



House of Commons  
Health Committee

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**Patient Safety: Care  
Quality Commission,  
Monitor, and Professor  
Sir Ian Kennedy's  
Responses to the  
Committee's Sixth  
Report of Session  
2008–09**

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**First Special Report of  
Session 2008–09**

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## The Health Committee

The Health Committee is appointed by the House of Commons to examine the expenditure, administration, and policy of the Department of Health and its associated bodies.

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### Committee staff

The current staff of the Committee are Dr David Harrison (Clerk), Martin Gaunt (Second Clerk), David Turner (Committee Specialist), Lisa Hinton (Committee Specialist), Frances Allingham (Senior Committee Assistant), Julie Storey (Committee Assistant) and Gabrielle Henderson (Committee Support Assistant).

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# First Special Report

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The Committee published its Sixth Report of Session 2008–09 on 3 July 2009. The Government Response was published as Cm 7709 on 13 October. Further responses have been received in the form of memoranda from the Care Quality Commission and Monitor. The Chairman also received a letter from Professor Sir Ian Kennedy, former Chair of the Healthcare Commission, to which he replied. They are published as Appendices to this report.

## Care Quality Commission's Response

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1. **The Care Quality Commission (“CQC”) welcomes the opportunity to respond to the Health Select Committee’s report on its Inquiry into Patient Safety. Safety is the first dimension of CQC’s model of high quality care, and our new system of registration is designed around ensuring essential standards of safety and quality in all care sectors. Our regulatory work will therefore bring improvements in this vitally important area by assessing the performance of providers and commissioners, holding them to account where necessary, and helping to empower people who use services by providing them with information to support informed choices. This will allow them hold providers and commissioners to account at a local level.**
2. **CQC is also actively engaged in the National Quality Board’s review of the systems and processes to ensure that poor care is identified and dealt with, and the National Patient Safety Agency’s work on its policy framework for serious untoward incident reporting and learning and data set development for root cause analysis.**
3. **This response separates our thoughts on the general issues raised by the inquiry and those which have a specific bearing on our work.**

### General issues

4. **CQC broadly supports the majority of the general findings, conclusions and recommendations from the inquiry, in particular in clarifying the roles and responsibilities of organisations and placing the focus on board accountability and proactive leadership in an open and fair culture of safety. However, there are a few areas where we would wish to comment as follows:**

- The recommendation to introduce case note review as a more accurate means of measuring the scale of patient harm is welcomed. However, this should be done using a recognised tool such as the Global Trigger Tool (developed for various care settings).
- We too would like to see more published information being made available, with the parallel message that reporting is a good thing. People who use services deserve to know about the risks they face on all aspects of safety, not just about healthcare associated infections. However—this must be done responsibly to avoid any

perverse incentives or unintended consequences (for example inappropriate media attention) which might discourage reporting and learning.

- We would also wish to see boards using a broad range of safety-related indicators to routinely evaluate their safety performance and the quality of their information, and using this information to set challenging safety goals. This will be important in the run up to the new registration system when boards will need to demonstrate compliance and not just assurance.
- Better use of technology can clearly bring benefits, but proper attention needs to be given to training, risk assessment and evaluation to ensure that new risks are not introduced as a consequence.
- While the effectiveness of whistle blowing policies should be reinforced, this should not be seen as a substitute for the development of more open and fair cultures where staff are encouraged to raise concerns locally and have them addressed.
- We echo the note of caution around linking payment to ‘never events’, due to the potential perverse incentives for reporting in the absence of effective validation mechanisms.
- We acknowledge that the emphasis on quality and safety in the Darzi review indicates that insufficient progress has been made in these areas across the board. However, safety is not something which can be achieved once and for all and then put to one side. It requires constant vigilance. Every time a new technique, change in personnel, process or way of doing things is introduced it brings new risks, which must be monitored and managed. This is particularly true in times of major organisational and system change.
- While serious untoward incidents will of course warrant special attention, it is also important to continue to collect and analyse information about lower grade harm and near miss incidents. These may signal more significant events yet to happen, and/or indicate a culture of complacency as regards safety, where tolerance of less serious incidents desensitises the organisation to warnings of more serious failure. The analysis of less serious incidents can also help to inform the analysis of serious untoward incidents, involving similar circumstances, as is the case in the development of the National Patient Safety Agency’s Rapid Response Reports.

## Regulation

**5. The report makes some specific comments about regulation and recommends that the Government should examine the contribution of regulatory deficiencies to failures in patient safety. In particular, it criticises:**

- the cost and burden of regulation
- the role of performance assessment in spotting serious service failures
- duplication of regulatory activities
- the focus on processes and procedures rather than outcomes.

### *Cost and burden of regulation*

6. The report states that it was not possible to quantify the cost imposed on the NHS by the Healthcare Commission over and above its operating costs at 0.1% of public funding allocated to the sector.

7. The Healthcare Commission's independent evaluations of the Annual Healthcheck carried out by OPM in 2007<sup>1</sup> demonstrated that there have been clear benefits from, and wide provider support for, the Annual Healthcheck, even though the costs have not been fully quantified. It should be noted that both study teams included health economists, but they were unable to quantify the costs or benefits, as the work to respond to the Annual Healthcheck had become embedded in trusts' internal processes, as was to be expected. Although trusts were able to identify benefits from the process, they were unable to put a monetary value on any additional activity to respond to the Annual Healthcheck that was over and above their normal operating costs.

8. Of 220 trusts responding to a survey in the 2007 evaluation:

- 70% of trusts agreed that the assessment of core standards is a good use of staff time, i.e., "the benefits outweighed the costs".
- 93% thought that it had a positive impact on patient care. Data from case studies provided examples of both direct (for example, improved infection control) and indirect (for example, raised staff awareness) benefits.
- 68% agreed that core standards assessment had improved the care of patients.
- 67% agreed that it had improved the safety of patients.
- 89% agreed that self-assessment had a positive impact for the trust and builds on the evidence that organisations should be gathering anyway.
- 25% reported an increase in benefits in the second year; 57% reported benefits about the same—the impact has not declined.
- Overall, experience from the case studies in year two was more positive and trusts wanted continuity in the regulatory approach.
- There is support from patients and the public for the new system. ("The annual health check is a lever to get things done at the PCT.")

9. Responses to the earlier evaluation were also positive, with 31 out of 58 respondents saying that the benefits outweighed the costs.

10. Indeed, the Secretary of State said in his response to *Aspiring to Excellence: Final report of the Independent Inquiry into Modernising Medical Careers* (Department of Health, 2008):

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1 Healthcare Commission (2008) *Making a difference?: An evaluation of the performance of the Healthcare Commission 2004–2008*

“Performance assessment by the Healthcare Commission has been a powerful incentive for leveraging up the performance of healthcare organisations.”

