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# 1. Summary of findings

## Warning signs

1.1 During the course of both the first inquiry and the present there has been a constant refrain from those charged with managing, leading, overseeing or regulating the Trust's provision of services that no cause for concern was drawn to their attention, or that no one spoke up about concerns.

1.2 This Inquiry has examined some of the more significant issues that were in fact identified or identifiable throughout the period leading up to the publication of the HCC report. These include the following:

- Loss of star rating – In 2004, the Commission for Health Improvement (CHI) re-rated the Trust, and it went from a three star trust to zero stars. The SHA knew not only of the loss of rating, but also of the factors likely to have been behind this: failure to meet targets for elective surgery, outpatient waiting times, cancer waiting times and financial performance. A "Stars Recovery Plan" was produced by the Trust which analysed the reasons for the change. The evidence suggests that officials from the Shropshire and Staffordshire Strategic Health Authority (SaSSHA) were unconcerned at these developments, and thought that the loss of stars was mainly due to poor record keeping and relied on results of the balanced scorecard. Yet the SHA, as with other organisations in the system, relied on the star ratings as an assurance that the quality of service was adequate. Indeed, it was intended to be the principal measure in that regard.

- Peer reviews – Peer reviews, including the Cancer Peer Review in 2005, the Care of Critically Ill and Critically Injured Children's Peer Review in 2006, and a follow up of the Children's Peer Review, were conducted during this period. Each of these reviews identified a number of concerns, often serious concerns, with the Trust's ability to deliver a safe service, and raised questions about management capability. The Inquiry has heard evidence to the effect that it was unclear who had responsibility for following up peer review reports.

- HCC reviews – In October 2006, the HCC published its own national review of children's services, which stated that the Trust did not meet the requirements or the reasonable expectations of patients and the public. In response, the Trust explained that this was partly due to a lack of data submitted, and that an action plan for improvement had been developed.

- Auditors' reports – During the relevant period, auditors' reports identified and reported to the Board serious concerns about deficiencies in the Trust's risk management and

assurance systems and made serious criticisms which called into question the accuracy and reliability of the Trust's compliance with standards. To any reasonably informed reader, the findings of this report would or should have called into question the competence of senior management and leadership at the Trust. The findings would or should have been of serious concern to the HCC and, in the context of an application for FT status, to Monitor and the DH.

- Surveys – The HCC commissioned annual surveys of staff and patient opinion conducted by the Picker Institute. The results of the survey taken for the previous year were published in about April the following year. The 2007 inpatient survey, while identifying many areas in which the Trust did well or performed satisfactorily, in several areas rated the Trust as being in the worst performing 20% in the country.

- Whistleblowing – It is clear that a staff nurse's report in 2007 made a serious and substantial allegation about the leadership of A&E. This was not resolved by Trust management. These issues were not made known by the Trust at the time to any external agency, but they were known to the Royal College of Nursing (RCN) because of its involvement with the personnel involved.

- The Royal College of Surgeons (RCS) report in January 2007 – The RCS reached critical conclusions about the operation and management of the Trust's surgical department, which it described as "dysfunctional". The report itself was known at the time only to the Trust and the relevant staff, and the Royal College. It showed a state of affairs which would have been expected to cause serious concern to the public, and any regulator, if known to them.

- The Trust's financial recovery plan and the associated staff cuts – Savings in staff costs were being made in an organisation which was already identified as having serious problems in delivering a service of adequate quality, and complying with minimum standards. Yet no thought seems to have been given in any part of the system aware of the proposals to the potential impact on patient safety and quality. There is no evidence that any effective questioning of this nature was undertaken. No detailed scrutiny of the possible impact of such changes seems to have been conducted by the SHA.

- The Trust's application for FT status – While the process of assessing such applications was, it is now accepted, largely focused on financial and governance rather than quality issues, the concerns that were made apparent by it about the Trust had potential implications for the standard of care delivered. The senior leadership of the SHA was aware of critical diagnostic findings, and yet did not think to look at whether a trust with such problems was actually delivering safe and acceptable care. Further, although the management was changed, there was no sense of urgency evinced by the SHA leadership with regard to the need for the newly installed management to make and evidence significant improvements. The assessment process leading up to the Minister giving his support did

not provide him with adequate information. While the HCC was looking into concerns that eventually led to the HCC setting up its investigation, it remained unaware at national level that an application for FT status was pending. Monitor remained unaware of the HCC's concerns about the Trust until after it authorised the Trust as an FT. The HCC's regional team was aware of the application but had not communicated that information to HCC Head Office.

- The HCC investigation – A formal investigation of the type launched by the HCC into this Trust was an unusual event, only embarked upon where there was serious cause for concern. The reaction of other bodies responsible for oversight and regulation was to await the outcome of the investigation and to rely on the HCC to inform them of matters requiring the urgent attention, rather than to consider for themselves what was wrong and what if anything, needed to be done for the protection of patients.

1.3 The above is only part of the story demonstrating the warning signs that were emanating from the Trust during this period and the corresponding reaction from external agencies. An examination of the evidence the Inquiry has heard reveals a pattern of concerns which, taken together, and in some cases even singly, such as certain examples of the systemic failure to deliver proper care to one patient, showed that there were serious systemic issues at the Trust requiring a degree of urgent and effective attention which they were not receiving.

## Analysis of evidence

1.4 The Inquiry report examines what each organisation knew, or should have known, which might have been expected to give cause for concern or further inquiry, and to what extent, if any, action was taken to address these concerns.

### The Trust and the Trust Board

1.5 The problems at the Trust identified by the HCC in its investigation and subsequently by the first inquiry's report were longstanding and apparently intractable. It was clear to the new Chair and Chief Executive on their arrival in 2004 and 2005 respectively that this was the position.

#### *Negative culture*

1.6 While it is clear that, in spite of the warning signs, the wider system did not react to the constant flow of information signalling cause for concern, those with the most clear and close responsibility for ensuring that a safe and good standard care was provided to patients in Stafford, namely the Board and other leaders within the Trust, failed to appreciate the enormity of what was happening, reacted too slowly, if at all, to some matters of concern of which they were aware, and downplayed the significance of others. In the first report, this was attributed in a large part to an engrained culture of tolerance of poor standards, a focus

on finance and targets, denial of concerns, and an isolation from practice elsewhere. Nothing I have heard in this Inquiry suggests that this analysis was wrong. Indeed the evidence has only reinforced it.

**1.7** The Trust's culture was one of self promotion rather than critical analysis and openness. This can be seen from the way the Trust approached its FT application, its approach to high Hospital Standardised Mortality Ratios (HSMRs) and its inaccurate self declaration of its own performance. It took false assurance from good news, and yet tolerated or sought to explain away bad news.

### *Professional disengagement*

**1.8** Consultants at Stafford were not at the forefront of promoting change. The Inquiry heard evidence which added justification to the view formed at the first inquiry that clinicians did not pursue management with any vigour with concerns they may have had. Many kept their heads down. A degree of passivity about difficult personnel issues is all too common in the NHS as, perhaps, elsewhere. However, a system that is safe for patients requires a much more rigorous approach. The Trust lacked a sufficient sense of collective responsibility or engagement for ensuring that quality care was delivered at every level.

### *Patients not heard*

**1.9** Trust management had no culture of listening to patients. There were inadequate processes for dealing with complaints and serious untoward incidents (SUIs). Staff and patient surveys continually gave signs of dissatisfaction with the way the Trust was run, and yet no effective action was taken and the Board lacked an awareness of the reality of the care being provided to patients. The failure to respond to these warning signs indicating poor care could be due to inattention, but is more likely due to the lack of importance accorded to these sources of information.

### *Poor governance*

**1.10** The Board failed to get a grip on its accountability and governance structure throughout the period under review, despite these being issues that were apparent to the incoming Chair and Chief Executive in 2004 and 2005. The national general acceptance of the importance of clinical governance had failed to permeate sufficiently into Stafford to result in a functioning, effective system by 2009. The evidence fully supports the description of the Trust's clinical governance process throughout the period with which this Inquiry is concerned as "vestigial".[1] The absence of such a system meant that the leadership of the Trust was bound to be blind to many concerns which it took the HCC to uncover by its investigation.

1 CLO000003416 Counsel to the Inquiry's closing submissions, chapter 9, the Trust, para 100

### *Lack of focus on standards of service*

**1.11** It is clear from the evidence at both inquiries that the Trust was operating in an environment in which its leadership was expected to focus on financial issues, and there is little doubt that this is what it did. Sadly, it paid insufficient attention to the risks in relation to the quality of service delivery this entailed.

**1.12** Throughout the period with which this Inquiry is concerned, the Trust suffered financial challenges. These pressures were regarded both inside and outside the Trust to be nothing particularly remarkable compared with other similar organisations, and therefore they were never treated as a particular cause for concern. However, I have no doubt that the economies imposed by the Trust Board, year after year, had a profound effect on the organisation's ability to deliver a safe and effective service.

### *Inadequate risk assessment of staff reduction*

**1.13** There was an unacceptable delay in addressing the issue of shortage of skilled nursing staff. There can be little doubt that the reason for the slow progress in the review, and the slowness of the Board to inject the necessary funds and a sense of real urgency into the process, was the priority given to ensuring that the Trust books were in order for the FT application. The result was both to deprive the hospital of a proper level of nursing staff and provide a healthier picture of the situation of the financial health of the Trust than the true reality, healthy finances being material in the achievement of FT status. While the system as a whole appeared to pay lip service to the need not to compromise services and their quality, it is remarkable how little attention was paid to the potential impact of proposed savings on quality and safety.

### *Nursing standards and performance*

**1.14** As a result of poor leadership and staffing policies, a completely inadequate standard of nursing was offered on some wards in Stafford. The complaints heard at both the first inquiry and this one testified not only to inadequate staffing levels, but poor leadership, recruitment and training. This led in turn to a declining professionalism and a tolerance of poor standards. Staff did report many incidents which occurred because of short staffing, exhibited poor morale in their responses to staff surveys, and received only ineffective representation of concerns from the RCN.

### *Wrong priorities*

**1.15** The Trust prioritised its finances and its FT application over its quality of care, and failed to put patients at the centre of its work.

**1.16** The Board of the time must collectively bear responsibility for allowing the mismatch between the resources allocated and the needs of the services to be delivered to persist without

protest or warning of the consequences. However, they were able to fail in this way because of deficiencies in the system around them.

