>

- Knowledge and experience are not the *only* factors which employers should consider when they develop local performance standards;
- Employers now have the flexibility to consider not only what staff do for patients, but how they care for patients, encouraging the right behaviours and values.

Staff appraisal is a critical part of staff performance and should be used to hold staff to account on how their behaviour demonstrates the values of the NHS and/or their organisation. The evidence shows that where staff performance is regularly and effectively reviewed, outcomes for patients are better.

Recommendation 8

Contractors providing outsourced services should also be required to abide by these requirements and to ensure that staff employed by them for these purposes do so as well. These requirements could be included in the terms on which providers are commissioned to provide services.

Accepted.

The NHS Standard Contract requires all providers to have regard to the *NHS Constitution*⁸. NHS England will strengthen this requirement in respect of subcontractors in future.

The care patients receive should reflect NHS core values, as outlined in the Constitution, regardless of whether staff have been externally contracted. NHS commissioners are committed to ensuring core values permeate provider organisations and the wider system.

By December 2013, NHS England will amend the NHS Standard Contract for 2014–15 to require providers to ensure their subcontractors fully understand, and abide by, the importance of the Constitution.

NHS England will also include an equivalent requirement in November 2013 in standard contracts for commissioning support services. This will ensure the values outlined in the Constitution extend beyond providers of services through the wider system.

8 <http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/2013/the-nhs-constitution-for-england-2013.pdf>

Fundamental standards of behaviour

The Inquiry emphasised the need for a commitment to standards which should be applied by those who work in the healthcare system. It also recommended that the NHS Constitution should set out relevant professional and managerial codes, along with an expectation that staff follow guidance and comply standards relevant to their work.

The Constitution already sets out a legal duty for staff *to 'accept professional accountability and maintain the standards of professional practice as set by the appropriate regulatory body applicable to your profession or role'* and the Department of Health will further consider how to appropriately reflect the issue of standards and guidance in the NHS Constitution and its Handbook when they are next updated.

Recommendation 9

The NHS Constitution should include reference to all the professional and managerial codes by which NHS staff are bound, including the Code of Conduct for NHS Managers.

Accepted in principle.

We support the principle of making clear which codes staff are expected to follow. However, as the *NHS Constitution*⁹ is intended to be a succinct and enduring document, the details of codes are more appropriately set out in the *Handbook to the NHS Constitution*¹⁰ rather than the Constitution.

The Constitution already includes a duty for staff *'to accept professional accountability and maintain the standards of professional practice as set by the appropriate regulatory body applicable to your profession or role'*. The handbook, which provides more detailed guidance on each of the rights, pledges and responsibilities included in the Constitution, sets out the relevant professional bodies but does not currently reference the relevant codes of these bodies nor any managerial codes.

When the Constitution is next updated, the Department of Health will consider how best to reflect in the Handbook the codes of conduct including the relevant professional and managerial codes, by which NHS staff are bound at that time.

9 <http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/2013/the-nhs-constitution-for-england-2013.pdf>

10 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170649/Handbook_to_the_NHS_Constitution.pdf

Recommendation 10

The NHS Constitution should incorporate an expectation that staff will follow guidance and comply with standards relevant to their work, such as those produced by the National Institute for Health and Clinical Excellence and, where relevant, the Care Quality Commission, subject to any more specific requirements of their employers.

Accepted in principle.

The *NHS Constitution*¹¹ already sets out a legal duty for staff to ‘accept professional accountability and maintain the standards of professional practice as set by the appropriate regulatory body applicable to your profession or role’. This includes having regard to the relevant guidance or regulations of their regulatory bodies, and applies to staff in regulated professions. However, the Constitution does not include an expectation that all staff (whether in a regulated profession or not) should follow guidance and standards relevant to their work, nor does the existing provision in the Constitution encompass standards and guidance produced by non-regulatory organisations to which staff may be expected to have regard.

When the Constitution is next updated, the Department of Health will therefore consult on how best to reflect an expectation that staff will have regard to guidance, standards and codes that are relevant to their role. The Department will also consider how to reflect this issue in the *Handbook to the NHS Constitution*.¹²

Recommendation 11

Healthcare professionals should be prepared to contribute to the development of, and comply with, standard procedures in the areas in which they work. Their managers need to ensure that their employees comply with these requirements. Staff members affected by professional disagreement about procedures must be required to take the necessary corrective action, working with their medical or nursing director or line manager within the trust, with external support where necessary. Professional bodies should work on devising evidence-based standard procedures for as many interventions and pathways as possible.

Accepted.

Where there is good evidence that standardised procedures minimise risk and promote safer care, then it is the responsibility of healthcare staff to comply with these. Healthcare professionals are obliged by their professional code of conduct to comply with local standardised procedures and employers and line managers should take responsibility for addressing non-compliance.

The Department of Health is drawing up a new set of fundamental standards of care that will sit within the legal requirements that providers of health and adult social care must meet to be registered with the Care Quality Commission. Fundamentals of care will be set out in regulations, supplemented by guidance about compliance developed by the Care Quality

11 <http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/2013/the-nhs-constitution-for-england-2013.pdf>

12 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170649/Handbook_to_the_NHS_Constitution.pdf

Commission, and will also signpost guidance produced by the National Institute for Health and Care Excellence and others. Many of the fundamental standards of care will include human rights dimensions, for example, they will (subject to Parliamentary approval) confer on providers a duty to, among other things, treat people with dignity and respect, protect them from abuse, involve them in their care, and look after their care and welfare. The fact that fundamental standards of care will cover issues also protected by human rights mean that patients and other service users will have additional protection to that which already exists under the Human Rights Act 1998 and equality legislation.

NHS England has agreed with the National Institute for Health and Care Excellence that the Inquiry's concept of enhanced standards will be in the form of the existing quality standards, which are developed by National Institute for Health and Care Excellence and endorsed by NHS England. Commissioners will be expected to ensure compliance with these.

In terms of input by professional bodies, the Academy of Royal Medical Colleges and Faculties have always taken an active leadership role in setting clinical service delivery standards. The Academy of Royal Medical Colleges and Faculties is working with the Care Quality Commission and the National Institute for Health and Care Excellence on how professional bodies will contribute to the development of standards and compliance measures and through this work, the Academy of Royal Medical Colleges and Faculties will make a significant contribution to consistency of patient experience, patient safety and clinical efficiency.

Recommendation 12

Reporting of incidents of concern relevant to patient safety, compliance with fundamental standards or some higher requirement of the employer needs to be not only encouraged but insisted upon. Staff are entitled to receive feedback in relation to any report they make, including information about any action taken or reasons for not acting.

Accepted.

The Government agreed in its response to the Inquiry, *Patients First and Foremost*, that clear accountability for Trust Boards is essential so that they understand their responsibilities to patients. This includes a regard to patient safety and fundamental standards.

The Care Quality Commission will develop and inspect against the fundamental standards, of which patient safety will be an essential component. NHS England is committed to working with the Care Quality Commission on developing a shared and agreed approach to measuring safety in the NHS (both for regulatory and improvement purposes) and is actively in discussion with the Care Quality Commission on the patient safety measures, including incident reporting, best suited for use in their surveillance model and how NHS England can contribute to this.

'Patient safety incidents reported' is also one of the overarching indicators in Domain 5 of the NHS Outcomes Framework and describes the readiness of the NHS to report harm and learn from it. Therefore, it is important that staff receive feedback on any concerns they raise about patient safety including via local incident reporting systems. At a national level, NHS England will re-commission the National Reporting and Learning System to improve its functionality,

uses and benefits. This will also aim to strengthen reporting and learning from the most serious incidents, with quicker notification and feedback of the relevant lessons learnt, and with more efficient mechanisms for distributing incident reports to relevant organisations, such as clinical commissioning groups, the Care Quality Commission, Monitor, the National Trust Development Authority and the Medicines and Healthcare products Regulatory Agency.

A common culture made real throughout the system – an integrated hierarchy of standards of service

Among the negative aspects of culture in the system that the Inquiry identified were: misplaced assumptions in organisations about the judgements and actions of others; an acceptance of poor standards; and a failure to put the patient first in everything that is done. To remedy this, the Inquiry recommended a change in culture, with a relentless focus on patients' interests, keeping patients safe, with no tolerance of substandard care. Frontline staff needed to be empowered to act to achieve this, and in order for them to be empowered to do so, they need strong and stable leadership. As a key means of enabling this, The Inquiry recommended the introduction of a set of readily accessible standards that providers must comply with, and readily accessible means of complying with those standards.

In response to these recommendations, the Department of Health, the National Institute for Health and Care Excellence, NHS England and the Care Quality Commission are working together on a new framework of standards. New regulations, upon which the Department will consult widely, will set out fundamental standards of care that will come into effect during 2014. Through its Chief Inspectors, the Care Quality Commission is engaging with providers, professionals and the public on what guidance it should publish on complying with these regulations, and how they should relate to the Care Quality Commission's broader assessments of the quality of services. The new fundamental standards of care will give a clearer focus on governance requirements, which will be reflected in the Care Quality Commission's new approach to inspection.

THE NATURE OF STANDARDS

Recommendation 13

Standards should be divided into:

- **Fundamental standards of minimum safety and quality – in respect of which non-compliance should not be tolerated. Failures leading to death or serious harm should remain offences for which prosecutions can be brought against organisations. There should be a defined set of duties to maintain and operate an effective system to ensure compliance.**
- **Enhance quality standards – such standards could set requirements higher than the fundamental standards but be discretionary matters for commissioning and subject to availability of resources;**

- **Developmental standards which set out longer term goals for providers – these would focus on improvements in effectiveness and are more likely to be the focus of commissioners and progressive provider leadership than the regulator.**

All such standards would require regular review and modification.

Accepted.

The Department of Health, the National Institute for Health and Care Excellence, NHS England and the Care Quality Commission are working on a new framework of standards. New regulations setting out fundamental standards of care will come into effect during 2014, and will apply to all providers of health and social care required to register with the Care Quality Commission. Through its Chief Inspectors, the Care Quality Commission is engaging with providers, professionals and the public on what guidance it should publish on complying with these regulations and how they should relate to the Care Quality Commission's broader assessments of the quality of health and care services.

In *Patients First and Foremost*¹³ the Government confirmed that the Care Quality Commission would work with stakeholders to draw up a set of simpler fundamental standards that would make explicit the basic standards, and set a clear bar below which care should never fall. In June 2013, the Care Quality Commission issued *A new start – Consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care*.¹⁴ This document started the public discussion on what the fundamental standards of care should be. On 17 October 2013, the Care Quality Commission published the responses to the consultation in *A new start: Responses to our consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care services*,¹⁵ which showed that there is broad agreement with the new approach. The Department will consult shortly on the draft regulations; these will set in legislation the fundamental standards of care as outcomes that providers must meet. The final set of standards is likely to cover areas such as: care and safety of patients and service users; abuse, including neglect; respecting and involving service users; nutrition; consent; governance; cleanliness and safety of premises and equipment; staffing; fitness of directors; and duty of candour.

The Care Quality Commission will issue succinct guidance on meeting the regulations' requirements, which it will take into account when considering prosecutions. This guidance will sit alongside the broader handbook that the Care Quality Commission will issue on how it decides ratings of providers and services.

The fundamental standards of care will be part of the regulatory system in their own right, alongside the Care Quality Commission's broader assessments of the overall quality of a provider's services. This will start initially in the hospital sector, but also alongside new Chief Inspectors of General Practice and Adult Social Care, who will extend and develop the approach for their respective sectors over time. The Care Quality Commission will keep

13 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170701/Patients_First_and_Foremost.pdf

14 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

15 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_newstartresponse_2013_14_tagged_sent_to_web.pdf

guidance for their sectors under review and will advise Ministers if changes to the regulations are needed.

The National Institute for Health and Care Excellence has an existing programme of production of quality standards that define what high quality care should look like in a defined care or service area. Topics in healthcare are referred by NHS England to the National Institute for Health and Care Excellence, and the National Institute for Health and Care Excellence provides guidance for commissioners to help them to commission for quality improvement within these areas. Enhanced quality standards are set out for commissioners in the National Institute for Health and Care Excellence quality standards, which in future will also specify developmental standards.

Recommendation 14

In addition to the fundamental standards of service, the regulations should include generic requirements for a governance system designed to ensure compliance with fundamental standards, and the provision and publication of accurate information about compliance with the fundamental and enhanced standards.

Accepted in principle.

The Department of Health will consult on regulations which introduce fundamental standards of care and a clearer focus on governance arrangements for complying with them. These will be reflected in the Care Quality Commission's new approach to inspection. The Care Quality Commission has powers to access any information that it deems necessary to carry out its functions, and through its checks on governance (including information governance), can assure that hospitals provide it with accurate information on how they are providing care that is safe, effective, caring, responsive and well-led. However, in order that the public can find information in one place, it is the Care Quality Commission rather than each provider that should publish information about providers' performance, which it will do via ratings. Placing this information with the Care Quality Commission will allow the public to make informed comparisons and decisions about the care provider they choose. The Care Quality Commission's ratings will report on overall quality, which will be broader than fundamental and enhanced standards.

The Care Quality Commission consulted over summer 2013 on what should be considered fundamental standards of care. The Department will consult on regulations which will set these fundamental standards in legislation. The final set of standards is likely to cover areas such as: care and safety of patients and service users; abuse, including neglect; respecting and involving service users; nutrition; consent; governance; cleanliness and safety of premises and equipment; staffing; fitness of directors; and duty of candour. In parallel with the Department's consultation on the regulations, the Care Quality Commission will consult on statutory guidance that it will take into account in enforcement, including prosecution, and issue a handbook to provide clarity on how it awards ratings. The regulations should come into force during 2014 and will also streamline and make clearer other requirements on providers, including governance arrangements for complying with fundamental standards.

The Care Quality Commission started implementing its new approach to hospital inspection in September 2013. The approach is based around judging five dimensions of quality, one of

which is how well-led a service is. This includes the governance and leadership of culture of the service. In December 2013 the Care Quality Commission will set out information in more detail in guidance, so that there is transparency in how it will rate acute hospitals. This will build on the proposals in *A new start – Consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care*¹⁶ by providing more detail on:

- what the five questions that the Care Quality Commission inspects* will cover
- the definition of each level of the rating scale (outstanding, good, requires improvement inadequate)
- key lines of enquiry that will always be followed to ensure consistent ratings
- indicators and data that contribute to the rating, and any methods or rules for aggregating them
- how judgements are made from inspection findings and data, to place a provider in a ratings band.

New Chief Inspectors of General Practice and Adult Social Care took up post at the Care Quality Commission in October 2013. They will spearhead the extension and development of the new inspection approach that has started in hospitals, to their respective sectors, and together will ensure that the Care Quality Commission is providing assurance that health and adult social care services join up seamlessly from the perspective of people who use services. The Deputy Chief Inspector of Mental Health will report to the Chief Inspector of Hospitals on how this applies to mental health services.

*Is the service safe? Is the service effective? Is the service caring? Is the service responsive? Is the service well-led?

Recommendation 15

All the required elements of governance should be brought together into one comprehensive standard. This should require not only evidence of a working system but also a demonstration that it is being used to good effect.

Accepted in principle.

The Department of Health will consult on new regulations which introduce fundamental standards of care and a clearer focus on governance arrangements for complying with them. The Care Quality Commission will consult on and issue guidance for providers, which will cover all elements of governance covered by the new regulations. Subject to consultation and Parliament, the regulations will be put in place during 2014 and then implemented progressively in all sectors.

In June 2013, the Care Quality Commission issued *A new start – Consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care*.¹⁷ This set out proposals to assess providers and services with regard to five key questions, one of which is whether the service is well-led. Being well-led particularly concerns the culture, leadership and governance of the service and the provider. On 17 October 2013, the Care

16 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

17 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

Quality Commission published the responses to the consultation in *A new start: Responses to our consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care services*,¹⁸ which showed that there is broad agreement with the new approach.

The Care Quality Commission has introduced a new approach to inspection, including making judgements on five dimensions of quality*, one of which is how well-led a service is. This includes the effectiveness and existence of governance systems. The Care Quality Commission is working with Monitor, the NHS Trust Development Authority and NHS England to ensure that there is a single, coherent approach to oversight of governance. This will result in a single aligned framework for monitoring governance, coherent across all the elements of governance which are covered variously by the Care Quality Commission, NHS Trust Development Authority, Monitor or NHS England's areas of responsibility.

*Is the service safe? Is the service effective? Is the service caring? Is the service responsive to people? Is the service well-led?

RESPONSIBILITY FOR SETTING STANDARDS

Recommendation 16

The Government, through regulation, but after so far as possible achieving consensus between the public and professional representatives, should provide for the fundamental standards which should define outcomes for patients that must be avoided. These should be limited to those matters that it is universally accepted should be avoided for individual patients who are accepted for treatment by a healthcare provider.

Accepted.

The Department of Health will shortly consult on new regulations that will provide for fundamental standards of care. The final set of standards is likely to cover areas such as: care and safety of patients and service users; abuse, including neglect; respecting and involving service users; nutrition; consent; governance; cleanliness and safety of premises and equipment; staffing; fitness of directors; and duty of candour. The consultation will include engagement events with professionals and the public to ensure that a wide a spectrum of views is collected. Subject to Parliament, these will come into force during 2014.

In *Patients First and Foremost*¹⁹ the Government confirmed that the Care Quality Commission would work with stakeholders to draw up a set of simpler fundamental standards to make explicit the basic standards and set a clear bar below which care should never fall. In June 2013, the Care Quality Commission issued *A new start – Consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care*.²⁰ This document started the public discussion on what the fundamental standards of care should be. The consultation

18 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

19 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170701/Patients_First_and_Foremost.pdf

20 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

engaged 5,154 individuals and 4,500 organisations, plus 41 consultation events. Respondees included the medical and nursing Royal Colleges and the Nursing and Midwifery Council. The professional bodies were also part of a stakeholder advisory group with the Care Quality Commission. On 17 October 2013, the Care Quality Commission published the responses to the consultation in *A new start: Responses to our consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care services*,²¹ which showed that there is broad agreement with the new approach. The Department is using the responses to this consultation to develop its new draft regulations.

Through the Chief Inspector of Hospitals, the Care Quality Commission will consult on guidance for hospital providers on how they should comply with the requirements in the regulations. In December 2013 the Care Quality Commission will set out information in more detail in guidance, so that there is transparency in how it will rate acute hospitals. This will build on the proposals in *A new start*²² by providing more detail on:

- what the five questions that the Care Quality Commission inspects* will cover
- the definition of each level of the rating scale (outstanding, good, requires improvement inadequate)
- key lines of enquiry that will always be followed to ensure consistent ratings
- indicators and data that contribute to the rating, and any methods or rules for aggregating them
- how judgements are made from inspection findings and data, to place a provider in a ratings band.

While the focus is on hospital services in the first instance, new Chief Inspectors of General Practice and Adult Social Care, who took up post in the Care Quality Commission in October 2013, will extend and develop guidance on the regulations for providers in their respective sectors. The Deputy Chief Inspector of Mental Health will report to the Chief Inspector of Hospitals on how this applies to mental health services. Together they will ensure that the Care Quality Commission is providing assurance that health and adult social care services join up seamlessly from the perspective of people who use services.

*Is the service safe? Is the service effective? Is the service caring? Is the service responsive? Is the service well-led?

Recommendation 17

The NHS Commissioning Board together with clinical commissioning groups should devise enhanced quality standards designed to drive improvement in the health service. Failure to comply with such standards should be a matter for performance management by commissioners rather than the regulator, although the latter should be charged with enforcing the provision by providers of accurate information about compliance to the public.

21 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

22 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

Accepted in principle.

NHS England and clinical commissioning groups will have regard to enhanced quality standards in the way they commission services, and the Care Quality Commission will use them to inform their ratings of providers.

NHS England will work with clinical commissioning groups to use enhanced quality standards to drive improvements in the health service. NHS England has agreed with the National Institute for Health and Care Excellence that the concept of enhanced standards is represented by the existing quality standards, developed by National Institute for Health and Care Excellence and endorsed by NHS England. Compliance with these standards should indeed be a matter for commissioners rather than the regulator. NHS England is currently required in legislation to have regard to quality standards, and clinical commissioning groups are required to do the same through NHS England's planning guidance.

The Care Quality Commission will use enhanced quality standards to inform its quality ratings of providers. In line with recommendation 13, where there are emergent evidence-based technologies with the potential to drive widespread improvements, the National Institute for Health and Care Excellence will also include developmental standards within quality standards.

As outlined in the response to recommendation 249, providers are required to publish a Quality Account each year, providing accurate information on their performance in relation to quality standards. NHS England will review Quality Accounts before the 2014–15 cycle to ensure that they give patients appropriate information on the services they use, and that they add value to the quality assurance infrastructure used by trusts, local and national organisations.

Recommendation 18

It is essential that professional bodies in which doctors and nurses have confidence are fully involved in the formulation and in the means of measuring compliance.

Accepted.

The Care Quality Commission is taking steps to ensure that stakeholders, particularly including professional bodies, are fully involved in designing and developing its new approach to inspection. The Care Quality Commission's new approach to inspecting hospitals involves large teams of specialists as well as patient experts. The Care Quality Commission is working with medical and nursing Royal Colleges to resource the inspection teams. These teams give professionals a key role in how a hospital's quality of care is assessed.

The Care Quality Commission has consulted extensively on its new approach to inspection. The consultation engaged 5,154 individuals and 4,500 organisations, plus 41 consultation events. Professional bodies, and individual professionals, have been prominent contributors to these. On 17 October 2013, the Care Quality Commission published the responses to the consultation in *A new start: Responses to our consultation on changes to the way the Care*

Quality Commission regulates, inspects and monitors care services,²³ which showed that there is broad agreement with the new approach.

The Care Quality Commission is undertaking further work to deepen the engagement of professional bodies in developing its new approach, and in particular medical, nursing and midwifery Royal Colleges. Memoranda of understanding are in development with all of these bodies, covering collaboration in:

- resourcing inspection teams;
- developing standards and expectations of 'what good looks like' in different services; and
- recognising accreditation schemes where that can encourage achievement of best practice standards and avoid duplicated inspection.

23 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_newstartresponse_2013_14_tagged_sent_to_web.pdf

Responsibility for, and effectiveness of, healthcare standards

The Inquiry found that the existing system for regulating the quality and safety of services resulted in overlapping functions that allowed one regulator to assume that another held responsibility to ensure compliance, when that was not necessarily the case. The Inquiry therefore recommended that there should be a single regulator to deal with corporate governance, financial competence, viability and compliance with patient safety and quality standards for all trusts. He also recommended concerning who should hold responsibility for regulating and monitoring compliance with fundamental standards of care, how information on compliance should be derived (for example from complaints, media coverage, patient safety alerts, quality and risk profiles) and how the sharing of information between regulators should be improved. The Inquiry also made a series of recommendations to make the Care Quality Commission more effective, such as by reviewing its processes to incorporate more of a patient perspective in its functions, and by adopting a clearer strategic vision. He also recommended zero tolerance of failures in quality of care.

In response to these recommendations, instead of transferring Monitor's powers to the Care Quality Commission, the Government is putting in place a series of measures to ensure clearly defined responsibilities for the Care Quality Commission, Monitor, and the NHS Trust Development Authority; this includes a new single failure regime. Subject to the passage of new regulations, in 2014 the Care Quality Commission will have new powers to prosecute a provider for failing to provide fundamental standards of care, without first having to issue a formal warning. The Government is seeking to legislate on sanctions where individuals or organisations are unequivocally guilty of wilful or reckless neglect or mistreatment of patients. This will help ensure there is ultimate accountability for those guilty of the most extreme types of poor care.

At local and regional levels, Quality Surveillance Groups bring together commissioners, regulators, local Healthwatch representatives and other bodies on a regular basis to share information and intelligence about quality across the system, including the views of patients and the public. Alongside the better use of information, measures of this kind will bring about more decisive and prompt action on the part of the regulators where they identify the need to intervene in how a provider operates.

GAPS BETWEEN THE UNDERSTOOD FUNCTIONS OF SEPARATE REGULATORS

Recommendation 19

There should be a single regulator dealing with both corporate governance, financial competence, viability and compliance with patient safety and quality standards for all trusts.

Not accepted, although we agree with the principle of a single regulatory process.

We agree with the principle that there should be a single regulatory process with clearly defined responsibilities across governance, finance and compliance with safety and quality standards. It is important that the system is able to identify and act quickly where there are potential risks to service users and, in ensuring this, that there are clear roles and responsibilities for all those involved in that process.

In *Patients First and Foremost* (2013) we stated that the Care Quality Commission, Monitor and the NHS Trust Development Authority would establish a single failure regime that would further clarify the separate functions of the Care Quality Commission and Monitor across health and social care. This will ensure that the role of inspecting Trusts is kept clearly separate from the responsibility for the turnaround of failing organisations, and there can be no conflict of interest in assessing quality. It also allows us to address, more fully, the Inquiry's concerns regarding the potential impact on the whole system of rapid changes to the quality regulator.

The Care Bill lays the framework for a simple, flexible process for tackling quality failures in NHS Trusts and Foundation Trusts. It will remain the primary responsibility of the board of a Trust, working with their commissioners, to ensure the provision of good quality care.

The Care Quality Commission will not exercise its enforcement powers, beyond issuing a new warning notice outlined in the Care Bill, in respect to Trusts unless patients and service users are at immediate risk of harm, in which case it will be able to act immediately. Where intervention is required it will be the role of Monitor (for Foundation Trusts) and the NHS Trust Development Authority (for NHS trusts) to take action. Ultimately, if it proves impossible for an NHS Trust or Foundation Trust to turn their performance around, the organisation may be placed into Trust special administration on quality grounds. Special administration will provide a framework for determining how best to secure a comprehensive range of high quality services that are both financially and clinically sustainable. In very serious cases, the Care Quality Commission (subject to Parliamentary approval) will have the power to prosecute a provider for a breach of fundamental standards of care.

The Care Quality Commission, Monitor and the NHS Trust Development Authority will work together to publish further guidance on how they work together to address risks to quality. This will include details of how concerns, including immediate concerns, will be addressed; how and when special measures and the single failure regime could be triggered; and what guidance and support would be made available to the public in the event of large scale, significant failure. This guidance will build on the joint policy statement, *The Regulation and oversight of NHS Trusts and Foundation Trusts* (May 2013) published by the Care

Quality Commission, Monitor, the NHS Trust Development Authority, NHS England and the Department of Health.

RESPONSIBILITY FOR REGULATING AND MONITORING COMPLIANCE

Recommendation 20

The Care Quality Commission should be responsible for policing the fundamental standards, through the development of its core outcomes, by specifying the indicators by which it intends to monitor compliance with those standards. It should be responsible not for directly policing compliance with any enhanced standards but for regulating the accuracy of information about compliance with them.

Accepted in part.

In June 2013 the Care Quality Commission issued *A new start – Consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care*.²⁴ Following this extensive consultation, in September 2013 it carried out its first new-style hospital inspections. The new approach to inspections is based on an overall view of quality and safety, divided into five domains, and includes ratings on each domain as well as overall ratings. This is a substantial change from the previous approach, which focused only on policing compliance with standards. The new-style inspections are underpinned by a published list of indicators, which formed part of the consultation. The inspection approach will include checking providers' governance arrangements, as necessary checking information governance, and the provider's ability to assure its performance information generally. The Care Quality Commission's ratings are also likely to consider specific enhanced standards, as the National Institute for Health and Care Excellence quality standards will be taken into account when awarding a rating, particularly at the 'good' and 'outstanding' levels.

However, it would not be appropriate for the Care Quality Commission to be responsible beyond this for regulating the accuracy of information about compliance with enhanced standards. By means of contract management, commissioners will have the specific lead responsibility for holding providers to account for the accuracy of information they provide on performance against enhanced standards. The Care Quality Commission's monitoring will look more broadly at the provider's capability to use information effectively for assurance and improvement, with an expectation that it will disclose relevant information fully and honestly.

Recommendation 21

The regulator should have a duty to monitor the accuracy of the information disseminated by providers and commissioners on compliance with standards and their compliance with the requirement of honest disclosure. The regulator must be willing to consider individual cases of gross failure as well as systemic causes for concern.

24 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

Accepted in principle.

The Care Quality Commission already has powers to require information and explanations, with failure to provide these or obstructing an inspector constituting an offence, and has started to put steps in place to improve its monitoring. The Care Quality Commission will not be wholly reliant on one information source; its new surveillance model, combined with the existing information resources available to it, will allow it to cross- refer concerns and build up a picture of care. It is also a condition of Monitor's licence that information provided to Monitor is accurate, complete and not misleading. Monitor can and has pursued cases where information provided to it has been inaccurate.

The Care Quality Commission has developed a new approach to monitoring hospitals' performance, which helps direct the timing and focus of inspection. It includes measures of data quality, which may prompt assessment of culture, leadership and governance and, within that, information governance. The Care Quality Commission has a strong key role in that area through its National Information Governance Committee. The Care Quality Commission's monitoring of hospitals includes a range of systemic indicators, such as outliers on different measures over time), and individual events (examples include reports from whistle blowers, safeguarding incidents, notifiable deaths and incidents). All of these are able to trigger interventions, including inspection.

The Care Quality Commission will consider further measures related to data quality as its new system for monitoring providers matures, in order continuously to improve its sensitivity to this aspect of quality of care. Taken together, therefore, the Care Quality Commission already take a range of robust approaches to assessing and verifying the extent to which providers are complying with standards; it is therefore unnecessary to impose a new duty on it.

Recommendation 22

The National Institute for Health and Clinical Excellence should be commissioned to formulate standard procedures and practice designed to provide the practical means of compliance, and indicators by which compliance with both fundamental and enhanced standards can be measured. These measures should include both outcome and process based measures, and should as far as possible build on information already available within the system or on readily observable behaviour.

Accepted in principle.

A range of guidance, indicators and measures will be provided to support the implementation of quality standards. Guidance, technology appraisals and standards provided by the National Institute for Health and Care Excellence make an essential and key contribution to how the Care Quality Commission assesses the quality of NHS services, alongside bodies accredited by the National Institute for Health and Care Excellence and other appropriate sources of guidance and standards. The National Institute for Health and Care Excellence, the Care Quality Commission and NHS England will work together on the objective of ensuring that authoritative guidance is available on fundamental and enhanced standards. The National Institute for Health and Care Excellence already develops indicators to go alongside quality standards, and the National Institute for Health and Care Excellence and NHS England develop tools to support commissioners in commissioning for quality.

The Department of Health will shortly consult on new regulations that will set out fundamental standards of care. The Care Quality Commission will then consult on sector-specific statutory guidance for providers that it will take into account when enforcing those regulations, including prosecution, and how it decides a rating. In this guidance the Care Quality Commission will signpost guidance and measures by the National Institute for Health and Care Excellence and other appropriate bodies.

Recommendation 23

The measures formulated by the National Institute for Health and Clinical Excellence should include measures not only of clinical outcomes, but of the suitability and competence of staff, and the culture of organisations. The standard procedures and practice should include evidence-based tools for establishing what each service is likely to require as a minimum in terms of staff numbers and skill mix. This should include nursing staff on wards, as well as clinical staff. These tools should be created after appropriate input from specialities, professional organisations, and patient and public representatives, and consideration of the benefits and value for money of possible staff:patient ratios.

Accepted.

The Department of Health have therefore tasked the National Institute for Health and Care Excellence to set out authoritative, evidence-based guidance on safe staffing. By Summer 2014, the National Institute for Health and Care Excellence will have produced guidance on safe staffing in acute settings, including its view of existing staffing tools. This initial phase will be followed by further work to develop full accreditation of staffing tools against the evidence-based guidance, and work on safe staffing in non-acute settings, including mental health, community services and learning disability. The focus of the work will be nursing and maternity staffing levels, but it will also take into account the importance of getting skill mix right and the wider context of other workforce groups, along with the importance of multi-disciplinary working in modern healthcare.

The work led by the National Institute for Health and Care Excellence will be driven by an independent advisory committee for staffing. This will consider the evidence and draft the guidance, but it will also be able to signal the need for changes to existing tools where the evidence clearly indicates that there is an urgent need for them to be updated.

Ahead of the work being undertaken by the National Institute for Health and Care Excellence, the National Quality Board is publishing alongside this response a guidance document that sets out the current evidence on safe staffing and makes clear the immediate expectations on all NHS bodies what they must do to ensure that every ward and every shift has the staff needed to ensure that patients receive safe care.

NHS Trusts should therefore, from today, take account of the guidance issued by the National Quality Board. They should follow this advice until guidance developed by the National Institute for Health and Care Excellence advisory committee for staffing is rolled-out from Spring 2014.

The guidance issued by the National Institute for Health and Care Excellence is not expected to include absolute staffing ratios given the inflexibility of such an approach, and the potential risks and disadvantages that the rigid application of ratios could have for patient care. The guidance will, however, provide an evidenced, authoritative basis for staffing decisions. The National Institute for Health and Care Excellence, NHS England, Health Education England and other national organisations will work together to ensure that NHS Trusts have the tools they need to make decisions to secure safe staffing; and these decisions will then be subject to external scrutiny and challenge by commissioners, regulators and the public, and inspection by the Chief Inspector of Hospitals.

Recommendation 24

Compliance with regulatory fundamental standards must be capable so far as possible of being assessed by measures which are understood and accepted by the public and healthcare professionals.

Accepted.

The Care Quality Commission has consulted on fundamental standards of care, which the Department of Health will reflect in regulations. The Care Quality Commission will engage with the public, providers and professionals to develop guidance that makes clear what it will take into account when enforcing the regulations, and prepare a handbook on how it awards ratings.

In June 2013, the Care Quality Commission issued *A new start – Consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care*.²⁵ This document started the public discussion on what the fundamental standards of care should be. The consultation engaged 5,154 individuals and 4,500 organisations, and held 41 consultation events. On 17 October 2013, the Care Quality Commission published the responses to the consultation in *A new start: Responses to our consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care services*.²⁶ which showed that there is broad agreement with the new approach.

The Department of Health will shortly consult on the draft regulations; these will set in legislation the fundamental standards of care as outcomes that must be avoided; they will also streamline and improve the clarity of requirements that must be positively achieved in order for a provider to register with the Care Quality Commission (these requirements were called 'expected standards' in its consultation.) Subject to Parliament, the regulations will come into force during 2014.

While the focus is on hospital services in the first instance, in October 2013 new Chief Inspectors of General Practice and Adult Social Care took up post in the Care Quality Commission, and it will extend and develop guidance on the regulations for providers into all three of the Chief Inspectors' respective sectors. The Deputy Chief Inspector of Mental Health will report to the Chief Inspector of Hospitals on how this applies to mental health services.

25 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

26 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_newstartresponse_2013_14_tagged_sent_to_web.pdf

The three Chief Inspectors will engage the public, professionals and providers in developing guidance for all sectors. Attention will be given to how the fundamental standards of care are presented to the public, in particular so as to clarify the relationship to rights under the NHS Constitution and consumer rights.

Many of the fundamental standards of care will include human rights dimensions, for example, subject to Parliamentary approval, they will confer a duty on providers to, among other things, treat people with dignity and respect, protect them from abuse, involve them in their care, and look after their care and welfare. The fact that fundamental standards of care will cover issues also protected by human rights means that patients and other service users will have additional protection to that which already exists under equality legislation and the Human Rights Act 1998.

Recommendation 25

It should be considered the duty of all specialty professional bodies, ideally together with the National Institute for Health and Clinical Excellence, to develop measures of outcome in relation to their work and to assist in the development of measures of standards compliance.

Accepted.

The Academy of Royal Medical Colleges and Faculties are committed to delivering consistent and high quality patient experiences and outcomes and will continue to support the design, implementation and review of clinical standards and the processes for assuring their use. The Academy will do this in a patient-focused way and in conjunction with key partners. The Academy of Royal Medical Colleges and Faculties have always taken an active leadership role in setting clinical service delivery standards. In addition, with individual Royal College and Faculty activity such as accreditation schemes and invited reviews and the Academy's membership of the National Institute for Health and Care Excellence's Implementation Collaborative, involvement in assuring compliance with clinical standards is continuing to strengthen.

In response to the Inquiry, the Academy and the National Institute for Health and Care Excellence are also working to agree and implement how medical and other Colleges will contribute to the development of outcomes measures. For example, on staff suitability and competence; evidence based tools for establishing what each service is likely to require as a minimum in terms of staff numbers and skill mix; and measures of standards compliance.

The Care Quality Commission will look at the implementation of the National Institute for Health and Care Excellence clinical and other guidelines as part of their inspection process and there is a move to greater transparency of clinical outcomes – NHS England has for the first time published clinical outcomes by consultant for ten medical specialties and has also begun to publish data on the friends and family test.

Recommendation 26

In policing compliance with standards, direct observation of practice, direct interaction with patients, carers and staff, and audit of records should take priority over monitoring and audit of policies and protocols. The regulatory system should retain the capacity to undertake in-depth investigations where these appear to be required.

Accepted.

In *A new start – Consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care*,²⁷ the Care Quality Commission consulted on new approaches to inspection which fully reflect this recommendation. On 17 October 2013, it published the responses to the consultation in *A new start: Responses to our consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care services*,²⁸ which showed that there is broad agreement with the new approach. It has appointed a Chief Inspector of Hospitals to take the new approaches forward, starting in acute hospitals, but also alongside new Chief Inspectors of General Practice and Adult Social Care, who will extend and develop the approaches for their respective sectors over time. The Deputy Chief Inspector of Mental Health will report to the Chief Inspector of Hospitals on how this applies to mental health services.

The first of new hospitals inspections have already begun, and the Care Quality Commission is reviewing its approach to carrying out investigations in light of its new inspection methodology, the single failure regime and the learning from its report of its own regulatory process at University Hospital of Morecambe Bay.

Through the use of larger inspection teams and longer inspection visits, the Care Quality Commission inspections now include more observation of care and contact with patients and staff. The use of specialist inspectors means a stronger focus on practice and case note review. A key part of the new inspection is to hold 'listening events' prior to each inspection to inform the focus of the inspection. The overall focus on quality, rather than regulations, means far less emphasis on checking policies and procedures.

The Care Quality Commission's large, specialist inspection teams, and their focus on the delivery and experience of services rather than only on compliance with regulations, means that the new inspections are able to include in-depth investigation of individual providers.

The Care Quality Commission also has a specific power of investigation which can cover providers, services across providers, and commissioners. The Care Quality Commission is reviewing its approach to using this power.

Recommendation 27

The healthcare systems regulator should promote effective enforcement by: use of a low threshold of suspicion; no tolerance of non-compliance with fundamental standards; and allowing no place for favourable assumptions, unless there is evidence

27 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

28 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_newstartresponse_2013_14_tagged_sent_to_web.pdf

showing that suspicions are ill-founded or that deficiencies have been remedied. It requires a focus on identifying what is wrong, not on praising what is right.

Accepted.

The Care Quality Commission's new approach to inspection includes clearly recognising and encouraging high quality care through ratings which will highlight outstanding practice. But where it identifies concerns, the Care Quality Commission will also have the ability to act swiftly and firmly on it.

The Department of Health will consult shortly on new regulations which will make clearer the fundamental standards of care, and enable enforcement against them without a prior warning notice. Subject to Parliamentary approval, the regulations will come into force during 2014. The Care Quality Commission will consult on a new enforcement policy for all sectors, making clear how any breach of the fundamental standards of care will be acted upon, so that these new regulations can be enforced effectively as they come into effect. Through its policies, the Care Quality Commission will ensure its actions are as transparent and understandable to the public as possible, and that information is made available about providers subject to enforcement.

For NHS Trusts and NHS Foundation Trusts there is a single failure regime to ensure that the various means of holding NHS providers to account for failures of finance or governance are equally available for failures of quality. It ensures that the Chief Inspector of Hospitals' concerns trigger action by commissioners, the NHS Trust Development Authority or Monitor, rather than the Care Quality Commission acting alone. The action triggered includes credible strong sanctions, such as a managed process for placing a provider into administration and reconfiguring its services.

While this new approach to effective action in the NHS has already started, it will be further underpinned by legislation upon adoption of the Care Bill, currently before Parliament. The new legislation will strengthen the current administrative arrangements and give a statutory basis for the means by which, through the Chief Inspector, the Care Quality Commission refers a Foundation Trust to Monitor for intervention.

SANCTIONS AND INTERVENTIONS FOR NON-COMPLIANCE

Recommendation 28

Zero tolerance: A service incapable of meeting fundamental standards should not be permitted to continue. Breach should result in regulatory consequences attributable to an organisation in the case of a system failure and to individual accountability where individual professionals are responsible. Where serious harm or death has resulted to a patient as a result of a breach of fundamental standards, criminal liability should follow and failure to disclose breaches of these standards to the affected patient (or concerned relative) and a regulator should also attract regulatory consequences. Breaches not resulting in actual harm but which have exposed patients to a continuing risk of harm to which they would not otherwise have been exposed should also be regarded as unacceptable.

Accepted.

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

The Care Quality Commission has clear legal powers to take swift and decisive action if patients are at immediate risk of harm, ensuring that the service or ward in question is closed immediately until the risk is addressed. New fundamental standards will be introduced which will set the level below which standards of care should not fall. Where the Care Quality Commission finds an NHS Trust or Foundation Trust to be failing systematically, for example with serious or repeated breaches of the fundamental standards, it will issue a warning notice requiring the provider to improve within a fixed period. If problems persist, the NHS Trust Development Authority, for an NHS Trust, or Monitor, for an NHS Foundation Trust will intervene. Levels of service performance and standards of care quality form part of Monitor's regular risk assessment of Foundation Trusts including the Care Quality Commission judgements on the quality of care provided. Monitor also expects licence holders to notify them in the event of any incident, event or report that may raise potential concerns over compliance with the licence. Breaches of licence conditions will attract enforcement action that can range from informal action, imposition of special licence conditions, removal or suspension of directors and revoking provider's licence.

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

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

The Department of Health will revise the requirements for registration with the Care Quality Commission so that they will include fundamental standards. Under the revised registration requirements the intention is that it will be possible to prosecute providers in the most serious

cases of poor care without the need for an advance warning notice. These new powers will build on and be compatible with powers already provided to the Care Quality Commission under the provisions of the Mental Health Act 1983 (as updated and amended by the Mental Health Act 2007) and supported by the Code of Practice to the Mental Health Act 2012 to monitor the use of the Mental Health Act and protect the interests of people whose rights are restricted under that Act.

For individual healthcare providers, Monitor and the NHS Trust Development Authority have a range of intervention powers. For example, Monitor is able to remove, suspend or replace NHS Foundation Trusts' Governors or Directors. The NHS Trust Development Authority is able to remove Directors in NHS Trusts. The Department has also consulted on proposals that will allow the Care Quality Commission to hold Board members to account for the provision of poor care, which could result in them being removed from their posts. The Care Quality Commission does not have the power to take action against individuals. However, in instances where an individual is found to have caused death or serious harm, existing legislation can be used by the appropriate authority to hold them to account, as has happened with staff who were charged with neglect or ill-treatment at Winterbourne View. In addition, the Government agrees with Professor Don Berwick's recommendation that there should be legal sanctions where individuals or organisations are guilty of wilful neglect or mistreatment of patients. This will help ensure there is ultimate accountability for those guilty of the most extreme types of poor care. The Government will seek to legislate on this, and will work with stakeholders beforehand to determine the details of this measure, and will consult on proposals for legislation as soon as possible.

Professional regulators can take a decision to remove clinical practitioners through the fitness to practice processes. The Nursing and Midwifery Council has responded to say that it will undertake a comprehensive review of its current Code in the light of the recommendations in the Inquiry report to explore how key messages can be strengthened and developed. This will include ensuring that a duty to comply with any relevant national fundamental standards is addressed in the revised Code. The General Medical Council is undertaking a programme to reform its fitness to practice processes including speeding up investigations work, modernising and streamlining the adjudication procedures and strengthening confidence in the independence of its adjudication function. The latter has resulted in the launch of the Medical Practitioners Tribunal Service in June 2012.

Recommendation 29

It should be an offence for death or serious injury to be caused to a patient by a breach of these regulatory requirements, or, in any other case of breach, where a warning notice in respect of the breach has been served and the notice has not been complied with. It should be a defence for the provider to prove that all reasonably practical steps have been taken to prevent a breach, including having in place a prescribed system to prevent such a breach.

Accepted.

We agree that there should be serious consequences for any organisation that breaches basic quality standards in the provision of care.

In its response to the Inquiry, *Patients First and Foremost*, the Government committed to draw up a new set of fundamental standards of care that will sit within the legal requirements that providers of health and adult social care must meet to be registered with the Care Quality Commission. The fundamental standards of care set a clear bar below which standards of care should not fall and focus on the very basics of care that matter to people and will be easily understood by all. These fundamental standards will be consulted on soon, and further details of this are set out in recommendation 13.

There will be immediate, serious consequences for services where care falls below these standards. Subject to the passage of regulations, the Care Quality Commission will have new powers during 2014, including the ability to prosecute a provider for failing to provide fundamental levels of care, without having to issue a formal warning first. See recommendation 28 for further details.

INTERIM MEASURES

Recommendation 30

The healthcare regulator must be free to require or recommend immediate protective steps where there is reasonable cause to suspect a breach of fundamental standards, even if it has yet to reach a concluded view or acquire all the evidence. The test should be whether it has reasonable grounds in the public interest to make the interim requirement or recommendation.

Accepted.

As part of the overall single failure regime (see recommendation 19) it is important that where the Care Quality Commission identify breaches of fundamental standards that it is able to act quickly. As such the Care Quality Commission will retain its ability to stop a service from providing care if it is putting people at immediate risk of harm as outlined by the *Health and Social Care Act 2008*. The Act states that where the Care Quality Commission has 'reasonable cause' to believe that unless it acts people may be exposed to the risk of harm, it may impose, or vary a condition of a provider's registration or suspend it from the point written notice is given as part of an urgent response.

In addition, subject to the passage of regulations, during 2014 the Care Quality Commission will also have new powers to prosecute a provider for failing to provide fundamental levels of care, without having to issue a formal warning first. See recommendation 28 for further details.

The powers outlined above are supported by the Care Quality Commission's new regulatory model, and its new approach to inspections. This approach is outlined in more detail in recommendations 50 and 51.

Recommendation 31

Where aware of concerns that patient safety is at risk, Monitor and all other regulators of healthcare providers must have in place policies which ensure that they constantly review whether the need to protect patients requires use of their own powers of

intervention to inform a decision whether or not to intervene, taking account of, but not being bound by, the views or actions of other regulators.

Accepted.

We agree that where routine monitoring and inspection identifies risks to patients' safety, regulators must be able to intervene swiftly and in a coordinated way that promotes joint action as part of a single failure regime (see recommendation 19).

In April 2013 a network of local and regional Quality Surveillance Groups was established that brought together commissioners, regulators, local Healthwatch representatives and other bodies on a regular basis to share information and intelligence about quality across the system, including the views of patients and the public. Quality Surveillance Groups help to proactively spot potential problems early on and coordinate any action that is needed to respond where risks to patients are identified. Where potential concerns arise of a serious failure, members of the Quality Surveillance Groups will be able to act quickly by triggering a risk summit. All Quality Surveillance Group members relevant to the provider in question attend these summits so that they can, together, give specific, focused consideration to the concerns raised and develop a joined-up response.

As part of its regulatory model, the Care Quality Commission monitors evidence and information to detect if a provider is performing outside of what would be expected. This includes the monitoring of a small set of key measures that have a high impact on people and can alert the Care Quality Commission to changes in those areas. These include mortality rates, never events, results from staff and patient surveys, information from whistleblowers, comments from patients and the public on the quality of care, and information from Quality Surveillance Groups. Any indicator within that set which points to a potential concern will trigger a response from the Care Quality Commission depending on the concerns raised. This may vary from asking the Trust for further information and an explanation to conducting an inspection or, in extreme cases, the suspension of a service. On 24 October 2013, the Care Quality Commission published for the first time surveillance data for all acute trusts as part of its new regulatory regime. For further details on the Care Quality Commission's new inspection and surveillance programme see the responses to recommendations 20, 50 and 51.

The NHS Trust Development Authority published *Delivering High Quality Care for Patients* (April 2013) which outlines the oversight model that will use to hold non- Foundation Trusts to account for their performance. Where necessary, the NHS Trust Development Authority will directly intervene by requesting recovery plans and additional reporting, increasing engagement with the organisation, commissioning 'deep dive' investigations into a trust's performance, reviewing the skills and competency of the board, and commissioning interim support to provide additional management capacity.

For NHS Foundation Trusts, Monitor will continue to assess breaches to its licence system that sets conditions covering financial viability and governance as well as other areas that reflect Monitor's expanded role within healthcare. Monitor's licence conditions include compliance with healthcare standards specified by the Secretary of State for Health, the Care Quality Commission, NHS England and statutory regulators of healthcare professions. To do this, Monitor uses a risk based system of regulation that determines the intensity of monitoring

required for each Foundation Trusts. Where Monitor determines that a Foundation Trust has breached its licence it may impose additional conditions to resolve any concerns including where the Care Quality Commission has issued a warning notice to a Foundation Trust. These are in addition to Monitor's powers to apply discretionary requirements or seek enforcement undertakings from a provider that has breached its licence. Monitor also has a formal weekly process to review the need for intervention and, if required, calls urgent special meetings to take a formal decision to intervene where patient safety might be at risk. Decisions are closely informed by the views and actions of the Care Quality Commission but are not bound by them.

Recommendation 32

Where patient safety is believed on reasonable grounds to be at risk, Monitor and any other regulator should be obliged to take whatever action within their powers is necessary to protect patient safety. Such action should include, where necessary, temporary measures to ensure such protection while any investigation required to make a final determination is undertaken.

Accepted.

As part of the overall single failure regime (see recommendation 19) it is important that where the Care Quality Commission, Monitor or the NHS Trust Development Authority identify breaches of fundamental standards that they can act swiftly to resolve those issues.

As such, the Care Quality Commission has retained both its ability to impose enforcement action to ensure that patient safety risks are addressed and to stop the provision of a service where it is putting people at immediate risk of harm as outlined by the *Health and Social Care Act 2008*.

Subject to the passage of appropriate regulations, the Care Quality Commission will also be able to prosecute a provider for failing to provide fundamental levels of care, without having to issue a formal warning first. See recommendations 28 and 30 for further details.

Monitor and the NHS Trust Development Authority have retained their powers to intervene at their discretion if urgent action is required. Details of this are outlined as part of the response to recommendation 31.

Recommendation 33

Insofar as health regulators do not consider they possess any necessary interim powers, the Department of Health should consider the introduction of the necessary amendments to legislation to provide such powers.

Accepted in principle.

The Care Quality Commission already has the power of immediate intervention where it considers that the quality of services to be insufficient, or the safety of service users is at risk. The NHS Trust Development Authority and Monitor each have powers to intervene and direct change where it is considered necessary.

The Department of Health will consult shortly on new regulations which will make clearer the fundamental standards of care and enable enforcement against them without a prior warning

notice. The Care Quality Commission will consult on a new enforcement policy for all sectors so that these new regulations can be enforced effectively when they come into force, subject to Parliament, during 2014.

In *Patients First and Foremost*²⁹ the Government announced that the Care Quality Commission, Monitor and the Trust Development Authority would establish a single failure regime to provide clarity while retaining the Care Quality Commission and Monitor as separate regulators with defined responsibilities across health and social care. To support this, specific clauses within the Care Bill lay the framework for a simple, flexible process for tackling quality failures in trusts and to provide the Care Quality Commission with the powers to issue a new warning notice to trusts where there are systematic failures in the quality of services requiring improvement.

To address failures of quality where providers are unable to resolve problems on their own, the Care Quality Commission will be able to prompt intervention from Monitor (for NHS Foundation Trusts) or the NHS Trust Development Authority (for NHS Trusts). If the Chief Inspector finds a serious breach of health and safety requirements, the Care Quality Commission would refer the matter immediately to the Health and Safety Executive, which in serious cases could decide to prosecute.

The Care Quality Commission plans to introduce this programme in November 2013 through a protocol setting out how it, Monitor and the NHS Trust Development Authority will coordinate their respective powers of intervention. This will be underpinned by legislation when the Care Bill completes its Parliamentary passage.

Recommendation 34

Where a provider is under some form of regulatory investigation, there should be some form of external performance management involvement to oversee any necessary interim arrangements for protecting the public.

Accepted in principle.

It remains the responsibility of providers' Boards to identify and resolve risks to patients swiftly. However, where there are significant issues that require action the Care Quality Commission will issue an enforcement notice and it is the roles of Monitor or the NHS Trust Development Authority to ensure that this is complied with.

The response to recommendation 19 outlines a single failure regime that can be enacted where risks to quality and patient safety are identified. As part of that regime, the Care Quality Commission, the NHS Trust Development Authority or Monitor will work together, with the Trust and its commissioners, to ensure that where concerns are raised, the Trust acts swiftly to resolve them and to protect patients.

29 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170701/Patients_First_and_Foremost.pdf

NEED TO SHARE INFORMATION BETWEEN REGULATORS

Recommendation 35

Sharing of intelligence between regulators needs to go further than sharing of existing concerns identified as risks. It should extend to all intelligence which when pierced together with that possessed by partner organisations may raise the level of concern. Work should be done on a template of the sort of information each organisation would find helpful.

Accepted.

The sharing of local intelligence between professional and system regulators in an appropriate and timely way is key to ensuring that risks to service users are identified and acted upon as needed. The *Government's response to the Caldicott Review*³⁰ (Department of Health, September 2013) states that, '*Health and social care professionals should have the confidence to share information in the best interests of their patients within the framework set out by [the Caldicott principles]. They should be supported by the policies of their employers, regulators and professional bodies.*' The response to recommendation 252 outlines further how data can be shared through appropriate anonymised routes.

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

Quality Surveillance Groups help to proactively spot potential problems early on and coordinate any action that is needed to respond where risks to patients are identified. Where potential concerns arise of a serious failure, members of the Quality Surveillance Groups will be able to act quickly by triggering a risk summit. All Quality Surveillance Group members relevant to the provider in question attend these summits so that they can, together, give specific, focused consideration to the concerns raised and develop a joined-up response.

The National Quality Board is currently conducting a review of how the Quality Surveillance Group network is operating, and what support it needs to be as effective as possible. It will publish revised guidance and support materials by the end of the 2013 to support all Quality Surveillance Groups to reach their full potential.

At a national level, professional and system regulators have agreements and Memoranda of Understanding supported, as appropriate, by statutory requirements to ensure information is shared. It is the responsibility of all organisations to review what information can, appropriately, be shared openly with its partners and the public to support transparency and improvement.

As part of this agenda, the Care Quality Commission:

- uses a range of information from regulators and partners to supports its surveillance process and collects that data routinely to support its processes. For example, when any

30 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/251750/9731-2901141-TSO-Caldicott-Government_Response_ACCESSIBLE.PDF

reports to prevent future deaths are produced by a coroner they are shared with the Care Quality Commission to support their understanding of risk (see recommendation 282);

- contacts professional regulators, and others, to request relevant intelligence to inform them of the inspections that it is undertaking as part of its new regime and to request appropriate intelligence. The Care Quality Commission also collects information from the Nursing and Midwifery Council and the General Medical Council routinely to support its surveillance model and intelligence used within its data packs;
- has a detailed memorandum of understanding with Monitor regarding the sharing of intelligence and the working practices that support this. The Care Quality Commission and Monitor will continue to review this document and update it in the light of the Care Quality Commission's *A New Start*;
- will, as part of the single failure regime, send any notices regarding performance to Monitor and the NHS Trust Development Authority.