**11. CQC is taking steps to respond reduce the administrative burden of its regulation by 25% and the burden of data and information collection by 30% by 2010. Of the 240 data sources utilised to assess progress against national priorities, only 17 require a special data collection by the regulator.**

**12. We are currently working with partner regulators to further align our processes and data and information collections, and to identify and remove duplication and overlap. We are also carrying out regulatory impact assessments for our new activities. We are establishing a baseline against which to demonstrate a reduction in unnecessary burden.**

### ***The role of performance assessment in spotting serious service failures***

**13. The report raises doubts about the effectiveness of regulation owing to the failure of the Annual Healthcheck to spot “appalling cases of lethally unsafe care”, such as the serious failings identified at Mid Staffordshire, Stoke Mandeville and Maidstone and Tunbridge Wells. While we recognise that the Annual Healthcheck may have had some externally imposed constraints, we do not fully accept the criticisms levelled in the report.**

**14. The Annual Healthcheck aimed to provide an overall assessment of the performance of NHS trusts, looking at compliance with core standards and performance against indicators reflecting national priorities. It was part of a range of regulatory activity, which also included more in-depth work. The approach and design were agreed with the Department of Health and were in line with Government principles on better regulation and public service inspection. The intention being that organisations should be more aware of their own performance resulting in a lighter touch approach to regulation.**

**15. The Annual Healthcheck therefore relied upon existing national data collections and the rigour and honesty with which trust boards make their declarations. It has already been highlighted in the Health Committee report that:**

- trust boards vary in their grasp of the safety agenda, and the robustness of their assurance systems. The Healthcare Commission report *Safe in the Knowledge* (2009) explored this issue in detail and made recommendations for improvement
- the Department of Health has not put arrangements in place to collect adequate data on safety
- safety has not been given sufficient prominence in national targets.

**16. Nonetheless, the Healthcare Commission’s screening database contained approximately 450 data items relating to safety assessed via the Annual Healthcheck, and inspections in 2007/08 and 2008/09 were enhanced to focus more on safety by using specific areas of risk to test more generic assurance with safety related standards.**

**17. It should also be recognised that the Annual Healthcheck was not the only tool available to the Healthcare Commission to detect concerns about individual healthcare services. The following additional mechanisms were used to identify the three high profile failings referred to in the report. These clearly demonstrate the regulator's effectiveness to react to immediate concerns:**

- The programme to follow up apparently high death rates in trusts (“mortality outliers”). This process involves analysing data that suggests concerning trends in the death rate for specific conditions or operations. All such alerts go through an investigative process. CQC is building on this programme of work by monitoring other outcome measures such as emergency readmission rates. It has also started to publish the results of closed cases and will continue to do so on a quarterly basis.
- The system for investigating serious concerns raised directly with the Healthcare Commission. CQC retains these investigation functions under the Health and Social Care Act 2008.
- Requests for an investigation from the Secretary of State for Health. This power is retained in relation to the Care Quality Commission in the Health and Social Care Act 2008.

**18. In addition, the following tools were also used to supplement the Annual Healthcheck in identifying more specific concerns with individual organisations or services:**

- Screening and surveillance programmes
- Follow up activity where concerns were raised in relation to serial non-compliance with core standards. This included discussing action plans for making improvements with the trust and responsible SHA.
- The healthcare associated infections programme of inspections.
- Collaborative risk summits to identify and discuss common concerns, and if necessary to arrange further action to respond to them.
- Policies and procedures for handling concerns raised through local engagement or our helpline based around the organisational risk profiles
- Independent assessment of second stage complaints
- Service reviews into specific services or client groups
- Surveys of patients and staff
- Making comparative indicators available to trust boards to allow them to assess their achievements against measures of clinical effectiveness and safety.

**19. At a more strategic level, the Healthcare Commission also conducted two in depth studies into the governance of safety at board level, and the implementation of safety solutions and published two reports *Safe in the knowledge* and *Safely does it* in March 2009. These reports address many of the issues covered in the Health Select Committee**

**report and provide trust boards with examples of good practice and signposts to additional guidance.**

**20. The majority of the tools listed above will continue to be used by CQC a part of its regulatory approach. However, as a new regulatory body, with additional powers, CQC is reviewing its systems of monitoring and assessment.**

- We will give a higher priority to ensuring care is planned around the needs of the individual;
- we will promote the importance of joining up across health and social care where this is in the best interests of people in need of care; and
- we will work with others to promote improvement and the dissemination of best practice.

**21. CQC has already identified areas for improvement, which will be reflected in the design of new systems of regulation, including improved methods for identifying risk and taking swift action where necessary, for example:**

- developing dynamic quality and risk profiles
- operating clear judgement frameworks for registration and ongoing compliance
- an approach for responding to concerns which is proportionate to the degree of risk and outcomes for people who use services
- building on the collaborative risk summits
- prioritising regulatory activity on the weakest performers.

**22. Two of our five strategic priorities, currently being consulted on, concern acting swiftly to eliminate poor quality care, and ensuring and promoting high quality care. We will work with others to identify the critical factors in good and poor performance and to demonstrate how regulation can drive up standards and quality, leading to improved practice, outcomes, and performance.**

**23. We will also be considering how the uneven reliability of trusts' self declarations can be remedied.**

### ***Duplication of regulatory activities***

**24. The report points to duplication of some activities by different regulators, namely the Healthcare Commission/CQC, the Audit Commission, Monitor and the NHS Litigation Authority. Each body has very different regulatory functions and, where appropriate, information is exchanged to inform each other's assessments. For example:**

- The financial management component of the Annual Healthcheck and Monitor's assessment is directly informed by the Audit Commission's findings

- NHSLA assessments are used as cross checking information in the Annual Healthcheck to either rule out inspections or reduce the number of lines of enquiry
- CQC must keep Monitor informed about the provision of care by NHS foundation trusts, and on request the CQC must provide Monitor with any material relevant to work undertaken by the CQC. Also, Monitor must give CQC any information it has about care by an NHS foundation trust which would assist CQC in the exercise of its functions.

**25. The report goes further to recommend that the inspection process currently undertaken by the NHS Litigation Authority should be subsumed within the work of CQC. CQC would be keen to explore how the costs of regulation could be reduced still further by looking for additional opportunities to integrate the NHS Litigation Authority assessment of risk management standards with the new regulatory system, subject to a full evaluation of the impact on the remit and resources of the regulator, and the requirements of the NHSLA's Clinical Negligence Scheme for Trusts.**

**26. CQC has committed to deliver, in collaboration with external partners, a programme of planned collaborative reviews using broadly similar methodology to that used by the Healthcare Commission for risk summits. The 2009/10 programme will comprise planned and triggered reviews as part of the assessment process. The aim of the planned collaborative reviews is to share information about individual providers, agree a collective level of concern and then develop a collective and proportionate regulatory plan of action to support improvement.**

**27. By adopting this approach, CQC is able to coordinate and target activities, thereby reducing duplication and acting in a more efficient and effective manner.**

**28. The benefits of these reviews include:**

- Getting a more rounded picture of local situations through sharing information with others;
- Reduced likelihood of duplication as organisations share details of their activities;
- Making local personnel more effective in their work through increased local knowledge;
- Improving working relationships at local level, leading to a better understanding of organisations' respective roles and how they can best work together.

**29. CQC continues to work with all other relevant regulators, SHAs, Government offices and improvement agencies, including planning and co-ordinating our work to reduce regulatory burden for commissioners and providers of care services. In so doing, we embody the Government's principles of good regulation.**

***The focus on 'rules-based' processes and procedures rather than outcomes***

**30. The inquiry report states that regulation has been "too rule-based, looking at processes and procedures, rather than actual outcomes and consequences".**

31. The importance of outcomes and the views of people who use services are enshrined in the Health and Social Care Act 2008 that established the Care Quality Commission. The Commission is charged with ‘performing its functions for the purpose of encouraging the provision of health and social care services in a way that focuses on the needs and experiences of people who use services’. In particular it must have regard to the ‘experiences of people who use health and social care services and their families and friends, and the views expressed by local involvement networks about the provision of health and social care services in their areas’.

