Witness Name: **Sir Ian Kennedy**
Statement No: **First**
Exhibits: **IK1 to IK15**
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THE MID STAFFORDSHIRE NHS FOUNDATION TRUST PUBLIC INQUIRY

Witness Statement of **Sir Ian Kennedy**

I, **Sir Ian Kennedy,** will say as follows:-

Background

1. I make this statement in my capacity as former Chairman of the Commission for Healthcare Audit and Inspection ("the Healthcare Commission").

2. I was Chairman of the Healthcare Commission from 1 April 2004 to 31 March 2009. Prior to that, I was Chairman-designate from January 2003 to April 2004. I was appointed by the NHS Appointments Commission, in line with the Code of Practice issued by the Commissioner for Public Appointments. My role of Chairman was set out in the Standing Orders of the Healthcare Commission. As Chairman, I had particular responsibility for promoting effective strategic leadership on matters including:
   a. Formulating the Healthcare Commission's strategy for discharging its statutory duties;
   b. Ensuring that the Healthcare Commission, in reaching decisions, took proper account of guidance provided by the Secretary of State for Health or Department of Health;
   c. Promoting the efficient and effective use of staff and other resources;
   d. Encouraging high standards of propriety;
   e. Liaising with the Government, the Department of Health, professional bodies and other interested parties; and

f. Representing the views of the Healthcare Commission to the general public.

3. As non-executive members of the board of a public body, all Commissioners of the Healthcare Commission, including the Chairman, had corporate responsibilities. In particular, we had corporate responsibility for the stewardship of public funds and for ensuring that the Healthcare Commission complied with any statutory or administrative requirements for the use of public funds. Other responsibilities included:
   a. ensuring that high standards of corporate governance were observed in the Healthcare Commission at all times;
   b. establishing the overall strategic direction of the Healthcare Commission within the framework of policy and resources agreed with the Secretary of State for Health;
   c. ensuring that the Healthcare Commission did not exceed its powers or functions; and
   d. ensuring that the Healthcare Commission considered guidance issued by the Department of Health and complied with any statutory duties imposed on public bodies.

4. I have had the opportunity to read the provisional statement made by Anna Walker, the former Chief Executive of the Healthcare Commission, prepared for the purposes of the Inquiry, as requested in its letter dated 6 July 2010. I agree with and have nothing further to add to those paragraphs of Ms Walker's provisional statement which deal with the strategic vision and aims of the Healthcare Commission and with its operation in general terms. That said, as the former Chairman, I am not able to provide a day to day account of the workings of the Healthcare Commission. However I am able to provide a conceptual view of our roles, duties and the vision for the regulation of healthcare.

The Bristol Inquiry

5. I was the Chairman for the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary ("the Bristol Inquiry"), which was conducted between October 1998 and July 2001. When writing the report for the Bristol Inquiry, it struck me that the events and issues that had arisen echoed those of the Sir

Geoffrey Howe investigation into Ely Hospital Cardiff some 30 years previously. In the same way, some may say that there are clear parallels between the Bristol Inquiry and the events that took place at Mid Staffordshire.

6. I attach as Exhibit IK1 [ ] relevant extracts from the Report prepared for the Bristol Inquiry and dated July 2001. A number of the conclusions and recommendations from the Bristol Inquiry are important to highlight for Mid Staffordshire.

7. At pages 255-258 of the Report, I and the 3 other members of the Panel set out a number of principles, which I consider are essential in ensuring that the quality of care in the healthcare system is improved and sustained over time. The following principles that are of particular note for Mid Staffordshire are:
   - consistency of direction – paragraph 11, page 256;
   - the legitimate needs of patients must be at the centre of the NHS – paragraph 12, page 257;
   - a first condition for achieving quality in healthcare is that the service is safe. Once safety, as a fundamental prerequisite, has been addressed, attention must turn to the pursuit of quality – paragraph 14, pages 257-258; and
   - to secure care of high quality across the NHS, we can no longer overlook those elements of the service which go beyond technical skills and competence and beyond the systems in which they are practised. We have to care about attitudes – paragraph 15, page 258.

8. The Report also identified recommendations for the future of regulation of the NHS. This was particularly dealt with at page 261 where the Report states, "While it is the proper role of Government to establish the regulatory framework, to ensure safety and promote quality, that framework must be as independent as possible of the Department of Health. This is quite simply because it is not in the interests of the public or of patients that the monopoly provider should also set and monitor the standards of care. Instead, these functions must be carried out by independent bodies within a statutory regulatory framework. The regulatory bodies, embracing, as we have said, matters to do with safety, quality and standards as well as the competence of healthcare professionals, must themselves be co-ordinated and their efforts aligned by some overarching system. Duplication must be reduced. Equally holes in the system must be stopped. Only in this way will the fragmentation

and lack of clarity about responsibility for regulating the quality of healthcare, which was such a feature of Bristol, be addressed."

9. Chapter 24 of the Report also looked at the future framework for the regulation of the quality of healthcare and gave views and recommendations about the activities of regulators. Some of the key points that were made are as follows:-

- "Various activities must be brought together and properly coordinated. The role of the various bodes must be clearly identified and all of the bodies should be brought under the overall leadership of one overarching body." (paragraph 37 of page 315);
- "The systems for monitoring the extent to which it is meeting its day to day stated aims must, in our view, be de-politicised, so as thereby to rekindle and maintain public confidence in the NHS." (paragraph 38 of page 316); and
- "A plethora of organisations, all with their own ambitions and anxious to defend their 'territories' was one of the defining features of what happened in Bristol." (paragraph 44 of page 318);

10. Finally, I have considered the recommendations that were set out in the Bristol Report. When we formulated these recommendations, there was a sense that we did not want to recommend the introduction of lots of new bodies, but to make an attempt at working with what existed. Again, I have set out below a number of the key recommendations that may inform consideration of the relevant issues for this Inquiry:-

- the patient must be at the centre of everything that the NHS does;
- there must be openness and transparency in everything that the NHS does;
- the safety of patients must be the foundation of the NHS's commitment to the quality of its services;
- the role of central government in relation to the NHS should be to act as its headquarters in terms of management and to create independent mechanisms for creating the quality of healthcare and the competency of healthcare professionals; and
- the various independent bodies must themselves be coordinated so as to avoid the fragmentation of responsibility which arose in the past: existing bodies, suitably shaped, must be used. We recommend the creation of only one new body:

the Council for the Regulation of Healthcare Professionals. We did not recommend the creation of the Healthcare Commission. We proposed that CHI, 'suitably structured' should take on the relevant regulatory roles. The Government of the day decided to abolish CHI and create a new body with new responsibilities and powers.

11. Having considered these recommendations again, particularly in light of Mid Staffordshire, there is none which I would demur from or would define further. Overall, my view is that an independent regulator is key, and regulation that has safety, quality and standards at its core, must be co-ordinated and aligned, to ensure roles and responsibilities are clear. This avoids both gaps and duplication. Most importantly, patients should be at the centre.

12. One of the important questions that may fall for consideration as part of this Inquiry (as did the Bristol Inquiry), is what is it about healthcare and the NHS that it does not seem able to learn lessons and put in place systems to prevent their recurrence? If one compares the NHS with other industries such as the oil, airline or rail industries, the picture is very different. One can find a significant, catastrophic event that occurred within each of these industries, such as Pan Am or Potters Bar, and in each case, the industry internalised that event and significant changes were made as a result. The NHS seems less able to do that. This may be because a lot of the events that take place within the NHS including, sadly, deaths, are on a different scale to say, for example, a plane crash. There may be a tendency to atomise events and not see them as endemic in the system.

13. At page 259 of the Report I also highlighted the following: "The history of the NHS is littered with the reports of Inquiries and Commissions: most have soon been consigned to gather dust on shelves... It will only be a matter of time therefore, before the same, or a similar, set of problems arises again in the same place or elsewhere in the NHS." As mentioned above, some may consider that there are obvious parallels between this Inquiry and the Bristol Inquiry, and suggest that necessary lessons have yet to be learned. I have also lectured on this topic, please see my publication "Learning from Bristol: are we?" which was delivered 5 years after the Report on the Bristol Inquiry was published and which is attached as Exhibit IK2 [ ].

14. Regulation has an important part to play as a key element of the context in which healthcare is provided. What I and others from the Healthcare Commission will say, is that one cannot address and improve the situation identified in the Bristol Report without making those running the organisations recognise their own responsibilities. Trust Boards have legal responsibilities for operating as organisations, but these responsibilities have not been universally and successfully embraced in a way that one might expect or see in responsible boards in other industries.

15. I can recall at a press conference following the Bristol Inquiry, I was asked if there would be another Bristol. I recall saying this was very difficult to answer and my strong view was there could be no guarantee. Reports go on shelves, even when recommendations are accepted and there is something in the NHS that militates against recommendations like this entering the DNA of an organisation. I have devoted my life to wrestling with why this is the case and I can offer a few views, in the hope that they may assist this Inquiry.

16. I do not believe in the magic wand of public policy solving everything. I am utterly convinced that what Sir Michael Bichard, Chairman to the Soham Inquiry, did was very important, in that he insisted that he would revisit the recommendations from his report. This should be part of the terms of reference of any public inquiry: that the Chair and Parliament scrutinise what progress and action has been taken. This provides a timescale for actions to be taken and revisited so that questions can be asked of the relevant Secretary of State.

