

NHSCB8/11/12/4

BOARD PAPER - NHS COMMISSIONING BOARD

Title: The NHS Commissioning Board's role in maintaining quality

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Purpose of Paper:

 To set out the role of the NHS Commissioning Board in maintaining quality, in light of the National Quality Board's report 'Quality in the new health system – maintaining and improving quality from April 2013' and to update Board members on action that is being taken forward to make this a reality.

Key Issues and Recommendations:

 This paper is intended to update Board members on the model for maintaining quality developed by the National Quality Board (NQB), and to fulfil an NQB commitment that each statutory organisation represented on the Board would hold a Board-level discussion on their role in relation to quality.

Actions Required by Board Members:

The Board is asked to:

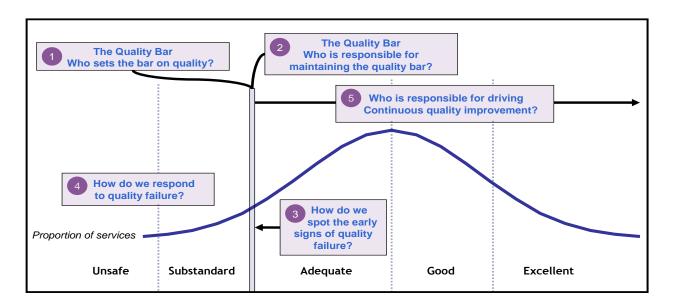
- note the role of the NHS CB in maintaining quality; and
- endorse the actions that various directorates of the NHS CB are taking to ensure that the organisation fulfils its distinct role, and works with other parts of the system.

The NHS CB's role in maintaining quality

Introduction

- Quality is systemic. It is not the responsibility of any one part of the system or, indeed, any one part of the NHS Commissioning Board (NHS CB). Rather, it is a collective endeavour, requiring collective effort and collaboration at every level of the system in order to safeguard patients and drive continuous quality improvement.
- 2. It is in this context that the National Quality Board (NQB), chaired by Sir David Nicholson, published a report setting out how quality will operate across the new system: 'Quality in the new health system maintaining and improving quality from April 2013'¹. The NQB brings together the leaders of the key national organisations responsible for the health and care system (e.g. NHS CB, Department of Health (DH), Care Quality Commission (CQC), Monitor, NICE) alongside a number of expert and lay members. Its role is to provide collective leadership and drive system alignment for quality across the NHS and its interface with social care.
- 3. The NQB's report seeks to provide clarity around the distinct roles and responsibilities for quality of organisations in the new system and sets out new processes for strengthening the sharing of information and intelligence on quality between organisations. The report was published in draft in August 2012 and will be finalised once the findings and recommendations of the Mid Staffordshire NHS Foundation Trust Public Inquiry are known.
- 4. This paper guides the Board through the NQB's report (**Annex A**) by looking at different points along a conceptual 'Quality Curve' (**Figure 1**). The paper focuses on the NHS CB's role in relation to each point on the curve and describes the action being taken to fulfil it responsibilities.

Figure 1- the 'Quality Curve'



- 5. When considering quality, the NQB identify two overarching objectives which form a common purpose for the system:
 - maintaining the essential standards of quality and safety to protect people receiving care; and
 - continuously improving the quality of care provided to people and the outcomes which are delivered as a result of that care.
- 6. Points 1 4 on the curve relate to the first objective and are the primary focus of the NQB's report. Point five relates to the second objective which is only briefly touched on in the NQB's report.

Who sets the bar on quality?

- 7. The NQB's report, *Quality in the new health system maintaining and improving quality from April 2013* is clear that, in the new system, two principal 'quality bars' will be placed on organisations providing NHS funded care:
 - the 'essential standards of quality and safety' set out through the system of registration (16 registration standards), with compliance defined by CQC; and
 - any **contractual requirements** set by commissioners over and above the 'essential standards of quality and safety'.
- 8. The 'essential standards of quality and safety' represent the legal minimum standards that all providers of regulated activities must meet and therefore help define what constitutes a quality failure. A provider organisation that is genuinely compliant with the 'essential standards' cannot, by definition, be experiencing a quality failure.
- 9. Although it is the CQC's responsibility to set this 'quality bar' through its guidance about compliance, the NHS CB should play a proactive role in working with the CQC to continually raise the bar through the commissioning process e.g. turning the Quality Standards of today (which define excellence) into the essential standards of tomorrow.

- As members of the Board are aware, the NHS CB is developing a partnership agreement with CQC. The recently published CQC consultation on their future strategy indicates their intention to strive to ensure that today's high quality standards become tomorrow's minimum standards. In light of the above, the NHS CB can commit to working with CQC to develop a medium to long-term strategic approach to raising the minimum bar on quality as defined by the 'essential standards of quality and safety' This will be taken forward jointly by the Policy clinical directorates.
- There is potentially a misalignment between the focus on quality improvement which is driven via the NHS Outcomes Framework and the focus on minimum standards as defined by the CQC through 16 registration requirements. Therefore, the NHS CB will proactively engage DH and CQC on how the system of registration can be more closely aligned with the definition of quality and the NHS Outcomes Framework. This will be taken forward jointly by the Policy clinical directorates.
- 10. Any quality requirements over and above the 'essential standards of quality and safety' set by CQC will need to be set through the contracts that clinical commissioning groups (CCGs) and the NHS CB (as a direct commissioner) hold with provider organisations.
- 11. In terms of CCG commissioning, these quality requirements will primarily be set locally, according to local health challenges working with the local Health and Wellbeing Board. The NHS CB will have a role in supporting and enabling CCGs to be able to set quality requirements locally. This should involve providing CCGs with the data they need to determine what local requirements might look like, and supporting them to have the capability to make the right choices for their communities.

NHS CB ACTION

- To support CCGs in commissioning and contracting for quality, the NHS CB will make data available to support their decisions as to local priorities and provide a range of commissioning resources. This is being taken forward by Commissioning Development Directorate, supported by the clinical directorates and the NHS CB's analytical resource.
- 12. Nationally, the NHS Standard Contract provides the NHS CB with a mechanism for setting consistent quality requirements e.g. building NICE Quality Standards into the NHS Standard Contract with the option of allowing performance thresholds to be locally determined or set nationally.
- 13. In terms of the NHS CB's direct commissioning responsibilities, the fact that the NHS CB is a single organisation provides a tremendous opportunity to drive

- improvements in a consistent way across the NHS through the contracting process.
- 14. A failure by provider organisations to meet any quality requirements in their contract, over and above the 'essential standards of quality and safety' required by CQC, amounts to a contractual failure rather than a quality failure i.e. it will not attract regulatory enforcement action. Although, given that the requirement to meet the 'essential standards' set by CQC is built into the NHS Standard Contract, a failure to meet these also amounts to a contractual failure.

The Planning Guidance, enacted through the NHS Standard Contract, will play a vital role in setting consistent, national quality requirements on provider organisations over and above the 'essential standards of quality and safety' set by CQC. The clinical directorates are working with the Operations and Commissioning Development Directorate to ensure that the Planning Guidance is consistent with the intent and spirit of the NHS Outcomes Frameworks in specifying requirements to CCGs, and that the NHS Standard Contract is best used to support improvement in quality

Who is responsible for maintaining the quality bar?

- 15. In terms of responsibility for maintaining the bar on quality, the NQB report is clear that this ultimately rests with the leadership of provider organisations (the Board or equivalent). They should ensure that their organisation is meeting, in full, the 'essential standards of quality and safety' set by the CQC.
- 16. However, this does not mean that other parts of the system do not have responsibility for ensuring that providers are meeting these 'essential standards'. CQC clearly has a leading role to play and they have direct responsibility for ensuring that providers are firstly registered and then that they continue to comply with the 'essential standards of quality and safety', taking enforcement action when they are breached.
- 17. However, neither the NHS CB nor CCGs can or should simply rely on CQC judgements. The NQB's report is clear that both the NHS CB (in its direct commissioning role) and CCGs must take responsibility for the quality of the services that they have commissioned as part of their duty to secure the provision of services for their populations. This does not mean they should duplicate the functions of CQC, whose ongoing compliance activity will provide high-level assurance that the essential requirements for quality and safety are being met. However, they should use rigorous contract monitoring, ongoing engagement with patients and the public and other soft intelligence to assure themselves about the quality of the care being provided, including that 'essential standards' are being met. Where concerns are identified, they must be raised promptly with

relevant parts of the system, making use of the new network of Quality Surveillance Groups agreed by the NQB and set out in the next section.

NHS CB ACTION

- The significance of the statement 'commissioners are responsible for the quality of care that they commission' should not be underestimated. As we move towards commissioning for quality and outcomes, and away from commissioning for activity / volume, ensuring clarity around what is expected of commissioners in terms of quality monitoring is vital. Developing guidance on this has been prioritised as a key deliverable to be developed jointly between the NHS CB and CCGs via the Quality Working Group of the Commissioning Assembly and will be published before April 2013.
- For all directly commissioned services, a set of indicators needs to be identified (similar to those that have been developed for CCGs in the Commissioning Outcomes Framework) against which the NHS CB will judge how it is performing as a commissioner. The Intelligence Tool will support the NHS CB in assuring itself of the quality of services being directly commissioned, by bringing all information against those indicators into one portal.

Spotting the early signs of quality failure

- 18. The previous section established the key role that the NHS CB and CCGs must play in assuring the quality of the care being provided to patients. However, the distinct roles and responsibilities for quality of different parts of the system, including the commissioning system, means that no one organisation is likely to have the full picture on quality within a provider organisation. A major lesson coming out of the Mid Staffordshire NHS Foundation Trust Public Inquiry, and a key thread running through the NQB's report, is the importance of sharing information and intelligence about quality and risk within provider organisations across the system as part of a 'culture of open and honest cooperation'. This will be key to spotting any quality problems at an early stage and the operation of an effective early warning system for quality in the NHS.
- 19. The NQB's report therefore sets out a new model for proactively sharing information and intelligence on quality at local and regional levels through a new network of Quality Surveillance Groups (QSGs) (see **Figure 2**). These groups will bring together commissioners, regulators and other parts of the system on the footprint of the NHS CB's local area and regional teams to share information on quality and to raise concerns where they arise. They are designed to foster collaborative working relationships and support a culture of open and honest cooperation between different parts of the system, without impinging on the statutory responsibilities and independence of member organisations.

Frontline operations in the NHS Surveillance across local areas Surveillance across the region Routine day-today conversations and information sharing as part of the business of the NHS Regular bilateral and multilateral discussions Regular mulitlateral discussions across a region
- Quarterly Meetings of all parties - Monthly meetings initially advised Regional Quality Surveillance Groups Local Quality Surveillance Groups Support and Chair: NHSCB Support and Chair: NHSCB embership: NHSCB local area office Membership:
• NHSCB Regional office
• NHSCB Local Offices CCG Leads Local Authority Leads
Local Healthwatch NHS Trust Development Authority
 National Healthwatch NHS Trust Development Health Education England
Professional Regulators (GMC, NMC) Local Education and Training

Figure 2: Quality Surveillance Groups

Patient & Public Engagement (Including via Local Healthwatch

- 20. The NQB has agreed that the NHS CB is best placed to support and facilitate the effective operation of QSGs at both local and regional levels, which will involve:
 - proactively ensuring that all parties who need to be involved are involved:
 - helping to build effective and trusted working relationships between different members of the QSG;
 - facilitating the routine sharing of information between members;
 - ensuring that there is a clear understanding as to how the Group will consider all providers and system wide issues over time; and
 - chairing formal meetings of the QSG, including providing a record of discussions and agreed actions.
- 21. To be effective, QSGs will need to look at information and intelligence, both hard and soft, from a range of sources. One critical supporting tool will be the Quality Dashboard that is being developed jointly between the NHS CB, the NHSTDA, CQC and Monitor. This dashboard will be available to each local QSG with data relevant to their geography. It will also be available at regional level for regional QSGs and will help national organisations build an overall picture on quality within provider organisations.
- 22. The NQB's report only provides a high-level overview of how the new Quality Surveillance Group model will operate in practice. The next steps will need to ensure that it is fully operational across the country by 1 April 2013.

- A steering group, involving organisations from across the system which will be involved in QSGs has been established chaired by Paul Watson (Regional Director, Midlands and East), supported by the Operations Directorate and Quality Framework Team in the Medical Directorate. This group is overseeing a pilot of the Quality Surveillance Group model with a view to producing a detailed 'How to run a QSG' manual by end Dec early Jan 2013. The group will also provide assurance to the NHS CB and the NQB that QSGs are fit for purpose and ready to go live from April 2013.
- Partnership agreements with key organisations will reflect the agreement to work together in a culture of open and honest cooperation, including as part of Quality Surveillance Groups. The Policy Directorate is taking this forward, in consultation with the Quality Framework Team in the Medical Directorate.
- As local area team (LAT) and Regional Directors take up post and build their teams there will need to be organisational development activity to ensure that they understand the QSG model and the NHS CB's role within it. This will be crucial to the effective operation of relationships locally.