USE OF INFORMATION FOR EFFECTIVE REGULATION

Recommendation 36

A co-ordinated collection of accurate information about the performance of organisations must be available to providers, commissioners, regulators and the public, in as near real time as possible, and should be capable of use by regulators in assessing the risk of non-compliance. It must not only include statistics about outcomes, but must take advantage of all safety related information, including that capable of being derived from incidents, complaints and investigations.

Accepted.

The *Health and Social Care Act 2012*,³¹ requires the Health and Social Care Information Centre to establish and operate a system for the collection or analysis of information in connection with the provision of health services and adult social care in England, if so directed by the Secretary of State or NHS England. The Informatics Services Commissioning Group, established in 2013, has been set up to enable the Health and Social Care Information Centre to become the focal point for data collected at the national level and that it increasingly becomes a checkpoint for those seeking new data collections.

The Health and Social Care Information Centre publishes more than 130 statistical publications annually via its [website](http://www.hscic.gov.uk/).³² It also publishes a range of national indicators and metrics many of which are available publicly through its [indicator portal](http://www.hscic.gov.uk/indicatorportal).³³ This includes, for example, the Summary Hospital-level Mortality Indicator, indicators from the Quality Outcomes Framework and measures from the NHS Outcomes Framework.

In addition, a range of metrics are collected and published by other organisations across the health sector that relate directly to the quality of patient care. This includes data on infection

31 <http://www.legislation.gov.uk/ukpga/2012/7/contents>

32 <http://www.hscic.gov.uk/>

33 <http://www.hscic.gov.uk/indicatorportal>

control published by Public Health England and information on safety incidents that are published by NHS England. From November 2013, NHS England will increasingly make such information accessible through NHS Choices in order to bring together the most reliable and relevant data from national web services and act as a ‘front door’ to the best information on health and social care on the internet.

Published data can be readily accessed by regulators to assess the risk of non-compliance. Where needed, however, additional data can be made available to regulators, for example, through local arrangements such as direct memoranda of understanding with the appropriate data collector.

Published Official Statistics are subject to the UK Statistics Authority’s *Code of Practice for Official Statistics*³⁴ (January 2009) which expects that statistical reports should be released as soon as they are ready to avoid unnecessary delays and that such publication should take into account the needs of data users and the public.

In the light of this, and other similar recommendations in the Review, we expect that the Health and Social Care Information Centre should explore options and make proposals for using standard reporting formats that can be made more available to all organisations, in line with the ‘do once and use many times’ principle, with a view to improving consistency of analysis across the system.

USE OF INFORMATION ABOUT COMPLIANCE BY REGULATOR FROM QUALITY ACCOUNTS

Recommendation 37

Trust Boards should provide, through quality accounts, and in nationally consistent format, full and accurate information about their compliance with each standard which applies to them. To the extent that it is not practical in a written report to set out detail, this should be made available via each trust’s website. Reports should no longer be confined to reports on achievements as opposed to a fair representation of areas where compliance has not been achieved. A full account should be given of the methods used to obtain the information. To make or be party to a wilfully or recklessly false statement as to compliance with safety or essential standards in the required quality account should be made a criminal offence.

Accepted.

The *National Health Service (Quality Accounts Regulations) 2010*,³⁵ the *National Health Service (Quality Accounts) Amendment Regulations 2011*³⁶ and the *National Health Service (Quality Accounts) Amendment Regulations 2012*³⁷ set out information that must be included within Part 2 of the Quality Accounts to ensure they are comparable including information on

34 <http://www.statisticsauthority.gov.uk/assessment/code-of-practice/index.html>

35 http://www.legislation.gov.uk/uksi/2010/279/pdfs/uksi_20100279_en.pdf

36 http://www.legislation.gov.uk/uksi/2011/269/pdfs/uksi_20110269_en.pdf

37 http://www.legislation.gov.uk/uksi/2012/3081/pdfs/uksi_20123081_en.pdf

their compliance (see recommendation 246). The Quality Accounts are published nationally via the NHS Choices website to ensure that they are accessible and the information they contain on quality is available to patients and the public (see recommendation 247).

We also agree that reports should not be confined to achievements and should reflect a balanced view of quality. Professor Sir Bruce Keogh's report *Review into the quality of care and treatment provided by 14 hospital trusts in England*³⁸ (NHS England, July 2013) stated as an ambition that '*...patients and the public, will have rapid access to accurate, insightful and easy to use data about quality at service line level*'. This includes an action that the '*...the requirements for Quality Accounts for the 2014–15 round begin to provide a more comprehensive and balanced assessment of quality.*'

NHS England will review Quality Accounts before the 2014–15 cycle to ensure that they give patients appropriate information regarding the services they use, and that they add value to the quality assurance infrastructure used by trusts, local and national organisations. The review will consider recommendations 246 to 251 concerning the Quality Accounts along with the action highlighted in Sir Bruce's report and will report in early 2014. It is expected that the review will be complete such that guidance can be issued in March 2014 and trusts advised of expected changes in early 2014.

USE OF INFORMATION ABOUT COMPLIANCE BY REGULATOR FROM COMPLAINTS

Recommendation 38

The Care Quality Commission should ensure as a matter of urgency that it has reliable access to all useful complaints information relevant to assessment of compliance with fundamental standards, and should actively seek this information out, probably via its local relationship managers. Any legal or bureaucratic obstacles to this should be removed.

Accepted.

In June 2013, the Care Quality Commission issued *A new start – Consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care*.³⁹ This made clear that information from individual members of the public who make complaints, raise concerns and provide feedback about the quality and safety of their care would be a vital source of information and that a well-led service or organisation would have a good complaints procedure that drives improvement. On 17 October 2013, it published the responses to the consultation in *A new start: Responses to our consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care services*,⁴⁰ which showed that there is broad agreement with the new approach.

38 <http://www.nhs.uk/NHSEngland/bruce-keogh-review/Documents/outcomes/keogh-review-final-report.pdf>

39 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

40 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_newstartresponse_2013_14_tagged_sent_to_web.pdf

The Care Quality Commission already has a customer service centre which receives comments from the public, and it ensures that these comments are fed into inspections. No legal obstacles to the Care Quality Commission accessing information have been identified. Any bureaucratic obstacles to information sharing are being addressed through the development of information sharing protocols. The Care Quality Commission and the General Medical Council have published an operational protocol which sets out in detail how coordination and information sharing will work between the two regulators. The Care Quality Commission is in agreement with the Nursing and Midwifery Council that they will develop a similar joint working protocol by December 2013. Arrangements are in place for updated information sharing arrangements thereafter with the General Dental Council and the Health and Care Professions Council.

The Care Quality Commission is examining how it needs to develop its systems further to ensure that it can use feedback and complaints from all sources to inform its inspection system, and ensure that people contacting the Care Quality Commission with information are clear what the Care Quality Commission will do with that information, and what action it may take in response. This work will be shaped by findings set out in *A review of the NHS hospitals complaints system: putting patients back in the picture*,⁴¹ and to ensure that complaints information and feedback from people who use services is embedded consistently and given significant weighting, the Care Quality Commission has committed to develop the way it uses these in its surveillance model by early 2014.

Recommendation 39

The Care Quality Commission should introduce a mandated return from providers about patterns of complaints, how they were dealt with and outcomes.

Accepted in principle.

Information from people who use care services about the quality and safety of their care, including concerns and complaints, is a vital source of information which needs to be available to the regulator. As part of the introduction of its new approach to inspection, the Care Quality Commission will ensure that it has access to this information so that it is a central part of how it focuses inspections. Through its engagement activity and refinement of its new approach, the Care Quality Commission will consider how best to ensure that it has access to this information.

The Care Quality Commission already accesses and uses a range of information about complaints to inform the timing and focus of its inspections. The information ranges from aggregated numbers and patterns of complaints, to individuals who contact it and tell inspectors about their experience. The Care Quality Commission also has a Memorandum of Understanding with Monitor that allows the two-way sharing of patient complaints information so that Monitor can act on it.

The Care Quality Commission started implementing its new approach to hospital inspection in September 2013. The approach is based around judging five dimensions of quality. In December 2013 it will set out information in more detail in a handbook for providers, so that

41 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/253320/complaints_review_report.pdf

there is transparency in how it will rate acute hospitals. This will build on the proposals in *A new start – Consultation on changes to the way the Care Quality Commission regulates, inspects and monitors care*⁴² by providing more detail on:

- what the five questions that the Care Quality Commission inspects* will cover;
- the definition of each level of the rating scale (outstanding, good, requires improvement inadequate);
- key lines of enquiry that will always be followed to ensure consistent ratings;
- any additional indicators and data that contribute to the rating (beyond those used for surveillance), and any methods or rules for aggregating them;
- how judgements are made from inspection findings and data, to place a provider in a ratings band.

In all inspections, the Care Quality Commission will use key information to identify priorities to check, and this will always include complaints information as an essential component. This is likely to require definition of a comprehensive, standardised information set which the Care Quality Commission can access as part of pre-inspection planning and as and when required for on-going monitoring.

The information could be required on a mandatory basis by incorporating it in regulations or through the Care Quality Commission's general power to require access to whatever information it needs to exercise its functions. However, it is premature to make decisions on requiring mandatory information until the implications of Rt Hon Ann Clwyd MP and Professor Tricia Hart's *Review of the Handling of Complaints in NHS Hospitals*⁴³ are fully understood, until the NHS Confederation's review of bureaucracy has reported, and the Care Quality Commission has evaluated its information requirements in light of its first inspections using its new approach. The Care Quality Commission will review whether to require routinely from providers a report on complaints, self-assessment or other form of declaration, in order to inform its monitoring and inspections, as it continues to test and engage on refining its new approach to inspection between now and April 2014.

*Is the service safe? Is the service effective? Is the service caring? Is the service responsive? Is the service well-led?

Recommendation 40

It is important that greater attention is paid to the narrative contained in, for instance, complaints data, as well as to the numbers.

Accepted.

The new approach to inspection introduced by the Care Quality Commission places a stronger focus on how care is delivered in practice and how it is experienced, rather than only on compliance with regulations. In line with this, it is now making greater use of the information that it holds on complaints.

42 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

43 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/253320/complaints_review_report.pdf

The Care Quality Commission already uses a range of information about complaints to inform the timing and focus of its inspections. The information ranges from aggregated numbers and patterns of complaints, to individuals who contact the Care Quality Commission and tell inspectors about their experience. The Care Quality Commission will review how it makes best use of the complaints that it receives directly from individuals, and the individual stories in complaints as well as the aggregated trends, in light of Rt Hon Ann Clwyd MP and Professor Tricia Hart's *Review of the Handling of Complaints in NHS Hospitals*.⁴⁴

USE OF INFORMATION ABOUT COMPLIANCE BY REGULATOR FROM PATIENT SAFETY ALERTS

Recommendation 41

The Care Quality Commission should have a clear responsibility to review decisions not to comply with patient safety alerts and to oversee the effectiveness of any action required to implement them. Information-sharing with the Care Quality Commission regarding patient safety alerts should continue following the transfer of the National Patient Safety Agency's functions in June 2012 to the NHS Commissioning Board.

Accepted in principle.

The Care Quality Commission already monitors compliance with patient safety alerts, such as those issued by the Medicines and Healthcare products Regulatory Agency, and is able to investigate further where it identifies the need to do so in order to hold providers to account for failures to act on them. The Care Quality Commission is currently exploring how it can give greater prominence to safety alerts in its revised surveillance and inspection model. However care is needed to be clear that providers retain accountability for implementing patient safety alerts. It is not the Care Quality Commission's role to oversee providers' individual decisions or actions. Providers must be able to explain and account for how they act on safety alerts; the Care Quality Commission's role will be to assess their capability and performance in terms of whether it results in good quality care.

NHS England is developing proposals for a new system of safety alerts, and, to strengthen the ability to monitor alerts and compliance with them, the Care Quality Commission is closely involved in that work. The role of regulation is integrated into an overall approach that allows for both safety improvement and accountability.

USE OF INFORMATION ABOUT COMPLIANCE BY REGULATOR FROM SERIOUS UNTOWARD INCIDENTS

Recommendation 42

Strategic Health Authorities/their successors should, as a matter of routine, share information on serious untoward incidents with the Care Quality Commission.

44 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/253320/complaints_review_report.pdf

Accepted.

Information on serious untoward incidents is shared routinely with the Care Quality Commission, and Quality Surveillance Groups have been established to support the sharing of information and intelligence more generally at a local level.

NHS England is the relevant successor to Strategic Health Authorities. It continues routinely and regularly to share with the Care Quality Commission information on serious untoward incidents reported to the Strategic Executive Information System and the National Reporting and Learning System.

The Care Quality Commission has direct access to the Strategic Executive Information System, and is able to view all the information submitted to that system regarding serious incidents. Information on National Reporting and Learning System reported incidents is shared on a weekly basis with the Care Quality Commission.

The Care Quality Commission is reviewing how it uses incident data in its new surveillance and monitoring approach to support inspections carried out on behalf of the new Chief Inspector of Hospitals, looking at both incident severity and levels/consistency of reporting. The Care Quality Commission and NHS England are working closely on these developments and have agreed to use the same indicators and approach to their analyses where this is possible.

Quality Surveillance Groups have been established from April 2013 in each area and in each region. These groups actively share between commissioners, regulators, all local NHS organisations and others, information and intelligence on the quality of care being delivered, including on untoward incidents and how they are managed. The National Quality Board is currently conducting a review of how the Quality Surveillance Group network is operating, and what support it needs to be as effective as possible. It will publish revised guidance and support materials by the end of the 2013 to support all Quality Surveillance Groups to reach their full potential.

USE OF INFORMATION ABOUT COMPLIANCE BY REGULATOR FROM MEDIA

Recommendation 43

Those charged with oversight and regulatory roles in healthcare should monitor media reports about the organisations for which they have responsibility.

Accepted.

Regulatory bodies and commissioners of NHS services do monitor media reports about relevant organisations for which they hold responsibility.

Within the Care Quality Commission's new approach to inspection, it will be monitoring media reports with those contributing to decisions on when and where to inspect. They are reflected in the data packs the Care Quality Commission uses to focus its inspections. Monitor and the NHS Trust Development Authority monitor media reports about the organisations they regulate, and this information feeds into their assessment processes and on-going regulation

activity. NHS England actively monitors media reports about clinical commissioning groups and providers. The Nursing and Midwifery Council monitors media coverage of potential fitness to practise issues relating to registered nurses and midwives, and opens investigations when serious concerns appear to have been raised. The General Medical Council conducts extensive monitoring of print, online, broadcast and social media as part of its commitment to be proactive in identifying risk to patients and patient care, and it opens investigations when there appears to be a serious concern.

Since April 2013, NHS England has rolled out Quality Surveillance Groups across England. These groups actively share among commissioners, regulators and other organisations information and intelligence on the quality of care being delivered, including issues and cases of media and public interest. The National Quality Board is currently conducting a review of how the Quality Surveillance Group network is operating, and what support it needs to be as effective as possible. It will publish revised guidance and support materials by the end of the 2013 to support all Quality Surveillance Groups to reach their full potential.

Recommendation 44

Any example of a serious incident or avoidable harm should trigger an examination by the Care Quality Commission of how that was addressed by the provider and a requirement by the trust concerned to demonstrate that the learning to be derived has been successfully implemented.

Accepted in part.

The Care Quality Commission's new approach to inspection includes a published set of 'Intelligent Monitoring' indicators for monitoring quality in providers: for the first time indicators in relation to acute trusts were published on 24 October 2013, and these will be published quarterly. The indicators use information on serious incidents and avoidable harm, all of which is valuable to the Care Quality Commission. While it would not be feasible to follow up on every reported incident of patient harm as there are more than 250,000 incidents each year with over 200,000 of these categorised as low harm incidents, the Care Quality Commission has defined a number of these indicators as 'tier one indicators', which always trigger rigorous follow up action to obtain assurance. Tier one indicators include serious incidents such as 'never events'. The Care Quality Commission's new Intelligent Hospital Monitoring system will also trigger a response whenever there is a statistically significant number of severe harm incidents or avoidable deaths at a provider location. The Care Quality Commission also analyses information over time and takes action on patterns of differences between expected and observed outcomes of care, and patterns of incidents.

The indicators on their own will not be used to draw definitive conclusions or judge the quality of care – that will be a matter for inspection. Instead the indicators will be used as 'smoke detectors', which will start to sound if a hospital is outside the expected range of performance for one or more indicators. The Care Quality Commission will then assess what the most appropriate response should be. Providers are required to inform the Care Quality Commission of a range of incidents that may point to failings in the care provided.

The Care Quality Commission will consider further ways to monitor and act on incidents and avoidable harm as its new system of monitoring providers matures, in order continuously

to improve its sensitivity to this aspect of quality of care. However, it needs to avoid any duplication with local arrangements for ensuring that providers address serious incidents and avoidable harms and demonstrate learning, as set out in NHS England's *Serious Incident Reporting and Learning Framework*.⁴⁵ For this reason, while the Care Quality Commission should ensure high priority to responding to concerns about patient safety, it should not follow up *any* serious incident or avoidable harm, given that other arrangements are in place and the Care Quality Commission needs to target its resources where it will have greatest impact in promoting better quality care.

USE OF INFORMATION ABOUT COMPLIANCE BY REGULATOR FROM INQUESTS

Recommendation 45

The Care Quality Commission should be notified directly of upcoming healthcare-related inquests, either by trusts or perhaps more usefully by coroners.

Accept in principle.

Coroners' investigations and inquests can provide useful information on the quality of services delivered by care providers and any risk of future deaths. As a result, the Care Quality Commission already receives *Reports to Prevent Future Deaths* and disclosure in inquests where they have interested person status.

Since 25 July, coroners are under a statutory duty to make details of the date, time and place of all inquests available before hearings commence. However, in order to support its new inspection model, the Care Quality Commission may require further details regarding upcoming inquests.

To this end, the Care Quality Commission will undertake an analysis of the information available from coroners' investigations and inquests, along with other information it already receives relating to expected and unexpected deaths. It will consider the findings of that analysis, including how it could target requests for information from coroners and any burden that collecting this data might impose, working with the Coroners' Society of England and Wales, the Office of the Chief Coroner, the Ministry of Justice and the Department of Health. Together, they will develop an appropriate way forward.

In addition, the Care Quality Commission is also working with the Coroners' Society of England and Wales and the Office of the Chief Coroner in establishing a Memorandum of Understanding with the aim of achieving better working relationships and the sharing of information between the Care Quality Commission and coroners.

45 <http://www.nrls.npsa.nhs.uk/report-a-patient-safety-incident/serious-incident-reporting-and-learning-framework-sirl/>

USE OF INFORMATION ABOUT COMPLIANCE BY REGULATOR FROM QUALITY AND RISK PROFILES

Recommendation 46

The Quality and Risk Profile should not be regarded as a potential substitute for active regulatory oversight by inspectors. It is important that this is explained carefully and clearly as and when the public are given access to the information.

Accepted.

Replacing the quality and risk profile approach, since October 2013 the Care Quality Commission has published its analysis of risk indicators for the entire hospital sector, showing how all hospital providers perform against these indicators of risk. Updates will be published quarterly. Under its new inspection approach, spearheaded by the Chief Inspector of Hospitals, as it carries out each inspection under its new approach, the Care Quality Commission will publish the data pack at the same time as publishing the inspection report. A data pack is a detailed analysis of key information that the Care Quality Commission holds about a provider, including its performance on risk indicators, other sources of data, and qualitative information such as views of local organisations and feedback from patients.

The Care Quality Commission's new approach is designed to support inspection by specialist teams, through inspections based on identifying lines of enquiry from whatever quantitative and qualitative information suggest about standards of care, rather than focused on regulations. Under the new approach the Care Quality Commission also analyses information about providers to decide the timing of inspections so that there is timely follow-up to potential concerns. This is to clarify the difference between on-going monitoring, and judgements by inspectors at certain points within that.

The Care Quality Commission has begun its new approach to monitoring providers in the hospital sector. New Chief Inspectors of General Practice and of Adult Social Care took up post in October 2013 and will now spearhead the extension and development of new approaches to monitoring standards of care in those sectors. The Deputy Chief Inspector of Mental Health will report to the Chief Inspector of Hospitals on how this applies to mental health services.

USE OF INFORMATION ABOUT COMPLIANCE BY REGULATOR FROM FOUNDATION TRUST GOVERNORS, SCRUTINY COMMITTEES

Recommendation 47

The Care Quality Commission should expand its work with overview and scrutiny committees and Foundation Trust governors as a valuable information resource. For example, it should further develop its current 'sounding board events'.

Accepted.

The Care Quality Commission has taken steps to engage Overview and Scrutiny Committees and Foundation Trust Governors, to increase their input to its new approach to inspection and monitoring.

All Overview and Scrutiny Committees now receive a two-monthly bulletin from the Care Quality Commission to update them on work and encourage feedback from their scrutiny reviews and activity. Each Overview and Scrutiny Committees has received a welcome letter from Professor Sir Mike Richards, the Chief Inspector of Hospitals. Local Trusts being inspected under the Care Quality Commission's first wave of new in depth inspections have received a second letter inviting them to the public listening events and encouraging specific feedback about the Trusts.

The Care Quality Commission has put in place a contract with the Centre for Public Scrutiny to further develop information sharing and relationships with Overview and Scrutiny Committees across the regions. A sounding board of Overview and Scrutiny Committees was held in August 2013, which included encouraging Overview and Scrutiny Committees to access the Care Quality Commission's local data to inform their scrutiny work programmes.

The Care Quality Commission and Monitor have worked together so that Monitor's new statutory guidance for Governors⁴⁶ provides briefing on the Care Quality Commission's role and new approach to inspection. It sets out ways in which Governors can have an effective role in the Care Quality Commission's monitoring and inspection, and how information should be shared.

Recommendation 48

The Care Quality Commission should send a personal letter, via each registered body, to each Foundation Trust governor on appointment, inviting them to submit relevant information about any concerns to the Care Quality Commission.

Accepted in principle.

Professor Sir Mike Richards, the Chief Inspector of Hospitals, has already written to Foundation Trust Councils of Governors about the first wave of his new NHS Trust inspections, setting out how Councils of Governors can be involved in listening events, can feed in information to the inspections, and can contact the local Care Quality Commission manager if at any time they wish to raise questions or provide further information to it in relation to the quality of care provided by the trust. The Foundation Trust Council of Governors was used to convey this information to individual Governors because of their requirement to work collectively as a Council.

The Care Quality Commission has worked with Monitor to ensure that Foundation Trust governors have clear guidance on the Care Quality Commission's role and how to raise concerns. This information will be available to governors on an on-going basis, and to newly appointed governors, in addition to the one-off letter that has been sent.

46 <http://www.monitor.gov.uk/home/news-events-publications/our-publications/browse-category/guidance-health-care-providers-and-co-54>

ENHANCEMENT OF MONITORING AND THE IMPORTANCE OF INSPECTION

Recommendation 49

Routine and risk-related monitoring, as opposed to acceptance of self-declarations of compliance, is essential. The Care Quality Commission should consider its monitoring in relation to the value to be obtained from:

- **The Quality and Risk Profile;**
- **Quality Accounts;**
- **Reports from Local Healthwatch;**
- **New or existing peer review schemes;**
- **Themed inspections.**

Accepted.

The Care Quality Commission is fundamentally changing the way it monitors providers on the quality of their services. Through its Chief Inspector of Hospitals, it has introduced a new system in the hospital sector. The Chief Inspectors of General Practice and Adult Social Care have been appointed, and will similarly lead the development of new approaches in their sectors.

The Care Quality Commission has consulted on and started implementing a new approach to monitoring providers, based on identification of the indicators that are most important in signalling potential concerns in each type of care. This has started in the hospital sector, and the Chief Inspector of Hospitals has been clear that information from people who use the service, or their representatives, information from accreditation and peer review, and information from other oversight bodies are also important alongside indicators from national data. In October 2013 the Care Quality Commission began regularly publishing its analyses of the indicators for each hospital trust.

The Care Quality Commission will continue to develop the approach to monitoring hospitals, and extend it to mental health, community health and ambulance providers both in the NHS and the independent sector. The Chief Inspector of General Practice, on behalf of the Care Quality Commission, will bring forward proposals for his sector and consult on them. A signposting document on adult social care, *A fresh start for the regulation and inspection of adult social care*,⁴⁷ was issued in October 2013 by the Chief Inspector of Social Care.

The Care Quality Commission is engaged in a review of quality accounts that the National Quality Board has requested and will play its part in ensuring that quality accounts add value, are robust and have accountability for inaccurate or inappropriate information.

The Care Quality Commission is developing Memoranda of Understanding with all the medical, nursing and midwifery Royal Colleges in order to explore the potential to use their

47 http://www.cqc.org.uk/sites/default/files/media/documents/20131013_cqc_afreshstart_2013_final.pdf

accreditation schemes in its monitoring, where that can encourage achievement of best practice standards and avoid duplicated inspection.

The Care Quality Commission is reviewing its approach to themed inspections, including how they can contribute to its broader monitoring of providers.

Recommendation 50

The Care Quality Commission should retain an emphasis on inspection as a central method of monitoring non-compliance.

Accepted.

The Care Quality Commission has introduced a fundamentally different and strengthened approach to inspection as the centrepiece of how it assures standards of care.

The Care Quality Commission's new approach to inspection involves large teams of specialists and public listening events, resulting in judgements about the quality of care rather than compliance with regulations. The new approach is led by the Chief Inspector of Hospitals, Professor Sir Mike Richards; several thousand specialists and members of the public have put themselves forward to join his inspection teams. This level of engagement, and the more relevant outputs, ensures that inspection is at the heart of the Care Quality Commission's role and purpose. The new approach is designed to support inspection by specialist teams, through inspections which, rather than being focused on regulations, are based on identifying lines of enquiry from whatever quantitative and qualitative information suggest about standards of care.

The Care Quality Commission's new approach to monitoring the quality and safety of services has been introduced initially in acute hospitals. New Chief Inspectors of General Practice and of Adult Social Care took up post in October 2013, and will now spearhead the extension and development of new approaches to monitoring and inspecting standards of care in those sectors. The Deputy Chief Inspector of Mental Health will report to the Chief Inspector of Hospitals on how this applies to mental health services.

Recommendation 51

The Care Quality Commission should develop a specialist cadre of inspectors by through training in the principles of hospital care. Inspections of NHS hospital care providers should be led by such inspectors who should have the support of a team, including service level user representatives, clinicians and any other specialism necessary because of particular concerns. Consideration should be given to applying the same principle to the independent sector, as well as to the NHS.

Accepted.

The Chief Inspector of Hospitals has begun inspecting in this way. Useful lessons were learnt from the Care Quality Commission's targeted inspections of 150 learning disability in-patient units following events at Winterbourne View hospital; these benefitted enormously from the involvement in inspection of trained and supported learning disabled self-advocates and family carers.

Also, building on the approach developed by Professor Sir Bruce Keogh's reviews of mortality in 14 NHS trusts, the Chief Inspector of Hospitals has started inspections involving teams made up of senior and junior doctors, nurses and allied health professionals; senior managers; and people with experience of using hospital services. Six thousand individuals put themselves forward to be part of these inspections, and the number continues to increase. This is encouraging progress towards ensuring that inspection teams with a range of specialist and lay perspectives will be sustainable.

Through its Chief Inspector of Hospitals, the Care Quality Commission will extend this approach to mental health, community healthcare and ambulance services during 2014–15, with appropriate adaptation and tailoring to those sectors. The approach will be adapted to independent as well as NHS providers.

New Chief Inspectors of General Practice and of Adult Social Care took up post in October 2013, and will similarly spearhead the extension and development of new approaches to monitoring and inspecting standards of care in those sectors.

Recommendation 52

The Care Quality Commission should consider whether inspections could be done in collaboration with other agencies, or whether they can take advantage of any peer review arrangements available.

Accepted.

The Care Quality Commission is developing Memoranda of Understanding with medical, nursing and midwifery Royal Colleges. These will ensure that peer review and accreditation schemes are taken fully into account as new methods of inspection are introduced in each sector and evolve. The Care Quality Commission will continue joint inspection with other regulators and inspectorates. This will include extending from December 2013 the approach to coordination developed with the General Medical Council (see below), to other professional regulators.

In *A new start – Consultation on changes to the way Care Quality Commission regulates, inspects and monitors care*⁴⁸ the Care Quality Commission consulted on new approaches to regulation and, as part of that, proposed closer work with other agencies and better use of accreditation and peer review schemes. On 17 October 2013, it published the responses to the consultation in *A new start: Responses to our consultation on changes to the way Care Quality Commission regulates, inspects and monitors care services*,⁴⁹ which showed that there is broad agreement with the new approach.

The Care Quality Commission and the General Medical Council have explored coordination through shadowing each other's inspections and assessments of professional education; this is reflected in an operational protocol⁵⁰ that they have published. Discussions are under way

48 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

49 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_newstartresponse_2013_14_tagged_sent_to_web.pdf

50 http://www.gmc-uk.org/24072013_FINAL_EXTERNAL_VERSION_OF_PROTOCOL.pdf_53053221.pdf

on how best to learn from this, and extend the learning to other professional regulators in healthcare.

CARE QUALITY COMMISSION INDEPENDENCE, STRATEGY AND CULTURE

Recommendation 53

Any change to the Care Quality Commission's role should be by evolution – any temptation to abolish this organisation and create a new one must be avoided.

Accepted.

There are no plans to abolish the Care Quality Commission. The Care Quality Commission has set out a new strategy for the next three years, and has a new Board in place, with five new Non-executives and its three Chief Inspectors. The Care Quality Commission has begun a process of fundamental change, begun in the hospital sector and to be rolled out to the other services that it regulates.

On 1 October 2013, the Secretary of State for Health announced the intention to give the Care Quality Commission greater independence. Under the proposals, the Secretary of State will relinquish a range of powers to intervene in the operational decisions of the Care Quality Commission. This means that the Care Quality Commission will no longer need to ask for Secretary of State approval to carry out an investigation into a hospital or care home. It will also remove the Secretary of State's power to direct the Care Quality Commission on the content of its annual report. The Government proposes to make these changes via the Care Bill, by amending the Health and Social Care Act 2008, under which the Care Quality Commission was established. The Care Bill will also put the Chief Inspectors' posts into statute to ensure their longevity.

In April 2013 the Care Quality Commission published its future strategy document in *Raising Standards, putting people first – our strategy 2013–16*,⁵¹ In this it sets out how it will work better with partners in health and social care, build relationships with the public and those it regulates, and build a high performing organisation.

A change programme is underway for the Care Quality Commission to develop into a strong, independent, expert inspectorate whose evidence based, professional judgements are welcomed and instructive. The Chair and Board is reviewing governance structures throughout the organisation to ensure that decisions are taken by the right people at the right time.

In *A new start – Consultation on changes to the way Care Quality Commission regulates, inspects and monitors care*⁵² the Care Quality Commission consulted a new approach to hospital inspections. On 17 October 2013, it published the responses to the consultation, *A new start: Responses to our consultation on changes to the way Care Quality Commission*

51 http://www.cqc.org.uk/sites/default/files/media/documents/20130503_cqc_strategy_2013_final_cm_tagged.pdf

52 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

regulates, inspects and monitors care services,⁵³ which showed that there is broad agreement with the new approach. The new Chief Inspector of Hospitals is leading the new inspections which started in September 2013. Chief Inspectors of General Practice and Adult Social Care took up their posts in October 2013, and will similarly spearhead the extension and development of new approaches to monitoring and inspecting standards of care in those sectors.

Recommendation 54

Where regulatory issues are discussed between the Care Quality Commission and other agencies, these should be properly recorded to avoid any suggestion of inappropriate interference in the Care Quality Commission's statutory role.

Accepted.

The Care Quality Commission is implementing this recommendation by means of partnership agreements and operational protocols which include criteria to make and store a formal record of meetings. So far, these cover the Care Quality Commission's relationships with Monitor, the NHS Trust Development Authority, Healthwatch England and the General Medical Council. The Care Quality Commission will extend this approach to other stakeholders, foremost among which are the other professional regulators and the Ombudsmen.

Recommendation 55

The Care Quality Commission should review its processes as a whole to ensure that it is capable of delivering regulatory oversight and enforcement effectively, in accordance with the principles outlined in this report.

Accepted.

The Care Quality Commission has begun implementing a new approach to inspection and enforcement that is fundamentally different. It has appointed chief inspectors to lead this new approach in each sector. Key means of assuring its effectiveness include the extensive consultation and engagement that has helped to shape it, and the appointment of a Chief Inspector of Hospitals who personally spearheads it, ensuring that it commands the support of the sector and the public.

The Department of Health will consult on new regulations which will come into effect during 2014. Subject to Parliamentary approval, these will set out clearly the fundamental standards below which care should never fall, and enable the Care Quality Commission to enforce against these standards without issuing a prior warning notice. The Care Quality Commission will consult on a new enforcement policy for all sectors (to sit alongside the failure regime for the NHS) so that these new regulations can be enforced effectively as they come into effect.

Chief Inspectors of General Practice and Adult Social Care have been appointed, who will now start a similar process of consultation and engagement on new regulatory approaches for their sectors.

53 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_newstartresponse_2013_14_tagged_sent_to_web.pdf

An independent evaluation of the Care Quality Commission's new approach to hospital inspections has been commissioned from the King's Fund and Manchester Business School, and work began in October 2013. This will evaluate the effectiveness and efficiency of the new inspection model, and how inspection teams have used and acted upon the available surveillance information. The report of this evaluation will be published in May 2014.

The Care Quality Commission is also developing a set of new strategic measures, which from 2014 will be reported in its quarterly performance reports to the Board and in its monthly scorecards on the Care Quality Commission website. These measures will include: how quickly it has responded to risks identified through the surveillance model; the proportion of providers judged to be poor, but for whom no risk information had been available; and the impact of action taken when providers have been judged to be poor or requiring improvement.

Recommendation 56

The leadership of the Care Quality Commission should communicate clearly and persuasively its strategic direction to the public and to its staff, with a degree of clarity that may have been missing to date.

Accepted.

In April 2013 the Care Quality Commission published its new three year strategy, *Raising Standards, putting people first – our strategy 2013–16*.⁵⁴ This document sets out how the Care Quality Commission will make major changes to what it does and how it does it. This was reinforced in June 2013, when the Care Quality Commission issued *A new start – Consultation on changes to the way Care Quality Commission regulates, inspects and monitors care*⁵⁵ to start the public discussion on what the fundamental standards of care should be and how surveillance, inspection and monitoring might work. On 17 October 2013, it published the responses to the consultation in *A new start: Responses to our consultation on changes to the way Care Quality Commission regulates, inspects and monitors care services*,⁵⁶ which showed that there is broad agreement with the new approach.

Chief Inspectors of Hospitals, General Practice and Adult Social Care have been appointed and will start a similar process of consultation and engagement on new regulatory approaches for their sectors. The Deputy Chief Inspector of Mental Health will report to the Chief Inspector of Hospitals on how they apply to mental health services.

Recommendation 57

The Care Quality Commission should undertake a formal evaluation of how it would detect and take action on the warning signs and other events giving cause for concern at the Trust described in this report, and in the report of the first inquiry, and open that evaluation for public scrutiny.

54 http://www.cqc.org.uk/sites/default/files/media/documents/20130503_cqc_strategy_2013_final_cm_tagged.pdf

55 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

56 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_newstartresponse_2013_14_tagged_sent_to_web.pdf

Accepted.

The Care Quality Commission has carried out a significant review of how it uses information to identify potential failures in the quality of care in hospitals. Taking each of five key questions – is a service safe, effective, caring, responsive and well led – the review undertook to define an ‘ideal’ set of indicators that the Care Quality Commission could routinely monitor to identify these potential failures. The review then scoured national and international best sources in quality measurement. A short list of potential measures was then identified and tested through analysis and a series of engagements with the sector and experts in the measurement of quality. In *A new start – Consultation on changes to the way Care Quality Commission regulates, inspects and monitors care*⁵⁷ the Care Quality Commission consulted on the set of indicators. It analysed the resulting set of indicators, and published on 24 October 2013 for the first time the analysis outputs, which it will publish quarterly. This way it will ensure wider feedback on its approach. It is also committed to on-going evaluation of the indicators to learn and improve the new approach.

Recommendation 58

Patients, through their user group representatives, should be integrated into the structure of the Care Quality Commission. It should consider whether there is a place for a patients’ consultative council with which issues could be discussed to obtain a patient perspective directly.

Accepted.

The Care Quality Commission uses a wide range of means to engage people who use services in its work. It is holding a number of events and activities to ask people how they it can best involve patients, relatives and carers in its work. This includes looking specifically at a ‘People’s Panel’

Healthwatch England is the independent consumer champion for health and social care in England, and works closely with the Care Quality Commission. The Chair of Healthwatch England sits on the Care Quality Commission’s Board and is able to ensure a focus in the board’s considerations on the views of people who use health and care services.

The Care Quality Commission engages directly with people who use health and social care services to consult on its strategy and policy activity, as well as involving people who use services in the development of its regulatory methodologies. It also recruits, trains and supports people who use services to accompany its inspection staff on inspections (these people are known as ‘Experts by Experience’); the benefits of involving learning disabled Experts by Experience in the post-Winterbourne View hospital inspections of learning disability in-patient units were very clear. The Care Quality Commission works at a local level with overview and scrutiny committees, and Foundation Trust councils of governors, who scrutinise the different elements of the local system, to share information about the safety and quality of local services. The Care Quality Commission works with local Healthwatch and other local voluntary and community organisations, to share surveillance and intelligence to support the Commission’s regulatory function.

57 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

Recommendation 59

Consideration should be given to the introduction of a category for nominated board members from representatives of the professions, for example, the Academy of Medical Royal Colleges, a representative of nursing and allied healthcare professionals, and patient representative groups.

Accepted in principle

Steps have already been taken by Care Quality Commission to establish a series of sector specific advisory groups, which include senior representatives from Royal Colleges and patient groups. These groups support the three new Chief Inspectors by:

- contributing to the design and development of methods and approaches by providing expert advice, opinion and challenge;
- providing a steer on any issues arising;
- acting as an advocate for the Care Quality Commission and as a communication channel to their 'community/membership', helping to share the understanding, seek wider input;
- recommending individuals to join task and finish groups, to provide expert knowledge and advice on detailed areas of work, such as the drafting of guidance.

In September 2013 the Care Quality Commission also appointed a National Advisor on Patient Safety, Culture and Quality.

The Care Quality Commission is also considering whether this recommendation could provide a renewed impetus to its Advisory Committee as a statutory, advisory body to the Board in order to ensure that different perspectives on quality and safety of care are all taken into account.

In addition, Since publication of the Inquiry report, the Care Quality Commission has appointed a new Board of executive and non-executive directors. The three new Chief Inspectors have been appointed to the Board; they provide leadership to ensure that hospital, social care and primary care perspectives are fully taken into account. A strong voice for people who use health and care services is provided by the Chair of Healthwatch England. The Care Quality Commission, in particular through the Chief Inspectors, also has close links to the Royal Colleges through a sector-specific advisory committee. It has also set out a strategy which commits it to ensuring that providers, professionals and people who use health or care services will help shape the approach to regulation.

Responsibility for, and effectiveness of, regulating healthcare systems governance – Monitor’s healthcare systems regulatory functions

The Inquiry made a series of recommendations about regulation and governance of NHS Foundation Trusts including significant improvement of the way Foundation Trusts are authorised based on local opinion, quality and sustainability. These recommendations include provision for enhancing the role of Foundation Trust Governors, and the accountability of Board-level Directors, ensuring Directors are fit and proper persons for the role.

The NHS Trust Development Authority, the Care Quality Commission and Monitor have already improved the Foundation Trust authorisation process to learn the lessons from the first Inquiry and ensure stronger focus on quality. They are now undertaking a complete end-to-end analysis of the authorisation process and will embed the fundamental standards of care discussed in recommendations 21, 24 and others. In addition, the Care Quality Commission will inspect Trusts prior to application, and no Trust will go forward for authorisation unless or until it is rated ‘good’ or ‘outstanding’ under the Care Quality Commission’s new inspection regime. There will also be further improvement on capturing local opinion, including commissioners, patients and the public. Monitor have also taken steps to strengthen the role of Governors, issuing new guidance, setting up a panel for advising Governors, and working with the NHS Leadership Academy and the Foundation Trust Network to provide a new national training programme.

The Government issued in July 2013 a consultation on *Strengthening corporate accountability in health and social care* which proposes that all Board Directors (or equivalents) of providers registered with Care Quality Commission must meet a new fitness test.

CONSOLIDATION OF REGULATORY FUNCTIONS

Recommendation 60

The Secretary of State should consider transferring the functions of regulating the governance of healthcare providers and the fitness of persons to be directors, governors or equivalent persons from Monitor to the Care Quality Commission.

Accepted in principle.

However, we believe that the best way to achieve the desired outcome is through closer co-operation between Monitor and the Care Quality Commission rather than through the transfer of functions. The Care Quality Commission’s inspection regime will include a focus on whether or not an organisation is ‘well-led’.

We agree that the public have the right to expect that people in leading positions in NHS organisations are fit and proper persons; and that where it is demonstrated that a person is

not fit and proper, they should not be able to occupy such a position. Monitor and the Care Quality Commission are committed to ensuring that, taken together, their processes for registration and licensing reflect these principles. The Care Quality Commission's inspection regime will include a focus on whether or not an organisation is 'well-led'.

In order to support this, the Government issued in July 2013 a consultation on *Strengthening corporate accountability in health and social care*. This proposes a new requirement that all Board Directors (or equivalents) of providers registered with the Care Quality Commission must meet a new fitness test. We are proposing that this test includes checks about whether the person is of good character including past employment history, and if the individual has the qualifications, skills and experience necessary for the work or office as well as the more traditional consideration of criminal and financial matters.

The Government proposes that the fit and proper persons test will now be used as a mechanism for introducing a scheme for barring Directors who are unfit from individual posts by Care Quality Commission at the point of registration. Where a Director is considered by Care Quality Commission to be unfit it could either refuse registration, in the case of a new provider, or require the removal of the Director on inspection, or following notification of a new appointment. Further details will be set out in the response to the consultation on corporate accountability which will be published shortly. We plan to publish the draft regulations for consultation at the same time.

See also recommendations 79 and 80.

Recommendation 61

A merger of system regulatory functions between Monitor and the Care Quality Commission should be undertaken incrementally and after thorough planning. Such a move should not be used as a justification for reduction of the resources allocated to this area of regulatory activity. It would be vital to retain the corporate memory of both organisations.

Not accepted, although we agree with the principle regarding changes to the regulatory system.

While we do not accept this recommendation in the light of the response to recommendation 19, we agree with the principles that it outlines regarding changes to the regulatory system. If changes are required between regulatory functions, they should be considered carefully and implemented appropriately to ensure that the organisational memory is retained and that, where change is needed, it is undertaken after appropriate consultation.

However, as outlined in relation to recommendation 19, we do not intend to merge regulatory functions through the development of a single regulator. Rather we intend to implement a single failure regime with clear roles and responsibilities, keeping separate the responsibility for inspecting and assessing quality from the responsibility for improvement.

IMPROVED PATIENT FOCUS

Recommendation 62

For as long as it retains responsibility for the regulation of FTs, Monitor should incorporate greater patient and public involvement into its own structures, to ensure this focus is always at the forefront of this work.

Accepted.

A central theme of Monitor's Quality Governance Framework is whether the Boards of NHS organisations actively engage patients, staff and other key stakeholders on quality. From April 2013 it is also a licence condition that Foundation Trusts actively engage with patients on the quality of care and take into account their views. Monitor's assessment process includes reviews of patient surveys and the NHS staff survey, meetings with staff and patient groups, review of access and outcome metrics, local media coverage and interviews with lead commissioners, the Care Quality Commission and external and internal auditors. Monitor also writes to local MPs and Healthwatch to see if they have any concerns they wish to raise. As part of Monitor's Quality Governance review they seek to understand the Trust Board's arrangements to actively engage with patients. Levels of service performance and standards of care quality form part of Monitor's regular risk assessment of Foundation Trusts including the Care Quality Commission's judgements on the quality of care provided. Monitor also expects licence holders to notify them in the event of any incident, event or report that may raise potential concerns over compliance with the licence. Regulatory action may also be triggered by information from local patient groups if it represents a material concern. This is underpinned by two-way sharing of information on patient complaints by Monitor and Care Quality Commission and sharing of intelligence on the quality of care by regional and local Quality Surveillance Groups. Where enforcement action is required further intelligence may be sought including seeking the views of patient representatives and undertaking further analysis of the complaints made to the Foundation Trust, Monitor and Care Quality Commission.

To further embed patient involvement in Monitor's processes, Monitor is currently engaging with the Department of Health on the recruitment of a Medical Advisor and Director of Patient and Clinical Engagement, and has developed three patient engagement work strands which will be taken forward over the next 12 months.

Projects are underway working with a social research consultancy, patient representative bodies, Healthwatch and other national level health organisations, to help Monitor better understand what good practice looks like when engaging and consulting with patients, the public and their representatives.

Monitor has also pledged to build the use of patient intelligence and complaints into their regulatory approach, working closely with the Care Quality Commission, and will put in place a plan to ensure that 'patients first' is embedded into its culture and ways of working.

IMPROVED TRANSPARENCY

Recommendation 63

Monitor should publish all side letters and any rating issued to trusts as part of their authorisation or licence.

Accepted.

Monitor has published all side letters since 2011 and risk ratings are published on a quarterly basis. Side letters are issued in certain circumstances where an applicant meets the statutory requirements for authorisation but there are matters that need to be addressed within a specified timeframe. The letter will detail the issue that needs to be addressed and the monitoring arrangements to be put in place to ensure delivery.

The welcome letter to a newly authorised trust sets out risk ratings for the first year. The quarterly risk rating is published on Monitor's web-site in the first quarter following authorisation. Monitor's risk-based framework assigns risk ratings to each NHS Foundation Trust on the basis of its forward plan and in-year performance against that plan. Monitor uses these ratings to guide the intensity of monitoring and to signal Monitor's degree of concern with specific issues identified, and consequently the risk of breach of the Continuity of Services or governance conditions of the licence.

AUTHORISATION OF FOUNDATION TRUSTS

Recommendation 64

The authorisation process should be conducted by one regulator, which should be equipped with the relevant powers and expertise to undertake this effectively. With due regard to protecting the public from the adverse consequences inherent to any reorganisation, the regulation of the authorisation process and compliance with Foundation Trust standards should be transferred to the Care Quality Commission, which should incorporate the relevant departments of Monitor.

Not accepted, although we agree with the principle of better regulation of the authorisation process.

As outlined in relation to recommendation 19, we agree with the principle of better regulation of the authorisation process, but we do not intend to merge regulatory functions. What is needed is radically better coordination between the regulators, and a far stronger focus on the quality and safety of services within the authorisation process, than was the case at Mid Staffordshire NHS Trust.

The Department of Health, with the Care Quality Commission's chief inspectors, is currently developing fundamental standards and will consult on setting these out in regulations, which make clear the standards below which care should never fall. A provider who is in breach of fundamental standards should not be authorised as a Foundation Trust.

As set out in recommendation 20, the Care Quality Commission's new approach to inspection will look more broadly than just compliance with regulations. It will reach judgements about

the overall quality of services, taking into account how safe, effective, caring, responsive and well-led they are. No provider will be authorised as a Foundation Trust unless the Care Quality Commission, through its Chief Inspector of Hospitals, judges that the quality of their services is 'good' or 'outstanding'.

The NHS Trust Development Authority, Monitor and the Care Quality Commission have undertaken an end-to-end review of the Foundation Trust assessment and authorisation process. The review aligns Monitor's Quality Governance Framework with the Care Quality Commission's approach to assessing leadership, culture and governance as part of the new inspection methodology. Monitor, the NHS Trust Development Authority and the Care Quality Commission will also develop a common set of quality indicators. This should ensure that there is a seamless process at every stage of assessment.

QUALITY OF CARE AS A PRE-CONDITION FOR FOUNDATION TRUST APPLICATIONS

Recommendation 65

The NHS Trust Development Authority should develop a clear policy requiring proof of fitness for purpose in delivering the appropriate quality of care as a pre-condition to consideration for support for a Foundation Trust application.

Accepted.

The NHS Trust Development Authority has published its Accountability Framework which sets out how Trusts will be held to account for delivering the appropriate quality of care. Trusts which are failing to meet these standards are subject to a robust and transparent escalation process.

The first priority for all provider organisations and for the bodies that oversee them should be to secure high quality services for patients. NHS Trusts are only able to progress through the Foundation Trust pipeline if they have been consistently delivering high quality care, as assessed against the standards in the Accountability Framework, which include concerns raised by the Care Quality Commission and others, such as commissioners.

The Board of the NHS Trust Development Authority will not support applications to progress to Monitor where there are any doubts about the quality of the services being provided by a Trust. In order to ensure this, future inspections of the quality of services provided by aspirant Foundation Trusts and their quality governance processes will take place earlier in the application process, prior to the NHS Trust Development Authority Board making its decision as to whether an application should be supported. No provider will be put forwards for authorisation as a Foundation Trust unless the Care Quality Commission, through its Chief Inspector of Hospitals, judges that the quality of their services is 'good' or 'outstanding'.

IMPROVING CONTRIBUTION OF STAKEHOLDER OPTIONS

Recommendation 66

The Department of Health, the NHS Trust Development Authority and Monitor should jointly review the stakeholder consultation process with a view to ensuring that;

- **local stakeholder and public opinion is sought on the fitness of a potential applicant NHS Trust for Foundation Trust status and in particular on whether a potential applicant is delivering a sustainable service compliant with fundamental standards;**
- **an accessible record of responses received is maintained;**
- **the responses are made available for analysis on behalf of the Secretary of State, and, where an application is assessed by it, Monitor.**

Accepted.

The NHS Trust Development Authority will test Trusts' Patient and Public Involvement strategies to ensure they are engaging with their patients and local community throughout the Foundation Trust application process, particularly on the quality of care being provided. It will also verify that Trusts are explicitly asking questions about quality of care in their public consultation and triangulating responses with any identified issues of clinical quality.

The NHS Trust Development Authority will follow up with the Trust on what it has done in response to any concerns raised during the consultation process and record this feedback, sharing the information with Monitor as necessary throughout the application process.

Monitor's assessment process also includes reviews of patient views and the NHS staff survey, meetings with staff and patient groups, review of access and outcome metrics, local media coverage and interviews with lead commissioners, the Care Quality Commission and external and internal auditors. Monitor also writes to local MPs and Healthwatch to see if they have any concerns they wish to raise. As part of their Quality Governance review they also seek to understand the Trust board's arrangements to actively engage with patients. Monitor will continue to consider the content of the consultation and the applicant's response to the issues raised as part of the assessment process.

FOCUS ON COMPLIANCE WITH FUNDAMENTAL STANDARDS

Recommendation 67

The NHS Trust Development Authority should develop a rigorous process for the assessment as well as the support of potential applicants for Foundation Trust status. The assessment must include as a priority focus a review of the standard of service delivered to patients, and the sustainability of a service at the required standard.

Accepted.

The focus of the NHS Trust Development Authority is to enable NHS Trusts to provide high quality, sustainable services for their local communities. It does this by overseeing all aspects

of a Trust Board's performance on delivering high quality care and supporting them to become sustainable organisations, thereby preparing them to become a Foundation Trust. The Board of the NHS Trust Development Authority will only approve a Trust's application to be passed to Monitor, when it is satisfied that the Trust has clearly demonstrated both these aspects.

The NHS Trust Development Authority has set out its rigorous process for assessing aspirant Foundation Trusts in its Accountability Framework *Delivering High Quality Care For All*. There will be a comprehensive inspection by the Care Quality Commission of the quality of services delivered by an aspirant Foundation Trust, as well as the quality governance arrangements within a Trust, prior to any decision by the Board of the NHS Trust Development Authority as to whether a Foundation Trust application will be supported. No provider will go forward for Foundation Trust authorisation unless the Care Quality Commission, through its Chief Inspector of Hospitals, judges that the quality of their services is 'good' or 'outstanding'.

Recommendation 68

No NHS trust should be given support to make an application to Monitor unless, in addition to other criteria, the performance manager (the Strategic Health Authority cluster, the Department of Health team, or the NHS Trust Development Authority) is satisfied that the organisation currently meets Monitor's criteria for authorisation and that it is delivering a sustainable service which is, and will remain, safe for patients, and is compliant with at least fundamental standards.

Accepted.

The Board of the NHS Trust Development Authority will only approve a Trust's application to be passed to Monitor, when it is satisfied that the Trust has clearly demonstrated that it is able to provide high quality care for patients, and has the right business plan in place to ensure it can continue to deliver well into the future.

The NHS Trust Development Authority has set out its rigorous process for assessing aspirant Foundation Trusts in its Accountability Framework, *Delivering High Quality Care For All*, of which the quality and sustainability of services is the focus. The NHS Trust Development Authority considers information from the public consultation, the Care Quality Commission, NHS England, the relevant Clinical Commissioning Group(s) and other national and local system partners prior to the NHS Trust Development Authority Board making a decision as to whether a Foundation Trust application will be supported. No provider will go forward for Foundation Trust authorisation unless the Care Quality Commission, through its Chief Inspector of Hospitals, judges that the quality of their services is 'good' or 'outstanding'.

Recommendation 69

The assessment criteria for authorisation should include a requirement that applicants demonstrate their ability to consistently meet fundamental patient safety and quality standards at the same time as complying with the financial and corporate governance requirements of a Foundation Trust.

Accepted.

The NHS Trust Development Authority has set out its rigorous process for assessing aspirant Foundation Trusts in its Accountability Framework *Delivering High Quality Care For All*. Quality and sustainability are the focus of the Foundation Trust application approvals process. This involves a comprehensive inspection by the Care Quality Commission of the quality of services delivered by an aspirant Foundation Trust, as well as the quality governance arrangements within a Trust, prior to any decision by the Board of the NHS Trust Development Authority as to whether a Foundation Trust application will be supported.

Trusts are challenged throughout Monitor's assessment process to demonstrate that they meet all of the assessment criteria relating to quality and safety. A number of changes in relation to providing evidence of quality have already been implemented to strengthen this (see recommendations 62 and 66 for details), and in particular NHS Trusts who aspire to become Foundation Trusts will in future no longer be able to do so unless and until they have achieved a 'good' or an 'outstanding' rating under the new Care Quality Commission inspection regime.

A joint working group between Monitor, the Care Quality Commission and NHS Trust Development Authority has been formed to ensure that the process for assessing applicant trusts reflects the recommendations of the Inquiry. This work is intended to strengthen further the assessment of quality in the approvals process through better sharing of information and expertise, alignment of metrics and ensuring more consistent judgements on quality.

DUTY OF UTMOST GOOD FAITH

Recommendation 70

A duty of utmost good faith should be imposed on applicants for Foundation Trust status to disclose to the regulator any significant information material to the application and to ensure that any information is complete and accurate. This duty should continue throughout the application process, and thereafter in relation to the monitoring of compliance.