17. Secondly, while the politicisation of the NHS is in some respects a good thing, as political commitment to the magnificent enterprise of the NHS is positive, there is an obvious tendency for the system to reflect the political ambitions of the current government. The lack of continuity in terms of vision and the desire to tinker with the structure of the NHS may be a consequence. Whilst the NHS is separate from government at a constitutional level, the government of the day does not treat it as an independent entity. The distinction between the Department of State and the NHS is at best blurred.

18. Thirdly, structures are important, but are a means to an end. My view is that the NHS has lost sight of its end purpose. There is a tribalisation of local

groups who look inward, and not at what the purpose of their existence is. The patient is at best a supplicant to these groups.

19. Lastly, there is a clear tension between the desire of Government to confine its dealings with the NHS to macro-allocatory and strategic issues and the accountability of the Secretary of State to the House of Commons for the disbursement of a huge sum of the taxpayers' money. When asked about a particular case, it is difficult to say "it's noting to do with me, ask the relevant managers". The tendency therefore, is to slip into micro-management.

20. Therefore, there are a number of constraints operating within the NHS. If one adds to the mix the conflicting ambitions of politicians and managers, and a regulatory system that organisations and managers had never encountered prior to the establishment of the Healthcare Commission, an attitude towards regulation between incomprehension and defiant objection is created.

21. The concept that regulation is a burden is incorrect. If agreement can be reached on what organisations need to do to drive improvement, and Boards insist on knowing what is going on, all regulation does is ask for evidence that this is happening. The benefit of a regulator is that it provides an independent assessment: it can test what is coming out of the organisations against other available information to see if it raises any questions. That is all regulation is.

My Vision of Regulation

22. My role as Chairman of the Bristol Inquiry led me to reach many conclusions about the vision for the regulation of healthcare. In my view, echoing that of the then Better Regulation Executive, the only purpose of regulation is to promote improvement in services; to add value. The objective is to engage those involved in delivering the services and raise the bar. The biggest challenge for the Healthcare Commission was winning over managers so that they understood the true purpose of regulation, which is more about improvement than holding individuals to account. It was also important to win over clinicians, but once one can persuade those delivering services that the regulator has the same objective, which was to ensure that good and improved services are delivered, this created a notion that regulators received consent from those that

were regulated. The objective was to get buy in from the "bottom up" – not imposition from the "top down".

23. Post Bristol, I envisaged the need for a new regime of regulation to prevent anything similar happening again. There were some core elements to this vision:

(1) regulation should be based on standards that are agreed with clinicians and patients to achieve the "buy in";
(2) intelligence and data is a prerequisite to the role of regulation; and
(3) the number of regulatory bodies be limited, carefully defined and the main regulator must be independent.

24. The first cornerstone of the vision is that one needed to agree national standards by reference to what was deemed appropriate in clinical practice and what was deemed appropriate service for patients. As stated, those standards also needed to be created bottom up; not imposed from the top down. This is part of the notion of consent. If standards are created bottom up, this creates engagement with the regulated communities and those served by them, which in turn produces buy in and engagement to regulation and improving services.

25. When the Healthcare Commission was created, I said that our statutory duty was to encourage improvement and it was the clinicians and patients who knew what "improvement" was, given their area of expertise and their experience. The standards upon which the NHS was judged needed to be based on clinicians' and patients' ideas of "improvement".

26. The second cornerstone to my vision for regulation was information and intelligence. One of the key messages that came out of the Bristol Inquiry was when the Chair of the Regional Health Authority said to us that she would not know from the data available to her how many patients had lived or died in a particular hospital. Her concern was "throughput". That was a stunning piece of information for me. Data and information about what matters – the care of patients - are central to the monitoring of an organisation. This is a simple and straight forward message.

27. My interest in the use of information was born of my experience during the Bristol Inquiry and my firm conviction that a critical requirement for improving care in the NHS was the collection, analysis and dissemination of information about the performance of those providing care. One aspect of this interest was my encouragement of the regulator to develop methods of analysing data so as to predict as early as possible when care might be putting patients at risk. The publication of information to those affected – public and patients – was also key and needed to be done in a sensitive and fair way that did not alienate clinicians particularly.

28. Then, the most searingly important thing for me was to drive the analysis of this information and to render post-hoc audits, examining the information when the disaster had already happened, increasingly redundant. In this way, regulation could be anticipatory and we could judge information against a background of what else was happening at the time. I wanted to get to the point where there was a system of surveillance, and prevention as a consequence of it.

29. There was also the need for Trust Boards to have and generate that information so that they would know what was going on, the Board being legally responsible for the organisation. The Board must demand that information. By placing that responsibility on them, we wished Boards to interrogate their Executive. We said very early on that it was not acceptable for Boards or managers to say that they did not know something; if they did not have the data, they needed to collect it. The second point in relation to management and the notion of information and data is that it is absolutely crucial that in the vision of regulation, within a period of years, one is collating information that is already being generated by managers and clinicians for their Board, thus lessening any burdens of regulation.

30. There is a tendency for regulation to be publicly perceived as 'inspection' which in turn is seen as amounting to "visits". However, the sense that one could reflect agreed standards of care and see whether these standards are being delivered solely through the vehicle of visiting institutions involves a degree of self deception. There were over 400 NHS trusts for which the Healthcare Commission was responsible and one will never know what happens in every corner of an organisation; there are good days and bad days and this level of attention is difficult to achieve. Therefore, focussed and proportionate visits

triggered by information and, followed by the intellectual analysis of the data collected during the visits, are key, as the only realistic and proportionate measure.

31. The final cornerstone of my vision was to limit the number of regulatory bodies; it was the concept of two regulators and two alone; one to regulate professionals and one to regulate organisations. I have touched on this earlier in my statement, as this was one of my conclusions reached in the Bristol Inquiry. My view is that regulators should be aligned and co-ordinated so as to avoid duplication of effort and responsibilities, and to avoid any gaps in this regulation.

The Legislation Introducing the Healthcare Commission

32. Following the Bristol Inquiry, I was approached, although I cannot recall by whom, with the notion that the envisaged organisational regulatory body be set up, and I was asked if I would like to apply for the position of Chairman. At the time, two things went through my mind: one, I and my colleagues from the Panel wrote the Bristol Report and set out recommendations, so in some sense I felt an obligation to see this through, and secondly, I was committed to public service and felt I had a duty to take on such an appointment. In some way I felt obligated as well as being interested.

33. I applied for the position of Chairman and was initially appointed as Chairman-designate. Upon appointment, I started to debate the extent to which the new regulatory body, the Healthcare Commission, could encapsulate my vision for the healthcare system and what limits there would be. I was realistic enough to know that my vision of ideals would always come up against the pressures of reality.

34. When I was first appointed, I was kindly brought into discussions about the healthcare bill by the then minister, Lord Hunt. This was an iterative process and I had meetings when I would give my views about various aspects of the bill. There was a sense that the Commission for Healthcare Improvement ("CHI"), the former regulatory body, had not endeared itself to the politicians, as it showed itself to be too independent.

35. CHI was a very significant breakthrough insofar as it was a first attempt to inject regulation into the system of the NHS, albeit that professional regulation was already in existence. Whilst CHI's remit was relatively narrow in that it focused primarily on clinical governance, it was a step forward. However, the Healthcare Commission's remit was quite different. We had a lot more formal obligations such as achieving value for money, driving improvement and dealing with second tier complaints.

36. At the time, I can remember pleading that dealing with complaints should not be within the remit of the regulator. I thought it was a good idea for regulators to receive information about complaints, but not to adjudicate upon them. I thought this would be hugely onerous and it would remove the incentive for Trusts to resolve complaints themselves. The Healthcare Commission however was made responsible for dealing with second stage complaints, and we were initially overwhelmed in dealing with this task.

37. I also remember having serious conversations with the minister about information and whether the Healthcare Commission could have a role in pulling all information together. I had recently finished the Bristol Inquiry and, as mentioned above, one of the key recommendations arising from that Inquiry was the use of data. I felt there was a wealth of data available that could be mined to serve both patients and those performing services to check how good the services were and to drive improvement. I remember drawing a diagram for the minister setting out the notion that all information that was out there should be sucked in and kept in one place.

38. I was not of the view that the Healthcare Commission had to be the repository for this information, but I felt it was important that wherever the data was held should be perceived as independent, without any political overlays. The real problem was that without this element of independence people would not believe the credibility of information and we needed to create an independent data repository, to convey the message that the data was inviolable. The best example of where this has been achieved is the National Office of Statistics. Indeed, I wrote to Jack Straw in relation to the National Office of Statistics, as he was interested in the concept of information, and asked him if he thought that this concept could operate successfully in the context of health. Unfortunately I did not receive a reply.

39. I suggested that the Healthcare Commission be the repository for the information. However, there was some tension between this proposal and the desire of the Department of Health to control this information, which went against the concept of information being free of manipulation. I recall having conversations with the Department of Health at the Permanent Secretary level about this issue. The engagement of the Department of Health was one of interest, but the impression I got was that a concentrated focus on the collection and analysis of information about the safety and quality of the care provided by the NHS was not part of their agenda. I recall having a conversation with the then minister about my idea of an independent repository of information. He said it would be a challenge for the government to surrender the control of that information.

40. I was then invited to a discussion led by Lord Warner in relation to an Information Centre that was being created. At that meeting, the creation of the Information Centre was discussed and I expressed my views that the proposals were less than ideal as it was housed under the control of the department, and lacked the independence that I thought desirable. However, the Information Centre was set up and it was effectively a clearing house for data. It took the concept that you needed all information in one place, but did not take the extra step of it being independent, to ensure that data was inviolable. It was therefore data that was susceptible to debate, and manipulation.