32. The regulation of health and adult social care is changing. From April 2010 all regulated health and adult social care providers will be required by law to register with CQC. National Minimum Standards and Standards for Better Health for the NHS are being replaced by new Registration Requirements—essential common quality standards across the care sector. These Requirements are enshrined in law in the Health and Adult Social Care Act (Registration Requirements) Regulations 2009 due to be laid before parliament in October. The requirement to register will apply to independent health care and adult social care providers (currently registered under the existing system), to NHS Trusts for the first time, and to new providers coming into the market.

33. To register with Care Quality Commission, all health and adult social care providers must show they are meeting the new Registration Requirements, or essential common quality standards. This means that common standards will apply right across the care sector.

34. We have already completed the registration process for NHS providers for the new regulation relating to healthcare associated infections. Our registration of 21 trusts was made subject to conditions, which are legally enforceable and must be met within agreed timescales or enforcement action will follow.

35. By law, CQC is required to produce guidance about compliance which makes clear to providers what they need to do to be compliant with the Registration Requirements. The guidance is generic across health and adult social care and is primarily focussed on outcomes—what constitutes a quality experience for people who use services, rather than primarily on the policies, systems and processes used to deliver care and it has been introduced in direct response to what people who used services, providers and stakeholders said was needed.

36. A 12 week consultation on the guidance about compliance with the new registration requirements was launched on 1 June. We will expect providers to make improvements, where needed, to meet these standards. We will work with those providers who are not compliant—and with the commissioners of those services—to stimulate improvement. We also have a wide range of enforcement powers where necessary.

37. The Health and Social Care Act 2008 states that the Care Quality Commission must have regard to:

- views expressed by or on behalf of members of the public about health and social care services,

- experiences of people who use health and social care services and their families and friends,
- views expressed by local involvement networks about the provision of health and social care services in their areas.

**38. CQC has consulted on how people who use services can get involved in regulation and has published its statement on involvement: *Voices into Action*. This statement embodies CQC's commitment to involve people who use health and adult social care services in everything we do, and make sure that services involve people and respond to their views. We firmly believe that this involvement is central to improving services for everyone. We are also actively developing our relationship with Local Involvement Networks, to make sure that we have a simple route for them to give us their views and that we are making full use of what they tell us.**

**39. CQC's regulatory framework and methods to support registration and monitoring of ongoing compliance are still under development, but are designed entirely around outcomes for people who use services. The approach will make effective use of qualitative as well as quantitative information, including comparative information and the views of people who use services to support dynamic and flexible monitoring and response systems, and will use this approach to reach a judgement on the level of risk posed to patients.**

**40. We will bring together information on performance from our wide range of regulatory activities and make it available to people who use services—as well as to providers and commissioners—so that they can make better informed decisions and determine where improvements are needed.**

**41. We are working with the Department of Health and National Patient Safety Agency to develop a rational approach to collecting and monitoring information on serious untoward incidents, and using this to inform our risk assessment at organisational and strategic levels.**

**42. Other developments underway include:**

- A more rapid and responsive approach to concerns about quality and safety, including enforcement action against providers who fail to meet the standards set out in our *Guidance about compliance*.
- Expanding our screening and mortality outlier surveillance programmes to take on board additional indicators of risk
- Taking forward the findings from work inherited from the previous commissions relating to safe care where appropriate.

**43. There are two issues raised in the report where we would welcome further dialogue:**

- The report recommends the establishment of a new independent investigations body. CQC has been invested with statutory powers of investigation and enforcement. Regulations will also make it a requirement for health and social care providers to notify CQC of specific incidents, including those leading to

unexpected death or severe harm. CQC is therefore already able to provide this function, which can be triggered either by a statutory notification or a concern raised via other avenues. The Health and Safety Executive also have a remit in this area. We are working closely with the National Patient Safety Agency to ensure that this new notification and response system is aligned with the national reporting and learning systems already in place and the development of Patient Safety Direct.

- CQC will be setting out the expectations on providers regarding the essential standards for handling complaints through its guidance about compliance with the relevant Regulations. These registration requirements include the need for organisations to have effective complaints handling systems. CQC has the responsibility for assessing the quality of these procedures. The law requires that NHS organisations produce an annual report on complaints received, issues raised and matters where action has been taken to make improvements. The new registration requirements for NHS providers also require that they submit this report to Care Quality Commission. Concerns and complaints about services can give us information about the quality of care, and about how well services are meeting people's needs. We would also expect commissioners of services to make these expectations clear in their contracts with providers.
- The Parliamentary and Health Service Ombudsman (PHSO) and Local Government Ombudsman (LGO) are encouraging CQC to play a key role in shaping the regulatory framework for complaint-handling in health and social care. The PHSO in particular has outlined proposals for a strategic alliance. CQC is working closely with PHSO to establish a Memorandum of Understanding to share information on unresolved complaints, which could be used to inform our assessment of organisations. In addition, CQC may need to follow-up the findings or recommendations made by the ombudsmen following their investigations as part of our regulatory activity with local organisations. Whilst we have no role to play in investigating individual complaints we do have the power of inspection and enforcement and can as the regulator require services to comply.
- While CQC cannot offer personal remedy and redress for individual complainants we do accept and value information from a variety of sources, including from individuals via our National Contact Centre, website feedback, and third party commentaries. We will incorporate this information into our quality and risk profiles of providers wherever possible.

**44. We hope that this response demonstrates how CQC is committed to working with other organisations, including the National Quality Board and National Patient Safety Forum, to improve the quality and safety of services. Formal consultation on our 5 year strategy is now underway, and safe care will be an underpinning theme in any resulting programmes of work. We would be happy to discuss any of these points in more detail if required.**

# Monitor's Response

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## Introduction

The House of Commons Health Select Committee published its report on Patient Safety on Friday 3rd July 2009.

This paper provides responses from Monitor, the Independent Regulator of NHS Foundation Trusts, to those recommendations related to NHS Foundation Trusts, to the role of Monitor as independent regulator of NHS foundation trusts and to matters directly related to Mid Staffordshire NHS Foundation Trust.

## Response to Recommendations

**37. The performance-management role of Strategic Health Authorities appears to be ill-defined and to vary between SHAs. We are not convinced that this function is being effectively discharged throughout the NHS. There seems to be no definition of it laid down by the DH; and the Department was unable to supply this when we asked. We recommend that the DH produce a formal definition of the performance management role of SHAs. (Paragraph 257)**

The Committee has expressed concern about the performance management role played by SHAs and the lack of performance management of NHS foundation trusts. It is important to note that while a clearer definition of the role of SHAs may be helpful, NHS foundation trusts do not fall within the performance management regime of the strategic health authorities. In line with the core purpose of the foundation trust policy—to better serve patients and tax-payers by increasing the autonomy and local accountability of NHS providers—NHS Foundation Trusts instead fall within the regulatory regime of Monitor.

As the regulator of NHS foundation trusts, Monitor is responsible for the design and update of a regulatory and reporting regime for NHS foundation trusts, which is to ensure ongoing compliance with the terms under which NHS foundation trusts are authorised. Where there is a breach of those terms by an NHS foundation trust, Monitor will take action. Where that breach may be significant, Monitor will use its formal powers of intervention if necessary to ensure that the matter is rectified in a timely and effective manner. These powers may include, for instance, the removal or appointment of members of the board of Directors and Governors, or a requirement for the appointment of independent advisors or to cease to provide unsafe services.