Accepted.

NHS Trusts are expected to be open with the NHS Trust Development Authority and regulators throughout the Foundation Trust application process. In order to further support this duty of utmost good faith, the NHS Trust Development Authority will explicitly ask Trusts if they have anything to declare in relation to their application in the final Board-to-Board meeting before it is formally considered by the board of the NHS Trust Development Authority for approval to proceed to Monitor.

The Care Quality Commission is working closely with both Monitor and the NHS Trust Development Authority to ensure that all applicants are subject to inspection so that comprehensive, up-to-date information on the quality of care and governance process is available at the appropriate stages of the application process, and prior to any decision by the board of the NHS Trust Development Authority as to whether a Foundation Trust application will be supported. Monitor also now requires all applicants to sign a letter to confirm that

they have provided all information relevant and material to the Foundation Trust assessment process.

The Care Quality Commission is also involving Monitor and NHS Trust Development Authority in developing its new inspection methods and surveillance model, so as to ensure that opportunities for information-sharing are identified and used fully on an on-going basis.

In addition, as set out in recommendation 173, every healthcare organisation and everyone working for them must be honest, open and truthful. This will build upon the existing requirement of Monitor's licence that information provided is accurate, complete and not misleading and the expectation that licence-holders notify Monitor in the event of any incident, event or report that may raise concerns over compliance with their licence.

ROLE OF SECRETARY OF STATE

Recommendation 71

The Secretary of State's support for an application should not be given unless he is satisfied that the proposed applicant provides a service to patients which is, at the time of his consideration, safe, effective and compliant with all relevant standards, and that in his opinion it is reasonable to conclude that the proposed applicant will continue to be able to do so for the foreseeable future. In deciding whether he can be so satisfied, the Secretary of State should have regard to the required public consultation and should consult with the healthcare regulator.

Accepted.

The NHS Trust Development Authority's role is to ensure, on behalf of the Secretary of State for Health, that aspirant Foundation Trusts are ready to proceed for assessment by Monitor. This role is discharged on behalf of the Secretary of State by the Board of the NHS Trust Development Authority, which will not refer to Monitor any Trust where there are concerns relating to the compliance with any of the relevant standards either now or in the future. The decision of the Board is made with regard to the public consultation and after consulting with the Care Quality Commission, NHS England and other national and local system partners.

No provider should be authorised as a Foundation Trusts unless the Care Quality Commission, through its Chief Inspector of Hospitals, judges that the quality of their services is 'good' or 'outstanding'.

ASSESSMENT PROCESS FOR AUTHORISATION

Recommendation 72

The assessment for an authorisation of applicant for Foundation Trust status should include a full physical inspection of its primary clinical areas as well as all wards to determine whether it is compliant with fundamental safety and quality standards.

Accepted.

The Care Quality Commission has agreed that, in the future, it will inspect NHS Trusts while the NHS Trust Development Authority is assessing whether to support their Foundation Trust application to progress to Monitor. This inspection earlier in the process will provide invaluable information as to the applicant Trust's compliance with fundamental quality and safety standards. The Care Quality Commission's new inspection process is significantly more in-depth than its former approach and allows for large teams of specialist inspectors to visit any areas of a provider as they see fit.

NEED FOR CONSTRUCTIVE WORKING WITH OTHER PARTS OF THE SYSTEM

Recommendation 73

The Department of Health's regular performance reviews of Monitor (and the Care Quality Commission) should include an examination of its relationship with the Department of Health and whether the appropriate degree of clarity of understanding of the scope of their respective responsibilities has been maintained.

Accepted.

As part of the normal accountability processes that the Department of Health has set in place as a sponsor, the state of the relationship between the Department and its arm's length bodies is kept under regular review. Discussions include key areas of risk, consideration of how well the Department and the relevant arm's length body are working together and what could be done to improve co-operation and shared understanding. These discussions also include consideration of how the arm's length body is working within the wider health and care system, including areas of significant uncertainty or concern in relation to other arm's length bodies.

ENHANCEMENT OF ROLE OF GOVERNORS

Recommendation 74

Monitor and the Care Quality Commission should publish guidance for governors suggesting principles they expect them to follow in recognising their obligation to account to the public, and in particular in arranging for communication with the public served by the Foundation Trust and to be informed of the public's views about the services offered.

Accepted.

Monitor published a number of guidance documents for Foundation Trust governors, most recently (August 2013) a revised version of *Your statutory duties: a guide for NHS Foundation Trust Governors*. This includes guidance on the new statutory duties from the *Health and Social Care Act 2012*, including that of representing the interests of members and of the

public. This guidance has been published in association with the Department of Health, Care Quality Commission, Foundation Trust Network and Foundation Trust Governors Association.

Working in partnership with Monitor and the Foundation Trust Network, the NHS Leadership Academy has commissioned the GovernWell Programme, a new national training programme for Foundation Trust governors. The GovernWell programme is designed to help equip governors and non-executives with the skills they need to perform effectively, including improving their ability to challenge quality problems.

Monitor has also set up the Panel for Advising Governors, which has a former Foundation Trust chair as its Chair, together with 16 other experienced Members. The Panel has been operational since May 2013 and is ready to take questions from governors on topics as per the *Health and Social Care Act 2012*.

Monitor, the Department of Health, Care Quality Commission, Foundation Trust Network and Foundation Trust Governors Association have agreed to publish jointly a summary guide for all Councils of Governors on the respective roles of the sponsoring organisations, how they work together and how they work with Governors, by the end of December 2013.

Following this, the group is planning a series of good practice guides on key aspects of the governor role. The first of these guides is planned to be on representing the interests of members and the public, and is intended also to guide Foundation Trusts on how they will need to support governors in this aspect of their role.

Recommendation 75

The Council of Governors and the board of each Foundation Trust should together consider how best to enhance the ability of the council to assist in maintaining compliance with its obligations and to represent the public interest. They should produce an agreed published description of the role of the governors and how it is planned that they perform it. Monitor and the Care Quality Commission should review these descriptions and promote what they regard as best practice.

Accepted in part.

In August 2013 Monitor published a revised version of *Your statutory duties: a guide for NHS Foundation Trust Governors* which includes guidance on the new statutory duties from the *Health and Social Care Act 2012*. This guidance has been published in association with the Department of Health, Care Quality Commission, Foundation Trust Network and Foundation Trust Governors Association.

The above organisations recognise the variety of non-statutory duties that governors may perform, as well as the importance of preserving the autonomy of individual trusts and therefore the guidance does not seek to prescribe how governors should work day-to-day; NHS Foundation Trust boards and governors will agree this between themselves. Monitor and the Care Quality Commission will not review the descriptions produced by each Foundation Trust agreed between boards and governors.

Monitor, the Department, Care Quality Commission, Foundation Trust Network and Foundation Trust Governors Association are planning a series of good practice guides to support governors in carrying out their duties. The first of these guides is planned to be on

representing the interests of members and the public. In addition, Monitor, the Foundation Trust Network and the NHS Leadership Academy have commissioned the GovernWell programme, a new national training programme for Foundation Trust governors designed to help equip governors and non-executives with the skills they need to perform effectively.

Recommendation 76

Arrangements must be made to ensure that governors are accountable not just to the immediate membership but to the public at large – it is important that regular and constructive contact between governors and the public is maintained.

Accepted.

The *Health and Social Care Act 2012* provides that one of the general duties of the Council of Governors is to represent the interests of the members of the corporation as a whole and the interest of the public. Governors are elected from the membership of the Foundation Trust, who in turn consist of staff members, the general public and sometimes, patients or service users and their carers.

How governors engage and represent the public is not defined in law, as Foundation Trust boards and governors will agree between themselves how governors should work day-to-day. Examples of methods by which governors may represent the interests of the public are included in Chapter 4 of Monitor's publication *Your statutory duties: a reference guide for NHS Foundation Trust governors* (Aug 2013).

Monitor, Department of Health, Care Quality Commission, Foundation Trust Network and Foundation Trust Governors Association are planning a series of good practice guides to support governors in carrying out their duties. The first of these guides is planned to be on representing the interests of members and the public.

Recommendation 77

Monitor and the NHS Commissioning Board should review the resources and facilities made available for the training and development of governors to enhance their independence and ability to expose and challenge deficiencies in the quality of the Foundation Trust's services.

Accepted.

Working in partnership with Monitor and the Foundation Trust Network, the NHS Leadership Academy has commissioned the GovernWell programme, a new national training programme for Foundation Trust governors. The GovernWell programme is designed to help equip governors and non-executives with the skills they need to perform effectively, including improving their ability to challenge quality problems.

Monitor has surveyed Foundation Trust governors to review the current levels of support available and shares good practice with Foundation Trust Chairs, chief Executives and non-executive Directors on working effectively with their governors. Monitor also speaks regularly to Trust staff and councils of governors on the role of governors and what the expectations should be of it.

Monitor will be reviewing the uptake and feedback on the GovernWell programme on an ongoing basis. Monitor will also be supporting events hosted by the Foundation Trust Network for NHS Trust and Foundation Trust Chairs on working effectively with governors.

Monitor will update the Code of Governance to reflect the statutory duty of Foundation Trust boards to provide appropriate training for Foundation Trust governors. Foundation Trust boards will also be asked to self-certify on this as part of the Annual Plan Review.

Recommendation 78

The Care Quality Commission and Monitor should consider how best to enable governors to have access to a similar advisory facility in relation to compliance with healthcare standards as will be available for compliance issues in relation to breach of a licence (pursuant to section 39A of the National Health Service Act 2006 as amended), or other ready access to external assistance.

Accepted.

Monitor has set up the Panel for Advising Governors, which has a former Foundation Trust chair as its Chair, together with 16 other experienced members. The panel has been operational since May 2013 and is ready to take questions from governors on topics as per the *Health and Social Care Act 2012*.

Governors may therefore put a question to the existing panel on a breach or potential breach of the trust's constitution, breach of licence or any other matter under chapter 5 of the *National Health Service Act 2006*.

The Care Quality Commission has recently written to all Councils of Governors to confirm the appointment of Professor Sir Mike Richards as the new Chief Inspector of Hospitals, and to highlight and inform governors of the ways in which they can share information and raise issues with the Care Quality Commission, and contribute to the new NHS inspections.

The Care Quality Commission will be piloting ways for governors to contribute directly to the new hospital inspections, as a further route to raising issues.

ACCOUNTABILITY OF PROVIDERS' DIRECTORS

Recommendation 79

There should be a requirement that all directors of all bodies registered by the Care Quality Commission as well as Monitor for Foundation Trusts are, and remain, fit and proper persons for the role. Such a test should include a requirement to comply with a prescribed code of conduct for directors.

Accepted in principle.

We agree that the public have the right to expect that people in leading positions in NHS organisations are fit and proper persons; and that where it is demonstrated that a person is not fit and proper, they should not be able to occupy such a position. Monitor's licence conditions for providers of NHS services already prevents licensees from allowing unfit persons to become or continue as governors or directors (or those performing similar or

equivalent functions. They are also required to ensure that their contracts of service with its Directors contain a provision permitting summary termination in the event of a Director being or becoming an unfit person. The Licensee is also required to ensure that it enforces that provision promptly upon discovering any Director to be an unfit person.

The Government issued in July 2013 a consultation on *Strengthening corporate accountability in health and social care*. This proposes a new requirement that all Board Directors (or equivalents) of providers registered with the Care Quality Commission must meet a new fitness test. We are proposing that this test includes checks about whether the person is of good character including past employment history, if the individual has the qualifications, skills and experience necessary for the work or office, as well as the more traditional consideration of criminal and financial matters.

The Government proposes that the fit and proper persons test will now be used as a mechanism for introducing a scheme for barring Directors who are unfit from individual posts by Care Quality Commission at the point of registration. Where a Director is considered by Care Quality Commission to be unfit it could either refuse registration, in the case of a new provider, or require the removal of the Director on inspection, or following notification of a new appointment. Further details will be set out in the response to the consultation on corporate accountability which will be published shortly. We plan to publish the draft regulations for consultation at the same time.

The standards produced by the Professional Standards Authority (*Standards for members of NHS boards and Clinical Commissioning Group governing bodies in England*) provide the basis for assessing the fitness of senior board-level leaders and managers.

Recommendation 80

A finding that a person is not a fit and proper person on the grounds of serious misconduct or incompetence should be a circumstance added to the list of disqualifications in the standard terms of a Foundation Trust's constitution.

Accepted in principle.

We agree that the public have the right to expect that people in leading positions in NHS organisations are fit and proper persons; and that where it is demonstrated that a person is not fit and proper, they should not be able to occupy such a position. Monitor and the Care Quality Commission are committed to ensuring that, taken together, their processes for registration and licensing reflect these principles. Monitor's licence conditions already require providers to ensure that no person who is an unfit person may become or continue as a Director and that they ensure that its contracts of service with its Directors contain a provision permitting summary termination in the event of a Director being or becoming an unfit person.

In order to strengthen this, the Government issued in July 2013 a consultation on *Strengthening corporate accountability in health and social care*. This proposes a new requirement that all Board Directors (or equivalents) of providers registered with the Care Quality Commission must meet a new fitness test. We are proposing that this test includes checks about whether the person is of good character including past employment history, if the individual has the qualifications, skills and experience necessary for the work or office, as well as the more traditional consideration of criminal and financial matters.

The Government proposes that the fit and proper persons test will now be used as a mechanism for introducing a scheme for barring Directors who are unfit from individual posts by Care Quality Commission at the point of registration. Where a Director is considered by Care Quality Commission to be unfit it could either refuse registration, in the case of a new provider, or require the removal of the Director on inspection, or following notification of a new appointment. The Government believes that this will be a robust method of ensuring that Directors whose conduct or competence makes them unsuitable for these roles are prevented from securing them. The scheme will be kept under review to ensure that it is effective, and we will legislate in the future if the barring mechanism is not having its desired impact. Further details will be set out in the response to the consultation on corporate accountability which will be published shortly. We plan to publish the draft regulations for consultation at the same time.

In addition to regulatory mechanisms, we also believe it is important for organisations appointing and employing senior leaders to use the means already available to them (most notably recruitment, appraisal, exit procedures and provision of references) to ensure and strengthen the quality of the senior leaders in their organisations and the wider system, and to identify and deal with issues of performance and behaviour. This will on occasion (but not always) include action to remove someone from a senior role. The Government, the Care Quality Commission, the NHS Trust Development Authority and Monitor will continue to work with NHS Employers and other organisations with a responsibility for and an interest in these issues to ensure a focus on improving the way that existing mechanisms operate. We believe that the focus for this issue should be the internal processes described above, and the Care Quality Commission's registration requirements rather than the constitution of the Foundation Trust.

Recommendation 81

Consideration should be given to including the criteria for fitness a minimum level of experience and/or training, while giving appropriate latitude for recognition of equivalence.

Accepted.

We agree that people in leading positions in NHS organisations should have the appropriate experience and training to take up those positions and that this should be one of the criteria for any assessment of whether someone is a fit and proper person. It is vital that they are assessed as a key element of the recruitment process and of ongoing appraisal. As set out in *The Healthy NHS Board 2013*, as well as experience and technical skill, values and behaviour are also critical to getting the right leaders in place. We also endorse the document's advice that regular skills audits of current board members should be carried out.

Monitor's Risk Assessment Framework sets out how it oversees NHS Foundation Trusts compliance with the provider licence. Where a breach has occurred in respect of governance, one of the areas Monitor may investigate is the Foundation Trust's management and organisational capability in making an assessment about return to compliance. Monitor's Code of Governance for Foundation Trusts sets a clear expectation that there should be a formal, rigorous and transparent procedure for the appointment of directors and that care should be taken to ensure that new appointees have relevant skills and experience.

Monitor is working with the Foundation Trust Network to offer a 2-day induction programme for new non-executive directors of NHS Foundation Trusts. The first of these programmes was run in September 2013. Monitor will be working together with the NHS Leadership Academy, NHS Trust Development Authority and Foundation Trust Network to increase external support for chief executives of NHS Trusts and Foundation Trusts. Monitor will also consider how best to support medical directors in the coming year.

Recommendation 82

Provision should be made for regulatory intervention to require the removal or suspension from office after due process of a person whom the regulator is satisfied is not or is no longer a fit and proper person, regardless of whether the trust is in significant breach of its authorisation or licence.

Accepted.

Under the revised registration requirements, in cases where a Director was deemed by the Care Quality Commission to be unfit, the Care Quality Commission will be able to insist on their removal by placing a condition on the provider's registration. If the provider failed to remove the director that would be an offence for breach of the condition, and the provider would be liable to prosecution.

The Government proposes that the fit and proper persons test will now be used as a mechanism for introducing a scheme for barring Directors who are unfit from individual posts by the Care Quality Commission at the point of registration. Where a Director is considered by the Care Quality Commission to be unfit it could either refuse registration, in the case of a new provider, or require the removal of the Director on inspection, or following notification of a new appointment. Further details will be set out in the response to the consultation on corporate accountability which will be published shortly. The Government plans to publish the draft regulations for consultation at the same time.

Recommendation 83

If a 'fit and proper person test' is introduced as recommended, Monitor should issue guidance on the principles on which it would exercise its power to require the removal or suspension or disqualification of directors who did not fulfil it, and the procedure it would follow to ensure due process.

Accepted.

Monitor and the Care Quality Commission are committed to ensuring that, taken together, their processes for registration and licensing work effectively to ensure that people in leading positions are fit and proper persons. The Care Quality Commission will set out in guidance how it will apply the fit and proper persons test as part of its regulatory regime and will ensure that as far as possible its approach in relation to registration is aligned with Monitor's assessment of fitness as part of its licensing process (which applies to a narrower range of organisations than registration). Monitor has also published guidance on how it will exercise its enforcement powers which are used where there is a breach of licence conditions. This includes procedures for imposing additional licence conditions on NHS Foundation Trusts and removing, suspending or disqualifying directors or governors of NHS Foundation Trusts.

Recommendation 84

Where the contract of employment or appointment of an executive or non-executive is terminated in circumstances in which there are reasonable grounds for believing that he or she is not a fit person to hold such a post, licensed bodies should be obliged by the terms of their licence to report the matter to Monitor, the Care Quality Commission and the NHS Trust Development Authority.

Accepted in principle.

In cases where there are reasonable grounds that a person is not fit to hold such a post, we would expect this view to be reflected in the references provided by the employer to a prospective new employer. Prospective employers have a responsibility to seek references from previous employers. NHS Employers are working on how to support organisations so that all information relating to recruitment into Board positions is presented, known and used by employers. Rather than use a regulatory intermediary as a register of concerns about a person's fitness of the kind identified by this recommendation, we therefore believe it would be better to make references and recruitment processes more effective.

We agree that the public has the right to expect that people in leading positions in NHS organisations are fit and proper persons; and that where it is demonstrated that a person is not fit and proper, they should not be able to occupy such a position. Monitor's licence conditions for providers of NHS services already prevents licensees from allowing unfit persons to become or continue as governors or directors (or those performing equivalent functions). They are also required to ensure that their contracts of service with its Directors contain a provision permitting summary termination in the event of a Director being or becoming an unfit person. The Licensee is also required to ensure that it enforces that provision promptly upon discovering any Director to be an unfit person.

In order to strengthen this, the Government issued in July 2013 a consultation on *Strengthening corporate accountability in health and social care*. This proposes a new requirement that all Board Directors (or equivalents) of providers registered with Care Quality Commission must meet a new fitness test. We are proposing that this test includes checks about whether the person is of good character including past employment history, if the individual has the qualifications, skills and experience necessary for the work or office, as well as the more traditional consideration of criminal and financial matters.

The Government proposes that the fit and proper persons test will now be used as a mechanism for introducing a scheme for barring Directors who are unfit from individual posts by Care Quality Commission at the point of registration. Where a Director is considered by Care Quality Commission to be unfit it could either refuse registration, in the case of a new provider, or require the removal of the Director on inspection, or following notification of a new appointment. Further details will be set out in the response to the consultation on corporate accountability which will be published shortly. We plan to publish the draft regulations for consultation at the same time.

Recommendation 85

Monitor and the Care Quality Commission should produce guidance to NHS and Foundation Trusts on procedures to be followed in the event of an executive or non-

executive director being found to have been guilty of serious failure in the performance of his or her office, and in particular with regard to the need to have regard to the public interest in protection of patients and maintenance of confidence in the NHS and the healthcare system.

Accepted.

In cases where a Director was deemed by the Care Quality Commission to be unfit, the Care Quality Commission would be able to insist on their removal by placing a condition on the provider's registration. If the provider then failed to remove the director that breach of the registration condition would be an offence for which the provider would be liable to prosecution.

The Care Quality Commission will publish guidance setting out how the process will work, and how it will co-operate with Monitor and the NHS Trust Development Authority.

Under the single failure regime, Monitor and the NHS Trust Development Authority would be able to use their existing powers to enforce fit and proper persons requirements (such as the removal of directors) on licence holders and NHS Trusts.

REQUIREMENT OF TRAINING OF DIRECTORS

Recommendation 86

A requirement should be imposed on Foundation Trusts to have in place an adequate programme for the training and continued development of directors.

Accepted.

Monitor's licence conditions require providers to ensure that no person who is an unfit person may become or continue as a Director and that they ensure that its contracts of service with its Directors contain a provision permitting summary termination in the event of a Director being or becoming an unfit person. The Licensee is also required to ensure that it enforces that provision promptly upon discovering any Director to be an unfit person.

We agree that it is important for directors of all NHS organisations (including Foundation Trusts) to be provided with the development they need to operate effectively and responsibly. The recently published *The Healthy NHS Board 2013* document sets out a number of measures for the development of individual directors and boards as a whole, including 360 degree feedback, structured induction, peer learning, whole board performance assessment and individual appraisal. Monitor's Code of Governance for Foundation Trusts sets out an expectation that Directors should also have access, at the NHS foundation trust's expense, to training courses and/or materials that are consistent with their individual and collective development programme. Monitor's Quality Governance framework guidance also challenges boards to ensure they have the necessary leadership, skills and knowledge to ensure delivery of the quality agenda. It also suggests boards conduct regular self-assessments to test its skills and capabilities and attend training sessions covering the core elements of quality governance and continuous improvement.

Monitor already has in place programmes provided jointly with others to support chairs, non-executive directors and finance directors. Monitor additionally provides a one-day induction programme for new chairs and chief executives of NHS Foundation Trusts and is working with the Foundation Trust Network to offer a 2-day induction programme for new non-executive directors of NHS Foundation Trusts. The first of these programmes was run in September 2013 and the next cohort will take place in January 2014. Monitor will be working together with the NHS Leadership Academy, NHS Trust Development Authority and the Foundation Trust Network to increase external support for chief executives of NHS Trusts and Foundation Trusts and will also consider how best to support medical directors in the coming year. The Foundation Trust Network also offers development programmes for executive directors and company secretaries.

Responsibility for, and effectiveness of, regulating healthcare systems governance – Health and Safety Executive functions in healthcare settings

The Inquiry raised concerns about the limited scope with which the Health and Safety Executive exercised its powers in relation to healthcare and similarly the constraints of the Care Quality Commission, as a healthcare regulator to bring about a prosecution. The Inquiry highlighted a ‘regulatory gap’, as well as the need for clarity of roles and information sharing between the organisations responsible for regulating the providers and healthcare professionals.

The Care Quality Commission will be able to take more effective action where there are clear failures to meet basic standards of care as part of a new set of fundamental standards by 2014. The Care Quality Commission will draw more on the expertise of the Health and Safety Executive in investigations and prosecutions. This will be achieved through a new liaison agreement between the two organisations that will also ensure better cooperation in sharing information. The Health and Safety Executive will retain its powers to bring about prosecutions in health and social care in exceptional circumstances.

ENSURING THE UTILITY OF A HEALTH AND SAFETY FUNCTION IN A CLINICAL SETTING

Recommendation 87

The Health and Safety Executive is clearly not the right organisation to be focusing on healthcare. Either the Care Quality Commission should be given power to prosecute 1974 Act offences or a new offence containing comparable provisions should be created under which the Care Quality Commission has power to launch a prosecution.

Accepted in principle.

The Care Quality Commission is the right organisation to focus on healthcare, investigate and act where patients have been seriously harmed because of unsafe or poor care. Investigation of such incidents can give early warning of more widespread management failure.

The Government recognises that, although the Care Quality Commission is able to prosecute providers, directors and unincorporated associations under the Health and Social Care Act 2008, in practice there have been few prosecutions. This suggests that the Care Quality Commission’s approach to enforcement needs to be strengthened. The Department of Health is developing revised requirements for registration with the Care Quality Commission to include fundamental standards that will enable prosecutions of providers to occur where patients have been harmed because of unsafe or poor care, without the need for an advance warning notice. This will ensure that the current regulatory gap identified in the Inquiry report is

filled. *A new start – Consultation on changes to the way Care Quality Commission regulates, inspects and monitors care*⁵⁸ set out plans to introduce fundamental standards which will enable the Care Quality Commission to take more effective action, including prosecution, where there are clear failures to meet basic standards of care. On 17 October 2013, the Care Quality Commission published the responses to the consultation in *A new start: Responses to our consultation on changes to the way Care Quality Commission regulates, inspects and monitors care services*,⁵⁹ which showed that there is broad agreement with the new approach.

The Department is also working with the Care Quality Commission and the Health and Safety Executive to ensure that the Health and Safety at Work Act 1974 and its relevant statutory provisions will continue to be used by the Health and Safety Executive where it provides for the most specific breaches. Given the Health and Safety Executive's more limited role for patient safety, the Care Quality Commission and the Health and Safety Executive will together develop and agree criteria and handling arrangements for the matters that the Health and Safety Executive will investigate.

The Care Quality Commission and the Health and Safety Executive have published a Liaison Agreement, which describes how the two organisations currently work together. This will need to change to reflect the revised registration requirements, the Care Quality Commission's role, the criteria for matters which the Health and Safety Executive will investigate, and the mechanism for referral. The Care Quality Commission and the Health and Safety Executive will ensure that this is done in line with the implementation of the revised registration requirements.

The Health and Safety Executive will support the Care Quality Commission in developing its role in investigating and prosecuting in cases of unacceptable care. The Department of Health will work with the Department of Work and Pensions and the Health and Safety Executive to ensure that Health and Safety Executive has the necessary capacity to support the Care Quality Commission.

INFORMATION SHARING

Recommendation 88

The information contained in reports for the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations should be made available to healthcare regulators through the serious untoward incident system in order to provide a check on the consistency of trusts' practice in reporting fatalities and other serious incidents.

Accepted in principle.

Access to accurate and up to date information and intelligence is essential to the effective regulation of health and adult social care providers by the Care Quality Commission. In practice, few patient incidents fall under the category of Reporting of Injuries, Diseases and

58 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

59 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_newstartresponse_2013_14_tagged_sent_to_web.pdf

Dangerous Occurrences Regulations (RIDDOR) and the Care Quality Commission would in any case be informed of these incidents through the statutory notifications that registered providers are required to make them. In addition, there is an information sharing agreement in place between the Health and Safety Executive and the Care Quality Commission. Currently, in addition to the information shared via the Liaison Agreement, the Health and Safety Executive shares quarterly investigated RIDDOR accidents, complaints, and enforcement and prosecution notices data.. This information will be shared on a more frequent basis under new working arrangements and will be reflected in the liaison agreement between the Care Quality Commission and the Health and Safety Executive.

Recommendation 89

Reports on serious untoward incidents involving death of or serious injury to patients or employees should be shared with the Health and Safety Executive.

Accepted in principle.

The Care Quality Commission is the regulator of the safety and quality of health and adult social care providers in England. Providers registered with the Care Quality Commission are required to notify it of serious untoward incidents involving death or serious injury either directly or through the National Reporting and Learning System in the case of NHS organisations. The Care Quality Commission uses the intelligence that it receives from these notifications as part of its risk assessment. An initial assessment of serious untoward incidents should be carried out by the Care Quality Commission as the specialist inspector of the health and adult social care providers, with the ability to draw on the Health and Safety Executive's expertise in investigations and prosecutions. This will be set out in the revised liaison agreement between the Care Quality Commission and the Health and Safety Executive.

ASSISTANCE IN DECIDING ON PROSECUTIONS

Recommendation 90

In order to determine whether a case is so serious, either in terms of the breach of safety requirements or the consequences for any victims, that the public interest requires individuals or organisations to be brought to account for their failings, the Health and Safety Executive should obtain expert advice, as is done in the field of healthcare litigation and fitness to practise proceedings.

Accepted.

The Health and Safety Executive has always sought expert advice. Such advice might come from its own specialist inspectors or subject matter experts, from staff within the Health and Safety Laboratory, from other regulators such as the Medicines and Healthcare products Regulatory Agency, from the Department of Health, from external associations such as the National Back Exchange, from independent medical practitioners who are experts in their field or others.

The Care Quality Commission will also seek appropriate specialist advice in investigating potential breaches of the new fundamental standards.

Enhancement of the role of supportive agencies

The NHS Litigation Authority, the National Patient Safety Agency (whose functions have now been transferred to NHS England) and the Health Protection Agency have role supportive functions in promoting quality and safety across the NHS. The Public Inquiry focused on how the roles of these organisations might be enhanced as well as how they relate to all other part of health and social care in terms of access to and sharing of safety information.

The NHS Litigation Authority will introduce a new safety and learning service that will replace the current risk management standards and assessments and provide members with support to learn from claims and reduce harm and thereby reduce claims in the future. The Government has decided that the functions of the National Patient Safety Agency should remain with NHS England, who will be held to account for improvement in patient safety in the NHS. The Department of Health will also respond to the review led by Professor Don Berwick which sets out the implementation of a whole-system approach to patient safety. Public Health England, which since April 2013 has taken on the functions of the Health Protection Agency, is working together with the Health and Social Care Information Centre to coordinate the collection, analysis and publication of information in relation to Healthcare Associated Infections. Work is also underway to implement new arrangements for sharing expertise and escalating concerns with the Care Quality Commission, Monitor, NHS England and the NHS Trust Development Authority.

NHS LITIGATION AUTHORITY IMPROVEMENT OF RISK MANAGEMENT

Recommendation 91

The Department of Health and NHS Commissioning Board should consider what steps are necessary to require all NHS providers, whether or not they remain members or the NHS Litigation Authority scheme, to have and to comply with risk management standards at least as rigorous as those required by the NHS Litigation Authority.

Accepted in principle.

We agree that the effectiveness of any national scheme of this kind to promote the improvement of risk management and any associated benefits for patient safety will be dependent on it continuing to have near universal coverage of providers. It is also accepted that the NHS Litigation Authority's risk management standards and assessments have assisted in improving processes for risk management in the NHS. However, the existence of a risk management system, even one complying with the NHS Litigation Authority's standards

does not of itself mean that a trust is safe. There are many other factors that are relevant which should be considered when assessing whether practices are safe for staff and patients. The Government is clear that there should be fundamental standards that represent the basic requirements and that should be the core of all services. The new fundamental standards will sit within the legal requirements that providers of health and adult social care must meet to be registered with Care Quality Commission. Together with a new ratings systems, developed and published by the Care Quality Commission, providers will be assessed on how well they meet the standards for safe and high quality care.

All NHS Trusts and Foundation Trusts are currently members of the NHS Litigation Authority's clinical negligence scheme. In addition, the number of independent providers funded to provide NHS healthcare joining the scheme, is increasing. The scheme is voluntary and there is no requirement for trusts that opt out to meet the NHS Litigation Authority's standards.

As well as the Inquiry, recent reviews led by Sir Bruce Keogh and Professor Dr Don Berwick, when considered with the views of the NHS Litigation Authority's members, indicate that the time is right to move away from assessments against a set of risk management standards to a new outcome focused approach. The new approach to safety and learning will support members to reduce claims by focussing on areas which cause significant harm and in working towards improving clinical outcomes. These changes will also seek to reduce bureaucracy and the burden on front line staff, and avoid duplication with other agencies.

This means that the NHS Litigation Authority risk management standards the Inquiry refers to will be discontinued and the last assessment will be carried out on March 2014. Therefore, the Department considers it would not be appropriate to require any NHS provider leaving the scheme to have and to comply with the outgoing standards.

Recommendation 92

The financial incentives at levels below level 3 should be adjusted to maximise the motivation to reach level 3.

Accepted.

From 1 April 2013, the NHS Litigation Authority introduced a revised pricing methodology for the Clinical Negligence Scheme for Trusts.

The new approach means that organisations with a good claims record will see the benefit of this in their Clinical Negligence Scheme for Trusts pricing whereas those organisations with a less favourable claims history will contribute more to the risk pool. These changes were discussed extensively with members of the scheme. The Department of Health and other relevant parties across the system agreed this represents a more equitable way of distributing the costs of the scheme.

The NHS Litigation Authority is also already bringing the focus of NHS organisations onto their claims activity which it is hoped will in turn assist in reducing the costs associated with Clinical Negligence Scheme for Trusts and ultimately reduce the level of harm to patients.

Recommendation 93

The NHS Litigation Authority should introduce requirements with regard to observance of the guidance to be produced in relation to staffing levels, and require trusts to have regard to evidence-based guidance and benchmarks where these exist and to demonstrate that effective risk assessments take place when changes to the numbers or skills of staff are under consideration. It should also consider how more outcome based standards could be designed to enhance the prospect of exploring deficiencies in risk management, such as occurred at the trust.

Accepted in principle.

As in the response to recommendation 91, the NHS Litigation Authority will move away from assessments against a set of risk management standards to a new outcome focused approach. The new approach which will support members to reduce claims by focussing on areas which cause significant harm and in working towards improving clinical outcomes. These changes will also seek to reduce bureaucracy and the burden on front line staff, and avoid duplication with other agencies.

The NHS Litigation Authority is not in a position to introduce requirements with regard to the observance of guidance in relation to staffing levels, or to require the assessment of appropriate skill mix, staffing level and staff patient ratios. It is for trusts (and where appropriate, regulators) to have regard to evidence based guidance and benchmarks and to undertake effective risk assessments when changes to numbers or skills of staff are under consideration.

However, the NHS Litigation Authority's revised pricing methodology for setting member contributions for their indemnity cover takes account of staffing and activity levels. This mean that if all other factors are equal, organisations which have more staff to undertake activities with the same level of risk will pay less for their indemnity cover. It also ensures that organisations with fewer claims pay less for the indemnity cover, therefore rewarding safer organisations.

EVIDENCE-BASED ASSESSMENT

Recommendation 94

As some form of running record of the evidence reviewed must be retained on each claim in order for these reports to be produced, the NHS Litigation Authority should consider the development of a relatively simple database containing the same information.

Accepted.

The NHS Litigation Authority has launched a new extranet which provides members with detailed information about their claims so they can easily identify areas where they need to focus on reducing claims. The information is real time and shows total volumes and values but also broken down by speciality. Members can use the information to benchmark themselves against similar organisations.

The extranet also provides materials to support learning.

INFORMATION SHARING

Recommendation 95

As the interests of patient safety should prevail over the narrow litigation interest under which confidentiality or even privilege might be claimed over risk reports, consideration should also be given to allowing the Care Quality Commission access to these reports.

Accepted.

In response to the Caldicott Review, *Information: To Share or Not to Share (2013)*, the Department of Health stated that health and care professionals must make decisions about how information is shared and used in the best interests of people and patients using the five rules of confidentiality set out in new Health and Social Care Information Centre's guidance, *Guide to Confidentiality in Health and Social Care (2013)*.

The NHS Litigation Authority also supports the view that the patient safety should prevail over litigation interests. It actively supports explanations and apologies and will never refuse to indemnify a member because they have apologised. It shares information which supports learning from claims with the NHS and makes such information available to members and where appropriate, other stakeholders. The NHS Litigation Authority is sharing relevant claims information as part of the Care Quality Commission's inspection regime. The NHS Litigation Authority is also putting in place an information sharing agreement with regulators to enable us to share relevant information.

Recommendation 96

The NHS Litigation Authority should make more prominent in its publicity an explanation comprehensible to the general public of the limitations of its standards assessments and of the reliance which can be placed on them.

Accepted.

The NHS Litigation Authority has included a comprehensible explanation of the limitations of the standards and assessments process on its website. Following the publication of the NHS Litigation Authority's Industry Review in January 2012, the NHS Litigation Authority has reviewed the standards and assessment process and advised members that it is moving away from assessment against standards to an outcome focus approach. This will support the NHS to learn from claims by sharing information and learning and through price incentivisation.

NATIONAL PATIENT SAFETY AGENCY FUNCTIONS

Recommendation 97

The National Patient Safety Agency's resources need to be well protected and defined. Consideration should be given to the transfer of this valuable function to a systems regulator.

Accepted in part.

The functions of the National Patient Safety Agency were moved to NHS England in order to ensure that improving safety is core business for the NHS. The Department of Health and NHS England agree this vital function should continue to have its resources protected. The Mandate for NHS England includes the objective to continue to reduce avoidable harm and make measurable progress by 2015 to embed a culture of patient safety in the NHS including through improved reporting of incidents. NHS England will be held accountable for progress against the objectives and will use its position as the leadership body for the NHS to support quality improvement throughout the healthcare system, which by definition includes safety improvement.

Patient safety is a critical component of what an effective regulator seeks to secure, maintain and improve and is rightly at the heart of the Care Quality Commission's new inspection regime. The Chief Inspector of Hospitals' assessment will include an inspection for patient safety which will inform the ratings of all NHS providers. In addition, the Care Quality Commission and NHS England will work closely together to share information, including reported incidents from the National Reporting and Learning System, to support Care Quality Commission's surveillance and inspection.

The Government has considered the case for the transfer of the functions of the National Patient Safety Agency to a system regulator. These functions were primarily focused on learning, improvement and innovation rather than regulation and assurance. The core functions were to collect patient safety incident reports from all healthcare organisations, so that those reports could be analysed by safety experts in order to learn from what had gone wrong and then to use that knowledge to encourage patient safety improvement across the system. No system is ever 100% safe and patient safety demands an active commitment to continually reducing harm. Professor Don Berwick's report, *Improving the Safety of Patients in England*,⁶⁰ emphasises that regulation is a crucial component of patient safety, but is not sufficient alone to secure patient safety. Ensuring the continual reduction of harm to patients requires the underlying culture of the NHS to be devoted to learning, improvement and innovation, and delivering that is a role that goes much wider than the system regulator's remit. The Government believes this role rightly sit within NHS England.

In order to realise the Berwick report's vision of the NHS as an organisation devoted to continual learning and improvement, NHS England and NHS Improvement Quality are leading to establish a nationwide Patient Safety Collaborative Programme and will bring a significant level of resource and support to patient safety and improvement science over the next

60 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf

5 years. Each collaborative will be locally-led and nationally supported. They will be designed to inspire and support a culture of continuous learning and improvement of patient safety in the NHS and be expected to deliver on a set of core patient safety priorities as well as their own priorities. As set out in the NHS Mandate refresh, NHS England and NHS Improvement Quality will seek to finalise the design of the programme, put in place the support and development capacity and recruit participating organisations by spring 2014. NHS England is also working with others on the best ways to develop much greater patient safety capability in the NHS through the education and training of the healthcare workforce in patient safety skills.

Recommendation 98

Reporting to the National Reporting and Learning System of all significant adverse incidents not amounting to serious untoward incidents but involving harm to patients should be mandatory on the part of trusts.

Accepted in principle.

Reporting of patient safety incidents involving severe harm and death is already mandatory nationally under the Care Quality Commission regulations and these incidents are actively reviewed by NHS England as well as being shared with the Care Quality Commission.

The Government's current policy is not to introduce a mandatory reporting system at this stage however the Government does agree there should be a new duty on providers to be candid to patients (as set out in recommendation 174) and more should be done to promote the reporting of all patient safety incidents among healthcare professionals (as set out in recommendation 181).

The National Reporting and Learning System already receives over 1.2 million incident reports a year and NHS England continues to encourage increased reporting from across the healthcare system. Indicator 5.1 of the NHS Outcomes Framework requires that the NHS continues to increase the numbers of incidents that are reported to the National Reporting and Learning System as this is a good indication of the development of a mature patient safety culture where organisations are open about incidents. NHS England will continue to drive the development of the safety culture within the NHS, not least by implementing relevant recommendations from the Berwick report. Organisations should routinely collect, analyse and respond to local measures that serve as indicators of the level of quality and safety of healthcare, including the voices of patients and staff, staffing levels, the reliability of critical processes and other quality metrics.

As stated in recommendation 97, the Chief Inspector of Hospitals' assessment will include an inspection for patient safety which will inform the ratings of all NHS providers and the Care Quality Commission and NHS England will work closely together to share information, including reported incidents from the National Reporting and Learning System, to support Care Quality Commission's surveillance and inspection.

Recommendation 99

The reporting system should be developed to make more information available from this source. Such reports are likely to be more informative than the corporate version where an incident has been properly reported, and invaluable where it has not been.

Accepted in principle.

This recommendation refers to the reporting of patient safety incidents by individuals as opposed to via the 'standard' route of uploading incident reports from organisations' local risk management systems. It is predicated on the view that these reports may contain more information than those reported via an organisation's own reporting system (the 'corporate version') and are of use where individuals feel unable to report an incident to their own organisation.

An online incident reporting e-form that can be used by individual staff, patients and the public to report patient safety incidents directly to the exists. While staff who use the online e-form form are encouraged to also report the incident to their employer's local systems, there is no automatic link back to local systems. Therefore there is a risk that by encouraging wider use of reporting routes that avoid local organisations' own reporting systems, important information about the incident may not reach the organisation concerned. This would severely compromise local learning and improvement. In addition, creating an automatic link may well discourage people from using the e-form if they are concerned about the response of the organisation in question. Taking into account these considerations, NHS England will consider how to make the online e-form more widely available and explore the feasibility of online reports being fed back to trusts at the same time as they are reported to the National Reporting and Learning System. NHS England is reviewing the National Reporting and Learning System in order to redesign and re-commission the system to ensure it is more responsive, easier and simpler to use and makes incident reporting and feedback a more worthwhile activity for users. In particular, NHS England is looking to make sure the reporting portal is more widely known and advertised.

More importantly, NHS England's programme of work will further encourage a culture in the NHS where staff feel able to report any incident to their own organisation in as full and informative a way as necessary. This together with work being taken forward by the professional regulators in response to recommendation 181, should create a more open and transparent culture and promote a climate of learning to drive improvements in patient safety.

Recommendation 100

Individual reports of serious incidents which have not been otherwise reported should be shared with a regulator for investigation, as the receipt of such a report may be evidence that the mandatory system has not been complied with.

Accepted in principle.

All serious incidents involving severe harm and death reported by individuals to via the on-line e-form, or any route, are routinely shared with the Care Quality Commission on a weekly basis. The Care Quality Commission also receives all incident reports to the National Reporting and Learning System on a weekly basis, regardless of the seriousness of the incident or the source of the report. The Care Quality Commission also has direct access to the national Serious Incident reporting system, STEIS (the Strategic Executive Information System), which is used by commissioners and providers to report and manage serious incidents in NHS-funded care. It is therefore able to view all the information submitted to that system regarding Serious Incidents as well.

The Government does not support the view at this stage that there should be a mandatory reporting system for all incidents however, as set out in recommendation 98, NHS England and the Care Quality Commission are committed to working together to develop a shared and agreed approach to measuring safety in the NHS, both for regulatory and improvement purposes. NHS England and the Care Quality Commission are working together to agree a set of patient safety measures, including all incidents reported. The Care Quality Commission will also be reviewing its approach to looking at serious untoward incidents as part of our pre-inspection activity.

Recommendation 101

While it may be impracticable for the National Patient Safety Agency or its successor to have its own team of inspectors, it should be possible to organise for mutual peer review inspections or the inclusion in Patient Environment Action Team representatives from outside the organisation. Consideration could also be given to involvement from time to time of a representative of the Care Quality Commission.

Accepted.

Patient Environment Action Team inspections have now been replaced by Patient-led Assessments of the Care Environment. These are annual inspections of all NHS hospitals (and some independent sector ones) that cover provisions for privacy and dignity, cleanliness, food, and general décor/maintenance of hospital buildings. They are carried out by teams that include at least 50% patients or members of the public, which increases the external scrutiny (the Patient Environment Action Team process was entirely self-assessment). The Department of Health has advised that Patient-led Assessments of the Care Environment assessments should also include an external validator.

External validation, in this context, means that an individual with experience of the patient assessment process attends the assessment at another organisation to observe the process and ensure that it is conducted in accordance with published advice, guidelines and recommendations. Such individuals do not normally take part in the assessment and would not count as a Patient Assessor for the purposes of ensuring a minimum of 50% of assessors were from outside the organisation being assessed. Patient-led Assessments of the Care Environment inspections are voluntary, but in the first year (2013) every single eligible NHS hospital and well over 200 independent sector hospitals took part. The results are used by the Care Quality Commission in their risk assessment of sites prior to inspection.

Importantly, the principle of this recommendation will also be met through the new functions of the Chief Inspector of Hospitals and Care Quality Commission's inspection regime. The Chief Inspector of Hospitals is expected to provide an honest and independent assessment about how well or badly hospitals are serving patients and the public. Expert inspections are envisaged whereby inspectors will be specialists in the areas they review; and judgement will be based on first-hand expert experience combined with data and feedback from patients and staff. Building on the approach developed by Professor Sir Bruce Keogh's reviews of mortality in 14 NHS trusts, the Chief Inspector of Hospitals has started inspections involving teams made up of senior and junior doctors, nurses and allied health professionals; senior managers; and people with experience of using hospital services. Six thousand individuals put themselves forward to be part of these inspections, and the number continues to

increase. This is encouraging progress towards ensuring that inspection teams with a range of specialist and lay perspectives will be sustainable.

TRANSPARENCY, USE AND SHARING OF INFORMATION

Recommendation 102

Data held by the National Patient Safety Agency or its successor should be open to analysis for a particular purpose, or others facilitated in that task.

Accepted.

In its response to the Caldicott Review, *Information: To Share or Not to Share (2013)*, the Department of Health stated that health and care professionals must make decisions about how information is shared and used in the best interests of people and patients using the five rules of confidentiality set out in new Health and Social Care Information Centre guidance, *Guide to Confidentiality in Health and Social Care (2013)*. This guidance provides a balance between confidentiality and information sharing and states that, *'People using services deserve a lot more than just information security. Individuals need the teams of professionals who are responsible for their care to share information reliably and effectively. Confidential information about an individual must not leak outside of the care team, but it must be shared within it in order to provide a seamless, integrated service.'*

Greater sharing of National Reporting and Learning System information is a stated aim of NHS England, within the bounds of an information governance framework. NHS England publishes patient safety incident data from the National Reporting and Learning System including information on levels and severity of harm to patients. NHS England is exploring the extent to which information on Serious Incidents can be disclosed in more detail without breaching the Data Protection Act. As part of the review of the National Reporting and Learning System, NHS England is considering how greater access can be provided to others for the purposes of analysis of patient safety incident data. Fundamentally NHS England is of the view that improving patient safety is more important than preserving unnecessary confidentiality.

The National Clinical Assessment Service, previously a division of the National Patient Safety Agency, was transferred to the NHS Litigation Authority in April 2013. The release of information relevant to this service is consistent with the NHS Litigation Authority's approach to making information and data available which is not subject to data protection legislation and regulation, and would not result in breach confidentiality and/or rules of the court or litigation practice.

The Care Quality Commission and NHS England will develop a dedicated hospital safety website for the public which will draw together up to date information on all the factors, for which robust data is available, that impact on the safety of care. This will include information on staffing, pressure ulcers, healthcare associated infections and other key indicators, where appropriate, at ward level. The website will aim to begin publication from June 2014. This will over time become a key source of public information, putting the truth about care at the fingertips of patients. NHS England will begin to publish never events data quarterly before the end 2013, and then monthly by April 2014 to help Trusts, patients and the public drive

improvement of services. In addition, new Patient Safety Collaboratives will be created from April 2014, which will bring together expertise on learning from mistakes, encourage open reporting of safety incidents and near misses, and support NHS organisations to take a rigorous approach to transforming patient safety. Initial priorities will include tackling pressure ulcers, hospital associated infections, falls and medication errors. The National Director of Patient Safety, Dr Mike Durkin, will lead the work to develop the collaboratives.

Recommendation 103

The National Patient Safety Agency or its successor should regularly share information with Monitor.

Accepted.

NHS England is actively working directly with Monitor to ensure they have access to patient safety data they require and that they are able to use it appropriately. NHS England agrees that the Care Quality Commission will also play a key role in coordinating the patient safety information to be shared or highlighted with organisations such as Monitor. More widely, NHS England is working to collate and make available a patient safety measurement framework to provide more clarity on patient safety data available, and what it can be used for and not used. Ultimately NHS England, Monitor, the Care Quality Commission and the NHS Trust Development Authority will work to bring together a common dataset for quality which could be used in a consistent way by all commissioners and regulators.

National Clinical Assessment Service previously a division of the National Patient Safety Agency was transferred to the NHS Litigation Authority in April 2014. The NHS Litigation Authority is also developing a data sharing process for sharing relevant information with Monitor, the Care Quality Commission and the NHS Trust development Authority to support patient and staff safety.

Recommendation 104

The Care Quality Commission should be enabled to exploit the potential of the safety information obtained by the National Patient Safety Agency or its successor to assist it in identifying areas for focusing its attention. There needs to be a better dialogue between the two organisations as to how they can assist each other.

Accepted.

*A new start – Consultation on changes to the way Care Quality Commission regulates, inspects and monitors care*⁶¹ set out the Care Quality Commission's intentions to gather information from a range of sources to inform its work. It noted that the Care Quality Commission's Chief Inspectors will use the expert judgements of their teams of inspectors, together with information and evidence held both by the Care Quality Commission and its partners in the system, to provide a single, authoritative assessment of the quality and safety of care services.

61 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

*A New Start*⁶² made clear that the Care Quality Commission would be looking, among other things, at whether a service is safe (i.e. people are protected from physical, psychological or emotional harm) and set out proposals for safety indicators. The consultation closed on 12 August 2013, and responses were considered alongside the recommendations from the Berwick Review, *Improving the Safety of Patients in England*,⁶³ which included recommended actions around better streamlining of data requests via the Care Quality Commission acting as the coordinating hub for intelligence about quality and safety of care. On 17 October 2013, the Care Quality Commission published the responses to its consultation in *A new start: Responses to our consultation on changes to the way Care Quality Commission regulates, inspects and monitors care services*,⁶⁴ which showed that there is broad agreement with the new approach. NHS England and the Care Quality Commission are committed to working together to develop a shared and agreed approach to measuring safety in the NHS, both for regulatory and improvement purposes. They are working to develop a set of patient safety measures that are best suited for use the Care Quality Commission in their surveillance model and NHS England is providing patient safety expertise on how patient safety data might be used by the Care Quality Commissions for its surveillance and inspection processes. A joint statement between NHS England and the Care Quality Commission is being published setting out how the two organisations will align their work to support inspection and surveillance work for safety.

The National Clinical Assessment Service, previously a division of the National Patient Safety Agency transferred to the NHS Litigation Authority in April 2013. The NHS Litigation Authority is also putting in place an information sharing agreement with regulators, which will include relevant information relating to the National Clinical Assessment Service.

Recommendation 105

Consideration should be given to whether information from incident reports involving deaths in hospital could enhance consideration of the hospital standardised mortality ratio.

Accepted.

As part of Professor Sir Bruce Keogh's *Review of the Quality and Safety of Care and Treatment Provided by 14 Hospital Trusts in England*, NHS England provided detailed reports from the National Reporting and Learning System for each of the 14 trusts that were looked at. That process was informative and resulted in key lines of inquiry for the inspection teams on the ground. It in effect acted as a pilot for a stronger method of utilising the National Reporting and Learning System data in Care Quality Commission inspections. It was also found that data from the National Reporting and Learning System correlated well with other datasets to indicate problems with safety. NHS England will work with the Care Quality Commission to build on the learning from Sir Bruce Keogh's Review to address this.

62 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

63 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf

64 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_newstartresponse_2013_14_tagged_sent_to_web.pdf

NHS England is also leading work to develop proposals for ensuring every trust undertakes retrospective case note reviews of patient deaths according to a consistent methodology to further encourage learning from adverse events. This will help trusts address common issues associated with avoidable hospital mortality, such as management of deteriorating patients.

HEALTH PROTECTION AGENCY COORDINATION AND PUBLICATION OF PROVIDERS' INFORMATION ON HEALTHCARE ASSOCIATED INFECTIONS

Recommendation 106

HPA and its successor, should co-ordinate the collection, analysis and publication of information on each provider's performance in relation to healthcare associated infections, working with the Health and Social Care Information Centre.

Accepted.

Public Health England, which since April 2013 has taken on the functions of the Health Protection Agency, is working together with the Health and Social Care Information Centre to coordinate the collection, analysis and publication of information in relation to Healthcare Associated Infections.

This includes a number of on-going activities: exploration of linkage of Public Health England Healthcare Associated Infections patient-level surveillance data with Hospital Episode Statistics data for enhanced epidemiological analyses; exploration of linkage of Public Health England Healthcare Associated Infections surveillance data with the death registrations (for mortality trends) to improve understanding of causality; Public Health England facilitation of voluntary surveillance within the Infections in Critical Care Quality Improvement Programme to increase the knowledge and evidence base, leading to quality improvement; a review of priority categories for Surgical Site Infection surveillance to inform strategic development and support needs of local users; taking a key role in the finalisation, roll-out and on-going development of the new Data Capture System to incorporate and support the above-mentioned surveillances activities. Public Health England is also working with trusts and Clinical Commissioning Groups to facilitate the Post Infection Review process for MRSA.

Additionally, Public Health England is providing advice and support to the Care Quality Commission in its regulatory work to develop its new surveillance model for the construction of quality indicators.

SHARING CONCERNS

Recommendation 107

If the Health Protection Agency or its successor, or the relevant local director of public health or equivalent official, becomes concerned that a provider's management of healthcare associated infections is or may be inadequate to provide sufficient protection of patients or public safety, they should immediately inform all responsible commissioners, including the relevant regional office of the NHS Commissioning Board, the Care Quality Commission and, where relevant, Monitor, of those concerns.

Sharing of such information should not be regarded as an action of last resort. It should review its procedures to ensure clarity of responsibility for taking this action.

Accepted.

Public Health England is reviewing its governance framework which underpins its responsibilities (in partnership with local, regional and national partners) for sharing and escalating concerns. As part of this work and as new structures emerge, Public Health England is revisiting and updating its internal operational guidelines, which provide a standardised risk-based approach within the framework, for its regional centres. This work formalises the process whereby Public Health England internally escalates, and informs local and national commissioners and regulators about, any concerns they might have regarding the management of Healthcare Associated Infection-related risks linked with health and adult social care providers (e.g. during outbreaks and incidents of infectious diseases).

A peer support toolkit, previously developed by the Health Protection Agency (whose functions were transferred into Public Health England from 1 April 2013), is also under review. The toolkit clarifies the process whereby expert and peer support might be offered to, or requested by, healthcare providers. It includes recommended timelines, and the format the advice might take, as deemed appropriate for the situation.