41. I cannot comment on the performance of the Information Centre itself as I do not know how it was subsequently operated, but certainly the Healthcare Commission interacted with it. The fact that the Information Centre was not based within the Healthcare Commission did not cause particular difficulties and did not stop us doing our job, but an opportunity was missed.

42. The next big question was what national standards were going to be introduced. I was not involved in the creation of these standards. This was dealt with by the Chief Medical Officer, Sir Liam Donaldson, who was also responsible with his department for drafting the standards, of which there were two types: core and developmental. When published, the standards incorporated government targets, and there were seven domains, for example a governance domain, clinical and cost-effectiveness domain and safety

domain. However, none of these seemed to focus specifically on the patient. My view was that I wanted three domains built into the standards; the outcome for patients, the safety of the care received by patients and the experience of patients. However, the standards did not emerge in this patient focused way. My view was that the standards did not address outcomes for patients and how these should be tested. The standards were a typical Whitehall set of propositions; they would not frighten too much but were a step in the right direction.

43. The other disappointment arose from the fact that the standards were divided into core and developmental standards. The developmental standards were designed to indicate development over time to encourage improvement. I was particularly keen on this as it mirrored the Healthcare Commission's statutory remit to encourage improvement. However, disappointingly, the Department of Health decided that we should not assess compliance with the developmental standards in the first year of that Annual Health Check process but concentrate on measuring the core standards. Thereafter, the developmental standards were effectively shelved. I thought this was an unfortunate step and a missed opportunity.

44. As I have already explained, my vision was also for the standards to be implemented from the bottom up, to achieve "buy in" from clinicians and patients. However, in reality, the "tablets of stone" standards were passed down by the Chief Medical Officer via the Department of Health to us, and we had to work with what we were given.

45. At an advanced stage in the discussions with the Department of Health in relation to the legislation for the establishment of the Healthcare Commission, literally out of nowhere, we were joined by a number of Department of Health civil servants who told us about plans for the creation of another regulator, "Monitor". I had no inkling that this was even in the pipeline. To say I was surprised is an understatement. My impression was that the Department of Health officials who communicated this information had been developing this plan independently of other parts of the Department of Health that were dealing with the Healthcare Commission.

46. In response to these proposals, I said that the purpose of the Healthcare Commission was to make regulation more streamlined and efficient so that we could achieve a good understanding of the NHS; this was one of the key cornerstones of my vision. The reasoning behind the creation of another regulator and another relationship with the Healthcare Commission and the Department of Health was not clear to me. It soon became obvious that the purpose of the creation of Monitor was to introduce some element of competition into the NHS and to release the tight grip of the Department of Health on the NHS.

47. As mentioned earlier, the Bristol Inquiry report talked about there being one organisational regulator to ensure clarity of roles and responsibilities. With the introduction of Monitor, this did not happen. It introduced me to the fact that one can have an ideal, but the political world will ultimately decide what happens. One can either walk away or work with what you have. While another regulator was not part of my vision for the healthcare system, I was not an elected individual and did not have a licence to create organisations based on my own whim; so I had to engage with it.

48. In relation to this issue, I recall that shortly after I was appointed as the interim Chairman, I took a telephone call from Nick Timmons from the Financial Times. He asked whether the Healthcare Commission had the power to criticise the Strategic Health Authorities ("SHAs"). I responded that we did not formally have the power to do so but if we felt that a SHA had not taken proper action in response to a recommendation of the Healthcare Commission, we would have commented on this. I very quickly received a call from the Department of Health saying that I had overstepped the mark, as I gave the impression that the Healthcare Commission was regulating the management of the whole NHS including the SHAs. I rejected this comment and said that my role would be to issue recommendations and my responsibility was to comment on whether these were adequately implemented.

49. What we therefore ended up with was the Healthcare Commission and Monitor as regulators with a lack of clarity of roles, with the SHAs having a performance management role. With several players on the pitch, striving for clarity of purpose, it became necessary to seek to forge an understanding of how these varying roles were to inter-link. The Healthcare Commission had a statutory

duty to promote co-ordination of activity between various bodies. A concordat was therefore devised – at Exhibit IK3 [ ], to seek to create an understanding of how it would all work, and how data and information would be shared. Monitor however refused to be a signatory to this Concordat.

50. I felt it was disappointing that more of the organisations were not cleared away. The NHS is not always good at getting rid of organisations, but they are good at changing them. It was also disappointing not to have the central information role based independently, for example, with the Healthcare Commission.

51. It was disappointing to me that the regulatory simplicity I sought had not been achieved. I accepted however the reality that my radicalism and focus on change had been limited by politicisation and general inertia; my focus and energies then turned to making the Healthcare Commission as effective as it could be.

The Creation of the Healthcare Commission

52. When I was first appointed, I was pressed to appoint a Board or Commission made up of a Medical Director, a Director of Nursing and other standard posts. However, I said that I did not want to replicate the structure of a trust. I also wanted to make certain tactical decisions to try and win the profession over. For example, I appointed three senior national clinical advisers; a surgeon, a GP and a nurse. They were my link to the clinical professions. For example, they interacted with the Royal Colleges and other bodies. This helped with my aim to win over the profession, who at the time saw regulators as policemen trying to enforce government targets. We also made speeches and talked to the bodies in conclave, to make it clear that the regulator espoused the concept of regulating with the consent of the regulated.

53. In terms of setting up the Healthcare Commission, I thought it was important to ensure that the staff, and to a degree the Board members, should bring forward experience from CHI to challenge what we were doing. I was delighted that Bruce Keogh (now Sir Bruce) and Nick Partridge (now Sir Nick) agreed to serve on the Commission after previously being on CHI's Board. No-one from the CHI staff was required to be made redundant, as they were offered the opportunity to come to the Healthcare Commission. I am not an expert in what

CHI did, but I believe that we took advantage of any existing knowledge and expertise from CHI, including retaining a presence at board level.

54. In the early days, I was particularly interested in developing the innovative use of data and I wanted to capture the expertise of CHI personnel who had the experience of collating relevant data, to help further that objective. I also wanted to capture the expertise of other professionals who were involved with CHI, such as nurses, doctors etc, so that we had professional expertise integrated at every level of the organisation; I was keen to ensure continuity.

55. I was engaged in the original design of the Healthcare Commission. One of the things that I wanted to ensure was that the organisation was as non-hierarchical as possible and that each limb had to necessarily interact with each other, so that everyone knew what the other was doing. For example, I wanted the complaints team to feed into the Annual Health Check, the investigations team to feed into operations etc. With others, I designed the organisation by various functions, which overlapped and interacted.

56. While there were various parts of the organisation that dealt with particular areas such as the informatics team, complaints etc, what I saw as crucial in the organisational design was that the senior team should also work with each other and with all the various limbs of the organisation.

57. The "informatics" or intelligence section was the principal engine of the organisation as a source and a driver. Lorraine Foley or Anna Walker will be able to describe in more detail the role of informatics, but as far as the Board was concerned, informatics sorted out, received, fed back and checked information that was coming in, ensuring that all other parts of the organisation were aware of information relevant to their functions.

58. I was also keen on the introduction of our customer relations management system ("CRM System"). I felt that, as a regulatory body that was committed to using information intelligently from any source, we should know what interactions we had with organisations. For example, if there had been a call, a meeting, an email, a memo, all that needed to be captured to build up the picture of those organisations being contacted and regulated. The CRM System held this information, so that we could "mine" what we knew about a

particular trust in various ways. The CRM System functioned to offer a better service to the organisation and the wider public.

59. During the early period of the Healthcare Commission's tenure, we were aware of the need to lay the groundwork and do things carefully. We were trying to develop complex systems, and I bore in mind the risks for the organisation that we needed to be sure of our ground, as it was not fair to the public and patients if we did something or said something that was not supported by reliable intelligence. As a regulator, we were also on unstable ground in terms of criticism, so anything we said or did had to be right. Therefore, it was not a case of simply hitting the ground running. We needed to design the Annual Health Check, agree a series of reviews to conduct and develop our capabilities, and develop the tools necessary to become an effective regulator.

The Reality of the Healthcare Vision

60. The decision to merge the Healthcare Commission was in fact made as early as May 2005. I banned the word "merge" as really we were to be abolished. We were described by some as "collateral damage" and a target of the Chancellor's speech on regulation in the private sector that was primarily addressed to other sectors. However, at the time, I said I would seek to persuade the political leaders that whatever the future might hold, we should at least start the journey of regulation. I thought that on behalf of the patients, we needed to put something in train and begin to turn over some stones, even if ultimately we were to be abolished. This was the backdrop to the operation of the Healthcare Commission.

The Political and Regulatory Environment

61. As mentioned earlier in my statement, as Chair of the Healthcare Commission I sought to embed as much of my vision for the NHS as possible into the creation of the organisation. Whilst this was not always possible, I resolved to do my best with the system that I was given. I was concerned to provide innovative solutions to satisfy the political need for regulation whilst driving my vision.

62. I was also conscious of the political pressure we were put under as a regulator all of the time and there was a need to have guile and toughness. The political realities of the healthcare system were omni-present throughout the life of the Healthcare Commission.