Monitor's regulatory regime is published, regularly reviewed and proposed changes are the subject of public consultation before being incorporated. Key documents include:-

- The Compliance Framework

- The Prudential Borrowing Code

- The Financial Reporting Manual

- The Audit Code.

**38. Regulation has been burdensome and costly and its main mechanism, the Annual Health Check, has failed to pick up major failings in healthcare, although the HCC did through other means identify the problems in cases such as Mid-Staffordshire Trust and things would have been even worse without regulation. We do not, of course, know how much poor care the Annual Health Check failed to identify. (Paragraph 258)**

Effective regulation is characterised by both the early identification of potential or actual issues, and the taking of effective action to rectify failings if and when they occur. Whilst the learning from Mid Staffs point to improvements which can be made in the system, and specifically to our assessment process, it is important to note that Mid Staffordshire had not operated within Monitor's regulatory system at the point at which the investigation was launched in March 2008 by the Healthcare Commission, which was four weeks after the trust's authorisation.

In the particular case of Mid Staffs, and following the publication of the Healthcare Commission's report in March 2009, Monitor and the Care Quality Commission have worked together to ensure that the failings were fully understood, that appropriate actions were quickly put in train to rectify them, measures were established to track progress and full time leadership is now in place to deliver agreed actions to provide a satisfactory and sustainable solution.

This has involved Monitor using its formal powers on two separate occasions, first to ensure interim appointments were made at the Trust to put in place high quality interim management ahead of publication of the report and then, second, once the position was stabilised and in co-operation with the Department of Health, to appoint a full time Chief Executive to lead to trust to full recovery. This is to ensure that high quality care can be provided to patients from a stable and secure platform. During this time Monitor continues to hold the Trust board and senior management accountable for the delivery of measurable outcomes which will deliver the rectification of failures and delivery of a sustainable recovery within a reasonable timescale.

In close cooperation with Monitor, but without the need for us to use our statutory powers, a new chairman and three new non-executive directors were appointed by the governors, a wide variety of changes were made to the senior management team, a transformation plan was produced and the structure put in place to deliver it and monitor its impact.

Monitor has recently published a report by its internal auditors, KPMG setting out the lessons which may be learnt by Monitor and others related to events at Mid Staffordshire.<sup>2</sup> It makes 14 recommendations for Monitor and for improved working across the regulatory system. Many of these recommendations have already been taken forward by Monitor in the period since the commencement of the Healthcare Commission investigation a year and a half ago. We continue to implement the remaining recommendations.

One of the key themes of the report is the importance of effective joint working between Monitor and the Care Quality Commission going forward. This requires that information is shared appropriately and action taken by the appropriate body to ensure failures are avoided and where they occur are addressed as soon as possible.

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2 [http://www.monitor-nhsft.gov.uk/sites/default/files/KPMG%20internal%20audit%20report\\_0.pdf](http://www.monitor-nhsft.gov.uk/sites/default/files/KPMG%20internal%20audit%20report_0.pdf)

Monitor and the Care Quality Commission have recently signed a Memorandum of Understanding setting out how information will be shared during an assessment of an NHS trust for foundation status and to establish and operate effective communication where there are concerns as to ongoing compliance with both registration standards and the NHS foundation trust's terms of Authorisation.

This has helped us to clarify between Care Quality Commission and Monitor the respective roles and responsibilities of each. The primary role in ensuring essential standards of quality and safety are met lies with the Care Quality Commission. We do not seek to duplicate this role and will take significant account of their assessment in our own work. In relation to safety and quality our focus remains on the governance of NHS foundation trusts, particularly the role of the board. We will in both our assessment and compliance activities focus on the financial, clinical and wider governance of an NHS foundation trust. By clinical governance we mean the combination of structures and arrangements in place at, and immediately below, the board level to manage and monitor clinical performance, plan and manage continuous improvement in patient care, identify performance that may be below standard or out of line, investigate it and take management action.

Monitor's regulatory regime has allowed it to effectively address actual or potential material failings in performance without requiring the use of our statutory powers of intervention. The regulatory regime has identified and allowed Monitor to secure the necessary improvements in service, financial or governance performance in more than 30 NHS foundation trusts.

**42. The relationship between commissioning, performance-managing and regulating bodies is not defined clearly enough. There are, as Baroness Young put it, "a lot of players on the pitch" and we are concerned that too often they are not an effective team. There is evidence of overlapping functions and multiple submission of information to different regulators. Most disturbing of all is that Foundation Trusts appear to be operating in an entirely different regulatory framework from non-Foundation Trusts. (Paragraph 262)**

Healthcare is delivered by individual clinicians and clinical teams working with patients. These clinical teams are usually organised into and managed by provider organisations. The delivery of high quality care is both a professional responsibility of the individual clinicians and the responsibility of the Board of the provider organisation.

The existing systems for regulation, commissioning and performance management hold boards and clinicians to account for meeting the required standards and to promote quality improvement. The main functions can be briefly described as set out below:

- Regulators ensure that health care organisations meet the standards required of them, and intervene to correct failings where necessary. There are two major regulators in the health sector, the Care Quality Commission, and Monitor.
- The Care Quality Commission will ensure that all providers of health and social care (NHS trusts, NHS foundation trusts, local authority providers, independent sector providers) meet essential standards of care. All providers will be required to register with the Care Quality Commission, and where failings against the essential standards are identified, it has powers to cancel registration, impose or vary

conditions to the registration or levy fines on the provider, in order to ensure any services provided meet the essential standards. From April 2010, all providers of regulated services, including NHS foundation trusts, will be required to comply with a full set of registration requirements that will establish essential levels of safety and quality.

- Monitor, the Independent Regulator of NHS Foundation Trusts, ensures that NHS foundation trusts continue to meet the standards of governance and financial stability required of them and is set out in the terms of authorisation of each NHS foundation trust. Monitor uses risk based regulation to provide NHS foundation trusts with the necessary freedoms and autonomy to realise the benefits intended to result from the foundation trust policy but also to ensure NHS foundation trusts operate in the interests of patients and taxpayers, within the terms agreed as part of their Authorisation. Monitor has wide ranging powers of intervention including requiring foundation trusts to take or not to take particular actions, affecting clinical services, finance and governance related matters. In extreme circumstances, Monitor has the power to require a foundation trust to stop delivering a specified service or to provide it in a particular way. Monitor also has the power to remove the board in a foundation trust. Monitor's remit provides important safeguards for the taxpayer in relation to the performance of public owned but autonomous NHS foundation trusts.
- Commissioners are responsible for the quality of the care they purchase on behalf of their populations. They should monitor the quality of the care they commission and where they identify concerns relating to essential standards share these with the regulators to allow the regulators to make informed decisions and intervene as required. Commissioners will use the levers available to them, deciding who to buy care from, promoting patient choice, and contractual quality requirements, to drive up quality beyond the essential requirements. These commissioning and contractual processes could be described as a performance management role for commissioners in relation to the services they purchase.
- Strategic health authorities are responsible for managing the performance of PCT commissioners and NHS trusts. These organisations are accountable to the SHA for their performance and subject to direction by the Secretary of State. NHS foundation trusts are not subject to SHA performance management, but are (as described above) accountable to Monitor for meeting their terms of Authorisation.