## The voice of the local community

1.17 It is a significant part of the Stafford story that patients and relatives felt excluded from effective participation in the patients' care. The concept of patient and public involvement in health service provision starts and should be at its most effective at the front line.

1.18 Analysis of the patient surveys of the Trust conducted by the HCC and the Picker Institute shows that they contained disturbing indicators that all was not well from long before the intervention of the HCC.

1.19 Community Health Councils (CHCs) were almost invariably compared favourably in the evidence with the structures which succeeded them. It is now quite clear that what replaced them, two attempts at reorganisation in 10 years, failed to produce an improved voice for patients and the public, but achieved the opposite. The relatively representative and professional nature of CHCs was replaced by a system of small, virtually self-selected volunteer groups which were free to represent their own views without having to harvest and communicate the views of others. Neither of the systems which followed was likely to develop the means or the authority to provide an effective channel of communication through which the healthcare system could benefit from the enormous resource of patient and public experience waiting to be exploited.

1.20 Patient and Public Involvement Forums (PPIFs) relied on a variably effective, locally provided infrastructure. The system gave rise to an inherent conflict between the host, which was intended to provide a support service but in practice was required to lead with proposals and initiatives offered to lay members, and members of the forum, who were likely to have no prior relevant experience and to be qualified only by reason of previous contact with the hospital to be scrutinised.

1.21 In the case of the Trust's PPIF, the evidence shows quite clearly the failure of this form of patient and public involvement to achieve anything but mutual acrimony between members and between members and the host. A preoccupation with constitutional and procedural matters and a degree of diffidence towards the Trust prevented much progress.

1.22 If anything, local Involvement Networks (LINks) were an even greater failure. The, albeit unrealised, potential for consistency represented by the Commission for Patient and Public Involvement in Health (CPPIH) was removed, leaving each local authority to devise its own working arrangements. Not surprisingly, in Stafford the squabbling that had been such a feature of the previous system continued and no constructive work was achieved at all.

1.23 Thus, the public of Stafford were left with no effective voice – other than CURE – throughout the worst crisis any district general hospital in the NHS can ever have known.

1.24 Under the new reforms, local healthwatch is intended to be the local consumer voice with a key role in influencing local commissioning decisions through representation on the local Health and Well-being Board. They will be expected to build on existing LINks functions. The responsibility for establishing Local Healthwatch will rest with the local authorities in the same way as it had for LINks. As is the position with LINks, the DH does not intend to prescribe an operational model, leaving this to local discretion. It does not prejudice local involvement in the development and maintenance of the local healthcare system for there to be consistency throughout the country in the basic structure of the organisation designed to promote and provide the channel for local involvement. Without such a framework, there is a danger of repetition of the arguments which so debilitated Staffordshire LINks.

1.25 The local authority scrutiny committees did not detect or appreciate the significance of any signs suggesting serious deficiencies at the Trust. The evidence before the Inquiry exposed a number of weaknesses in the concept of scrutiny, which may mean that it will be an unreliable detector of concerns, however capable and conscientious committee members may be.

1.26 Local MPs received feedback and concerns about the Trust. However, these were largely just passed on to others without follow up or analysis of their cumulative implications. MPs are accountable to their electorate, but they are not necessarily experts in healthcare and are certainly not regulators. They might wish to consider how to increase their sensitivity with regard to the detection of local problems in healthcare.

1.27 There are a wide range of routes through which patients and the public can feed comments into health services and hold them to account. However, in the case of Stafford, these routes have been largely ineffective and received little support or guidance.

1.28 Local opinion is not most effectively collected, analysed and deployed by untrained members of the public without professional resources available to them, but the means used should always be informed by the needs of the public and patients. Most areas will have many health interest groups with a wealth of experience and expertise available to them, and it is necessary that any body seeking to collect and deploy local opinion should avail itself of, but not be led by, what groups offer.

## General practitioners

1.29 The local GPs only expressed substantive concern about the quality of care at the Trust after the announcement of the HCC investigation, when it had become obvious there were issues and when they were specifically asked.

1.30 No individual or organisation can be singled out for criticism in this; they were not explicitly required to act in this way, and unfortunately it did not occur to any of them to suggest it. It will be important for the future that all GPs undertake a monitoring role on behalf of their patients who receive acute hospital and other specialist services. They have a role as an independent, professionally qualified check on the quality of service, in particular in relation to an assessment of outcomes. They need to have internal systems enabling them to be aware of patterns of concern, so that they do not merely treat each case on its individual merits. They have a responsibility to all their patients to keep themselves informed of the standard of service available at various providers in order to make patients' choice a reality. A GP's duty to a patient does not end on referral to hospital, but is a continuing relationship. They will need to take this continuing partnership with their patients seriously if they are to be successful commissioners of services. They should exploit to the full this new role in ensuring their patients get safe and effective care.

## The Primary Care Trusts

1.31 PCTs were large organisations with substantial budgets and staff, particularly in comparison with SHAs. They were under a duty to monitor and improve the quality of the services they commissioned. They were over time provided with tools which in theory would have enabled them to lay down safety and quality standards, monitor performance, and pursue remedies on behalf of patients, individually and collectively, where those standards had not been met. In general, however, the nationally available guidance did not lend itself to more than relatively crude measures in this regard, the focus remaining, as elsewhere in the NHS system, on financial control and a handful of access targets. Development of more sophisticated tools, both locally and nationally, was slow, with the result that it is not in the least surprising that, in spite of the rhetoric of quality, one of the worst examples of bad quality service delivery imaginable was not detected by this system. There was a significant gap between the theory of the PCTs role and their capacity to deliver.

1.32 Throughout the period under review, the purchaser/commissioning arm of the system was subjected to constant reorganisation, usually taking place well before it had been possible to put fully into practice and embed the aspirations of the previous changes. The time and resources required to be devoted to reorganisation undoubtedly made it more difficult for PCTs to develop effective methods of imposing standard quality requirements and of effectively monitoring their delivery. Whilst the PCT cannot be criticised for the fact of reorganisation itself, it failed to put in place systems and processes to manage the inevitable risks that would occur as the new system established itself.

1.33 During this period, undue comfort was taken from the assumption that others had responsibility in terms of quality, and little if any attempt was made to collect quality information in a systematic way. Agreements with provider organisations were lacking in sophistication and the tools to enforce standards. It is not possible on the evidence before

this Inquiry to determine if the PCTs of the West Midlands were exceptional in this regard, but those who worked for them who gave evidence did not believe they were. If this is true, then there was a highly concerning gap in the system of oversight of safety and quality throughout the country.

1.34 South Staffordshire PCT (SSPCT) did monitor quality at the Trust with increasing intensity following the announcement of the HCC investigation. It did not rely entirely on an assumption that it had to await the outcome of the investigation. What was less satisfactory was the time taken to address issues and the difficulty experienced in using contractual solutions to expedite improvements. This was in part due to the dilemma faced by many commissioners in not wishing to exacerbate an already undesirable situation by destabilising the provider when there was no alternative available. There was also a willingness to accept that clinical safety was not compromised in spite of evidence which, if viewed from the perspective of a patient, should have suggested that it was. It should have been clear from the history and the nature of the deficiencies being reported, particularly in relation to staffing, that a dangerous situation had been allowed by the Trust leadership to develop and that urgent action and intervention were required.

1.35 The commissioning landscape has now changed, with the introduction of the national NHS Commissioning Board, its regional offices and clinical commissioning groups. However, the essential tenets required of the commissioning process may not have changed. The experience of Stafford shows an urgent need to rebalance and refocus commissioning into an exercise designed to procure fundamental and enhanced standards of service for patients as well as to identify the nature of the service to be provided. However, none of this will turn a theory of effective commissioning or monitoring into practice unless commissioners are recognisable public bodies, visibly acting on behalf of the public they serve and with a sufficient infrastructure of technical support. Effective local commissioning can only work with effective local monitoring. And that cannot be done without knowledgeable and skilled local personnel engaging with an informed public.

### The Strategic Health Authorities

1.36 The role expected of SHAs was challenging. They were required to perform this throughout a time of extensive reorganisation, financial challenge, and reduction in staff and organisational resources. There also appears to have been a lack of clarity with regard to the extent to which SHAs were expected to address concerns about quality and safety.

1.37 The structural reorganisation of SHAs and their relationship with PCTs and providers in 2005/06 appears to have been conducted without any assessment of the risks to patient safety or the quality of service posed by the process of change. The reconfiguration of PCTs and development of the concept of commissioning meant that there was a serious lack of connection between the understandings of PCT leadership and of the SHA, and between

strategic overview and performance management. This increased the risks attached to mutual misunderstandings about where a function was being performed, and widened the gap through which poor performance could pass unnoticed. It does not seem to have been realised within the leadership of the West Midlands SHA (WMSHA), at that time, that these issues gave rise to a serious risk of compromises to patient safety going unnoticed or uncorrected.

**1.38** There was also no system for ensuring the transfer of information and knowledge from one iteration of the SHA to the next, in spite of the very substantial staff cuts that accompanied the change.

**1.39** In spite of these difficulties, few of which were of SaSSHA's or the WMSHA's own making, the evidence shows that the WMSHA did not explicitly relinquish an involvement in the performance management and oversight of provider trusts, but, on the contrary, was willing to intervene, forcefully if necessary. It did not proactively seek out quality and safety concerns, but it did seek to respond to concerns of which it became aware.

**1.40** However, the WMSHA's handling of concerns raised in connection with the Trust often resulted in a collective judgement being made that there was nothing of concern warranting exceptional action. It took false comfort from the notion that some potential causes for concern were not exceptional in trusts under its oversight. This was due to an overall culture which was too ready to place trust in provider boards, was readier to defend providers than to consider the implications of criticisms and concerns being expressed, and was prepared to assume that others would share information showing concern and requiring action without being asked. In that sense, the WMSHA became far too remote from the patients it was there to serve, and it failed to be sufficiently sensitive to signs that patients might be at risk.