How do we respond to a potential or actual quality failure?

- 23. Locally and regionally, QSGs will provide a proactive mechanism for sharing information and intelligence on quality across whole health and care economies, helping to spot the early signs of quality problems and agreeing action to prevent these from becoming more serious quality failures.
- 24. However, no system can be 100% fail safe and from time to time potential or actual serious quality problems will emerge where providers are failing to meet the 'essential standards of quality and safety'. Such problems may relate to a specific service or be indicative of even more serious and systemic problems within a provider organisation. In such circumstances, the NQB's report is clear that there must be a robust mechanism in place for reactively responding to such concerns which might arise as a result of the routine sharing of information through QSGs or from new intelligence coming to light e.g. from a whistleblower, patient, undercover reporter or local or national media exposure. The NQB has agreed that the existing Risk Summit model should be built upon to provide this reactive mechanism.
- 25. Key features of the Risk Summit model are as follows:
 - any statutory organisation local, regional or national, including providers themselves – who has a serious concern about the quality of care in a provider organisation can trigger a Risk Summit. The Risk Summit should normally be convened within 24/48 hours of the request;

- all relevant members of the QSG, and others as appropriate, would come
 together at the Risk Summit to give specific, focussed consideration to the
 concerns raised. This should facilitate rapid, collective judgements about
 quality within the provider organisation in question. However, it will be for the
 CQC to make an independent judgement as to whether there has been a
 significant breach in the 'essential standards of quality and safety'. Even
 where the CQC determines that there has not been a material breach in
 registration, other parts of the system may determine that action is needed;
- in forming its judgement, the CQC can ask the other participants of the Risk Summit to carry out a rapid impact assessment of any potential regulatory action it is considering, such as closing a service. The commissioner will need to play a significant role in such an impact assessment. For CCG commissioned services, the CCG will need the capability to be able to do this, which may require advice and support from the NHS CB. It may be that the NHS CB local area office needs to lead this with input from the CCG. For directly commissioned services, the NHS CB will need to carry out this impact assessment with input from other regulatory and relevant organisations; and
- once a judgement has been taken that there has been, or that there is the
 potential to be a serious quality failing, the different parts of the system will
 need to determine what action needs to be taken. The package of actions
 taken forward to respond to an actual or potential serious quality failure
 should aim to:
 - o rapidly safeguard patients;
 - o ensure the continued provision of services to the population; and
 - begin the process of securing improvements at the provider organisation, including supporting staff as necessary.
- 26. The NQB report is clear that to make the above process operate effectively, one party should be recognised as 'holding the ring' where actions are being discussed and agreed, to ensure an aligned and coordinated system-wide response, in what may be a fast-moving situation of high pressure. This role will involve:
 - convening the initial Risk Summit and any subsequent meetings needed to reach a judgement about quality and to monitor agreed actions;
 - chairing these meetings, including providing a record of the discussion and agreed actions; and
 - recognising other parties' roles and statutory responsibilities, i.e. that one party cannot direct any other party in the exercise of their statutory functions.
- 27. The NQB has agreed that to ensure maximum flexibility in responding to situations, the QSG members locally should determine for themselves which organisation should 'hold the ring' according to the particular circumstances. However, it recognises that this approach could risk delay and confusion, if for some reason the parties cannot agree on who should 'hold the ring'. Therefore, it has been agreed that the NHS Commissioning Board will take on this role by

- default unless it is agreed that another organisation is better placed e.g. the NHS TDA in the case of an NHS Trust.
- 28. The local area teams and regional teams, who may need to perform this role will need the skills and expertise to manage such situations. This will include managing relationships with and between the different organisations and taking a firm hand to ensure that actions happen as agreed, or that there is an explanation.

- The NHS CB is likely to take a leading role in Risk Summits once SHA's are abolished, 'holding the ring' in situations of actual or potential quality failure, or supporting CCGs as they seek to 'hold the ring'. As LAT/ Regional Directors take up post and build their teams, there will need to be organisational development activity to ensure that they understand how effective Risk Summits operate and the NHS CB's role within those.
- To support this, the cross-system steering group established to oversee the roll out of Quality Surveillance Groups will also be working to update the 2012/13 'How to Run a Risk Summit' guide to reflect the position from April 2013. This approach will need to be agreed with other interested parties including CQC, NHSTDA and Monitor.

Who is responsible for driving continuous quality improvement?

- 29. Although the NQB's report was primarily focussed on failure, it did touch on how the system would improve quality and outcomes. In particular, it emphasised that a system that was focussed on continuously improving quality, was more likely to spot the early signs of failure.
- 30. When it comes to driving quality improvement, the NHS CB can be considered to be 'primus inter pares'. This is reflected in the fact that it is the NHS CB which will be held to account against the NHS Outcomes Framework.
- 31. In terms of delivering the NHS Outcomes Framework, the NHS CB has three distinct but interconnected roles:
 - A leader and enabler of the overall commissioning system: The NHS
 CB will provide leadership to the local commissioning system. It will
 support CCGs to commission services for their local communities,
 including delivering improvements in quality and outcomes. It will need to
 be aware where CCGs are not commissioning services of a satisfactory
 quality and improving outcomes, hold them to account for not meeting their
 objectives, and support them to be the best commissioners they can be.

- A direct commissioner: The NHS CB will directly commission primary care, certain specialised services and military and offender health and so will be under the same obligations as CCGs in relation to delivering quality improvement through the commissioning process. Successful commissioning of these services will be a key driver in meeting the NHS CB's quality improvement objectives.
- A system-wide leader for quality improvement: Improving the
 outcomes in the NHS Outcomes Framework will require collaboration with
 other parts of the system e.g. Public Health England (PHE), NICE, Health
 Education England (HEE), Monitor, Professional Bodies etc. The NHS CB
 must become the system wide leader for quality improvement, identifying
 shared goals, and driving collaboration.

- To support the NHS CB, and the wider commissioning system, in meeting its objectives around quality and outcomes, the clinical directorates have developed a model for taking a strategic approach to each domain of the NHS Outcomes Framework. This will support prioritisation locally and nationally, in doing so, enabling the commissioning system to deliver the outcomes against it which it will be held to account. It will guide how the NHS CB uses the tools, levers and business processes at its disposal which will enable and drive improvement.
- The Medical Directorate has been working to apply this approach to Domains 1-3, identifying a number of key areas for action to support delivery of each domain. These will be developed further and in more detail over coming months, including engaging with CCGs through the Commissioning Assembly's Quality Working Group. The 'visions' will inform the NHS CB's 2013/14 business planning process, how the NHS CB uses the various tools and levers at its disposal, and will be reflected at a high level in the Planning Framework.

John Stewart Director, Quality Framework

Bruce Keogh National Medical Director

October 2012

Quality in the new health system

- Maintaining and improving quality from April 2013

A draft report from the National Quality Board

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Foreword

The Health and Social Care Act 2012 is fundamentally changing the way the NHS in England is organised and run. Over the past two years, there has been much debate about these changes. This debate has often been emotive, polarised and technical in nature, and the focus on quality has tended to be implicit rather than explicit. Yet improving the quality of care for patients and service users is the driving force behind these changes and is what unites us around a common purpose.

The NHS is organising itself around a single definition of quality: care that is effective, safe and provides as positive an experience as possible. This simple, yet powerful definition that arose out of the NHS Next Stage Review has now been enshrined in legislation. It lies at the heart of the first ever NHS Outcomes Framework and continues to help unite the ambitions and motivations of staff with the hopes of patients and the expectations of the public.

But, quality must never become some abstract concept or theoretical pursuit. A relentless focus on quality means a relentless focus on how we can positively transform the lives of the people who use and rely on our services. In contrast, a failure to focus on quality and to make it our primary concern can result in lasting emotional and physical damage to patients and even death. The appalling failures at Mid Staffordshire NHS Foundation Trust and at the independent hospital, Winterbourne View, provide stark reminders that when we fall short on our responsibilities in respect of quality, the consequences for patients, service users and their families can be catastrophic.

At the same time, we must also recognise that the provision of high quality care is an inherently complex and fragile operation. Quality is systemic - the patient journey cuts across primary and secondary care, health and social care, and involves multiple professionals. Therefore, it is a collective endeavour, requiring collective effort and collaboration at every level of the system. It is with this in mind and against the backdrop of a changing system that the members of the National Quality Board have come together to produce this report which represents a refresh of our February 2010 report, 'Review of Early Warning Systems in the NHS'1.

We are clear in this report that quality is everyone's responsibility. But, we are equally clear that an effective early warning system for quality must begin within the organisation providing care. This view is consistent with the conclusion of a recent publication by the King's Fund on assuring quality in the NHS². Here, they set out three lines of defence 'in the battle against serious quality failures in healthcare':

- The first line of defence is frontline professionals, both clinical and managerial, who deal directly with patients and carers and are responsible for their own professional conduct and competence and for the quality of the care that they provide.
- The second line of defence is the boards and senior leaders of healthcare providers responsible for ensuring the quality of care being delivered by their organisations.
 They are ultimately accountable when things go wrong.
- The third line of defence is the structure and systems that are external, usually at national level, for assuring the public about the quality of care.

As the leaders of the national system of commissioning, regulation and performance monitoring we are, nevertheless, clear about our individual and collective responsibility for creating the conditions and the environment which allows quality to prevail and ensures that the interests of patients always come first. Overall, our report:

- reaffirms our commitment to the primacy of quality in the new system;
- emphasises the critical importance of values and behaviours in creating a system that
 is truly focussed on quality and always places the interests of patients ahead of
 individual or organisational ambition;
- sets out the central role that patients and service users must play in the oversight and scrutiny, design and measurement of high quality services;
- provides clarity around the distinct roles and responsibilities for quality of individuals and organisations across the new system architecture;
- presents a new approach for supporting collaboration across the system and facilitating the sharing of information and intelligence on quality through a new network of Quality Surveillance Groups; and
- ensures that there is a clear and agreed approach to taking swift and coordinated system-wide action in the event of a serious quality failure being identified, in order to rapidly protect patients and service users.

We are publishing this report in draft at this stage so we can update it, as necessary, in light of any relevant findings and recommendations arising from the Mid Staffordshire NHS Foundation Trust Public Inquiry, which is due to report in the autumn. We will need to keep this report under constant review as it describes a system that has not yet gone live.

Successful implementation will depend on the ethos, values and actions of people working across the system and at every level. The process of producing this report has, therefore, been hugely important. It has allowed us to identify, explore and reconcile different points of view, build new relationships and collectively remain focussed on our common purpose during a time of significant organisational change and financial challenge. Similar conversations must take place at every level of the system and new relationships will need to be forged. These relationships will need constant nurturing and attention if we are to put patients truly at the heart of everything we do.

I would like to thank Prof. Ian Cumming, Managing Director for Quality during the Transition, for his leadership in developing this report with others across the system. On behalf of the members of the National Quality Board, I commend this report to the service. Collectively, as the leaders of the national system, we seek your help, support, commitment and energy in our continuing drive to improve quality and ensure that our NHS consistently provides the best possible care to the patients it serves.

Sir David Nicholson KCB CBE Chair, National Quality Board

Chapter 1:

Introduction

The Role of the National Quality Board

The National Quality Board (NQB) brings together the leaders of national statutory organisations across the health and care system, alongside expert and lay members. Its role has been to provide leadership and system alignment for quality and to provide a forum for developing collective, cross-system advice to the Department of Health and Ministers on quality.

The NQB was established in 2009 following the NHS Next Stage Review and the publication of *High Quality Care for All*³, with a remit to consider quality across the NHS system and at the interface between health and social care.

The NQB plays a unique role. It is the only place in the system where the national organisations tasked with safeguarding and improving quality come together. It is the only national forum with the express aim of aligning the system around quality.

Review of Early Warning Systems in the NHS, February 2010

In 2008, the NQB was asked by the Secretary of State for Health to conduct a review into the systems and processes in place for safeguarding quality in the NHS. This followed the Healthcare Commission's report into serious failings at Mid Staffordshire NHS Foundation Trust. The NQB reported in February 2010⁴, setting out the roles and responsibilities at every level of the system for safeguarding quality. The report also set out how different parts of the system needed to work together, as part of a culture of open and honest cooperation, to identify potential or actual serious quality failures and take corrective action in the interests of protecting patients.

As summary of the key findings and principles from our 2010 report is set out in the box on the following page.