**44. The case of Mid-Staffordshire Trust has also exposed serious shortcomings in Monitor's assessment process when granting authorisation. Not only did Monitor fail to detect unsafe care—it effectively allowed the Trust to compromise patient safety in premature pursuit of Foundation status. We note the Healthcare Commission found that achieving Foundation status was one of the factors that distracted the Trust from patient safety issues. Monitor's acceptance at face value of the Trust's excuse that its poor mortality figures were a statistical anomaly is wholly unacceptable. (Paragraph 264)**

Monitor is very clear in its message to both existing NHS foundation trusts and applicant trusts that high quality patient care must always be their priority. Robust finances cannot

be achieved at the expense of quality; rather, financial stability provides a platform from which to achieve improved services for patients.

Monitor has now authorised 122 NHS foundation trusts, and it is clear that the vast majority are more than capable of maintaining robust finances in addition to delivering high quality care. Overall, there is evidence that the foundation trust sector outperforms the non-foundation trust sector on both clinical and non-clinical measures of performance. 42 trusts across the entire NHS were rated ‘excellent’ for both Quality of Services and Use of Resources in the last Healthcare Commission Annual Health Check—90% of these (38) were NHS foundation trusts.

However, patients and their families were failed at Mid Staffordshire. This was a failure across the system in which a number of bodies played a part. Monitor has since strengthened the assessment process, and are committed to an ongoing programme of actions that ensure the lessons learnt from Mid Staffordshire improve both the way they operate and how they work with others.

It is important to recognise that Monitor’s assessment process is not designed to assess the quality of care delivered by an applicant NHS Trust. At the time of the assessment of Mid Staffs this was the role of the Healthcare Commission. It is now the role of the Care Quality Commission. In addition applicants to become foundation trusts must obtain the support of the Secretary of State. Were Monitor to seek to assess the quality of care, this would duplicate the work of the Care Quality Commission and any assessment made by the Secretary of State.

Monitor’s assessment process is forward looking, designed to assess whether the organisation is capable of operating as an autonomous body once authorised. Decisions made by applicants about the steps they should take to obtain authorisation as a foundation trust are matters for the board of the applicant, under the supervision of their SHA. Monitor’s role is to assess whether the business plan of an applicant meets the published tests that all applicants have to meet to be authorised as a foundation trust, i.e. financially stable, well led and legally constituted.

Nonetheless, in response to the issues at Mid Staffordshire, in the summer of 2008 Monitor further refined its assessment process. Although the tests applied and the processes adopted have not changed materially, Monitor now devotes more time to examining evidence of poor clinical quality or inadequate services. This includes:

- formalised reporting and feedback arrangements with the Care Quality Commission to ensure Monitor has up-to-date information of any concerns, including details of concerns around mortality rates and details of any planned or ongoing investigations
- systematic review and consideration of internal performance data including Serious Untoward Incidents, Complaints, Patient and Staff Surveys; and
- wider triangulation of external intelligence—e.g. Dr Foster mortality alerts.

Monitor also continues to develop its approach to assessing the political impact of applicants’ cost improvement programmes (CIPs) on quality.

In addition to the measures implemented in the summer of 2008, Monitor recently commissioned a report from its internal auditors to review the lessons learned from Mid Staffordshire. The report of the internal auditors<sup>3</sup> and Monitor's response<sup>4</sup> are available on our website. Monitor has accepted all the findings of the internal audit review and action plans have been put in place to address the concerns raised.

The report highlights the need for better communication with key stakeholders including the Care Quality Commission (already implemented), the need to clarify roles in the system and the need for Monitor to focus more closely on clinical governance.

In relation to the high mortality figures at Mid Staffordshire, Monitor did not accept the trust's explanations at face value. The analysis of the reasons for high mortality was supported by the external review conducted by CHKS, the findings of which had been discussed with the SHA. Action plans had been put in place to address the findings. The SHA confirmed that they did not have any concerns in relation to clinical quality at the trust, a position arrived at by the SHA after they had commissioned additional work examining the trusts mortality data from the University of Birmingham.

However since Mid Staffordshire, Monitor has enhanced the work it carries out with respect to mortality figures. Monitor now receives information directly from the Care Quality Commission if there are concerns around mortality data. In such cases Monitor defers the authorisation decision until the Care Quality Commission has confirmed that the case has been satisfactorily resolved. This has occurred in two instances since Mid Staffordshire.

**45. We are also concerned about Monitor's role in regulating Foundation Trusts following authorisation. We are told that Monitor does not replicate the performance management role played by SHAs in respect of Trusts, but it is unclear by exactly which means Foundation Trusts are intended to be performance managed—or whether they are supposed to be performance managed at all. In Monitor's defence it could be said that too many SHAs have also done no effective**

NHS foundation trusts are autonomous public bodies. They are free from the direction of the Secretary of State and the Strategic Health Authorities have no performance management role in relation to NHS foundation trusts. This autonomy is intended to ensure that those running the services are free to decide how best to do so. Operational autonomy coupled with clear incentives for improvement is seen as the best approach to improving performance.

NHS foundation trusts are accountable to local people and patients through their members and governors, to their commissioners for delivery of their contractual commitments, to Parliament before whom they lay their accounts and to Monitor, the Independent Regulator of NHS Foundation Trusts, for compliance with their terms of authorisation.

The terms of authorisation set out the requirements placed on the performance of NHS foundation trusts. These include:

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3 Ibid

4 <http://www.monitor-nhsft.gov.uk/sites/default/files/Management%20response%20to%20the%20internal%20audit%20report%20on%20lessons%20learnt%20from%20Mid%20Staffs.pdf>

- to meet any statutory requirements, including the requirement to be registered with the Care Quality Commission;
- to put in place arrangements to monitor and improve the quality of healthcare provided by the foundation trust;
- to comply with national standards and Department of Health national priority targets;
- to provide mandatory services; and
- to exercise its functions effectively, efficiently and economically.

In the case of a significant breach of the terms of authorisation, Monitor has statutory powers of intervention including the power to require the foundation trusts to take (or not take) specific actions, which may include removing all or any members of the Board of Directors or Board of Governors.

The regulatory system which Monitor operates is published and regularly reviewed. The main documents are listed in response to recommendation 37. Copies are available on our website.

Monitor's functions are those of a regulator. It is able to set the required standard and intervene to correct any breach of those standards. Monitor's regulatory framework does not aim to drive performance improvement in those NHS foundation trusts exceeding the requirements of the terms of authorisation (a performance manager may seek an improvement in relation to such organisations).

Beyond the desire of the clinicians and staff of an NHS foundation trust to provide the best possible care, the main driver for performance improvement in an NHS foundation trust is commissioning.

PCTs can and will increasingly choose which providers to purchase care from on the basis of quality. Patient choices of provider will also become increasingly based on information about the quality of care on offer. Once a PCT chooses to enter into a contract with an NHS foundation trust it is free to specify contractual quality requirements and enforce these through contract management. The national contract already allows incentive payments for improved quality (CQUIN) and penalties for failure to deliver the required performance on waiting times and HCAI.

**46. There appears to be considerable potential for confusion, and possibly conflict, regarding the respective roles of Monitor and the Care Quality Commission, as Monitor itself has indicated. The DH must clarify exactly what these two organisations' regulatory roles are in respect of Foundation Trusts and how those roles fit together. (Paragraph 266)**

Monitor and the Care Quality Commission have clear, specific and complimentary roles in relation to the regulation of NHS foundation trusts.