**1.41** In relation to the Trust's application for FT status, the SHA did not offer information to the DH about a series of concerns arising in relation to the quality of services at the Trust, of which it was, or should have been, aware. Its approach, doubtless driven by the focus of the process as a whole on financial and corporate governance and not clinical standards, was to be supportive and focus on a goal of advancing the Trust as a successful applicant as an end in itself. This meant the SHA's focus was on financial and governance issues, as the key criteria valued by the DH and Monitor. However, the SHA should not have allowed itself to forget that the purpose of any development in the NHS should be to improve the ability of the system to care for its patients. There were Board to Board "challenge" meetings, but those gave insufficient consideration to whether the deficiences found in the planning process raised concerns about the general competence of the management of the Trust. The support of the SHA offered false reassurrance to the DH as to the soundness of the Trust as a potential applicant. No attempt appears to have been made to consult the HCC as the regulator or to inform it that the Trust was entering the FT "pipeline". No consideration was given to whether

the demands of the process of applying for FT status gave rise to any unacceptable risks for patients.

**1.42** During the HCC investigation, although the SHA offered support to the Trust, it was not in a position to lead or direct performance management of the Trust as an FT and in any event it felt reluctant to do more, given the level of scrutiny to which the Trust was already being subjected. What it could have done was to have taken a more direct interest in the commissioning relationship via its oversight of the PCT. By whatever route, there was a need, in the interests of patients, for joint action by all those in a position to take it. While some steps were taken, the impression given has been one of waiting to see the outcome of the investigation rather than to accept that there was a current fundamental crisis giving rise to risks to patient care.

**1.43** The underlying reason for the failure of SaSSHA and the WMSHA to adequately seek out or address patient safety and quality concerns about service provision at the Trust, was a failure of the leadership to give sufficient explicit priority to the protection of patients and to ensuring that patient safety and quality standards were being observed there. In common with the system as a whole at the time, the focus was unduly directed at financial and organisational issues and an over reliance on assurances given by others, while losing sight of the central purpose of the service it was seeking to support.

**1.44** The analysis of the evidence shows that important opportunities to detect and act upon the serious systemic failings in the Trust were missed because no one at the WMSHA seems to have realised or appreciated the significance of the issues.

**1.45** A proper and reasonable strategic direction taken by the WMSHA was the attempt to develop metrics focused on patient safety. However, this initiative not only took a long time to complete, it was watered down by replacing the idea of outcome-based measures with more indirect ones. The WMSHA recognised, correctly, that there was a gap in safety monitoring that required a means of measuring safety. However, at a time when the metrics were not ready to be implemented and incorporated into contracts and PCTs had few, if any, other tools available to them to undertake their own monitoring, the SHA gave insufficient consideration to the implications of this delay in developing its own metrics for the performance of its duties.

**1.46** The WMSHA has pointed out to the Inquiry that the Trust was but one of many organisations in the region with problems, and the WMSHA was relatively small and had a lot to cope with. This again is not an excuse for inaction. Either the SHA had the resources and ability to do the entire job which had been delegated to it, and it failed to carry out that job, or it did not have the resources and ability and failed to alert those responsible to the problem.

1.47 It may be thought that an analysis of the faults of an SHA is now redundant, as they are now being abolished. This could not be further from the truth. Whatever the changes made under the recent reforms, or which might be made in the future to the structure of the NHS, a performance management and strategic oversight function will reside somewhere in the system.

## Monitor and the failure of the foundation trust authorisation process and oversight

1.48 It is fair to point out that even if Monitor had refused FT status to the Trust this would not have avoided much of the suffering endured by so many patients before January 2008. The deficiencies which have come to light at the Trust subsequently are not attributable to FT status as such. However, there is no doubt that an elaborate regulatory assessment process of the nature required by the National Health Service Act 2006 ought to have brought those deficiencies to light, and its failure to do so calls into question the effectiveness of the FT regulatory system as a whole. While the Inquiry has been warned, rightly, of the dangers of extrapolating from an extreme case, it has to be questioned whether the system could reliably detect concerns relevant to patients of any significant nature, if it could not detect a case as gross as that of the Trust.

1.49 The application process provided an opportunity for a comprehensive investigation of an applicant's capability and capacity to deliver a consistent and sustainable service to its patients which was safe, effective and compliant with minimum safety and quality standards. It was clearly not intended that a trust suffering from a systemic failure to provide such a service should be authorised as an autonomous entity, thus removing it from the Secretary of State's sphere of accountability and control.

1.50 It is clear from the evidence that the Trust would not have been in a position to be authorised as an FT in early 2008 if:

- The eligibility criteria had not been loosened;
- A thorough assessment of the Trust's compliance with minimum patient safety and quality standards had been performed, rather than the focus of Monitor's assessment being on finance and corporate governance;
- The DH applications committee had been unwilling to support marginal cases;
- The Minister had been offered a full picture of the Trust when considering giving his support;
- Monitor had not relied on, but had probed more deeply, the Trust's assurances on quality issues;

- Monitor and the HCC had communicated with each other and shared their knowledge.

1.51 In short, an elaborate, resource-consuming process failed to achieve what should have been its primary objective; ensuring that the only organisations authorised were those with the ability and capacity to deliver services compliant with minimum standards on a consistent and sustainable basis.

1.52 The erroneous authorisation of the Trust as an FT came about almost entirely because the HCC and Monitor were separate organisations, going about their regulatory business without coordinating their activities with each other. This was not just a matter of communication but of different, unaligned methods of assessment. Thus, no effective consideration was given to the potential effects of cost savings and staff cuts on patient safety and quality. The HCC had little by way of financial expertise available to it, and Monitor, likewise, little clinical resource. The impact of one on the other does not seem to have been fully appreciated.

1.53 This communication failure may in part have been as a result of Monitor fiercely guarding its independence, at the expense of fostering good relationships with others.

1.54 Monitor did not formally decide that the Trust was in significant breach of its authorisation until after the publication of the HCC report. However, it had been aware since at least May 2008 that there was a likelihood that it was in significant breach. Even before then, there were substantial grounds for suspecting that there was a continuing breach. Monitor did, in the event, take some action before the publication of the report, when it became clear to it that the position of the Chair, and, in reality, the Chief Executive as well, were untenable.

1.55 The reason no intervention took place earlier was the view of Monitor's senior management that it should wait for the HCC's final report or for it to make interim recommendations for intervention. It did so because it took the view that, until either of those conditions were fulfilled, it lacked the evidence on which to proceed.

1.56 The evidence shows that the reasoning adopted was flawed. The constant complaint to the HCC that the investigation was taking too long arose out of Monitor's concern that regulatory action was required. It could have, but did not, request the HCC to furnish it with an interim report presenting the evidence and any recommendations that Monitor believed to be lacking. In any event, it was wrong to believe there was insufficient evidence to act. It had evidence that the HCC had concluded that there was a sufficient threat to safety to require the Trust to take immediate action. It became over-preoccupied with a distinction between evidence and information, while failing to give sufficient regard to its duty to protect patients.

1.57 The result of this hesitation to act was that the Trust continued, for a sustained period, to have a leadership which was deficient and unable to command confidence, in circumstances where there were serious and widespread deficiencies relevant to patient safety, of which both systems regulators were aware. During that period, while individual concerns were beginning to be addressed, fundamental issues remained. Put shortly, the public remained exposed to an unacceptable level of risk. While it can be said that the HCC could have made express recommendations to Monitor for action, Monitor retained its own statutory responsibility and judgement, as well as the power of intervention. Insofar as it exercised these, it did so with undue delay.

## The Healthcare Commission

1.58 The system of regulation which the HCC was given to run failed to prevent or detect over three-quarters of its lifetime what has been described as the biggest scandal in NHS history. At the same time, it was the first organisation out of the plethora with relevant responsibilities to identify serious cause for concern, and to take the action which led to the full exposure of the scandal. This success was due to an eventual willingness to take the only action available to establish the true level of concern, namely a thorough and challenging investigation of the true facts on the ground.

1.59 At the heart of the failure to detect or prevent the appalling events at Stafford sooner was the concept of the core standards and the means of assessing compliance: the annual health check (AHC). The core standards suffered from a number of deficiencies.

1.60 Generic standards were formulated not by the regulator but by the Government, thereby inhibiting the engagement with the standards of those working in the system and therefore the effectiveness of the regulator. While there was a consultation period and the manner of assessing compliance was left to the HCC, the fact is that the standards were formulated and handed down by the DH. This must have contributed to the impression that the process was Government controlled and thereby reinforced the disengagement of frontline clinicians from a concept, which if it was to work, demanded their involvement and endorsement.

1.61 A further difficulty was that the standards included a confusing mixture of the general and the specific: minimum standards and aspirations. They were expected to do too much: to set a minimum below which no provider should fall, to include targets in areas of particular interest to Government and to be a basis for comparison of providers to assist the public in making choices.

1.62 The assessment process also suffered a number of defects. Principal among them was the reliance on self-assessment and self-declaration as the basis of regulation. The checks put in place by the HCC to verify self-declarations were inevitably a net with a wide mesh through which inaccurate self-assessment and deficiencies in practice could pass undetected. The focus

was on examining providers' apparent performance in relation to standards, most of which focused on the presence of theoretical systems, not on real achievements and outcomes for patients. Many of these issues revealed the HCC's willingness to accept assurances of action from the Trust at face value. Regulation cannot be effective if it does not challenge claims of compliance made by the regulated organisations, and its prime purpose in protecting patients cannot be served by such a passive approach. It would be easy to offer criticism of individuals in relation to the failure to investigate more intrusively, but the fault lay in the inadequacy of the systems in place to pursue a potentially serious concern effectively.

**1.63** It was perhaps inevitable that, in the first instance, the new concept of setting national standards would remain under the close control of Government: the move to setting standards at all was a progressive development designed to promote the protection of patients and improvement to the service. However, the experience of such an approach reveals a need for a more transparent standard-setting process – one whose requirements are understood and accepted by patients, the public and the staff who apply them. This would leave responsibility for improvement to the commissioning system for which, ultimately, the Government can be held to account via its use of the NHS Commissioning Board "mandate".

**1.64** While a close relationship with the DH was inevitable, the way in which the standards to be applied were handed down might at least have given the appearance of compromising its independence. To this day, the boards of regulators are hired and fired by the Secretary of State. Professor Sir Ian Kennedy had recommended in his Bristol Inquiry report that the regulator be independent of the DH. In practice, there appear to have been constraints on the extent of its independence which were not helpful to the performance of its role.