Following discussions with the key parties outlined in this recommendation, joint draft proposals are being developed to share expertise across all the key stakeholders in relation to infection, including those that are healthcare associated. These stakeholders include the Care Quality Commission, Monitor, NHS England and the NHS Trust Development Authority. The draft proposals strengthen current practices on information sharing among these organisations and will also establish an agreed set of principles and information flows setting out the lines of communication for sharing information where there are concerns that may require further investigation. The overarching principles and lines of communication were established in July 2013.

SUPPORT FOR OTHER AGENCIES

Recommendation 108

Public Health England should review the support and training that health protection staff can offer to local authorities and other agencies in relation to local oversight of healthcare providers' infection control arrangements.

Accepted.

Public Health England recognises the importance of supporting local infection control and prevention arrangements, and has undertaken a review. Although the offer of support and training would be a significant undertaking, Public Health England is considering options as to how it will be able to provide this in the future and is discussing these with the Department of Health.

Effective complaints handling

All feedback from patients, whether it is concerns voiced on the ward at the time, or complaints made once they are back home, should make a difference.

If it is not possible to resolve a concern on the ward patients must feel able to complain about their care in a way that feels fair, open, and respectful of the emotional and physical pain they have suffered. This means having clear, simple information about the complaints process available to them, and advice and support if they need it. Most importantly, it means feeling that the hospital takes them seriously and that lessons will be learned from their experience.

Locally and nationally, in line with what has been said in Rt Hon Ann Clwyd MP and Professor Tricia Hart's *Review of the Handling of Complaints in NHS Hospitals*, and in the Inquiry, the Department of Health wants to:

- Ensure that all forms of feedback help to improve care for patients
- Ensure that when things do go wrong, the complaints system is clear, fair, and open
- Ensure that at every level, the NHS scrutinises and learns from mistakes to improve care for patients.

Recommendation 109

Methods of registering a comment or complaint must be readily accessible and easily understood. Multiple gateways need to be provided to patients, both during their treatment and after its conclusion, although all such methods should trigger a uniform process, generally led by the provider trust.

Accepted.

Feedback of any kind, but particularly concerns and complaints, are important; they enable things to be put right for the complainant and drive the improvement of hospital services. But there is evidence that not everyone who would wish to make a complaint does so. This can be for a number of reasons, of which ease of access to the complaints arrangements is an important one.

The overall framework for complaints handling is laid down in regulation and it is important that the overall process is consistent across the NHS and clear to patients.

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

- How they can complain to the hospital when things go wrong

- Who they can turn to for independent local support if they want it, and where to contact them
- That they have the right to go to the Ombudsman if they remain dissatisfied, and how to contact them; and
- Details of how to contact their local HealthWatch.

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

It is important that local Healthwatch, as the patient and public champion for health and care services, should be as strong and effective as possible so that it can speak up for patients and provided independent support on complaints. The Department of Health supports Healthwatch England in their plans to coordinate a consumer-facing complaints campaign with their partners. This will help ensure there is better quality information for patients about how to raise a concern and the standards they should expect if they make a complaint.

The Department of Health wants to see patient advice and liaison services well-sign posted, funded and staffed in every hospital so patients can go and share a concern with someone else in the hospital if they do not feel confident talking to their nurse or doctor on the ward. The Department agrees it is appropriate to review the patient advice and liaison services, and will undertake to begin that work in 2014.

Furthermore Rt Hon Ann Clwyd MP and Professor Tricia Hart's *Review of the Handling of Complaints in NHS Hospitals* makes two recommendations on good practice to support patients who have some dissatisfaction with their healthcare that would assist in the delivery of this recommendation:

- Trusts should provide patients with a way of feeding back comments and concerns about their care on the ward, including simple steps such as putting pen and paper by the bedside, and making sure patients know who to speak to if they have a concern – this could be a nurse or a doctor, or a volunteer on the ward;
- Hospitals should actively encourage and use volunteers to support patients in expressing concerns or complaints. This is particularly important where patients are vulnerable or alone, when they might find it difficult to raise concerns at the time the problem arises: volunteers should be regularly refreshed.

As part of its new inspection regime, the Care Quality Commission will be including complaints handling in its assessment of Trust performance which includes how Trusts have learnt from complaints.

LOWERING BARRIERS

Recommendation 110

Actual or intended litigation should not be a barrier to the processing or investigation of a complaint at any level. It may be prudent for parties in actual or potential litigation to agree to a stay of proceedings pending the outcome of the complaint, but the duties of the system to respond to complaints should be regarded as entirely separate from the consideration of litigation.

Accepted.

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

Prior to April 2009, where a complaint was received about which the complainant had indicated in writing that they were intending to take legal proceedings, the complaint was excluded from the NHS complaints arrangements. In 2009, the Department of Health removed this regulation because it considered there should be no direct link between responding to a complaint and consideration of litigation. In some cases, it will be appropriate for the complaint to be put on hold, but that should be an exception.

The Department of Health will work with Action Against Medical Accidents (AvMA) and NHS England to clarify that a threat of future litigation should not delay the handling of a complaint.

Recommendation 111

Provider organisations must constantly promote to the public their desire to receive and learn from comments and complaints; constant encouragement should be given to patients and other service users, individually and collectively, to share their comments and criticisms with the organisation.

Accepted.

Feedback, of which complaints are an important part, is a strong indicator of patient experience, and serves to assist organisations to improve service delivery. It should be encouraged and welcomed as a matter of good practice.

The *Review of the Handling of Complaints in NHS Hospitals* and the Inquiry showed that complaints should be dealt with fairly and lessons learned when things go wrong. The emphasis is rightly on hospital Boards and Chief Executives to correct their mistakes, explain to patients what went wrong, and show how they will put it right. The management of an effective system of complaints and patient feedback is a Board level responsibility. An effective Trust Board will promote a culture of openness, recognise the value of patient comments and complaints, and make it easy for patients, their families and carers to give feedback. An effective Trust Board will also be open about and publish regular information about the complaints it receives and the action it is taking as a result.

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

- How they can complain to the hospital when things go wrong
- Who they can turn to for independent local support if they want it, and where to contact them
- That they have the right to go to the Ombudsman if they remain dissatisfied, and how to contact them; and
- Details of how to contact their local HealthWatch.

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

It is important that local Healthwatch, as the patient and public champion for health and care services, should be as strong and effective as possible so that it can speak up for patients and provided independent support on complaints. The Department of Health supports Healthwatch England in their plans to coordinate a consumer-facing complaints campaign with their partners. This will help ensure there is better quality information for patients about how to raise a concern and the standards they should expect if they make a complaint.

The *Review of the Handling of Complaints in NHS Hospitals* recommends the following:

- Trusts should actively encourage both positive and negative feedback about their services. Complaints should be seen as essential and helpful information, and welcomed as necessary for continuous service improvement.
- Trusts should provide patients with a way of feeding back comments and concerns about their care on the ward, including simple steps such as putting pen and paper by the bedside, and making sure patients know who to speak to if they have a concern – this could be a nurse or a doctor, or a volunteer on the ward to help people.
- Hospitals should actively encourage volunteers. Volunteers can help support patients who wish to express concerns or complaints. This is particularly important where patients are vulnerable or alone, when they might find it difficult to raise a concern. Volunteers should be trained.

As part of its new inspection regime, the Care Quality Commission will be including complaints handling in its assessment of Trust performance, looking at how they have learnt lessons and what action they have taken as a result.

Recommendation 112

Patient feedback which is not in the form of a complaint but which suggests cause for concern should be the subject of investigation and response of the same quality as a formal complaint, whether or not the informant has indicated a desire to have the matter dealt with as such.

Accepted.

In many respects, the distinction between a 'concern' and a 'complaint' is artificial. Both indicate some level of dissatisfaction and require a response. Patients or their relatives will often feel more comfortable in raising a concern than in making a complaint, but a concern may be just as likely to indicate a potential patient safety issue. It is important that concerns and complaints are handled in accordance with the needs of the individual case, and investigated.

COMPLAINTS HANDLING

Recommendation 113

The recommendations and standards suggested in the Patients Association's peer review into complaints at the Mid Staffordshire NHS Foundation Trust should be reviewed and implemented in the NHS.

Accepted.

At present, standards of complaints handling are judged on the basis of the 2009 regulations and the Health Service Ombudsman's *Principles of Good Complaints Handling*. While both of these remain important, a more formal statement of standards is likely to be of benefit to the NHS, whether complaints managers and Trust Boards at local level, or regulators.

The *Review of the Handling of Complaints in NHS Hospitals* recommends that:

- Commissioners and regulators establish clear standards for hospitals on complaints handling. These should rank highly in the audit and assessment of the performance of all hospitals.

The Government has asked the Parliamentary and Health Service Ombudsman and Healthwatch England, working with the Department of Health, to develop a patient-led vision and expectations for complaints handling in the NHS. The Parliamentary and Health Service Ombudsman, Healthwatch England and the Department of Health will work with the Patients Association, patients, regulators, commissioners and providers to develop universal expectations for complaints handling. These will be used across the NHS to drive improvements in patient satisfaction with complaint handling. The vision and expectations will inform:

- Patients about what to expect when they make a complaint about NHS services
- The work of the Healthwatch network in challenging local providers to improve their practices
- Providers and commissioning bodies about what they can do to use patient concerns and complaints to improve services and how they can measure their own progress
- Regulatory assessment of hospital complaint handling
- The Parliamentary and Health Service Ombudsman investigation of complaints about NHS services brought to them by patients and their families.

Recommendation 114

Comments or complaints which describe events amounting to a serious or untoward incident should trigger an investigation.

Accepted.

A fundamental principle of the current complaints arrangements for handling NHS and adult social care complaints is that a case should be handled according to the needs of that individual case. Investigation should be proportionate to the needs of the case, but any concern about patient safety needs to be robustly investigated. The Department of Health strongly agrees that complaints amounting to a serious or untoward incident warrant independent local investigation and we want to see all NHS Trusts using their statutory powers to offer this to patients.

NHS England's guidance *The Serious Incident Framework* (<http://www.england.nhs.uk/wp-content/uploads/2013/03/sif-guide.pdf>) sets out how Serious Incidents should be managed. It states that 'Initial incident grading should err on the side of caution, categorising and treating an incident as a serious incident if there is any possibility that it is.' Furthermore it states that 'All serious incidents should be investigated using best practice methodologies such as root cause analysis.' Any complaint alleging that a Serious Incident has occurred should therefore be investigated. The Care Quality Commission already uses a range of information about complaints to inform the timing and focus of its inspections, and through the Chief Inspectors, is currently exploring how it can give greater prominence to complaints and safety alerts in its revised surveillance and inspection model.

The definition of a Serious Incident is:

- an incident that occurred during NHS funded healthcare (including in the community), which resulted in one or more of the following:
 - unexpected or avoidable death or severe harm of one or more patients, staff or members of the public;
 - a never event – all never events are defined as serious incidents although not all never events necessarily result in severe harm or death;
 - a scenario that prevents, or threatens to prevent, an organisation's ability to continue to deliver healthcare services, including data loss, property damage or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population;
 - allegations, or incidents, of physical abuse and sexual assault or abuse; and/or
 - loss of confidence in the service, adverse media coverage or public concern about healthcare or an organisation.

The current NHS England Serious Incident Framework is a working draft and will therefore be updated and clarified in relation to this recommendation.

INVESTIGATIONS

Recommendation 115

Arms length independent investigation of a complaint should be initiated by the provider trust where any one of the following apply:

- **A complaint amounts to an allegation of a serious untoward incident;**
- **Subject matter involving clinically related issues is not capable of resolution without an expert clinical opinion;**
- **A complaint raises substantive issues of professional misconduct or the performance of senior managers.**
- **A complaint involves issues about the nature and extent of the services commissioned.**

Accepted in part.

Investigation of any complaints should be proportionate to the needs of the individual case. This follows the fundamental principle that complaints cases should be handled according to the needs of that individual case. In serious or complex complaints, the investigator may often be expected to be from outside the organisation being complained about.

Where a serious incident is alleged via a complaint, it must be treated as a serious incident identified through any other means until the incident has been investigated, responded to and closed or the investigation reveals the allegation is not supported by the evidence. Investigation of incidents by fully independent teams from outside an organisation are extremely useful for ensuring that the lessons from an incident are identified, learned and relevant actions initiated to prevent recurrence, particularly in the case of very complex, sensitive or wide-ranging serious incidents. It is an important principle, however, that serious incident investigations should be proportionate to the severity of the incident in question, given the resources involved in a full independent investigation and the length of time they can take.

NHS England has published a Serious Incident Framework, which sets out the various types of investigation that must be undertaken following a serious incident. This makes clear that the level of investigation required following a serious incident will vary according to the severity of the incident. The need for independent investigation must be determined in conjunction with the relevant commissioner. Investigations for less severe serious incidents can be undertaken by organisations themselves provided the staff undertaking the investigation are sufficiently removed from the incident to be able to provide an objective view and that there is no conflict of interest, real or perceived.

Regarding the need for an expert clinical opinion, the *Review of the Handling of Complaints in NHS Hospitals* raises the issue of a need for a greater degree of independence at local level, and makes a recommendation that supports this general approach:

- When Trusts have a conversation with patients at the start of the complaints process on a serious failing in care they should immediately offer truly independent clinical and lay advice... to the complainant.

However, we consider there to be an important distinction between an independent investigation and an expert clinical opinion. An independent investigation seeks to determine the facts of the case. They will seek the views of an expert clinician, where appropriate. Independent investigation should be determined on the nature of the complaint, with serious failings in particular warranting independent investigation.

Similarly, we do not consider it appropriate for independent investigation to take place in all cases. The complaints manager in each Trust should be sufficiently senior and competent to be able to judge effectively when a complaint merits independent advice or investigation.

Depending on the nature of a complaint, fully independent investigation of the serious incident by an external team may be appropriate. However in some cases, particularly where it is not clear that a serious incident has occurred, it is appropriate, particularly in the initial phase, for an organisation to undertake its own investigation using staff sufficiently removed from the incident with no conflict of interest, until such a time as the facts require an independent investigation to be commissioned. The current NHS England Serious Incident Framework is a working draft and will therefore be updated and clarified in relation to this recommendation.

If the person making the complaint is not satisfied with the outcome at this local resolution stage, they have the right to ask the Health Service Ombudsman to investigate the case. The Ombudsman is independent of Government and the NHS, accountable to Parliament. The Government welcomes the commitment of the Ombudsman to expand the number of cases she considers.

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

- How they can complain to the hospital when things go wrong
- Who they can turn to for independent local support if they want it, and where to contact them
- That they have the right to go to the Ombudsman if they remain dissatisfied, and how to contact them; and
- Details of how to contact their local HealthWatch.

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

SUPPORT FOR COMPLAINTS

Recommendation 116

Where meetings are held between complainants and trust representatives or investigators as part of the complaints process, advocates and advice should be readily available to all complainants who want those forms of support.

Accepted.

People making complaints can feel isolated and intimidated when in meetings with complaints managers and trust representatives. Some patients, relatives or friends remain deeply affected by their experiences. It is right that support is available, particularly where there may have been a serious failing in care, not only to help them navigate through the process but also for someone to be there to speak for them.

Local Authorities are responsible for commissioning NHS complaints advocacy services, and are able to determine the appropriate model of delivery for these services for their local community. The Department of Health considers the recommendations above to be best practice and the best local advocacy services will provide support that complainants can access easily, and that meets their needs.

NHS Trusts, and particularly the Patient Advice and Liaison Services within those Trusts, will be aware of the NHS complaints advocacy providers within their areas. It is right that they publicise these arrangements for people who have made a complaint or who are thinking of making one. The Department of Health wants to see patient advice and liaison services well-sign posted, funded and staffed in every hospital so patients can go and share a concern with someone else in the hospital if they do not feel confident talking to their nurse or doctor on the ward. The Department agrees it is appropriate to review the patient advice and liaison services, and will undertake to begin that work in 2014.

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

- How they can complain to the hospital when things go wrong
- Who they can turn to for independent local support if they want it, and where to contact them
- That they have the right to go to the Ombudsman if they remain dissatisfied, and how to contact them; and
- Details of how to contact their local HealthWatch.

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

The *Review of the Handling of Complaints in NHS Hospitals* made the following recommendations:

- When Trusts have a conversation with patients at the start of the complaints process on a serious failing in care they should immediately offer truly independent clinical and lay advice and independent advocacy support to the complainant; and
- Hospitals should actively encourage volunteers. Volunteers can help support patients who wish to express concerns or complaints. This is particularly important where patients are

vulnerable or alone, when they might find it difficult to raise a concern. Volunteers should be trained.

Recommendation 117

A facility should be available to Independent Complaints Advocacy Services advocates and their clients for access to expert advice in complicated cases.

Accepted in part.

We agree that expert advice should be provided in appropriate cases, and in appropriate cases, the providers of NHS complaints advocacy would obtain advice from an independent clinical expert. However complaints advocacy services are no longer commissioned nationally. From April 2013, Local Authorities have been responsible for commissioning NHS complaints advocacy services, and are able to determine the appropriate model of delivery for these services for their local community.

We consider that the need for expert clinical advice ought not to be determined by how complicated a case might be, but whether it is appropriate in the individual case. In those cases, the trust should offer that advice, along with independent investigation.

The *Review of the Handling of Complaints in NHS Hospitals* recommends:

- When Trusts have a conversation with patients at the start of the complaints process they must ensure the true independence of the clinical and lay advice and advocacy support offered to the complainant.

The Department of Health will work with Healthwatch England and the Local Government Association to develop a set of 'good practice' standards for NHS Complaints advocacy services; these standards may be expected to include access to clinical advice in appropriate cases.

LEARNING AND INFORMATION FROM COMPLAINTS

Recommendation 118

Subject to anonymisation, a summary of each upheld complaint relating to patient care, in terms agreed with the complainant, and the trust's response should be published on its website. In any case where the complainant or, if different, the patient, refuses to agree, or for some other reason publication of an upheld, clinically related complaint is not possible, the summary should be shared confidentially with the Commissioner and the Care Quality Commission.

Accepted in part.

An open culture demands that information is available to service users, their families and carers to enable them to make informed choices about their healthcare.

Trusts currently have to publish an annual report on complaints handling. This report contains information on the number of complaints received, the number referred to the Health Service Ombudsman, and a summary of the subject matter of those complaints, any matters arising from them, and any matters where action has been taken (or will be taken) as a result of the

complaint. These reports are sent to the commissioning body, and made available to anyone who requests one, but the Government believes we can go further.

Rt Hon Ann Clwyd MP and Professor Tricia Hart's *Review of the Handling of Complaints in NHS Hospitals* recommends that:

- There should be Board- led scrutiny of complaints. All Boards and Chief Executives should receive monthly reports on complaints and the action taken, including an evaluation of the effectiveness of the action. These reports should be available to the Chief Inspector of Hospitals.

The Department of Health will ensure that each quarter every hospital publishes information on the complaints it has received. This will include:

- the number of complaints received, as a percentage of patient interventions in that period;
- the number of complaints the hospital has been informed have subsequently been referred to the Ombudsman; and
- lessons learned and improvements made as a result of complaints.

The Department of Health will work with NHS England and other key partners to determine the most effective mechanism through which to achieve these outcomes. The Chief Inspector and Care Quality Commission will require regular reporting of complaints from all providers to inform its surveillance and risk profiling regime. Care Quality Commission will naturally be particularly interested in complaints concerning death, serious injury or 'near misses' but will also want to harness information about other aspects of patient experience and concern which would be indicative of trust culture and performance. Care Quality Commission will be discussing with Monitor, Trust Development Authority and providers a proportionate and cost-effective means of doing so.

The Department would wish to reconsider this recommendation in relation to complaints of a serious nature, and making them available in a wider range of formats, once an agreed and consistent standard exists against which to judge the handling of an individual complaint. This would lead to more consistency in outcomes.

Recommendation 119

Overview and scrutiny committees and Local Healthwatch should have access to detailed information about complaints, although respect needs to be paid in this instance to the requirement of patient confidentiality.

Accepted.

Complaints data, along with other sources of feedback, have the potential to provide important information to local Healthwatch Organisations and Overview and Scrutiny Committees. It is important that Trusts respect patient confidentiality when releasing information on complaints to outside organisations but, subject to this caveat, we consider that Trusts should seek to provide to these organisations with the complaints data that are requested.

The Department of Health will ensure that each quarter every hospital publishes information on the complaints it has received. This will include:

- the number of complaints received, as a percentage of patient interventions in that period;
- the number of complaints the hospital has been informed have subsequently been referred to the Ombudsman; and
- lessons learned and improvements made as a result of complaints.

The Department of Health will work with NHS England and other key partners to determine the most effective mechanism through which to achieve these outcomes. Rt Hon Ann Clwyd MP and Professor Tricia Hart's *Review of the Handling of Complaints in NHS Hospitals*⁶⁵ recommends that:

- There should be Board-led scrutiny of complaints. All Boards and Chief Executives should receive monthly reports on complaints and the action taken, including an evaluation of the effectiveness of the action. These reports should be available to the Chief Inspector of Hospitals.
- Patients, patient representatives and local communities and local Healthwatch organisations should be fully involved in the development and monitoring of complaints' systems in all hospitals.

Local Healthwatch has an important role to play as patient champion, and it is right that individual local Healthwatch organisations have access to detailed information about complaints, subject to respect for patient confidentiality. Local Healthwatch have an important role to play in scrutinising complaints data locally.

The Department of Health will work with the Health and Social Care Information Centre to put complaints data into the existing NHS electronic data collection system, better enabling comparison between hospitals.

Recommendation 120

Commissioners should require access to all complaints information as and when complaints are made, and should receive complaints and their outcomes on as near a real-time basis as possible. This means commissioners should be required by NHS Commissioning Board to undertake the support and oversight role of GPs in this area, and be given the resources to do so.

Accepted in part.

We accept that commissioning bodies play an important role in ensuring that the organisations from which it commissions services are delivering effective and open complaints arrangements, and delivering their statutory responsibilities. Complaints contain valuable information that commissioners should be aware of. However, we consider requiring Trusts to provide all complaints information will place a significant bureaucratic burden on both the service provider and the commissioning body. To be meaningful, commissioners would

65 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/253320/complaints_review_report.pdf

need to be aware of, and understand each complaint, which would also be an unjustifiable duplication of resources.

The *Review of the Handling of Complaints in NHS Hospitals*⁶⁶ recommends that:

- There should be Board-led scrutiny of complaints. All Boards and Chief Executives should receive monthly reports on complaints and the action taken, including an evaluation of the effectiveness of the action. These reports should be available to the Chief Inspector of Hospitals.

The Department of Health will ensure that each quarter every hospital publishes information on the complaints it has received. This will include:

- the number of complaints received, as a percentage of patient interventions in that period;
- the number of complaints the hospital has been informed have subsequently been referred to the Ombudsman; and
- lessons learned and improvements made as a result of complaints.

The Department of Health will work with NHS England and other key partners to determine the most effective mechanism through which to achieve these outcomes.

Recommendation 121

The Care Quality Commission should have a means of ready access to information about the most serious complaints. Their local inspectors should be charged with informing themselves of such complaints and the detail underlying them.

Accepted.

Information received from people who use care services about the quality and safety of their care, including concerns and complaints, is a vital source of information which needs to be available to the regulator. The Care Quality Commission accesses and uses a range of information about complaints to inform the timing and focus of its inspections. This information ranges from aggregated numbers and patterns of complaints, to individuals who contact the Care Quality Commission and tell inspectors about their experience. The Care Quality Commission participates in the Quality Surveillance Groups that have been established in each area. These groups actively share between commissioners, regulators, all local NHS organisations and others, information and intelligence on the quality of care being delivered.

The new approach to inspection that the Care Quality Commission has introduced places a stronger focus on how care is delivered in practice and how it is experienced, rather than just compliance with regulations. In line with this, the Care Quality Commission is now making greater use of the information that it has on complaints.

In light of the recommendations made in *Review of the Handling of Complaints in NHS Hospitals*⁶⁷ the Care Quality Commission will review how it makes best use of the complaints that it receives directly from individuals, and the individual stories in complaints, as well as

66 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/253320/complaints_review_report.pdf

67 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/253320/complaints_review_report.pdf

the aggregated trends. As it continues to test and engage on refining its new approach to inspection between now and April 2014, it will also review whether or not routinely to require of providers a report on complaints, self-assessment or other form of declaration, to inform its monitoring and inspections. This consideration will be coordinated with other information requirements on providers, and decided in light of the NHS Confederation's *Review of Bureaucracy in the NHS*.

The Department of Health will work with the Care Quality Commission to ensure that its new surveillance model for monitoring risk at NHS acute hospitals includes information on complaints handling.

HANDLING LARGE-SCALE COMPLAINTS

Recommendation 122

Large-scale failures of clinical service are likely to have in common a need for:

- **Provision of prompt advice, counselling and support to very distressed and anxious members of the public;**
- **Swift identification of persons of independence, authority and expertise to lead investigations and reviews;**
- **A procedure for the recruitment of clinical and other experts to review cases;**
- **A communications strategy to inform and reassure the public of the processes being adopted;**
- **Clear lines of responsibility and accountability for the setting up and oversight of such reviews.**

Such events are of sufficient rarity and importance, and requiring of coordination of the activities of multiple organisations, that the primary responsibility should reside in the National Quality Board.

Accepted in principle.

We agree that in the rare circumstances that significant failures are identified as part of regulatory action, part of the response to that failure will be the consideration of advice and information to the public about the nature of that failure and potential support to those directly affected by the issues identified. However, while we also agree that such a response needs clear coordination across a number of involved organisations we do not agree that this should be a function of the National Quality Board. Rather such action should be part of a response to the single failure regime outlined in recommendation 19 and be agreed jointly between the trust, Care Quality Commission, Monitor and the NHS Trust Development Authority as appropriate to ensure that all those directly involved in the identified failure are work together through that regime.

The Care Quality Commission, Monitor and the NHS Trust Development Authority will work together to publish further guidance, as soon as possible after April 2014, to provide further detail on how these organisations work together to address risks to quality. This will include

details of how concerns, including immediate concerns, will be addressed, how and when the single failure regime could be triggered and what guidance and support would be made available to the public in the event of large scale, significant, failure. This guidance will build on the joint policy statement, *The Regulation and oversight of NHS Trusts and Foundation Trusts* (May 2013) published by the Care Quality Commission, Monitor, NHS Trust Development Authority, NHS England and the Department of Health and the experience from Professor Sir Bruce Keogh's *Review into the quality of care and treatment provided by 14 hospital trusts in England* which included, for example, an independent review that included the views of clinical and other experts.

Commissioning for standards

The Inquiry concluded that commissioners should have been more effective in commissioning for quality services, involving patients, the public and professionals in their commissioning activity, monitoring contracts better in order to drive improvements in quality, and taking a stronger role in identifying the delivery of poor services and imposing sanctions on providers. The Inquiry recommended that the principle focus of commissioners should be on ensuring that patients are safeguarded through the maintenance of fundamental and quality standards. Commissioners should also require delivery of services against enhanced standards to promote quality, and should intervene when a service is substandard or unsafe.

The NHS Standard Contract, NHS England's assurance of clinical commissioning groups, and the development of commissioning support services together provide a new infrastructure to ensure that commissioners have the capacity and capability to scrutinise providers' services. NHS England is undertaking a review of incentives, rewards and sanctions through the use of the NHS Standard Contract. NHS England and clinical commissioning groups are developing a Framework for Commissioning for Quality which will set out the steps that commissioners should take to assure themselves and their patients that the services that they are commissioning are safe, clinically effective and result in a positive experience for patients.

RESPONSIBILITY FOR MONITORING DELIVERY OF STANDARDS AND QUALITY

Recommendation 123

GPs need to undertake a monitoring role on behalf of their patients who receive acute hospital and other specialist services. They should be an independent, professionally qualified check on the quality of service, in particular in relation to an assessment of outcomes. They need to have internal systems enabling them to be aware of patterns of concern, so that they do not merely treat each case on its individual merits. They have a responsibility to all their patients to keep themselves informed of the standard of service available at various providers in order to make patients' choice reality. A GP's duty to a patient does not end on referral to hospital, but is a continuing relationship. They will need to take this continuing partnership with their patients seriously if they are to be successful commissioners.

Accepted.

GPs, both in their roles as care providers and in clinical commissioning groups, should be continuously reviewing the quality of care provided by the acute hospital and specialised

services they commission. NHS England continues to develop relevant guidance and tools for clinical commissioning groups to monitor the quality of service provision and support continuous improvement in quality.

Clinical commissioning groups are under an important duty to assist and support NHS England in securing continuous improvement in the quality of primary medical services. They will need to do this working alongside the NHS England Area Teams, local Healthwatch and other parts of the system. NHS England and clinical commissioning groups are developing a *Framework for Commissioning for Quality*, through the NHS Commissioning Assembly, which will set out the steps that commissioners should take to assure themselves and their patients that the services that they are commissioning are safe, clinically effective and result in a positive experience for patients. This will be published in Autumn 2013.

Clinical commissioning groups in a local area will be part of the new local Quality Surveillance Groups, where they should share information and intelligence with other parts of the local system. If they have concerns about whether providers are meeting the essential standards of quality and safety, they should raise these with the Care Quality Commission and with any other parts of the system with an interest through that Group. This should include concerns they have about providers from whom they do not commission services, such as primary care providers, but with whom they interact'

There are other mechanisms through which GPs can report concerns about services. As health professionals, GPs are able to exercise their discretion when updating patient records, to incorporate comments on a patient's care, and patients themselves will be able to gain online access to their GP record by 2015. In addition, NHS providers should be publishing online aggregated feedback on the quality of care delivered by their organisation, and we would expect GPs to make themselves aware of this feedback and to use it to advise patients on their care. NHS England are undertaking further work to improve and increase the level of patient safety incident reporting to the National Reporting and Learning System by GPs through work with the Primary Care Patient Safety Expert Group and as part of the Strategic Framework for Commissioning Primary Care. Finally, any serious incidents that GPs identify should be reported to the NHS SI reporting system, the Strategic Executive Information System, as set out in the NHS England Serious Incident Framework published in March 2013.

The clinical commissioning groups authorisation process was built around six domains, and was developed by working with clinical commissioning groups, national primary care organisation and other stakeholders. Assessing clinical commissioning groups through these six domains provides assurance that clinical commissioning groups can safely discharge their statutory responsibilities for commissioning healthcare services. They are also intended to encourage clinical commissioning groups to be organisations that are clinically led and driven by clinical added value.

One domain, 'Meaningful engagement with patients, carers and their communities' specifically looked at how clinical commissioning groups could show how they will ensure inclusion of patients, carers, public communities of interest and geography, health and wellbeing boards and local authorities. This included showing their mechanisms for gaining a broad range of views then analysing and acting on these. It should be evident how the views of individual

patients are translated into commissioning decisions and how the voice of each practice population will be sought and acted on.

One of NHS England's key functions is to develop the assurance process which identifies how well clinical commissioning groups are performing against their plans to improve services and deliver better outcomes for patients, as well as working together to assess how they can realise their full potential and provide support on that journey. Sitting alongside NHS England as fellow commissioners, clinical commissioning groups need to secure quality today and transform services for the future.

And we will go even further in clarifying the role of the GP in coordinating patient care. On 5 July 2013, the Secretary of State for Health announced an intention that every vulnerable older person should will have a named clinician responsible for overseeing their care at all times when they are out of hospital, whether they are at home or in a care home. Through the work to develop a vulnerable older people's plan, the Department of Health is working with NHS England and others to look at how we can achieve better integrated, coordinated out of hospital care.

To do this role well, clinicians both inside and outside of hospitals will have to work together to share information and provide a seamless, integrated pathway of care to patients. A part of the work to develop a *Vulnerable Older People's Plan* is about making sure that information can be shared between services and people providing care in a coordinated and timely way, including all clinicians and carers having access to the same information about patients regardless of setting.

When the NHS has got this right for older people – those who need healthcare services the most and who often have complex health and care needs – this should become a much broader transformation in out of hospital care – one which will eventually help every NHS patient.

DUTY TO REQUIRE AND MONITOR DELIVERY OF FUNDAMENTAL STANDARDS

Recommendation 124

The commissioner is entitled to and should, wherever it is possible to do so, apply a fundamental safety and quality standard in respect of each item of service it is commissioning. In relation to each such standard, it should agree a method of measuring compliance and redress for non-compliance. Commissioners should consider whether it would incentivise compliance by requiring redress for individual patients who have received substandard service to be offered by the provider. These must be consistent with fundamental standards enforceable by the Care Quality Commission.

Accepted in principle.

Fundamental standards of care will be a key part of Care Quality Commission registration requirements and so commissioners will only contract with providers that are meeting these standards.

Commissioners must have regard to any fundamental standard that relates to a service they commission, and they should apply it where they can. They can set safety and quality standards for all services they commission, through clear specification. The NHS Standard Contract allows for agreement at local level of the method of measuring compliance with such standards, and any appropriate sanctions.

We have considered whether commissioners should consider incentivising compliance through redress for individual patients, which has been tested with providers and commissioners, and the overwhelming response was that this would not be practicable. Potential difficulties would be:

- a drain of funds from the local health community, where funds may be most needed;
- the potential for perverse incentives to claim compensation;
- duplication with existing rights for patients to be recompensed through litigation; and
- methodological challenges in assessing the appropriate level of recompense.

RESPONSIBILITY FOR REQUIRING AND MONITORING DELIVERY OF ENHANCED STANDARDS

Recommendation 125

In addition to their duties with regard to the fundamental standards, commissioners should be enabled to promote improvement by requiring compliance with enhanced standards or development towards higher standards. They can incentivise such improvements either financially or by other means designed to enhance the reputation and standing of clinicians and the organisations for which they work.

Accepted.

The NHS Standard Contract allows for agreement on a range of quality standards or development towards higher standards. Incentives should thus contribute to improved outcomes through improvement in the quality of health services for patients, their families and carers, and through reducing health inequalities. NHS England will be setting and incentivising enhanced standards through a 'pick-list' of evidence based indicators for improvement, against which it and clinical commissioning groups can set improvement trajectories and a number of non-mandated best practice service specifications to use with providers. NHS England will continue to make significant funding available (up to 2% of provider contract value) for commissioners to use in setting local improvement goals.

PRESERVING CORPORATE MEMORY

Recommendation 126

The NHS Commissioning Board and local commissioners should develop and oversee a code of practice for managing organisational transitions, to ensure the information conveyed is both candid and comprehensive. This code should cover both transitions

between commissioners, for example as new clinical commissioning groups are formed, and guidance for commissioners on what they should expect to see in any organisational transitions among their providers.

Accepted.

NHS organisations have gained significant learning from the transition to the reformed NHS system in 2013. NHS England will continue to work with commissioners to build on this, so that information handed over in future transitions is comprehensive and candid.

The handover process from Strategic Health Authorities and Primary Care Trusts to the reformed NHS system was developed with guidance on effective quality handover from the National Quality Board, to address the requirements of managing organisational transitions. This will be used as a template for future transitions.

The key lessons on effective transition identified by the National Quality Board included:

- the need for clarity of purpose with time for the system to understand and meet the requirements of a handover process;
- documenting information is an important discipline, but the most valuable part of the process was the face-to-face conversations between individuals;
- information should not only be handed over in order to reduce risk; the ambition for quality improvement should be handed over, so that services continue to improve for patients;
- documents need to be easy to access and navigate by the recipient, so that it is apparent where the areas of risk are in terms of quality. Too much information is as unhelpful as too little;
- the documents are for the benefit of recipients, and should tell them whatever they need to know in order to help them exercise their new accountabilities. They should not be confused with an attempt to record the achievements of the existing organisation;
- triangulation of data (both hard and soft) did not always happen between all of the relevant bodies, such as the regulators, but when it did it was extremely helpful. We need to be much clearer about the requirements of our key stakeholders;
- it is vital that patient experience data is captured as part of the quality assessment and to find ways of engaging with patient groups as part of the process of triangulation;
- 'looking and seeing' should form part of the triangulation process wherever possible;
- while data was generally strong and comprehensive on the acute sector, we need to extend and improve our inclusion of data on the quality of primary, secondary and tertiary care, social care, ambulance services, screening programmes, offender health, mental health and the independent and third sectors;
- the responsibility for the handover should sit equally with both the receiver and the sender. i.e. if there are gaps in the documentation handed over, then it is the duty of the recipient to proactively seek to fill those gaps;

- the requirement to take handover documents to the public sessions of boards helped the process to be taken seriously, and was in line with the proposed new Duty of Candour. On the whole the media treated this information responsibly;
- embedding documents is not good practice, as the information can be lost as links and websites close down. We need to use technology better to ensure that documents are kept 'live' and electronically available to those who need it, with better version control;
- some issues transcend individual organisations, and there may be a need for a small number of thematic handovers in order to maintain quality during transition.

NHS England will consider with clinical commissioning groups what further support and guidance might be required.

RESOURCES FOR SCRUTINY

Recommendation 127

The NHS Commissioning Board and local commissioners must be provided with the infrastructure and the support necessary to enable a proper scrutiny of its providers' services, based on sound commissioning contracts, while ensuring providers remain responsible and accountable for the services they provide.

Accepted.

The NHS Standard Contract, NHS England's assurance of clinical commissioning groups, and the development of commissioning support services, together provide a new infrastructure to ensure that commissioners have the capacity and capability to scrutinise providers' services.

The NHS Standard Contract provides a clear framework through which commissioners can hold providers to account for service quality and safety, and NHS England will continue to develop this further for 2014–15.

Commissioning comprises some activities for which the statutory commissioning body must retain ultimate responsibility, but there is also a range of other, key support functions which it may be more effective and efficient to be secured externally. These are known as 'commissioning support services'. Commissioning support services typically include:

- Health Needs Assessment;
- business intelligence;
- support for redesign;
- communications and patient and public engagement;
- procurement and market management (agreeing contracts);
- provider management (monitoring contracts).

Provision of commissioning support services is currently dominated by 19 commissioning support units, created from Primary Care Trusts and hosted by NHS England and the NHS Business Services Authority until 2016.

Work has already been done through NHS England's clinical commissioning groups assurance programme and through the development of commissioning support services to assure the quality of infrastructure and support within, and available to, commissioning organisations. NHS England will continue to develop this as an objective in its Commissioning Support Services Strategy.

EXPERT SUPPORT

Recommendation 128

Commissioners must have access to the wide range of experience and resources necessary to undertake a highly complex and technical task, including specialist clinical advice and procurement expertise. When groups are too small to acquire such support, they should collaborate with others to do so.

Accepted.

Commissioning support services have been developed to provide commissioners with the range of capacity and expertise required to commission effectively.

Commissioning comprises some activities for which the statutory commissioning body must retain ultimate responsibility, but there is also a range of key support functions which the statutory body not only does not have to undertake itself, but for which it may be more effective and efficient to secure externally. These are known as 'commissioning support services'. Commissioning support services typically include:

- Health Needs Assessment;
- business intelligence;
- support for redesign;
- communications and public and patient engagement;
- procurement and market management (agreeing contracts);
- provider management (monitoring contracts).

Provision of commissioning support services is currently dominated by 19 commissioning support units, created from Primary Care Trusts and hosted by NHS England and the NHS Business Services Authority until 2016.

NHS England will prioritise the further development of the expertise and resources required in its Commissioning Support Services Strategy, and in underpinning products such as quality standards, continuity of service, and procurement vehicles.

ENSURING ASSESSMENT AND ENFORCEMENT OF FUNDAMENTAL STANDARDS THROUGH CONTRACTS

Recommendation 129

In selecting indicators and means of measuring compliance, the principal focus of commissioners should be on what is reasonably necessary to safeguard patients and to ensure that at least fundamental safety and quality standards are maintained. This requires close engagement with patients, past, present and potential, to ensure that their expectations and concerns are addressed.

Accepted.

NHS England will support and assure clinical commissioning groups to develop indicators and measures of compliance with appropriate patient involvement. These will include, and build on, the fundamental standards of care that providers of care will be required to meet.

NHS England and clinical commissioning groups are developing a *Framework for Commissioning for Quality* which will set out the steps that commissioners should take to assure themselves and their patients that the services that they are commissioning are safe, clinically effective, and result in a positive experience for patients.

RELATIVE POSITION OF COMMISSIONER AND PROVIDER

Recommendation 130

Commissioners – not providers – should decide what they want provided. They need to take into account what can be provided, and for that purpose will have to consult clinicians both from potential providers and from elsewhere, and to be willing to receive proposals, but in the end it is the commissioner whose decision must prevail.

Accepted.

We agree with the principle that it is for commissioners to determine what must be provided. Commissioners will increasingly commission for outcomes, in line with the NHS Outcomes Framework, leaving to providers some of the detail of how the service is delivered to achieve those outcomes.

As part of the reformed commissioning system, there are a range of mechanisms for providers, and particularly their clinicians, to offer advice and proposals to commissioners. Strategic Clinical Networks, hosted by NHS England, bring together clinicians to drive change and improvements in the areas of cancer, coronary heart disease, mental health, and maternity and children's services. In addition, Clinical Senates bring together clinicians from all sectors of healthcare, patients and other partners, to give advice to commissioners and providers in their area to help them make the best decisions about healthcare for the populations they represent.

The reforms to the commissioning system will strengthen the ability of commissioners to secure the services they want for their population. NHS England and clinical commissioning

groups are developing a Framework for Commissioning for Quality which will set out the steps that commissioners should take to assure themselves and their patients that the services are safe, clinically effective and result in a positive experience for patients.

DEVELOPMENT OF ALTERNATIVE SOURCES OF PROVISION

Recommendation 131

Commissioners need, wherever possible, to identify and make available alternative sources of provision. This may mean that commissioning has to be undertaken on behalf of consortia of commissioning groups to provide the negotiating weight necessary to achieve a negotiating balance of power with providers.

Accepted.

Commissioners should only decide on models of provision based on the needs and best interests of their patients, in accordance with best practice and with Monitor's *Guidance for commissioners in ensuring the continuity of health services*.⁶⁸ In doing this, commissioners should prioritise those services for which alternative sources of provision should be made available.

NHS England supports commissioning being undertaken collaboratively, where appropriate. NHS England has provided guidance on collaborative commissioning, to support commissioners who wish to collaborate with one another. It is currently reviewing with clinical commissioning groups whether additional guidance and support would be helpful for 2014–15.

MONITORING TOOLS

Recommendation 132

Commissioners must have the capacity to monitor the performance of every commissioning contract on a continuing basis during the contract period:

- Such monitoring may include requiring quality information generated by the provider.
- Commissioners must also have the capacity to undertake their own (or independent) audits, inspections, and investigations. These should, where appropriate, include investigation of individual cases and reviews of groups of cases.
- The possession of accurate, relevant, and useable information from which the safety and quality of a service can be ascertained is the vital key to effective commissioning, as it is to effective regulation.
- Monitoring needs to embrace both compliance with the fundamental standards and with any enhanced standards adopted. In the case of the latter, they will be the

⁶⁸ <http://www.monitor-nhsft.gov.uk/home/news-events-publications/our-publications/browse-category/guidance-health-care-providers-and-co-19>

only source of monitoring, leaving the healthcare regulator to focus on fundamental standards.

Accepted.

Commissioning support services exist to provide this resource and expertise. Commissioning support services typically include:

- Health Needs Assessment;
- business intelligence;
- support for redesign;
- communications and public and patient engagement;
- procurement and market management (agreeing contracts);
- provider management (monitoring contracts).

These functions cover the key elements of this recommendation regarding monitoring quality information, including compliance with fundamental and enhanced standards, and undertaking audits.

NHS England will include this effective contract management and monitoring as an objective in its Commissioning Support Services Strategy and underpinning products, such as quality standards, continuity of service, and procurement vehicles.

NHS England and clinical commissioning groups are developing a Framework for Commissioning for Quality which will set out the steps that commissioners should take to assure themselves and their patients that the services that they are commissioning are safe, clinically effective and result in a positive experience for patients.

ROLE OF COMMISSIONERS IN PROVISION OF SUPPORT FOR COMPLAINTS

Recommendation 133

Commissioners should be entitled to intervene in the management of an individual complaint on behalf of a patient where it appears to them it is not being dealt with satisfactorily, while respecting the principle that it is the provider who has primary responsibility to process and respond to complaints about its services.

Accepted in principle.

While we accept the spirit of this recommendation, we are concerned that it risks creating uncertainty over roles and responsibilities in the management of complaints. Clarity and consistency are critical for the patient.

The NHS complaints process is based upon the premise that complaints are best dealt with by the local organisation. If the complainant remains dissatisfied, they are able to seek an independent review through the Health Service Ombudsman.

We accept that in the cases of complaints of a serious nature, that may indicate a possible failure in care or a continued risk to patient safety, commissioners will want to be aware and take action where they believe a provider is in breach of their contract with regard to patient safety and service quality. The NHS standard contract requires providers to ‘implement Lessons Learned from complaints and demonstrate at Review Meetings the extent to which Service improvements have been made as a result’ – these review meetings take place between the provider and the commissioner. However, one of the lessons of the Mid Staffordshire Inquiry has been that this information needs to be meaningful – just noting the numbers of complaints received by an organisation is not effective. For 2014–15, NHS England are considering broadening the requirement on Lessons Learned to cover a wider spectrum of information, such as complaints, incidents and feedback from service users and staff, and the extent to which service improvements have been made as a result.

The Department of Health will ensure that each quarter every hospital publishes information on the complaints it has received. This will include:

- the number of complaints received, as a percentage of patient interventions in that period;
- the number of complaints the hospital has been informed have subsequently been referred to the Ombudsman; and
- lessons learned and improvements made as a result of complaints.

The Department of Health will work with NHS England and other key partners to determine the most effective mechanism through which to achieve these outcomes.

The standard contract also requires the Provider to provide a complaints monitoring report. For 2014–15 NHS England are considering clarifying the expected content of the complaints report, to include meaningful information on complaints such as analysis of key themes in the content of complaints as well as the number of complaints received for each theme.

The NHS Standard Contract already provides commissioners with powers to intervene in certain circumstances, for example to require remedial action, to impose financial sanctions, to suspend services or to terminate a contract. However, we are examining whether these provisions should be strengthened for 2014–15, with a view to making more specific provision for commissioner intervention, to suspend a service or an element of it, where there are reasonable grounds for material concern about patient safety or outcomes.

However, enabling commissioning bodies to intervene in the management of an individual complaint would undermine the fundamental principle that local organisations themselves are, in the first instance, responsible for seeking to resolve a complaint. A commissioner could intervene if it considers an organisation’s general handling of complaints cases needs to be improved – but their intervention would not be about the specifics of an individual case.

The current complaints arrangements (laid out in regulations) are based on a 2-stage model. The first stage is local resolution. At this local level, a complaint about service provision may be made to *either* the service provider *or* to the body commissioning the service (but not both). If the person making the complaint is not satisfied with the outcome at this local resolution stage, they have the right to ask the Health Service Ombudsman to investigate the case. The Ombudsman is independent of Government and the NHS, accountable to Parliament.

ROLE OF COMMISSIONERS IN PROVISION OF SUPPORT FOR COMPLAINANTS

Recommendation 134

Consideration should be given to whether commissioners should be given responsibility for commissioning patients' advocates and support services for complaints against providers.

Accepted.

The *Health and Social Care Act 2012* gave responsibility for commissioning NHS complaints advocacy to individual Local Authorities; the Local Authorities took responsibility from April 2013. Local Authorities are best able to determine the needs of their local populations.

The review of the handling of NHS complaints has recommended that 'the independent NHS Complaints Advocacy Service should be re-branded, better resourced and publicised. It should also be developed to embrace greater independence and support to those who complain. Funding should be protected and the service attached to local Healthwatch organisations.'

The Department of Health recognises that the current arrangements for the commissioning of complaints advocacy services are new. The Department of Health will begin an evaluation of the current arrangements for commissioning NHS advocacy services in 2014.

PUBLIC ACCOUNTABILITY OF COMMISSIONERS AND PUBLIC ENGAGEMENT

Recommendation 135

Commissioners should be accountable to their public for the scope and quality of services they commission. Acting on behalf of the public requires their full involvement and engagement:

- There should be a membership system whereby eligible members of the public can be involved in and contribute to the work of the commissioners.
- There should be lay members of the commissioners' board.
- Commissioners should create and consult with patient forums and local representative groups. Individual members of the public (whether or not members) must have access to a consultative process so their views can be taken into account.
- There should be regular surveys of patients and the public more generally.
- Decision-making processes should be transparent: decision-making bodies should hold public meetings.

Commissioners need to create and maintain a recognisable identity which becomes a familiar point of reference for the community.

Accepted in part.

Provisions for a new commissioning system in the Health and Social Care Act 2012 address most of the elements of this recommendation. For example, provisions cover the new role of lay members on Clinical Commissioning Group governing bodies, the duty on public involvement and consultation on both NHS England and clinical commissioning groups, and the key role of local Healthwatch in giving people a powerful voice locally in improving and shaping health services.

A range of mechanisms is now available for involving the public in commissioning decisions without requiring the development of new 'membership' models. In September 2013 NHS England issued Transforming Participation In Health And Care,⁶⁹ statutory guidance for clinical commissioning groups on involving patients in planning services and in their own care. By December 2013, 80% of clinical commissioning groups will be commissioning support for patients' participation and decisions in relation to their own care or will have a plan to do so. This will include information and support for self-management, personalised care planning and shared decision-making.

There are a number of regular national and local patient and public surveys. These include the annual national GP patient survey, run for NHS England by Ipsos MORI, and a national programme of patient surveys run for the Care Quality Commission by Picker Institute Europe. In addition, since April 2013 all providers of NHS funded care have been required to offer inpatients and users of accident and emergency services the opportunity to provide feedback through the NHS friends and family test. The first set of data for the Accident and Emergency friends and family test, covering April, May and June was published on 30 July 2013. A second set of this data was published on 30 August and a third on 3 October. 793,448 responses have been received to date. The current response rate is 17.1%.

The friends and family test allows hospital trusts to gain real time feedback on their services down to individual ward level, and increases the transparency of NHS data to drive up choice and quality. The real strength of friends and family test lies in the follow-up questions that can be attached to the initial question, and a rich source of patient views can be used locally to highlight and address concerns much more rapidly than with more traditional survey methods.

It is our intention that by March 2015, all NHS service users will be given the opportunity to provide feedback through the friends and family test. Maternity services started using the Test from 1 October 2013, with the first set of results to be published after the first quarter, at the end of January 2014. Work is currently underway to develop guidance for the introduction of the test to all other NHS settings. Guidance for staff to support the introduction of the friends and family test from April 2014 is on course to be published by the end of December 2013.

NHS England is developing plans to establish in 2014 a Citizens Assembly – pioneering a new approach to ensuring citizen voice is able to hold it to account. NHS England has also established a 'Voices in Governance' model in Specialised Commissioning, to ensure that the patient and public voice is at the heart of commissioning processes.

NHS England and clinical commissioning groups are developing, through the NHS Commissioning Assembly, a *Framework for Commissioning for Quality* which will be published

69 <http://www.england.nhs.uk/wp-content/uploads/2013/09/trans-part-hc-guid1.pdf>

in Autumn 2013. It will set out the steps that commissioners should take to assure themselves and their patients that the services that they are commissioning are safe, clinically effective and result in a positive experience for patients.

Clinical Commissioning Groups are required to take a number of steps to ensure transparency in their decision making processes. The constitution of the Clinical Commissioning Group must specify the arrangements made for securing that there is transparency about the decisions of the group and the manner in which they are made. The governing body must also publish papers considered at its meetings (except where it would not be in the public interest to do so).

Recommendation 136

Commissioners need to be recognisable public bodies, visibly acting on behalf of the public they serve and with a sufficient infrastructure of technical support. Effective local commissioning can only work with effective local monitoring, and that cannot be done without knowledgeable and skilled local personnel engaging with an informed public.

Accepted.

NHS England will support and assure clinical commissioning groups to be recognisable, visible local bodies.

*The National Health Service (Clinical Commissioning Groups) Regulations 2012*⁷⁰ already require that clinical commissioning groups' names reflect their local community, so that they are recognisable and have a clear link to their locality.

Clinical Commissioning Groups demonstrate their accountability to their members, local people, stakeholders and NHS England in a number of ways, including by:

- a) publishing their constitution;
- b) appointing independent lay members and non GP clinicians to the governing body;
- c) holding meetings of the governing body in public;
- d) publishing annually a commissioning plan;
- e) complying with local authority health overview and scrutiny requirements;
- f) meeting annually in public to publish and present its annual report (which must be published);
- g) producing annual accounts in respect of each financial year which must be externally audited;
- h) having a published and clear complaints process;
- i) complying with the Freedom of Information Act 2000;
- j) providing information to NHS England as required.

Commissioning support services have been developed to provide the infrastructure of technical support that clinical commissioning groups require. Commissioning support services typically include:

- Health Needs Assessment;
- business intelligence;
- support for redesign;
- communications and public and patient engagement;
- procurement and market management (agreeing contracts);
- provider management (monitoring contracts).

These services underpin the effective local monitoring required to support clinical commissioning groups be effective, visible and well engaged local commissioners.

INTERVENTION AND SANCTIONS FOR SUBSTANDARD OR UNSAFE SERVICES

Recommendation 137

Commissioners should have powers of intervention where substandard or unsafe services are being provided, including the substitution of staff or other measures necessary to protect the patients from the risk of harm. In the provision of commissioned services, such powers should be aligned with similar powers of the regulators so that both commissioners and regulators can act jointly, but with the proviso that either can act alone if the other declines to do so. The powers should include the ability to order a provider to stop the provision of a service.

Not accepted, however we agree the underlying of this recommendation to avoid inaction on the part of regulators and commissioners because of a lack of clarity about their respective roles.

The respective roles of commissioners and regulators in their relationships with providers are different and must be distinct. Commissioners arrange the provision of high quality services to meet the needs of the people they are responsible for, and can take direct action with providers when they are not delivering to contractual specifications. The regulators are charged to ensure that providers meet set standards, and to give regulators and commissioners equivalent powers of intervention would blur the distinction of these roles and risk causing confusion in the system, resulting in inaction because of assumptions that another body is intervening to address a problem.

The NHS Standard Contract enables commissioners to intervene where substandard or unsafe services are being provided. In extremis, under the terms of the standard contract, the commissioners can suspend services, or elements of them, and terminate contracts. Enforcement action, which may entail the substitution of staff, is properly the role of the regulators: the Care Quality Commission will retain all of its existing enforcement powers and will not be constrained from taking swift and decisive action if patients are at immediate risk

of harm. Where there is no immediate risk of harm to patients but concerns exist, the Care Quality Commission will normally look to Monitor or the NHS Trust Development Authority to exercise their powers to take enforcement action at NHS Trusts and Foundation Trusts. In determining the potential benefits of an intervention, Monitor will consider whether the best outcome for healthcare service users can be achieved by acting themselves or acting together with another organisation, or whether another organisation such as the Care Quality Commission, NHS Trust Development Authority or NHS England has tools that could tackle an issue more effectively, or is already taking steps that are likely to address the potential harm. However any enforcement activity by the Care Quality Commission does not preclude Monitor from exercising its enforcement powers if relevant to do so, and vice versa.