63. I can recall an example of this in 2005. During an investigation into Northwick Park Hospital in North London, Healthcare Commission staff discovered that nine women had died in childbirth over a two year period. This was far above anticipated levels. The level of concern was such that we discussed recommending special measures to run the hospital for an interim period. We therefore needed to inform the Secretary of State of our recommendation.

64. At that time, we were in a period of election "Purdah". This is a term to describe the month long pre-election period between an announced election and the final election result. It is effectively a period during which major decisions on policy are postponed, unless it is in the national interest to proceed. We spoke to the Permanent Secretary, who then communicated with the Secretary of State about imposing these special measures. I recall we received a response from the permanent secretary having consulted with his political masters to the effect that the Department of Health noted the importance of the issue, but asked if we could delay the implementation of these special measures until a particular date, which happened to be the date after the election results. To me, this was an important health issue which should not be affected by political considerations. Therefore, I said I would be delighted to delay the implementation and announcement of the special measures, if the Permanent Secretary was prepared to be accountable to the public by appearing on "Newsnight" if a woman subsequently died at the hospital in the interim period.

65. I feel such pressure was inappropriate. My stance resulted in immediate action so that the solution was in place when the special measures were announced. This enabled politicians to announce the solution rather than just the problem. Throughout this issue, there was a real sense that I had to manage my way through these political pressures. This is an example of what is meant by the politicisation of the NHS.

66. This is just one example of the political environment the healthcare system was operating in, and the political realities we were facing every day.

67. One of the other uncertainties and one of the great unresolved constitutional issues is what should be managed by the Department of State and what should be managed by the NHS; it was never clear who had primacy over us. There were 3 permanent secretaries, responsible for the Department, the NHS and the Chief Medical Officer. The politicians took ownership for the NHS, despite this constitutional divide. One of the other issues, with which we were constantly registering concern, was who was the responsible officer in the Department of Health with whom the Healthcare Commission could liaise. I felt it was important to have a contact who was sufficiently senior within the Department of Health and who did not change roles, with which we could have frank discussions. In addition, it was not always clear who was the relevant Permanent Secretary with whom we should be having contact.

68. The point is that every arms length body needs to have a "critical friend" in the Department of Health. The Department of Health holds the purse strings and has ultimate control. The critical friend is the liaison officer for improving understanding between the Department and regulator and, in particular, of explaining the Commission's actions to the Department. We never truly succeeded in persuading the Department of the importance of this role and the unsatisfactory nature of the arrangements.

69. In terms of the environment the Healthcare Commission was operating in, when talking about regulatory activity, we were in a field crowded by others. Anna Walker worked hard to make the Concordat work through a process of collaboration, but she found this was something of a challenge in the NHS. In my view, as mentioned earlier, the Concordat was very unsatisfactory as any organisation could refuse to share information or collaborate if they chose to. The biggest challenge for the Healthcare Commission was that it had the duty to co-ordinate, but no power to take forward or enforce. Therefore, we had to rely on other agencies to take into account other aspects of information and take that role seriously. For example, the SHA are performance managers but the Healthcare Commission had no power to regulate their activities and manage their role, or compel performance management.

70. To add into that, Monitor, one of the major players, as stated, would not join the Concordat. We wrote formally to Monitor about this issue and I received a number of responses saying, for example, that they were not an inspector so they did not need to be part of the Concordat, or they did not want their freedom of operation compromised. We gave these responses credit as being rational. However, Monitor's approach sent curious signals to the community and I was of the view that Monitor wanted to send a signal that they were different and not part of the same system. This did create some tensions, although Anna Walker did work hard on the relationship with Monitor.

71. I have been referred to a copy of the Memorandum of Understanding between the Healthcare Commission and Monitor, a copy of which I attach as Exhibit IK4 [ ]. In particular, I have been referred to the following clauses:

- Clause 9 – "more generally, the Healthcare Commission must keep Monitor informed about the provision of healthcare by and for NHS Foundation Trusts"; and
- Clause 14a – "in particular, there needs to be the proper exchange of information in relation to NHS Foundation Trusts or NHS Trusts/public benefit corporations that have applied for Foundation Trust status."

I am also aware of a more specific Memorandum of Understanding addressing the particular issues of investigations.

72. It is important to highlight that there is a risk of reading memoranda of understanding as contracts with restrictive clauses, when they were simply an approach to the way organisations could work collaboratively. I have been asked whether the Healthcare Commission would have known who was applying for Foundation Trust status so that the proper exchange of information could be engaged. I was removed from this level of detail and therefore would not be aware of who was applying.

73. Another player in the regulatory environment and a repository of useful data, was the National Patient Safety Agency ("NPSA"). We, as the Healthcare Commission, saw their work as important, but found it difficult to work with them. The NPSA was not a regulator, but they were an information source and analyst. They collected very important data, which we were keen to share, however their view was that all data had to be collected on a confidential basis,

otherwise people would not report to them. I never understood this argument. For example, the NPSA could receive a report that said there was a risk to patients' safety at a particular hospital and an alert was issued, but they would not tell us which hospital this related to, as they said this was confidential. The NPSA was concerned that people may not report issues to them if they thought the data was disclosed elsewhere. I said to them that we could not do our job if we were not given this information. Discussions went round and round like this unresolved, and consequently the NPSA were never easy to work with. This reinforced my view that important data would always have been best housed with us.

Development of the National Standards

74. As referred to earlier, I do not know how the national standards were devised by the Chief Medical Officer. I was not involved in drafting the standards and I was not invited to comment, and when the standards emerged I was disappointed, as I felt there was not enough of a focus on patients and outcomes, as stated earlier. Therefore, when the standards were passed down, my first challenge was to make representations that these standards were not ideal, which I did on a number of occasions. However, I was told that the standards were not to be reviewed for around four or five years.

75. However, I had made clear in my vision statement for the Healthcare Commission that implementing the standards was only one of the Healthcare Commission's tools, and engagement with clinicians and patients still remained key. Therefore, I sought to accrete onto the national standards other elements that were important to clinicians and patients, thereby introducing processes and ideas into the Healthcare Commission's work to ensure that patients were at the centre, and to seek to circumvent the "top down" approach that was being imposed. Additionally, during the lifetime of the Healthcare Commission, developments were made in the way the core standards were being assessed and interpreted with other data and intelligence being fed into the Annual Health Check.

76. One of the first things I was keen to do was to promote improvement and to seek to understand from bodies the key ways that we could measure patients' experience. I recall that we spoke to a number of bodies in the regulatory field

to obtain their views, and some bodies really engaged with this idea. For example, I can recall that one of the Royal Colleges came back with 140 suggestions for ways to measure outcomes and patients' experiences. This approach was tactical to some extent as it helped to engage the professions in the concept of regulation. There was a sense that we, as the regulator, were on a journey to seek to improve on behalf of patients and clinicians what they thought was key to improvement. The view was that the sooner we could embed this into our processes, the sooner we would be able to interrogate Trust Boards and measure compliance with these standards.

77. In my view, as the Healthcare Commission was winding down, so was clinical input into our work increasing. For example, additional issues that focussed on the patient were beginning to be incorporated into the Annual Health Check process. While these additional questions had to be agreed by the Department of Health, there was a degree of understanding that began to develop with the Department of Health, with an appreciation of what the Healthcare Commission was trying to do. It did have its challenges, as if we asked for things they did not want, there would always be tensions, but that said, I got the sense that we were pushing at a door that was starting to open.

78. I can recall an example of this. I had unilaterally decided that I would make more importance of safety, as in 2006, we were in a position where safety was not the top priority; this to me was staggering. Safety was all important. I tried to bring together any organisations that had an involvement with safety and get them to sign a charter. This charter detailed what each agency had done about safety in the last three months so that we could plot this. The then minister became involved with the safety charter, and it was agreed that any progress on safety issues would be published. Safety then became part of the agenda. This safety charter was just an extra regulatory role for the Healthcare Commission, but it demonstrated that the Department of Health were increasingly open to developing ideas.

79. Therefore, while the standards that were imposed by the Department of Health did not accord with my vision for regulation, we did work hard to develop these standards, to increase the focus on driving the improvement that was most important to patients, and to develop tools that supplemented our intelligence –

such as effective reviews, and hard hitting investigations, coupled with input from the regions, the helpline, and the complaints departments.

80. Another goal of mine during the Healthcare Commission's tenure was to expand the ambit of the regulator to include a role in regulating the care that was provided by general practitioners. We were beginning to develop a way to get information about general practice just prior to being abolished. For example, we were looking to measure the number of elective admissions rather than emergency admissions. When reviewing the types of admissions versus mortality rates, we could begin to assess and comment on how general practice was being managed. This gave us a data source for the quality of care at a general practice level. Whilst this level of regulation was in its infancy, it was an objective we were keen to develop, though our limited powers demanded that we had to be imaginative in the way that we collated such material. Formally, we had regulatory jurisdiction over Primary Care Trusts only, not general practices.

The Annual Health Check

81. The Annual Health Check was a complex exercise. It was not just about self assessment and it was not the only activity that the Healthcare Commission undertook.

82. The first step of the Annual Health Check was to require a Trust Board to declare they were compliant with standards, and targets. This met our ambition to place the responsibility on the Board, where it should be. However, the self declaration was only the first step in this process. However, it was a critical step as it got the Board to sign off what it was doing. It therefore had a clearly defined responsibility. The aim was that in the exercise of this responsibility the Board would insist that the Executive provide it with that information necessary for it to declare compliance or non-compliance.