**1.65** It is clear that the AHC was not a satisfactory means of establishing whether the Trust or any other provider was complying with satisfactory standards of care, but this was not the only means by which the safety and quality of the Trust's service could be assessed, and there were warning signs which could have triggered a greater level of concern sooner. This included complaints about hygiene and concerns about appraisals in 2006, the Trust's handling of the Children's Services Review and concerns about resuscitation equipment in 2006, inconsistencies between the AHC self-declaration and other information, and the hygiene code inspection in 2007. Taken cumulatively, these areas of concern should have triggered an earlier regulatory response and more proactive intervention than in fact occurred. It has been suggested that the failure to take action might have been the result of "regulatory capture" of the HCC's regional team, but it is more likely that the cause was the system which discouraged intervention and required information to be filed centrally, where insufficient weight was allowed to be given to individual items which, when examined, were in themselves cause for concern – all this was against a background which placed considerable reliance on assurances from trusts as to remedial action.

1.66 The period under review in this Inquiry was one of transition from one end of the spectrum to the other. Having set up a new system of regulation under the HCC, which for all its faults was an advance on what went before, the demands of embedding and developing new concepts were compounded by a decision to abolish it wholesale before it had really got going. Inevitably, this slowed the development process while resources and attention were devoted to the running down of one organisation and the setting up of yet another.

1.67 Communication of intelligence between regulators needs to go further than sharing existing concerns identified as risks, and it should extend to all intelligence which when pieced together with that possessed by partner organisations may raise the level of concern. Too many assumptions were made that others would be aware of important information.

1.68 The HCC was subjected to a great deal of pressure from Monitor and the WMSHA about the length of time taken for the investigation to report. This criticism was and remains ill-founded. It is quite clear that Dr Heather Wood from the HCC and her team found an unprecedented range of issues suggestive of serious concerns. If they had acted as suggested, it is highly unlikely that the full breadth and gravity of the issues would have been brought to light. The HCC was absolutely right to insist on undertaking a thorough and searching investigation and to take the time necessary to do that.

1.69 When the information coming into the HCC's possession during the investigation is looked at sequentially it is clear that a situation was being uncovered in which patient safety was not being properly ensured. It is often not practical to take steps to close a service, let alone a whole hospital, but it is unacceptable to find deficiencies of the nature described in Dr Wood's letters and, while leaving the public in ignorance of those findings, to continue relying on the assurances of the provider's management that they are taking action. At the very least, some form of external performance management presence was required at the Trust to oversee interim arrangements for protecting the public. The system at the time did not allow the HCC to take that sort of action, and the culture did not encourage it to advise other organisations how to do their jobs. It is therefore not surprising that neither the investigation team nor the higher echelons of the organisation was thinking in those terms. If there is a criticism to be made, it is that they did not spell out with sufficient clarity the safety implications of the findings in terms of the increased level of risk presented to patients.

1.70 What was undoubtedly a success was the achievement of the formal investigation to root out the full extent of the appalling problems at the Trust. If criticism can be made of some of the detail of how the investigation was carried out, there is no doubt that without what was done many more patients would have had to suffer before any effective action was taken. The investigation demonstrates how powerful the combination of direct observation of practice, contact with patients, families, frontline staff and examination of real cases is, as opposed to reliance on files of policies, committee minutes and overall figures. This is not to say that examination of systems is not important, but it is not and never will be sufficient.

## Care Quality Commission

1.71 The general theory of the new regulatory model is encouraging: it depends on the collection of a wide range of information which is used to identify a level of risk of non-compliance, which informs decisions on what organisations to target for review.

1.72 However, the CQC has had many challenges since its inception, including the need to merge three organisations, the creation and administration of an entirely new system of registration and the monitoring of compliance with a new set of standards. Added to the challenge has been the requirement to take on the regulation of other healthcare sectors. All this has had to be achieved within a short timescale. There can be no one correct way to have set about this task and it was inevitable that changes of strategic direction will have been necessary to react to growing experience. The evidence does, however, give the impression that strategy has to some extent been driven by a perceived need to fit the activity of the organisation to the resources available.

1.73 These pressures have, perhaps predictably, led to it being less than easy to fulfil the basic task that the CQC is charged with, namely protecting patients from substandard care, and the provision of accurate information on which the public and others can rely to make decisions.

1.74 The evidence received by this Inquiry does not suggest that the CQC is a happy environment to work in. The massive upheaval that has taken place in its creation has led at least some elements of staff, from the frontline to the Board, to express concerns and to believe they have not received an adequate response. While it is clear that the CQC aspires to be an organisation which welcomes constructive comment, the Inquiry has seen evidence of a defensive institutional instinct to attack those who criticise it, however honestly and reasonably those criticisms are made. A healthcare regulator needs to be a model of openness and therefore welcome constructive criticism.

1.75 The current structure of standards, laid down in regulation, interpreted by categorisation and development in guidance, and measured by the judgement of a regulator, is clearly an improvement on what has gone before, but it requires improvement.

1.76 While a tremendous amount of work has obviously gone into matching the outcomes in the essential standards with the regulations, there is a lack of clarity which derives from the regulations combining in one regulatory requirement a number of different concepts, such as "safety" and "welfare." They are requirements which have to be met, but are not necessarily given very much attention as statutory obligations, in day-to-day clinical work.

1.77 The standards to be enforced by the regulator should be a clear fundamental set of standards, driven by the interests of patients, and devised by clinicians; a "bottom up" as opposed to a "top down" system. Unfortunately, for all its good intentions and its improvement on what

went before, the current outcomes are over-bureaucratic and fail to separate clearly what is absolutely essential from that which is merely desirable.

1.78 The sense to be gained from the evidence before the Inquiry is that there has been a change of direction from an emphasis on planned, routine reviews, to more focused responsive reviews triggered by concerns. In addition, a substantial series of inspections have been carried out at the direction of the Secretary of State. It is clear on the other hand that the CQC intends to maximise the ability to make decisions based on a comprehensive database of risk information relevant to the assessment of risk.

1.79 The need for risk-based reviews or inspections is recognised by the CQC, and it appears that an increasing amount of inspectors' time is taken up with them. That inevitably causes a challenge in relation to the performance of planned or routine reviews of organisations which have not shown an increased level of risk on the quality and risk profile (QRP). The story of Stafford shows the importance of not ignoring trusts which have failed to appear on the radar of concern.

1.80 While the CQC is to be commended for its efforts, the impression is that patient information and feedback are not priorities as a means to obtaining relevant information about an organisation or generally when the CQC is considering its regulatory approach. It is service users, including visitors and families, who are likely to be the first to witness poor outcomes or the warning signs that standards are slipping. It is here that a more specific focus by local inspectors on complaints, allowing perhaps for contact with complainants, would be of great assistance.

## Professional regulation

### *The General Medical Council and the Nursing and Midwifery Council*

1.81 The story of Stafford shows that the conduct of individual doctors and nurses can be relevant to the analysis of the failure of an organisation to perform its duty to its patients. Currently, such cases, where they come to light, are dealt with by the relevant professional regulator as if in a silo, applying a differently worded code of conduct, a different approach to sanctions, and by reason of the matters being dealt with in different systems, the possibility of inconsistent outcomes.

1.82 The General Medical Council (GMC) and the Nursing and Midwifery Council (NMC) have faced similar challenges in regulating the role of healthcare professionals at the Trust, with the absence of referrals from professionals. This may well have been due to the unhealthy culture described in the first inquiry report. The lack of complaints from the public may well have been due to the lack of profile each organisation has. Both the public and professionals may also be deterred from referring cases by the apparent complexity of the process and the time taken to resolve cases.

1.83 Where referral is absent, as was the case at the Trust, then other means are necessary to ensure that the public is protected. Both organisations need to develop their capacity to examine and investigate concerns even where no named individual has been identified to them. However, at the moment, the impression is that neither the GMC nor the NMC has the capacity or skills to undertake this sort of work.

### *Deanery/universities*

1.84 The system of regulation and oversight of medical training and education in place between 2005 and 2009 failed to detect any concerns about the Trust other than matters regarded as of no exceptional significance. There were a number of factors contributing to this:

- While patient safety was theoretically given primacy in the system, the domain to be monitored was unduly limited to the potential risk posed to patients by the trainee.
- Insufficient consideration was given to the relevance of good quality training of practice in a setting which complied with minimum patient safety and quality standards, and to the professional obligation to protect patients from harm.
- The Postgraduate Medical Education and Training Board (PMETB)/GMC/deanery wide reviews focused on deanery systems of quality management, resulting in only superficial examination of the standards being observed. Such reviews did not consistently consider compliance with patient safety standards.
- When concerns were raised about inappropriate pressure or bullying by staff towards trainees these were not followed up or investigated.
- Systematic communication of indications of serious concern, such as the HCC investigation, was almost completely lacking between the regulators, and between them and the deanery.
- A reluctance to prejudice the provision of a service or the training of trainees has resulted in the implied threat of removal of approval for providing training places being largely theoretical.

1.85 While requirements for remedial action must be proportionate, training should not be allowed to take place in an environment where patient safety is not being adequately protected. Perceived difficult consequences should never be permitted to hinder steps required to protect patients, and the oversight of medical training should not condone or support unacceptable practice. As elsewhere in the system, a sense of urgency may have been lacking, even after the scale of the deficiencies at the Trust had become apparent.

1.86 All doctors, whether fully qualified or in training, work in environments where they are under a duty to protect patients. Good practical training should only be given where there is good clinical care. Absence of care to that standard will mean that training is deficient. Therefore, there is an inextricable link between the two that no organisation responsible for the provision, supervision or regulation of education can properly ignore. Trainees are invaluable eyes and ears in a hospital setting.

## Others

### *Health Protection Agency*

1.87 The Health Protection Agency's (HPA's) involvement with trusts and often intimate knowledge of their systems for controlling healthcare associated infections (HCAIs) mean that it will often come into possession of information which could be of value to those responsible for oversight of the healthcare system, including the quality regulator.

1.88 The HPA did not escalate its concerns about infection control at the Trust promptly to the HCC or the SHA. It did not volunteer information to the HCC despite its knowledge that an investigation was being undertaken. It did not have any contact with Monitor in relation to the Trust, despite the Trust's FT status from February 2008.

1.89 There was insufficient consideration given to the importance of communication with regulatory and supervisory bodies in order to ensure that relevant information pertinent to patient safety was properly disseminated, discussed and appropriate action considered. There has, therefore, been a concerning absence of proactive sharing of information or consideration of how this should be arranged. Organisational boundaries and cultures should not prevent the use by all of information and advice designed to enhance patient safety.