SUMMARY OF KEY FINDINGS AND PRINCIPLES FROM FEBRUARY 2010 REPORT

- Ensuring that patients receive high quality care is an inherently complex and fragile operation.
- Robust systems and processes to monitor, manage performance and regulate the quality of care provided to patients are essential. However, the success of these is almost entirely dependent on the values and behaviours of staff and organisations working throughout the system.
- The NHS needs to embrace a culture of open and honest cooperation where individuals and organisations are transparent about the quality of care being provided to patients, and the whole system works collaboratively to share information, address concerns and raise standards.
- The quality of care provided to patients should never be compromised by the ambitions or management pressures of the organisations commissioning or providing services. Organisations need to look beyond their organisational boundaries and concerns about their autonomy and always consider the needs of the patient first.
- Listening to patient and service users' experiences of care and concerns is a key part of the early warning system. However, relying on patients alone to hold the system to account, even with the increasing information that is being made available publicly, cannot be sufficient. There will always be an asymmetry of information and understanding on the part of patients compared with others who work in or with the system.
- There must be absolute clarity about the different roles and responsibilities for quality of individuals and organisations across the system.
- NHS staff and clinical teams are the first line of defence in preventing serious failure in the NHS. However, ultimate responsibility for safeguarding quality rests with the organisation providing care through its board or equivalent.
- No system can be 100% failsafe and where a failure does occur there needs to be a system-wide response with three key objectives:
 - safeguarding patients;
 - ensuring the continued provision of services to the population; and
 - securing rapid improvements to the quality of care at the failing provider.
- A single organisation should 'hold the ring' on this response to ensure that action across the system is swift and remains aligned and coordinated at all times. The Strategic Health Authority should take on this role.

Purpose of this Report

We believe that the conclusions and key findings in our 2010 report are equally as relevant in the new system as they are currently. However, as we move to the new system, we will see many new organisations being established and existing organisations taking on new responsibilities and functions. There will be new relationships to be built, roles and responsibilities to be understood and interdependencies to be appreciated. We therefore decided to review and update our 2010 report to ensure there continues to be clarity around roles and responsibilities for quality once the new system goes live from April 2013. We have also used this opportunity to think about what more we could do collectively to support collaboration and to bring us closer to achieving the culture of 'open and honest cooperation' we described in our 2010 report.

We have taken forward our work in two phases: Phase 1 has focussed on how the NHS should maintain quality during transition. In March 2011, when we published our Phase 1 report, we emphasised the importance of the system maintaining its focus on quality and on ensuring that there are robust handovers between organisations who are transferring responsibilities⁵. Phase 2 of our work has focussed on how quality will be maintained and improved in the new system from April 2013. This report represents the conclusion of that work.

The system is changing...

Over the next few years, the structures in the NHS will change, both as a result of the Health and Social Care Act 2012 and in response to the NHS rising to the challenge of delivering better quality care in a tighter financial environment.

In summary, by April 2013:

- Strategic Health Authorities and Primary Care Trusts will have been abolished (end March 2013);
- an independent NHS Commissioning Board will have been established and have taken up its full statutory functions, including responsibility for allocating funding to clinical commissioning groups and supporting them to commission high quality services and directly commissioning primary care and certain specialised services (April 2013);
- clinical commissioning groups will have been established and authorised, with responsibility for commissioning the majority of local health services for their populations (starting in October 2012 with full authorisation by April 2013);

- Health and Wellbeing Boards, based in local authorities, will be established across the country, bringing together NHS commissioners with local government to help join up the commissioning of NHS, public health, social care and other local services (April 2013);
- Monitor will have become the new sector regulator for all NHS-funded care. It will focus on promoting value for money in the provision of services, for example, by regulating prices and taking action against anti-competitive behaviour that harms the interests of patients. As sector regulator, Monitor will issue licences jointly with CQC to providers of NHS funded care (from April 2013⁶);
- all NHS Trusts will be on their way to becoming Foundation Trusts, free from central direction or control but subject to a new system of economic regulation;
- the NHS Trust Development Authority will be established to oversee the performance of NHS trusts and support them to provide sustainable, high quality services as they work to achieve foundation trust status (April 2013);
- Health Education England will be established to provide leadership for professional education, training and workforce development, ensuring it has the right capacity and capability. It will allocate education and training resources and oversee provider-led local allocation of resources (April 2013);
- HealthWatch will become the new champion for the patient voice both nationally and locally, with local HealthWatch bodies across the country (April 2013); and
- a number of arms length bodies will have been abolished, including the National Patient Safety Agency (NPSA) and the NHS Institute for Innovation and Improvement (the NHS Institute) with their roles and functions transferring elsewhere. (April 2013).

...but some things will remain the same

These changes mean that the NHS landscape will look very different in terms of the organisations that are operating within it. However, certain crucial elements will not change:

 improving quality and healthcare outcomes remains the primary purpose of all NHS funded care and is the responsibility of everyone working in the NHS. These responsibilities are now reinforced through their definition in statute in the Health and Social Care Act 2012;

- healthcare professionals and clinical teams, their ethos, values and behaviours, will remain the first line of defence in safeguarding quality;
- the leadership within organisations who provide care remains ultimately responsible for the quality of care being delivered by their organisation, across all service lines;
- commissioners remain responsible for meeting the needs of their populations through commissioning high quality services;
- the Care Quality Commission remains the statutory regulator for the quality of health and social care in England. It will drive improvement in the quality of health and social care in England. It will be responsible for registering and monitoring services; for making sure people's views and experiences inform its regulatory work; for providing an authoritative voice on the state of care; and for working with strategic partners across the system;
- professional regulators continue to be responsible for setting the standards of behaviour, competence and education of regulated healthcare professionals, and taking action where those standards are not met;
- the National Institute for Health and Clinical Excellence will continue to be the source of national guidance and standards on the promotion of good health and social care and the prevention and treatment of ill health; and
- the Secretary of State remains ultimately accountable to Parliament for the health service in England.

Scope of this report

The health system is currently in a period of transition, which is also creating change in the social care sector as relationships and arrangements evolve. However, the safety, effectiveness and responsiveness to patients of services must continue to be the focus for all involved in delivering care.

In developing this report, we have come together as different parts of the new system, underneath the auspices of the National Quality Board, to describe how quality will operate in the new system in the context of the new legislative framework.

This report describes:

- the nature and place of quality in the new system (chapter 2);
- the values and behaviours required across the system to put the interests of patients first (chapter 3);
- the distinct roles and responsibilities across the new system in relation to quality (chapter 4);
- the importance of the different parts of the new system working together in the single pursuit of improving and assuring the quality of care to patients (chapter 5); and
- what is needed to make this joint work happen clear accountability and effective systems and process underpinned by the right values and behaviours (chapter 6).

In describing how the system will assure quality in the new architecture, we have sought to cover the whole health system, i.e. primary, secondary and tertiary care, across primary, community, acute, mental health, and ambulance services provided by NHS and independent sector organisations.

We have focussed primarily on the health system, and its boundaries with the care and support system. However, we feel that the model we describe may also bring some insight into the quality of social care provision, where commissioners and NHS organisations have relevant information and intelligence. The social care system is soon to go through a period of change following publication of *Caring for our Future:* reforming care and support. As the Government takes forward reform of care and support, we will work together to consider how best to align the health and care systems in their focus on quality.

This is a draft report

We are publishing this report as a final draft, setting out our collective view as to how the new system should operate to improve and maintain quality. We are conscious that Robert Francis QC is soon to publish his final report from the Mid Staffordshire NHS Foundation Trust Public Inquiry, which may include findings and recommendations that have a bearing on the operation of the new system and on the approach we describe in this report. We will finalise and re-publish this report once we have considered and taken account of the recommendations from the Inquiry in advance of the new system coming into affect from 1 April 2013.

Chapter 2:

Our common purpose – improving quality and delivering better outcomes

The primary purpose of the NHS

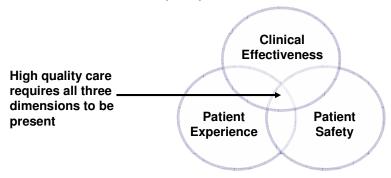
"Building on Lord Darzi's work, the Government will now establish improvement in quality and healthcare outcomes as the primary purpose of all NHS funded care"8

A single definition of quality for the NHS was first set out in *High Quality Care for All*⁹ in 2008, following the NHS Next Stage Review led by Lord Darzi, and has since been embraced by staff throughout the NHS and by the Coalition Government.

This definition sets out three dimensions to quality, all three of which must be present in order to provide a high quality service:

- clinical effectiveness quality care is care which is delivered according to the best evidence as to what is clinically effective in improving an individual's health outcomes;
- safety quality care is care which is delivered so as to avoid all avoidable harm and risks to the individual's safety; and
- patient experience quality care is care which looks to give the individual as positive an experience of receiving and recovering from the care as possible, including being treated according to what that individual wants or needs, and with compassion, dignity and respect.

FIGURE 1: Definition of quality



This definition of quality has now been enshrined in legislation through the Health and Social Care Act 2012. 10

The Act has also defined success in terms of the outcomes that are actually achieved for patients and service users. The NHS Outcomes Framework sets out the national

outcomes that all providers of NHS-funded care should be contributing towards. The framework builds on the definition of quality through setting out five overarching outcomes or domains, which capture the breadth of what the NHS should be striving to achieve for patients. It helps move the definition of quality away from the purely abstract.

FIGURE 2: The domains of the NHS Outcomes Framework



The purpose of the NHS Outcomes Framework is threefold:

- firstly, to provide a national level overview of how well the NHS is performing which the public and Parliament can use to hold the Government to account for progress;
- secondly, to act as an accountability mechanism between the Secretary of State for Health and the NHS Commissioning Board and as part of the Mandate set for the Board; and
- thirdly, to act as a catalyst for driving quality improvement and the measurement of outcomes throughout the NHS.

Quality is complex and systemic

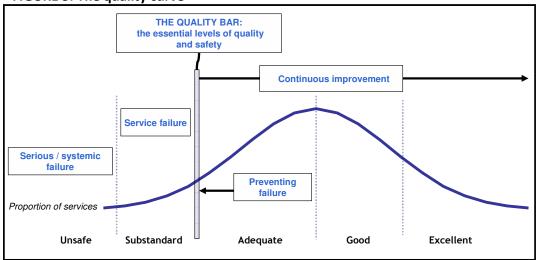
Ensuring that patients receive high quality care relies on a complex set of interconnected roles, responsibilities and relationships between professionals, provider organisations, commissioners, system and professional regulators and other national bodies including the Department of Health. The system's collective objectives in relation to quality are to:

- ensure that the essential standards of quality and safety are maintained; and
- drive continuous improvement in quality and outcomes.

We find the following diagram helpful in thinking through the different facets of quality. The remainder of this chapter provides clarity around who sets the bar on quality and then goes on to describe the high level framework we use for thinking

systematically about driving continuous improvements in quality. Chapter 5 considers how, across the system, we will work together to prevent serious failures in quality through detecting problems at an early stage. It also sets out our approach to responding to serious failures in quality should they emerge.

FIGURE 3: The quality curve



Setting the bar on quality

In terms of providing clarity around who sets the bar on quality, it is helpful to think about this in relation to i) provider organisations; and, ii) individual healthcare professionals.

Provider Organisations

The Health and Social Care Act 2008 established the Care Quality Commission as the regulator of health and social care services in England. Like many other bodies, CQC drives improvement in the quality of health and social care services. It regulates against the registration requirements set out in regulations to the 2008 Act. These are the 'essential standards of quality and safety' that providers are legally required to meet. These standards therefore represent the minimum 'quality bar' which all providers of regulated activities must meet and should not dip below.

Providers of 'regulated activities' must be registered with CQC to be able to operate. CQC has been rolling out a process of registering, monitoring and inspecting all providers of 'regulated activities' against the standards since 2010. CQC's *Guidance about compliance: Essential standards of quality and safety*¹¹ sets out guidance for providers and the outcomes people should experience when the standards are being met.

Where CQC finds that providers are not meeting the standards, it requires them to improve and has a range of enforcement powers it can use. These powers include warning notices, penalties, suspension or restriction of a provider's activities, or in

extreme cases, cancellation of a provider's registration which effectively means closure of a service.

The CQC takes a proportionate approach to regulation. In reality, from time to time a provider may dip temporarily below the bar breaching one or more of the 'essential standards of quality and safety'. Where there are significant, repeated, multiple and/or sustained breaches of registration requirements, it is likely that the provider is experiencing a serious failure, and that there are systemic problems within the organisation. In order to regulate successfully, the CQC works in conjunction with other organisations such as commissioners, other national bodies, and regulators.

Providers who train healthcare professionals also have a responsibility to deliver training in a safe and effective way in line with the standards set by the professional regulators. The CQC and the professional regulators have a joint interest where the quality of training may put patients at risk.