83. In addition to the "self declaration", views were sought from local government and patients' organisations. These included patients' forums, and oversight and scrutiny committees. These views were published and incorporated into the Trust's declaration Following submission of the Trusts' self-declarations, the third step in the process was to check the submissions against risk profiles.

The risk profiles set out what was the norm, reasonable and expected performance. I do not know in detail how the risk profiles for the Annual Health Check were established, however it was about having enough data on appropriate performance to assess what should be expected. Calls to the Healthcare Commission's helpline, complaints, information from patients etc, it all fed into the analysis of performance. What informatics had to do was grapple with the qualitative and quantitative data. Qualitative data requires the allocation of scores so they can weight it in a way that becomes useful. It was a complex process. If the declaration was spiking or at any variance with this risk profile, then this would prompt the Healthcare Commission to interrogate a Trust about its declaration. This could take a number of forms, including a targeted visit, or it could be settled as one of those to be tested on its self declaration, as one of those trusts identified for scrutiny on the basis of risk. If there was such a visit, this would involve requiring the trust to demonstrate by way of information what it had relied on to reach its conclusions about its performance. If the data did not justify the trust's declaration this resulted in the declaration being qualified.

84. In addition to visiting Trusts by way of reference to their risk profiles, we also visited Trusts on a random basis to ensure compliance and to validate our system. I am not sure of the percentage split, but believe it was an 8% random check and 12% risk profile check, around a 10%/10% split. The variance against the risk profiles in those Trusts that were randomly chosen was much lower, which showed that the approach adopted of analysing by reference to risk was valid.

85. These visits were targeted, but proportionate in their approach. The Healthcare Commission did not have the resources to inspect Trusts all of the time. Further, Trusts have good days and bad days, so the notion of wandering up and down wards seeking to identify generic problems is implausible and impractical and provides a false reassurance to the public. Therefore, the reason for visiting was based on a premise that there was something to go and see – it was part of the vision and was politically (given the declared view of the Better Regulation Executive) and proportionately the right thing to do.

86. I would however accept that there were inherent weaknesses in the Annual Health Check, these weaknesses being based upon the limitations of the

legislative framework within which we worked and the standards that we had to apply. To a certain extent, it was destined not to be as effective as we wanted it to be. One of these weaknesses was that the Annual Health Check only looked at certain pieces of the jigsaw. I could not examine the patients' movement between services. In my view, you cannot look at improving the whole picture if you are only examining a part, this was because the legislation required us to be concerned with performance of "NHS organisations". To me, that was an error as it meant that for example, we were limited to looking at primary care trusts and could not look at general practice, or the movement of patients between services. This limited view meant that we could not obtain all of the "richer picture" of performance in the NHS that was part of our vision. That is why the Healthcare Commission also conducted reviews focused on particular services, conditions or groups of patients.

87. The second weakness with the Annual Health Check was that it was predicated on standards that were developed from the top down, and that were not heavily focussed on the patient. To some extent they were weighted towards process, although it was not possible to satisfy the standards simply by pointing to the existence of a system. I have already touched on this earlier in my statement. A third weakness lay in its being an organisation-wide assessment, as called for in the statute, which meant that the overall performance could mask problems or concerns in particular areas.

88. I am anxious to highlight that the Annual Health Check was not the Healthcare Commission's only activity. There has been a suggestion by the Health Select Committee that the Annual Health Check was our primary focus. This was not the case. The Annual Health Check was part of a portfolio of activity to encourage improvement.

89. The reviews that the Healthcare Commission conducted were another important aspect of the Healthcare Commission's work. These reviews focussed on particular areas to reflect our statutory obligations and our strategic commitment to vulnerable people. For example, there was a review of children's services and of dignity in old age. The reviews were intended to have a national effect. Certainly, the results from the Annual Health Check also indicated areas for us to focus our reviews on.

90. I have been referred to a document titled "The Annual Health Check: Assessing and Rating the NHS", which is dated October 2006. I attach a copy of this document as Exhibit IK5 [ ]. I have been referred to page three of this document where it states, "The Annual Health Check assesses for the first time, that general standards in areas such as safety, patient focus, and clinical effectiveness are being met on behalf of patients across the NHS." I have been told that in her evidence to the Inquiry, Dr Heather Wood has commented that she felt that the Annual Health Check, in describing itself as a measure of patient safety and clinical effectiveness, "over claimed", and "did not do what it said on the tin". I think the difference lies in the fact that the Annual Health Check did indeed assess performance in relation to general standards, but that these standards were those laid down by the Department of Health. As I have said already, they did not satisfactorily address a number of matters relating to performance that were important. Dr Wood found this unfortunate, as did I.

91. I have also been referred to page five of the document and the description that, "The Annual Health Check provides important assurance that providers of healthcare in the NHS are meeting a minimum standard of performance." I have been asked whether this is a correct description of the process. My view is that the Annual Health Check provided such an assurance when an organisation succeeded in meeting the standards notwithstanding the limitations of the standards. The intrinsic limitations of the standards, the organisation-wide nature of assessment, plus the relative immaturity of the system meant that the AHC was not always able to identify failure. The continued development of the risk profiles and cross-checking were making the AHC more robust over time, as was the work of the mortality outlier panel, plus the work I refer to in paragraph 104.

92. Finally, I have been referred to page nine of the document where it states: "The Annual Health Check assessment is more comprehensive than the system of star ratings and it is more difficult to be 'excellent' under the new system." In response to this, I would say that CHI looked at organisations according to their more narrow statutory remit. The Healthcare Commission's remit was different. The approach was much more comprehensive, based as it was on a wide range of national standards and targets. Also, we drew on a wider range of

information. Therefore, we could have come to different conclusions for a variety of reasons.

93. I recall that when the results of the first Annual Health Check process were published, there was quite a significant variance between the declarations received from Trusts and what we expected, based on information we had, drawn from a wide range of sources. My view was that the Trusts were still thinking the system could be "gamed", i.e. the response could be manipulated and couched in a particular way to achieve compliance. Particularly with targets, I felt that organisations could "game" the system, by focussing their efforts on the achievement of targets in order to secure compliance, but to the detriment of the rest of the organisation's activities. However, with the Annual Health Check process, it was difficult for the Trusts to do this on an ongoing basis as we had a multitude of sources of data to challenge what they said. We made clear to the Trusts that this was the case and the system would not pay dividends unless declarations were frank. The following year there was a significant drop in variance between the declarations and our risk profile. Therefore, this demonstrated learning from the process in the space of a year.

94. I do remember attending a meeting with Andy Burnham, the then Minister of Health and his team of civil ministers to brief him in advance of the publication of the first year's Annual Health Check. I recall that Anna Walker and Gary Needle from the Healthcare Commission were also present at this meeting, and possibly Jamie Rentoul, our Head of Strategy. I do not now recall the details, but Mr Burnham was concerned as to how the results, which scored a large number of trusts as "weak" or "fair" would be perceived by the media and politically. He asked strongly that the categories should be revisited and the message made more politically acceptable. I responded saying that these categories had been agreed six months earlier with the Department of Health officials. There were a lot of discussions around this issue, but ultimately I said no, that the categorisation would not be changed.

95. It was a typically difficult meeting, as we were carrying news that was unwelcome. This was always a tension at a departmental and political level. I cannot recall exactly what Andy Burnham and his team wanted us to do with the categories, but I cite this as an example of the Department of Health becoming quite determined that the shape of the results was not appropriate,

as they conveyed too much bad news, rather than it reflecting what was really happening in practice. Across Whitehall, Government, political parties etc, there is always that political pressure.

96. I have been referred to a copy of a letter dated 15 October 2007, which was sent to Martin Yeates of Mid Staffordshire Trust from Celine Wilkinson, a Healthcare Commission senior manager. I attach a copy of this letter as Exhibit IK6 [ ]. This letter confirms that Mid Staffordshire had passed the Annual Health Check. I would not have been aware of the detail of individual scorings for Trusts.

97. I have also been referred to a copy of a Healthcare Commission paper, dated 22 November 2007, which was prepared by Jamie Rentoul. Jamie was our Head of Strategy and the paper relates to the Healthcare Commission's programme of work in relation to the safety of patients' care. I attach a copy of the paper as Exhibit IK7 [ ].

98. I have been referred to page seven of this paper, which examined what the Healthcare Commission then knew about the key risks to patients' safety from the Annual Health Check. In particular, the paper states, "In the past, our assessment of compliance against the standards for better health has focused, perhaps to too great an extent, on the specific standards set out by government and the specific words in those standards." I think what Jamie was saying here was very important to the understanding of the Annual Health Check process and the Healthcare Commission's role; the process was developing so that we could use measures and assess organisations beyond the "tablets of stone" standards. The Annual Health Check process was initially operated in a very careful way, with the wording of the standards being followed to the letter. In the early days, Healthcare Commission staff were anxious not to go beyond their remit. This was understandable as they were concerned about the possible legal action being taken by trusts. It took a while to give the staff the confidence to learn about what lay behind each of the standards; including outcomes and experience. However, as I have mentioned earlier in my statement, we had to operate with the cards we were dealt and the wording of the standards we were given; this was the system, but we needed to be creative to work around it. Staff needed to be supported to feel that they were

able to do that and to seek to input data to supplement self declarations into the assessment process.

99. This document summarised the Healthcare Commission's creative thinking at that time and what we needed to do to drive forward the vision for regulation of healthcare. It was a programme of work.