### *The Health and Safety Executive*

1.90 The Health and Safety Executive (HSE) has responsibilities over virtually every form of workplace and activity, and the scope of its activity is extremely wide. Therefore, the HSE has devised a policy seeking to define the factors on which its discretion to involve itself or not in healthcare will be based. Inevitably, it is not possible for a full investigation, still less a prosecution, to be brought in every case where there has been a possible breach of the Health and Safety at Work Act 1974 or the regulations made under it.

1.91 However, while it is always going to be difficult to devise policies which will satisfy the many conflicting requirements of the public interest, it is clear that the principles by which the HSE has sought to decide whether or not to involve itself in healthcare cases has led to a particularly unsatisfactory situation when placed alongside the CQC's refusal to investigate individual cases. This has led to a regulatory gap which needs to be closed.

1.92 Given the current gap through which serious cases of safety breaches in a healthcare setting are likely to fall, the approach of the HSE is not calculated to maintain public confidence. The approach has the appearance of looking for reasons for not taking action rather than starting from a consideration of what is in the public interest. A concentration on the effect of a decision on resources has led to the unacceptable position that the more serious and widespread a failure is, the less likely it is that HSE will decide to intervene.

1.93 A perceived lack of expertise within the HSE is not regarded in other spheres as a reason for it not to investigate a case otherwise requiring it. The answer is of course to obtain external and independent expert advice, as is done day in and day out in the field of healthcare litigation and fitness to practise proceedings.

1.94 This regulatory gap needs to be closed. It should be recognised that there are cases which are so serious that criminal sanction is required, even where the facts fall short of establishing a charge of individual or corporate manslaughter. The argument that the existence of a criminal sanction inhibits candour and cooperation is not persuasive. Such sanctions have not prevented improvements in other fields of activity.

1.95 The HSE has faced difficulties and dilemmas in applying its very broad jurisdiction to healthcare. There has been a gap between what the HSE and the CQC are respectively able or willing to regulate. This has caused distress to patients and those close to them who seek redress for safety breaches. Either the CQC should be given power to exercise the statutory health and safety functions in respect of regulated organisations, or a new comparable offence should be created in respect of which the CQC has power of prosecution.

### *National Patient Safety Agency*

1.96 Patient safety information, in the form of incident reports, is a vital part of what is required for patient protection, and the development of a system to collect such information nationally is welcome. The National Patient Safety Agency (NPSA), up to its abolition in June 2012, sought to master a challenging field, and made considerable progress. However, further development is still required, as the existing system played no part in the uncovering of the lack of safety at the Trust.

1.97 These very positive developments have taken a long time to implement, due in part to the challenges thrown up by the many structural reorganisations of the NHS during the period in question, and the relatively low priority accorded to this area of activity as a result.

### *Royal College of Nursing*

1.98 At Stafford, the RCN was ineffective both as a professional representative organisation and as a trade union. Little was done to uphold professional standards among nursing staff or to address concerns and problems being faced by its members.

1.99 A prime reason for this was the lack of effective representation from elected officers on site. Further, the support available from RCN officials at a regional and national level was limited.

1.100 The RCN is not, of course, a regulator but a combination of a professional representative body and a trade union. However, it does represent a group of qualified professionals and seeks, as it should, to promote high standards of service and conduct. The evidence reviewed in this report suggests that the RCN has not been heard as might have been expected in pursuing professional concerns about the standard of care.

1.101 It appears there is a concerning potential for conflict between the RCN's professional role of promoting high quality standards in nursing, and its union role of negotiating terms and conditions and defending members' material and other narrow interests.

### Department of Health

1.102 The senior officials in the DH have accepted it has responsibility for the stewardship of the NHS and in that sense that it bears some responsibility for the failure of the healthcare system to detect and prevent the deficiencies at Mid Staffordshire sooner than it did. There is no doubt about the authenticity of their expressions of shock at the appalling story that has emerged from Mid Staffordshire. However, it is not possible to avoid the impression that it lacks a sufficient unifying theme and direction, with regard to patient safety, to move forward from this point in spite of the recent reforms put in place by the current Government.

1.103 The structural reorganisations examined during the course of the Inquiry tend to suggest that many policy changes over the period of review, put forward with the intention of improving the standards of the health service, were not given time to succeed before the next wave of reorganisation occurred. The former Secretary of State for Health, the Rt Hon Andy Burnham MP, accepted that there was often a disconnect between the policy decisions being made and their practical implementation.

1.104 Where there are perceived deficiencies, it is tempting to change the system rather than to analyse what needs to change, whether it be leadership, personnel, a definition of standards or, most importantly, culture. System or structural change is not only destabilising but it can be counterproductive in giving the appearance of addressing concerns rapidly while in fact doing nothing about the really difficult issues which will require long-term consistent management. While the DH asserted the importance of quality of care and patient safety in its documentation and its policies, it failed to recognise that the structural reorganisations imposed upon trusts, PCTs and SHAs implementing such policy have on occasion made such a focus very difficult in practice.

1.105 The Trust was criticised in the first inquiry report for not undertaking sufficient impact or risk assessments before making significant changes. The same also appears to be the case at a system-wide level.

1.106 Nevertheless, it is to the credit of successive Governments and the DH that they have over the last decade or so recognised the importance of setting standards for the delivery of healthcare rather than merely trusting organisations and professionals to deliver an acceptable service and assuming that regulation of individual professionals was a sufficient guarantee. However, the development of a structure that is effective has been very difficult, and it is clear that the journey is not yet complete.

1.107 The story of the development of standards within the healthcare system has been one of struggle between the rhetoric of improvement and the need for clarity about what is unacceptable.

1.108 The reality is that it is not the setting of national standards in itself which will "catch" a Mid Staffordshire but having effective methods of policing those standards. It is important that such policing is not confined to one method applied by a single organisation, but is undertaken in as many different ways as possible, through provider internal leadership, external but local public scrutiny, commissioning, and the regulator all working to a common set of values, standards and priorities. The DH has struggled to get the balance right between "light touch" regulation and the need to protect service users from harm.

1.109 In addition, despite the DH possessing highly impressive senior clinical figures, all of whom are clearly dedicated to making the NHS work for the people it serves, there is an impression that senior clinicians were not at the heart of decision-making on several key issues that have been examined at this Inquiry. Although a focus on quality has developed significantly in the last 10 years, the DH has failed to place it firmly at the core of its policy by assessing the impact of key policies, such as financial rebalance, the FT agenda and structural reform on quality. The DH should ensure that there is senior clinical involvement in all decisions which may impact on patient safety and well-being.

1.110 Some of the evidence the Inquiry has heard shows that DH officials are at times too remote from the reality of the service they oversee. They need to connect to its patients and frontline staff more personally and directly. Nothing is more likely to focus the mind on the impact of decisions on patients than to listen to patients' experiences. The most important cultural change should be to require all who work there to place the patient perspective at the forefront of their minds and deliberations in all they do. Evidence has shown that the DH has not always put patients first, prioritising other policies over patient considerations.

1.111 In considering the DH as a cultural leader, the evidence before the Inquiry does not justify a conclusion that there is in fact a culture within the Department which could properly be described as one of bullying. What the evidence does establish is that well-intentioned decisions and directives emanating from the DH have either been interpreted further down the hierarchy as bullying, or resulted in them being applied locally in an oppressive manner. It is not the intent that is in question, but the unintended consequences and perceptions of others as a reaction to DH requirements. There needs to be a careful balance between avoiding tolerance of unacceptable standards of performance and incentivising short cuts to compliance by applying career-threatening pressure to uphold such standards. The DH must ensure that performance requirements are balanced by provision of qualifications to allow patient safety and well-being to remain the priority, resources and support which enable the requirements to be met, and the restriction of suggestions of adverse career consequences to cases of misconduct or serious incompetence.

1.112 It is a truism that organisational culture is informed by the nature of its leadership. The DH has an important leadership role to play in promoting the change of culture required throughout the healthcare system.

1.113 The very complexity and size of the NHS presents challenges in creating and maintaining a positive patient-focused culture throughout. This challenge will increase as the autonomy of frontline organisations increases and each becomes more susceptible to the vagaries of local leadership. The DH has primary responsibility for providing the means for developing a consistent culture.

### Why things were not discovered sooner

1.114 A primary purpose of this Inquiry is "to examine why problems at the Trust were not identified sooner; and appropriate action taken." This report identifies common themes that, when combined, led to the devastating state of affairs eventually discovered at the Trust:

- As identified during the first inquiry, the Trust was an organisation that lacked insight and awareness of the reality of the care being provided to patients. It was generally defensive in its reaction to criticism and lacked openness with patients, the public and external agencies.

- The responsibilities and accountabilities of external agencies were not well defined, often resulting in "regulatory gaps" or failure to follow up warning signs. Organisations operated in silos, without consideration about the wider implications of their role, even guarding their territories on occasion.

- This situation was exacerbated by a lack of effective communication across the healthcare system in sharing information and concerns. Organisations relied on others to keep them

informed rather than actively seeking and sharing intelligence. At the heart of the failure was a lack of openness, transparency and candour in the information emanating from the Trust and over-reliance on that information by others.

- This was not helped by the constant reorganisation of NHS structures, often leading to a loss of corporate memory and misunderstandings about an organisation's functions and responsibilities. Information flow was generally poor.

- The combination of these "regulatory gaps", lack of effective communication and constant reorganisation led to a systemic culture where organisations took inappropriate comfort from assurances given either by the Trust itself or from action taken by other regulatory organisations. As a result, organisations often failed to carry out sufficient scrutiny of information, instead treating these assurances as fulfilling their own, independent obligations.

- This culture of assurances was operating in a structure where identifying systems and processes and meeting targets were the main measures of performance. Outcomes-based performance and risk-based, intelligence-informed regulation were still developing concepts.

- The focus of the system resulted in a number of organisations failing to place quality of care and patients at the heart of their work. Finances and targets were often given priority without considering the impact on the quality of care. This was not helped by a general lack of effective engagement with patients and the public, and failure to place clinicians and other healthcare professionals at the heart of decision-making. Complaints were not given a high enough priority in identifying issues and learning lessons. Patients, clinicians and the public need to be at the heart of the health service and the decisions being made.