Individual healthcare professionals

Whereas the CQC is responsible for monitoring the compliance of provider organisations with the 'essential standards of quality and safety', it is the role of the professional regulatory bodies to set and uphold standards for individual healthcare professionals. There are nine UK health professions regulators which are responsible for setting standards of competence, practice, conduct and ethics for all registered healthcare professionals. Although the codes of conduct for the different professional groups all vary to some extent, broadly speaking all registered healthcare professionals must:

- ensure that patient safety and patient interests are paramount;
- take action to protect patient safety, including reporting concerns about patient safety / the actions of colleagues where necessary; and
- protect confidentiality where any concerns are raised.

Where healthcare professionals fail to observe the standards required of them, action may be taken against them by their regulatory body. The professional regulatory bodies uphold these standards by specifying the training and education outcomes for entry onto professional registers and the requirements for continuing professional development as well as through investigation of complaints about a professional's competence or behaviour.

Continuously improving quality

In our 2010 report we were clear that the most effective mechanism for preventing quality failure was for organisations and individuals providing care to be continuously striving for improvement; for the system to support and expect professional pride and ambition to deliver the very best quality of care for patients across all services.

The new system architecture is designed around every part of the system constantly striving for quality improvement. The Health and Social Care Act 2012 defines what quality is but also requires that different parts of the system carry out their roles and responsibilities with a view to securing continuous improvement in the quality of care provided for people using NHS-funded services:

- there is a duty on the Secretary of State for Health to exercise his functions in relation to health services with a view to securing continuous improvement in the quality of services and the outcomes that are achieved from the provision of services¹²;
- there is a duty on the NHS Commissioning Board to exercise its functions with a view to securing continuous improvement in the quality of services and the outcomes that are achieved from the provision of services¹³;
- there is a duty on clinical commissioning groups to exercise their functions with a view to securing continuous improvement in the quality of services and the outcomes that are achieved from the provision of services¹⁴; and
- there are duties on Monitor in exercising its functions to protect and promote the interests of people who use healthcare services by promoting services that maintain or improve the quality of care to patients¹⁵.

There are further duties related to quality:

- CQC's role is to drive improvement in the quality of health and social care services through regulating and monitoring services, listening to people and putting them at the centre of its work, providing an authoritative voice on the state of care and working with strategic partners across the system; and
- there are statutory duties on the professional regulatory bodies, such as the General Medical Council and the Nursing and Midwifery Council, to ensure that the public are protected from unsafe professional practice.

These are powerful duties, which enshrine into law the existing focus of the different parts of the system on quality. High Quality Care for All set out a seven step framework for systematically thinking about how to improve quality – the quality framework as shown in Figure 4. As a Board we have found this useful collectively in considering quality and will continue to use it in the new system.

FIGURE 4: The quality framework

Bring	Massura	Publish	Reward I	_eadership	Innovate Saf	eguard
clarity to quality	Measure quality					uality
1	2	3	4	5	6 / 7	

- 1. Bring clarity to quality there must be clear and accepted definitions of what high quality care looks like, which patients, commissioners and providers can unite around. The NHS Commissioning Board will commission the National Institute for Health and Care Excellence¹⁶ (NICE) to produce NICE Quality Standards setting out what high quality care looks likes for a particular condition, pathway or patient group, covering the majority of care that the NHS provides. Rather than representing the essential standards of quality and safety that the Care Quality Commission will regulate against, they will be aspirational, yet achievable, supporting the whole system in striving for excellence. As such, the Quality Standards of today will need to become the essential standards of tomorrow.
- 2 & 3. Measure and publish quality the system can only hope to improve what it measures. There must be robust, relevant and timely information transparently available on the quality of care being provided at every level of the system. This information should be used to drive quality improvement at the front line, for the purposes of accountability and to support patient choice. The NHS Outcomes Framework sets out the national quality goals which the NHS will be aiming to deliver, and will be used by the Secretary of State, through the Mandate, to hold the NHS Commissioning Board to account. The NHS Commissioning Board, in turn, will develop a Commissioning Outcomes Framework, drawing on NICE Quality Standards, to hold clinical commissioning groups to account for the outcomes they are achieving for their populations. Provider organisations and their clinical teams should be drawing on the wealth of comparative quality indicators, including from clinical audits, to drive improvement across all services. All measures of quality at every level of the system, must be made transparently available to support accountability, patient choice and prioritisation.
- 4. Reward quality payments and incentives must be structured to encourage quality improvement. Monitor will design payment mechanisms such as the tariff. The NHS Commissioning Board will develop standard contracts, CQUINs and the Quality and Outcomes Framework (primary care payment mechanism) to incentivise providers to deliver high quality care, drawing on NICE Quality Standards. Clinical commissioning groups and other commissioners will use these payment mechanisms to contract with providers for the delivery of high quality care and to manage those contracts. The NHSCB will use the quality premium, linked to indicators in the Commissioning Outcomes Framework, to reward commissioners for securing improvement in particular outcomes.
- 5. Leadership for quality leadership nationally and locally is essential for quality improvement to be embedded, encouraged and rewarded. The National Quality Board brings together different parts of the system nationally to provide leadership for quality, ensuring that there is alignment between how the different organisations carry out their responsibilities. Clinical Senates and Clinical

Networks will provide leadership locally and regionally for quality improvement to commissioners and healthcare professionals. **Health and Wellbeing Boards** will provide local leadership for quality improvement, with local health and care commissioners coming together with the local community to jointly assess needs and determine a joint health and wellbeing strategy to improve outcomes. **Professional bodies and Royal Colleges** have a critical role to play in supporting healthcare professionals in their pursuit of delivering high quality care.

- 6. Innovate for quality continuous quality improvement requires health services to search for and apply innovative approaches to delivering healthcare, consistently and comprehensively across the system. Academic Health Science Networks will bring together the local NHS, universities, public health and social care to work with industry to identify and spread proven innovations and best practice to improve the quality and productivity of health care resulting in better patient outcomes and population health. Academic Health Science Centres who seek out new and innovative ways of caring for people will be nested within these networks. NICE's technology appraisal process and the associated compliance regime ensure innovations that will deliver quality improvement are assessed expediently and that funding for NICE-recommended drugs and treatments is made available across the NHS, promoting rapid and consistent patient access in line with the NHS constitution
- 7. Safeguard quality Any system that strives for quality improvement must, at the same time, ensure that the essential standards of safety and quality are maintained. In respect of individuals, the professional regulatory bodies already publish and regularly update clear standards of competence and conduct for regulated health and social care professionals. This report describes how the system will prevent, identify and respond to serious quality failures. Each part of the system must fulfil their distinct roles and responsibilities in relation to quality, as well as working together in a culture of open and honest cooperation in the best interests of patients.

We must always keep foremost in our minds that quality is not an abstract term or concept relevant only in policy debates. It is the measure of how health and care services are treating and caring for patients and service users in their care. Where services fall below the quality bar, there are not only regulatory or financial consequences - real people's lives are affected, their health potentially jeopardised with hugely damaging consequences, both physically and psychologically, for themselves and their families. Across the system, we must be united in our responsibilities for preventing serious failure and for taking action to put it right where it does occur.

In the rest of this report, we focus on how the system can ensure that the 'essential standards of quality and safety' are met, that organisations do not fall below the quality bar, and what happens when they breach the quality bar in order to protect patients. In doing so, we seek to provide clarity as to distinct roles and responsibilities, and how different parts of the system must work together to best serve the interests of patients.

Chapter 3:

Our shared values and behaviours - putting patients and service users first

The NHS belongs to the people.

It is there to improve our health and well-being, supporting us to keep mentally and physically well, to get better when we are ill and, when we cannot fully recover, to stay as well as we can to the end of our lives. It works at the limits of science – bringing the highest levels of human knowledge and skill to save lives and improve health. It touches our lives at times of basic human need, when care and compassion are what matter most.

NHS Constitution

The NHS is founded on a common set of principles and values that bind together the communities and people it serves, the staff who work for it, with the organisations who operate within it. These principles and values were set out in the NHS Constitution in 2010, along with the rights and responsibilities of patients and staff.

The NHS Constitution sets out the **principles** that should guide the actions of all those who work for the NHS:

- 1. The NHS provides a comprehensive service, available to all
- 2. Access to NHS services is based on clinical need, not an individual's ability to pay
- 3. The NHS aspires to the highest standards of excellence and professionalism
- 4. NHS services must reflect the needs and preferences of patients, their families and their carers
- 5. The NHS works across organisational boundaries and in partnership with other organisations in the interests of patients, local communities and the wider population
- 6. The NHS is committed to providing best value for taxpayers' money and the most effective, fair and sustainable use of finite resources
- 7. The NHS is accountable to the public, communities and patients that it serves

The NHS Constitution also sets out the **values** that should guide the behaviours of those who work in the NHS:

- 1. Respect and dignity
- 2. Commitment to quality of care
- 3. Compassion
- 4. Improving lives
- 5. Working together for patients
- 6. Everyone counts

All NHS bodies and independent sector providers supplying NHS services are required by law to take account of the NHS Constitution in their decisions and actions.

The values set out in the NHS Constitution must apply equally to organisations working within the health system as it does to individuals on the frontline providing NHS care. Efforts to drive quality improvement must be in line with these principles and values. This report has been prepared with these values at its core.

A culture that puts patients first

Our 2010 report highlighted the need for there to be a culture of open and honest cooperation at every level, in every part of the health and care system.

"The quality of care provided to patients should never be compromised by the ambitions or management pressures of the organisations commissioning or providing the services. This does not mean, for example, that they should disregard the need to deliver value for money, but rather that the survival or profitability of the organisation should not be the principal driver for providers or commissioners in providing care to patients. Organisations need to look beyond their organisational boundaries and concerns about their autonomy, and always consider the needs of the patient first"

Review of early warning systems in the NHS, NQB, February 2010

This goes to the heart of what it means to put patients first. Our conclusion that a culture of open and honest cooperation is essential to safeguard the quality of care to patients has become increasingly more relevant over the last two years, evidenced by events such as the serious failings at Winterbourne View Independent Hospital.

An organisation that is truly putting patients first will be one that embraces and nurtures a culture of openness and learning.

The NHS is a complex system, not a single organisation; therefore, this culture needs to reach beyond organisational boundaries. The whole system – from individual clinicians to politicians in government – has a part to play in fostering a culture of open and honest cooperation. We need to shift the culture of the system from one of reluctance and blame, where failings automatically result in a race to point the finger, to one of openness, learning and continuous improvement.

But what does a culture of open and honest cooperation look like or mean for the NHS?

 Healthcare professionals and all NHS frontline staff feel encouraged and rewarded for raising concerns about the quality of care at an early stage.
 Clinical teams understand the quality of service they are providing to patients through routinely measuring and benchmarking their performance with peers across the three dimensions of quality – safety, effectiveness and patient experience.

- The leadership with provider organsiations see their fundamental role as ensuring high quality care for patients. As part of this, they routinely:
 - o monitor the quality of care being provided across all services;
 - o challenge poor performance or variation in quality;
 - o ask for help and raise concerns should significant problems arise;
 - o incentivise and reward high quality care and quality improvement;
 - work with other health and social care organisations to ensure that care is centred on people's needs; and
 - foster a culture of openness and transparency throughout their organisation.
- Commissioning and regulatory bodies work together to share information and intelligence on risk; be seen as a source of advice and support in the event of concerns being raised; and visibly work together to support improvement where potential or actual failures in the quality of care being provided to patients are identified.
- All parts of the system are actively listening to and proactively engaging with patients and the public to understand concerns.

Patient and service user participation

In the new system, patients and service users must be able to play an even more central role in the oversight and scrutiny, design and measurement of the provision of high quality services.

Individually, patients and service users will be taking more control of their own care, and becoming more involved in the decisions taken with their clinicians about the services they receive, when and where. Their experience of care will be measured and taken account of through the NHS Outcomes Framework nationally, the Commissioning Outcomes Framework locally, through contracting with providers, and within providers as part of their own quality surveillance and assurance mechanisms.

At every level of the system, patient participation must become a central component of how services are provided, designed and assured, reaching well beyond some of the formal mechanisms set out below:

within provider organisations, patients, the public and service users are able to be part of their local foundation trust as a foundation trust member and elect patient and public governors to the NHS foundation trust's Council of Governors. Within GP practices there should be patient participation groups or on-line methods of involvement;

- commissioners are under a duty to involve patients and service users in designing pathways of care, so that they meet the needs of those who will be using services. The NHSCB is also under a duty to involve patients and service users. Ensuring that their views and needs are reflected in all that the Board does is a central principle of how the new organisation is being established;
- the Care Quality Commission, as part of the information it uses to determine
 whether providers are meeting the essential standards of quality and safety,
 will be looking at information from patients, both directly and by way of
 complaints and survey data; and
- Healthwatch is being established to enable people to help shape and improve health and social care services. It will operate at both a local and national level, championing the views and experiences of patients, their families, carers and the public.

The following chapter sets out the distinct roles and responsibilities in relation to

monitoring the quality of care, and touches on each part of the system's role regarding quality improvement.