Where Health Education England has concerns about the quality of clinical placements or training being provided by a provider it will take action to remedy this. If necessary, Health Education England will withdraw clinical placements or training programmes from a provider until they are able to demonstrate the required level of improvement and ensure a safe training environment for patients, students and trainees

In Patients First and Foremost⁷¹ the Department of Health agreed that, ‘...regulators and commissioners should ensure that they have a shared picture of provider performance...’ NHS England, clinical commissioning groups, the Care Quality Commission, Monitor, the NHS Trust Development Authority, Health Education England and the professional regulators (General Medical Council and Nursing and Midwifery Council) can align their powers of intervention by means of Quality Surveillance Groups. NHS England has rolled Quality Surveillance Groups out across England in each area and region. These are all actively engaged in sharing information and intelligence between commissioners, regulators and other organisations on the quality of care being delivered. If commissioners have concerns about whether providers are meeting the essential standards of quality and safety, Quality Surveillance Groups are one of the mechanisms through which they can raise their concerns with the Care Quality Commission, Monitor and with any other parts of the system with an interest. This includes concerns individual commissioners have about providers from whom they do not commission services, but with whom they interact (for example, clinical commissioning groups and primary care providers). The National Quality Board is currently conducting a review of how the Quality Surveillance Group network is operating, and what support it needs to be as effective as possible. It will publish revised guidance and support materials by the end of 2013 to support all Quality Surveillance Groups in reaching their full potential.

71 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170701/Patients_First_and_Foremost.pdf

Local scrutiny

The Inquiry recommended that commissioners should have contingency plans to ensure that patients are protected from harm, if they are at risk from substandard or unsafe services. NHS England is supporting commissioners to do just this, and a new single failure regime will ensure that financial and quality failures are handled in a consistent way.

Recommendation 138

Commissioners should have contingency plans with regard to the protection of patients from harm, where it is found they are at risk from substandard or unsafe services.

Accepted.

Commissioners must develop plans to ensure that safe and effective services can continue to be provided in the event of a provider failure.

NHS England is supporting commissioners to develop plans for responding to a serious provider failure, in line with Monitor's guidance and rules on service continuity.

The Department of Health, the Care Quality Commission, NHS England, Monitor and the NHS Trust Development Authority are working together to develop a single failure regime (outlined in the response to recommendation 19), which will ensure that financial and quality failures are handled in a consistent way and can be enacted where risks to quality and patient safety are identified. As part of that regime, the Care Quality Commission, NHS Trust Development Authority and Monitor will work together, with the trust and its commissioners, to ensure that where concerns are raised, the trust acts swiftly to resolve them. This will provide external support and assurance that appropriate action has been taken or may indicate that further action is needed.

Performance management and strategic oversight

In its recommendations, the Inquiry repeatedly stated the need to put patients first at all times. In managing the performance of providers, commissioners and regulators alike should be clear on their own roles and responsibilities, using good quality information on which to base their judgements on performance, sharing that information between organisations effectively and yet all the time ensuring that fundamental patient safety and quality standards are met.

We agree with these recommendations. Commissioners and regulators should have clear and distinct roles in ensuring the safety of people who use services and should act swiftly where patients are at risk. Registration by the Care Quality Commission and Monitor's licencing of providers gives an assurance to commissioners that a provider meets fundamental standards of care. The NHS Standard Contract provides a framework for commissioners to receive on-going assurance on compliance with standards, through its routine performance management processes. A series of measures, outlined in this section, to enable metrics that relate directly to the quality of patient care to be collected and published.

THE NEED TO PUT PATIENTS FIRST AT ALL TIMES

Recommendation 139

The first responsibility for any organisation charged with responsibility for performance management of a healthcare provider should be ensuring fundamental patient safety and quality standards are being met. Such an organisation must require convincing evidence to be available before accepting that such standards are being complied with.

Accepted.

Registration by the Care Quality Commission and Monitor's licencing of providers gives an assurance to commissioners that a provider meets fundamental standards of care. The NHS Standard Contract provides a framework for commissioners to receive on-going assurance on compliance with standards, through its routine performance management processes.

PERFORMANCE MANAGERS WORKING CONSTRUCTIVELY WITH REGULATORS

Recommendation 140

Where concerns are raised that such standards are not being complied with, a performance management organisation should share, wherever possible, all relevant information with the relevant regulator, including information about its judgement as to the safety of patients of the healthcare provider.

Accepted.

The processes associated with Quality Surveillance Groups and risk summits provide the framework for this. NHS England is reviewing the effectiveness of these arrangements. Strong bilateral relationships should also be in place between the commissioners, regulators and NHS England's area teams

Key organisations and regulators, including the NHS Trust Development Authority, Monitor, the Care Quality Commission and NHS England, have published agreements that set out the ways in which they are working together and sharing information outside of Quality Surveillance Group meetings so that there is a single common assessment of the quality and sustainability of any given provider.

TAKING RESPONSIBILITY FOR QUALITY

Recommendation 141

Any differences of judgement as to immediate safety concerns between a performance manager and a regulator should be discussed between them and resolved where possible, but each should recognise its retained individual responsibility to take whatever action within its power is necessary in the interests of patient safety.

Accepted in principle.

Commissioners and regulators should have clear and distinct roles in ensuring the safety of people who use services and should act swiftly where patients are at risk. Local and regional Quality Surveillance Groups actively share information and intelligence, including qualitative intelligence, including issues and cases of media and public interest, between commissioners, regulators and other organisations on the quality of care being delivered. This provides a mechanism to share and discuss safety concerns between commissioners and regulators. In addition to the coordinated process outlined in recommendation 19 as part of the single failure regime, the NHS Standard Contract enables commissioners to intervene where substandard or unsafe services are being provided. This includes the ability to suspend services, or elements of them, and terminate contracts. See recommendation 137 for further details.

In addition, the Care Quality Commission will retain its ability to stop a service from providing care if it is putting people at immediate risk of harm as outlined by the *Health and Social Care Act 2008*. The Act states that where the Care Quality Commission has 'reasonable cause' to believe that unless it acts people may be exposed to the risk of harm, it may impose or vary a

condition of a provider's registration or suspend it from the point written notice is given as part of an urgent response.

In addition, subject to the passage of regulations, during 2014 the Care Quality Commission will also have new powers to prosecute a provider for failing to provide fundamental levels of care, without having to issue a formal warning first. See recommendation 28 for further details.

CLEAR LINES OF RESPONSIBILITY SUPPORTED BY GOOD INFORMATION FLOW

Recommendation 142

For an organisation to be effective in performance management, there must exist unambiguous lines of referral and information flows, so that the performance manager is not in ignorance of the reality.

Accepted.

The reformed NHS system includes a number of different lines of accountability, so it is crucial that there is no ambiguity or confusion about these accountabilities or about the information flows which inform them.

Providers are accountable to their commissioners for the quality of services they deliver. The NHS Standard Contract provides for clarity on information flows between provider and commissioner.

In primary care, the introduction of the General Practice Extraction Service and Calculating Quality Reporting Service ensures that clear and accurate performance management information is provided within services commissioned from GP contractors.

NHS Trusts are also accountable to the NHS Trust Development Authority for their overall performance, including for providing high quality services. The accountability arrangements for NHS Trusts are set out in *Delivering High Quality Care for Patients: The Accountability Framework for NHS Trusts*.⁷² The *Accountability Framework*⁷³ is aligned with the standards set by Monitor and the Care Quality Commission, and the Trust Development Authority continues to work with its partners to ensure that it reflects any relevant changes, such as the Care Quality Commission's new regime for the monitoring, inspection and rating of healthcare providers.

NHS England and the NHS Trust Development Authority have agreed protocols to ensure that there is no uncertainty or duplication in processes for intervening in local health communities where there are concerns about quality or safety.

72 http://www.ntda.nhs.uk/wp-content/uploads/2012/04/framework_050413_web.pdf

73 http://www.ntda.nhs.uk/wp-content/uploads/2012/04/framework_050413_web.pdf

CLEAR METRICS ON QUALITY

Recommendation 143

Metrics need to be established which are relevant to the quality of care and patient safety across the service, to allow norms to be established so that outliers or progression to poor performance can be identified and accepted as needing to be fixed.

Accepted.

A range of metrics are collected and published across the health sector that relate directly to the quality of patient care. This includes data on infection control (Public Health England), safety incidents (NHS England), Summary Hospital-level Mortality Indicator (Health and Social Care Information Centre) and, patients' feedback reported on NHS Choices among other sites.

The Health and Social Care Information Centre publishes performance information and statistics, using transparent calculations, so that they can be used across the health and care system to review performance and identify concerns. The Health and Social Care Information Centre's [Indicator Portal](http://www.hscic.gov.uk/indicatorportal)⁷⁴ for national quality indicators extend this service.

In addition, from November 2013 NHS England will begin to extend NHS Choices so that it will bring together the most reliable and relevant data from national web services and act as a 'front door' to the best information on health and social care on the internet.

Details of how this information will be used by Care Quality Commission as part of its new inspection regime is outlined in recommendation 20.

NHS England and Care Quality Commission are committed to working together to develop a shared and agreed approach to measuring safety in the NHS, both for regulatory and improvement purposes. NHS England is currently in discussion with Care Quality Commission about which patient safety measures, including incident reporting, are best suited for use in their surveillance model, and how NHS England can contribute to their interpretation. This includes providing Care Quality Commission with access to the relevant patient safety expertise to inform how they use patient safety data in their surveillance and inspection processes, including what 'good' looks like and what data should be considered a cause for concern. Care Quality Commission will be setting out its new surveillance and inspection model and NHS England will be setting out its safety measurement framework in due course.

74 <http://www.hscic.gov.uk/indicatorportal>

NEED FOR OWNERSHIP OF QUALITY METRICS AT A STRATEGIC LEVEL

Recommendation 144

The NHS Commissioning Board should ensure the development of metrics on quality and outcomes of care for use by commissioners in managing the performance of providers, and retain oversight of these through its regional offices, if appropriate.

Accepted.

*The NHS Outcomes Framework 2013–14*⁷⁵ (Department of Health, November 2012) contains a range of indicators that provide a balanced coverage of NHS activity that, taken together, provide a national overview of how well the NHS is performing. They provide the accountability mechanism between the Secretary of State for Health and NHS England for the effective spending of public money. The indicators are set out in five domains that cover the preventing of premature mortality; enhancing quality of life for people with long term conditions; helping people recover from episodes of ill health; ensuring the people have a positive experience of care; and treating people in safe environments and protecting them from avoidable harm.

In addition to this, NHS England also publishes a range of data that supports improvement. In June 2013, NHS England published the first two specialties level data, cardiac surgery and vascular, and announced the publication schedule for a further eight specialties. All specialties have since been published.

NHS England will widen this programme to include other specialties over time and the data published will, initially, be refreshed annually. This data will continue to be published as part of NHS Choices website.

75 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213055/121109-NHS-Outcomes-Framework-2013-14.pdf

Patient, public and local scrutiny

The Inquiry found that the bodies which replaced Community Health Councils – Public and Patient Involvement Forums and Local Involvement Networks were preoccupied with constitutional and procedural matters, and by doing so failed to represent the patient voice in Stafford. He therefore recommended a consistent structure for local Healthwatch organisations, and that funding for them should be accounted for and ring-fenced. He also recommended that guidance, support and training should be provided to help strengthen local Government’s scrutiny of local health and care services, to which local Healthwatch is an important contributor.

In response to these recommendations, the Government has worked with partners to develop guidance that will support effective scrutiny by local government of the commissioning and delivery of local services, helping to ensure they are effective and safe. The guidance is due to be published in November. While the Government does not accept the mandation of a single structure for local Healthwatch organisations, we do agree that local Healthwatch organisations need to be focused on their role as effective consumer champions for local communities rather than getting bogged down in questions of form and procedure. Local authorities are responsible for ensuring their local Healthwatch providers are delivering effectively, and Healthwatch England has a key role in maintaining an overview of the network, in building capability [and providing targeted support where needed] Equally, while the Government does not accept the ring-fencing of funding for local Healthwatch, it believes actions being taken with Healthwatch England to increase transparency will help to ensure that local authorities can be scrutinised and held to account for the funding decisions they make in relation to local Healthwatch.

STRUCTURE OF LOCAL HEALTHWATCH

Recommendation 145

There should be a consistent basic structure for Local Healthwatch throughout the country, in accordance with the principles set out in *Chapter 6: Patient and public local involvement and scrutiny*.

Not accepted, however we share the underlying intention behind this recommendation to ensure consistency of outcomes for local communities with each local Healthwatch organisation providing a strong voice for their local population and helping to shape an effective local health and care system.

We believe that local Healthwatch organisations should be set up in a way that best meets the needs and reflects the circumstances of their local communities; taking a top-down approach and imposing a fixed structure would undermine the need for flexibility.

We believe that consistency of outcomes – with each local Healthwatch organisation providing a strong voice for the local population and helping to shape an effective local health and care system – is more important than consistency of form. As every local authority has now commissioned its Healthwatch provider, we also believe that retrospectively imposing a consistent structure at this stage would divert effort and resources from the important work that local Healthwatch organisations should be doing in their role as local consumer champions.

We do, however, fully recognise the concerns about previous arrangements for patient and public involvement in Staffordshire, and the disproportionate – and ultimately damaging – focus on governance and organisational matters at the expense of ensuring the local community's concerns were heard and acted on. As part of the new arrangements, one of the core roles of Healthwatch England at the national level is to provide support and leadership to local Healthwatch organisations. This year, as local Healthwatch organisations have been establishing themselves, Healthwatch England and the Local Government Association have provided important support to help them put in place clear governance arrangements that will enable them to focus on effective delivery of their local priorities.

It is vital that local Healthwatch organisations continue to be supported and that any early signs that they are struggling to fulfil their role are identified and addressed. Local authorities are responsible for commissioning and performance managing their local Healthwatch provider. Alongside this, Healthwatch England has a crucial role in building capability across the network, and it will ensure that best practice is shared and there are clear standards in place for what a good local Healthwatch should be achieving. We will also work with Healthwatch England to ensure that they can develop and provide targeted support for local Healthwatch organisations that may need it.

FINANCE AND OVERSIGHT OF LOCAL HEALTHWATCH

Recommendation 146

Local authorities should be required to pass over the centrally provide funds allocated to its Local Healthwatch, while requiring the latter to account for its stewardship of the money. Transparent respect for the independence of Local Healthwatch should not be allowed to inhibit a responsible local authority – or Healthwatch England as appropriate – intervening.

Accepted in part.

We do not accept that local authorities should be required to pass over centrally-provided funds. We believe that local authorities are best-placed to make decisions about funding services that meet the needs of their local communities – including local Healthwatch. We expect local Healthwatch organisations to have sufficient funding to deliver against their local priorities, but we do not believe it is for the Government to dictate what this level should be.

As the Healthwatch network is new, it is not possible at this stage to specify the level of funding that is required to deliver an effective local Healthwatch function. But we do believe it is important that there is *transparency* about funding for local Healthwatch, and that this

principle of transparency is embedded at the outset. We will therefore require each local Healthwatch to set out the amount of funding it receives in its annual report. Healthwatch England will also publish in December the amount of funding each local Healthwatch has received, and we are working with Healthwatch England to see what further steps can be taken to enable transparency.

We agree that local Healthwatch should account to its local authority, as commissioner of Healthwatch, for its use of funding provided and it is the responsibility of local authorities to ensure that appropriate arrangements are in place.

We agree that there is a balance to strike between respect for the independence of local Healthwatch organisations and the need to ensure that they are functioning effectively. Local authorities are responsible for holding their local Healthwatch provider to account. Healthwatch England already has the power to alert local authorities to concerns it may have around the performance of a local Healthwatch provider. In addition, as part of its own role in supporting local Healthwatch it has put in place measures to ensure that it has a robust overview of how the network is performing. We will work with Healthwatch England to ensure that, if needed, providers who may be struggling get the right support at the right time.

COORDINATION OF LOCAL PUBLIC SCRUTINY BODIES

Recommendation 147

Guidance should be given to promote the coordination and cooperation between Local Healthwatch, Health and Wellbeing Boards, and local government scrutiny committees.

Accepted.

The Department of Health has worked with partners to develop guidance that will support effective scrutiny by local government of the commissioning and delivery of local services, helping to ensure they are effective and safe.

The guidance is aimed at local authorities, Health and Wellbeing Boards, NHS commissioners and providers, and local Healthwatch. The guidance underlines the importance of all partners in the system understanding their own and each other's roles and responsibilities, and working together to improve the quality of services.

The guidance also describes the new powers provided to local Healthwatch by the *Local Authorities (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013*,⁷⁶ and describes how Health and Wellbeing Boards and local Healthwatch can work collaboratively with local government scrutiny committees to ensure that the views and concerns of patients and public are heard throughout the scrutiny process.

The guidance is due to be published in November 2013.

76 http://www.legislation.gov.uk/uksi/2013/218/pdfs/ukxi_20130218_en.pdf

TRAINING

Recommendation 148

The complexities of the health service are such that proper training must be available to the leadership of Local Healthwatch as well as, when the occasion arises, expert advice.

Accepted.

Healthwatch England is working to support local Healthwatch in their identification and analysis of issues in their communities and to support them to raise these issues in the appropriate manner. Already, local Healthwatch organisations are rightly working in partnership with local community and interest groups that have a wealth of expertise and experience available to them. Local Healthwatch organisations also have the flexibility to source expert advice as they require, while training and support is being made available through Healthwatch England.

As an example of what has already been achieved, Healthwatch England has this year delivered training to local Healthwatch organisations across the country to ensure that they can maximise the impact of their power to enter and view local services.

EXPERT ASSISTANCE

Recommendation 149

Scrutiny committees should be provided with appropriate support to enable them to carry out their scrutiny role, including easily accessible guidance and benchmarks.

Accepted.

The Department of Health has worked with partners to develop guidance that will support local authorities to carry out effective scrutiny of the commissioning and delivery of local services, helping to ensure they are effective and safe.

The guidance will help Local Authorities (along with local partners including NHS commissioners and providers, Health and Wellbeing Boards and Healthwatch) to understand the new powers and duties provided by the *Local Authorities (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013*.⁷⁷

The Department is also delivering a range of programmes to increase the availability and transparency of data for local authorities, to support local democratic accountability including scrutiny processes.

The guidance is due to be published in November 2013.

77 http://www.legislation.gov.uk/ukxi/2013/218/pdfs/ukxi_20130218_en.pdf

INSPECTION POWERS

Recommendation 150

Scrutiny committees should have powers to inspect providers, rather than relying on local patient involvement structures to carry out this role, or should actively work with those structures to trigger and follow up inspections where appropriate, rather than receiving reports without comment or suggestions for action.

Accepted in principle.

Under current provisions, bodies carrying out local authority scrutiny functions have legal powers to require providers of NHS services to provide information and to attend scrutiny meetings to answer questions. This could include making a request to visit providers' premises. Where a body carrying out local authority scrutiny function had concerns about a specific provider, they could refer the matter to the Care Quality Commission, who have powers of inspection.

Meanwhile, local Healthwatch has the power to enter and view certain premises, as well as powers to provide information and refer concerns to local authority scrutiny bodies.

Giving further powers to local authorities would therefore be duplicative and potentially burdensome. It might also create confusion over roles and responsibilities.

The work of Local Authority health scrutiny is already integral to ensuring an appropriate inspection regime is in place locally. By working collaboratively with both providers and local Healthwatch, local authority scrutiny bodies can ensure that concerns from patients and the public trigger further investigation where necessary.

The Department of Health has worked with partners to develop guidance that will support local authorities to carry out effective scrutiny. The guidance describes the new powers and duties provided by the *Local Authorities (Public Health, Health and Wellbeing Boards and Health Scrutiny) Regulations 2013*,⁷⁸ and underlines the importance of all partners in the local system working together to improve the quality of services.

The guidance is due to be published in November 2013.

COMPLAINTS TO MPS

Recommendation 151

MPs are advised to consider adopting some simple system for identifying trends in the complaints and information they received from constituents. They should also consider whether individual complaints imply concerns of wider significance than the impact on one individual patient.

78 http://www.legislation.gov.uk/uksi/2013/218/pdfs/ukxi_20130218_en.pdf

Accepted in principle.

It is not for the Government to advise individual MPs on the systems they employ to identify the wider significance of individual complaints about health and care services. That said, the Department of Health recognises the invaluable insights which can be gained from letters written to MPs. Without wanting to suggest to MPs how they handle their own business, the Department would be willing to highlight the scope – for MPs who desired it or believed it appropriate – to identify themes and patterns in complaints by sharing correspondence with regulators (for example the Care Quality Commission, NHS Trust Development Authority and Monitor) using informed consent, and to gain intelligence about patient experience in their constituency's health and care services by building strong relations with their local Healthwatch organisations. The Department would be willing to work with regulators and any interested MPs – while respecting their position as elected office holders- to share best practise and advice.

Medical training and education

The Inquiry made the point that all organisations responsible for medical education and training have a role in protecting patients. An unsafe, poor quality training environment is clearly one which will impact on the quality of training received by students within it. Students and trainees need to be encouraged and empowered to speak out about concerns, and system partners should act on those concerns and share information across professional and system regulators.

There is a shared commitment and drive in the system to work more collaboratively to share information about the quality of training placements. New Memoranda of Understanding and information protocols have been developed between system and professional regulators. At a local level, Quality Surveillance Groups will bring together bodies such as Health Education England and the Care Quality Commission, to share concerns about the quality and safety of care and agree on appropriate actions.

There will be a strengthened patient and clinical voice within the education and training system, as Health Education England have appointed a medically qualified Director of Education and Quality, and a Non-Executive Director to represent patients on its Board.

The General Medical Council have accepted the spirit of all recommendations aimed at them, and will build these into their Review of Quality Assurance of Education, due to report by the end of 2013. They are also carrying out a fundamental review of Approved Practice Settings, due to report in 2014, to determine if this is still fit for purpose.

MEDICAL TRAINING

Recommendation 152

Any organisation which in the course of a review, inspection or other performance of its duties, identifies concerns potentially relevant to the acceptability of training provided by a healthcare provider, must be required to inform the relevant training regulator of those concerns.

Accepted.

In the new health and care system architecture, Memoranda of Understanding exist between key partners such as Health Education England and the Care Quality Commission, to share information and concerns about the quality and safety of providers. Memoranda of Understanding and other protocols for sharing information also exist between the Care Quality Commission and the General Medical Council and the Nursing and Midwifery Council. Health

Education England will work with the system and professional regulators to develop these further.

The recently established Quality Surveillance Groups bring together the different parts of the system to share information including shared views of risks to quality and any early warning signs of risk about poor quality. Health Education England as well as the system and professional regulators are members of the regional Quality Surveillance Groups.

Recommendation 153

The Secretary of State should by statutory instrument specify all medical education and training regulators as relevant bodies for the purpose of their statutory duty to cooperate. Information sharing between the deanery, commissioners, the General Medical Council, the Care Quality Commission and Monitor with regard to patient safety issues must be reviewed to ensure that each organisation is made aware of matters of concern relevant to their responsibilities.

Accepted in principle.

As stated in recommendation 152, in the new health and care system architecture, Memoranda of Understanding exist between key partners such as Health Education England and the Care Quality Commission, to share information and concerns about the quality and safety delivered of providers. The Health and Social Care Act 2012 further strengthened this by placing a statutory duty on Monitor and the Care Quality Commission to cooperate in the interests of patients. Monitor and Care Quality Commission have a Memorandum of Understanding in place to facilitate the necessary collaboration and information sharing. There are similar duties on organisations across the system, including Health Education England.

The Care Quality Commission and the General Medical Council have published an operational protocol which sets out in detail how coordination and information sharing will work between the two regulators. A similar arrangement will be in place between the Care Quality Commission and the Nursing and Midwifery Council by December 2013, and updated information sharing arrangements thereafter between the Care Quality Commission, the General Dental Council and Health and Care Professions Council. Information from third parties such as the General Medical Council and the Royal Colleges is a potential trigger for regulatory intervention in Monitor's Risk Assessment Framework. Recently established Quality Surveillance Groups bring together the different parts of the system to share information, including shared views of risks to quality and any early warning signs of risk about poor quality. If any part of the local, regional or national system has concerns that there may be a serious quality failure within a provider organisation, which cannot be addressed through established and routine operational systems, a Risk Summit can be called.

Recommendation 154

The Care Quality Commission and Monitor should develop practices and procedures with training regulators and bodies responsible for the commissioning and oversight of medical training to coordinate their oversight of healthcare organisations which provide regulated training.

Accepted

The Care Quality Commission and the General Medical Council have developed an operation protocol which describes when and how to share information on emerging and urgent concerns (for example about individual doctors, systems and environments) as well as processes for the routine sharing of information, local liaison meetings any on-going activities and risk summits. There is also a process for deciding when joint planned inspections are required. The Care Quality Commission is working on developing operational protocols with the Healthcare Professions Council and the Nursing and Midwifery Council.

Information from third parties such as General Medical Council and Royal Colleges is a potential trigger for regulatory intervention in Monitor's Risk Assessment Framework and information and any identified concerns are shared with the Quality Surveillance Groups of which the General Medical Council and Nursing and Midwifery Council are also members of regional the Quality Surveillance Groups.

Recommendation 155

The General Medical Council should set out a standard requirement for routine visits to each local education provider, and programme in accordance with the following principles:

- **The Postgraduate Dean should be responsible for managing the process at the level of the Local Educational Training Board, as part of overall deanery functions**
- **The Royal Colleges should be enlisted to support such visits and to provide the relevant specialist expertise where required.**
- **There should be lay or patient representation on visits to ensure that patient interests are maintained as the priority.**
- **Such visits should be informed by all other sources of information and, if relevant, coordinated with the work of Care Quality Commission and other forms of review.**

The Department of Health should provide appropriate resources to ensure that an effective programme of monitoring training by visits can be carried out.

All healthcare organisations must be required to release healthcare professionals to support the visits programme. It should also be recognised that the benefits in professional development and dissemination of good practice are of significant value.

Accepted.

The General Medical Council has stated its commitment to a thorough and consistent inspection regime, and to building on its quality assurance arrangements to address the issues raised in this recommendation.

The General Medical Council is working with the Academy of Medical Royal Colleges and with Postgraduate Deans to develop a more explicit statement about how Colleges should support visits to local providers. The General Medical Council's Quality Improvement Framework is clear that Deans must draw on a range of external advice to support their scrutiny of local providers, including from patients and the public, as well as from doctors.

The evidence pack supporting the General Medical Council inspection teams contain information from the Care Quality Commission and other external organisations. The outcomes of visits and information about serious concerns which the General Medical Council is monitoring are shared with the Care Quality Commission.

In February 2012, the General Medical Council Chair, Professor Sir Peter Rubin, and the four UK Chief Medical Officers wrote a joint letter to NHS organisations setting out the importance of releasing clinical staff to perform roles that improve the overall quality of patient care, medical education and the effective running of the health service.

Recommendation 156

The system for approving and accrediting training placement providers and programmes should be configured to apply the principles set out above.

Accepted.

The General Medical Council are taking the response to this recommendation forward in detail through its *Review of Quality Assurance in Education*. The General Medical Council will share its proposals in the first half of 2014.

MATTERS TO BE REPORTED TO THE GENERAL MEDICAL COUNCIL

Recommendation 157

The General Medical Council should set out a clear statement of what matters; deaneries are required to report to the General Medical Council either routinely or as they arise. Reports should include a description of all relevant activity and findings and not be limited to exceptional matters of perceived non-compliance with standards. Without a compelling and recorded reason, no professional in a training organisation interviewed by a regulator in the course of an investigation should be bound by a requirement of confidentiality not to report the existence of an investigation, and the concerns raised by or to the investigation with his own organisation.

Accepted.

We accept this recommendation. The General Medical Council already has a structured reporting template supported by guidance setting out what Deans are required to report to the General Medical Council. It is considering, through its review of quality assurance in education, how it will improve the value of these reports so that the information required on issues such as concerns and good practice is able to be of most benefit. The General Medical Council will share its proposals in the first half of 2014.

TRAINING AND TRAINING ESTABLISHMENTS AS A SOURCE OF SAFETY INFORMATION

Recommendation 158

The General Medical Council should amend its standards for undergraduate medical education to include a requirement that providers actively seek feedback from students and tutors on compliance by placement providers with minimum standards of patient safety and quality of care, and should generally place the highest priority on the safety of patients.

Accepted.

The General Medical Council has made it clear that it places a high priority on feedback from students and tutors in ensuring both quality education and patient safety, and will look to reinforce this through its *Review of Quality Assurance in Education*. The General Medical Council will share its proposals in the first half of 2014.

Recommendation 159

Surveys of medical students and trainees should be developed to optimise them as a source feedback of perceptions of the standards of care provided to patients. The General Medical Council should consult the Care Quality Commission in developing the survey and routinely share information obtained with healthcare regulators.

Accepted.

The General Medical Council has made it clear that it views surveys of medical students and doctors in training as vital in assessing the quality of education and an important tool in evaluating the standards of care provided to patients. The General Medical Council is now including questions about the quality of care provided to patients in the National Training Survey. The General Medical Council also surveys medical students ahead of formal visits to their medical schools, and is committed to considering, by 2015, whether to survey all medical students, as is done with doctors in training, in 2015. The results of the National Training Survey of trainees are published on the General Medical Council's web site and are shared with other regulators such as the Care Quality Commission, for example, to support their recent inspections of Acute Hospitals.

Recommendation 160

Proactive steps need to be taken to encourage openness on the part of trainees and to protect them from any adverse consequences in relation to raising concerns.

Accepted.

The General Medical Council has made clear its commitment to build on the progress to date in this area (the inclusion of a patient safety question in the National Training Survey, the development of new guidance on raising concerns and the introduction of a new confidential helpline for doctors), and recognises it needs to do more to raise awareness and encourage openness. Among other things the General Medical Council is running 'professionalism' events at all medical schools every year. The General Medical Council will also shortly be

publishing a report highlighting the issue of bullying of trainees (which can lead to a culture in which trainees feel unable to raise concerns), illustrated by case studies showing the impact of such behaviour and how it can be tackled.

Recommendation 161

Training visits should make an important contribution to the protection of patients:

- Obtaining information directly from trainees should remain a valuable source of information – but it should not be the only source of information used.
- Visits to, and observation of, the actual training environment would enable visitors to detect poor practice from which both patients and trainees should be sheltered.
- The opportunity can be taken to share and disseminate good practice with trainees and management.

Visits of this nature will encourage the transparency that is so vital to the preservation of minimum standards.

Accepted.

The General Medical Council has made it clear that it views visits as an important tool within its quality assurance programme for assuring high quality training and protection of patients. The General Medical Council taken a policy decision to publish information on validated concerns about an educational setting on its website, and will implement this more transparent approach in late 2013 or early 2014. The General Medical Council's review of quality assurance in education is considering how to strengthen the role of visits and how the General Medical Council reports on them. The General Medical Council will share its proposals in the first half of 2014.

Recommendation 162

The General Medical Council should in the course of its review of its standards and regulatory process ensure that the system of medical training and education maintains as its first priority the safety of patients. It should also ensure that providers of clinical placements are unable to take on students or trainees in areas which do not comply with fundamental patient safety and quality standards. Regulators and deaneries should exercise their own independent judgement as to whether such standards have been achieved and if at any stage concerns relating to patient safety are raised, they must take appropriate action to ensure these concerns are properly addressed.

Accepted.

The General Medical Council has made it clear that it agrees that this is a fundamentally important principle which is given prominence in its guidance for doctors. The General Medical Council is considering as part of its review of quality assurance in education how it can be assured of the adequacy and appropriateness of training environments. The General Medical Council will share its proposals in the first half of 2014.

SAFE STAFF NUMBERS AND SKILLS

Recommendation 163

The General Medical Council's system of reviewing the acceptability of the provision of training by healthcare providers must include a review of the sufficiency of the numbers and skills of available staff for the provision of training and to ensure patient safety in the course of training.

Accepted.

The General Medical Council's standards for training includes (at Domain 8) educational resources and capacity and provides that there must be a suitable ratio of trainers to trainees. The General Medical Council has made it clear that it will use its *Review of Quality Assurance in Education* to consider whether the standard should be more specific while allowing necessary scope for local flexibility.

APPROVED PRACTICE SETTINGS

Recommendation 164

The Department of Health and the General Medical Council should review whether the resources available for regulating Approved Practice Setting are adequate and, if not, make arrangements for the provision of the same. Consideration should be given to empowering the General Medical Council to charge organisations a fee for approval.

Accepted in principle.

The General Medical Council has undertaken a fundamental review of Approved Practice Settings. This review considered Approved Practice Settings in the context of the General Medical Council's functions and how they promote assurance and patient safety. Since Approved Practice Settings was introduced in 2007, the General Medical Council has acquired significant powers relating to quality assuring medical training environments the Responsible Officer regulations have come into force and revalidation has begun. Revalidation is the process by which licensed doctors are required to demonstrate on a regular basis that they are up to date and fit to practise. It represents a major step forward in the quality assurance of practising doctors.

The General Medical Council review has found that these new powers have superseded Approved Practice Settings as a source of regulatory assurance and has recommended that the legal provisions that deal with Approved Practice Settings should be reviewed as part of the Law Commission review of the regulation of health and social care professionals. This will however take time, and in the meantime there is an opportunity for the General Medical Council to align the Approved Practice Settings requirements with those in the Responsible Officer Regulations. In effect, this would mean that newly registered doctors or doctors recently restored to the register must, while in the UK, practise in circumstances where they have a connection to a designated body, which is an organisation that will provide regular appraisal and help with revalidation.

Recommendation 165

The General Medical Council should immediately review its approved practice settings criteria with a view to recognition of the priority to be given to protecting patients and the public.

Accepted in principle.

The priority should, as in all regulatory activity, be protecting patients and the public.

The General Medical Council has undertaken a fundamental review of Approved Practice Settings. This review considered Approved Practice Settings in the context of the General Medical Council's functions and how they promote assurance and patient safety. Since Approved Practice Settings was introduced in 2007, the General Medical Council has acquired significant powers relating to quality assuring medical training environments the Responsible Officer regulations have come into force and revalidation has begun. Revalidation is the process by which licensed doctors are required to demonstrate on a regular basis that they are up to date and fit to practise. It represents a major step forward in the quality assurance of practising doctors.

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Recommendation 166

The General Medical Council should in consultation with patient interest groups and the public immediately review its procedures for assuring compliance with its approved practice settings criteria with a view in particular to provision for active exchange of relevant information with the healthcare systems regulator, coordination of monitoring processes with others required for medical education and training, and receipt of relevant information from registered practitioners of their current experience in approved practice settings approved establishments.

Accepted in principle.

The General Medical Council has undertaken a fundamental review of Approved Practice Settings. This review considered Approved Practice Settings in the context of the General Medical Council's functions and how they promote assurance and patient safety. Since Approved Practice Settings was introduced in 2007, the General Medical Council has acquired significant powers relating to quality assuring medical training environments the Responsible Officer regulations have come into force and revalidation has begun. Revalidation is the process by which licensed doctors are required to demonstrate on a regular basis that they are up to date and fit to practise. It represents a major step forward in the quality assurance of practising doctors.

The General Medical Council review has found that these new powers have superseded Approved Practice Settings as a source of regulatory assurance and has recommended that the legal provisions that deal with Approved Practice Settings should be reviewed as part of the Law Commission review of the regulation of health and social care professionals. This will however take time, and in the meantime there is an opportunity to align the Approved Practice Settings requirements with those in the Responsible Officer Regulations. In effect, this would mean that newly registered doctors or doctors recently restored to the register must, while in the UK, practise in circumstances where they have a connection to a designated body, which is an organisation that will provide regular appraisal and help with revalidation.

The General Medical Council has emphasised its commitment to working with other regulators as effectively as possible in the interests of patients.

Recommendation 167

The Department of Health and General Medical Council should review the powers available to the General Medical Council in support of assessment and monitoring of approved practice settings establishments with a view to ensuring that the General Medical Council (or if considered more appropriate, the healthcare systems regulator), has the power to inspect establishments, either itself or by an appointed entity on its behalf, and to require the production of relevant information.

Accepted in principle.

The General Medical Council has undertaken a fundamental review of Approved Practice Settings. This review considered Approved Practice Settings in the context of the General Medical Council's functions and how they promote assurance and patient safety. Since Approved Practice Settings was introduced in 2007, the General Medical Council has acquired significant powers relating to quality assuring medical training environments the Responsible Officer regulations have come into force and revalidation has begun. Revalidation is the process by which licensed doctors are required to demonstrate on a regular basis that they are up to date and fit to practise. It represents a major step forward in the quality assurance of practising doctors.

The General Medical Council review has found that these new powers have superseded Approved Practice Settings as a source of regulatory assurance and has recommended that the legal provisions that deal with Approved Practice Settings should be reviewed as part of the Law Commission review of the regulation of health and social care professionals. This will however take time, and in the meantime there is an opportunity to align the Approved Practice Settings requirements with those in the Responsible Officer Regulations. In effect, this would mean that newly registered doctors or doctors recently restored to the register must, while in the UK, practise in circumstances where they have a connection to a designated body, which is an organisation that will provide regular appraisal and help with revalidation.

Recommendation 168

The Department of Health and the General Medical Council should consider making the necessary statutory (and regulatory changes) to incorporate the approved practice settings scheme into the regulatory framework for post graduate training.

Accepted in principle.

The General Medical Council has undertaken a fundamental review of Approved Practice Settings. This review considered Approved Practice Settings in the context of the General Medical Council's functions and how they promote assurance and patient safety. Since Approved Practice Settings was introduced in 2007, the General Medical Council has acquired significant powers relating to quality assuring medical training environments the Responsible Officer regulations have come into force and revalidation has begun. Revalidation is the process by which licensed doctors are required to demonstrate on a regular basis that they are up to date and fit to practise. It represents a major step forward in the quality assurance of practising doctors.

The General Medical Council review has found that these new powers have superseded Approved Practice Settings as a source of regulatory assurance and has recommended that the legal provisions that deal with Approved Practice Settings should be reviewed as part of the Law Commission review of the regulation of health and social care professionals. This will however take time, and in the meantime there is an opportunity to align the Approved Practice Settings requirements with those in the Responsible Officer Regulations. In effect, this would mean that newly registered doctors or doctors recently restored to the register must, while in the UK, practise in circumstances where they have a connection to a designated body, which is an organisation that will provide regular appraisal and help with revalidation.

ROLE OF THE DEPARTMENT OF HEALTH AND THE NATIONAL QUALITY BOARD

Recommendation 169

The Department of Health, through the National Quality Board, should ensure that procedures are put in place for facilitating the identification of patient safety issues by training regulators and cooperation between them and healthcare systems regulators.

Accepted in principle.

The National Quality Board brings together a number of key national partners, including the Care Quality Commission, the Nursing and Midwifery Council and the General Medical Council to champion quality and ensure alignment in quality throughout the NHS.

The General Medical Council and the Nursing and Midwifery Council both participate in regional quality surveillance groups. These groups bring together commissioners, regulators, local Healthwatch representatives and other bodies on a regular basis to share information and intelligence about quality across the system, including the views of patients and the public.

The General Medical Council has made it clear that it recognises the need to contribute to the identification and in some cases the investigation of generic concerns, building on its progress in recent years to become a more proactive and collaborative regulator. This includes signposting complainants to the appropriate regulator if their concerns are not for the General Medical Council; making referrals to systems or other professional regulators; investigating concerns arising from the media (including those which do not specifically name a doctor)

and sharing information with and participating in regional quality surveillance groups and risk summits.

The Nursing and Midwifery Council have made it clear that they are determined to work closely with other regulators, including the Care Quality Commission to share information and analyses, and that it should not have to wait until a disaster has occurred to intervene with its fitness to practise procedures.

In addition, as set out in the responses to recommendations 164 and 165, the General Medical Council has undertaken a fundamental review of Approved Practice Settings and the final recommendation is that the provisions of section of the Medical Act 1983, which deals with Approved Practice Settings, should be repealed through the next available legislative vehicle. In the meantime, the General Medical Council will place the scheme on a firmer footing through alignment with the existing statutory duties for healthcare organisations, namely the Responsible Officer Regulations. This would, in effect, prevent doctors newly registered or recently restored to the register from practising in circumstances where they do not have a prescribed connection to a designated body (a prescribed connection means making sure every licensed doctor is supported with revalidation and that they are always working in an environment that monitors and improves the quality of its services). The General Medical Council will also build on its relationships with systems regulators in each of the four countries – they have an important role in ensuring that organisations comply with the duties for designated bodies set out in the Responsible Officer regulations.

HEALTH EDUCATION ENGLAND

Recommendation 170

Health Education England should have a medically qualified director of medical education and a lay patient representative on its board.

Accepted.

Health Education England employs a medically qualified Director of Education and Quality who is responsible for all professional education and training. Professor Chris Welsh currently occupies this post and is supported by a Director of Nursing and a Director of Medical Education. He took up this post in April 2013. Health Education England also has a clinically qualified Director of Nursing and Medical Director.

Mary Elford has been appointed as a Non-Executive Director for the board of Health Education England and will have a specific focus on the interests of patients and service users. She began in this role on 1 September 2013. Mary will chair Health Education England's new national patient forum, to incorporate the views of patients into the education and training programme.

DEANS

Recommendation 171

All Local Education and Training Boards should have a post of medically qualified postgraduate dean responsible for all aspects of postgraduate medical education.

Accepted.

All Local Education and Training Boards do have a qualified postgraduate dean responsible for postgraduate medical education and training.

However, a multi-professional approach to education and training is important. Although Local Education and Training Boards have a dean looking after the specifics of postgraduate medical education, they are part of a multi-professional team under the leadership of a Director of Education and Quality who is responsible for all education and training.

PROFICIENCY IN THE ENGLISH LANGUAGE

Recommendation 172

The Government should consider urgently the introduction of a common requirement of proficiency in communication in the English language with patients and other persons providing healthcare to the standard required for a registered medical practitioner to assume professional responsibility for medical treatment of an English-speaking patient.

Accepted.

The Department of Health has been working with the General Medical Council to ensure that all doctors working in the UK have the necessary knowledge of English to treat patients safely.

Overseas doctors (non-EU) are currently required to demonstrate that they have the necessary language skills before they are registered with the General Medical Council. The Government wishes to ensure that all doctors (including EU nationals) working in the UK has the necessary knowledge of English to treat patients in a safe and competent manner and the Department of Health has been working with the General Medical Council to achieve this policy.

The Department of Health launched its consultation paper *Language Controls for Doctors: Proposed Changes to the Medical Act 1983* on 7 September, seeking amendments to the *Medical Act 1983*. The proposals will give the General Medical Council the power to require evidence of English language capability as part of the licensing process where concerns about language have been identified during the registration process; and create a new category of impairment relating to the necessary knowledge of English, strengthening the General Medical Council's ability to take fitness to practise action where concerns about language competence are identified.

Also, the new *National Health Service (Performers List) (England)* Regulations have been streamlined and will allow NHS England to nationally refuse to include a GP on its list where

it is not satisfied that they have sufficient knowledge of the English language necessary to perform their work.

The initial focus has been on arrangements for doctors however, we are committed to ensuring all healthcare professionals coming to work in the UK can speak English well enough to communicate with patients. The revision of the Mutual Recognition of Professional Qualifications (MRPQ) Directive, which impacts on registrations from within the European Economic Area, clarifies that healthcare regulators, can undertake proportionate language controls on professionals following registration.

Openness, transparency and candour

The Inquiry identified the principles of openness, transparency and candour as the 'cornerstone of healthcare' and that 'every healthcare organisation and everyone working for them must be honest, open and truthful in all their dealings with patients and the public, and organisational and personal interests must never be allowed to outweigh the duty to be honest, open and truthful.' The Inquiry pointed to the lack of uniformity by which these principles are upheld by organisations and healthcare professionals. There are measures that will give people more confidence in the information they receive from the NHS and will make the NHS more open, honest and accountable.

The Government has introduced a new statutory duty of candour on providers that will ensure patients are given the truth when things go wrong, and that honesty and transparency are the norm in every organisation. The new duty will be overseen by the Care Quality Commission and come into force during 2014. *The NHS Constitution* emphasises the importance of honesty and openness and was updated in March 2013 to reflect the contractual duty of candour. The General Medical Council and the Nursing and Midwifery Council will be working with the other regulators to agree consistent approaches to candour and reporting of errors, including a common responsibility across doctors and nurses and other health professions to be candid with patients when mistakes occur whether serious or not. Subject to the passage of the Care Bill, a new criminal offence will be introduced to penalise providers giving false or misleading information.

In April, the Enterprise and Regulatory Reform Act 2013 strengthened the position of whistleblowers so that an individual now has the right to expect their employer to take reasonable steps to prevent them suffering detriment from a co-worker as a result of blowing the whistle. The Government now requires the inclusion of an explicit clause in compromise agreement to make it clear that staff can make a protected disclosure in the public interest, and the Care Quality Commission is using staff surveys and the whistleblowing concerns it receives as part of the data in its new intelligent monitoring system. Since September the Care Quality Commission's new inspection system includes discussions with hospitals about how they deal with, and handle, whistleblowers.

PRINCIPLES OF OPENNESS, TRANSPARENCY AND CANDOUR

Recommendation 173

Every healthcare organisation and everyone working for them must be honest, open and truthful in all their dealings with patients and the public, and organisational and

personal interests must never be allowed to outweigh the duty to be honest, open and truthful.

Accepted.

Promoting honesty, openness and transparency, and instilling a culture that values compassion, dignity and the highest quality of care is one of the key responsibilities of the Department of Health as part of its role in championing improvement and innovation in health. In *Patients First and Foremost*, the Government's initial response to the Inquiry, leaders of health and social care organisations signed up to a Statement of Common Purpose that included reaffirming their commitment to putting patients first before the interest of their organisations and to uphold the value that patients are best served where there is a culture of candour, openness, honesty and acceptance of challenge. In *A new start – Consultation on changes to the way Care Quality Commission regulates, inspects and monitors care*, the Care Quality Commission proposed a framework for inspection which includes a judgement of organisations based on their ability to promote an open, fair and transparent culture. Openness and honesty is already a requirement in healthcare professionals' codes of practice and the principles and the NHS Constitution already emphasises the importance of honesty and openness. The Education Outcomes Framework and in turn, the Mandate for Health Education England also identifies recruitment, education, training and development that are consistent with the values and behaviours identified in the NHS Constitution as a key deliverable.

CANDOUR ABOUT HARM

Recommendation 174

Where death or serious harm has been or may have been caused to a patient by an act or omission of the organisation or its staff, the patient (or any lawfully entitled personal representative or other authorised person) should be informed of the incident, given full disclosure of the surrounding circumstances and be offered an appropriate level of support, whether or not the patient or representative has asked for this information.

Accepted.

The Secretary of State for Health legally required NHS England to insert a contractual duty of candour into the NHS Standard Contract in 2013–14. This means that NHS Trusts and Foundation Trusts are contractually required to operate a duty of candour. The contract also refers organisations to the *Being Open* framework that was first produced by the National Patient Safety Agency. This provides guidance on best practice for all healthcare organisations to create an environment where patients, their carers, healthcare professionals and managers all feel supported when things go wrong and have the confidence to act appropriately. The framework gives healthcare organisations guidance on how to develop and embed a being open policy that fits local organisational circumstances. Another key element of the framework is the process on how to communicate with patients, their families and carers following harm.

The Government has also introduced in the Care Bill a new requirement for a statutory duty of candour and will be included as a new registration requirement for health and social care

providers registered with the Care Quality Commission. The duty will require providers to be open with patients and service users about failings in care provide an explanation, and where appropriate an apology. As a mark of the Government's commitment to the duty of candour, the Care Bill puts a requirement on the Secretary of State for Health to establish a requirement for registered with the Care Quality Commission to meet a duty of candour

Recommendation 175

Full and truthful answers must be given to any question reasonably asked about his or her past or intended treatment by a patient (or, if deceased, to any lawfully entitled personal representative).

Accepted.

All regulated professionals through the principles that underpin their standards and codes of conduct are required to be open and transparent with patients in respect of discussions about treatment and care. As set out in recommendation 181, the General Medical Council and the Nursing and Midwifery Council will be working with the other regulators to agree consistent approaches to candour and reporting of errors, including a common responsibility across doctors, nurses and other health professions to be candid with patients when mistakes occur whether serious or not. The Department of Health will also ask the Professional Standards Authority to advise and report on progress with this work. The professional regulators will also review their guidance to panels taking decisions on professional misconduct to ensure they take proper account of whether or not professionals have raised concerns promptly.

OPENNESS WITH REGULATORS

Recommendation 176

Any statement made to a regulator or a commissioner in the course of its statutory duties must be completely truthful and not misleading by omission.

Accepted.

The Government's response to the Inquiry, *Patients First and Foremost* reaffirmed a commitment to the values of openness, honesty and acceptance of challenge and when things go wrong to learn from and not conceal mistakes. There is a clear expectation that every health and care provider should abide by these values. There is a similar expectation of truthfulness between commissioners and providers – service condition 4.1 of the NHS Standard Contract is explicit that 'Parties must at all times act in good faith towards each other' and between providers and regulators. Also, the Care Quality Commission will assess whether providers have an open and transparent culture, backed up by effective leadership, governance and clinical involvement as part of its new approach to inspection and regulation. As set out in recommendation 182, the Government is putting in place additional measures to ensure that certain key information is truthful and not misleading. There is an existing requirement of Monitor's licence that information provided is accurate, complete and not misleading and an expectation that licence-holders notify Monitor in the event of any incident, event or report that may raise concerns over compliance with their licence. The Care Bill contains provisions to introduce a new criminal offence applicable to care providers that

supply or publish certain types of false or misleading information, where that information is required to comply with a statutory or other legal obligation.

OPENNESS IN PUBLIC STATEMENTS

Recommendation 177

Any public statement made by a healthcare organisation about its performance must be truthful and not misleading by omission.

Accepted.

Accountability is a key leadership role and effectively means organisations operate effectively and with openness, transparency and candour at all times.

The NHS Leadership Academy's guide, *The Healthy NHS Board 2013 – Principles for Good Governance* describes the principles of high quality governance that all care providers should be implementing. The board of a healthcare organisation itself will be held to account by a wide range of stakeholders, for the overall effectiveness and performance of the organisation that it oversees, and the extent to which the board and the organisation operates with openness, transparency and candour. One key part of accountability is the need for the board to ensure that published figures on all aspects of the quality of care are accurate and provide an honest and fair account to commissioners, regulators, patients and the public.

As set out in recommendation 182, the Government is putting in place additional measures to ensure that certain key information is truthful and not misleading. The Care Bill contains provisions to introduce a new criminal offence applicable to care providers that supply or publish certain types of false or misleading information, where that information is required to comply with a statutory or other legal obligation.

IMPLEMENTATION OF THE DUTY: ENSURING CONSISTENCY OF OBLIGATIONS UNDER THE DUTY OF OPENNESS, TRANSPARENCY AND CANDOUR

Recommendation 178

The NHS Constitution should be revised to reflect the changes recommended with regard to a duty of openness, transparency and candour, and all organisations should review their contracts of employment, policies and guidance to ensure that, where relevant, they expressly include and are consistent with above principles and these recommendations.

Accepted in principle.

We agree that staff should be honest and open with patients, and *The NHS Constitution* already emphasises the importance of honesty and openness in its values and sections outlining staff responsibilities, rights and pledges. In addition, wording was included in the March 2013 update of *The NHS Constitution* to reflect the contractual duty of candour.

We note that the Inquiry has made a number of recommendations which relate to openness and transparency in policies and guidance of providers and other healthcare organisations, along with the reporting processes of these organisations and how they interact with regulators. While we generally agree with the importance of these recommendations, *The NHS Constitution* focuses specifically on setting out the values of the NHS along with the rights and pledges to patients and staff, and their responsibilities. As it is not intended to address organisational reporting processes and interactions with regulatory bodies, it is not considered appropriate to reflect these issues in *The NHS Constitution*.

If, as is currently planned, a new legal duty of candour is created, we will consult on how best to reflect this in *The NHS Constitution* when it is next updated.

We do not think that including a duty of openness, transparency and candour into contracts of employment is relevant, not least because of the difficulty in defining these terms for contractual purposes. We think that this recommendation can be best delivered through improved appraisal and, for example, revalidation arrangements being developed by the Nursing and Midwifery Councils (see response to recommendation 193) and other professional regulators. Steps have already been taken to improve staff performance and appraisal systems (as set out in the response to recommendation 7).

NHS Employers will support NHS organisations in strengthening local policies on appraisals so that there is a clear link on the need for candour, openness and transparency in local appraisals and performance arrangements.

IMPLEMENTATION OF THE DUTY: RESTRICTIVE CONTRACTUAL CLAUSES

Recommendation 179

‘Gagging clauses’ or non disparagement clauses should be prohibited in the policies and contracts of all healthcare organisations, regulators and commissioners; insofar as they seek, or appear, to limit bona fide disclosure in relation to public interest issues of patient safety and care.

Accepted.

We understand the critical importance of fostering and sustaining an open culture in which concerns about care can be raised, investigated and acted upon without fear of retribution. Our policy is clear that any attempts to prevent individuals from speaking out in the public interest will not be tolerated. NHS guidance has been consistently clear that local policies should prohibit the inclusion of confidentiality clauses in contracts of employment and compromise agreements which seek to prevent an individual from making a disclosure in accordance with the Public Interest Disclosure Act (PIDA). We are, however, also aware that some confidentiality clauses that may make some people feel as though they are being ‘gagged’ even though they are not. Such clauses, although not illegal, may have what is known as a ‘chilling effect’ on some people. We now therefore require the inclusion of an explicit clause in the compromise agreement to make it absolutely clear to staff signing an

agreement that they can make a disclosure in the public interest in accordance with PIDA, regardless of what other clauses may be included in the agreement.

IMPLEMENTATION OF THE DUTY: CANDOUR ABOUT INCIDENTS

Recommendation 180

Guidance and policies should be reviewed to ensure that they will lead to compliance with *Being Open*, the guidance published by the National Patient Safety Agency.

Accepted.

As stated in recommendation 174, the intention is introduce an explicit duty of candour on providers as a Care Quality Commission registration requirement. The Department of Health will publish shortly draft regulations on a Statutory Duty of Candour during the autumn for further consultation. The Department of Health will ensure that advice such as the *Being Open* framework produced by the National Patient Safety Agency is considered as we consult on the new duty of candour.

ENFORCEMENT OF THE DUTY: STATUTORY DUTIES OF CANDOUR IN RELATION TO HARM TO PATIENTS

Recommendation 181

A statutory obligation should be imposed to observe a duty of candour:

- **On healthcare providers who believe or suspect that treatment or care provided by it to a patient has caused death or serious injury to a patient to inform that patient or other duly authorised person as soon as is practicable of that fact and thereafter to provide such information and explanation as the patient reasonably may request;**
- **On registered medical practitioners and registered nurses and other registered professionals who believe or suspect that treatment or care provided to a patient by or on behalf of any healthcare provider by which they are employed has caused death or serious injury to the patient to report their belief or suspicion to their employer as soon as is reasonably practicable.**

The provision of information in compliance with this requirement should not of itself be evidence or an admission of any civil or criminal liability, but non-compliance with the statutory duty should entitle the patient to a remedy.

Accepted in principle.