**1.115** Each of these common themes is examined in detail throughout the main report.

## Lessons learned and related key recommendations

### A common culture made real throughout the system

**1.116** The negative aspects of culture in the system were identified as including:

- A lack of openness to criticism;
- A lack of consideration for patients;
- Defensiveness;

- Looking inwards not outwards;
- Secrecy;
- Misplaced assumptions about the judgements and actions of others;
- An acceptance of poor standards;
- A failure to put the patient first in everything that is done.

**1.117** It cannot be suggested that all these characteristics are present everywhere in the system all of the time, far from it, but their existence anywhere means that there is an insufficiently shared positive culture.

**1.118** To change that, there needs to be a relentless focus on the patient's interests and the obligation to keep patients safe and protected from substandard care. This means that the patient must be first in everything that is done: there must be no tolerance of substandard care; frontline staff must be empowered with responsibility and freedom to act in this way under strong and stable leadership in stable organisations.

**1.119** To achieve this does not require radical reorganisation but re-emphasis of what is truly important:

- Emphasis on and commitment to common values throughout the system by all within it;
- Readily accessible fundamental standards and means of compliance;
- No tolerance of non compliance and the rigorous policing of fundamental standards;
- Openness, transparency and candour in all the system's business;
- Strong leadership in nursing and other professional values;
- Strong support for leadership roles;
- A level playing field for accountability;
- Information accessible and useable by all allowing effective comparison of performance by individuals, services and organisation.

**1.120** By bringing all this together, all who work to provide patient care, from porters and cleaners to the Secretary of State, will be working effectively in partnership in a common and positive culture.

## Common values: putting the patient first – the NHS Constitution

1.121 The common values of the service must be enshrined in and effectively communicated by the NHS Constitution and owned and lived by all members of the service. The NHS Constitution should be the first reference point for all NHS patients and staff and should set out the system's values, and the rights, obligations and expectations of patients.

1.122 Patients must be the first priority in all of what the NHS does by ensuring that, within available resources, they receive effective care from caring, compassionate and committed staff, working within a common culture, and protected from avoidable harm and any deprivation of their basic rights.

1.123 The overarching value and principle of the NHS Constitution should be that patients are put first, and everything done by the NHS and everyone associated with it should be informed by this ethos.

1.124 The Constitution should incorporate reference to all codes of conduct and standards with which staff are expected to comply. All need to recognise their duty to contribute to the formulation of standard procedures facilitating compliance with required standards.

### *Standards*

1.125 Enshrined in the NHS Constitution and systems regulations should be a commitment to abide by an integrated hierarchy of standards:

- Fundamental standards, which need to be applied by all those who work and serve in the healthcare system. Behaviour at all levels and service provision need to be in accordance with at least these fundamental standards. No provider should provide any service that does not comply with these fundamental standards, in relation to which there should be zero tolerance of breaches.
- Enhanced quality standards, which set requirements over and above the fundamental standards, which are a matter for definition and enforcement by the commissioners of services.
- Developmental standards setting longer term goals devised by commissioners and providers.

## Simplifying regulation

1.126 In the case of Mid Staffordshire, the regulatory regime that allowed for overlap of functions led to a tendency for regulators to assume that the identification and resolution of non-

compliance was the responsibility of someone else. Effective accountability to the public demands a simpler regime of regulation.

1.127 Important information about the Trust did not pass from one organisation to another, leading to an erroneous decision about FT authorisation being made. The assessment of risk to patients would be more effective if the direct monitoring of compliance with fundamental standards and the monitoring of the organisation's ability to deliver compliance were the responsibility of one organisation. Such a change should not be seen as a reason to reduce the resources available for these tasks, and the merger of the functions should be undertaken incrementally and after thorough planning. The responsibility for the FT authorisation process should also be transferred. There is no logical case to have these issues dealt with by different bodies. The single regulator should deal with issues of patient safety, adherence to fundamental standards, corporate governance and financial competence and viability.

1.128 The Secretary of State should therefore consider transferring the functions of regulating governance of healthcare providers and fitness of persons to be directors, governors or equivalent persons (as dealt with elsewhere in the recommendations) from Monitor to the CQC. Merging of functions should not be undertaken with undue haste and without adequate planning to ensure that the corporate memory of Monitor is not lost. The merger should not be used as a justification for making cost savings in a way that would result in the merged body being under-resourced to undertake the required tasks.

### Monitoring of compliance with fundamental standards

1.129 The fundamental standards should be policed by a single regulator, the CQC, monitoring both compliance with fundamental standards, and the governance and financial sustainability which will enable a provider to deliver compliant services on a sustainable basis. It should not be the role of the CQC to ensure improvement by the provider, but rather to ensure that compliance with the fundamental standards is such as to protect the safety of patients and the quality of the service provided.

1.130 The fundamental standards should be set out in a clear manner so they can be understood and accepted by providers, patients and the public. Whilst they will require Government approval, as they should be incorporated as regulations, they should not be imposed as "top down" standards but should be the subject of extensive consultation, particularly to ensure that patients, doctors and nurses have full confidence in them.

1.131 Compliance with the fundamental standards should be policed by reference to developing the CQC's outcomes into a specification of indicators and metrics by which it intends to monitor compliance. These indicators should, where possible, be produced by the National Institute for Health and Clinical Excellence (NICE) in the form of evidence-based procedures and practice

which provide a practical means of compliance and of measuring compliance with fundamental standards.

1.132 The procedures and metrics produced by NICE should include evidence-based tools for establishing the staffing needs of each service. These measures need to be readily understood and accepted by the public and healthcare professionals.

1.133 Adoption of these practices, or at least their equivalent, is likely to help ensure patients' safety. Where NICE is unable to produce relevant procedures, metrics or guidance, assistance could be sought and commissioned from the Royal Colleges or other third-party organisations, as felt appropriate by the CQC, in establishing these procedures and practices to assist compliance with the fundamental standards.

### Enforcement of compliance with fundamental standards

1.134 Any service or part of a service that does not consistently fulfil the relevant fundamental standards should not be permitted to continue, and the CQC as regulator should have the ability to take immediate protective steps in the interest of patients' safety if it has concerns on the issue, even whilst considering or investigating the extent of non-compliance.

1.135 Non-compliance with a fundamental standard leading to death or serious harm of a patient should be capable of being prosecuted as a criminal offence, unless the provider or individual concerned can show that it was not reasonably practical to avoid this. Reliance might be placed for that purpose on effective implementation of the procedures devised by NICE, but this would offer no defence to those who had not followed such a procedure.

1.136 Information needs to be used effectively by regulators and other stakeholders in the system wherever possible by use of shared databases. Regulators should ensure that they use the valuable information contained in complaints and many other sources. The CQC's quality risk profile is a valuable tool, but it is not a substitute for active regulatory oversight by inspectors, and is not intended to be.

1.137 Inspection should remain the central method for monitoring compliance with fundamental standards. A specialist cadre of hospital inspectors should be established, and consideration needs to be given to collaborative inspections with other agencies and a greater exploitation of peer review techniques.

### Applying for foundation trust status

1.138 It is recognised that the functions of Monitor will continue whilst the implementation of a recommendation to merge functions with the CQC is deliberated. The following recommendations apply to the manner of application for FT status whether prior to, or after,

the merger. For these purposes, reference will be made to "Monitor", recognising that upon implementation of the recommendation of merger with the CQC, these functions would be exercised by the merged body. Full recommendations in relation to Monitor appear in the table of recommendations in *Chapter 2* of this executive summary and *Chapter 27* of the main report.

**1.139** No NHS trust should be supported to make an application for FT status unless the organisation meets the criteria for authorisation at the date that the application is made. Those criteria must include compliance with the fundamental standards, and any application must be preceded by a physical inspection of its primary clinical areas as well as wards by the CQC. Such criteria must also include compliance with good governance, so as to satisfy the requirement that the fundamental standards are maintainable on an ongoing and regular basis.

**1.140** Ongoing obligations of transparency, openness and honesty should be imposed on applicants for FT status, and such obligations include an obligation to disclose to Monitor any significant information material to the application, whether favourable to it or not. Failure to honour such obligations will be subject to the same criminal sanctions outlined below.

**1.141** The DH, the NHS Trust Development Authority and Monitor should jointly review the consultation process required to ensure that local opinion has been captured, and this material should be provided to the Secretary of State when assessing any application. The Secretary of State should not support an application unless he or she is satisfied that the applicant is compliant at the time of his decision with fundamental standards and that the commissioner is satisfied that enhanced standards are being complied with, and will continue to be complied with.

**1.142** The focus of the process of authorisation must be on fitness for purpose in delivering the appropriate quality of care, and it must include reviews of the standard of service delivered and the ability of the organisation to deliver fundamental standards sustainably. The process of authorisation should include a full physical inspection of the primary clinical areas and wards to determine whether the applicant is compliant.

**1.143** Applicants for FT status should be under a duty of utmost good faith to disclose any significant information material to the application.

### Accountability of board level directors

**1.144** There has been understandable concern at the circumstances surrounding the departure from the Trust of the Chair and Chief Executive. While the business demands of the Trust may have required their swift departure and therefore a commercially understandable compromise, the public demand for accountability was left unsatisfied. Directors should be liable to

disqualification from the role unless they are fit and proper persons for it. The test of fitness should include a requirement to comply with a prescribed code of conduct. A finding that a person is not a fit and proper person should disqualify a person from being a director of any healthcare organisation. Where a regulator is no longer satisfied that a director is a fit and proper person, there should be a power to remove or suspend that person from office after due process. Where a director's employment or appointment is terminated in circumstances where there is reasonable cause to suspect he or she is not a fit and proper person, the organisation should be obliged to report that information to the regulator.

### Enhancement of governors' role

**1.145** The role of FT governors needs to be enhanced, improved and made accountable.

**1.146** Monitor and, post-merger, the CQC, should publish guidance to assist the recognition of the importance and accountability of the public role of a governor, and what is required to be a fit and proper person to undertake such a role and the steps that an FT should take in the event of it needing to disqualify a governor as not fulfilling such criteria.

**1.147** Governors should be provided with appropriate training, and consideration should be given to establishing a minimum level of relevant experience, as a requisite to holding a post as a governor.

**1.148** Published guidance should also set out the principles that governors should follow to ensure effective public accountability. This should include access to external assistance and support to be provided by their national association.