Chapter 4:

Our distinct roles and responsibilities for quality

Driving continuous improvement and tackling quality failure is a collective responsibility.

This chapter provides greater clarity around the individual roles and responsibilities of different elements of the new system architecture in relation to maintaining the 'essential standards of quality and safety'. It identifies the tools and levers that are available to the system in monitoring and dealing with quality failures. A summary of the high level roles and responsibilities is set out in bullet points below and the toolkit of intervention powers available to the system is provided in the table at page 44.

This chapter will show that the distinct roles of organisations in relation to quality result in the various parts of the system holding different information and intelligence on quality within provider organisations and on different groups of health and care professionals. Therefore, the system cannot operate effectively to improve and maintain quality if different parts of the system work in isolation. They must work together in the best interests of patients. Chapter 5 then looks at how the system should work together to ensure this information and intelligence is shared across the system and acted upon where concerns about quality care are identified.

IN SUMMARY

- Individual health and care professionals, their ethos, behaviours and actions, are the first line of defence in maintaining quality.
- The leadership within provider organisations is ultimately responsible for the quality of care being provided by that organisation.
- Commissioners are responsible for commissioning services that meet the needs of their local populations. They must assure themselves of the quality of care that they have commissioned.
- Regulators should perform their statutory functions with the best interests of patients at heart.
- Commissioners, regulators and other national bodies should share information and intelligence on the quality of services in an open and transparent way, and take coordinated action where appropriate in the event of an actual or potential quality failure.

1. Providers

- The early wanring system for quality beings within the organisation providing care
- Health and care professionals and clinical leaders, their ethos, values and actions are the first line of defence in maintaining quality.
- The leadership at a provider organisation is ultimately responsible for the quality of care that is provided by their organisation.
- Provider leadership hold clinical teams and leaders to account for the quality of care they provide.

In this report, we have described a system which applies to all providers of health services. We recognise that they come in all shapes and sizes, and that their governance structures vary greatly according to their scale and function.

When we refer to a 'provider' we mean the legal entity with which commissioners contract that is registered by CQC to provide certain regulated activities in certain settings. In our 2010 report, we referred to the 'provider board' as being ultimately responsible for the quality of care that is provided by their organisation. We recognise that not all provider organisations will have a 'board' as such, for example, in general practice there is unlikely to be a board; rather it is the person, partnership or company that holds the contract who is ultimately responsible. Where we would have referred to a 'provider board', in this report we now refer to 'provider leadership'.

1a. Health and care professionals

All staff, whether they work in a large acute hospital, a care home, in general practice or in providing community care, and whether they are employed by a public sector, private or not-for-profit organisation, have a role in ensuring safe care for patients and users through their own ethos, values and actions. They are the first line of defence against quality failure.

Health and care professionals working in teams should be regularly participating in clinical and quality governance and continuously measuring and monitoring indicators on the quality of care they are providing, identifying areas for improvement and reporting within their organisation. They should be using data from a range of quality metrics and other sources of intelligence, including clinical audits and peer review and patient feedback, and ensuring that the care they provide is in line with NICE Clinical Guidelines. They should be seeking to improve the quality of their care so that it meets the relevant NICE Quality Standards. At a minimum, they must ensure that the services they provide meet the CQC's 'essential standards of quality and safety'.

This applies equally to primary care, where GP partnerships and independent practitioners should have quality at the heart of their activity. They should be

regularly reviewing performance against quality indicators such as clinical audits; regularly reviewing any complaints; and demonstrating variance within the practice team by regular data analysis

The quality of care provided by an organisation is dependent on the people it employs. In the health sector, the professional codes and standards set by the professional regulatory bodies require health professionals to make the care of their patients their first concern, and to protect and promote the health of patients in all that they do. ¹⁷ Through their codes of conduct and other guidance, professional regulators set the standards of behaviour, competence and education that health professionals must meet. These standards include a general obligation on healthcare professionals to raise concerns they may have about patient and public safety and wherever possible to act to prevent a risk to patient safety.

Where health and care professionals do have concerns about the quality of care in their employer organisation, or any provider organisation with which they have contact, they should raise these with the leaders in their team, or the clinical leaders in their organisation. If they feel they cannot raise concerns with a particular individual, or where they have raised concerns which have not been acted upon, individuals should follow their organisation's published whistleblowing procedures. This may include seeking the help of their staff-side organisation. In general practice there may be a particular issue if the senior clinical leader (or sole practitioner) is the perceived problem. In such circumstances, the clinical leader would be the Medical Director or equivalent in the NHS Commissioning Board local area team.

1b. Clinical Leaders

Clinical leaders within provider organisations will include anyone who has a leadership role in respect of health and care professionals, such as the Medical and Nursing Directors, the consultant body, clinical managers, the matrons/sisters at ward level or team leaders in care homes.

Clinical leaders have a key responsibility for ensuring effective clinical and quality governance and that the culture in the organisation supports the right values and behaviours amongst their staff, so that they are able to provide quality care and feel comfortable to raise any concerns they may have. They also need to be aware of and promote awareness of the 'essential standards of quality and safety'.

Clinical leaders are also responsible for supporting staff to fulfil any professional obligations and for investigating concerns about the behaviour or clinical practice of the professionals they oversee in the first instance. They must ensure that referrals are made to the relevant professional regulatory body where necessary.

The new role of Responsible Officer (RO) in the medical profession includes ensuring that systems within their organisation support doctors in delivering improving quality of care. Revalidation will be a process whereby doctors will be subject to an ongoing evaluation of their fitness to practise through participation in annual appraisal. They will need to demonstrate that they remain up to date and fit to practice. ROs will make recommendations to the GMC, usually every five years, as

to whether doctors in their organisation should be revalidated. ROs will have a key role in improving patient care and, over time, should be able to identify and deal with problems in a doctor's practice earlier.

1c. Provider leadership (partnerships, boards or their equivalents)

The leadership of a provider organisation (including the executive and non-executives in leadership roles) is ultimately responsible for the quality of care being provided across their organisation.

The provider leadership must ensure that their organisation is registered to provide the services they are providing with the Care Quality Commission, and that the organisation continues to meet the 'essential standards of quality and safety', including statutory notifications. For licence holders, the leadership should ensure that the organisation continues to be compliant with the conditions of its licence, as determined by Monitor.

The provider leadership should recognise that quality is equally as important as stewardship of public resources, and where they have formal meetings, their agendas and discussions should reflect this.

Provider leadership should ensure that the right systems and processes are in place across the organisation to support staff in driving quality improvement and to allow them to raise any concerns about quality that they may have. In providers with Medical and Nurse Directors, they are likely to have a significant role in overseeing the quality of care being delivered. They must also be aware of their statutory obligations as Designated Bodies under the Responsible Officer regulations which set out key requirements in relation to clinical governance arrangements and support for medical practice.

The provider's relationships with its commissioners will be vital – this should be a mature, constructive dialogue about the services that the commissioner has commissioned and the quality of services being provided. The provider leadership should be able to raise concerns it may have with its commissioners, and the commissioners should work with the provider to address any quality problems as far as possible.

The provider leadership will need to have constructive relationships with its CQC representatives, with the NHS TDA and with Monitor as appropriate. The provider will also need to work constructively with its local health and wellbeing board, Local Education and Training Board, and Healthwatch.

1d. Governors (for NHS foundation trusts)

The governors of NHS foundation trusts oversee the board of those trusts, holding directors collectively to account for the performance and the quality of care of their organisation. Governors are responsible for representing the interests of NHS foundation trust members and local partner organisations in the governance of their trust. They consist of elected members (the public, patients and NHS staff who wish to be involved in their local health services) and appointed representatives from local stakeholder organisations. By representing members, Governors connect their organisation with the local populations it serves.

Governors must operate with the interests of local communities and patients at the fore. Although they do not undertake operational management of NHS foundation trusts, governors should be particularly interested in scrutinising information about the quality of care in their organisation - acting as a sounding board and providing constructive challenge in holding the board to account for the quality of its care.

Through the Health and Social Care Act 2012, governors have been given additional powers to help them hold directors to account more effectively. The Act gives governors voting rights on amending the NHS foundation trust's constitution, agreeing to undertake significant transactions such as a merger or acquisition, and approving a significant increase in non-NHS activity and income derived from it, to ensure that these decisions are taken in the best interests of the trust's membership and the public.

In the new system architecture, the role of governors will provide a vital level of oversight. NHS foundation trusts must ensure governors have the support they need to perform their roles effectively. The Government is also funding a national governors training project, to be sponsored by the NHS Leadership Academy, which we welcome.

2. Commissioners

- Commissioners are responsible for securing a comprehensive service within available resources, to meet the needs of their local population.
- They must commission 'regulated activities' from providers that are registered with the CQC, and should contract with their providers to deliver continuously improving quality care.
- They must assure themselves of the quality of the services that they have commissioned.
- Where commissioners have significant concerns about the quality of care provided they should inform the CQC.

2a. Clinical Commissioning Groups

Clinical commissioning groups (CCGs) will bring together a range of clinical professionals to commission the majority of NHS-funded healthcare services, including:

- planned hospital care;
- rehabilitative care;
- urgent and emergency care (including out-of-hours services);
- most community health services; and
- maternity, mental health and learning disability services.

In commissioning these services, CCGs will be responsible for securing a comprehensive service within available resources, to meet the needs of their local population. At the very least, these services must meet the Care Quality Commission's 'essential standards of quality and safety' and all providers of regulated activities must be registered with CQC.

Over and above this, CCGs should be identifying the improvements they wish to secure in the quality of services they commission and using the commissioning process to drive continuous quality improvement. CCGs are likely to use commissioning support services to support them in managing contracts.

The NHS Commissioning Board will support CCGs by providing guidance on what high-quality services look like (including commissioning NICE to produce Quality Standards) and on how to commission for quality, together with the practical tools (including the NHS Standard Contract) to support commissioning. NICE will also support CCGs by providing clinical guidance and access to high quality information through NHS Evidence.

CCGs must assure themselves of the quality of services that they commission. They should be aware of the information that the CQC collects in its Quality and Risk Profiles. However, they will also have their own information and intelligence about their providers, collected through contract monitoring, engagement with patients and the public, and general interaction in the local health economy.

They should use their interactions with providers to seek to drive continuous quality improvement but also be alert to any concerns about quality of services which may arise. Where there are concerns they should work with providers to put quality problems right.

CCGs will need to work with each other and with other local partners. For example, where a number of CCGs each commission a significant volume of care from the same provider, they may wish to agree collaborative arrangements that enable them to collectively specify services and monitor the quality of services. They will also need to actively engage the local communities, patients and service users whom they serve.

CCGs in a local area will be part of the new local Quality Surveillance Group (see page 46), 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 CQC 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.

2b. Local authority commissioners

Local Authorities are responsible for commissioning social care services, managing the contracts they hold with providers of care services. Through these contracts, they can set requirements for providers in relation to the quality of care delivered.

Responsibility for the quality of care being provided should be recognised by the governance within the local authority. The local authority commissioners should use their interactions with providers to seek to drive continuous improvement as well as to identify any actual or potential quality problems or failings.

Local Authorities also have a particular role to play in safeguarding adults in vulnerable circumstances who are abused or at risk of abuse. Information about abuse or potential abuse should be shared with local authority safeguarding teams and, depending on the circumstances, may also require involvement of the police

Local Authorities will be part of the new local Quality Surveillance Groups (see page 46), where they should share information and intelligence. If they have concerns about whether providers are meeting the 'essential standards of quality and safety' they should raise these with the CQC and with any other parts of the system with an interest through that Group.

2c. NHS Commissioning Board

Once formally established in April 2013, the NHS Commissioning Board (NHSCB) will be the national element of the commissioning system in England, ensuring that the NHS is truly a national health service for England. It will support, develop and hold to account an effective and comprehensive system of health commissioning, including commissioning by clinical commissioning groups, and drive improvements in quality and outcomes as measured at national level through the NHS Outcomes Framework.

Its role in relation to quality is two-fold:

Leading and enabling the overall commissioning system

Here, the NHSCB's role will be to support and enable CCGs to commission services for their local populations, and to secure continuous quality improvement in those services. The NHSCB will also hold CCGs to account for securing improvement in outcomes and delivering their contribution to the joint health and wellbeing strategy.

The NHSCB will interact with CCGs on a day-to-day basis through its local area and regional teams. These offices should use their regular interactions with CCGs to gather intelligence and information about the quality of services being commissioned.

The NHSCB will support and facilitate, and be a member of, the new Quality Surveillance Groups (see page 46) at the local and regional levels. If it has concerns about quality, it should raise them with the relevant commissioners, with the CQC and with other parts of the system with an interest through these Groups.