The Care Quality Commission is responsible for ensuring that NHS foundation trusts, and all other healthcare providers meet essential standards of safety and quality. NHS

foundation trusts will be registered by the Care Quality Commission and if they fail to maintain the essential standards, the Care Quality Commission will be able to intervene, including the ability to remove or impose conditions to the registration.

Monitor, the Independent Regulator for NHS Foundation Trusts, is responsible for setting the terms of authorisation for NHS foundation trusts and ensuring that NHS foundation trusts continue to maintain the standards required in their terms of authorisation. Maintaining registration with the Care Quality Commission is a requirement of the terms of authorisation. However, the terms of authorisation are more broadly drawn than the registration requirements for NHS foundation trusts and also cover governance, financial performance and mandatory services. In cases of significant breach of the terms of authorisation, Monitor has statutory powers to intervene including requiring an NHS foundation trust to take (or not take) specific actions, including the removal of any or all of the members of the Board of Directors and Board of Governors.

In essence, the Care Quality Commission seeks to ensure services meet the essential standards of quality and safety and Monitor seeks to ensure that NHS foundation trusts are well led and financially robust and deliver their contractual obligations to their commissioners.

There is a clear need for Monitor and the Care Quality Commission to work together to ensure the efficient and effective regulation of NHS foundation trusts, and indeed the Health and Social Care Act 2008 requires co-operation in the exercise of their functions.

Monitor and the Care Quality Commission have recently codified their approach to co-operation in a Memorandum of Understanding which sets out in some detail, how the two bodies will coordinate their activities in relation to assessment of applicants for foundation trusts status and regulation of authorised foundation trusts.

Monitor has been clear that it does not wish to duplicate the activities of the Care Quality Commission in assessing the quality and safety of clinical services. It will place significant weight on the information provided by and judgements of the Care Quality Commission in assessing the governance of an NHS foundation trust.

**49. There is disturbing evidence of catastrophic failure on the part of some Boards in cases such as Maidstone and Tunbridge Wells Trust and Mid-Staffordshire Trust. While other Boards are not failing as comprehensively, there is substantial room for improvement. (Paragraph 288)**

Monitor's recognises that the quality of boards is crucial to delivering sustainable improvement across the NHS. Monitor has repeatedly re-enforced, through our interactions with both applicant and authorised foundation trusts, the necessity of boards with the right balance of skills and experience, who have the ability to inquire and provide robust challenge on clinical and financial issues and who are able to think strategically about the future challenges facing their organisations.

Monitor has identified a gradual improvement in the quality in the composition and challenge provided by foundation trust and applicant boards over the last four years. However, driven by ongoing concerns, Monitor has this year joined forces with the NHS Institute of Improvement & Innovation, the North West Academy, and the East of

England SHA to establish an intensive development course aimed at non-executive directors.

The programme, delivered by Cass Business School and Manchester Business School, is intended to provide non-executive directors with the opportunity to develop their existing skills and add value to the organisations they represent. Modules cover areas such as

- developing and implementing strategic change;
- driving the right culture where constructive challenge around the board table is welcomed as adding value;
- ensuring clinical quality discussions in the boardroom are not the sole responsibility of the medical and nursing directors; and
- delivering financial stability over a sustained period, in a tougher economic climate.

**50. Boards too often address governance and regulatory issues, believing that they are thereby discharging their responsibilities in respect of patient safety—when what they should actually be doing is promoting tangible improvements in services. The concept of clinical governance may be to blame for spawning a structural approach, focused on processes rather than on the actual state of frontline services. (Paragraph 289)**

We do not believe that the pursuance of good clinical governance should be perceived by the Committee as unrelated to, or a distraction from, the delivery of improved, safer patient care. Monitor is increasingly focussed, in both its assessment and compliance activities, on whether boards have effective clinical governance in place. By clinical governance we mean the combination of structures and arrangements in place at, and immediately below, the board level to manage and monitor clinical performance, plan and manage continuous improvement in patient care, identify performance that may be below standard or out of line, investigate it and take management action.

It is the absence of good clinical governance—a lack of engagement in quality and safety issues and the mechanisms and information flows by which to gain that understanding and identify risks—which underpin many past failures of care in the NHS. The positive example of board level safety and patient experience committees at Luton & Dunstable NHS Foundation Trust, referred to by the Committee in recommendation 51, demonstrates the importance of good clinical governance.

Quality accounts have the potential to deliver real benefits in improved transparency and accountability for performance on quality including patient safety.

Monitor and NHS East of England have required all NHS foundation trusts and NHS trusts in East of England to produce Quality Reports for 2008/2009 following a joint consultation exercise by Monitor, the Care Quality Commission, NHS East of England and the Department of Health. This work was initiated by Monitor. The Quality Reports set out the trusts priorities for improvement and the metrics selected by the trust to track patient safety, clinical effectiveness and patient experience. NHS foundation trusts have included their Quality Reports as a section of their Annual Accounts which were laid before parliament before the summer recess.

**55. We strongly endorse the DH’s view that no Board in the NHS should always be meeting behind closed doors. We urge the Government to legislate as necessary to ensure Foundation Trust Boards meet regularly in public; the public should only exceptionally be excluded. (Paragraph 294)**

The two key requirements of NHS foundation trust Boards are that they are effective—to ensure that their organisations operate efficiently and manage resources well—and that they are publically accountable. It is crucial that they fulfil *both* of these requirements, but legislation and Monitor’s regulatory regime leave it to each foundation trust to determine locally how they best achieve this. The Act which established NHS foundation trusts does require that the meetings of a foundation trusts board of Governors are open to the public.

There is no legal requirement for NHS foundation trusts to hold public board meetings; it is at the discretion of the individual foundation trust to decide whether to allow public access to meetings of the board. The NHS Foundation Trust *Code of Governance*, which sets out a framework for what Monitor believes is good governance, states that the board of directors of an NHS foundation trust should

*“follow a policy of openness and transparency in its proceedings and decision making unless this conflicts with a need to protect the wider interests of the public or the NHS FT (including commercial-in-confidence matters) and make clear how potential conflicts of interests are dealt with”.*

The Code of Governance is reflected in Monitor’s *Compliance Framework* on a comply or explain basis.

Foundation trusts boards have taken different approaches to the conduct of board meetings. Approximately a third hold board meetings in private with the remainder either holding all or some board meetings in public.

Our approach is that genuine transparency on decision-making is more important than a trust which pays ‘lip service’ to public accountability. There is an argument that building effective Boards is made easier by holding board meetings in private; if key issues and risks are to be discussed (including staff and commercial issues), Boards need to be free to be both candid and challenging.

We do not believe that there is any link between board meetings held in private and quality of care. In the case of Mid Staffordshire, it is worth noting that for the great majority of the period covered by the Healthcare Commission’s review, Mid Staffordshire was not a foundation trust and its board met in public; this did not prevent failures of care. It would be hard to demonstrate that open board meetings of themselves have created genuine openness and engagement in non-NHS foundation trusts, or indeed have protected the interests of patients as a result of being public.

The key means by which the public can hold NHS foundation trusts to account is through their membership and board of governors; governors are elected by members to represent their interests, and have considerable powers at their disposal, including the power to appoint or remove the chairman and non-executive directors. Monitor emphasises the need for strong governors who can challenge Boards of Directors on behalf of NHS foundation trust members, patients and the community.