### Supportive agencies

**1.149** The NHS Litigation Authority (NHSLA), through its risk management ratings, has made a contribution to the assessment of providers governance, but the significance of this has been misunderstood and sometimes misapplied. The NHSLA should set more demanding levels for financial incentivisation, and arrangements should be made for the more effective sharing and recording of information.

**1.150** The functions of the former NPSA with regard to incident reporting and analysis need to be well protected and defined. More could be made of this important source of information.

**1.151** The HPA obtained information of potential concern about the Trust's attitude to hospital acquired infections. Its valuable resource of information should be coordinated in conjunction with the NHS Information Centre (NHSIC). Infection control officials should share their concerns with commissioners and regulators wherever there is cause for concern about patient safety.

## Effective complaints and incidents

1.152 Complaints, their source, their handling and their outcome provide an insight into the effectiveness of an organisation's ability to uphold both the fundamental standards and the culture of caring. They are a source of information that has hitherto been undervalued as a source of accountability and a basis for improvement.

1.153 The recommendations and standards suggested in the Patients Association's peer review into complaints at the Trust should be reviewed and implemented nationally. They are set out in the full set of recommendations that follow this summary of findings.

1.154 Whilst a uniform process of complaints handling should be applied, the making of a complaint should be easy to do, and any expression of concern made by a patient should be treated as a complaint, unless the patient's permission is refused. The clarity of the responsibility of a senior clinician and nurse for each patient, and their obligation to be involved in responding to any complaint, should facilitate access to the complaints system and facilitate a speedy resolution, wherever possible.

1.155 Whilst a complaints system should be consistent, it must never be applied in a formulaic or insensitive manner.

1.156 Complaints relating to possible breaches of fundamental standards and serious complaints should be accessible to the CQC, relevant commissioners, health scrutiny committees, communities and Local Healthwatch.

1.157 Learning from complaints must be effectively identified, disseminated and implemented, and it must be made known to the complainant and the public, subject to suitable anonymisation.

## Commissioning for quality and for improvement: enhanced quality standards

1.158 Owing to a combination of organisational change and implementation of a policy intending to pass them responsibility for quality before the necessary tools for exercising this were available, PCTs were not as effective as might have been expected in commissioning or monitoring delivery of quality.

1.159 Commissioners of services, as the paying party for services they contract from providers, must ensure that those services are well provided and are provided safely. The fundamental standards to be policed by the CQC form the minimum level of service that should be provided, but the commissioner in its contracting arrangements will wish to set standards over and above that minimum standard for the services that it wishes to contract, and will set out redress for non-compliance with those contracted standards.

1.160 These contractual standards – enhanced quality standards – give commissioners the opportunity to promote improvement in the areas of service they wish to purchase. Commissioners could also set out longer term goals for, or in conjunction with, providers by way of developmental standards and focus on improvements in effectiveness.

1.161 The NHS Commissioning Board should be responsible for devising and designing the enhanced standards to be incorporated into commissioning contracts or assisting local commissioners to do so.

1.162 The NHS Commissioning Board and the local commissioners of services must be adequately resourced to enable a proper scrutiny that providers are delivering the standard of service required under their contracts. The resource available to the commissioners to monitor the provision of contractual services should extend as necessary to the capacity to undertake audits, inspections and investigations, of individual cases (bearing in mind that they will have access to individual complaints as outlined above) and of groups of cases. The commissioners must have access to quality accounts and all QRPs available to the CQC.

1.163 Responsibility for driving improvement in the quality of service should therefore rest with the commissioners through their commissioning arrangements. Commissioners should promote improvement by requiring compliance with enhanced standards that demand more of the provider than the fundamental standards.

1.164 Commissioners should have powers of intervention where services are being provided which do not accord with their contracts. If fundamental standards are not being provided, the CQC, as regulator, should also be informed, and the commissioner and the CQC should in such cases be able to act jointly or alone. The commissioner should be able to stop the provision of a service being supplied in breach of the fundamental and/or enhanced standards and/or require the provision of the service to be done in a different way, or by different personnel, to protect patients. The CQC and commissioners should have contingency plans in place in the event of needing to exercise these powers.

1.165 In contracting providers, commissioners – not the provider – should decide what needs to be provided, but they should consider the views of clinicians, including those from providers and elsewhere, on commissioning needs as they consider it appropriate. Commissioners should also consult others, as they deem necessary, including GPs and procurement expertise, to improve their commissioning arrangements. Commissioners should also consult and liaise with other commissioning bodies, as they deem necessary, to achieve the necessary expertise or commissioning power to secure effective arrangements.

1.166 Commissioners should, in their contracts, require the boards of providers to seek and record the views and advice of its clinical and nursing directors of the impact on the fundamental

standards of any proposed major change to clinical or nurse staffing arrangements or the provision of facilities.

1.167 Commissioners need to recognise their accountability to the public they serve by measures designed to involve the public in commissioning and enable their views to be taken into account. For this purpose, commissioners need to raise their public profile.

### Local public and patient engagement and partnership

1.168 The arrangements for public and patient involvement, and for local government scrutiny in Stafford, were a conspicuous failure.

1.169 Local authorities should be required to pass over the funds received for the purposes of Local Healthwatch to that organisation which shall become accountable for its use of the funding. Should the Local Healthwatch become incapable of performing its functions, then the local authority or Healthwatch England should intervene, as appropriate.

1.170 Local Healthwatch should work to a consistent structure nationally, with the benefit of appropriate training and access to advice.

1.171 Oversight and scrutiny committees should have power to inspect providers, using information from local patient involvement to trigger such inspections as necessary.

### Medical training and education

1.172 Medical education and training systems provide an opportunity for enhancing patient safety. Students and trainees should not be placed in establishments which do not comply with the fundamental standards, and those charged with overseeing and regulating these activities should, like all other participants in the system, make the protection of patients their priority. A number of recommendations for this purpose have been made.

### There must be real involvement of patients and the public in all that is done

1.173 The CQC needs to evidence its own compliance with the principles of openness, honesty, transparency and candour described above. It should consider integrating patients through their user group representatives into its structure and/or through liaison with the patient's consultative council. Consideration should also be given to inviting nominated members from groups such as the Academy of Medical Royal Colleges and Nursing and Allied Healthcare Professionals.

1.174 Those with responsibility for commissioning should also seek the involvement of the public, as set out in the full table of recommendations.

1.175 Providers need to review unnecessary restrictions on visiting hours. They should be as open to visitors as would be a patient's home, subject to health protection requirements.

### Openness, transparency and candour

1.176 For a common culture to be shared throughout the system, these three characteristics are required:

- Openness: enabling concerns to be raised and disclosed freely without fear, and for questions to be answered;
- Transparency: allowing true information about performance and outcomes to be shared with staff, patients and the public;
- Candour: ensuring that patients harmed by a healthcare service are informed of the fact and that an appropriate remedy is offered, whether or not a complaint has been made or a question asked about it.

1.177 This requires all organisations and those working in them to be honest, open and truthful in all their dealings with patients and the public.

1.178 In addition, organisations and their leaders must be completely truthful when making statements to regulators, and they must not be misleading by omission. Public statements must also be truthful and not misleading.

1.179 The NHS Constitution should include clear obligations to comply with these principles, and all contracts and policies should be reviewed to ensure consistency with them. For example, "gagging" or non-disparagement clauses should not be permitted to limit legitimate disclosure of public interest issues concerning patient safety and care.

1.180 The common culture of caring requires a displacement of a culture of fear with a culture of openness, honesty and transparency, where the only fear is the failure to uphold the fundamental standards and the caring culture.

1.181 A statutory obligation should be imposed:

- On healthcare providers, registered medical and nursing practitioners to observe the duty of candour;
- On directors of healthcare organisations to be truthful in any information given to a regulator or commissioner. There should be a criminal offence for any registered doctor or nurse or allied health professional or director of a registered or authorised organisation to

obstruct the performance of these duties or dishonestly or recklessly to make an untruthful statement to a regulator.

1.182 Enforcement of these duties should rest with the CQC, which should be supported by commissioners' and others' monitoring.

1.183 The CQC should keep on constant review its ability to deliver the necessary regulatory oversight and enforcement, bearing in mind its duties of openness, honesty and candour, and ensure that its strategy and performance are communicated effectively to its staff.

### Peer review

1.184 The creation of a caring culture would be greatly assisted if all those involved in the provision of healthcare are prepared to learn lessons from others and to offer up their own practices for peer review. Whilst peer review will have a specific relevance in cases of practitioners where there may be concerns about substandard performance, it has a far more fundamental role in changing behaviour to ensure a consistent and caring culture throughout the healthcare services. Peer review therefore needs to be a key part of the delivery and monitoring of any service or activity, and those involved need to demonstrate that this element of monitoring and learning is integral to the process of compliance with fundamental standards and of improvement.

### Caring, compassionate and considerate nursing

1.185 There should be an increased focus on a culture of compassion and caring in nurse recruitment, training and education. Nursing training should ensure that a consistent standard is achieved by all trainees throughout the country. The achievement of this will require the establishment of national standards. The knowledge and skills framework should be reviewed with a view to giving explicit recognition to nurses' commitment to patient care and the priority that should be accorded to dignity and respect in the acquisition of leadership skills.

1.186 Practical hands-on training and experience should be a prerequisite to entry into the nursing profession.

1.187 Training and continuing professional development for nurses should apply at all levels, from student to director, and commissioning arrangements should reflect the need for healthcare services to be delivered by those who are suitably trained.

1.188 Nurse leadership should be enhanced by ensuring that ward nurse managers work in a supervisory capacity and are not office bound. They should be involved and aware of the plans and care for their patients.

1.189 The NMC should introduce a system of revalidation similar to that of the GMC as a means of reinforcing the status and competence of registered nurses as well as providing additional protection to the public. It is essential that the NMC has the resources and the administrative and leadership skills to ensure that this does not detract from its existing core function of regulating fitness to practise.

1.190 There should be a responsible officer for nursing in each trust, and they should be accountable to the NMC.

1.191 Consideration should be given by the NMC to introducing an aptitude test to be taken by aspirant registered nurses prior to entering into the profession to explore the candidate's attitude towards caring, compassion and other necessary professional values. Once nurses have received appropriate training, the NMC should ensure the professional development of registrants and should ensure that nurses' training is more practical.

1.192 The special requirements of caring for the elderly should be recognised by consideration of the introduction of a new status of a registered older person's nurse.