As set out in recommendation 174, the Government will introduce an explicit duty of candour as a Care Quality Commission registration requirement. The duty would apply to health and adult social care providers of regulated activities. This duty will be enforced using the Care Quality Commission powers. The Care Quality Commission consulted on the potential introduction of a Duty of Candour in its document *A new start – Consultation on changes to the way Care Quality Commission regulates, inspects and monitors care*. Its consultation

response, published in October 2013, showed respondents were strongly in favour of a statutory duty. As a mark of the Government's commitment to the duty of candour, the Care Bill puts a requirement on the Secretary of State to include a duty of candour in the requirements for registration with the Care Quality Commission. The Department of Health will consult on the regulations setting this duty which would require providers to inform people of the incident, provide an explanation, and where appropriate an apology. The Department will seek advice from experts on how to improve the reporting of patient safety incidents, including whether or not the threshold for the statutory duty of candour should include moderate harm. The final details will be set out in new regulations, which provide the flexibility to amend or vary the regulations over time as the new duty is established.

As a further incentive for Trusts to promote a culture of openness across their organisation, the Government will consult on proposals about whether Trusts should reimburse a proportion or all of the NHS Litigation Authority's compensation costs when they have not been open about a safety incident. Where the NHS Litigation Authority finds that a Trust has not been open with patients or their families about a patient safety incident which turns into a claim, it could have the discretion to reduce or remove that Trust's indemnity cover for that claim. The NHS Litigation Authority will continue to make compensation payments due to patients. Trusts who were not open with their patients could be required to reimburse the NHS Litigation Authority for a proportion or all of the payment.

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

ENFORCEMENT OF THE DUTY: STATUTORY DUTY OF OPENNESS AND TRANSPARENCY

Recommendation 182

There should be a statutory duty on all directors of healthcare organisations to be truthful in any information given to a healthcare regulator or commissioner, either personally or on behalf of the organisation, where given in compliance with a statutory obligation on the organisation to provide it.

Accepted.

Subject to the passage of the Care Bill, a new criminal offence will be introduced applicable to care providers that supply or publish certain types of information which is false or misleading, where that information is required to comply with a statutory or other legal obligation. The offence will allow for the prosecution of directors and senior individuals, where the offence has been committed with their consent or connivance or through their neglect, and a successful prosecution has been brought against the provider.

This offence will give providers an additional incentive to ensure data and the information it provides are accurate. The offence will aid transparency and accountability in the provision of care so that regulators, commissioners and the public have a more accurate picture about a provider's performance. The offence will apply to those care providers that falsify certain types of management and performance information and fail to exercise due diligence. Providers that make a genuine administrative error would not be convicted, providing they have processes and procedures in place to demonstrate they took all reasonable steps and exercised due diligence.

Our current intention is that regulations will limit the application of this offence in the first instance to providers of NHS funded secondary care and, more specifically, to the patient level information on outpatient, elective and accident and emergency activity that they are required to provide to the Health and Social Care Information Centre. However, we intend to test and confirm our thinking through further consultation before draft regulations are laid.

ENFORCEMENT OF THE DUTY: CRIMINAL LIABILITY

Recommendation 183

It should be made a criminal offence for any registered medical practitioner, or nurse, or allied health professional or director of an authorised or registered healthcare organisation:

- **knowingly to obstruct another in the performance of these statutory duties;**
- **to provide information to a patient or nearest relative intending to mislead them about such an incident;**
- **dishonestly to make an untruthful statement to a commissioner or regulator knowing or believing that they are likely to rely on the statement in the performance of their duties.**

Not accepted, however we agree with the intention behind this recommendation.

The duty of candour is a further drive towards openness and transparency. We have set out in the Care Bill that in future, as a registration requirement with the Care Quality Commission, providers must be open with patients about care failings. We are working with the General Medical Council, Nursing and Midwifery Council and other professional regulators to strengthen the references to candour in their work – including clear guidance that professionals who seek to obstruct others in raising concerns or being candid would be in breach of their professional responsibilities. Recommendation 181 outlines the approach, and along with the new duty itself should drive an open culture throughout organisations, including

its staff. We do not believe an individual obstruction offence is necessary at this time, but will carefully watch the impact of this approach as the new duty evolves.

In addition, in April, the Enterprise and Regulatory Reform Act 2013 strengthened the position of whistleblowers so that an individual now has the right to expect their employer to take reasonable steps to prevent them suffering detriment from a co-worker as a result of blowing the whistle.

As the regulator of health and care, the Care Quality Commission is using staff surveys and the whistleblowing concerns it receives as part of the data in its new intelligent monitoring system. This data will guide the Care Quality Commission about which hospitals to inspect. Since September the Care Quality Commission's new inspection system includes discussions with hospitals about how they deal with, and handle, whistleblowers.

The Government does not intend to criminalise untruthful statements to commissioners and regulators made by healthcare professionals. However, the Government has already introduced the false or misleading information offence into the Care Bill [see recommendation 182], which will allow for the prosecution of directors and senior individuals, where the offence has been committed with their consent or connivance or through their neglect, and a successful prosecution has been brought against the provider. This will include a fine and/or custodial sentence of up to two years for directors/senior individuals.

There is an equivalent provision regarding consent or connivance, in relation to directors and senior individuals, in the Care Quality Commission legislation (Health and Social Care Act 2008) which applies to all registration requirements, including the duty of candour when it is introduced. In addition, professional regulators will be working to agree consistent approaches to candour and reporting of errors, including a common responsibility across the professions to be candid as set out in recommendation 181.

ENFORCEMENT BY THE CARE QUALITY COMMISSION

Recommendation 184

Observance of the duty should be policed by the Care Quality Commission, which should have powers to prosecute in the last resort in cases of serial non-compliance or serious and wilful deception. The Care Quality Commission should be supported by monitoring undertaken by commissioners and others.

Accepted.

This is accepted in respect of the statutory duty of candour. This new duty will be a requirement for registration with the Care Quality Commission. In line with other registration requirements, Care Quality Commission will monitor compliance with the duty of candour and has a range of enforcement powers it can use where providers fail to meet the registration requirement.

Nursing

These recommendations recognise the central importance of nurses and healthcare support workers to the delivery of safe, compassionate care. Many of the themes apply equally to other professions. The responses to the recommendations demonstrate the health and care system's commitment to ensuring that nurses and healthcare support workers are recruited with the right values, and that these values are embedded in initial and continuing education and training, and appraisal.

The introduction of nurse revalidation will enhance public protection by ensuring that nurses and midwives continue to meet the Nursing and Midwifery Council's standards and Codes of Practice.

Nurse leadership is critical to delivering safe, compassionate care for patients, and we are strengthening this through a number of measures such as improving leadership training.

The Cavendish Review recognised the importance of the group of healthcare assistants and social care support workers as a workforce but also identified problems with consistency and quality of training and support they need to do their jobs. This is why we have broadly accepted the findings of the review and are committed to driving forward implementation to ensure they have the fundamental training which ensures they have the skills and the behaviours needed to deliver compassionate care across health and social care.

FOCUS ON CULTURE OF CARING

Recommendation 185

There should be an increased focus in nurse training, education and professional development on the practical requirements of delivering compassionate care in addition to the theory. A system which ensures the delivery of proper standards of nursing requires:

- **Selection of recruits to the profession who evidence the:**
 - **Possession of the appropriate values, attitudes and behaviours;**
 - **Ability and motivation to enable them to put the welfare of others above their own interest;**
 - **Drive to maintain, develop and improve their own standards and abilities;**
 - **Intellectual achievements to enable them to acquire through training the necessary technical skills:**

- **Training and experience in delivery of compassionate care;**
- **Leadership which constantly reinforces values and standards of compassionate care;**
- **Involvement in, and responsibility for, the planning and delivery of compassionate care;**
- **Constant support and incentivisation which values nurses and the work they do through:**
 - **Recognition of achievement;**
 - **Regular, comprehensive feedback on performance and concerns;**
 - **Encouraging them to report concerns and to give priority to patient well-being.**

Accepted.

Building on the actions set out in the Government's initial response to the Inquiry, *Patients First and Foremost*, and *Compassion in Practice*, the nursing vision and strategy for England, various actions are underway to address this recommendation.

The Nursing and Midwifery Council has introduced new education standards. These require students to be tested for aptitude in literacy, numeracy and communication skills, and assessed as to health and good character on admission to programmes. Students must also pass all assessments at every progression point before they complete their programmes and be assessed for good health and good character as to their fitness for award and fitness to practice. Education programmes are half theory, half practice, and education and training takes place as a partnership between a university and practice environment. Students must meet all theory and all practice requirements to complete a programme, and there is no facility to compensate for poor performance in one area with strong performance in the other. The first nurses to have followed programmes approved against these new standards will commence practice in 2014.

The NHS Leadership Academy's new leadership development programmes – underpinned by a revised leadership model – will focus on values, attitudes and behaviours and will see a range of NHS staff including doctors, allied health professionals, nurses, midwives, pharmacists and healthcare scientists learning in a multi-professional environment more conducive to prompting compassionate care. From preceptorship programmes through to programmes for those working at the most senior levels these high quality, accredited programmes put in place the training and development needed to address the challenges presented in this recommendation. Additionally successful completion of the programme and award will help in the recruitment and selection of suitably qualified nurses into more senior roles. NHS England is also working with Health Education England to embed the '6Cs' set out in *Compassion in Practice* in all nursing and midwifery university education and training. The Government will invest up to £40 million in nurse leadership at all stages of the nursing career.

The Government's Mandate to Health Education England contained a requirement to ensure that selection into all new NHS funded training posts incorporates testing of values. NHS England is working with Health Education England and NHS Employers to support the introduction of value-based recruitment and appraisal for all registered or unregistered staff.

We believe that placing a strong emphasis on values at the outset of training potential staff is vital to embed the principles of compassion and caring from the very beginning in those who will one day provide care to patients. It is essential that the staff of tomorrow are able to demonstrate not only academic and technical ability, but also that they have the values of kindness and compassion that are needed to care for patients in an emotionally demanding environment.

One of the most important things for securing compassionate care is making sure that the right staff, with the right capabilities, are recruited into posts involving direct care at the outset.

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

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

In September 2013, Health Education England established the first set of pilots, and approximately 150 aspiring student nurses began working as healthcare assistants. Health Education England is looking to introduce further pilots in Spring 2014. On completion the pilot will be evaluated to see how pre-degree care experience could be rolled out in an affordable and cost-neutral way, so that everybody who wants to train to be a nurse is able to get caring experience before they start their studies. The evaluation results of the pilot scheme will need to be considered in the context of the Nursing and Midwifery Council's 2010 pre-registration nursing standards and their application across the four countries of the United Kingdom.

We believe that students will enter their nursing degree course with increased confidence that this is the career for them, along with a genuine and demonstrated aptitude for caring. In addition, all nursing degree programmes last at least three years and require that 50 per cent of time is spent in practice learning and 50 per cent in academic study. The first progression point cannot be passed unless the student undertakes a period of practice learning and assessment, and so nursing students will continue to gain experience in care environments throughout their studies.

Alongside this, work is on-going to make a career in nursing more accessible for those staff who already give care, as set out in the Mandate to Health Education England.

PRACTICAL HANDS-ON TRAINING AND EXPERIENCE

Recommendation 186

Nursing training should be reviewed so that sufficient practical elements are incorporated to ensure that a consistent standard is achieved by all trainees throughout the country. This requires national standards.

Accepted.

The Nursing and Midwifery Council has already taken steps to address this.

The Nursing and Midwifery Council published new standards for all pre-registration nursing programmes in 2010 which must be followed at all the universities they approve to run nursing courses. The previous 2004 standards were updated and strengthened as a result of the findings of the first Francis Inquiry and emerging evidence at that time. The first nurses to have followed programmes approved against the new standards will commence practice in 2014.

These national pre-registration nursing standards include the content and practice/study time ratios required by European Directive. All the nursing programmes last at least three years and require 50 per cent of time to be spent in practice learning and 50 per cent in academic study. The first progression point cannot be passed unless the student undertakes a period of practice learning and assessment. Currently formal learning and supervised work as a healthcare support worker can be counted through accredited prior learning routes.

The Nursing and Midwifery Council will be undertaking a full evaluation of these new education standards, commencing in 2014, and will have particular regard to these issues of caring and compassion. This will give a proper evidence base for any further revisions to these new standards, and the Nursing and Midwifery Council will consider this recommendation in parallel with their evaluation.

Although the overarching national standards are in place, the detail of the nursing curriculum is dynamic. Employers, service providers and universities are now brought together in Local Education and Training Boards, as part of the Health Education England system, to ensure all NHS funded courses are fit for purpose and reflect service needs. We expect this new part of the system to recognise the importance of *Compassion in Practice*, the vision and strategy for nursing in England and the values and behaviours it describes in the '6Cs' to be part of the local review of courses and incorporated into the detailed undergraduate nursing curriculum.

Health Education England and the Nursing and Midwifery Council will continue to collaborate on ensuring the undergraduate nursing curriculum meets patient need.

Recommendation 187

There should be a national entry-level requirement that student nurses spend a minimum period of time, at least three months, working on the direct care of patients under the supervision of a registered nurse. Such experience should include direct care of patients, ideally including the elderly, and involve hands-on physical care. Satisfactory completion of this direct care experience should be a pre-condition to continuation in nurse training. Supervised work of this type as a healthcare support worker should be allowed to count as an equivalent. An alternative would be to require candidates for qualification for registration to undertake a minimum period of work in an approved healthcare support worker post involving the delivery of such care.

Accepted.

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

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

In September 2013, Health Education England established the first set of pilots, and approximately 150 aspiring student nurses began working as healthcare assistants. Health Education England is looking to introduce further pilots in Spring 2014. On completion the pilot will be evaluated to see how pre-degree care experience could be rolled out in an affordable and cost-neutral way, so that everybody who wants to train to be a nurse is able to get caring experience before they start their studies. The evaluation results of the pilot scheme will need to be considered in the context of the Nursing and Midwifery Council's 2010 pre-registration nursing standards and their application across the four countries of the United Kingdom.

We believe that students will enter their nursing degree course with increased confidence that this is the career for them, along with a genuine and demonstrated aptitude for caring. In addition, all nursing degree programmes last at least three years and require that 50 per cent of time is spent in practice learning and 50 per cent in academic study. The first progression point cannot be passed unless the student undertakes a period of practice learning and assessment, and so nursing students will continue to gain experience in care environments throughout their studies.

Alongside this, work is on-going to make a career in nursing more accessible for those staff who already give care, as set out in the Government's Mandate to Health Education England.

APTITUDE TEST FOR COMPASSION AND CARING

Recommendation 188

The Nursing and Midwifery Council working with universities, should consider the introduction of an aptitude test to be undertaken by aspirant registered nurses at entry into the profession, exploring, in particular, candidates' attitudes towards caring, compassion and other necessary professional values.

Accepted in principle.

The Government's Mandate to Health Education England contained a requirement to ensure that selection into all new NHS funded training posts incorporates testing of values. In addition, NHS England is working with Health Education England and NHS Employers to support the introduction of values-based recruitment and appraisal for all registered and unregistered staff.

We believe that placing a strong emphasis on values at the outset of training potential staff is vital to embed the principles of compassion and caring from the very beginning in those who will one day provide care to patients. It is essential that the staff of tomorrow are able to demonstrate not only academic and technical ability, but also that they have the values of kindness and compassion that are needed to care for patients in an emotionally demanding environment.

The Nursing and Midwifery Council introduced new education standards in 2010. These require students to be tested for aptitude in literacy, numeracy and communication skills and

assessed as to health and good character on admission to programmes. Students must also pass all assessments at every progression point before they complete their programmes and be assessed for good health and good character as to their fitness for award and fitness to practice. Education programmes are half theory, half practice, and education and training takes place as a partnership between a university and practice environment. Students must meet all theory and all practice requirements to complete a programme, and there is no facility to compensate for poor performance in one area with strong performance in the other.

The Nursing and Midwifery Council's standards for competence reinforce this, identifying the knowledge, skills and attitudes students must acquire by the end of their programme. For example, students must 'practise in a holistic, non-judgmental, caring and sensitive manner that avoids assumptions, supports social inclusion, recognises and respects individual choice and acknowledges diversity'.

The Nursing and Midwifery Council has committed to undertaking a full evaluation of its new education standards, commencing in 2014, and will have particular regard to issues of caring and compassion. This will give the Nursing and Midwifery Council an evidence base for any further revisions to these new standards, including the need for an aptitude test.

CONSISTENT TRAINING

Recommendation 189

The Nursing and Midwifery Council and other professional and academic bodies should work towards a common qualification assessment/examination.

Accepted in principle.

The Nursing and Midwifery Council is responsible for setting the UK-wide standards for all pre-registration nursing and midwifery education. These standards underpin all pre-registration nursing and midwifery education so that education programmes are comparable, and all nurses and midwives must meet the same standards. The Nursing and Midwifery Council set new standards for pre-registration nursing education in 2010. The standards require students to be tested for aptitude in literacy, numeracy and communication skills, and assessed as to health and good character on admission to programmes. Students must also pass all assessments at every progression point before they complete their programmes, and be assessed for good health and good character as to their fitness for award and fitness to practice. Education programmes are half theory, half practice, and education and training takes place as a partnership between a university and practice environment. Students must meet all theory and all practice requirements to complete a programme, and there is no facility to compensate for poor performance in one area with strong performance in the other.

The Nursing and Midwifery Council has committed to undertaking a full evaluation of its new education standards, commencing in 2014, and will have particular regard to issues of caring and compassion. This will give the Nursing and Midwifery Council an evidence base for any further revisions to these new standards.

NATIONAL STANDARDS

Recommendation 190

There should be national training standards for qualification as a registered nurse to ensure that newly qualified nurses are competent to deliver a consistent standard of the fundamental aspects of compassionate care.

Accepted in part.

The Nursing and Midwifery Council already sets national standards for undergraduate degrees, but Health Education England and NHS England, in collaboration with the Nursing and Midwifery Council and the universities, will work closely together to ensure newly qualified nurses are competent at the point of registration.

This collaboration is vital because the competence of nursing students is assessed not only in the classroom by the universities, but in clinical practice by mentors and assessors who are experienced, practising NHS nurses. NHS England should ensure that *Compassion in Practice*, the vision and strategy for nursing in England, and its behaviours and values expressed as the '6Cs', are used to assess student nurses during their clinical placements. The importance of robust mentoring and assessing of student nurses will be endorsed by NHS England so that only student nurses who are competent pass their assessments and are consequently recommended for registration. The Nursing and Midwifery Council has put a system of 'sign off mentors' in place so that experienced NHS nurses sign off student nurses achievements in clinical practice, and NHS England needs to ensure that mentors are sufficiently supported to make difficult decisions and confidently fail a student if necessary.

Competence at the point of registration needs to be enhanced in the first months of qualification by Health Education England, NHS England and employers giving appropriate support to newly qualified nurses. The established mechanism for this is through preceptorship, but Health Education England and NHS England will need to assure themselves that preceptorship programmes are systematically embedded and properly supported so that newly qualified nurses can grow in competence and confidence and effectively make the transition from being a student to a professional, practising registered nurse.

RECRUITMENT FOR VALUES AND COMMITMENT

Recommendation 191

Healthcare employers recruiting nursing staff, whether qualified or unqualified, should assess candidates' values, attitudes and behaviours towards the well-being of patients and their basic care needs, and care providers should be required to do so by commissioning and regulatory requirements.

Accepted.

The Government's Mandate to Health Education England contained a requirement to ensure that selection into all new NHS-funded training posts incorporates testing of values-based

recruitment. NHS England is working with Health Education England and NHS Employers to support the introduction of values-based recruitment and appraisal for all registered or unregistered staff.

Placing a strong emphasis on values at the outset of training potential staff is vital to embed the principles of compassion and caring from the very beginning in those who will one day provide care to patients. It is essential that the staff of tomorrow are able to demonstrate not only academic and technical ability, but also that they have the values of kindness and compassion that are needed to care for patients in an emotionally demanding environment.

Health Education England and Local Education and Training Boards (who are responsible for the education and training of NHS staff within 13 different regions in England), are working with employers and education providers to be responsible for the development of the future workforce. They also have a role to play to ensure that the current workforce is fit for purpose and able to provide care of the highest quality.

As set out in its Mandate, Health Education England is committed to the introduction of values based recruitment for all students entering NHS-funded clinical education programmes and to also support such processes for recruitment into NHS employment.

The three key objectives of Health Education England's national values-based recruitment programme focus on:

1. recruiting for Values in Higher Education Institutions;
2. recruiting for Values in the NHS; and
3. evaluating the impact of Recruiting for Values.

Over the long term, Health Education England sees values-based recruitment as part of a wider programme to change attitudes and behaviours of NHS staff, enhancing their engagement and continuously improving healthcare for its patients.

In addition, there is an on-going project to develop values-based recruitment tools for social care providers. This project, involving the National Skills Academy for Social Care, brings together a range of directly-targeted, free, easy-to-use tools that employers can use when recruiting staff, to assess candidates for appropriate social care values, as evidenced through their behaviours. These tools can sit alongside other tests around competencies and skills.

The toolkit adapts materials that are already currently available and brings them together in a package, in the first instance to support employers in recruiting the right candidates for a career in care. There is also an option to extend the toolkit to assist potential candidates in deciding whether they are suitable to pursue a career in care.

The toolkit can be found at: <https://www.nsasocialcare.co.uk/values-based-recruitment-toolkit>.

STRONG NURSING VALUES

Recommendation 192

The Department of Health and the Nursing and Midwifery Council should introduce the concept of a Responsible Officer for nursing, appointed by and accountable to, the Nursing and Midwifery Council.

Accepted in principle.

The aim of the recommendation, which is to have a role that is accountable for providing assurance to the Nursing and Midwifery Council that nurses are meeting professional standards and are keeping themselves up-to-date and fit to practise, is best achieved through the introduction of nursing revalidation. Unlike the General Medical Council's model of revalidation, the Nursing and Midwifery Council does not consider that this model of revalidation requires a Responsible Officer role.

The Nursing and Midwifery Council has committed to introducing a proportionate and effective model of revalidation, which is affordable and value for money, to enhance public protection. Subject to public consultation, the proposed model would require evidence that the nurse or midwife is fit to practise. Under the current proposals, the Nursing and Midwifery Council Code and standards would be reviewed and revised to ensure they would be compatible with revalidation, and guidance for revalidation would also be developed.

NHS Employers will lead work on ensuring that there is a clear link between the values in the *NHS Constitution*, the vision and strategy for nursing in England, its values and behaviours as set out in the '6Cs', and the organisation's own local values. Building on this, the Department of Health will commission NHS Employers to help local organisations develop and improve value based appraisal and performance management. This will also support the actions set out in *Compassion in Practice*.

STANDARDS FOR APPRAISAL AND SUPPORT

Recommendation 193

Without introducing a revalidation scheme immediately, the Nursing and Midwifery Council should introduce common minimum standards for appraisal and support with which responsible officers would be obliged to comply. They could be required to report to the Nursing and Midwifery Council on their performance on a regular basis.

Accepted in principle.

In advance of the introduction of revalidation by the Nursing and Midwifery Council, NHS Employers will:

- support NHS organisations in ensuring they have a clear link between the values in the NHS Constitution and their own local values

- support NHS organisations in developing and improving values based appraisal and performance management having taken steps to improve performance appraisals for the 1.1 million staff on Agenda for Change as set out in recommendation 7
- encourage NHS organisations to make the necessary links with the work the Nursing and Midwifery Council is leading on revalidation as they develop new local performance and appraisal arrangements.

The Nursing and Midwifery Council has committed to introducing a proportionate and effective model of revalidation, which is affordable and value for money, to enhance public protection. Subject to public consultation, the proposed model would require evidence that the nurse or midwife is fit to practise. Under the current proposals, the Nursing and Midwifery Council Code and standards would be reviewed and revised to ensure they would be compatible with revalidation, and guidance for revalidation would also be developed.

Recommendation 194

As part of a mandatory annual performance appraisal, each Nurse, regardless of workplace setting, should be required to demonstrate in their annual learning portfolio an up-to-date knowledge of nursing practice and its implementation. Alongside developmental requirements, this should contain documented evidence of recognised training undertaken, including wider relevant learning. It should also demonstrate commitment, compassion and caring for patients, evidence by feedback from patients and families on the care provided by the nurse. This portfolio and each annual appraisal should be made available to the Nursing and Midwifery Council, if requested, as part of a nurse's revalidation process. At the end of each annual assessment, the appraisal and portfolio should be signed by the nurse as being an accurate and true reflection and be countersigned by their appraising manager as being such.

Accepted in principle.

We consider that the aim of the recommendation, which is to have a role that is accountable for providing assurance to the Nursing and Midwifery Council that nurses can show they are keeping themselves up-to-date and fit to practise, is best achieved through the introduction of nursing revalidation.

The Inquiry also recommended that independent of the development of nurse revalidation, the Nursing and Midwifery Council could establish minimum standards for appraisal and support, which could be overseen by Responsible Officers appointed and accountable to the Nursing and Midwifery Council.

The Nursing and Midwifery Council has committed to introducing a proportionate and effective model of revalidation, which is affordable and value for money, to enhance public protection. Subject to public consultation, the proposed model would require evidence that the nurse or midwife is fit to practise. Under the current proposals, the Nursing and Midwifery Council Code and standards would be reviewed and revised to ensure they would be compatible with revalidation, and guidance for revalidation would also be developed.

In addition, before the introduction of revalidation by the Nursing and Midwifery Council, NHS Employers will:

- support NHS organisations in ensuring they have a clear link between the values in the NHS Constitution and their own local values
- support NHS organisations in developing and improving values based appraisal and performance management having taken steps to improve performance appraisals for the 1.1 million staff on Agenda for Change as set out in recommendation 7
- encourage NHS organisations to make the necessary links with the work the Nursing and Midwifery Council is leading on revalidation as they develop new local performance and appraisal arrangements.

High performing staff can improve outcomes for patients. The Government strongly encourages employers to use the full flexibilities in existing pay contracts so that pay progression is linked to quality of care, not time served. NHS Employers will support this by working with the service on new model performance frameworks, which will place greater emphasis on the quality of care, including the important NHS values of compassion, dignity and respect.

NURSE LEADERSHIP

Recommendation 195

Ward nurse managers should operate in a supervisory capacity, and not be office-bound or expected to double up, except in emergencies as part of the nursing provision on the ward. They should know about the care plans relating to every patient on his or her ward. They should make themselves visible to patients and staff alike, and be available to discuss concerns with all, including relatives. Critically, they should work alongside staff as a role model and mentor, developing clinical competencies and leadership skills within the team. As a corollary, they would monitor performance and deliver training and/or feedback as appropriate, including a robust annual appraisal.

Accepted in principle.

There needs to be local flexibility in delivering nursing care, so the Government are not mandating that ward nurse managers must operate solely in a supervisory capacity. However, in the initial Government response to The Inquiry, *Patients First and Foremost*, the Department of Health gave strong support to supervisory roles for Ward Managers (including Sister, Charge Nurse and Team Leader) in delivering oversight to all aspects of care on a ward and in a community, from cleanliness to allocation of staff. Nurse leadership and visibility at ward level provided by a Ward Manager is also important to the delivery of safe, high-quality care to patients.

Having sufficient nurses trained and with the capacity to ensure the delivery of safe, patient focused care is currently a core standard requirement of the Care Quality Commission. Nurse leadership is a core element of *Compassion in Practice*, the vision and strategy for nursing in England.

Key action areas include:

- using feedback to improve the reported experiences of patients;
- identifying strong patient experience measures that can be used between settings and sectors;
- a new leadership programme for ward managers, team leaders and nursing directors based on values and behaviours of the '6Cs' of

Compassion in Practice;

- providers reviewing options for introducing ward managers, team leaders and nursing directors based on values and behaviours of the '6Cs';
- providers reviewing supervisory status for ward managers and team leaders;
- strategies to secure meaningful staff engagement; and
- commissioners to ensure locally agreed targets to deliver high quality appraisals for their staff

Some Directors of Nursing are already achieving this or have plans and timetables in place to deliver it. Having supervisory leaders should be evaluated locally so that benefits can be demonstrated and shared.

The NHS Leadership Academy 'offer' includes leadership programmes for frontline staff – including nurses. We have already taken steps to improve staff performance and appraisal systems as set out in our response to recommendation 7.

Recommendation 196

The Knowledge and Skills Framework should be reviewed with a view to giving explicit recognition to nurses' demonstrations of commitment to patient care and, in particular, to the priority to be accorded to dignity and respect, and their acquisition of leadership skills.

Accepted.

Employers have the freedom to use the Knowledge and Skills Framework to develop their own local arrangements to ensure that dignity, respect and leadership is fully reflected in staff training and development and that capability, learning and development is part of local appraisal systems. This is made clear in the national Agenda for Change agreement which links pay progression more strongly to performance from March 2013, for more than 1.1 million NHS staff. NHS Employers are already working hard to help employers realise the benefits of the new national agreement on performance.

The Department of Health will commission NHS Employers to encourage NHS organisations to strengthen their local knowledge and skills frameworks so that there is a clear line of sight between the *NHS Constitution*, the values and behaviours set out in the '6Cs' of *Compassion in Practice*, the vision and strategy for nursing in England, and local values, performance and appraisal systems.

In addition, the Nursing and Midwifery Council's standards for competence require nurses to demonstrate their potential to develop management and leadership skills during their period

of preceptorship after registration and beyond. This means that the public can trust the newly registered nurse to be an autonomous and confident member of the multi-disciplinary or multi-agency team, and to inspire confidence in others. Nurses can then become more involved and responsible for the planning and delivery of care and improving future services. NHS Employers will encourage NHS organisations to make the necessary links with the work the Nursing and Midwifery Council is leading on revalidation as they develop new local performance and appraisal arrangements.

Recommendation 197

Training and continuing professional development for nurses should include leadership training at every level from student to director. A resource for nurse leadership training should be made available for all NHS healthcare provider organisations that should be required under commissioning arrangements by those buying healthcare services to arrange such training for appropriate staff.

Accepted in part.

Healthcare organisations have a responsibility to ensure that their staff and teams are appropriately trained and continuously developed: having properly trained staff is one of the requirements they have to meet to register with the Care Quality Commission. The NHS Leadership Academy core programmes will provide a structured and robust leadership development education from entry level to executive level. Focused on leadership for compassionate and effective care, the programmes will provide development on the skills, knowledge, behaviours and attitudes needed at every level to create a climate for staff that puts the patient first.

Action areas under *Compassion in Practice*, the vision and strategy for nursing in England, include:

- new leadership programme for ward managers, team leaders and nursing directors based on values and behaviours of the '6Cs' of *Compassion in Practice* (care, compassion, courage, communication, competence, commitment);
- providers to review options for introducing ward managers, team leaders and nursing directors based on values and behaviours of the '6Cs';
- commissioning leadership role (build into Action Area 4 in *Compassion in Practice*); and
- contracts to address the percentage of staff who have accessed leadership development.

Arrangements for training are primarily the responsibility of providers, but when commissioners deem it is necessary, in order to ensure the delivery of services by staff with the right skills, they can set training requirements in their contracts with providers.

The Nursing and Midwifery Council published new standards for all pre-registration nursing programmes in 2010 which must be followed at all the universities they approve to run nursing courses. The previous 2004 standards were updated and strengthened as a result of the findings of the first Francis Inquiry and emerging evidence at that time. The first nurses to have followed programmes approved against these new standards will commence practice in 2014.

The Nursing and Midwifery Council will be undertaking a full evaluation of these new education standards, commencing in 2014, and will have particular regard to the issues of caring and compassion. This will give a proper evidence base for any further revisions to these new standards, and the Nursing and Midwifery Council will consider this recommendation in parallel with their evaluation.

Although the overarching national standards are in place, the detail of the nursing curriculum is dynamic. Employers, service providers and universities are now brought together in Local Education and Training Boards, as part of the Health Education England system, to ensure all NHS funded courses are fit for purpose and reflect service needs. We expect this new part of the system to recognise the importance of *Compassion in Practice* and the values and behaviours it describes in the '6Cs', to be part of the local review of courses and incorporated into the detailed undergraduate nursing curriculum. The Department of Health will commission NHS Employers to encourage NHS organisations to strengthen their local knowledge and skills frameworks so that there is a clear line of sight between the NHS Constitution, the values and behaviours set out in the 6Cs of Compassion in Practice, the vision and strategy for nursing in England, and local values, performance and appraisal systems.

Health Education England and the Nursing and Midwifery Council will continue to collaborate on ensuring the undergraduate nursing curriculum meets patient need.

MEASURING CULTURAL HEALTH

Recommendation 198

Healthcare providers should be encouraged by incentives to develop and deploy reliable and transparent measures of the cultural health of front-line nursing workplaces and teams, which build on the experience and feedback of nursing staff using a robust methodology, such as the 'cultural barometer'.

Accepted.

Both teams and organisations should develop ways to measure their cultural health, and act on these measures to improve. Cultural health is a matter for all staff groups; everybody who works in the health and care system is integral to improving and maintaining good cultural health. Many tools and methods are available and the Department of Health and other arm's length bodies are promoting these. For example, the Cultural Barometer, which was highlighted as a case study in the Government's initial response to The Inquiry, *Patients First and Foremost*,⁷⁹ is being developed and piloted. The National Nursing Research Unit at Kings College London are evaluating the pilot and are expected to publish their report in November 2013. NHS England supports the use of tools such as the cultural barometer and real time staff experience feedback. The friends and family test for staff will be rolled out from April 2014.

79 *Patients first and foremost – The Initial Government Response to the report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*, published 26 March 2013

The Chief Nursing Officer is providing leadership through *Compassion in Practice*, the vision and strategy for nursing in England. Key action areas include:

- developing a set of tools that enable organisations to measure their culture;
- providers undertaking a review of their organisational culture and publish the results;
- reviewing implementation of the cultural barometer once pilots have taken place;
- strategies to secure meaningful staff engagement;
- commissioning leadership role (build into Action Area 4 in *Compassion in Practice*); and
- commissioning an approach to ensure that staff feedback is being used to develop cultural health of front-line staff.

KEY NURSES

Recommendation 199

Each patient should be allocated for each shift a named key nurse responsible for coordinating the provision of the care needs for each allocated patient. The named key nurse on duty should, whenever possible, be present at every interaction between a doctor and an allocated patient.

Accepted.

The Secretary of State for Health announced his support for patients having a named nurse in July 2013 and we are working with NHS England to support the delivery of this aim.

As The Inquiry made clear, organisations can take local action on this issue, and we are pleased that some organisations, such as University College London Hospitals NHS Foundation Trust, already have a system of named nurses. Where named nurses have been implemented, this should be evaluated so that lessons can be learnt and good practice shared.

At a seminar hosted by the Academy of Medical Royal Colleges on 25 September 2013, it was clear there is professional consensus around the issue of named clinicians, and the Academy is leading work to take this forward. The Academy will produce key principles with worked examples on how this can be implemented in a way that sustains professional support.

Recommendation 200

Consideration should be given to the creation of a status of Registered Older Person's Nurse.

Accepted in part.

The Department and its system partners have considered this recommendation and feel there are better ways of improving nursing care for older people. Caring for older people is core to the job of the vast majority of nurses working in wards throughout hospitals and across community settings. We will strengthen the focus on the complex physical and emotional

needs of frail older people throughout nurse training to ensure that older people needing nursing care will benefit from a nursing workforce that is trained to deal with their needs.

Many older people in hospitals are under the care of specialist teams (for example orthopaedics or cancer services) and require nurses to have those specialist skills. Additionally care of those older people who are frail, with many conditions, can take place in their own home and care homes as well as in hospitals.

All registered nurses at the point of qualification need to be competent in managing and implementing care for older people. As a nurse's career progresses we need to ensure they have the opportunity to specialise in the care of older people. In doing so, we need to ensure they have the right skills – not just their clinical expertise but also their decision-making and judgement skills, so that they can help navigate older people through the complex systems of health and social care. To do this they need to build from the firm foundation of their undergraduate experience to develop their expertise at each stage of their career. This is why we are proposing to offer access to practical, continuous professional development and have a clear and rewarding career path from novice to expert.

The Government has asked Health Education England, as part of its Mandate for 2013-2015, to work with Higher Education Institutions to review the content of pre-registration nurse education to ensure all new nurses have the skills to work with the large numbers of older people being treated in the healthcare system. Furthermore Health Education England, working with the Chief Nursing Officer, the Director of Nursing at the Department of Health and Public Health England and the nursing profession, will develop a bespoke older persons nurse post-graduate qualification training programme. Completion of this training programme and demonstrable expertise in working with older people will allow nurses the opportunity to become part of an Older Persons Nurse Fellowship programme that will enable nurses in this field to access a clinical academic pathway. The first cohort of students will commence on the post-graduate programme in September 2014.

Improving hospital care for people with dementia and their carers is a key component of the Prime Minister's Challenge on Dementia. The recent *National Audit of Dementia Care in Hospitals* showed that hospitals are making progress in improving dementia care in hospitals, but that there is still work to be done. Dementia champions are in place in most hospitals, the health needs of people with dementia are better assessed and there has been a welcome reduction in antipsychotic prescribing. The report shows that high quality dementia care is achievable and we want to see this delivered in every hospital.

We want people with dementia to be receiving better quality of care from informed and trained staff. Through the Commissioning for Quality and Innovation programme, NHS England has asked all hospitals to identify a senior clinical lead for dementia and to ensure that carers of people with dementia are adequately supported and that this is reported at board level. We want to see all staff being capable and competent in dementia care and, in January, we launched a new e-learning package for all health and social care staff.

The Department of Health supported the Dementia Action Alliance in its call to action on improving the quality of care for people with dementia in hospital, which asks all NHS acute trusts to commit to become dementia-friendly and over 140 hospitals have signed up to this challenge.

STRENGTHENING THE NURSING PROFESSIONAL VOICE

Recommendation 201

The Royal College of Nursing should consider whether it should formally divide its 'Royal College' functions and its employee representative/trade union functions and its employee representative/trade union functions between two bodies rather than behind internal 'Chinese walls'.

Accepted

The Royal College of Nursing has given careful consideration to whether it should split its trade union and professional functions and has decided that it should not. The Royal College of Nursing believes it is stronger as one organisation.

In its dual role, it believes that the elements are complementary to one another and make it a stronger organisation. It believes that trade union work is not simply consigned to fighting for better pay awards. Instead, it focuses on building a positive working environment for staff – and in healthcare that can have a direct impact on the quality of care delivered to patients.

The Government believes the separation of the Royal College of Nursing's professional and trade union roles, which are both important, would enhance the authority of its work, so that those outside the profession would know when they were speaking in the interests solely of patients and when they were speaking solely in the interests of their members.

Recommendation 202

Recognition of the importance of nursing representation at provider level should be given by ensuring that adequate time is allowed for staff to undertake this role, and employers and unions must regularly review the adequacy of the arrangements in this regard.

Accepted.

Implementation is a matter for local employers and unions. The Royal College of Nursing, UNISON and NHS Employers have endorsed this recommendation and will work with providers and commissioners to try to ensure that this is built into workforce and financial planning.

We will explore further models to strengthen recognition of nursing representation with the Social Partnership Forum, which is a forum for employer and staff representatives.

Recommendation 203

A forum for all directors of nursing from both NHS and independent sector organisations should be formed to provide a means of coordinating the leadership of the nursing profession.

Accepted.

The Chief Nursing Officer has established the Federation of Nurse Leaders, a national forum that has been established to raise the awareness and profile of the nursing voice at a national level. Its membership is drawn from various bodies, including the Care Quality Commission,

the NHS Trust Development Authority, Health Education England, Department of Health and Public Health England. It provides advice, challenge and scrutiny of nursing issues and provides the oversight of the delivery of *Compassion in Practice*, the vision and strategy and for nursing in England. It is chaired by the Chief Nursing Officer for England and the vice-chair is the Department of Health Director of Nursing.

The Nursing and Care Quality forum, established by the Prime Minister in January 2012, continues to play a role in supporting the Chief Nursing Officer and advising Government on nursing and care quality issues. It has been active in highlighting the issues which need to be addressed in improving care on the national level. It has promoted the use of technology to reduce bureaucracy, emphasised the need for better leadership and recruiting health and care staff based on their values. In future it will work more closely with the Chief Nursing Officer but will also retain its independent voice.

In addition, the Chief Nursing Officer has a monthly bulletin, an annual conference for Directors of Nursing and a new website launched to coincide with the 65th anniversary of the NHS. The website 6Cs live! (<http://www.6cs.england.nhs.uk>) provides a communications hub to enable all nurses including directors to come together, share good practice, concerns and leadership. The Chief Nursing Officer will review in 2014 whether more frequent meetings with Directors of Nursing from all organisations should take place.

Recommendation 204

All healthcare providers and commissioning organisations should be required to have at least one executive director who is a registered nurse, and should be encouraged to consider recruiting nurses as non-executive directors.

Accepted in part.

All provider organisations have at least one executive director who is a registered nurse. NHS England has the Chief Nursing Officer on its executive board, and director level (although not executive level) representation at area and regional team levels.

The National Health Service (Clinical Commissioning Groups) Regulations 2012 require clinical commissioning groups to have a nurse on their governing body, though not necessarily at executive level. This enables local flexibility. NHS England will consider the added value of, and mechanisms for, amending or strengthening the guidance for clinical commissioning groups on nurse leadership.

Recommendation 205

Commissioning arrangements should require the boards of provider organisations to seek and record the advice of its nursing director on the impact on the quality of care and patient safety of any proposed major change to nurse staffing arrangements or provision facilities, and to record whether they accepted or rejected the advice, in the latter case recording its reasons for doing so.

Accepted in principle.

Compassion in Practice, the vision and strategy for nursing in England, asks Boards to sign off and publish staffing levels. NHS England has asked that decisions on quality improvement

plans are signed off by medical and nursing directors, and will consider going further to ask for their sign off on staffing changes for clinical staff as well as service provision.

The NHS Standard Contract will be strengthened to require providers to set staffing levels on the basis of evidence, monitor actual versus intended staffing levels and share this information with commissioners and the public.

The Chief Nursing Officer is providing leadership through *Compassion in Practice*. Key action areas include:

- Boards to sign off and publish evidence based staffing levels at least every 6 months, linked to quality of care and patient experience; and
- deploying staff effectively and efficiently; identify the impact this has on quality of care and the experience of people in our care.

Recommendation 206

The effectiveness of the newly positioned office of Chief Nursing Officer should be kept under review to ensure the maintenance of a recognised leading representative of the nursing profession as a whole, able and empowered to give independent professional advice to the Government on nursing issues of equivalent authority to that provided by the Chief Medical Officer.

Accepted.

The Chief Nursing Officer for England provides professional leadership for all nurses, midwives and care staff across the healthcare system. The Chief Nursing Officer is also the principal advisor to the Government on all nursing and midwifery issues with the exception of public health nursing issues. The effectiveness of the Chief Nursing Officer role will be reviewed on an on-going basis, as will the effectiveness of the Federation of Nurse Leaders, established and chaired by the Chief Nursing Officer.

STRENGTHENING IDENTIFICATION OF HEALTHCARE SUPPORT WORKERS AND NURSES

Recommendation 207

There should be a uniform description of healthcare support workers, with the relationship with currently registered nurses made clear by the title.

Accepted in principle.

This is a complex issue as healthcare support workers carry out a number of different tasks in varied roles, so a uniform description can be difficult. The *Cavendish Review*⁸⁰ recommends that once healthcare assistants and healthcare support workers complete a 'Certificate of Fundamental Care', they should be allowed to use the title 'Nursing Assistant', where appropriate. The Chief Nursing Officer has agreed to lead the work around this

80 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/236212/Cavendish_Review.pdf

recommendation which should be understood as part of the wider desire to develop career development to simplified job roles and core competences framework linked to the career development framework.

Recommendation 208

Commissioning arrangements should require provider organisations to ensure by means of identity labels and uniforms that a healthcare support worker is easily distinguishable from that of a registered nurse.

Accepted in principle.

We agree that patients should be clear on the role of people caring for them, for example through identity labels, clear job titles and uniforms. Many organisations already do this.

However, the *Cavendish Review*⁸¹ does not make a firm recommendation that healthcare assistants and nurses should wear distinct uniforms, because so many Trusts already develop their own. The review does, however, support the need to provide more clarity to patients and relatives about who is looking after them. The Chief Nursing Officer will take forward work on this.

REGISTRATION OF HEALTHCARE SUPPORT WORKERS

Recommendation 209

A registration system should be created under which no unregistered person should be permitted to provide for reward direct physical care to patients currently under the care and treatment of a registered nurse or a registered doctor (or who are dependent on such care by reason of disability and/or infirmity) in a hospital or care home setting. The system should apply to healthcare support workers, whether they are working for the NHS or independent healthcare providers, in the community, for agencies or as independent agents. (Exemptions should be made for persons caring for members of their own family or those with whom they have a genuine social relationship.)

Not accepted, however we intend to achieve the intention behind this by ensuring that organisations have the right staff with the right skills to deliver care in a safe way.

The Government understands that the idea of compulsory, statutory regulation can seem an attractive means of ensuring patient safety however, the Inquiry demonstrates that regulation by itself does not prevent poor care. Regulation can be costly and introduce inflexibility into the system. It should only be considered when it is shown that it is the most effective, appropriate, and proportionate means of protecting the public.

We are keeping the situation under review but, currently, there is no solid evidence that demonstrates that healthcare and care support workers should be subject to compulsory statutory regulation, given the safeguards that are already in the system, such as:

- Care Quality Commission registration, which is being enhanced with the new role of the Chief Inspectors;

81 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/236212/Cavendish_Review.pdf

- the Disclosure and Barring Service which provides a further layer of assurance by helping employers make safer recruitment decisions and prevent unsuitable people from working with vulnerable groups that are already in the system; and
- the requirement on nurses to ensure that when they give a task to a support worker they effectively delegate, supervise and ensure the individual has the right training to do the job.

We recognise that there is a need to drive up standards and in 2011 the Department of Health commissioned Skills for Care and Skills for Health to develop a code of conduct and minimum training standards for healthcare assistants and support workers in England, which was published in March 2013. We welcome the recommendations of the *Cavendish Review* relevant to the importance of education, training and standards, and these are being developed further. The importance of this is recognised by the Government asking Health Education England to work with Skills for Care, Skills for Health and other stakeholders to consider how the 'Certificate of Fundamental Care' (now the Care Certificate) can be developed.

Where employers find that a healthcare assistant or social care support worker no longer meets the standards required by the Care Certificate, Health Education England and the Sector Skills Councils will set out in guidance the requirements for ensuring that appropriate re-training is given, or other disciplinary action is taken. The guidance will be that the worker in question should not work unsupervised until the problem has been resolved and the employer is confident that their care certificate remains valid.

CODE OF CONDUCT FOR HEALTHCARE SUPPORT WORKERS

Recommendation 210

There should be a national code of conduct for healthcare support workers.

Accepted.

Skills for Health and Skills for Care published a national code of conduct for healthcare support workers and adult social care workers⁸² in March 2013. The *Cavendish Review*⁸³ recommends that Skills for Health and Skills for Care should refine its proposed code. Skills for Health and Skills for Care will review the code to ensure the language is simple and that there is synergy with the *Social Care Commitment*, launched in September 2013, which the Department of Health has developed in conjunction with Skills for Care and other partners. The *Social Care Commitment* is the sector's promise to provide people who need care and support with safe, high quality services. It brings together other initiatives into a simple framework in simple language, giving clarity to employers and employees about what is expected of them.

82 <http://www.skillsforhealth.org.uk/about-us/news/code-of-conduct-and-national-minimum-training-standards-for-healthcare-support-workers/>

83 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/236212/Cavendish_Review.pdf

TRAINING STANDARDS FOR HEALTHCARE SUPPORT WORKERS

Recommendation 211

There should be a common set of national standards for the education and training of healthcare support workers.

Accepted.

The National Minimum Training Standards⁸⁴ for healthcare support workers were published in March 2013. The *Cavendish Review*⁸⁵ has also made a number of recommendations to improve the national standards on education and training, including a '*Certificate of Fundamental Care*.'

An amendment to the Care Bill was tabled updating the provisions in the Health and Social Care Act 2008 that would enable regulations to specify a body that would set training standards in respect of healthcare assistants and social care support workers. This issue was debated at Report Stage by the House of Lords on 21 October. In that debate, in advance of the formal Response to the Cavendish Review, Government asked Health Education England to lead work with the Skills Councils, other delivery partners and health and care providers to develop a 'Care Certificate.'

Recommendation 212

The code of conduct, education and training standards and requirements for registration for healthcare support workers should be prepared and maintained by the Nursing and Midwifery Council after due consultation with all relevant stakeholders, including the Department of Health, other regulators, professional representative organisations and the public.

Not accepted, however we intend to achieve the intention behind this by ensuring that organisations have the right staff with the right skills to deliver care in a safe way.

This recommendation is a step toward regulation (see recommendation 209) and for the same reasons, we are rejecting this recommendation. The Nursing and Midwifery Council also have no remit for codes of conduct for social care or healthcare support workers. The *Cavendish Review*⁸⁶ recognises the importance of the development of education and training standards which are being developed further.

Recommendation 213

Until such time as the Nursing and Midwifery Council is charged with the recommended regulatory responsibilities, the Department of Health should institute a nationwide system to protect patients and care receivers from harm. This system should be supported by fair due process in relation to employees in this grade who

84 <http://www.skillsforhealth.org.uk/about-us/news/code-of-conduct-and-national-minimum-training-standards-for-healthcare-support-workers/>

85 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/236212/Cavendish_Review.pdf

86 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/236212/Cavendish_Review.pdf

have been dismissed by employers on the grounds of a serious breach of the code of conduct or otherwise being unfit for such a post.

Not accepted, however we intend to achieve the intention behind this by ensuring that organisations have the right staff with the right skills to deliver care in a safe way.

We do not believe that regulation of healthcare assistants and support workers will improve the quality of care. The Nursing and Midwifery Council are an organisation going through a significant change programme focused around delivering their core functions relevant to the regulation of nurses and midwives, and should not be charged with these recommended regulatory responsibilities. In line with the recommendation from the *Cavendish Review*,⁸⁷ the Government has commissioned the Professional Standards Authority for Health and Social Care for advice on how employers can be more effective in managing the dismissal of unsatisfactory staff.

The Disclosure and Barring Service provides a further layer of assurance by helping employers make safer recruitment decisions and prevent unsuitable people working with vulnerable groups.

87 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/236212/Cavendish_Review.pdf

Leadership

The Inquiry highlighted failures of leadership at all levels of the NHS. It rightly identifies the importance of a clear leadership framework and the need to ensure that clear standards are in place for the most senior managers.

Developing a strong, positive culture of leadership for the NHS is the responsibility for all organisations and all leaders; and there is a particular role for the NHS Leadership Academy in ensuring that the right values and behaviours are driven through leadership development at all levels of the NHS. Leadership that embodies and reinforces a culture of compassion and the need to put safety first will be a central part of the Academy's mission.

SHARED TRAINING

Recommendation 214

A leadership staff college or training system, whether centralised or regional, should be created to: provide common professional training in management and leadership to potential senior staff; promote healthcare leadership and management as a profession; administer an accreditation scheme to enhance eligibility for consideration for such roles; promote and research best leadership practice in healthcare.

Accepted.

The NHS Leadership Academy, supported by NHS England, fills this role. It has developed a leadership model for the NHS and a suite of development programmes, tools and interventions to support a change in culture in NHS leadership through a national network of local delivery partners. It researches and champions the professionalisation of leadership.

The Academy provides a suite of career-long, academically accredited programmes which map against a leadership career, irrespective of professional background. This establishes the need for prior training and development before applying for significant and vital senior roles, and creates an expectation of sufficient experience, knowledge and a minimum level of academic achievement for leadership roles. The Academy works with partners and in-house experts on developing a model for leadership, based on research evidence and best practice.

SHARED CODE OF ETHICS

Recommendation 215

A common code of ethics, standards and conduct for senior board-level healthcare leaders and managers should be produced and steps taken to oblige all such staff to comply with the code and their employers to enforce it.

Accepted.

The standards produced by the Professional Standards Authority (*Standards for members of NHS boards and Clinical Commissioning Group governing bodies in England*) provide the basis for standards for senior board-level leaders and managers. The combination of behavioural standards along with technical competence and business processes sends an important signal about the need for leaders who have the right values and behaviour as well as the ability to get the business done. The standards will form part of a wider system of ensuring that senior people are fit and proper persons that will be developed in detail in the coming months. In addition to the responsibility of individual leaders for compliance with technical and behavioural standards, the corporate structures of NHS organisations also need to both reinforce these standards and provide effective oversight of individual and corporate performance to determine whether they are being met, and what needs to be done to improve performance. The NHS Leadership Academy has published *The Healthy NHS Board 2013*, which includes guidance on supporting board effectiveness and emphasises the importance of values and behaviours.

We agree that the public have the right to expect that people in leading positions in NHS organisations are fit and proper persons; and that where it is demonstrated that a person is not fit and proper, they should not be able to occupy such a position. Monitor and the Care Quality Commission are committed to ensuring that, taken together, their processes for registration and licensing reflect these principles. The Care Quality Commission's inspection regime will include a focus on whether or not an organisation is 'well-led'.

In order to support this, the Government issued in July 2013 a consultation on *Strengthening corporate accountability in health and social care*. This proposes a new requirement that all Board Directors (or equivalents) of providers registered with the Care Quality Commission must meet a new fitness test. We are proposing that this test includes checks about whether the person is of good character including past employment history, and if the individual has the qualifications, skills and experience necessary for the work or office as well as the more traditional consideration of criminal and financial matters.

LEADERSHIP FRAMEWORK

Recommendation 216

The leadership framework should be improved by increasing the emphasis given to patient safety in the thinking of all in the health service. This could be done by, for example, creating a separate domain for managing safety, or by defining the service to be delivered as a safe and effective service.

Accepted.

The NHS Leadership Academy is developing, with extensive stakeholder involvement, a new healthcare leadership model for the NHS. This will give due emphasis to leading for patient safety.

COMMON SELECTION CRITERIA

Recommendation 217

A list should be drawn up of all the qualities generally considered necessary for a good and effective leader. This in turn could inform a list of competences a leader would be expected to have.

Accepted in part.

The NHS Leadership Academy has developed, with extensive stakeholder involvement, a new healthcare leadership model for the NHS. In addition to technical competence, board-level leaders must also be 'fit and proper persons' in line with the registration requirements of the Care Quality Commission and Monitor.

The standards produced by the Professional Standards Authority (*Standards for members of NHS boards and Clinical Commissioning Group governing bodies in England*) provide the basis for standards for senior Board-level leaders and managers. The combination of behavioural standards along with technical competence and business processes sends an important signal about the need for leaders who have the right values and behaviour as well as the ability to get the business done.

The public have the right to expect that people in leading positions in NHS organisations are fit and proper persons; and that where it is demonstrated that a person is not fit and proper, they should not be able to occupy such a position. Monitor and the Care Quality Commission are committed to ensuring that, taken together, their processes for registration and licensing reflect these principles. The Care Quality Commission's inspection regime will include a focus on whether or not an organisation is 'well-led'.

Monitor's licence conditions already require providers to ensure that no person who is an unfit person may become or continue as a Director and that they ensure that its contracts of service with its Directors contain a provision permitting summary termination in the event of a Director being or becoming an unfit person.

In order to strengthen this, the Government issued in July 2013 a consultation on *Strengthening corporate accountability in health and social care*. This proposes a new requirement that all Board Directors (or equivalents) of providers registered with the Care Quality Commission must meet a new fitness test. We are proposing that this test includes checks about whether the person is of good character including past employment history, and if the individual has the qualifications, skills and experience necessary for the work or office as well as the more traditional consideration of criminal and financial matters.