Directly commissioning services of continuously improving quality

The NHSCB will directly commission around one fifth of the total value of NHS services, namely:

- GP services, community pharmacy, and primary ophthalmic services (mainly NHS sight tests);
- all dental services primary, community, hospital;
- specialised services;
- high-secure psychiatric services;
- offender health;
- some aspects of healthcare for members of the armed forces and their families;
 and
- public health services (screening, immunisation, services for children aged 0-5 including health visiting) on behalf of Public Health England.

In commissioning these services, its role is equivalent to a CCG or other commissioner in that they must commission services within available resources from providers who, where they provide a regulated activity, are registered with the CQC. The NHSCB should drive continuous quality improvement through the contracting process, and manage the delivery of those services through contract management.

In relation to primary care, the NHSCB will have responsibility for overseeing the quality of primary care provision, including performance management of individual GP practices and making sure all the doctors are competent and fit to practice. The NHSCB will also maintain a performers list. This will include all primary care professionals who have been assessed as being suitable to hold NHS contracts for the provision of primary care. For GPs, this assessment will include information received as part of the routine medical revalidation cycle and the Responsible Officers within the NHSCB will act as the link between the revalidation process and the maintenance of the performers list.

Where a GP is removed from the performers list due to concerns about the quality of care they are providing, the NHSCB will inform the GMC who will consider whether regulatory action is also required.

The NHSCB will need to assure itself of the quality of services that they commission, looking to the CQC in terms of whether a provider is compliant with the 'essential standards of quality and safety', as well as monitoring its own information and intelligence about providers.

Where the NHSCB has concerns about whether providers are meeting the essential standards of quality and safety, these should be raised with the CQC and any other parts of the system (particularly the professional regulators if there are professional standards issues) with an interest through local or regional Quality Surveillance Groups.

Sir David Nicholson Chief Executive NHS Commissioning Board Authority

3. Regulators

The regulatory bodies' overarching role is to provide assurance that health and care services are provided in a safe and effective way. In England, the regulation of quality of service provision is undertaken in two ways. The first is system regulation which looks at the organisations, systems and processes in place to manage and deliver care. The second is professional regulation which looks at the performance, competence and behaviour of individual healthcare practitioners.

3a. Care Quality Commission

The Care Quality Commission is the regulator of health and adult social care in England

It drives improvement in the quality of care by:

- registering and monitoring services;
- listening to people and putting them at the centre of our work;
- reporting authoritatively on the state of care; and
- working with strategic partners across the system.

The Care Quality Commission is the independent regulator of health and adult social care providers in England.

CQC ensures that only providers who have made a legal declaration that they meet the 'essential standards of quality and safety' and satisfy the registration process are allowed to enter the market and provide care. Once services are registered, CQC continues to monitor and inspect them against these essential standards. It acts quickly in response to any concerns and takes swift enforcement action where services are failing people. All acute, community, mental health, ambulance, dental and adult social care providers are already registered with CQC. From 1 April 2013, all primary medical care providers, including GP practices will be registered with the CQC.

Increasingly CQC will also identify and highlight what works well in the services it inspects. This will facilitate the sharing of useful intelligence about what works well and motivate providers to continuously improve. It will draw on its unique sources of evidence and intelligence to become a more authoritative voice on the state of care.

CQC will fulfil its objectives by:

- working closely with strategic partners to effectively pool and share information and intelligence that all can draw upon and use;
- understanding the patterns of good (what works well) and poor care;
- reporting on the state of the market, identifying problems and challenges in how services are provided and commissioned and recommending action;

- using 'special review' powers, themed inspection programmes and thematic reviews to deal with specific areas of concern that require improvement;
- working with regulators and commissioners to determine how best to regulate and influence the sector and providers;
- influencing the Department of Health on how the sector is regulated and any changes needed in the law to support regulation, including the ongoing review of the legislative framework;
- publishing information on inspections and reports; and
- listening to people and putting them at the centre of our work.

CQC is a vital member of the new local and regional Quality Surveillance Group (see page 46), where they will share information and intelligence about providers with other parts of the system, and use information and intelligence from others to inform their judgements on quality.

HealthWatch

Healthwatch will be a statutory committee of CQC, established to enable people to help shape and improve health and social care services. It will operate at both a local and national level, championing the views and experiences of patients, their families, carers and the public.

Healthwatch locally will be a valuable source of information and intelligence which they should share as members of Quality Surveillance Groups. If they have concerns about any of the providers in their area, QSGs are one of the routes through which they can be raised and shared.

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Dame Jo Williams Chair,

Care Quality Commission

3b. Monitor

- From 2013, Monitor will be the sector regulator for healthcare in England. It will jointly license providers of NHS-funded care with the CQC, and ensure continued access to essential services.
- Monitor can vary the terms of licence for different types of providers and can take action where a provider contravenes the terms of its licence.
- For NHS foundation trusts, Monitor can take action where there are quality problems as a result of poor governance within the provider
- Monitor will work with the CQC where there are concerns about compliance with the 'essential levels of quality and safety'.

During 2013, Monitor will become the sector regulator for healthcare. Amongst other functions, Monitor will jointly licence providers of NHS funded care with CQC¹⁸, and ensure continued access to essential services. Monitor may vary licence conditions between NHS foundation trusts and other providers of NHS funded care.

Monitor's main duty will be to protect and promote the interests of people who use healthcare services by promoting provision of healthcare services which is economic, efficient, effective and maintains or improves the quality of the services.

Monitor will have a variety of roles in relation to providers of NHS services, including:

- licensing all providers of NHS funded care, except those exempted;
- enforcing licence conditions, which may include conditions relating to governance;
- publishing the national tariff, including setting prices, determining the rules for payment and approving local variations from national tariff;
- ensuring essential services, as defined by commissioners, continue in the event of failure;
- concurrent powers with the Office of Fair Trading to prevent anticompetitive conduct that acts against the interest of patients, including conduct that jeopardises the quality of care they receive; and
- enabling integrated care.

The licence will, subject to consultation, include for all licence holders a requirement to hold CQC registration where a provider carries on a 'regulated activity'. Using new powers to enforce the licence, Monitor would be able to fine, order restitution or ultimately revoke a provider's licence if a condition of that licence is broken. However, Monitor could only use this provision where there is a significant risk to the continued delivery of an essential service, e.g., where the CQC suspends or cancels a provider's registration or imposes a condition on registration that affects the delivery of an essential service (e.g., the suspension of that essential service).

For NHS foundation trusts, Monitor will hold two additional powers:

- a power to set specific licence conditions for NHS foundation trusts relating to governance; and
- additional enforcement powers for NHS foundation trusts.

Where CQC judge that a provider is delivering poor care, and where Monitor determines that the poor care resulted from poor governance, Monitor could impose additional conditions to rectify the failings of governance. If these additional conditions were breached, Monitor has powers to suspend directors or governors, or appoint interim directors. While the licence condition on governance for NHS foundation trusts continues in perpetuity and can be enforced in the same way as the CQC registration condition, the powers to impose additional licence conditions to mitigate failings of governance will continue as long as the Secretary of State sees fit.

Monitor will licence all providers of NHS-funded care, except NHS trusts who have not yet secured foundation trust status. NHS trusts will still need to comply with Monitor's requirements on pricing and competition, and this will be monitored by the NHS TDA.

Monitor is a vital member of the new local and regional Quality Surveillance Group (see page 46), where they will share the information and intelligence about providers with other parts of the system.

Monitor will have a close working relationship with CQC in particular, working with them on judgements on quality. It should have regular bilateral discussions with CQC at every level, sharing information and intelligence routinely, and discussing any steps it intends to take as a result of quality concerns to ensure coordinated action.

David Bennett Chair, Monitor

3c. Professional Regulators

Professional regulators are responsible for ensuring that all who practice a health profession are doing so safely.

They do this by

- keeping up to date registers of health professionals in the UK;
- setting the standards of behaviour and competence that health professionals must meet;
- approving and quality assuring the education and training of healthcare professionals;
- dealing with concerns from patients, the public and others about healthcare professionals whose fitness to practise may be impaired because of poor health, misconduct or poor performance; and
- taking action to restrict or remove a healthcare professional's right to practise if it is necessary to protect patients.

The statutory purpose of professional regulators is to protect, promote and maintain the health and safety of the public by ensuring proper standards of practice in their respective professions. Most professional regulators have responsibilities across the whole of the UK, and all of them regulate professionals regardless of whether they work in the NHS or the independent sector.

All regulated healthcare professionals must meet the standards set by their professional regulator and are required to ensure that they stay up to date in terms of their clinical skills by participating in continuing professional development. Many professionals, including those regulated by the Nursing and Midwifery Council and the Health Professions Council, are already required to re-register periodically and to demonstrate to their regulatory body that they have been participating in continuing professional development as part of the re-registration process.

The introduction of medical revalidation will help strengthen the trust patients have in their doctors by making sure that all doctors are part of a governed system in which employers and contractors have to provide support, have a system of regular appraisals and be satisfied that the doctors who work for them are up to date and fit to practise. The non-medical professional regulatory bodies are considering options for strengthening their requirements in respect of continuing professional development and/or introducing a form of revalidation, which would involve a broader demonstration by a professional on a periodic basis that they remain up to date in terms of their clinical practice and otherwise fit to practise.

If health professionals fail to meet the standards, professional regulators can launch an investigation, which could lead to sanctions such as conditions on practice, suspension, or removal from the professional register. Organisations which employ or contract doctors also have a responsibility to take action to protect patients where there is a risk of harm even if regulatory action is underway.

The professional regulators are also responsible for quality assuring the education and training of healthcare professionals. While their powers vary, most can visit or inspect organisations that commission, oversee or provide education. They also have a range of powers to withdraw approval from training programmes, posts or providers if they are not satisfied that education and training is being provided in a safe and effective way.¹⁹

The Professional Regulators make an important contribution to quality across their statutory function of registering professionals, setting standards, education and fitness to practise. The success of professional regulation in driving quality improvement will require an effective interface between the professional regulators, the system regulators and other partners such as Health Education England.

Professional Regulators may have information which indicates wider problems within a healthcare organisation. This may arise either from dealing with an individual or group of fitness to practise cases or from information received through quality assuring education and training (either through inspections or other tools such as the General Medical Council's National Training Survey). They will be members of the new regional Quality Surveillance Groups (see page 46) and should liaise with the other parts of the system to share information and intelligence. They may also have information that they wish to feed in regularly or sporadically to the local Quality Surveillance Groups.

Similarly, if the CQC or any other organisation identifies concerns about an individual healthcare practitioner that professional standards are not being met, they should notify that professional's employer and make a referral to the relevant professional regulator.

Mill Duhan

Niall Dickson Chief Executive General Medical Council

4. Other National Organisations

4a. NHS Trust Development Authority

- The NHS Trust Development Authority (NHS TDA) will be responsible for overseeing the performance of NHS Trusts, including clinical quality, and driving their progress towards NHS foundation trust status
- The NHS TDA will have intervention and support mechanisms at its disposal to use if it has concerns about quality in an organisation and can work with commissioners and regulators to address concerns.
- The NHS TDA will provide scrutiny and assurance of NHS Trusts in their applications for NHS foundation trust status.

The NHS Trust Development Authority (NHS TDA) will be responsible for performance managing NHS trusts as they work towards clinical and financial sustainability by becoming a NHS foundation trust, merging with an existing NHS foundation trust or taking another organisational form. This role will include overseeing the quality of care provided by NHS trusts. The NHS TDA will have a Medical Director and Nursing Director with responsibility for overseeing the quality of care and providing professional leadership to NHS trusts.

The NHS TDA will hold NHS trusts to account for their performance and will support NHS trusts to drive up the quality of services and care delivered in their organisation, pushing them further along the quality curve and closer towards NHS foundation trust status. The NHS TDA will have as a clear priority the quality of services and the safety of patients in its performance management of NHS trusts. NHS trusts will be required to comply with the pricing and competition requirements set out by Monitor. The NHS TDA will monitor their compliance and will provide guidance to support trusts in this respect.

If there are concerns over the quality of care in an NHS trust, the NHS TDA will hold the trust to account for addressing those concerns. Where necessary it will provide support to NHS trusts or intervene to ensure that improvements are made. The NHS TDA will work closely with commissioners and the Care Quality Commission in responding to concerns about the quality of care in NHS trusts.

The NHS TDA will have its own insights and intelligence about the quality of care being delivered by NHS trusts, and so will be a vital member of new local and regional Quality Surveillance Groups (see page 46), where they will share their information and intelligence about providers with other parts of the system.

David From

David Flory Chief Executive, NHS Trust Development

4b. National Institute for Health and Care Excellence

- NICE is the independent organisation responsible for providing national guidance and standards on the promotion of good health and social care and the prevention and treatment of ill health.
- NICE produces guidance on public health, technologies and on clinical practices. It also produces standards for patient care in the form of Quality Standards.
- NICE provides advice and support on putting NICE guidance and standards into practice through its implementation programme, and it collates and accredits high quality health guidance, research and information through NHS Evidence to help health and social care professionals deliver the best patient care.