1.193 The professional voice needs to be strengthened:

- The RCN should consider how better to separate its trade union and professional representative functions.
- A forum of nursing directors should be formed.
- There should be at least one nurse on the executive boards of all healthcare organisations, including commissioners.
- The advice of the nursing director should be obtained and recorded in relation to the impact on the quality of care and patient safety of any proposed major change in nurse staffing or facilities.

### Healthcare support workers

1.194 Currently, healthcare support workers, whether working for the NHS or for independent healthcare providers, in the community or for agencies, are not subject to any system of registration. A registration system should be created under which no unregistered person should be permitted to provide for reward direct physical care to patients currently under the care and treatment of a registered nurse or a registered doctor or who are dependent on such care by reason of disability or infirmity in any hospital or care home setting. Exemptions will need to be made for persons caring for members of their own family or those with whom they have a genuine social relationship.

1.195 There should be a uniform code of conduct that would apply to all healthcare support workers who should receive education and training in accordance with common national standards. The necessary code of conduct, education and training standards should be prepared and maintained by the NMC after due consultation with all relevant stakeholders. There should be a means whereby members of the public can clearly identify and distinguish between registered nurses and registered healthcare workers.

## Leadership

1.196 The common culture and values of the NHS must be applied at all levels of the organisation, but of particular importance is the example set by leaders. A leadership staff college should be created to provide common professional training in management and leadership to potential senior staff. This could lead to an accreditation scheme enhancing eligibility for consideration for such roles and will have the effect of promoting and researching best practice.

1.197 This college should not be a "virtual organisation" facilitating events. It should be a physical presence that will serve the role of reinforcing the required culture through shared experience and will provide a common induction into the expectations of the NHS of those who lead and work in the system.

1.198 A common code of ethics, standards and conduct for senior board-level healthcare leaders and managers should be produced and should be consistent with the common culture. The principles appearing in those ethics and standards should apply to all staff, and it is the responsibility of employers to ensure that they are honoured. Serious non-compliance with the code should be grounds for considering a leader not a fit and proper person to be a director. An alternative would be to set up a professional regulator, the need for which could be better assessed after reviewing experience with the "fit and proper person" requirements.

1.199 Accreditation schemes for managers promoted by the staff college should be considered.

1.200 Appraisal systems are a key tool to monitor and enforce standards and to reinforce a caring culture. The GMC and the NMC should introduce common minimum standards for appraisal and support with which registered members would be obliged to comply.

1.201 As a part of this mandatory annual performance appraisal, each clinician and nurse should be required to demonstrate their ongoing commitment, compassion and caring shown towards patients, evidenced by feedback of the appraisee from patients and families, as well as from colleagues and co-workers. This portfolio could be made available to the GMC or the NMC, if requested as part of the revalidation process.

## Proactive professional regulation of fitness to practise

1.202 Both the GMC and the NMC should have a clear policy stating the circumstances in which they should be informed of generic complaints. Both should aim to be more proactive in monitoring fitness to practise, launching their own proactive investigations where appropriate.

1.203 The GMC should also give guidance to deaneries (or their successors) of the nature of matters to be reported, which should not be limited to exceptional matters of perceived non-compliance with standards.

1.204 The GMC and the NMC should ensure that patients' safety is the first priority of medical training and education.

1.205 To be more effective, it is more likely that there will be a need for increased resource. Both the GMC and the NMC should, as appropriate, liaise more closely with the CQC, and the three organisations should report regularly on their work. Other reviews suggest that the NMC is still to be found wanting in the administration of its functions; this needs to be remedied lest the regulatory gap widen, rather than narrow and close.

1.206 The GMC and the NMC should consider commissioning peer reviews, possibly in conjunction with the CQC, if generic concerns exist which might lead to individual concerns.

1.207 The GMC should systematise the exchange of information between it and the Royal Colleges.

1.208 Fitness to practise procedures should not delay or obstruct internal disciplinary actions taken by providers, so far as is practicable. Employment disciplinary procedures should be reviewed accordingly.

1.209 The same event, or series of events, may lead to fitness to practise procedures arising in more than one professional regulator. The Professional Standards Authority for Health and Social Care (PSA), formerly CHRE, should consider devising procedures to allow a common independent tribunal to determine fitness to practise issues and sanctions across the healthcare professional field.

1.210 Further recommendations to improve the profile and performance of the regulators are included in the table that follows this summary of findings.

## Caring for patients: approaches applicable to all but in particular the elderly

1.211 Hospitals should review, with a view to reinstatement, the practice of identifying a consultant or senior clinician and nurse who is in charge of each patient's care, so that patients and families are clear who is in overall charge of that care. Those persons in charge and

responsible for a patient's care should be directly responsible for assisting in the response to any complaints that may be lodged in relation to the quality of care that that patient has received.

1.212 Ward sisters and nurse managers should operate in a supervisory capacity and should not be office bound. The ward manager should know about the care plans relating to every patient on their ward and should be visible and accessible to patients and staff alike. Ward managers should work alongside staff as a role model and mentor, developing clinical competencies and leadership skills within the team and ensuring that the caring culture expected of professional staff is being consistently maintained and upheld.

1.213 No ward round should take place without the presence of the nurse in charge of the patients that are to be visited (or an appointed deputy or other replacement).

1.214 Regular interaction and engagement between nurses and patients should be systemised through regular ward rounds.

1.215 A truly caring culture does not stop at the door of the hospital provider. It should never be acceptable for patients to be discharged at any time without knowledge that the patient in need of care will receive it on arrival at their destination. The emphasis should be on continuity of care to include a follow-up as to a patient's well-being after discharge.

1.216 Continuity of care should also apply to the administration of medication, which should be overseen by the nurse in charge of the ward, and all necessary checks should be undertaken, particularly in the event of patient movement in or out of the ward.

1.217 This ongoing responsibility for continuing care should also embrace GPs and their practices. GPs should, as a part of their professional obligations, check on their patient after hospital treatment and assess whether the outcomes were satisfactory. GP practices should also monitor patterns of concern which should be made known to the CQC and the relevant commissioner.

1.218 GPs should have an obligation to their patients to keep themselves informed of the standard of service available from providers.

### Information

1.219 If the culture of those engaged in and with the NHS is to change, information must be made available about the performance and outcomes of the service provided to enable patients to make treatment choices and have a proper understanding of the outcomes for them.

1.220 The public should be able to compare relative performance, and therefore need access to open, honest and transparent information to assess compliance with appropriate standards. To achieve the culture that is necessary for the NHS to flourish, every healthcare organisation and everybody working within the healthcare system must be honest, open and truthful in all their dealings with patients and the public. No personal or organisational interest must ever be allowed to outweigh the duty to be honest, open and truthful.

1.221 Transparency and patient safety would be greatly enhanced by the introduction of user friendly electronic patient record systems. Patients should be able to in real time, or retrospectively, read and comment on their records. The system should be designed to include prompts and defaults to contribute to effective patient care and safety.

1.222 All healthcare provider organisations should develop and publish real time information on the performance of their consultants and specialist teams in relation to mortality, morbidity, outcome and patient satisfaction, and on the performance of each team and their services against the fundamental standards.

1.223 It must be a professional duty of healthcare professionals to collaborate in the provision of such information.

1.224 This information, available in as near real time as possible to providers, commissioners, regulators and the public, should include not only statistics of outcomes, but also all other available safety-related information, including that derived from investigations, complaints and incidents.

1.225 Every provider organisation should have a designated board member as a chief information officer.

### Quality accounts

1.226 Trust Boards should provide, through quality accounts, full and accurate information about their compliance or non-compliance with the fundamental standards and enhanced standards that apply to them. This data should be made available on each trust's website, and should be audited.

1.227 Quality accounts should contain information in a common form to enable comparisons to be made between organisations. This should include a minimum of prescribed information about compliance with fundamental and enhanced standards. Where there are issues of non-compliance, proposals for rectification should appear, and full details should be given on statistics on mortality and other outcomes. These quality accounts should contain the observations of commissioners and overview and scrutiny committees.

1.228 Each quality account should be accompanied by a declaration signed by all directors certifying the accounts to be true, or a statement of explanation should be given as to why any director is unable to sign or has refused to sign such a declaration. To make or be party to a wilfully or recklessly false statement as to compliance with fundamental standards in the required quality account should be made a criminal offence.

1.229 Healthcare providers should have their quality accounts independently audited and their accuracy, fairness, and balance should be considered by the CQC, exercising its regulatory jurisdiction.

### Health and Social Care Information Centre

1.230 The Health and Social Care Information Centre should be set up as an organisation tasked with the independent collection, analysis, publication and oversight of healthcare information. This body should house the information functions previously held by the NPSA.

1.231 This body should publish detailed breakdowns of clinically related complaints, SUIs, and other quality-related information.

### Maintenance of an effective health service requires stability

1.232 Before a proposal for any major structural change to the healthcare system is accepted, an impact and risk assessment should be undertaken by the DH and should be debated publicly. The merging of functions between Monitor and the CQC should be planned and timed carefully.

1.233 The NHS Commissioning Board should develop and oversee a code of practice to ensure that any future transitions are planned and managed accordingly, to deliverable timescales, in a candid and comprehensive manner. Corporate memory and information and documentation should be maintained. This code should include transitions between commissioners (eg as new clinical commissioning groups are formed) and guidance to commissioners on managing providers' transitions.

### The Department of Health leadership

1.234 The DH should ensure senior clinical involvement in all decisions which may impact upon patients' safety and well-being.

1.235 DH officials need to connect more to the NHS and its patients, and they need personal contact with those who have suffered poor experiences. Consideration should be given to involving a patient/service user representative service as a consultative forum within the DH.

## Conclusion

1.236 The first inquiry report stated that it should be patients – not numbers – which counted. That remains the view of this Inquiry. The demands for financial control, corporate governance, commissioning and regulatory systems are understandable and in many cases necessary, but it is not the system itself which will ensure that the patient is put first day in and day out. It is the people working in the health service and those charged with developing healthcare policy that need to ensure that is the case.

1.237 The extent of the failure of the system shown in this Inquiry's report suggests that a fundamental culture change is needed. That does not require a root and branch reorganisation – the system has had many of those – but it requires changes which can largely be implemented within the system that has now been created by the new reforms. I hope that the recommendations in this report can contribute to that end and put patients where they are entitled to be – the first and foremost consideration of the system and everyone who works in it.