Boards must also be transparent on performance and plans—and need to engage patients and the public in evaluating performance and determining plans. Monitor placed a new requirement on Foundation Trusts to report on the quality of care their organisations deliver—and how they plan to improve it—as part of their 2008–09 Annual Reports. Quality reports will help to develop more transparent and accountable public reporting and ensure that Boards have clear priorities and achievable plans in place for driving improvement. Patients and the public can also use this information to hold Boards to account on the commitments they make.

**58. The Government is to be praised for being the first in the world to adopt a policy which makes patient safety a priority. However, Government policy has too often given the impression that there are other priorities, notably hitting targets (particularly for waiting lists, and Accident and Emergency waiting times), achieving financial balance and attaining Foundation Trust status, which are more important than patient safety. This has undoubtedly, in a number of well documented cases, been a contributory factor in making services unsafe. We welcome Lord Darzi’s statement in the Next Stage Review of the importance of quality and safety. From now on, all Government policy in respect of the NHS must be predicated on the principle that the Service’s first priority, always and without exception, is to ensure that patients in its care do not suffer avoidable harm. The Government should state clearly that safety is the overriding priority of the NHS and that, if necessary, other targets should be missed where patient safety is being jeopardised; for example, A&E patients should not be moved to unsuitable wards just to meet the four-hour maximum waiting target. (Paragraph 301)**

As at August 2009, 122 NHS Foundation trusts have been authorised. There is no evidence to substantiate a claim that the pursuing of Foundation Trust status should or does systematically cause boards to neglect issues of patient safety.

Monitor requires that applicants are well governed, legally constituted and financial sustainable. Applicant trusts should be able to meet these requirements without any negative impact on the quality and safety of the care they provide.

A recent economic evaluation study into Monitor’s impact found that in general NHS foundation trusts’ performance on available measures such as MRSA infection rates and access to elective services is likely to improve following authorisation.

It is now clear that in the case of Mid Staffordshire, financial sustainability was pursued without consideration of the impact on patient care. This is not a necessary consequence of the pursuance of foundation trust status but the approach of this board to dealing with its significant historical financial challenge.

Monitor can identify a number of foundation trusts and applicant trusts have dealt with equally challenging circumstances and have brought their finances under control without compromising patient care.

In relation to further ensuring that NHS foundation trust status is not achieved at the expense of patient safety a range of actions have already been taken forward by Monitor:-

- Monitor continues to develop its approach to assessing the impact of applicants’ cost improvement programmes (CIPs) on quality. Monitor has increasingly

demanded that the boards of applicant and authorised foundation trusts clearly demonstrate an understanding of the relationship between their financial plans and quality of care.

- Monitor has formalised reporting and feedback arrangements with the Care Quality Commission to ensure concerns on quality of care are shared across the two regulators as they emerge.
- Monitor has introduced a systematic review of applicant trusts internal performance data including SUIs, complaints, patient and staff surveys, and wider triangulation of external intelligence (e.g. Dr Foster mortality alerts).

## Professor Sir Ian Kennedy's Response

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I write to express my disappointment at the views expressed about regulation and the Healthcare Commission in your Committee's recent report on safety "Patient Safety". I offer the following observations which I would be grateful if you would share with members of your Committee.

1. The report describes regulation by the Healthcare Commission as "burdensome". This is a somewhat tired cliché. It overlooks at least three points:

a) regulation is inevitably a burden in so far as it is something to be borne. Only the complete absence of regulation can answer this complaint. I would have thought that the excesses in the City and closer to your Committee's home, as well as the successes of regulation elsewhere (eg the Food Standards Agency) would persuade all but the unpersuadable that regulation has a place in the world;

b) if regulation has a place, the only question, in terms of burden, is whether the burden it imposes is justified: do its benefits outweigh its costs? Your report offers no evidence that the costs arising from the Healthcare Commission's regulation outweighed the benefits produced. Citing the exchange between me and Sandra Gidley MP is at best unhelpful. No evidence exists of the particular costs to particular trusts, and, as I said, such costs will vary. But, no detailed scientific evidence exists as to its benefits either. The point needs to be made that any calculation of the costs of the Healthcare Commission's regulation must be set against a similar calculation of the benefits, in the form of a reduction in harm to patients or an improvement in the extent to which patients are treated with dignity, which are attributable to regulation. Only when this calculation is done can any conclusion legitimately be expressed. And, it is worth noticing, as the Healthcare Commission's submission to your Committee made clear, that there was significant recognition by NHS trusts of the value of the Healthcare Commission's regulation as being a justifiable expenditure of their funds;

c) there is an inherent contradiction in your report's assertion that regulation by the Healthcare Commission was burdensome while at the same time criticising the Commission for failing to spot poor performance at Mid Staffs. Leaving aside the fact that the criticism is unwarranted, as I point out later, effective regulation has to probe fearlessly on behalf of patients, even if, as in the case of Mid Staffs, some found it burdensome. This is what the Commission did in the case of Mid Staffs, uniquely among all the organisations which could have done so, until the truth was exposed.

2. Your report criticises the focus of the Annual Health Check (AHC) and that it did not identify certain failings. As regards the latter, not only is this only partly accurate, but it also quite wrongly identifies the AHC as being the central feature, rather than one aspect of the Healthcare Commission's regulatory activity. The following points deserve to be borne in mind:

a) the focus of the AHC was on compliance with standards laid down by government (not the Healthcare Commission), as required by statute. The Commission

recognised from the outset that the standards were often less than rigorous tools for assessing performance by reference to what patients and those who look after them consider important. As a consequence, the Commission made a number of requests of the Department of Health that the standards be altered, with no success. Moreover, the Commission made it clear that the general perspective on performance offered by the AHC was incomplete and needed to be supplemented by a range of in-depth checks carried out through reviews, investigations and the like. In this way, the Commission could address concerns about particular areas of care and seek to ensure that the safety and quality of care along the pathway followed by patients was assessed, since the standards in themselves presented an atomised picture of care.

b) the Commission, therefore, worked closely with patients and professional groups (particularly the Academy of Medical Royal Colleges) to superimpose onto the government's standards, those elements of performance which those whom we consulted regarded as important. The principal shift was to focus increasingly on outcomes of care.

c) these changes took time. The Commission was working against the clock; its abolition had, in fact, been announced before the first AHC had been carried out!

d) by the time of the 3rd AHC, changes in what was being assessed were being introduced, with an increasing focus on outcomes. The Commission was abolished before the 4th AHC was completed.

e) the AHC was a revolutionary, information-led, risk-based regulatory tool. It is not surprising that it needed time to develop. That said, it was already recognised by trusts as a valuable exercise. It is described in your report as a form of "light touch" regulation. This is another cliché which lacks real meaning. Indeed, the Commission's various regulatory levers, when taken together, were anything but "light touch", as the reports of its investigations showed.

3. As regards your report's conclusion that the AHC failed to identify poor performance at Mid Staffs, this is not the case. As your Committee will be aware, the architecture of the NHS is such as that the regulator identifies poor performance but it is the responsibility of those charged with performance management to take the necessary action. The AHC was a mechanism for "holding the mirror": others then had to do something, if the picture was one of poor performance. The Commission pointed out on a number of occasions the need for the NHS to square this circle, since it was not always the case that action was taken. The AHC described Mid Staffs as "fair". This indicated that improvements were called for. The subsequent score of "good" which your report refers to, was, as is well known, based on the trust's own assessment (which is only the first step in the process of evaluation) and was not accepted by the Commission. It was posted on the Commission's web site accompanied by a qualification that the Commission was already investigating the trust's performance.