100. Paragraph 65 of the paper also refers to the Healthcare Commission developing a range of proposals which would result in amendments to processes of assessing compliance in the Annual Health Check process. By this stage, the Healthcare Commission were aware that we would be abolished, and yet we were still finding creative ways to improve regulation. Therefore, while there were limitations in relation to the standards that were adopted to assess the Trusts, the Healthcare Commission during its lifetime did move the process forward.

Surveillance of Data

101. Throughout the life of the Healthcare Commission I was also keen to develop a surveillance based system of regulation. As mentioned earlier in my statement, my vision for the regulation of healthcare had envisaged that one agency, which could be the Healthcare Commission, be a central repository for all information, and be independent of the Department of Health to avoid any suggestion that the data could be manipulated. While that information centre was not ultimately based in the Healthcare Commission, having thought analytically about this issue, I challenged the Healthcare Commission's informatics team to take forward a surveillance based system.

102. The first thing I did as interim Chair was to ask someone to tabulate all sources of information that touched on performance by or in the NHS, wherever it might be and however tangentially relevant it was. I was told that at best this was a difficult task. But it captured what I was interested in; that there were undoubtedly gaps in the important information that we held. For example, outcomes of care, serious untoward incidents, patients' experience etc. Given these gaps in knowledge, I was keen to identify how we could address this. At the early stage, these were all ideas about the creative ways we could try and obtain information.

103. Simultaneously, I was aware that there was a lot of information out there not being used. For example, the General Medical Council did have a lot of information in relation to complaints which, if analysed, would show trends about where the pinch points were. My theory was the information was out there and it could be used to build up a richer picture of performance.

104. One of the first ways we did this was to persuade cardiac surgeons to provide us with their mortality statistics that we could then publish on our website. Initially, some were reluctant to do this, but after a period, a number of cardiac surgeons did provide their data, which was all found to tell a positive story. Therefore, there became a sense that if you had not provided your data, there may be an issue. Once the surgeons saw that it was safe to provide us with their information, it gained their trust and they were willing to engage. This started to encourage development for the sharing of information. This was key to my vision of the way ahead.

105. The informatics team also began to develop more analysis alerts to help establish this system of surveillance.

Mortality outliers

106. Another area of interest for the Inquiry, which links to my concept of surveillance, was the mortality outliers. I have been asked whether the Healthcare Commission could have reacted sooner to the analysis of the mortality statistics, to be in a position to use this data pre-2007. Martin Bardsley and Nigel Ellis will be able to comment on this further. However, from my understanding, I was pressing informatics to get to the point of surveillance, as I have mentioned above, and as part of this they were working very hard to develop systems of information that could constitute an alert for mortality statistics. But first they had to develop and establish the database which was used to check the self declarations of trusts as part of the AHC. Moreover, the mortality outliers work has to be based on reliable data; this was an emerging and new area where there was a tendency to attack any new methodology – as was seen at Mid Staffordshire trust.

107. I had a saying, "the problem of the norm". If you have a system based on risk profiles, you can only drive that system by reference to what the expected profile should be. However, the "norm" depends on the area of concern being examined. It was always going to take a while to establish the relevant risk profiles for mortality statistics and it was difficult and complex to get agreement about what this should look like. It was, of course, even more difficult when outcomes other than mortality needed to be analysed. There is much talk of measuring outcomes but in fact this is an exceedingly difficult task. This problem was exacerbated by arguments that were used to paralyse the debate, for example, by saying that differences were based on coding, not on variations in performance.

108. This journey of analysis was essential to get to grips with what we were doing in relation to surveillance and the issue of mortality, so that we could assess if organisations were putting patients at risk. One cannot underestimate how complex a challenge it was. We needed to find ways to measure this data and ensure its reliability. One cannot allege, "you are killing people in ward 5, or performing this or that service", until you have the data to support that. Our methodology was to go further than generic mortality statistics – HSMR – and to drill down into outliers in areas of particular activity.

109. As stated, this was a new tool and they needed to find out what the data meant. This alert data was different from the Hospital Standardised Mortality Rates ("HSMR") that were used by Dr Foster, which is essentially something of a generic estimation. The value of the HSMR as an indicator of an issue or risk was, and remains, significantly contested. Informatics were using not just organisation-specific data, but the patients' pathways. For example, if they identified that the pathway of emergency care was an issue, we were able to engage an organisation with a focused understanding of what to look for and at. As far as I am aware, this work was groundbreaking. I believe this was the first time it has been developed worldwide, but the data was not rigorous enough to use until around 2007, though it had been discussed in the Healthcare Commission as far back as 2005.

Strategy

110. I have been referred to a copy of a document titled "Strategy Meeting of the Commission – April 25 & April 26 2007. Further thoughts for strategic planning for 2007/2008". I attach a copy of this document as Exhibit IK8 [ ]. This document set out the Healthcare Commission's strategy for developing regulation further.

111. In particular, I have been referred to the last paragraph on page one where it states, "The Department of Health recognises that we are seeking to deliver an information driven, risk based and analytical approach to regulation, supplemented by targeted visits, rather than the outdated dependence on periodical inspectoral visits of varying duration and regularity." I still agree with that view.

112. I have also been referred to the first paragraph on page two where it states, "At least parts of the Department of Health realise that there are risks in seeking to drive these reductions too far and too fast. The delivery of our functions in 2007/2008 may be damaged by destabilising the organisation to this extent; and, critically, we would be losing staff without knowing whether the new regulator would need such staff. In discussions, I have termed this "shooting the cavalry" before being able to establish whether the cavalry are an essential part of the planning of the new organisation."

113. I do not recall the detail of this issue, but I know that there was a time when our budget was proposed as £45m; cut from some £70m just two years earlier. In this document, I was rehearsing some of the implications of that. There were major discussions in the Healthcare Commission about the budget as we felt that the figure of £45m had been plucked out of the air, and we had to consider how to make cuts accordingly. We engaged in an exercise to consider what we needed to do to fulfil our statutory role, and then we tried to apply the necessary costs to that. We came up with a figure of £51.5m. I said that we needed to go to the Department of Health to say we needed £51.5m to do our job, but that if we did not get this, then the first cut we will need to make is 'x'. The Department of Health would then be responsible for that cut. It was a tactical move to achieve what we thought was important for the regulator to do on behalf of patients and those caring for them. Eventually our budget was agreed at £51.5m. The key issue is that this budget was agreed after us costing out necessary services, rather than adhering to a figure randomly

selected, and seeking thereafter to work out how we would operate within such a budget.

114. If one considers the parallel to Mid Staffordshire which I understand adopted an approach of selecting £10m as a figure to be saved as a part of a Cost Improvement plan, I would not accept that such an approach can work effectively. They needed to analyse the necessary components required to do their job, and then work out how much this would cost.

115. I have also been referred to a reference in the penultimate paragraph on page three where it states, "there are lessons to be learned from our experience of carrying out the Annual Health Check, which should result in savings." I cannot recall now what those lessons were.

116. Finally, I have been referred to page five of the document and the section that refers to, "the need for continuing self examination and re-shaping." Point (a) of this section refers to "enhanced coordination" and I suspect that this was from an internal perspective. Point (b) refers to "the need to increase the emphasis on analysis rather than inspecting through visiting has long been recognised." This is a reference to a continuing move to a surveillance and data driven process. Finally, point (c) states that, "It is now recognised that the Healthcare Commission employs a limited set of responses when concerns about healthcare arise...the need for a wider range of responses (for example the use of peer reviews) is understood and work is under way."

117. Very broadly, peer reviews were something that are used heavily in the US. They use peer reviews by fellow professionals and patients as a technique of assessing performance and getting a sense of ownership. This was replicated in the Bristol Inquiry when we had a group of experts in a room all arguing about the same issue. The public could see how complex some areas could be and there was a feeling that fellow professionals were more willing to talk to those who understood their field of expertise. Therefore, the introduction of peer reviews is something we were considering as part of the Annual Health Check. It was something that Sir Liam Donaldson was interested in and it involved an element of engaging professionals. This document demonstrated that we, as the Healthcare Commission were always trying to be active and develop further.

The investigation

118. The investigative function of the Healthcare Commission was a new statutory duty for the regulator, although CHI did have some inspection powers. In terms of the vision for regulation, the investigative function closed the circle insofar as if one came across something where one had serious concerns affecting patients' safety, this triggers an intervention or an investigation. The regulator must have that as a weapon within its armoury. It must also be prepared to use it.

119. The way that the investigative function of the Healthcare Commission was intended to operate was to engage with the management structure of Trusts. Initially the Trust itself and then, when necessary, the SHA or Monitor in the case of an FT. This would involve collaborative working with the SHAs to agree recommendations for Trusts where change was called for. I repeat that this was the intended way of operating. It was a very important part of the process to engage with the Trust, or the SHA who performance managed the Trust, or Monitor, to get them to endorse the idea that there was something wrong which required improvement. If they did not accept that, the regulator had the power to send in an investigation team.

120. I am unable to recall how many requests for investigations the investigation team dealt with during the lifetime of the Healthcare Commission, as I was not involved in this detail. I do recall that we carried out 16 formal investigations. Neither I nor the Chief Executive sat on the Investigations Committee of the Healthcare Commission. The Committee was chaired by a Commissioner and consisted of other Commissioners and members of staff. I received copies of the agenda, but took no part in the Committee's deliberations. The Board received the Minutes of the Investigations Committee. On occasions, the Chairman of the Committee reported orally on matters. Any such reports would be reported in the Board's Minutes. The reason for my not sitting on the Committee was the Board's commitment to ensuring that the Committee should proceed without any engagement by the Chairman who was then able to make decisions on behalf of the Board, either during, or at the conclusion of, an investigation, free of any possible previous influence.