ENFORCEMENT OF STANDARDS AND ACCOUNTABILITY

Recommendation 218

Serious non-compliance with the code, and in particular, non-compliance leading to actual or potential harm to patients, should render board-level leaders and managers liable to be found not to be fit and proper persons to hold such positions by a fair and proportionate procedure, with the effect of disqualifying them from holding such positions in future.

Accepted.

The Care Quality Commission will work with other organisations and interested parties to determine how the fit and proper person test will be applied in practice so that it draws on the standards set out in *Standards for members of NHS boards and Clinical Commissioning Group governing bodies in England*. We will support NHS organisations to make better use of recruitment and referencing processes to ensure that appointment processes are clear about whether or not an applicant is a fit and proper person of good standing.

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The Government proposes that the fit and proper persons test will now be used as a mechanism for introducing a scheme for barring Directors who are unfit from individual posts by Care Quality Commission at the point of registration. Where a Director is considered by Care Quality Commission to be unfit it could either refuse registration, in the case of a new provider, or require the removal of the Director on inspection, or following notification of a new appointment. The Government believes that this will be a robust method of ensuring that Directors whose conduct or competence makes them unsuitable for these roles are prevented from securing them. The scheme will be kept under review to ensure that it is effective, and we will legislate in the future if the barring mechanism is not having its desired impact. Further details will be set out in the response to the consultation on corporate accountability which

will be published shortly. We plan to publish the draft regulations for consultation at the same time.

A REGULATOR AS AN ALTERNATIVE

Recommendation 219

An alternative option to enforcing compliance with a management code of conduct, with the risk of disqualification, would be to set up an independent professional regulator. The need for this would be greater if it were thought appropriate to extend a regulatory requirement to a wider range of managers and leaders. The proportionality of such a step could be better assessed after reviewing the experience of a licensing provision for directors.

Accepted in part.

The Government agrees that a focus on standards and their enforcement through normal employment processes and a fit and proper person test is the right place to start. Further action may be justified following a review of how this approach works in practice; but the Government agrees that the proportionate approach is to test how well the combination of a standards-based approach and the use of a 'fit and proper persons' test by the regulators would work.

ACCREDITATION

Recommendation 220

A training facility could provide the route through which an accreditation scheme could be organised. Although this might be a voluntary scheme, at least initially, the objective should be to require all leadership posts to be filled by persons who experience some shared training and obtain the relevant accreditation, enhancing the spread of the common culture and providing the basis for a regulatory regime.

Accepted in part.

We think it is essential that those who fill leadership posts should be able to demonstrate that they share in the common values of the NHS and meet expected standards in respect of both leadership skills and behaviours. We do not, however, accept the need for a formal accreditation scheme.

A new suite of national leadership development programmes launched by the NHS Leadership Academy and supported by a revised healthcare leadership model will represent a consistent approach to developing leaders with the right skills and behaviours at all levels.

ENSURING COMMON STANDARDS OF COMPETENCE AND COMPLIANCE

Recommendation 221

Consideration should be given to ensuring that there is regulatory oversight of the competence and compliance with appropriate standards by the boards of health service bodies which are not Foundation Trusts, of equivalent rigour to that applied to Foundation Trusts.

Accepted.

The Care Quality Commission will be responsible for ensuring that all registered providers have appropriate and effective governance arrangements in place as part of its overall assessment of the health of the organisation. This will apply regardless of whether or not an organisation is a Foundation Trust.

One of the key questions that the Chief Inspector of Hospitals, will ask is whether or not an organisation is well-led. In addition, the NHS Trust Development Authority will be responsible for ensuring that NHS Trusts that do not have Foundation Trust status have effective governance arrangements in place. The approach used by the NHS Trust Development Authority is consistent with that used by Monitor, and both of these organisations along with the Care Quality Commission will continue to work closely to ensure that there is effective regulatory scrutiny of governance and compliance with appropriate standards. There will also be checks on quality governance by the NHS Trust Development Authority before referral to Monitor.

Professional regulation of fitness to practise

The Inquiry highlighted the importance of effective professional regulation in ensuring patient safety, and its report emphasises the need for professional regulators to work closely with each other and with system regulators.

Both professional and system regulators recognise the importance of sharing information, aligning processes and working together to improve and are putting in place measures to ensure the necessary changes take place.

GENERAL MEDICAL COUNCIL: SYSTEMIC INVESTIGATION WHERE NEEDED

Recommendation 222

The General Medical Council should have a clear policy about the circumstances in which a generic complaint or report ought to be made to it, enabling a more proactive approach to monitoring fitness to practise.

Accepted.

The General Medical Council has made it clear that it recognises the need to contribute to the identification and in some cases the investigation of generic concerns, building on its progress in recent years to become a more proactive and collaborative regulator. This includes signposting complainants to the appropriate regulator if their concerns are not for the General Medical Council; making referrals to systems or other professional regulators; investigating concerns arising from the media (including those which do not specifically name a doctor) and sharing information with and participating in regional quality surveillance groups and risk summits. In light of this recommendation, the General Medical Council will undertake to clarify in what circumstances it has an interest in generic reports or complaints and continue to build its relationship with the Care Quality Commission to ensure appropriate leadership in relation to generic concerns. We will continue to work with the General Medical Council and other organisations to ensure that communication and effective sharing of information between regulators of all kinds works well and in the interests of patients.

GENERAL MEDICAL COUNCIL: ENHANCED RESOURCES

Recommendation 223

If the General Medical Council is to be effective in looking into generic complaints and information it will probably need either greater resources, or better cooperation with the Care Quality Commission and other organisations such as the Royal Colleges to ensure that it is provided with the appropriate information.

Accepted in principle.

The General Medical Council has made it clear that it is determined to improve the way it shares information and works with other regulators and organisations such as the medical Royal Colleges. The General Medical Council has agreed an information sharing protocol with the Care Quality Commission, which builds on the existing memorandum of understanding, to ensure that both organisations work closely and effectively together to share information and ensure appropriate and effective cross-referral of concerns.

GENERAL MEDICAL COUNCIL: INFORMATION SHARING

Recommendation 224

Steps must be taken to systematise the exchange of information between the Royal Colleges and the General Medical Council, and to issue guidance for use by employers of doctors to the same effect.

Accepted.

The General Medical Council has made it clear that the exchange of information with Royal Colleges should be further systematised, and that it will take forward action to ensure that this takes place. The General Medical Council will share its proposals in the first half of 2014.

The General Medical Council will work with the Royal Academy of Medical Royal Colleges to develop information sharing agreements with all of the Medical Royal Colleges. In relation to education and training the General Medical Council has made it clear that the exchange of information with Royal Colleges should be further systematised, and that it will take forward action to ensure that this takes place. The General Medical Council will share its proposals in the first half of 2014.

The General Medical Council has developed a closer working relationship with employers through the Employer Liaison Service. It already produces guidance to help employers understand when to share information with the General Medical Council and will reiterate this guidance through meetings with Responsible Officers and Medical Directors.

GENERAL MEDICAL COUNCIL: PEER REVIEWS

Recommendation 225

The General Medical Council should have regard to the possibility of commissioning peer reviews pursuant to section 35 of the Medical Act 1983 where concerns are raised in a generic way, in order to be advised whether there are individual concerns. Such reviews could be jointly commissioned with the Care Quality Commission in appropriate cases.

Accepted.

The General Medical Council has made it clear that it is determined to work with others to explore the development of appropriate forms of joint ownership of generic issues, so that unacceptable patient care is identified and dealt with effectively. This may include (but need not be confined to) peer reviews.

NURSING AND MIDWIFERY COUNCIL: INVESTIGATION OF SYSTEMIC CONCERNS

Recommendation 226

To act as an effective regulator of nurse managers and leaders, as well as more front-line nurses, the Nursing and Midwifery Council needs to be equipped to look at systemic concerns as well as individual ones. It must be enabled to work closely with the systems regulators and to share their information and analyses on the working of systems in organisations in which nurses are active. It should not have to wait until a disaster has occurred to intervene with its fitness to practise procedures. Full access to the Care Quality Commission information in particular is vital.

Accepted in part.

The Nursing and Midwifery Council have made it clear that they are determined to work closely with other regulators, including the Care Quality Commission to share information and analyses, and that it should not have to wait until a disaster has occurred to intervene with its fitness to practise procedures. The Government notes that the Nursing and Midwifery Council have stated that they do not wish to be given the role of directly investigating systems issues given that the primary responsibility for such issues rests with the Care Quality Commission, but that they intend to address the underlying issue identified in this recommendation by working closely with the Care Quality Commission and other regulators to ensure that the most serious matters are appropriately addressed in a systematic manner.

Recommendation 227

The Nursing and Midwifery Council needs to have its own internal capacity to assess systems and launch its own proactive investigations where it becomes aware of concerns which may give rise to nursing fitness to practise issues. It may decide to seek the cooperation of the Care Quality Commission, but as an independent regulator

it must be empowered to act on its own if it considers it necessary in the public interest. This will require resources in terms of appropriately expert staff, data systems and finance. Given the power of the registrar to refer cases without a formal third party complaint, it would not appear that a change of regulation is necessary, but this should be reviewed.

Accepted in principle.

The Nursing and Midwifery Council are taking a different approach to achieving this recommendation. The Nursing and Midwifery Council is committed to working closely with the Care Quality Commission and with other regulators to ensure that the most serious matters are appropriately addressed in a systematic manner.

NURSING AND MIDWIFERY COUNCIL: ADMINISTRATIVE REFORM

Recommendation 228

It is of concern that the administration of the Nursing and Midwifery Council, which has not been examined by this Inquiry, is still found by other reviews to be wanting. It is imperative in the public interest that this is remedied urgently. Without doing so, there is a danger that the regulatory gap between the Nursing and Midwifery Council and the Care Quality Commission will widen rather than narrow.

Accepted.

The Nursing and Midwifery Council has made clear its commitment to implementing the recommendations and achieving the required improvements in the delivery of its regulatory functions set out in the strategic review undertaken by the Professional Standards Authority in 2012, most recently in its 2013-2016 corporate plans.

In relation to the recommendation to appoint a strong leadership team to drive forward turn around work, Mark Addison was appointed Chair of the Nursing and Midwifery Council in September 2012, and Jackie Smith was permanently appointed to the role of Nursing and Midwifery Council Chief Executive in June 2013. In addition, the Nursing and Midwifery Council was re-constituted from 1 May 2013.

The Government has demonstrated its determination to ensure the Nursing and Midwifery Council is an effective regulator that serves its members well. In February 2013, the Government provided a £20m grant to support the Nursing and Midwifery Council to achieve a number of improvements including clearing a backlog of historical fitness-to-practise cases, speeding up fitness to practise proceedings, ensuring free financial reserves are at agreed levels and reducing the effect of an annual fee rise for nurses and midwives. Departmental officials continue to closely scrutinise and monitor the Nursing and Midwifery Council's progress in making the required improvements within the timescales specified.

In addition, the Government is working on an order under section 60 of the *Health Act 1999* to amend the Nursing and Midwifery Order 2001. This is in advance of any measures which may be taken forward following the Law Commission review which is considering the overhaul of the complex legislative framework that governs the Nursing and Midwifery Council and the regulators of other UK health professionals and, in England, social care professionals into a

single Act, subject to Parliamentary timetables. Within this section 60 order the Government intends to make a number of amendments including change to achieve greater efficiency in fitness to practise procedures, including a reduction in the overall time that a case takes from start to finish.

NURSING AND MIDWIFERY COUNCIL: REVALIDATION

Recommendation 229

It is highly desirable that the Nursing and Midwifery Council introduces a system of revalidation similar to that of the General Medical Council, as a means of reinforcing the status and competence of registered nurses, as well as providing additional protection to the public. It is essential that the Nursing and Midwifery Council has the resources and the administrative and leadership skills to ensure that this does not detract from its existing core function of regulating fitness to practise of registered nurses.

Accepted.

The Nursing and Midwifery Council has committed to introducing a proportionate and effective model of revalidation, which is affordable and value for money, to enhance public protection. Subject to public consultation, the proposed model would require evidence that the nurse or midwife is fit to practise. Under the current proposals, the Nursing and Midwifery Council Code and standards would be reviewed and revised to ensure they would be compatible with revalidation, and guidance for revalidation would also be developed.

NURSING AND MIDWIFERY COUNCIL: PROFILE

Recommendation 230

The profile of the Nursing and Midwifery Council needs to be raised with the public, who are the prime and most valuable source of information about the conduct of nurses. All patients should be informed, by those providing treatment or care, of the existence and role of the Nursing and Midwifery Council, together with contact details. The Nursing and Midwifery Council itself needs to undertake more by way of public promotion of its functions.

Accepted.

The Nursing and Midwifery Council is working to develop its public profile, and will be re-launching its website and developing information for patients, the public and employers. It has embarked on a programme of increased face-to-face engagement with its stakeholders and introduced a new patient and public forum made up of patient advocates, health charities and members of the public. The group meet quarterly and have considered issues such as what can be done to restore confidence in the Nursing and Midwifery Council, and patients' experience of complaining to the Nursing and Midwifery Council. The forum is helping the Nursing and Midwifery Council to co-create a leaflet for the public on the quality assurance of education and how to make the Nursing and Midwifery Council's website more user-friendly.

As part of its engagement work, the Nursing and Midwifery Council has held a joint event with the Richmond Group of Charities and the General Medical Council involving representatives from regulators, health charities, patient advocacy groups and others to discuss what good patient and public engagement feels like. The council is also part of the health professions regulators patient and public engagement group to share experiences and look at ways to work better together.

In September 2013, the Nursing and Midwifery Council relaunched its guidance on raising concerns, and is publicising this guidance through various means. Its engagement work covers all its functions, including fitness-to-practise, registration, education, standards and revalidation and is undertaken across all four UK countries. This work will be enhanced further by the planned introduction of regional representatives.

NURSING AND MIDWIFERY COUNCIL: COORDINATION WITH INTERNAL PROCEDURES

Recommendation 231

It is essential that, so far as practicable, Nursing and Midwifery Council procedures do not obstruct the progress of internal disciplinary action in providers. In most cases it should be possible, through cooperation, to allow both to proceed in parallel. This may require a review of employment disciplinary procedures, to make it clear that the employer is entitled to proceed even if there are pending Nursing and Midwifery Council proceedings.

Accepted.

The Nursing and Midwifery Council have made clear their view that their procedures should not obstruct internal disciplinary action, and that it would not expect the making of an interim order by the Nursing and Midwifery Council to prevent the completion of disciplinary action. The Nursing and Midwifery Council will review the guidance it provides to employers and the public to ensure that this issue is addressed clearly.

NURSING AND MIDWIFERY COUNCIL: EMPLOYMENT LIAISON OFFICERS

Recommendation 232

The Nursing and Midwifery Council could consider a concept of employment liaison officers, similar to that of the General Medical Council, to provide support to directors of nursing. If this is impractical, a support network of senior nurse leaders will have to be engaged in filling this gap.

Accepted.

The Nursing and Midwifery Council have started planning the introduction of new regional advisors who will perform a function similar to the General Medical Council's employer liaison

advisers of providing support and guidance locally for employers and others with concerns about nurses and midwives. A pilot will be undertaken in 2014, with roll out planned for 2015.

FOR JOINT ACTION: PROFILE

Recommendation 233

While both the General Medical Council and the Nursing and Midwifery Council have highly informative internet sites, both need to ensure that patients and other service users are made aware at the point of service provision of their existence, their role and their contact details.

Accepted.

Both the General Medical Council and the Nursing and Midwifery Council have made clear their commitment to ensure that patients and the public have a clear understanding of the role of both organisations.

The General Medical Council is piloting meetings with patients and relatives who have made a complaint about a doctor. During the pilot, they are offering to meet individual complainants at the beginning and end of the case. The aim is to make sure that the complainant fully understands the nature and purpose of the General Medical Council's procedures and that the General Medical Council fully understands the nature of the complainant's concerns. The meeting when the case has concluded gives the General Medical Council an opportunity to explain the outcome.

FOR JOINT ACTION: COOPERATION WITH THE CARE QUALITY COMMISSION

Recommendation 234

Both the General Medical Council and Nursing and Midwifery Council must develop closer working relationships with the Care Quality Commission – in many cases there should be joint working to minimise the time taken to resolve issues and maximise the protection afforded to the public.

Accepted.

The General Medical Council has been working closely with the Care Quality Commission to build on its Memorandum of Understanding. Similar close joint working has also started with the Nursing and Midwifery Council.

The Care Quality Commission and General Medical Council have already reviewed their joint working arrangements to improve information sharing, allow evaluation and tracking of how information is used, and plan coordinated or joint inspections and visits. These arrangements were published in July 2013.

The Care Quality Commission and the Nursing and Midwifery Council began a similar review during September 2013, to develop a similar joint working protocol by December 2013.

The Care Quality Commission issued *Raising Standards, putting people first – our strategy 2013–16*⁸⁸ in February 2013. This set out the Care Quality Commission's plans for the next three years and made clear that it would work more closely with its partners in the health and social care system to improve the quality and safety of care and co-ordinate work better, including working with other regulators and organisations that manage and oversee the health and social care system to identify and act on the public's concerns. This was reinforced in June 2013, when the Care Quality Commission issued its consultation document 'A new start – Consultation on changes to the way Care Quality Commission regulates, inspects and monitors care'. This recognised the need to coordinate with existing visits and inspections to minimise duplication and overlap, for example through joint visits and re-use of each other's findings.

FOR JOINT ACTION: JOINT PROCEEDINGS

Recommendation 235

The Professional Standards Authority for Health and Social Care (PSA) (formerly the Council for Healthcare Regulatory Excellence), together with the regulators under its supervision, should seek to devise procedures for dealing consistently and in the public interest with cases arising out of the same event or series of events but involving professionals regulated by more than one body. While it would require new regulations, consideration should be given to the possibility of moving towards a common independent tribunal to determine fitness to practise issues and sanctions across the healthcare professional field.

Accepted in part.

The Professional Standards Authority oversees the work of the professional regulators, but it has no powers to intervene directly in cases (save that where it considers the outcome of a fitness to practise hearing has been unduly lenient it may refer the case for consideration by the high court). The Law Commission is undertaking a review of the legislation applicable to the regulators with a view to producing a draft Bill containing proposals for reform. Within this it has consulted on proposals which would provide powers for joint working between the regulators. We supported these proposals and, subject to the outcome of the consultation, would wish to consider taking them forward at a suitable legislative opportunity. If implemented, it would be for the regulators to determine how they are used but they would potentially enable greater co-operation and, thereby, greater consistency between regulators in cases affecting more than one class of professional. The Law Commission's consultation also included the possibility that regulators would be able to use these powers to share tribunal services for the determination of fitness to practice cases, although the full implications of this would need to be considered further.

88 http://www.cqc.org.uk/sites/default/files/media/documents/20130503_cqc_strategy_2013_final_cm_tagged.pdf

Caring for the elderly (applicable to all patients but requiring special attention for the elderly)

The Inquiry featured a chapter on hospital care for older people titled 'Common culture applied: the care of the elderly', and the Government agrees that the link between culture and compassionate care for older patients is fundamental, across all health and care settings. We need an NHS and social care system where care is just as important as treatment, where older people are valued and listened to, and are treated with compassion, dignity and respect by skilled staff who are engaged, understand the particular needs of older people and have time to care.

The Government and its system partners are taking forward the following actions to improve care for older people:

- proposing the introduction of a named accountable clinician for patients receiving care outside hospitals, starting with vulnerable older people, to take responsibility for ensuring that their care is coordinated and proactively managed;
- supporting safe and timely discharges through spending £1 billion between 2010 and 2015 on reablement services which help people to regain their independence and confidence following discharge from hospital;
- in 2015–16 the £3.8 billion Integration Transformation Fund will bring health and social care commissioners together to plan services around people to improve outcomes and experiences;
- awarding grant funding to the Malnutrition Taskforce, led by Age UK, to test a framework to reduce malnutrition among older people in a range of health and care settings;
- Health Education England, working with the Chief Nursing Officer, the Director of Nursing at the Department of Health and Public Health England and the nursing profession, will develop a bespoke older persons nurse post-graduate qualification training programme.
- Health Education England are making improvements to GP training to include more emphasis on care of older people including dementia;
- Health Education England developing specific post-graduate training for nurses caring for older people with complex needs; and
- NHS England asking all hospitals to identify a senior clinical lead for dementia.

IDENTIFICATION OF WHO IS RESPONSIBLE FOR THE PATIENT

Recommendation 236

Hospitals should review whether to reinstate the practice of identifying a senior clinician who is in charge of a patient's case, so that patients and their supporters are clear who is in overall charge of a patient's care.

Accepted.

In his speech on patient safety on 21 June 2013, the Secretary of State for Health signalled his support for the practice of hospitals identifying a named consultant who is responsible for a patient's care. This happens in a number of Trusts already – University College London Hospitals NHS Foundation Trust and Kings College Hospital in London have agreed to introduce it and the Department would encourage others to do so, including mental health providers. At a seminar hosted by the Academy of Medical Royal Colleges on 25 September 2013, it was clear there was a strong professional consensus on this approach and the Academy is leading work to take it forward. The Academy will produce key principles with worked examples on how this can be implemented in a way that sustains professional support.

The Government is also proposing the introduction of a named accountable clinician for patients receiving care outside hospitals, starting with vulnerable older people. The Government proposes that the most vulnerable elderly would benefit from having someone in primary care taking responsibility for ensuring that their care is coordinated and proactively managed. Just as patients in hospitals are under the care of a named consultant, we need to ensure that when a vulnerable older patient needs follow-up or ongoing support having left hospital, that somebody is accountable for their care. Although this clinician may not provide the care directly themselves, they would be the person with whom the buck stops and would be an identifiable point of contact for a patient or their family.

The Government has been testing its proposals over the summer through engagement with patients, carers, health and social care staff, and will be setting out its plan for improving out-of-hospital care for vulnerable older people later in the year. This was reflected in the refreshed Mandate to NHS England for 2014–15.

TEAMWORK

Recommendation 237

There needs to be effective teamwork between all the different disciplines and services that together provide the collective care often required by an elderly patient; the contribution of cleaners, maintenance staff, and catering staff also needs to be recognised and valued.

Accepted.

All staff should recognise that they impact on patient experience and take responsibility for their contribution to patients having a positive experience of care. Research commissioned

by the Department of Health has shown that effective teamwork is crucial to the delivery of improved patient care in a culture of safety and quality⁸⁹.

As part of its Mandate for 2013–15, the Government has asked Health Education England to implement improvements to GP training to include more emphasis on care of the elderly; work-based training modules in mental health, including dementia; and an understanding of working in multi-disciplinary teams to deliver good integrated care.

Camilla Cavendish's review raised the need to improve recruitment, training, development and supervision of health and social care support workers. The Government has asked Health Education England to lead the work with Skills Councils, and other delivery partners to develop a 'Certificate of Fundamental Care', relabelled as the 'Care Certificate'. This will provide assurance that healthcare assistants and social care support workers receive high quality training and consistent training and support they need to do their jobs. This should ensure that they understand the skills required and demonstrate the behaviours needed to deliver compassionate care across health and social care and help raise the status of caring.

Further delivery is for local consideration and action – The Inquiry made clear that Trusts/ organisations do not need to wait for a Government response before taking local action. However, the Department has asked NHS Employers to collate some of the resources available to employers to support team development and effective team working, and to create a web page with links to these resources. This will be made available to employers by the end of 2013.

Royal Wolverhampton Hospitals NHS Trust have ensured all their staff are dementia-trained, with the level of training varying from basic awareness to specialised dementia care training. Non clinical staff, such as receptionists, porters and catering staff are all trained to spot the signs of dementia and respond appropriately to people with the condition.

COMMUNICATION WITH AND ABOUT PATIENTS

Recommendation 238

Regular interaction and engagement between nurses and patients and those close to them should be systematised through regular ward rounds:

- **All staff need to be enabled to interact constructively, in a helpful and friendly fashion, with patients and visitors.**
- **Where possible, wards should have areas where more mobile patients and their visitors can meet in relative privacy and comfort without disturbing other patients.**
- **The NHS should develop a greater willingness to communicate by email with relatives.**
- **The currently common practice of summary discharge letters followed up some time later with more substantive ones should be reconsidered.**

89 Michael West, Richard Baker, Jeremy Dawson, Mary Dixon Woods, Richard Lilford, Graham Martin, Lorna McKee, Madeleine Murtagh, Patricia Wilkie, Quality and Safety in the NHS: Evaluating Progress, Problems and Promise, 2013, <http://www.lums.lancs.ac.uk/files/quality-safety-nhs-e.pdf>

- **Information about an older patient's condition, progress and care and discharge plans should be available and shared with that patient and, where appropriate, those close to them, who must be included in the therapeutic partnership to which all patients are entitled.**

Accepted.

All staff need to be enabled to interact constructively, in a helpful and friendly fashion, with patients and visitors.

As part of its Mandate for 2013-2015, the Government has asked Health Education England to work with healthcare providers, regulators and educational institutions to ensure both recruitment and selection for training curricula identify and reinforce the values and behaviours identified in the NHS Constitution.

Where possible, wards should have areas where more mobile patients and their visitors can meet in relative privacy and comfort without disturbing other patients.

The Department of Health's Health Building Note 04-01, published in December 2012, provided best practice guidance on the planning and design of in-patient facilities for adults. The Note recognises the need for breakout space and informal social space to enable patients to socialise, and interview rooms for more private discussions. Planning decisions should take account of privacy, modesty and same-sex accommodation.

As part of the implementation of the Prime Minister's Challenge on Dementia, on 25 July 2013 the Secretary of State for Health announced details of the 116 successful projects, 42 projects within the NHS (including hospital wards) and 74 within a local authority setting (including care homes) awarded a share of a £50million fund to create pioneering care environments designed with the needs of people with dementia in mind.

Funding was awarded to projects that demonstrated how practical changes to the environment within which people with dementia are treated will make a tangible improvement to their condition. Evidence and findings from these projects will be gathered and developed into policy and to inform best practice guidance for the NHS and Social Care providers.

The many strands of work to implement the Government's information strategy for health and care in England are beginning to bring improvements for patients and services, for example being able to book appointments and order repeat prescriptions online and communicate electronically with health and care professionals.

As it becomes more normal to communicate with our health and care professionals in ways that suit our own circumstances and interact with health and care services electronically, the Department would expect this change to extend to increasing use of technology for appropriate communications with carers, families and relatives. The Information Strategy published in 2012, *The Power Of Information*, set out an ambition that 'We need to be able to communicate with our health and care professionals in ways that suit our own circumstances.' It referenced the example of online care plans in Graham Care Group homes, as follows:

'Following initial trials at Rodwell Farm Nursing Homes, all residents in the Graham Care Group homes, their relatives and friends can now access securely current care plans and daily reports via email, internet, iPhone etc. Designated contacts can receive text alerts or

emails notifying them that updates have been uploaded. The newest and most innovative part of the system allows families and friends to use a text-based system to supply information, photographs etc, which designated care staff will share with residents. The system is being evaluated by the University of Surrey.'

The currently common practice of summary discharge letters followed up some time later with more substantive ones should be reconsidered.

Information about an older patient's condition, progress, and care and discharge plans should be available and shared with that patient and, where appropriate, those close to them, who must be included in the therapeutic partnership to which all patients are entitled.

The Government proposes that the most vulnerable elderly would benefit from having someone in primary care taking responsibility for ensuring that their care is coordinated and proactively managed. Just as patients in hospitals are under the care of a named consultant, we need to ensure that when a vulnerable older patient needs follow-up or ongoing support having left hospital, that somebody is accountable for their care. Although this clinician may not provide the care directly themselves, they would be the person with whom the buck stops and would be an identifiable point of contact for a patient or their family.

The Government has been testing its proposals over the summer through engagement with patients, carers, health and social care staff, and will be setting out its plan for improving out-of-hospital care for vulnerable older people in December 2014. This was reflected in the refreshed the Government's Mandate for NHS England for 2014–15.

In its initial response to The Inquiry, *Patients First and Foremost*, the Government committed to draw up a new set of fundamental standards of care that will sit within the legal requirements that providers of health and adult social care must meet to be registered with the Care Quality Commission.

More needs to be done to involve people in their own care and therefore statutory guidance for clinical commissioning groups on involving patients in planning services and in their own care has been published by NHS England along with a set of supportive tools^[1]. By December 2013, 80% of clinical commissioning groups will be commissioning support for patients' participation and decisions in relation to their own care or will have a plan to do so. This will include information and support for self-management, personalised care planning and shared decision-making.

In October 2012 the Royal College of Physicians and the Royal College of Nursing published joint guidance titled: 'Ward Rounds in medicine: principles for best practice.' The guidance is available at <http://www.rcplondon.ac.uk/sites/default/files/documents/ward-rounds-in-medicine-web.pdf> and includes principles that highlight the importance of regular ward rounds, full multi-disciplinary engagement and attendance, and sharing of information with a patient's relatives and carers.

CONTINUING RESPONSIBILITY FOR CARE

Recommendation 239

The care offered by a hospital should not end merely because the patient has surrendered a bed – it should never be acceptable for patients to be discharged in the middle of the night, still less so at any time without absolute assurance that a patient in need of care will receive it on arrival at the planned destination. Discharge areas in hospital need to be properly staffed and provide continued care to the patient.

Accepted.

Discharging patients where it is unsafe, because there is no care and support in place, is clearly a matter of clinical negligence and a breach of the duty of care that professionals have towards those they care for. The Department of Health can see few situations where it would be reasonable to discharge a patient at night, unless it was both safe and the express wish of the patient.

The current guidance '*Ready to Go*'

(http://www.thinklocalactpersonal.org.uk/_library/Resources/Personalisation/EastMidlands/PandEI/Ready_to_Go_-_Hospital_Discharge_Planning.pdf) sets out clear steps for local authorities and the NHS to work together to plan the safe and timely discharge of patients from hospital, or transfer of patients to another care setting. Strong multi-disciplinary discharge teams are vital to ensuring that patients are discharged in a safe and timely manner.

The Government is committed to ensuring safe and timely discharges, and reducing unnecessary delays. We are supporting safe and timely discharges through spending £1 billion between 2010 and 2015 on reablement services which help people to regain their independence and confidence following discharge from hospital. In 2015–16 the £3.8 billion Integration Transformation Fund will bring health and social care commissioners together to plan services around people to improve outcomes and experiences.

In its initial response to The Inquiry, *Patients First and Foremost*, the Government committed to draw up a new set of fundamental standards of care that will sit within the legal requirements that providers of health and adult social care must meet to be registered with the Care Quality Commission.

In June 2013, the Care Quality Commission issued *A new start – Consultation on changes to the way Care Quality Commission regulates, inspects and monitors care*. This document started the public discussion on what the fundamental standards of care should be. The Department of Health has issued draft regulations for consultation, which set these fundamental standards of care in legislation as outcomes that must be avoided, as well as streamlining and improving the clarity of requirements which must be positively achieved in order for a provider to register with the Care Quality Commission. The Care Quality Commission, through its Chief Inspector of Hospitals, is engaging with providers, professionals and the public on what guidance it should publish on complying with these regulations and how they should relate to the Care Quality Commission's broader assessments of the quality of hospital services. The new regulations setting out fundamental

standards of care, and the Care Quality Commission's associated guidance for providers on them, will come into effect during 2014, subject to Parliamentary approval.

Care Quality Commission inspectors will spend more time listening to patients, service users and the staff who care for them. They will also speak directly to senior managers and board members. Inspection will include a closer examination of records, and inspection visits at night and at weekends. The Chief Inspector and his inspectorate are committed to complete openness about where good and bad care is being delivered.

HYGIENE

Recommendation 240

All staff and visitors need to be reminded to comply with hygiene requirements. Any member of staff, however junior, should be encouraged to remind anyone, however senior, of these.

Accepted.

In its initial response to The Inquiry, *Patients First and Foremost*, the Government committed to draw up a new set of fundamental standards of care that will sit within the legal requirements that providers of health and adult social care must meet to be registered with the Care Quality Commission.

In June 2013, the Care Quality Commission issued *A new start – Consultation on changes to the way Care Quality Commission regulates, inspects and monitors care*. This document started the public discussion on what the fundamental standards of care should be. The Department of Health has issued draft regulations for consultation, which set these fundamental standards of care in legislation as outcomes that must be avoided, as well as streamlining and improving the clarity of requirements which must be positively achieved in order for a provider to register with the Care Quality Commission. The Care Quality Commission, through its Chief Inspector of Hospitals, is engaging with providers, professionals and the public on what guidance it should publish on complying with these regulations and how they should relate to the Care Quality Commission's broader assessments of the quality of hospital services. The new regulations setting out fundamental standards of care, and the Care Quality Commission's associated guidance for providers on them, will come into effect during 2014, subject to Parliamentary approval. The final set of standards is likely to cover areas such as: care and safety of patients and service users; abuse, including neglect; respecting and involving service users; nutrition; consent; governance; cleanliness and safety of premises and equipment; staffing; fitness of directors; and duty of candour.

Local Healthwatch organisations are using their 'enter and view' powers to get a clear picture of how health and care services are meeting the needs of the public, and their place on every local health and wellbeing board will ensure that voices of people using services is at the heart of local planning and decision-making. Local Healthwatch will also enhance the new inspection regimes. They will make sure inspection teams get a comprehensive picture of local people's opinions and concerns, and will maintain a focus on service quality issues after the inspection team has moved on.

In April 2013, a new system of Patient-led Assessment of the Care Environment was introduced. This annual inspection is carried out by teams including at least 50% patients or members of the public. It includes an assessment of visible cleanliness and prompts an action plan to address any shortcomings.

Furthermore, *The Code of Practice on the Prevention and Control of Infections and Related Guidance* (2010) sets out the ten criteria against which registered providers will be judged on how it complies with the registration requirement for cleanliness and infection control, although not all criteria will apply to every regulated activity. Currently, registered providers need to demonstrate to the Care Quality Commission that they have systems in place to manage and monitor the prevention and control of infection, which includes providing and maintaining a clean and appropriate environment.

Part of a Trust Board's work to focus its organisation around patient safety will include demonstrating behaviours that instil a culture of openness and learning, where junior members of staff feel able to challenge their senior colleagues, and those in authority react appropriately.

PROVISION OF FOOD AND DRINK

Recommendation 241

The arrangements and best practice for providing food and drink to elderly patients require constant review, monitoring and implementation.

Accepted.

In its initial response to The Inquiry, *Patients First and Foremost*, the Government committed to draw up a new set of fundamental standards of care that will sit within the legal requirements that providers of health and adult social care must meet to be registered with the Care Quality Commission.

In June 2013, the Care Quality Commission issued *A new start – Consultation on changes to the way Care Quality Commission regulates, inspects and monitors care*. This document started the public discussion on what the fundamental standards of care should be.

The Department of Health has issued draft regulations for consultation, which set these fundamental standards of care in legislation as outcomes that must be avoided, as well as streamlining and improving the clarity of requirements which must be positively achieved in order for a provider to register with the Care Quality Commission. The *www*, through its Chief Inspectors, is engaging with providers, professionals and the public on what guidance it should publish on complying with these regulations and how they should relate to the Care Quality Commission's broader assessments of the quality of services. The new regulations setting out fundamental standards of care, and the Care Quality Commission's associated guidance for providers on them, will come into effect during 2014, subject to Parliamentary approval. The final set of standards is likely to cover areas such as: care and safety of patients and service users; abuse, including neglect; respecting and involving service users; nutrition; consent; governance; cleanliness and safety of premises and equipment; staffing; fitness of directors; and duty of candour.

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The Department of Health is awarding grant funding to the Malnutrition Taskforce, led by Age UK, to run stage 1 of a pilot programme to test a framework to reduce malnutrition among older people in a range of health and care settings. The Malnutrition Taskforce’s pilot will bring together the relevant professionals from a range of care settings, to work together to improve the care of older people at risk of malnutrition, raise awareness to help prevent people becoming malnourished in the first place, and help carers and clinicians identify and treat people with malnutrition more effectively.

The Malnutrition Taskforce have published a series of guides offering expert advice on the prevention and early intervention of malnutrition in later life. These guides draw together principles of best practice to offer a framework developed to help those in a wide range of health and care settings make the changes needed to counter malnutrition. The guides are available at <http://www.malnutritiontaskforce.org.uk/resources.html>

Trusts are encouraged to implement Protected Mealtimes which the National Patient Safety Agency issued guidance on in 2007, http://www.rcn.org.uk/development/practice/nutrition/improvement_actions/protected_mealtimes. Shifts should be organised so that staff are not taking breaks at the same time as patients are being served meals, to ensure that staff are available at mealtimes to help patients eat and drink – this is particularly important for older patients and people with dementia.

MEDICINES ADMINISTRATION

Recommendation 242

In the absence of automatic checking and prompting, the process of the administration of medication needs to be overseen by the nurse in charge of the ward, or his/her nominated delegate. A frequent check needs to be done to ensure that all patients have received what they have been prescribed and what they need. This is particularly the case when patients are moved from one ward to another, or they are returned to the ward after treatment.

Accepted.

In the initial Government response to The Inquiry, *Patients First and Foremost*, the Department of Health gave strong support to supervisory roles for Ward Managers (including Sister, Charge Nurse and Team Leader) in delivering oversight to all aspects of care on a ward and in a community, from cleanliness to allocation of staff. Nurse leadership at ward level provided by a Ward Manager is also important to the delivery of safe, high-quality care to patients. However, we wish to allow for local flexibility in delivering nursing care and so the Government is not mandating that ward nurse managers must operate in a supervisory capacity.

Having sufficient nurses trained and with the capacity to ensure the delivery of safe, patient focused care is currently a core standard requirement of the Care Quality Commission.

Compassion in Practice, the vision and strategy for nursing in England, commits to ensuring we have the right staff, with the right skills in the right place. This includes supporting leaders to be supervisory, giving them time to lead action plans by December 2013.

In *Patients First and Foremost*, the Government committed to draw up a new set of fundamental standards of care that will sit within the legal requirements that providers of health and adult social care must meet to be registered with the Care Quality Commission.

In June 2013, the Care Quality Commission issued *A new start – Consultation on changes to the way Care Quality Commission regulates, inspects and monitors care*. This document started the public discussion on what the fundamental standards of care should be.

The Department of Health has issued draft regulations for consultation, which set these fundamental standards of care in legislation as outcomes that must be avoided, as well as streamlining and improving the clarity of requirements which must be positively achieved in order for a provider to register with the Care Quality Commission. The Care Quality Commission, through its Chief Inspector of Hospitals, is engaging with providers, professionals and the public on what guidance it should publish on complying with these regulations and how they should relate to the Care Quality Commission's broader assessments of the quality of hospital services. The new regulations setting out fundamental standards of care, and the Care Quality Commission's associated guidance for providers on them, will come into effect during 2014, subject to Parliamentary approval. The final set of standards is likely to cover areas such as: care and safety of patients and service users; abuse, including neglect; respecting and involving service users; nutrition; consent; governance; cleanliness and safety of premises and equipment; staffing; fitness of directors; and duty of candour.

Local Healthwatch organisations are using their 'enter and view' powers to get a clear picture of how health and care services are meeting the needs of the public, and their place on every local health and wellbeing board will ensure that voices of people using services is at the heart of local planning and decision-making. Local Healthwatch will also enhance the new inspection regimes. They will make sure inspection teams get a comprehensive picture of local people's opinions and concerns, and will maintain a focus on service quality issues after the inspection team has moved on.

Administration of medicines is one part of a system in hospitals designed to ensure patients have safe and effective access to the medicines they need. Other components of that system include safe prescribing and supply of medicines. The Nursing and Midwifery Council's Standards for Medicines Management sets standards for safe practice in the management and administration of medicines expected of registered nurses, midwives and specialist community public health nurses. The General Medical Council's guidance *Good practice in prescribing and managing medicines and devices* sets out expectations of registered medical practitioners. The General Pharmaceutical Council sets standards for registered pharmacists and registered pharmacy technicians. All of these members of the local clinical team contribute to safe use of medicines in an organisation.

However, the Royal Pharmaceutical Society's *Professional Standards for Hospital Pharmacy Services* makes clear that the hospital chief pharmacist (or equivalent) leads on ensuring that all aspects of medicines use within its organisation are safe. Therefore local hospital pharmacy teams must ensure systems are in place to minimise risks to patients from medicines, and working with doctors, nurses and management colleagues, ensure those systems are robustly and regularly monitored and audited. Importantly, local organisations must also encourage a culture and system which supports reporting and learning from medication mistakes and errors. Such systems and processes must be set out in local hospital medicines policies, signed off by the hospital Trust Board, with the board receiving regular reports (eg annually) on implementation and areas for improvement, together with remedial action plans.

On occasion it is necessary for nurses to withhold medicines from administration. For example, when some medicines need to be temporarily halted before surgery, or is the registered nurse considers that administration of the prescribed medicine or dose would put the patient at risk.

The Government's *Information Strategy*, published in May 2012, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213689/dh_134205.pdf outlined several elements which will be applicable to the administration of medicines. The Department will continue to collaborate with key partners such as the National Care Forum, the Royal Pharmaceutical Society and key Royal Colleges, building on existing work, to improve the use of medicines in care homes, including considering the role of technological innovation and commissioning incentives in transforming safety and efficiency.

The Department of Health also set out in *Transforming Care: a national response to Winterbourne View Hospital* a number of actions to address concerns raised about the prescription and administration of medications, including the overuse of anti-depressants and anti-psychotics for individuals with mental health conditions, learning disabilities, autism or behaviour that challenges and the use of rapid tranquilisation to restrain patients in crisis. The Department of Health is currently leading a cross-Governmental review of the Mental Health Act 1983 Code of Practice. This will include updating current guidance on the use of medications for individuals subject to the Mental Health Act. We will consult on a revised Code early in the New Year.

NHS England is also leading a review on the use of medications for individuals with a learning disability or behaviour that challenges. Working with NHS Improving Quality, NHS England is developing proposals for a collaborative to highlight and share best and safe practice in the prescribing, administration, dispensing and use of medications for individuals with a learning disability or behaviour that challenges. The proposals for the collaborative are currently being finalised and it will be launched shortly.

RECORDING OF ROUTINE OBSERVATIONS

Recommendation 243

The recording of routine observations on the ward should, where possible, be done automatically as they are taken, with results being immediately accessible to all staff electronically in a form enabling progress to be monitored and interpreted. If this

cannot be done, there needs to be a system whereby ward leaders and named nurses are responsible for ensuring that the observations are carried out and recorded.

Accepted.

In the initial Government response to The Inquiry, *Patients First and Foremost*, the Department of Health gave strong support to supervisory roles for Ward Managers (including Sister, Charge Nurse and Team Leader) in delivering oversight to all aspects of care on a ward and in a community, from cleanliness to allocation of staff. Nurse leadership at ward level provided by a Ward Manager is also important to the delivery of safe, high-quality care to patients. However, we wish to allow for local flexibility in delivering nursing care and so the Government is not mandating that ward nurse managers must operate in a supervisory capacity.

Having sufficient nurses trained and with the capacity to respond to ensure the delivery of safe, patient focused care is currently a core standard requirement of the Care Quality Commission. *Compassion in Practice* commits to ensuring we have the right staff, with the right skills in the right place. This includes supporting leaders to be supervisory, giving them time to lead action plans by December 2013.

The Government's Information Strategy, published in May 2012, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213689/dh_134205.pdf outlines the use of routine observations in improving the quality of data saying: 'Connected information can support safer, more integrated care for us and for the professionals providing our care – for example, through online access to GP records in hospitals, electronic prescriptions, barcode-scanning in care homes and hospitals to reduce medication errors, and electronic access to results, X-rays and scans. Many benefits and efficiencies can be achieved through information being recorded once, at first contact, and shared securely between those providing our care.'

In October 2012 the Prime Minister announced the Nursing Technology Fund, an investment fund of £100 million spread over 2013–14 and 2014–15. Three key technology types have been identified: digital pens, mobile technology and, of relevance to this recommendation, end of bed monitoring technologies. Full details of how NHS providers will be able apply for funding are to be announced shortly. The Nursing Technology Fund is available to support nurse or midwife led activity in all NHS Trusts and Foundation Trusts in England, including acute, community, mental health and ambulance trusts.

Local Healthwatch organisations are using their 'enter and view' powers to get a clear picture of how health and care services are meeting the needs of the public, and their place on every local health and wellbeing board will ensure that voices of people using services is at the heart of local planning and decision-making. Local Healthwatch will also enhance the new inspection regimes. They will make sure inspection teams get a comprehensive picture of local people's opinions and concerns, and will maintain a focus on service quality issues after the inspection team has moved on.

Information

It is important that data for the public and those who regulate, commission or provide services are shared openly and in a timely fashion.

The public will, over time, have greater access to information about their care and treatment. From 2015 every patient should be able to see their own GP record online and book appointments and repeat prescriptions.

National data will become increasingly available. This includes information from the Care Quality Commission's new inspection regime; outcome data from a range of specialities published by NHS England, and information on avoidable mortality. Such information must be coordinated to ensure that an unnecessary burden is minimised. The Health and Social Care Information Centre will increasingly become the focal point for data collected at the national level and will become a checkpoint for those seeking new data collections. Information will be shared more quickly and through centralised sites like NHS Choices, the Health and Social Care Information Centre's Indicator portal and care.data.

COMMON INFORMATION PRACTICES, SHARED DATA AND ELECTRONIC RECORDS

Recommendation 244

There is a need for all to accept common information practices, and to feed performance information into shared databases for monitoring purposes. The following principles should be applied in considering the introduction of electronic patient information systems:

- **Patients need to be granted user friendly, real time and retrospective access to read their records, and a facility to enter comments. They should be enabled to have a copy of records in a form useable by them, if they wish to have one. If possible, the summary care record should be made accessible in this way.**
- **Systems should be designed to include prompts and defaults where these will contribute to safe and effective care, and to accurate recording of information on first entry.**
- **Systems should include a facility to alert supervisors where actions which might be expected have not occurred, or where likely inaccuracies have been entered.**

- **Systems should, where practicable and proportionate, be capable of collecting performance management and audit information automatically, appropriately anonymised direct from entries, to avoid unnecessary duplication of input.**
- **Systems must be designed by healthcare professionals in partnership with patient groups to secure maximum professional and patient engagement in ensuring accuracy, utility and relevance, both to the needs of the individual patients and collective professional, managerial and regulatory requirements.**

Systems must be capable of reflecting changing needs and local requirements over and above nationally required minimum standards.

Accepted.

There is both a need for common information practices that support the extraction of data to central systems to support improvements in data quality and service provision, and a need for electronic patient systems.

The *Health and Social Care Act 2012*⁹⁰ gives the Secretary of State for Health and NHS England powers to publish, or adopt, data standards that specify how data should be processed. To support this work the Health and Social Care Information Centre also publishes performance information and statistics, using transparent calculations, so that they can be used across the health and care system. The Health and Social Care Information Centre's *Indicator Portal*⁹¹ which will extend this service.

Access to the summary care record is being rolled out across England and we will assess options for making them more accessible electronically.

We also agree that patients should have access to their own records. By spring 2015 every patient will be able to see their records, test results, book appointments and order repeat prescriptions online. See *Everyone Counts: Planning for Patients 2013–14*⁹² (NHS England, December 2012). Patients will also be able to communicate with their practice electronically as outlined in *The Power of Information*⁹³ (Department of Health, May 2012).

While we expect practices to make patients' records available online as fully possible, some practices will only be able to make records available from a specific date due to the way the records were stored originally.

The Department of Health is committed to connecting existing systems rather than expecting every organisation to use the same technology, see *Liberating the NHS: An Information Revolution*⁹⁴ (Department of Health, July 2010) and *The Power of Information*⁹⁵ (Department of Health, May 2012). As such, GP practices will set specific requirements for electronic patient records locally, based on national standards to ensure that information can be shared across

90 <http://www.legislation.gov.uk/ukpga/2012/7/contents>

91 <http://www.hscic.gov.uk/indicatorportal>

92 <http://www.england.nhs.uk/everyonecounts/>

93 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213689/dh_134205.pdf

94 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216664/dh_129580.pdf

95 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213689/dh_134205.pdf

the system. As such it is for local organisations to consider the substance of the points raised in this recommendation in that light.

Some national standards have already been set, including the use of the NHS number, and further standards will be included in NHS England's Technology Strategy, which is due to be published in early 2014.

As part of NHS England's publication *Safer Hospitals, Safer Wards: Achieving an Integrated Digital Care Record*⁹⁶ (July 2013) it announced a £260 million technology fund that can be used by NHS Foundation Trusts and NHS Trusts to progress their activities to replace paper based systems for patient notes with integrated digital care records. NHS organisations can also apply for funding to support them improve efficiency, quality and safety by introducing ePrescribing systems.

BOARD ACCOUNTABILITY

Recommendation 245

Each provider organisation should have a board level member with responsibility for information.

Accepted in principle.

Boards must have both reliable intelligence to support the delivery of high quality care and the skills and training needed to use that intelligence appropriately.

While it is for Trusts to agree the roles and responsibilities of individual Board members locally, in line with this recommendation the Department of Health supports:

- the NHS Leadership Academy who set out clear roles for Executive Directors in taking '*... principal responsibility for providing accurate, timely and clear information to the board*' as part of *The Healthy NHS Board*⁹⁷ (NHS Leadership Academy, 2013); and
- forums such as the Chief Clinical Information Officers Leaders Network, established by eHealth Insider, with the support of the Royal College of Physicians, to support doctors, nurses and allied health professionals who are taking the lead on information and its use within organisations.

The Department also support programmes that embed informatics within the work of non-board members including clinicians and staff. These include the Clinical Leaders Network's *Embedding Informatics in Clinical Education*,⁹⁸ an online tool to train about the use of informatics in clinical work.

In addition, the Care Quality Commission's new inspection process includes an assessment of whether a provider is well led. In *A New Start*⁹⁹ (Care Quality Commission, July 2013)

96 <http://www.england.nhs.uk/wp-content/uploads/2013/07/safer-hosp-safer-wards.pdf>

97 <http://www.leadershipacademy.nhs.uk/wp-content/uploads/2013/06/NHSLeadership-HealthyNHSBoard-2013.pdf>

98 <http://www.cln.nhs.uk/eice/>

99 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

they stated that ‘well led’ providers will have effective leadership that listens and learns from information about services such that they are able to have open discussions about the quality of services that are evidence based. The Care Quality Commission will start inspecting all acute service providers from 2014 using this new process.

COMPARABLE QUALITY ACCOUNTS

Recommendation 246

Department of Health/the NHS Commissioning Board/regulators should ensure that provider organisations publish in their annual quality accounts information in a common form to enable comparisons to be made between organisations, to include a minimum of prescribed information about their compliance with fundamental and other standards, their proposals for the rectification of any non-compliance and statistics on mortality and other outcomes. Quality accounts should be required to contain the observations of commissioners, overview and scrutiny committees, and Local Healthwatch.

Accepted.

While Quality Accounts provide information about local providers’ performance, and should be flexible enough to support reporting at that level, they should also contain key information, in a common form, that allows direct comparisons to be made. This includes information on compliance with basic requirements and performance on key metrics including a set of outcome statistics.

The *National Health Service (Quality Accounts Regulations) 2010*,¹⁰⁰ the *National Health Service (Quality Accounts) Amendment Regulations 2011*¹⁰¹ and the *National Health Service (Quality Accounts) Amendment Regulations 2012*¹⁰² set out prescribed information that must be included within Part 2 of the Quality Accounts.

This includes the following information:

- where the provider is subject to periodic review by the Care Quality Commission including:
 - the date of the most recent review;
 - the assessment made by the Care Quality Commission following the review;
 - the action the provider intends to take to address the points made in that assessment by the Care Quality Commission; and
 - any progress the provider has made in taking the action identified in the point above prior to the end of the reporting period.
- the value and banding of the summary hospital level mortality indicator; and

100 http://www.legislation.gov.uk/uksi/2010/279/pdfs/ukxi_20100279_en.pdf

101 http://www.legislation.gov.uk/uksi/2011/269/pdfs/ukxi_20110269_en.pdf

102 http://www.legislation.gov.uk/uksi/2012/3081/pdfs/ukxi_20123081_en.pdf

- other outcome measures including *C. difficile* per 100,000 bed days and the percentage of patients admitted to hospital who were risk assessed for venous thromboembolism. In addition, NHS England will issue guidance in October 2013 to include the patient component of the friends and family test as part of these measures.

In addition, the *National Health Service (Quality Accounts) Amendment Regulations 2012*¹⁰³ require all Quality Accounts to include an annex that contains the statements of the:

- Overview and Scrutiny Committee or joint Overview and Scrutiny Committee carrying out the functions of that Overview and Scrutiny Committee;
- relevant clinical commissioning group or NHS England where 50% or more of the relevant health services that the provider directly provides or sub-contracts during the reporting period are under contracts or arrangements with NHS England; and
- local Healthwatch organisation.

ACCOUNTABILITY FOR QUALITY ACCOUNTS

Recommendation 247

Healthcare providers should be required to lodge their quality accounts with all organisations commissioning services from them, Local Healthwatch, and all systems regulators.

Accepted.

The *National Health Service (Quality Accounts Regulations) 2010*¹⁰⁴ require that by 30 June following the end of the reporting period, Quality Accounts must be published by making them electronically available on the NHS Choices website or another website if that website is not available at the time of publication.

Prior to publication, and within 30 days of 1 April following the end of the reporting period, each provider is required to make a copy of the draft Quality Account available to the appropriate Local Healthwatch organisation, Overview and Scrutiny Committee and Clinical Commissioning Group.

Where 50% or more of the relevant health services that the provider directly provides or sub-contracts during the reporting period are under contracts or arrangements with NHS England the provider must make the draft Quality Account available to NHS England rather than a Clinical Commissioning Group.

Recommendation 248

Healthcare providers should be required to have their quality accounts independently audited. Auditors should be given a wider remit enabling them to use their professional judgement in examining the reliability of all statements in the accounts.

103 http://www.legislation.gov.uk/uksi/2012/3081/pdfs/uksi_20123081_en.pdf

104 http://www.legislation.gov.uk/uksi/2010/279/pdfs/uksi_20100279_en.pdf

Accepted.

Quality accounts are independently audited by external auditors of Foundation and non-Foundation Trusts.

For NHS Trusts, Directors of the Trust should take steps to assure themselves that their Quality Accounts comply with the requirements set out in the legislation governing Quality Accounts: Part 1 chapter 2 of the *Health Act 2009*¹⁰⁵ and the *National Health Service (Quality Accounts Regulations) 2010*¹⁰⁶ and the *National Health Service (Quality Accounts) Amendment Regulations 2012*.¹⁰⁷ A statement of Directors' responsibilities confirming that these steps have been taken must be included in the Trust's published Quality Account. Monitor requires Foundation Trusts to obtain an audit opinion on their Quality Accounts, this includes an opinion that the contents of the Quality Accounts comply with regulations and also an opinion on selected indicators included in the accounts.

Auditors also provide a signed limited assurance on a small number of indicators and provide assurance on the number of patient safety incidents that occurred within the Foundation Trust.