4. As the AHC was itself evolving, the Commission also relied on other elements of its regulatory armoury to identify poor performance. It did not, nor did the NHS, patients or clinicians, rely solely on the AHC. Three other tools are worth referring to here. The

first is the Commission's analysis of complaints and the use of local intelligence, to alert the Commission about concerns. The Commission could then take action or refer the matter to management. Second, there were wide-scale reviews of services, such as those provided to children and to women receiving maternity care. These reviews changed the way in which a number of services were provided and, thereby, made an important contribution to the safety of patients. Thirdly, there were investigations triggered sometimes by the AHC, or by complaints, or by requests from management. Mid Staffs was one such investigation. The Commission launched it because it had become able to analyse data to identify departures from the expected norm of performance in terms of the safety of care. This was the culmination of 3 years of planning to develop a capacity to identify risks, ultimately before they were translated into patients being harmed. This was a unique capacity, significantly more sophisticated than Dr Foster's use of Hospital Mortality Rates. It involved disaggregating mortality rates by condition, which was a completely new approach. It identified Mid Staffs as an outlier as regards emergency care. It then involved tenaciously pursuing the reasons, in the face of opposition from the Trust and SHA, why mortality was so high in the case of the pathway of emergency care. The Commission acted immediately and then persevered, with the result which is now well known. It was this analytical capacity and the data flowing from it which also allowed the Commission's Chief Executive to reassure herself that there were no other trusts which posed the same degree of risk, though some warranted very careful attention. Paragraph 2.37 is quite wrong, therefore, in suggesting that this assurance was derived from the AHC. The wider thrust of the report is equally wrong in identifying regulation and the Healthcare Commission with the AHC alone.

I regret the length of this letter, but I am anxious to set the record as straight as possible. The Commission no longer exists and it is clearly tempting to blame it for the NHS' failings. Shooting the messenger has always had an appeal to some. Moreover, campaigning groups tend to focus on a target: in the case of Mid Staffs it seems to be the regulator. But the world is usually more complicated and the story deserves to be told fairly. I am obliged to say that I do not think that your report's account of regulation or the role of the Healthcare Commission in addressing the safety of patients constitutes a fair account.

### **Reply to Professor Sir Ian Kennedy from the Chairman of the Committee**

Thank you for your letter of 4 August. I'm very sorry that it has taken so long to reply but the House of Commons has been in recess over the summer.

I'm very grateful to you for responding so thoughtfully and at such length to the Committee's report on Patient Safety. As I hope was clear when you appeared before the Committee on 5 March, the Members acknowledge the huge contribution that you have made to patient safety and the regulation of healthcare in this country, and we do take your views very seriously.

You refer to the statement in the Summary of our report that regulation has been "burdensome". In response, you point out that regulation is inevitably a burden; that regulation is necessary; and that "the only question, in terms of burden, is whether the

burden it imposes is justified: do its benefits outweigh its costs?" These are in fact all points with which the Committee agrees, as I hope our report makes plain.

You further state that our report "offers no evidence that the costs arising from the Healthcare Commission's regulation outweighed the benefits produced". However, we did not claim that we had such evidence. Rather, we noted that, as you acknowledged before the Committee, no evidence has been gathered of the overall costs of regulation; and we further noted that the failure of the Annual Health Check to bring to light "appalling cases of lethally unsafe care in the NHS" has raised "Doubts about the effectiveness of regulation" (para. 231). I note you also concede in your letter that "no detailed scientific evidence exists as to [the] benefits [of regulation]".

It is surely a legitimate matter of concern that there is a lack of good quality evidence on the overall costs and benefits of regulation. Further, we stand by our statement that the apparent shortcomings of the AHC, as evidenced by a number of recent cases, give reason to doubt the effectiveness of the regulatory system as hitherto constituted.

You say that the Committee was wrong in identifying the AHC as being "the central feature, rather than one aspect of the Healthcare Commission's regulatory activity". What we said was that "The heart of the regulatory process has been the AHC operated by the HCC until 1 April 2009" (para. 227). From the evidence presented to us, it seemed clear that the AHC was the central focus of the healthcare regulatory system, as set up by statute. We did acknowledge in our report the other aspects of the HCC's regulatory work; but it was apparent to us that in what you call the HCC's "regulatory armoury" the AHC was the first line of defence, with the other regulatory processes acting as back-up "fail safe" mechanisms.

We fully accept that, as you say, the HCC was obliged to operate a system determined by statute. We also note your statement that the Commission sought unsuccessfully to persuade the government to alter the standards underpinning the AHC; that the Commission developed means of supplementing, in various ways, the data provided by the AHC; and that the Commission was still developing its approach when it was abolished. I must emphasise that the Committee's criticisms of regulatory processes are essentially criticisms of the framework laid down by the government, not of the way that the HCC fulfilled the statutory remit that it was given. I accept that we could perhaps have made this point more clearly and explicitly in our report, and I'm happy to take this opportunity to clarify the point now.

You say our description of the AHC as a form of "light touch" regulation is a "cliché which lacks real meaning". However, I must point out that the HCC itself described the AHC in exactly those terms. For instance, the Foreword to *Developing the annual health check in 2008/2009: Have your say* (December 2007), which was signed by you and the Chief Executive, Anna Walker, states as follows (at p. 3):

"We also want to stick to our principles of keeping our system light touch, using self-assessments and then checking them with views of patients and the public and other available data."

Regarding the specific case of Mid Staffordshire Trust, you point out that the AHC did pick up shortcomings in the performance of this Trust—but this is clearly acknowledged in our

report (para. 233). You also point out that the HCC did detect, by other means, the serious failings at the Trust, which was then thoroughly investigated—this too is acknowledged in our report (para. 234). We fully accept that the HCC did eventually detect the disastrously unsafe care at Mid Staffordshire Trust and in other cases, such as at Maidstone and Tunbridge Wells Trust; and that the Commission then acted swiftly to investigate those cases in a commendably full and unflinching fashion. However, as we note in our report:

“the fact remains that annual assessment failed in each of these instances, so that abysmal standards of care continued for some time before finally being detected by other means, and then investigated and addressed.” (para. 235)

At para. 236 in our report we quote the reference by the then Minister of State for Health Services to the assurance given by the HCC’s Chief Executive that there were no other Trusts giving rise to similar concerns as those that arose in respect of Mid Staffordshire Trust. You say we are “quite wrong ... in suggesting that this assurance was derived from the AHC”. In fact, we quote the Minister of State referring to the HCC’s reliance on “hospital standardised mortality rates and other indicators” as the basis for giving this assurance. At the same time as indicating the AHC is not a sound basis for assuming there are no other Trusts giving cause for concern, we note that “absence of HSMR data giving cause for concern is no guarantee that there are not further undetected instances of things going badly wrong”.

The Members of the Committee felt strongly, on the basis of the evidence they received, that they could not be certain there were not more, as yet undetected, cases such as that of Mid Staffordshire Trust.

Finally, you are, of course, quite correct in the distinction that you make between regulation and performance management in the “architecture of the NHS”. However, our report also makes this distinction quite clearly and is unstinting in its criticism of the performance management function in the NHS (see paras. 215–224) and of poor coordination of regulation, performance management and commissioning within the service (see particularly para. 262).

It was certainly not our intention to “blame [the HCC] for the NHS’ failings”, as you put it in your final paragraph, and I don’t believe that our report does so; rather, it tries to apportion blame, and indeed praise, in a fair and even-handed fashion.