121. As regards the investigation into Mid Staffordshire, I rely on my memory of events. I was aware that an investigation was being carried out. As was the agreed practice, I played no part in the process. It is important for the Inquiry to understand that Mid Staffordshire was one of many acute trusts. I cannot say now what made Mid Staffordshire attract our attention beyond other trusts, or in fact whether it did, and at what point. I was not involved with the detail of each individual Trust. When regulating 400-500 NHS organisations, the Healthcare Commission's contact or relationship with individual Trusts was not an issue that would be referred to the Healthcare Commission's Board.

122. The investigations team was charged with interacting with Mid Staffordshire taking forward the investigation. The Board knew the hospital was involved in an investigation as it received minutes from the investigation committee.

123. My understanding is that the HCC investigation was caused by concerns over a number of mortality outliers that emerged from the Dr Foster Unit and internally during the course of 2007. I recall being shown a paper produced by two academics at Birmingham University casting doubt on the statistical analyses employed by the Dr Foster organisation, and, I think, the Healthcare Commission. As was well known in the Healthcare Commission, I had a keen interest in developing the techniques used by the Informatics Division, although I had no technical expertise myself. The paper from Birmingham struck me as important because I knew that the analysts in Informatics liaised closely with the Dr Foster organisation. I therefore asked the team what it meant for our work, since I was not qualified to take a view. I was advised that the team was aware of the paper and that they and others regarded it as flawed, and that a response had been prepared. I was reassured, not least because the team's adviser was Dr (now Professor) David Spiegelhalter, who is one of the world's leading experts in the field and had been an expert to the Bristol Inquiry.

124. I have been referred to an internal chain of emails with Monitor, dated 18 March 2008, which related to the Healthcare Commission's investigation. I attach a copy of these e-mails as Exhibit IK9 [ ]. The content of these e-mails show Monitor were pressing for the investigation to be curtailed and for it to be completed quicker and cheaper. In terms of my understanding, I only knew the investigation was going on and not the detail of it; I kept away

until the report was published. I did not have any contact with Bill Moyes, the Chair and Chief Executive of Monitor, in relation to the investigation.

125. I am aware that a month before the formal investigation was launched, Mid Staffordshire was awarded Foundation Trust status. I have been asked how Monitor and the Healthcare Commission were working in parallel and whether Monitor asked the Healthcare Commission if they had any concerns in relation to Mid Staffordshire. I must restrict my comments to what I know. I have no knowledge of communication between the Healthcare Commission and Monitor about Mid Staffordshire's application for Foundation Trust status.

126. As a Board, we were aware that Monitor was not a member of the Concordat. However, the Board did receive Chief Executive's reports, which would include any important information about Monitor. I do not recall these reports ever referring to Monitor consulting the Healthcare Commission in relation to potential applications for Foundation Trust status. I certainly remember the Board reports referring to the Concordat issue, and Monitor not wanting to be a member, but I do not recall anything beyond that.

127. As far as I can recall, my next engagement with the investigation into Mid Staffordshire was when the report was being drafted. I joined a meeting chaired by Anna Walker to agree the final text. This was because I adopted the practice of reviewing all drafts of reports of investigations and other major reports. The findings relating to the Trust were clearly of very great significance, such that they commanded significant attention to ensure that they were clear and accurate. I was made aware of the concerns expressed by the Department of Health and others, not least the Strategic Health Authority, about the way in which the data was presented in the draft report. I was anxious, therefore, to separate out what were concerns which could be described as political, i.e. the impact the report might have on how the public might view the way in which the NHS, or a part of it, was performing, and the concerns relating to what were statistical projections and what could be said about them. As regards the former, I and the Board had always held to the view that it was the Healthcare Commission's role to tell the truth as we saw it. As regards the latter, the central task was to tell that truth in a balanced way so that patients, members of the public, clinicians and others could know what we had found

and form a judgement. I recall that there was some tension within the Healthcare Commission as to how to present the data.

128. I recall that the draft report referred to 400 to 1,200 excess deaths occurring at Mid Staffordshire. I recall saying that we needed to be careful how these figures were expressed for two reasons. One, because the notions of "excess deaths" would not be understood and second, the variation between 400 - 1200 would spark another debate in relation to data, as these were new techniques being used by the Healthcare Commission. They were a statistical extrapolation, rather than based on any individual case studies.

129. I had some experience of using the term "excess deaths" from the Bristol Inquiry, when the statisticians referred to a number of excess deaths. As stated, the issue of excess deaths was not understood by the public; it is a statistical estimation, rather than a reference to actual deaths. Relying on such statistics therefore did have an element of cruelty in it in so far as dealing with possible victims was concerned. Parents of children wanted to know if their child was one of the 31 excess deaths, but, of course, it was not possible to say. It is a difficult concept to understand given that it is a statistical construct. Therefore, as this was such an important report, I said the only way to be fair and to tell the truth would be to remove the reference to "excess deaths" and say that what had happened was awful and appalling.

130. I remember that Heather Wood was not happy with the decision to remove the figures; Heather Wood's honesty and integrity are remarkable. I can recall asking her if she could identify the 400+ people who had died, as would be suggested to the public in the report. She said she could not and I said that excess deaths was not a concept that would be understood in the context of this report. However, I suggested that I would seek the attendance of the Medical Director of the NHS, who was a previous commissioner and a surgeon, who would respond to the report on behalf of the NHS and reinforce the Healthcare Commission's condemnation, and could explain the issue of "excess deaths" if it came up at any press briefing, as I was not an expert in this field.

131. As I have said, referring to the statistical projections of "excess deaths", which varied considerably and which on one interpretation were extremely high,

might provoke an argument about data. This was what had happened for years in Bristol and was the very thing that had dogged the Mid Staffs investigation, and which would distract attention from the report's conclusion. That conclusion was that very many people had died and been harmed as a consequence of what I chose to call appalling treatment. This must not be lost sight of. Measures had to be put in place to prevent its happening in the future and lessons for the whole of the NHS had to be learned.

132. However, the statistics were leaked in any event. As I have said, when the report was made public, I asked that the Medical Director of the NHS, himself an expert in the analysis of data, to appear with me at the launch and explain the statistical background, including the meaning and significance of statistical projections of "excess deaths". He readily agreed to do so.

133. There were no external pressures from the Department of Health, or indeed anyone else, to remove these statistics from the report. It was simply my view that this was a concept that could not be understood that could be cruel to some relatives and carers and that it could convert an issue of appalling care into an argument about numbers.

134. In terms of the report, the Department of Health's concern was that this was an awful story about the NHS, rather than it being an opportunity for the Department of Health to say we needed to shape up the NHS. My experience of the Department of Health is that they have a tendency to shoot the messenger, rather than embrace changes that need to be made. This is not particular to healthcare. Their first priority is to "handle" the situation, rather than consider and implement change, and those were the realities we had to work with. The politicians were most interested in how any story would be received. This was also true for Mid Staffs.

135. One of the fundamental challenges with healthcare is this deep politicisation, as it is very difficult to separate the Government and the NHS. All of the organisations within the NHS receive money from the public pot for which government is responsible. As a result, in the absence of massive political courage, it is impossible for politicians to let go of the NHS. This is unique in terms of other government bodies. The Secretary of State for Education can stand up and say that a headmaster has performed badly, and it becomes a

local problem not a problem for ministers. Healthcare is not and never has been the same.

Handover to the Care Quality Commission ("CQC")

136. As mentioned above, the decision to abolish the Healthcare Commission was made as early as May 2005. Despite this, throughout its existence, the Healthcare Commission worked hard to develop the concept of regulation and its operation in practise.

137. I thought that the abolition of the Healthcare Commission was a mistake and I thought that the merger of the Healthcare Commission with the Commission for Social Care Inspection and the Mental Health Act Commission was also a mistake for two reasons. First, the Healthcare Commission and the Commission for Social Care Inspection were immature and were only just responding to their legislative mandate and making progress. Second, the organisations were very different. In the social care sector, one does not have the multiple tribes of professionals or a lot of data to deal with, compared to the Healthcare Commission, where there was a huge variety of organisations. The environments were completely different. They were not natural bedfellows and they were developing their own different methodologies.

138. I wrote paper after paper for civil servants about the "merger", and I recall in one paper saying that if the then Chancellor did have his way (the "merger" had been announced in the Budget statement in March 2005), they should use the analogy of a holding company that was charged with the responsibility for all three Commissions. This would allow all aspects in common to be managed together, but all distinct aspects to be separately managed. However, the answer that I got back was that there couldn't be a holding company because there were no shareholders! This literal interpretation rather missed the point I was making.

139. I was certainly not interested in the survival of the Healthcare Commission for its own sake, other than as regards the people who worked in it. However, I was concerned that regulation of healthcare for the safety and care of patients survived and I was concerned that those aims might not survive when these

three Commissions were so different. However, that argument did not prevail and the Chancellor became the Prime Minister, so the "merger" went ahead.

140. Had I been asked to help with the handover, I would have volunteered to assist. I did have two or three meetings with the incoming Chair of the CQC, but a lot of these meetings were focussed on the incoming bill. I cared, and continue to care, deeply about the principle of regulation in the healthcare system, but this was not my job any more.