The Trust must produce an Annual Governance Statement, the content of which is determined by the Trust, which refers to the steps taken to assure themselves that their Quality Account is reliable and accurate.

In 2012–13 external assurance requires Foundation Trust auditors to:

- review the content of the Quality Report against the requirements set out in the *NHS Foundation Trust Annual Reporting Manual 2012–13*¹⁰⁸ (Monitor, March 2013);
- review the content of the Quality Report for consistency against the other information sources detailed in section 2.1 of this guidance;
- provide a signed limited assurance report in the Quality Report on whether anything has come to the attention of the auditor that leads them to believe that the Quality Report has not been prepared in line with the requirements set out in the *NHS Foundation Trust Annual Reporting Manual 2012–13*¹⁰⁹ (Monitor, March 2013) and is not consistent with the other information sources detailed in section 2.1 of this guidance;
- undertake substantive sample testing on two mandated performance indicators, and the newly mandated safety incidents indicator, (to include, but not necessarily be limited to, an evaluation of the key processes and controls for managing and reporting the indicators and sample testing of the data used to calculate the indicator back to supporting documentation);

105 http://www.legislation.gov.uk/ukpga/2009/21/pdfs/ukpga_20090021_en.pdf

106 http://www.legislation.gov.uk/uksi/2010/279/pdfs/uksi_20100279_en.pdf

107 http://www.legislation.gov.uk/uksi/2012/3081/pdfs/uksi_20123081_en.pdf

108 http://www.monitor-nhsft.gov.uk/sites/default/files/publications/ToPublishAnnual_Reporting_Manual_2012-13%205%20March.pdf

109 http://www.monitor-nhsft.gov.uk/sites/default/files/publications/ToPublishAnnual_Reporting_Manual_2012-13%205%20March.pdf

- provide a signed limited assurance report in the Quality Report on whether there is evidence to suggest that the two mandated indicators subject to a limited assurance report have not been reasonably stated in all material respects in accordance with the *NHS Foundation Trust Annual Reporting Manual 2012–13*¹¹⁰ (Monitor, March 2013); and
- provide a report (the Governors' Report) to the NHS Foundation Trust's council of Governors and Board of Directors of their findings and recommendations for improvements concerning the content of the Quality Report, the two mandated indicators, subject to a limited assurance report, the additional mandated indicator and any locally selected indicator(s), if applicable.

However, in addition to the information audited outlined above, Quality Accounts also include local information that is specific to the services, priorities and needs of patients locally. While this is useful information to report on within Quality Accounts it cannot be audited externally without considerable local knowledge. Instead, Quality Accounts are verified locally for their accuracy and a declaration is signed by order of the Board by the Chairman and the Chief Executive (see recommendation 249).

We will review Quality Accounts before the 2014–15 cycle to ensure that they give patients appropriate information regarding the services they use, and that they add value to the quality assurance infrastructure used by trusts, local and national organisations. The review will consider whether the remit of the audit process could be extended further and will report in early 2014.

Recommendation 249

Each quality account should be accompanied by a declaration signed by all directors in office at the date of the account certifying that they believe the contents of the account to be true, or alternatively a statement of explanation as to the reason any such director is unable or has refused to sign such a declaration.

Accepted in part.

The *National Health Service (Quality Accounts Regulations) 2010*¹¹¹ state that Quality Accounts must include a '*...written statement... signed by the responsible person for the provider that to the best of that person's knowledge the information in the document is accurate...*' While this does not include a separate signature from each director, the Quality Account is signed as an accurate and reliable record on their behalf.

*2012–13 Detailed Guidance for External Assurance on Quality Reports*¹¹² (Monitor, March 2013) states that for 2012–13 Foundation Trusts will be required to sign a Statement of Directors' Responsibilities in respect to the Quality Report that states that performance information reported in the Quality Report is reliable and accurate. This is signed by order of the Board by the Chairman and the Chief Executive.

110 http://www.monitor-nhsft.gov.uk/sites/default/files/publications/ToPublishAnnual_Reporting_Manual_2012-13%205%20March.pdf

111 http://www.legislation.gov.uk/uksi/2010/279/pdfs/ukxi_20100279_en.pdf

112 http://www.monitor.gov.uk/sites/default/files/publications/Detailed%20Guidance%20for%20External%20Assurance%20on%20Quality%20Reports%20201213%20-%20Revised%2026%204%2013_0.pdf

*Quality Accounts: 2011–12 audit guidance*¹¹³ (Department of Health, April 2012) states that Trusts must sign a statement of Directors' responsibilities in respect of the content of their quality accounts. This includes a statement that, '*...the performance information in the Quality Account is reliable and accurate*'. This is signed by order of the Board by the Chairman and the Chief Executive.

We will review Quality Accounts before the 2014–15 cycle to ensure that they give patients appropriate information regarding the services they use, and that they add value to the quality assurance infrastructure used by trusts, local and national organisations. While the review is yet to complete, we anticipate that NHS England will implement this recommendation and include it within guidance that it intends to issue by the end of March 2014. NHS England will advise Trusts of expected changes in early 2014 to support them to plan for the 2014–15 cycle.

Recommendation 250

It should be a criminal offence for a director to sign a declaration of belief that the contents of a quality account are true if it contains a misstatement of fact concerning an item of prescribed information which he/she does not have reason to believe is true at the time of making the declaration.

Accepted in principle.

We will use the consultation on False or Misleading Information to consider whether the False or Misleading Information offence should be applied to the information on quality accounts.

The Care Bill proposes a new offence where care providers give false or misleading information. This will give providers an additional incentive to ensure data and the information it provides are accurate. The offence will aid transparency and accountability in the provision of care so that regulators, commissioners and the public have a more accurate picture about a provider's performance. The offence will apply to those care providers that falsify certain types of management and performance information and fail to exercise due diligence. Providers that make a genuine administrative error would not be convicted, providing they have processes and procedures in place to demonstrate they took all reasonable steps and exercised due diligence.

The offence will allow for the prosecution of directors and senior individuals, where the offence has been committed with their consent or connivance or through their neglect, and a successful prosecutions has been brought against the provider.

Our current intention is that regulations will limit the application of this offence in the first instance to providers of NHS funded secondary care and, more specifically, to the patient level information on outpatient, elective and accident and emergency activity that they are required to provide to the Health and Social Care Information Centre. However, we intend to test and confirm our thinking through further consultation before draft regulations are laid.

113 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/215076/dh_133425.pdf

REGULATORY OVERSIGHT OF QUALITY ACCOUNTS

Recommendation 251

The Care Quality Commission and/or Monitor should keep the accuracy, fairness and balance of quality accounts under review and should be enabled to require corrections to be issued where appropriate. In the event of an organisation failing to take that action, the regulator should be able to issue its own statement of correction.

Accepted in principle.

Where inaccurate information is identified within a Quality Account it should be changed by the provider as soon as possible.

While responsibility for the accuracy of the Quality Accounts rests with providers, their external auditors audit these accounts to provide limited assurance of their accuracy. Where issues are located the auditors provide the Board, and the Board of Governors where applicable, with a report of their findings along with recommendations for improvement (see recommendation 248). Where issues are identified as a result of the audit process the issues must be addressed by the provider. In all cases the report must be published as part of the provider's Quality Account.

ACCESS TO DATA

Recommendation 252

It is important that the appropriate steps are taken to enable properly anonymised data to be used for managerial and regulatory purposes.

Accepted.

For electronic patient records to become the core information used to improve care, services and to inform research as outlined in *The Power of Information*¹¹⁴ (Department of Health, May 2012) these records must be anonymised or used securely to protect patients' confidential information. Data also need to become more available, linked appropriately and of good quality. The Health and Social Care Information Centre set out its objectives for 2013–14 in its publication *Informing Better Care*¹¹⁵ (2013), in which it stated that it would take over data collection responsibilities from other bodies, extend its data linkage services and consolidate its position as a national source of indicators.

A range of work has been taken forward already across the system to ensure that identifiable data is used appropriately. This includes, for example:

- the Health and Social Care Information Centre has set a new anonymisation standard, from April 2013, that provides an approach and a set of standard tools to anonymise

114 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213689/dh_134205.pdf

115 http://www.hscic.gov.uk/media/11860/HSCIC-business-plan-2013-14/pdf/80305_HSCIC_Business_plan_V1.0.pdf

information to ensure that, as far as it is reasonably practicable, information published does not identify individuals;

- recent guidance published by NHS England *Information Governance and Risk Stratification: Advice and Options for clinical commissioning groups and GP*¹¹⁶ (June 2013) advises clinical commissioning groups on the use of data for predictive modeling purposes. Further approvals are being put in place to ensure that the new commissioning organisations and structures are using Patient Confidential Data appropriately;
- the Health and Social Care Information Centre publications process allows pre-publication access to many of its statistics, mostly in aggregated form, for management purposes;
- the Health and Social Care Information Centre's Hospital Episode Statistics data service and linkage service facilitate the provision of data for managerial and regulatory purposes; and
- the use of anonymised data by the Clinical Practice Research Datalink, working with the Health and Social Care Information Centre, in research using linked anonymised data, to improve and safeguard public health. The *Government's response to the Caldicott Review*¹¹⁷ (Department of Health, September 2013) concluded that, '*...the research community has established many good practices and developed robust solutions to enable access to detailed patient information while ensuring that confidentiality is protected*'.

We will continue to support this area and, specifically:

- the Health and Social Care Information Centre will publish its *Code of Practice for the Management of Confidential Information* later this year outlining principles for managing confidential data that all NHS bodies must comply with. This will build on *A Guide to Confidentiality in Health and Social Care*¹¹⁸ (Health and Social Care Information Centre, September 2013). The Code will also clarify patients' rights to know how data about them is being used and to object to the Health and Social Care Information Centre having access to that data should they wish to as outlined in *Information: To share or Not to Share*¹¹⁹ (Department of Health, March 2013);
- the Health and Social Care Information Centre, commissioned by NHS England, will make information from Care.Data available to commissioners and providers, in anonymised or aggregated form, to support the development of integrated services for patients; and

116 <http://www.england.nhs.uk/wp-content/uploads/2013/06/ig-risk-ccg-gp.pdf>

117 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/251750/9731-2901141-TSO-Caldicott-Government_Response_ACCESSIBLE.PDF

118 <http://www.hscic.gov.uk/media/12822/Guide-to-confidentiality-in-health-and-social-care/pdf/HSCIC-guide-to-confidentiality.pdf>

119 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf

ACCESS TO QUALITY AND RISK PROFILE

Recommendation 253

The information behind the quality and risk profile – as well as the ratings and methodology – should be placed in the public domain, as far as is consistent with maintaining any legitimate confidentiality of such information, together with appropriate explanations to enable the public to understand the limitations of this tool.

Accepted.

The Care Quality Commission is developing a new approach to inspection, and has started routinely publishing for the NHS the information that it uses to focus its inspections. This information is based on monitoring a set of indicators of risk, which have replaced the former quality and risk profile approach. As the Care Quality Commission carries out each inspection under its new approach, it will publish a data pack at the same time as publishing the inspection report. A data pack is a detailed analysis of key information that the Care Quality Commission holds about a provider, including its performance on risk indicators, other sources of data, and qualitative information such as views of local organisations and feedback from patients.

In June 2013, the Care Quality Commission issued *A new start – Consultation on changes to the way Care Quality Commission regulates, inspects and monitors care*.¹²⁰ This set out the new approach to inspecting hospitals, and sought views on an annex with the full set of indicators that the Care Quality Commission proposed for monitoring hospitals, to identify potential risks and the priority order for inspection. On 24 October 2013 the Care Quality Commission published a full analysis of all its monitoring indicators for all acute hospital trusts, showing their performance against the indicators. The results of this intelligent monitoring work group, the 161 acute NHS trusts into six bands based on the risk that people may not be receiving safe, effective, high quality care – with band 1 being the highest risk and band 6 the lowest. The Care Quality Commission has undertaken to update and publish these analyses quarterly, with explanation of what should and should not be read into them. *Is the service safe? Is the service effective? Is the service caring? Is the service responsive? Is the service well-led?

120 http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

ACCESS FOR PUBLIC AND PATIENTS COMMENTS

Recommendation 254

While there are likely to be many different gateways offered through which patient and public comments can be made, to avoid confusion, it would be helpful for there to be consistency across the country in methods of access, and for the output to be published in a manner allowing fair and informed comparison between organisations.

Accepted.

Feedback from patients, carers and the public can be made on the quality of care through a range of technologies and channels including online, via bedside televisions, surveys and the friends and family test.

The NHS Constitution (26 March 2013) pledges that the NHS will encourage and welcome feedback on your health and care experiences and use this to improve services. Similarly, *The Mandate*¹²¹ for NHS England (Department of Health, November 2013) states that NHS England will consider how to make it easier for patients and carers to give feedback and see reviews by other people so that timely, easy to review feedback on NHS Services becomes the norm.

A number of organisations already exist that enable patients, carers and the public to provide online feedback about their care. This includes, but is not limited to, Patient Opinion, NHS Choices, Good Care Guide and iWantGreatCare. NHS England will make such comments accessible in a coherent and consistent way through NHS Choices.

USING PATIENTS FEEDBACK

Recommendation 255

Results and analysis of patient feedback including qualitative information need to be made available to all stakeholders in as near 'real time' as possible, even if later adjustments have to be made.

Accepted.

Many local Trusts are devising innovative ways to take this forward. Feedback from patients, carers and the public can be made on the quality of care through a range of technologies and channels including online, via bedside televisions, surveys and the friends and family test.

The *NHS Constitution*¹²² (Department of Health, March 2013) pledges that the NHS will encourage and welcome feedback on your health and care experiences and use this to improve services. Similarly, *The Mandate*¹²³ (Department of Health, November 2013) states that NHS England will consider how to make it easier for patients and carers to give feedback

121 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213131/mandate.pdf

122 <http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/2013/the-nhs-constitution-for-england-2013.pdf>

123 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213131/mandate.pdf

and see reviews by other people so that timely, easy to review, feedback on NHS Services becomes the norm.

The friends and family test is currently in use in all acute inpatient services, Accident and Emergency and in maternity. By December 2014 it will be rolled out to general practice, community and mental health services and the remainder of NHS services by the end of March 2015. The test asks all patients in acute inpatients and Accident and Emergency if they would recommend the care they have just received to their friends and family if they needed similar care or treatment. The results are published for every ward and every Accident and Emergency department and in real time – within a maximum of five weeks after the feedback was collected. From ward to Board, staff and managers are able to look at the results of the friends and family test, see areas of strength and weakness and take appropriate action. Patients, the public and commissioners can see where scores are good and less good and use the results to hold services to account and commission for improvement.

A number of organisations already exist that enable patients, carers and the public to provide online feedback about their care. This includes, but is not limited to, Patient Opinion, NHS Choices, Good Care Guide and iWantGreatCare.

NHS England will make such comments accessible in a coherent and consistent way through NHS Choices and, from November 2013, as part of a national Health and Social Care Digital Service that will begin to bring together the most reliable and relevant data from national web services and act as a ‘front door’ to the best information on health and social care on the internet.

The Government’s *Information Strategy* outlined that patient feedback and information on patient experience will be an even more important influence on shaping policy and the delivery and regulation of care services. Involving people in decisions about their health, care and services should be the norm, not the exception.

In the long term, electronic health and care records may prove to be a main vehicle for providing information on health and care outcomes and status, rating our experience of care, and leaving feedback and comment. Innovations linked to our online records could enable us to record and share health comments and also prompt better conversations between us as patients or users of services and the professionals providing our care.

FOLLOWING UP PATIENTS

Recommendation 256

A proactive system for following up patients shortly after discharge would not only be good ‘customer service’, it would probably provide a wider range of responses and feedback on their care.

Accepted.

A good trust will take every opportunity to seek patient feedback. A good complaints system will recognise that some people will give fuller feedback once they have had time to reflect and therefore it is worth making arrangements to follow-up with patients once they have been discharged. Trusts will need to work out how they do this.

The Care Quality Commission will be assessing complaints as part of its inspection process.

Case study: Northumbria Healthcare – developing a meaningful patient experience programme

Northumbria Healthcare NHS Foundation Trust provides acute and community health services and adult social care to a population of over half a million people in the North East. The Trust runs nine hospitals (three general hospitals plus six community hospitals) and employs about 9000 staff. The level of engagement they now enjoy means that every day, somewhere in the organisation, somebody will be having a conversation about patient experience.

The Trust listens to the views of more than 30,000 patients every year through the following different survey methods:

- **Patient Perspective surveys:** To ensure ownership, results are reported at an individual consultant level, ward level, site and specialty and business unit level. Conducting these once people leave hospital allows them to give a more rounded view of their experience of care – evidence suggests that patients are likely to be at their most dissatisfied two weeks after discharge. In many ways this is ‘right time’ data which is less likely to be biased by the gratitude people feel towards hospital services and staff during the very acute phase.
- **Real Time Surveys:** Initially the Trust conducted face to face interviews with patients on 8 pilot wards across 2 sites. The real time programme has been rolled out incrementally allowing the Trust to improve in a sustainable way – they now interview over 500 patients a month across 7 sites and 35 wards. These results are fed back to clinical teams within 24 hours of capture, allowing the Trust to act rapidly on patient feedback while patients are still in our care.
- **2 Minutes of Your Time:** This is a short quick exit survey which allows for a broad coverage across the Trust. Patients answer 6 key questions about the quality of care just before they leave hospital – this has included the Friends and Family question for the last 3 years. All data including all free text comments are fed back to clinical teams within a week.

Communicating results with the public: The Trust has developed innovative info graphics to ensure all the experience results are shared with patients, families and the public. Posters are updated each quarter so that the latest results are always on display.

Supporting staff to deliver patient-centred care: In designing the programme in 2010 the Trust deliberately aimed for a patient centred approach. What they hadn’t appreciated was the degree to which the real time programme would engage and support staff. In the annual NHS staff survey the Trust performs exceptionally well, with 94 per cent feeling their work makes a real difference.

Key learning from implementation has included the following:

- no single method has given the Trust all they need – they continue to rely on a combined approach;
- they’ve seen significant benefits of real time reporting;
- executive management team support has been crucial;

- ensure patients and families are part of the improvement team – this could be a ward based team or multidisciplinary team across a service;
- Patients have been involved in information development, teaching and training, service evaluation and mystery shopping;
- focusing on metrics that matter most has made sense;
- incremental roll out, change and improvement has given time for the programme to embed properly;
- keep expenditure on measurement to a minimum – invest in improving instead;
- qualitative feedback appears particularly important in engaging staff; and
- transparency of reporting matters.

ROLE OF THE HEALTH AND SOCIAL CARE INFORMATION CENTRE

Recommendation 257

The Information Centre should be tasked with the independent collection, analysis, publication and oversight of healthcare information in England, or, with the agreement of the devolved governments, the United Kingdom. The information functions previously held by the National Patient Safety Agency should be transferred to the NHS Information Centre if made independent.

Accepted in principle.

We accept that the Health and Social Care Information Centre should be made more independent. In April 2013, the Health and Social Care Information Centre was established as an Executive Non Departmental Public Body to further ensure its independence in the undertaking of its key functions.

The Health and Social Care Act 2012,¹²⁴ requires the Health and Social Care Information Centre to establish and operate a system for the collection or analysis of information in connection with the provision of health services and adult social care in England. As such, its work includes the publication of more than 130 statistical publications annually; providing a range of specialist data services; managing informatics projects and programmes and developing and assuring national systems against appropriate contractual, clinical safety and information standards.

The Informatics Services Commissioning Group, established in 2013, has been set up to enable the Health and Social Care Information Centre to become the focal point for data collected at the national level so that it increasingly becomes a checkpoint for those seeking new data collections.

At this time, we do not accept that this should include the information functions previously held by the NPSA. Following the abolition of the National Patient Safety Agency, its key functions were transferred to NHS England in 2012 including functions relating to the National

124 http://www.legislation.gov.uk/ukpga/2012/7/pdfs/ukpga_20120007_en.pdf

Reporting and Learning System. The operational management of the National Reporting and Learning System was transferred for two years from 1 April 2012 to Imperial College Healthcare NHS Trust.

Given the recent transfer of these functions, the Government stated in its initial response to The Inquiry, *Patients First and Foremost*¹²⁵ (Department of Health, 2013), that reallocating these functions at this stage would be unnecessarily disruptive. We will keep this decision under review.

Recommendation 258

The Information Centre should continue to develop and maintain learning, standards and consensus with regard to information methodologies, with particular reference to comparative performance statistics.

Accepted.

The Health and Social Care Information Centre publishes, and keeps under regular review, the methodologies used for the calculation of national indicators and statistics.

To support this function the Health and Social Care Information Centre:

- has introduced an assurance process for indicators on behalf of the Quality Information Committee (a subcommittee of the National Quality Board). This process ensures that indicators are fit for purpose and is available as a service for any organisation to use. The Health and Social Care Information Centre keeps indicators under review to ensure that, where improvements or quality issues are identified, learning is maintained and lessons implemented;
- adheres to principle four the *Code of Practice for Official Statistics*¹²⁶ (UK Statistics Authority, January 2009) which states, '*Statistical methods should be consistent with scientific principles and internationally recognised best practices, and be fully documented. Quality should be monitored and assured taking account of internationally agreed practices*'; and
- publishes additional contextual data to help people use or interpret the data it publishes, including, for example, information about palliative care coding in the context of the Summary Hospital-level Mortality Indicator.

Recommendation 259

The Information Centre, in consultation with the Department of Health, the NHS Commissioning Board and the Parliamentary and Health Service Ombudsman, should develop a means of publishing more detailed breakdowns of clinically related complaints

125 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170701/Patients_First_and_Foremost.pdf

126 <http://www.statisticsauthority.gov.uk/assessment/code-of-practice/index.html>

Accepted.

The Department of Health will work with the Health and Social Care Information Centre to put complaints data into the existing NHS electronic data collection system, better enabling comparison between hospitals.

INFORMATION STANDARDS

Recommendation 260

The standards applied to statistical information about serious untoward incidents should be the same as for any other healthcare information and in particular the principles around transparency and accessibility. It would, therefore, be desirable for the data to be supplied to, and processed by, the Information Centre and, through them, made publicly available in the same way as other quality related information.

Accepted in principle.

Where appropriate to do so, information standards should be applied to the reporting of serious incidents and that such information should be made as transparent and accessible as possible. The Government also supports the principle outlined in the UK Statistics Authority's *Code of Practice for Official Statistics*¹²⁷ (January 2009) that statistical producers will publish data that meets the needs of users and are readily available to them alongside a full and frank commentary.

Responsibility for the reporting of patient safety incidents was transferred to NHS England in 2012 following the abolition of the National Patient Safety Agency. See recommendation 257 for further details. NHS England publishes patient safety incident data each month from the National Reporting and Learning System, including information on levels and severity of harm to patients.

NHS England is exploring the extent to which information on serious incidents can be disclosed in more detail without breaching the *Data Protection Act 1998*.¹²⁸ It should be noted, however, that information reported on serious incidents is provided specifically to ensure the robust management of the response to a specific serious incident. The reported information is, therefore, sensitive and has to be appropriately protected. It is not collected for the purposes of measuring activity or outcomes and is in that sense very different from other types of information collected by the Health and Social Care Information Centre.

NHS England is reviewing the National Reporting and Learning System with a range of key stakeholders including the Health and Social Care Information Centre. As part of the review NHS England will consider the reporting of data from the National Reporting and Learning System and the data standards applied to the National Reporting and Learning System to ensure, where appropriate, they are the same as those applied by the Health and Social Care Information Centre to other data streams.

127 <http://www.statisticsauthority.gov.uk/assessment/code-of-practice/index.html>

128 <http://www.legislation.gov.uk/ukpga/1998/29/contents>

NHS England is also reviewing the Strategic Executive Information System, the reporting mechanism for both clinical and information incidents, in order to consider procuring a replacement. As information incidents are also reported through the information governance toolkit held by the Health and Social Care Information Centre, consideration will be given by NHS England and the Health and Social Care Information Centre to streamlining these reporting mechanisms to reduce burden.

Recommendation 261

The Information Centre should be enabled to undertake more detailed statistical analysis of its own than currently appears to be the case.

Accepted.

The Health and Social Care Information Centre collects and publishes national data and statistical information in health and social care as required by the *The Health and Social Care Act 2012*.¹²⁹ In doing so, the Health and Social Care Information Centre also has a role in undertaking high level analysis of data, where appropriate, to support the interpretation of information prior to its publication. For example in the preparation of the Summary Hospital-level Mortality Indicator. This is a useful function and the Health and Social Care Information Centre will continue to do this wherever appropriate.

The Health and Social Care Information Centre will also ensure that data which can be interpreted locally is available and in a format that would allow individual organisations to undertake that analysis. The Health and Social Care Information Centre does not provide local level interpretative analysis, rather it will continue to ensure that such information is available so that it can be used by local trusts and data intermediaries to add value by presenting the data in ways that are most useful to specific local audiences. This is in line with the Government's Information Strategy, *The Power of Information*¹³⁰ (Department of Health, May 2012).

ENHANCING THE USE, ANALYSIS AND DISSEMINATION OF HEALTHCARE INFORMATION

Recommendation 262

All healthcare provider organisations, in conjunction with their healthcare professionals, should develop and maintain systems which give them:

- **Effective real-time information on the performance of each of their services against patient safety and minimum quality standards;**
- **Effective real-time information of the performance of each of their consultants and specialist teams in relation to mortality, morbidity, outcome and patient satisfaction.**

In doing so, they should have regard, in relation to each service, to best practice for information management of that service as evidenced by recommendations of the

129 http://www.legislation.gov.uk/ukpga/2012/7/pdfs/ukpga_20120007_en.pdf

130 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213689/dh_134205.pdf

Information Centre, and recommendations of specialist organisations such as the medical Royal Colleges.

The information derived from such systems should, to the extent practicable, be published and in any event made available in full to commissioners and regulators, on request, and with appropriate explanation, and to the extent that is relevant to individual patients, to assist in choice of treatment.

Accepted.

Timely, accurate and robust data should be used by every provider to determine the quality of the services that they provide and identify whether there are any risks to patient safety. Wherever possible, such information should be available to commissioners, regulators and the public to drive improvement and support choice.

To support this, for example:

- the NHS Leadership Academy in *The Healthy NHS Board*¹³¹ (NHS Leadership Academy, 2013) set out clear roles for regarding the use of information across the board. It stated that Executive Directors should take ‘... *principal responsibility for providing accurate, timely and clear information to the board*’. (see recommendation 245); and
- data on providers’ performance is becoming increasingly available including data at specialty level (see recommendation 264) and the provider’s compliance with quality standards (see recommendation 246 regarding quality accounts).

However, rather than determining how local providers should meet their information needs centrally, the Department of Health is committed to connecting existing systems, see *Liberating the NHS: An Information Revolution*¹³² (Department of Health, July 2010) and *The Power of Information*¹³³ (Department of Health, May 2012). As such, providers will set specific requirements locally but based on national standards to ensure that information can be shared across the system.

Some national standards have already been set, including the use of the NHS number, and further standards, such as interoperability of patient records, will be outlined in NHS England’s Technology Strategy, which is due to be published in early 2014.

Recommendation 263

It must be recognised to be the professional duty of all healthcare professionals to collaborate in the provision of information required for such statistics on the efficacy of treatment in specialties.

131 <http://www.leadershipacademy.nhs.uk/wp-content/uploads/2013/06/NHSLeadership-HealthyNHSBoard-2013.pdf>

132 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216664/dh_129580.pdf

133 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213689/dh_134205.pdf

Accepted.

The Government stated in *Patients First and Foremost*¹³⁴ (Department of Health, 2013) that, 'From 2015, [NHS England] will ensure that data on services at specialty level is increasingly available. To do this they will work with providers, patient groups and specialty level organisations and those bodies such as the Health and Social Care Information Centre and the Care Quality Commission...'

It is important for healthcare professionals to provide information of this kind which will act as a catalyst for improvements in audit quality, participation and analysis that will enable fuller transparency. As the recent publication of outcome data for a number of surgical specialties has shown, we are at the start of an age of much greater openness about the quality of care, and all in the NHS, including health professionals, need to play their part in opening up information for patients and the public. The publication of this data has already stimulated specialist societies to take ownership of the setting and monitoring of clinical standards.

Recommendation 264

In the case of each specialty, a programme of development for statistics on the efficacy of treatment should be prepared, published, and subjected to regular review.

Accepted.

*The Mandate*¹³⁵ (Department of Health, November 2013) NHS England states that, 'The NHS should measure and publish outcome data for all major services by 2015, broken down by local clinical commissioning groups where patient numbers are adequate, as well as by those teams and organisations providing care.'

To meet this commitment, the Government stated in *Patients First and Foremost*¹³⁶ (Department of Health, 2013) that, 'From 2015, [NHS England] will ensure that data on services at specialty level is increasingly available. To do this they will work with providers, patient groups and specialty level organisations and those bodies such as the Health and Social Care Information Centre and the Care Quality Commission...'

In June 2013, NHS England published the first two specialties level data, cardiac surgery and vascular, and announced the publication schedule for a further eight specialties. All specialties have now been published. NHS England will widen this programme to include other specialties over time and the data published will, initially, be refreshed annually. The data can be accessed via *NHS Choices*.¹³⁷

Recommendations 265, 266 and 267 relate to this programme of work and are responded to accordingly.

134 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170701/Patients_First_and_Foremost.pdf

135 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213131/mandate.pdf

136 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170701/Patients_First_and_Foremost.pdf

137 <http://www.nhs.uk/choiceintheNHS/Yourchoices/consultant-choice/Pages/consultant-data.aspx>

Recommendation 265

The Department of Health, the Information Centre and the Care Quality Commission should engage with each representative specialty organisation in order to consider how best to develop comparative statistics on the efficacy of treatment in that specialty, for publication and use in performance oversight, revalidation, and the promotion of patient knowledge and choice.

Accepted.

On behalf of NHS England, the Healthcare Quality Improvement Partnership has worked with specialist associations to develop the data referred to in recommendation 264 from selected national clinical and medical audits for consultants practising in these areas. The data is currently made available through [NHS Choices](http://www.nhs.uk/choiceintheNHS/Yourchoices/consultant-choice/Pages/consultant-data.aspx)¹³⁸ websites so that it can be used to meet a wide range of purposes. Providers will be expected to link to this data from their own websites from the summer of 2013.

NHS England will continue to work on how to improve the experience of this data through NHS Choices and promote patient knowledge and choice.

Recommendation 266

In designing the methodology for such statistics and their presentation, the Department of Health, the Information Centre, the Care Quality Commission and the specialty organisations should seek and have regard to the views of patient groups and the public about the information needed by them.

Accepted.

There is a clear role for the users of services in the development of appropriate information and statistics. The UK Statistics Authority's *Code of Practice for Official Statistics*¹³⁹ (January 2009) outlines a protocol on user engagement the basis of which, including the need to understand the requirements and views of the users of information, are applicable to the development of all information.

The Health and Social Care Information Centre works with a range of relevant stakeholders and experts in the design and presentation of its statistics. It recognises that it needs to do more in this regard, and will be reviewing its publications strategy accordingly.

While the initial development of specialty level statistics as outlined in recommendation 264 had limited input from patient groups, NHS England will consider carefully the role of service users in taking this programme of work forward.

Recommendation 267

All such statistics should be made available online and accessible through provider websites, as well as other gateways such as the Care Quality Commission.

138 <http://www.nhs.uk/choiceintheNHS/Yourchoices/consultant-choice/Pages/consultant-data.aspx>

139 <http://www.statisticsauthority.gov.uk/assessment/code-of-practice/index.html>

Accepted.

The data referred to in recommendation 264 is made available through [NHS Choices](#)¹⁴⁰ website so that it can be used to meet a wide range of purposes. Providers are expected to link to this data from their own websites from the summer of 2013.

NHS England will continue to work on how to improve the experience of this data through NHS Choices and promote patient knowledge and choice.

RESOURCES

Recommendation 268

Resources must be allocated to and by provider organisations to enable the relevant data to be collected and forwarded to the relevant central registry.

Accepted.

In order to ensure that good quality data is collected locally and made available to central repositories such as the Health and Social Care Information Centre, resources need to be available to providers of services such that collections of data can be undertaken.

A wide range of data is collected locally to be used by providers, commissioners, regulators, patients and the public to determine performance and compliance with basic requirements of quality and safety. For example, recommendation 246 discusses data needed for comparable quality accounts and 98 recommendation outlines the reporting of serious patient safety incidents via the National Reporting and Learning System.

Where collections are mandated, resources are allocated to the provider as part of their overall budgets, by the relevant commissioning body via the NHS Standard Contract, to ensure their collection. It is the responsibility of all providers to ensure that resources are allocated internally to ensure that data are collected and made available as appropriate.

In addition to this, we also support initiatives that improve the use of appropriate technology and remove unnecessary burden from the collectors of data. The NHS Confederation's review, *Challenging Bureaucracy* (2013), the work and tools developed by the Health and Social Care Information Centre in busting bureaucracy, and NHS England's Clinical Bureaucracy Index are all intended to support a reduction of burden, nationally and locally, to allow staff to focus on the delivery of good quality care.

IMPROVING AND ASSURING ACCURACY

Recommendation 269

The only practical way of ensuring reasonable accuracy is vigilant auditing at local level of the data put into the system. This is important work, which must be continued and where possible improved.

140 <http://www.nhs.uk/choiceintheNHS/Yourchoices/consultant-choice/Pages/consultant-data.aspx>

Accepted.

It is the role of local providers to ensure that the accuracy of the data it generates and submits into the system. As such, existing requirements for local audit of clinical records and the external audit of clinical coding data quality are important and will continue.

However, the Health and Social Care Information Centre also has an important role to play regarding the assurance of the quality of the data it receives. It will assess the extent to which the information it collects meets the information standards and publish its findings routinely, when it publishes data or statistics.

The Health and Social Care Information Centre published the first national data quality report, *The Quality of Nationally Submitted Health and Social Care Data in England – 2012*¹⁴¹ (July 2012) which highlighted a number of consistent areas which lead to poor quality data including:

- lack of standards and guidance;
- poor training and awareness of the impact of poor quality data;
- local system updates and changes;
- reorganisation and reconfiguration of services; and
- knowledge and use of the data and its quality.

The Health and Social Care Information Centre has published its second annual report, *The Quality of Nationally Submitted Health and Social Care*¹⁴² (September 2013) built on these areas.

The Health and Social Care Information Centre is also developing a *National Data Quality Assurance Framework* that will outline data quality standards and compliance with these standards. The Health and Social Care Information Centre will publish these assessments in order to incentivise improvement in the quality of data. In 2012–13 The Health and Social Care Information Centre will develop the National Data Quality Assurance Framework by, for example:

- defining, developing and expanding measures for assessing data quality to provide more comprehensive assessments in future years;
- reviewing and developing collection and reporting systems and providing consistent and visible outputs on the quality of data; and
- publishing data quality assessments on a more frequent basis in the year.

The Health and Social Care Information Centre also produce a range of data quality reports and dashboards to help local providers improve the quality of the data they return. These include, for example, in relation to the Secondary Uses Service, Hospital Episode Statistics and the Mental Health Minimum Data Set.

141 <https://catalogue.ic.nhs.uk/publications/data-quality/quality/qual-nat-sub-heal-soc-care-data-eng-2012/firs-annu-data-qual-rep-2012-rep1.doc>

142 <https://catalogue.ic.nhs.uk/publications/data-quality/quality/second-annu-data-qual-rep-2013/second-annu-data-qual-rep-2013.pdf>

Recommendation 270

There is a need for a review by the Department of Health, the Information Centre and the UK Statistics Authority of the patient outcome statistics, including hospital mortality and other outcome indicators. In particular, there could be benefit from consideration of the extent to which these statistics can be published in a form more readily useable by the public.

Accepted.

The UK Statistics Authority is undertaking an independent review of patient outcome statistics recognised as official statistics. The review, among other things, is considering how to make such statistics more readily useable by the public. In undertaking the review the UK Statistics Authority has had discussions with the Health and Social Care Information Centre, NHS England, Department of Health, Care Quality Commission and the Office for National Statistics. The report will be published later in 2013 and we will study its findings closely with a view to help improve presentation of statistics to patients and the public.

Recommendation 271

To the extent that summary hospital-level mortality indicators are not already recognised as national or official statistics, the Department of Health and the Health and Social Care Information Centre should work towards establishing such status for them or any successor hospital mortality figures, and other patient outcome statistics, including reports showing provider-level detail.

Accepted.

The Summary Hospital-level Mortality Indicator which reports mortality data at trust level across the NHS in England, has been produced and published by the Health and Social Care Information Centre as an experimental Official Statistic since October 2011 (The data can be accessed from www.hscic.gov.uk/SHMI).

The UK Statistics Authority's independent review of patient outcome statistics referred to in relation to recommendation 270 includes in scope a review of the Summary Hospital-level Mortality Indicator, its accessibility to patients and the public, and its status as Official Statistics. We expect the review to recommend that the Summary Hospital-level Mortality Indicator is assessed by UK Statistics Authority against the *Code of Practice for Official Statistics*¹⁴³ (January 2009) with a view to securing designation as National Statistics.

In July 2013, Professor Sir Bruce Keogh published his *Review into the quality of care and treatment provided by 14 hospital trusts in England*.¹⁴⁴ In his report Sir Bruce announced that he had asked Professor Nick Black and Professor Lord Ara Darzi to undertake a study into the relationship between excess mortality rates and actual avoidable deaths. This study is expected to pave the way for the introduction of a new national indicator on avoidable deaths in hospital measured through case notes reviews.

143 <http://www.statisticsauthority.gov.uk/assessment/code-of-practice/index.html>

144 <http://www.nhs.uk/NHSEngland/bruce-keogh-review/Documents/outcomes/keogh-review-final-report.pdf>

Recommendation 272

There is a demonstrable need for an accreditation system to be available for healthcare-relevant statistical methodologies. The power to create an accreditation scheme has been included in the Health and Social Care Act 2012, it should be used as soon as practicable.

Accepted.

The *Health and Social Care Act 2012*¹⁴⁵ established powers for the Health and Social Care Information Centre to establish an accreditation scheme for information service providers. The Act allows the Health and Social Care Information Centre to establish a procedure, and set of criteria, for accrediting any information service providers.

The Health and Social Care Information Centre set out its objectives for 2013–14 in its publication *Informing Better Care*¹⁴⁶ (2013) including the delivery of all of its statutory responsibilities as set out in the *Health and Social Care Act 2012*.¹⁴⁷ The ambitious program includes the delivery of a safe transition from the existing information standards products and services in to the new operating model and the fulfillment of its data quality assurance roles. Given the scope of the program the Health and Social Care Information Centre has committed to deliver, they will not take forward an accreditation system this financial year but will consider how such a system can be taken forward in 2014–15.

145 <http://www.legislation.gov.uk/ukpga/2012/7/contents>

146 http://www.hscic.gov.uk/media/11860/HSCIC-business-plan-2013-14/pdf/80305_HSCIC_Business_plan_V1.0.pdf

147 <http://www.legislation.gov.uk/ukpga/2012/7/contents>

Coroners and inquests

The roles of coroners and medical examiners are key to taking forward the Inquiry's recommendations in this area.

The *Coroners and Justice Act 2009*¹⁴⁸ states that it is an offence to distort, alter or prevent evidence being provided for the purposes of an investigation, and it is vital that those responsible for disclosing information locally to coroners prioritise openness in sharing such information to support investigations into deaths.

To support the use of information, the Chief Coroner's Office has issued further guidance to coroners regarding sharing *Reports to Prevent Future Deaths* (previously referred to as 'rule 43' reports) with the Care Quality Commission and the Judicial College will continue to develop training to support coroners' officers in undertaking their roles including how to involve the bereaved when gathering information.

In addition, we expect to consult on the role of medical examiners and death certification including on the draft regulations that will underpin many of the changes needed to support The Inquiry's recommendations in these areas. The role of the medical examiner, where deployed in sufficient numbers by the local authorities and supported by appropriate guidance and training, will begin to improve the accuracy of death certification and the consistency in collecting information about a death including from the bereaved.

INFORMATION TO CORONERS

Recommendation 273

The terms of authorisation, licensing and registration and any relevant guidance should oblige healthcare providers to provide all relevant information to enable the coroner to perform his function, unless a director is personally satisfied that withholding the information is justified in the public interest.

Accepted in principle.

All relevant information should be shared with coroners to ensure that they are able to perform their roles fully. The *Coroners and Justice Act 2009* states that, '*It is 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*

148 <http://www.legislation.gov.uk/ukpga/2009/25/contents>

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’.

The Government does not agree, however, that this should be required in terms of the registration of providers by the Care Quality Commission the function of which is to ensure that providers meet a much wider set of basic requirements to ensure patients’ effective and safe treatment and care.

Recommendation 274

There is an urgent need for unequivocal guidance to be given to trusts and their legal advisers and those handling disclosure of information to coroners, patients and families, as to the priority to be given to openness over any perceived material interest.

Accepted.

The *Coroners and Justice Act 2009*¹⁴⁹ states that, ‘*It is 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’.*

Intentionally suppressing, concealing, altering or destroying a relevant document, except under specific circumstances, is an offence that may result in a fine and/or imprisonment.

INDEPENDENT MEDICAL EXAMINERS

Recommendation 275

It is of considerable importance that independent medical examiners are independent of the organisation whose patients’ deaths are being scrutinised.

Accepted in principle.

The Government agrees that medical examiners must be independent of the deceased and their medical practitioner. This is because medical examiners need carry out independent scrutiny of the medical circumstances and cause of apparently natural deaths, to ensure that the right deaths are notified or referred to a coroner.

However, we also need to ensure that there are sufficient numbers of medical examiners to carry out this work (recommendation 276), particularly in rural areas, and, therefore, appointees are likely to have some sort of professional relationship with local care providers.

As such, the draft death certification regulations for medical examiners in England does not require that medical examiners are independent of the organisation whose patients’ deaths are being scrutinised. However in order to support a greater level of independence in line with the spirit of this recommendation, the Government will review how it can include further safeguards to ensure that independence is protected.

149 <http://www.legislation.gov.uk/ukpga/2009/25/contents>

Where a medical examiner has any concern that their independence has, or will be, compromised, they are able to raise those concerns directly with the appropriate local authority and/or the National Medical Examiner as needed. The Government will consider the role of the National Medical Examiner further, and the need for best practice guidance, to ensure that medical examiners are not put under any pressure to operate where their independence is compromised.

Recommendation 276

Sufficient numbers of independent medical examiners need to be appointed and resourced to ensure that they can give proper attention to the workload.

Accepted.

The *Coroners and Justice Act 2009*¹⁵⁰ requires the appointment of enough medical examiners, and the availability of sufficient funds and resources, to ensure the functions of medical examiners are discharged within the appointing area.

It is the responsibility of local authorities, who will appoint medical examiners, to ensure that this is the case. However, to support local authorities in this task, the Department of Health will provide each local authority with estimated numbers of medical examiners that may be required locally based on expected levels of death and workload and match resourcing for medical examiners to that estimation.

DEATH CERTIFICATION

Recommendation 277

National guidance should set out standard methodologies for approaching the certification of the cause of death to ensure, so far as possible, that similar approaches are universal.

Accepted.

We intend to publish draft death certification regulations that states that the Chief Medical Officer of the Department of Health must issue guidance on how death certification forms are completed. This will include a standard methodology for completing medical certificate of cause of death and replace previous guidance including that supplied with the book of medical certificates of cause of death to doctors.

In addition, medical examiners will support doctors completing medical certificates of cause of death to ensure that they are consistent and of sufficient quality and may recommend further training for doctors where that is deemed necessary.

Recommendation 278

It should be a routine part of an independent medical examiners's role to seek out and consider any serious untoward incidents or adverse incident reports relating to

150 <http://www.legislation.gov.uk/ukpga/2009/25/contents>

the deceased, to ensure that all circumstances are taken into account whether or not referred to in the medical records.

Accepted.

The Government intends to publish draft death certification regulations for medical examiners in England that will require that medical examiners obtain and consider information available about patient safety to inform their professional judgement as to the cause of death in a particular case.

The Royal College of Pathologists and e-Learning for Healthcare have produced an online learning module to help those involved in the certification of death. This will be updated as soon as possible to reflect these recommendations.

Recommendation 279

So far as is practicable, the responsibility for certifying the cause of death should be undertaken and fulfilled by the consultant, or another senior and fully qualified clinician in charge of a patient's case or treatment.

Accepted.

Existing guidance that is provided with medical certificates of cause of death states that death certification should be completed by a consultant or senior clinician, although this could be delegated to a junior doctor who was in attendance but only where they are closely supervised. This advice will be retained in the new guidance issued by the Chief Medical Officer to accompany the new set of medical certificates of cause of death.

The Department of Health intends to publish draft death certification regulations that states that an attending practitioner is a registered medical practitioner who:

- attended the deceased in the last 28 days for the condition or disease that caused their death, or
- is a partner or employee of the same general practice as the attending practitioner and has attended the deceased within the last 12 months for the disease or condition that caused their death.

To support those certifying the cause of death:

- the Chief Medical Officer will issue guidance on how death certification forms are completed in 2014 that will replace existing guidance, and medical examiners will support doctors completing medical certificates of cause of death to ensure that they are consistent and of sufficient quality and may recommend further training where that is deemed necessary.

APPROPRIATE AND SENSITIVE CONTACT WITH BEREAVED FAMILIES

Recommendation 280

Both the bereaved family and the certifying doctor should be asked whether they have any concerns about the death or the circumstances surrounding it, and guidance should be given to hospital staff encouraging them to raise any concerns they may have with the independent medical examiner.

Accepted.

The Department of Health intends to publish draft death certification regulations that requires medical examiners to make arrangements to speak to anyone they consider necessary to discuss the circumstances and causes of death and to provide them with the opportunity to mention any matter that might cause a senior coroner to think that the death should be investigated. This includes the family of the deceased and/or the provider of care services.

In addition, the certifying doctor can provide any information necessary in establishing the cause of death or to protect individuals health and safety along with his/her certificate for scrutiny.

Recommendation 281

It is important that independent medical examiners and any others having to approach families for this purpose have careful training in how to undertake this sensitive task in a manner least likely to cause additional and unnecessary distress.

Accepted.

The Royal College of Pathologists and e-Learning for Healthcare have produced an online learning module to help those involved in the certification of death. The training is open to all NHS staff along with all prospective medical examiners.

This training consists of 91 sessions within 11 modules that fully trained Medical Examiners will be expected to complete. This training includes a module on interacting with the bereaved and covers topics on the bereavement office; the psychology of bereavement and loss and the medical examiner's role; and supporting the bereaved.

Prior to application, all candidates are required to complete a core component of the 91 sessions and present the local appointing panel with a certification of its completion as part of the application process.

Where an application is successful, the medical examiner will receive face-to-face training organised by the Royal College of Pathologists and must complete the remaining e-Learning within a year.

The e-Learning is currently being reviewed and Royal College of Pathologists and e-Learning for Healthcare will consider recommendations 277, 278, 280 in taking that forward.

INFORMATION FOR, AND FROM, INQUESTS

Recommendation 282

Coroners should send copies of relevant Rule 43 reports to the Care Quality Commission.

Accepted.

The *Coroners and Justice Act 2009*¹⁵¹ states that where a senior coroner has conducted an investigation and anything has been revealed that indicates a risk of other deaths then the coroner, ‘...must report the matter to a person who the coroner believes has the power to take such action’. (Schedule 5, Paragraph 7).

As stated in recommendation 45, the Care Quality Commission already receives prevention of future death reports (previously referred to as rule 43 reports). In September 2013 the Chief Coroner’s Office sent out additional guidance, *Reports to prevent Future Deaths*, to coroners to further support the sharing of this information. This guidance stated that, ‘Coroners should routinely send relevant reports to other organisations, such as ... the Care Quality Commission’

Recommendation 283

Guidance should be developed for coroners’ offices about whom to approach in gathering information about whether to hold an inquest into the death of a patient. This should include contact with the patient’s family.

Accepted.

The Judicial College has taken responsibility for training all coroners and coroner’s officers under the remit of the Chief Coroner’s Office from July 2013. The College has already supplied training to coroners on the *Coroners and Justice Act 2009*¹⁵² and will develop training for all coroners’ officers on their roles. This will cover how to involve bereaved families when gathering information in connection with the coroner’s investigation. We anticipate that this training will be available from 2014.

APPOINTMENT OF ASSISTANT DEPUTY CORONERS

Recommendation 284

The Lord Chancellor should issue guidance as to the criteria to be adopted in the appointment of assistant deputy coroners.

Accepted.

This has been taken forward by the Chief Coroner. Local Authorities are responsible for all coroner appointments with the consent of the Lord Chancellor and the Chief Coroner.

151 <http://www.legislation.gov.uk/ukpga/2009/25/contents>

152 <http://www.legislation.gov.uk/ukpga/2009/25/contents>

The Ministry of Justice and the Chief Coroner have developed guidance, *The Appointment of Coroners (July 2013)*, for Local Authorities on coronial appointments, including the qualifications and process for all coroner appointments. The guidance specifies details for the appointment of assistant coroners based on the main process for senior coroners with an understanding that there may be a need for appropriate flexibility due to the volume of posts and the need to involve the senior coroner in the process.

This guidance is intended to ensure that the process for appointments is as robust, consistent and transparent as possible.

APPOINTMENT OF ASSISTANT DEPUTY CORONERS

Recommendation 285

The Chief Coroner should issue guidance on how to avoid the appearance of bias when assistant deputy coroners are associated with a party in a case.

Accepted.

The Chief Coroner will look carefully at the issue of bias, and the appearance of bias, and consider whether guidance or training by the Judicial College could be used to address these concerns.

Department of Health leadership

The Inquiry set out a number of challenges for the Department of Health in its report. The Department is putting in place measures to ensure it takes on those challenges by connecting to health and care organisations, making policy more effectively and working to ensure it has the right culture and practices in place to be an effective steward of the health and care system.

IMPACT ASSESSMENTS BEFORE STRUCTURAL CHANGE

Recommendation 286

Impact and risk assessments should be made public, and debated publicly, before a proposal for any major structural change to the healthcare system is accepted. Such assessments should cover at least the following issues:

- **What is the precise issue or concern in respect of which change is necessary?**
- **Can the policy objective identified be achieved by modifications within the existing structure?**
- **How are the successful aspects of the existing system to be incorporated and continued in the new system?**
- **How are the existing skills which are relevant to the new system to be transferred to it?**
- **How is the existing corporate and individual knowledge base to be preserved, transferred and exploited?**
- **How is flexibility to meet new circumstances and to respond to experience built into the new system to avoid the need for further structural change?**
- **How are necessary functions to be performed effectively during any transitional period?**
- **What are the respective risks and benefits to service users and the public and, in particular, are there any risks to safety or welfare?**

Accepted.

It is good practice for all major changes of policy and of system structure to be carefully considered and taken forward on the basis of a clearly defined purpose and with a clear and detailed implementation plan that takes account of the major risks to the safety or welfare of patients, and to the effective operation of the system. When the policy or change of system

structure is completed, or has advanced to a predetermined degree, it should undergo a comprehensive evaluation.

Recommendation 287

The Department of Health should together with healthcare systems regulators take the lead in developing through obtaining consensus between the public and healthcare professionals, a coherent, and easily accessible structure for the development and implementation of values, fundamental, enhanced and developmental standards as recommended in this report.

Accepted.

The Care Quality Commission has consulted on fundamental standards of care, which the Department of Health will reflect in regulations. While the focus is on hospital services in the first instance, a new Chief Inspector of General Practice and Chief Inspector of Adult Social Care took up post in the Care Quality Commission in October 2013 and will extend and develop guidance on the regulations for providers into their respective sectors.

Attention will be given to how the fundamental standards of care are presented to providers and especially to the public, in particular so as to clarify the relationship to rights under the NHS Constitution and consumer rights, and to present their relationship to other standards and to the Care Quality Commission's own broader ratings of quality. The Care Quality Commission's three Chief Inspectors will engage with the public, providers and professionals to develop guidance that makes clear for all sectors what compliance with the regulations involves and how it joins up with other rights and entitlements, other standards, and the Care Quality Commission's broader assessment of the quality of services.

In June 2013, the Care Quality Commission issued *A new start – Consultation on changes to the way Care Quality Commission regulates, inspects and monitors care*.¹⁵³ This document started the public discussion on what the fundamental standards of care should be. The consultation engaged 5,154 individuals and 4,500 organisations, plus 41 consultation events. The Department will consult shortly on draft regulations in October 2013 which will specify the fundamental standards as outcomes that must be avoided. Subject to Parliament, these will come into force during 2014.

The Department has revised the *NHS Constitution*¹⁵⁴ to give greater prominence to NHS values, and it will consider further revision to the NHS Constitution to reflect this response to The Inquiry.

NHS England has agreed with the National Institute for Health and Care Excellence that the concept of enhanced standards is represented by the existing quality standards, which are developed by the National Institute for Health and Care Excellence and endorsed by NHS England. The Care Quality Commission will use (enhanced) quality standards to inform their quality ratings of providers. The National Institute for Health and Care Excellence will also include 'developmental' standards within quality standards, where there are emergent evidence-based technologies with the potential to drive widespread improvements.

¹⁵³ http://www.cqc.org.uk/sites/default/files/media/documents/cqc_consultation_2013_tagged_0.pdf

¹⁵⁴ <http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/2013/the-nhs-constitution-for-england-2013.pdf>

CLINICAL INPUT

Recommendation 288

The Department of Health should ensure that there is senior clinical involvement in all policy decisions which may impact on patient safety and well-being.

Accepted.

The Department of Health has put in place arrangements to ensure that it has access to clinical advice on the full range of issues it deals with. The mechanisms employed include direct employment of clinical advisers where appropriate, and access to advice from senior clinicians elsewhere in the system. In addition to these formal mechanisms, the Department's programme of connecting to front-line practitioners and organisations will, we believe, provide the basis for long-term informal networks of advice that officials will be able to draw upon when developing policy.

EXPERIENCE ON THE FRONT LINE

Recommendation 289

Department of Health officials need to connect more to the NHS by visits, and most importantly by personal contact with those who have suffered poor experiences. The Department of Health could also be assisted in its work by involving patient/service user representatives through some form of consultative forum within the Department.

Accepted.

A major programme has been established within the Department of Health to ensure that staff throughout the organisation are given the opportunity to experience the realities of life in front-line organisations. The programme has begun, with the most senior civil servants in the Department spending time with a wide range of health and care organisations. The early evidence is that the programme is having a profound and positive effect on those participating in it, and has provided them with invaluable insights into the realities of care that they are using to inform their work in the Department.

Recommendation 290

The Department of Health should promote a shared positive culture by setting an example in its statements by being open about deficiencies, ensuring those harmed have a remedy, and making information publicly available about performance at the most detailed level possible.

Accepted.

In respect of deficiencies wherever they come in the health and care system, the Department of Health needs to be explicitly and clearly on the side of patients and the public. We have put in place a number of measures to increase transparency in the NHS including the duty of candour on organisations, and the appointment of Chief Inspectors of Hospitals, Primary Care and Adult Social Care. These measures will help to identify poor practice, increase

public accountability and, while for some the exposure of failings in care will be difficult, over the long-term we expect these measures will increase public trust in health and care organisations.



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ISBN 978-0-10-187542-4



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