NICE produces guidance in three areas of health:

- public health guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector;
- health technologies guidance on the use of new and existing medicines, devices, diagnostics and procedures within the NHS; and
- clinical practice guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.

NICE produces standards for patient care in the form of NICE Quality Standards. These reflect the very best in high quality care, to help health and social care practitioners and commissioners of care deliver excellent services, and underpin the system for quality improvement as explained in Chapter 2.

NICE also develops clinical and health improvement indicators for the Commissioning Outcomes Framework (COF) and Quality and Outcomes Framework (QOF) on behalf of the NHS Commissioning Board.

NICE provides advice and support on putting NICE guidance and standards into practice through its implementation programme, and it collates and accredits high quality health guidance, research and information to help health and social care professionals deliver the best patient care through NHS Evidence.

Following the publication of the Health and Social Care Act, NICE's remit will expand from April 2013 and its name will change to the National Institute for Health and Care Excellence (but still abbreviated to "NICE"). This reflects the fact that it will be producing guidance, standards and advice for the social care sector.

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Professor Sir Michael Rawlins
Chair
National Institute for Health and Care Excellence

4c. Health Education England

- Health Education England (HEE) will be responsible for ensuring that the right numbers of health professionals are trained - with the right skills and behaviours - to support delivery of high quality service and health improvement across England.
- HEE will authorise and support the development of Local Education and Training Boards (LETBs).
- LETBs will lead workforce planning locally and commission high quality education and training. They will be responsible for securing quality and value from education and training providers locally.

Health Education England (HEE) was established as a Special Health Authority on 28 June 2012. From 1 April 2013, the national element of HEE will take on a range of responsibilities including:

- providing national leadership for planning and developing the whole healthcare and public health workforce;
- authorising and supporting development of Local Education and Training Boards and holding them to account;
- promoting high quality education and training;
- allocating and accounting for NHS education and training resources and the outcomes achieved;
- ensuring security of supply of the professionally qualified clinical workforce;
- supporting development of the whole healthcare workforce, within a multiprofessional and UK-wide context;
- assisting the spread of innovation across the NHS in order to improve quality of care;
- delivering against the national Education Outcomes Framework to ensure the allocation of education and training resources is linked to quantifiable improvements; and
- annually publishing and updating a Strategic Education Operating Framework for the health-related education and training system in England, setting out national priorities.

HEE's role in relation to quality relates to their responsibilities for ensuring that the professionally qualified workforce are suitably trained, with the right values to provide high quality care. As part of monitoring the quality of education and training, HEE may have information and intelligence about the quality of care being provided within provider organisations. HEE will be members of the new regional Quality Surveillance Groups (see page 46) where they will share information with other organisations across the system, and where they should raise any concerns they may have.

Local Education and Training Boards

Local Education and Training Boards (LETBs) will lead workforce planning locally and commission high quality education and training, acting as a forum for developing the whole health and public health workforce. They will bring healthcare providers and key health and care partners together with those who provide education and invest in research.

Part of LETBs' responsibilities will be to secure quality and value from education and training providers, and so they will need to work closely with those providers to monitor the quality of the education and training. This will give LETBs further intelligence and information about the quality of care in a provider. For example, they will collect information and intelligence from the trainee health professionals in their area, such as junior doctors, which may identify quality of care concerns. Trainees' wider experience of various healthcare institutions provides them with an objective view, which should be taken into account when considering the quality of care being provided across a local area or region.

LETBs will be part of the new local Quality Surveillance Groups (see page 46), where they should share information and intelligence, raising any concerns with the CQC and other parts of the system with an interest.

Professor Ian Cumming
Chief Executive
Health Education England

4d. Department of Health

- The Department of Health is responsible for the effective operation of the health and care system.
- It discharges this by designing the system and ensuring that it is fit for purpose, setting strategic objectives, and holding different parts of the system to account, directly or through Parliament, for the effective discharge of their roles.

The Department of Health (DH), led by the Secretary of State for Health, is responsible overall for the system of public health, health care and adult social care. The Secretary of State has ministerial responsibility to Parliament for the provision of the health service in England, and has a specific duty to exercise his functions with a view to securing continuous improvement in the quality of services.

The Department fulfils this role through ensuring the health and care system is well designed and operates effectively. It does this in three main ways:

Overall system design and goals.

The Department is responsible for ensuring the health and care system is designed to deliver quality care for patients and service users, and value for money for taxpayers.

The Department sets the objectives that the NHS Commissioning Board must seek to achieve, in a "mandate" that is updated every year. This includes objectives for improving the quality of care under the NHS Outcomes Framework.

The DH also sets out the essential standards of quality and safety in legislation that all organisations carrying out regulated activities must meet, which the CQC then registers providers against. It will need to keep these standards under regular review, to ensure that they are still fit for purpose.

In the longer term, the Department is responsible for the design of the overall health and care system, including putting forward primary and secondary legislation where required.

Holding national bodies to account.

The Department's role is to support the national health bodies to perform their functions as effectively as possible, providing the necessary autonomy to allow them to flourish. It is not the Department's role to micromanage, nor to intervene in day-to-day operational matters.

The Department must keep under review the effectiveness of the other national bodies in the system (including the NHS Commissioning Board, Monitor, the CQC and the NHS TDA). As a last resort, if these bodies were to significantly fail to undertake their functions, the Secretary of State could intervene. The Secretary of State must also publish an annual report to Parliament on the performance of the health service.

System leadership

As the overall leader of the health and care systems, the Department's role is to ensure all of the national health bodies work effectively together on areas of common purpose. This role includes providing a forum to work through issues of common strategic importance; ensuring that national bodies' efforts are aligned; and that there is a process to facilitate national health bodies cooperating with each other, ensuring that the interests of patients and the public supersede any sectional or organisational interest.

Una Stie.

Una O'Brien Permanent Secretary Department of Health

SUMMARY OF TOOLS AND LEVERS

Organisation Tools and levers relevant to quality failure		
	Monitoring	Intervening
Provider organisation	Continuous monitoring of quality and performance metrics collected as part of the provision of care	Organisational action to improve quality and performance Action with individuals to improve capacity or capability
Clinical Commissioning Groups	Information gathering and reporting as part of contract management and from wider sources	Contractual levers: • breach of contract • financial penalties • commissioning from another provider Referring primary care providers to the NHSCB
NHS Commissioning Board	National Quality Dashboard and corporate intelligence from local area, regional and national support teams	Contractual levers where it is a direct commissioner: • breach of contract • financial penalties • commissioning from another provider Referral to the regulators
Care Quality Commission	Quality and Risk Profiles Information from people using services	Inspection; Investigation; Warning notices; Penalty notices; Service/Ward restriction or closure; Criminal proceedings; Special Reviews; Themed Inspection Programmes and Thematic Reviews; publishing Information on good care (what works well) and poor care; reporting on the state of the Care market; influencing the Department of Health on how the sector is regulated
Monitor	Via third party information, e.g., CQC's Quality and Risk Profiles	For licence holders in general, interventions are limited For NHS foundation trusts where governance issues are identified: Additional conditions Removal of directors and governors Appointment of interim directors and governors
Professional Regulators	Assessment of individual competence through revalidation/re-registration and investigation of complaints about individuals. Quality assurance of education and training.	Range of powers to restrict or remove a healthcare professional's right to practice. Range of powers to impose conditions or remove recognition from organisations providing education, programmes or posts
NHS Trust Development Authority	Continuous monitoring of performance of NHS Trusts against agreed plans	Support and intervention to NHS trusts to improve performance and secure sustainable futures
Department of Health	Monitoring of performance of the NHS overall against the indicators in the NHS Outcomes Framework. Regular assessment of the performance of arm's-length bodies against their objectives	Holding the NHSCB and other arm's-length bodies to account for their performance. Making changes to how the system operates through legislation or ways or working.

Chapter 5:

How we will work together to maintain quality

In the last chapter, we explained the individual responsibilities in relation to quality across the system. For each part of the system, we described their responsibilities in relation to sharing information and intelligence with each other, and acting cooperatively where there are concerns in the best interests of patients.

Across the health and care system, we know that there are excellent examples of where local health and care economies have built strong working relationships between their organisations, where there is an active dialogue about quality and where concerns or risks are raised promptly and dealt with collectively in a coordinated way. But this is not the picture everywhere. The system from 1 April 2013 will be a new system, and it will be a system that continues to evolve over coming years.

To support the emerging system as it seeks to do the best for the people it cares for, we have developed a model for how the different parts should come together to share information and intelligence and to respond to quality problems when they arise. This is based on our belief that the system must:

- 1. **proactively work together** to share information and intelligence about the quality of care in order to spot potential problems early and manage risk; and
- reactively work together in the event of a potential or actual serious quality failure coming to light, to enable informed judgements about quality and to ensure an aligned response between those with performance management, commissioning and regulatory responsibilities, without undermining or overriding individual accountabilities.

Spotting the early signs of failure

Across a health and care economy, there will be a wealth of information and intelligence, gathered formally and informally, about the providers of services to that population. Often the information that one party alone has will not cause concern, however, when combined with intelligence that, for example, a regulator may have, would point to a potential problem that should be investigated further.

There will be various different organisations and individuals in a health and care economy who will have such information. For example, it is likely that a single provider will be commissioned by a number of local commissioners, and that any one commissioner will commission from a number of local providers, from the public sector, private sector and not-for-profit organisations. This wealth of knowledge and intelligence about how services are being delivered or commissioned will be useful to a range of parties.

Quality Surveillance Groups

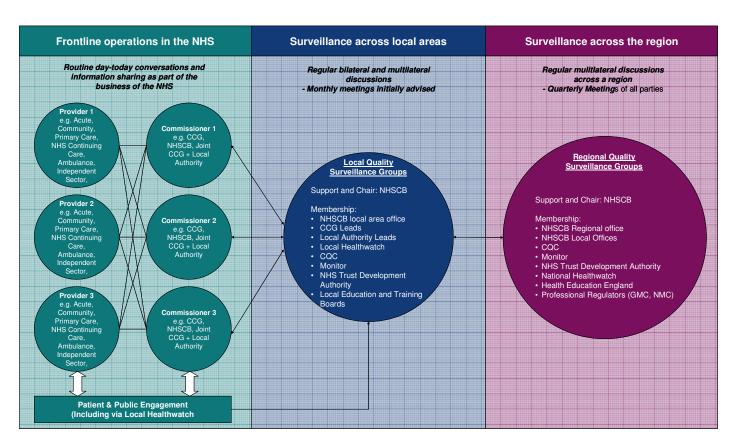
Different parts of the health and care economy should come together to share information and intelligence about quality as part of new Quality Surveillance Groups (QSGs). These QSGs will provide a forum for local health and care economies to realise the cultures and values of open and honest cooperation.

The diagram below presents the model for QSGs, which will operate at two levels:

- locally, on the footprint of the NHS Commissioning Board's 27 local area teams; and
- 2. regionally, on the footprint of the NHS Commissioning Board's four regional teams.

The QSG will act as a virtual team across a health and care economy, bringing together organisations and their respective information and intelligence gathered through performance management, commissioning, and regulatory activities to maintain quality in the system by routinely and methodically sharing information and intelligence.

The creation of QSGs should not add a level of bureaucracy to the system. In many areas, such information sharing and cooperation is already part of their business as usual, bilaterally and multilaterally. Rather, this model will create a network which encourages and creates an expectation of open and honest cooperation, in every local area, in a regular and tangible way. Where it is already happening, the model provides a wider network in which existing relationships will sit.



Members of the local QSGs should be determined locally but include as a minimum all local commissioners in the area (NHS Commissioning Board, CCGs and local authorities), representatives from the NHS Trust Development Authority where there are NHS trusts in the area, the Local Education and Training Board, local HealthWatch and from the regulators, Monitor and the Care Quality Commission.

This membership will be mirrored in the regional QSGs, with the addition of the professional regulators, Health Education England and Healthwatch England, where they wish to be involved. This regional tier will allow the parties to collectively form a wider geographic view of quality, and to consider some of the more strategic issues that arise.

Professional bodies, including the Royal Colleges, will have valuable insight, information and intelligence about quality in provider organisations. It will be important that such information is able to be shared with relevant parts of the system and inform the surveillance functions of QSGs.

The routine operation of a QSG will see regular bilateral and multilateral communications, and regular opportunities for all of the members to meet more formally. It would seem sensible that initially QSGs might come together monthly locally, and quarterly regionally, to have more formal discussions about quality.

For national organisations such as the CQC, Monitor and the NHS TDA, they will be members of all QSGs, involved in sharing information and intelligence along with other parties. However, they will take a risk-based approach to the meetings they attend, given limits to their resources.

Each QSG will not necessarily be able to discuss each provider within its local area every time it comes together. It is likely that Groups will wish to consider different groups of providers over a range of meetings or discussions, for example, according to type of provider or by local district. Such discussions will be risk and evidence-based to help ensure early consideration of priority areas.