141. My meetings with the incoming Chair did not focus on the lessons learned from the Healthcare Commission, but rather I spent more time explaining the political traps of the NHS. We did invite the incoming Chair to one of our public meetings of the Board in Cambridge, at my instigation, so that she could see how we operated and take aspects forward if she wanted to.

142. In fact, Anna Walker and I, and the Board, thought that the most helpful way of recording the legacy of the Healthcare Commission was to independently commission a study of the organisation and publish it. It became known as our "legacy document"; it was "warts and all" and its aim was to show what we had done (see exhibit 20 of Anna Walker's provisional statement dated 5 October 2010).

143. It was quite a tradition in the Healthcare Commission to commission these reports on an ongoing basis, to evaluate what we were doing well, or otherwise, and to be open with the public about this. We, the Board of the Healthcare Commission, saw this final legacy report as an important contribution to regulation. We were not precious about our survival, but we wanted to see the survival of the vision of regulation.

144. I have been referred to minutes from a meeting of the Healthcare Commission on 13 March 2008. I attach a copy of these minutes as Exhibit IK10 [ ]. In particular, I have been referred to the reference at the bottom of page five of the minutes which states that, "The Commission noted the significant impact on the Healthcare Commission resulting from difficulties of communication between it and the Department of Health, the lack of a clear plan for setting up the new regulator and the absence of clear objectives or outcomes for it." I

have been asked to what extent this reflected any frustrations during the transition period when the new regulator was being formed.

145. Our job was to ensure that we gave to our successor an enterprise that was suitably skilled and trained for whatever job it was called to do. However, intrinsic in this, is being aware of what the new organisation needs, so that we could help them during transition and hand over staff that were fit for purpose. The less we were informed about the role of the new regulator, the less able we were to do that. This was one of our main frustrations.

146. I have also been referred to a briefing note prepared for a meeting with the Chief Medical Officer on 1 May 2008, a copy of which I attach as Exhibit IK11 [ ]. I believe this document was a note of the agenda for the anticipated meeting. On page one of the agenda refers to Anna Walker and I recently writing to "TOTO". This is a reference to "Top of the Office" at the Department of Health. The following extracts from the agenda have been highlighted to me:

- Agenda item 1 – "The HC continues to be concerned that DH does not fully appreciate the position of an independent regulator";
- Agenda item 2 – "We do not think the HC is unclear about the specific roles within the DH but they are likely to be interested to hear your views about how this may develop".

147. I have no recollection of this meeting taking place or of the agenda items. However, as mentioned earlier, we always had concerns that there was only limited contact in the Department of Health with whom we could liaise and who sufficiently understood our role. By 2008, this issue had been going on for a while.

148. Finally, I have been referred to a copy of minutes from a meeting between David Nicholson and the Healthcare Commission on 14 May 2008, a copy of which I attach as Exhibit IK12 [ ]. Again, at the top of these minutes, there is reference to Anna Walker and I needing to work more closely with the "top of the office". As I have already said, we found it hard to get a dedicated contact in the Department of Health and we were constantly moved between people. We found that we were not getting to the "top of the office",

and it may be that they did not regard us as sufficiently important for this to be the case.

149. I have been asked about the reference on page five of these minutes, which refers to the strategic relationship between the Healthcare Commission and the Department of Health in encouraging improvement in healthcare. The minutes state, "Anna and Ian were keen to impress that the quality improvement as being a specific concern of the regulator, which should not be confined to simple assurance of minimum standards. Anna Walker also wrote to Giles Wilmore on 30 April about the absence of specific provision in the Health and Social Care Bill for the new regulator to recommend "special measures" (specific actions to address shortfalls and improve services). The Commission is concerned that this might prevent swift action being taken when patient safety is at risk." This document highlights that there was a change in policy in the Department of Health that moved the defining role of the regulator from a duty of improvement to a role of registration and validation. I have already said that I have a belief that regulators in the public sector exist to encourage improvement in services, and the new proposals would not achieve this. This was of concern to me.

150. The Department of Health's position, as described in these minutes, was "DH has decided to focus the new regulator, CQC, more determinedly on ensuring provider compliance with "gateway" registration requirements i.e. rather than devoting resource to encourage improvement above such a baseline. DH policy is to ensure that SHAs take the lead on the latter through performance management." I can recall delivering a lecture called "Learning from Bristol Five Years On" (a copy of which is attached as Exhibit IK2), during which I talked about my vision of regulation and saying there was, what I saw as a counter revolution, a push back on regulation by management in the NHS who felt that regulation other than initial registration was unnecessary and intrusive. It could be argued that what we were seeing with the move to the CQC and the registration model of regulation was evidence of a triumph of managerialism over regulation.

151. By the time the Healthcare Commission was abolished, it is difficult to say whether the Healthcare Commission had been at the top of its game. There was undoubtedly continued improvement in achieving the vision and objective

of regulation; but there was still a long way to go. It was only the beginning of developing what is important; whether care is delivered safely and with appropriate quality and how that could be measured and developed. If those goals had survived and been nurtured, and if we had achieved the power of real time surveillance, I believe we would have achieved a system of regulation that coincided with my vision of regulation.

152. We did spend a lot of time developing the national standards and how they were measured, by incorporating additional quality of care measures, and there was a degree of understanding that was developing with Department of Health. However, unfortunately, the "tablets of stone" style standards that were passed down to the Healthcare Commission still appear to exist in this format with the CQC.

153. In terms of the Healthcare Commission's successes, the agreement to signing up to a safety charter, whilst not a significant development, was very symbolic. This safety charter enabled the Chief Medical Officer to endorse a commitment to safety and to track what efforts were being made in relation to safety. The gesture was important to raise profile and focus attention, but it happened outside the ambit of formal regulation.

154. However, despite the positive steps that were made, there are a number of examples where the Healthcare Commission's attempts to develop its vision for regulation was frustrated, or were not as developed as we would have liked. For example, our proposals for the Information Centre were not adopted, the Healthcare Commission's collaborative powers over the Concordat were not robust, and the national standards did not focus enough on patients and outcomes.

155. Another example of where the Healthcare Commission's vision was frustrated was in relation to leadership. My view was that if the whole purpose of the regulatory thesis was to place responsibility for performance on those who were legally responsible to deliver it – Trust Boards – the Boards need to be able to drive improvement forward inside the organisation. To achieve this, the leadership of the Board has to be up to the task. I was of the view that, from evidence collected in reviews and from the Annual Health Check process, some Trust Boards were not up to the task. This was a view shared by Sir

William Wells, Chair of the NHS Appointments Commission and Bill Moyes of Monitor.

156. As a result, we three agreed to try and introduce a training and mentoring programme for the improvement of the quality of Boards. Sir William Wells was able to do this through the Appointments Commission, to ensure that those appointed to Boards had enough financial and leadership nous, and I was able to do this by driving Board responsibility in the reviews we conducted and the Annual Health Check process.

157. I also pressed for the assessment of leadership to be included as a further domain of the standards by reference to which we assessed the Trusts' performance. I believe I spoke to the Chief Medical Officer's office in relation to this. However, this was rejected on the basis that there was no objective assessment of leadership available. While it is difficult to assess leadership, I was aware of a leading expert, then at the University of Warwick, who was used in the Bristol Inquiry, who had written and communicated widely on ways of assessing leadership skills. However, this argument was never accepted. I do not know why. My belief is that this was considered to be an accountability mechanism too far for senior management in the NHS to find attractive. This was a missed opportunity.

The House of Commons Health Committee

158. I have been referred to a copy of the House of Commons Health Committee Patient Safety Sixth Report of Session 2008-2009, which is dated July 2009. I attach a copy as Exhibit IK13 [ ]. I have been referred to page 83 of the report and the following extract: "We have grave doubts about Primary Care Trust's performance in their commissioning role. The DH's hope is that World Class Commissioning would transform PCTs, but there is a danger that it will be another tick box exercise", and "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." I have been asked for my views in relation to these conclusions.

159. Anna Walker will be able to answer more fully, but I will say that the constant restructuring of the NHS puts at great risk the ideas of continuity, understanding and consistency of organisations. The frequency at which the organisations are introduced puts at risk the Health Service's objective of keeping a watchful eye on patients, and patients' safety.

160. I have also been referred to a copy of my response to the Patient Safety Report. I attach a copy of this response as Exhibit IK14 [ ]. In particular, this response highlights the following: "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 for the standard to be altered with no success."

161. I have mentioned earlier the Safety Charter which I tangentially suggested was one of the successes of the Healthcare Commission. However, changes do take time and by the third cycle of the Annual Health Check, changes focused on outcomes were being made. Mortality outliers and surveillance were also being developed.

162. I also attach a copy of a letter I sent to the Chair of the Health Select Committee on 31 March 2009, as Exhibit IK15 [ ]. This set out some misunderstandings that had emerged about the Healthcare Commission's investigation into Mid Staffordshire, and sought to clarify these to the Health Select Committee. Given that the letter was written on the last day of the Commission's existence, I was dependant on others for an account of relevant events and fell into error in some respects: I acknowledge that I was in error in referring to contact and liaison with the SHA.

163. I confirm that I am willing to attend the hearing and give oral evidence for this Inquiry if required to do so.

Statement of Truth

I believe the facts stated in this witness statement are true.

Signed .....

Sir Ian Kennedy

Dated..... April 20, 2011