The NHS Commissioning Board will provide a support and facilitation role to local and regional QSGs. This will involve:

- proactively ensuring that all parties who need to be involved, are involved;
- facilitating sharing of information if needed;
- ensuring that there is a clear understanding as to how the Group will consider all providers and system wide issues over time;
- chairing meetings where a chair is required by the group; and
- providing a record of the discussions and agreed actions.

The NHSCB local area teams will provide this support at a local level, and the regional offices will provide the function for the QSGs in each of the four regions. The NHSCB is well placed to fulfil this role on behalf of the commissioning function, as it is commissioners who have responsibility for the population of that area or region. The NHSCB will lead the establishment of QSGs so that by 1 April 2013, there is a comprehensive network in place across the country.

Judging when there has been a quality failure

Risk Summits

The Quality Surveillance Groups will provide routine and ongoing surveillance and assurance for quality within a local health and care economy. From time to time, concerns that there could be a serious quality failure, or the potential for there to be a serious quality failure, within a provider organisation may arise.

Any statutory organisation – local, regional or national – who has concerns about the quality of care of a provider should alert other QSG members to their concerns by triggering a Risk Summit. Concerns may arise as a result of the sharing of information and intelligence at a Quality Surveillance Group or as a result of new intelligence coming to light separately, for example, from a whistleblower, a patient, an undercover reporter or local or national media exposure.

QSG members relevant to the provider in question should come together to give specific, focussed consideration to the concerns raised. This should facilitate rapid, collective judgements to be taken about quality within the provider organisation in question.

CQC will make an independent regulatory judgement, informed by the range of available information and intelligence, as to whether there has been or there is the potential to be a significant breach of the essential standards of quality and safety. Where they determine there has been a breach, regulatory action will need to be taken by the CQC. Other parts of the system may also need to take action to safeguard patients and improve quality of care. Even where the CQC determine that there has not been a material breach in registration, the commissioners, Monitor or the NHS TDA may determine that further focussed action by different parts of the system is required.

As a matter of routine, consideration should be given as to whether any professional standards issues have arisen and if so whether a referral needs to be made to the relevant professional regulator.

As part of a Risk Summit, the CQC can ask the other members of the QSG to carry out a rapid impact assessment of any potential regulatory action it is considering, such as closing a service, where it would find this analysis useful.

There may be a need to involve other parties in the Risk Summit, e.g. other commissioners with an interest, other local government agencies, Local Education and Training Boards, the Local Supervising Authority Midwifery officer, the Police, Safeguarding Boards or the professional regulators. Each instance of potential or actual quality failure will be different, and so involvement of these other parties should be determined locally according to the circumstances.

Responding when things go wrong

Once a judgement has been taken that there has been, or that there is the potential to be a serious quality failing, the different parts of the system will need to determine what action needs to be taken. No longer will there be a 'system manager' in the form of a Strategic Health Authority on the scene to hold the ring in the event of a failure situation. Rather, the system will need to manage itself – the parties will need to collectively determine what actions should be taken forward and how they should be coordinated.

They will need to do this recognising the statutory responsibilities of the different parts of the system and that one part cannot direct another.

The package of actions taken forward to respond to an actual or potential serious quality failure should aim to:

- rapidly safeguard patients;
- ensure the continued provision of services to the population; and
- begin the process of securing improvements at the provider organisation, including supporting staff as necessary.

Actions will be agreed which need to be taken forward within defined timeframes. It will be important that one party is recognised as 'holding the ring' in these collective discussions, to ensure an aligned and coordinated system-wide response, in what may be a fast-moving situation of high pressure. This role will involve:

- ensuring that QSG members relevant to the particular provider(s) meet within 24/48 hours of the judgements on quality being made, or sooner if the situation demands it, and that they meet at regular and appropriate intervals until action has been taken;
- chairing these meetings, including providing a record of the discussion and agreed actions; and
- recognising other parties' roles and statutory responsibilities, i.e. that one party cannot direct any other party in the exercise of their statutory functions.

Each instance of actual or potential serious failure will be different, determined particularly by the type and size of the provider(s) in question. To ensure maximum flexibility in responding to situations, the different parts of the system should determine which organisation should 'hold the ring' according to the particular circumstances. For example, where it is a NHS trust in question, it may be most appropriate for the NHS TDA to provide this role. Where it is a primary care provider, it may be most appropriate for the NHSCB to step in.

The Quality Surveillance Group is responsible for ensuring that one party is agreed quickly and that they are appropriate. The party identified as 'holding the ring' should be legitimate and have the capability and capacity to perform the role.

To avoid unnecessary delay and confusion, if for some reason the parties cannot agree on who should 'hold the ring', the default should be that the NHS Commissioning Board takes on this role.

Where the concerns in question involve a potential adult safeguarding issue, the chair of the discussion must ensure that the relevant local authority safeguarding adults protocol is followed. This will help ensure that adult safeguarding processes are not compromised. Where the concerns involve a potential child safeguarding issue, the chair must ensure that the relevant Local Safeguarding Children Board is formally notified and engaged so that the QSG works within the statutory framework for child safeguarding.

The mechanisms to encourage the different parts of the system to come together locally and regionally that we describe in this chapter should be useful in supporting the system to identify actual or potential serious failures and to deal collectively with those situations, putting the safety of patients and service users first.

However, they do not provide a silver bullet. Maintaining quality requires commitment, endorsement and leadership from every part of the system, from national to local levels. It must be seen as the business as usual of organisations individually and collectively. The model we describe will not take away the risk of there being another serious failure in the NHS. There will always be an inherent risk of a serious failure occurring which can only be mitigated by providers, commissioners and regulators seeing quality as their business, everyday, and making quality improvement and maintaining the essential standards their priority.

The following chapter explains what the NQB, and the organisations that we represent are going to do to make the values and behaviours, and systems and processes we have described a reality.

Chapter 6:

Making it happen

Over the next few years, the structures in the NHS will change, both as a result of the Health and Social Care Act 2012 and in response to the NHS rising to the challenge of delivering better quality care for less. This report provides greater clarity for new and existing organisations, in terms of their individual and collective responsibilities with regard to quality. This report is in draft form. We are conscious that the final report of the Mid Staffordshire NHS Foundation Trust Public Inquiry may include findings and recommendations relevant to the approach we have described, and so intend to update and publish a final report before the new system goes live in April 2013.

But there is much more work to be done to ensure that the system is able to operate effectively from 1 April 2013. Further work will need to be undertaken both locally and nationally in order to develop the overall operating model for quality at the next level of detail.

Actions for each organisation in the system

As a minimum, we would expect each organisation to consider this report as a leadership team, board or partnership, as a Senior Executive Team, and as a group of clinical leaders and senior managers. They should commit to the principles and behaviours that underpin it and work through the following questions:

- Have you as Chief Executive and Chair taken a lead on your organisation's application of the report?
- Are we clear within our own organisation about our own roles and responsibilities, particularly statutory responsibilities, with regard to quality and identifying, responding and learning from failure?
- What further steps need to be taken between now and April 2013 in order to ensure that we are able to fulfil our roles and responsibilities effectively?
- Are we clear how we are performing in comparison to other similar organisations?
- Are we clear within our local/regional/national health care economy about what to expect from each other? Where there are differences of view or understanding, do we agree that we need to resolve them and do we know how we will go about resolving them?
- Do we have good relationships with our local/regional/national partners, built on open and honest cooperation? How can we strengthen these relationships, and honour the seven principles of public life, to provide a strong foundation for the new structures to build upon?
- Is there a reliable process in place to engage our staff and, for NHS foundation trusts, our Governors and members?

- How will we work with partners such as staff side organisations, social
 partnership groups, institutions of higher and further education involved
 with training staff for the NHS, Safeguarding Boards and Royal Colleges to
 make this happen where we need to?
- How can we ensure that the values and principles of the NHS Constitution are a reality within and between our different organisations? What should we do when we or others fall short?
- How can we ensure that we adhere not just to the legislation, but exercise our common sense and judgement in the interests of the patients who use the NHS and the public who pay for it?
- How can you best engage patients and carers, LINks and HealthWatch locally to help them understand this report and the part your organisation is playing to make it a reality. What contribution can they make?

Actions for statutory organisations on the NQB

The national organisations cited in this report commit to ensuring that their staff are aware of this report and understand the model it describes, including their role as part of it. They will seek to live the culture and values described in the report as they discharge their distinct roles and responsibilities and work together. They will provide evidence that this report has been discussed and addressed at board level, and declare a 'state of readiness' with respect to their responsibilities for quality in advance of April 2013, in the form of a public letter from the NQB to the Secretary of State for Health.

Members of the NQB will continue to work together to develop how this model will operate in practice, particularly how Quality Surveillance Groups will operate. The NHS Commissioning Board will lead on developing a guide on 'How to run a Quality Surveillance Group', and will train its local and regional staff so that they have the capability to provide the support and facilitation role for QSGs set out in this report.

The NQB will oversee these actions, and how the model we have described is operating from April 2013. We will provide further advice and guidance where required.

This report offers clarity and guidance on a new system that does not yet exist. As such, it cannot and should not answer every question. It cannot and should not provide assurance that the model described here will prevent quality problems from occurring in the NHS. Unfortunately, the provision of health care is an activity inherent with risk: each day our patients literally put their life in the hands of our staff.

But what we can and must do is everything we can to reduce risk and increase the quality of care. This report aims to help reduce risk by addressing some of the

uncertainties that exist about roles and responsibilities in the new system, as well as introducing new processes to facilitate collaboration across the system.

Whilst legislation and guidance is helpful, the NHS is made up of people, and it is the values and behaviours of those people that will determine our success or failure. When in doubt, the following operating principles should be used as a guide to action, alongside the values and behaviours set out in the NHS Constitution:

- The patient comes first not the needs of any organisation
- Quality is everybody's business from the ward to the board; from the supervisory bodies to the regulators, from the commissioners to primary care clinicians and managers
- If we have concerns we speak out and raise questions without hesitation
- We listen in a systematic way to what our patients and our staff tell us about the quality of care
- If concerns are raised, we listen and 'go and look'

This report is meant as a guide to support the system in exercising judgement and applying common sense to what will be complex situations, where the impact of the decisions made will be profound for individuals, families and communities.

ENDNOTES

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAn dGuidance/DH 113020

http://www.kingsfund.org.uk/publications/articles/francis report.html

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAn dGuidance/DH 085825

http://www.dh.gov.uk/health/2012/07/careandsupportwhitepaper/

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAn dGuidance/DH_117353

http://www.legislation.gov.uk/ukpga/2012/7/contents/enacted

¹ Review of early warning systems in the NHS, National Quality Board, February 2010. Available at:

² Preparing for the Francis Report: How to assure quality in the NHS, Kings Fund, July 2012. Available at:

³ High Quality Care for All: NHS Next Stage Review Final Report, Department of Health, June 2008. Available at:

⁴ibid 1

⁵ Maintaining and improving quality during the transition: safety, effectiveness, experience, National Quality Board, March 2011. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAn dGuidance/DH 125234

⁶ Monitor will license NHS foundation trusts from April 2013, subject to consultation on the licence conditions. Others, except those exempted from the licence, will be licensed from April 2014

⁷ Caring for our future: reforming care and support, Department of Health, July 2012. Available at:

⁸ Equity and Excellence: Liberating the NHS, Department of Health, July 2010. Available at:

⁹ ibid 3

¹⁰ Section 2, Health and Social Care Act 2012. The Health and Social Care Act 2012 is available at:

¹¹ Guidance about compliance: Essential standards of quality and safety, CQC. Available at: http://www.cqcguidanceaboutcompliance.org.uk/

¹² Section 2, Health and Social Care Act 2012

¹³ Section 23, Health and Social Care Act 2012

¹⁴ Section 26, Health and Social Care Act 2012

¹⁵ Section 62. Health and Social Care Act 2012

¹⁶ NICE, the National Institute for Health and Clinical Excellence, will be renamed the National Institute for Health and Care Excellence from 1 April 2013 as it takes over responsibility for setting standards and producing guidance in the care and support sector.

http://www.gmc-uk.org/guidance/good medical practice/duties of a doctor.asp For nurses and midwives: *The code: Standards of conduct, performance and ethics for nurses and midwives*, the Nursing and Midwifery Council. Available at: http://www.nmc-uk.org/Nurses-and-midwives/Standards-and-guidance1/The-code/

¹⁷ For doctors: *Good Medical Practice: Duties of a doctor*, the General Medical Council. Available at:

¹⁸ Smaller providers of NHS funded care and, subject to consultation, NHS trusts, will be exempted from Monitor's licensing regime

¹⁹ The General Optical Council and the General Pharmacy Council also regulate premises to ensure that drugs are kept safely and that hygiene standards are observed.