

Summary

Terms of Reference

1 Our Terms of Reference were:

To inquire into the management of the care of children receiving complex cardiac surgical services at the Bristol Royal Infirmary between 1984 and 1995 and relevant related issues; to make findings as to the adequacy of the services provided; to establish what action was taken both within and outside the hospital to deal with concerns raised about the surgery and to identify any failure to take appropriate action promptly; to reach conclusions from these events and to make recommendations which could help to secure high-quality care across the NHS.

2 The Public Inquiry was conducted between October 1998 and July 2001. The Panel was chaired by Professor Ian Kennedy. The other members were Rebecca Howard, Professor Sir Brian Jarman and Mavis Maclean. The work of the Inquiry was divided into two phases. In Phase One, the focus was on events in Bristol. Evidence from 577 witnesses, including 238 parents, was received in writing. The Inquiry also received 900,000 pages of documents, including the medical records of over 1,800 children. Oral evidence of selected witnesses was taken over 96 days. The focus of Phase Two was the future. One hundred and eighty papers were submitted to seven seminars in which 150 participants from the NHS, and the public and private sectors took part. In May 2000 the Inquiry produced an Interim Report on the Removal and Retention of Human Material.

Synopsis

3 The story of the paediatric cardiac surgical service in Bristol is not an account of bad people. Nor is it an account of people who did not care, nor of people who wilfully harmed patients.

4 It is an account of people who cared greatly about human suffering, and were dedicated and well-motivated. Sadly, some lacked insight and their behaviour was flawed. Many failed to communicate with each other, and to work together effectively for the interests of their patients. There was a lack of leadership, and of teamwork.

5 It is an account of healthcare professionals working in Bristol who were victims of a combination of circumstances which owed as much to general failings in the NHS at the time than to any individual failing. Despite their manifest good intentions and long hours of dedicated work, there were failures on occasion in the care provided to very sick children.

- 6 It is an account of a service offering paediatric open-heart surgery which was split between two sites, and had no dedicated paediatric intensive care beds, no full-time paediatric cardiac surgeon and too few paediatrically trained nurses.
- 7 It is an account of a time when there was no agreed means of assessing the quality of care. There were no standards for evaluating performance. There was confusion throughout the NHS as to who was responsible for monitoring the quality of care.
- 8 It is an account of a hospital where there was a 'club culture'; an imbalance of power, with too much control in the hands of a few individuals.
- 9 It is an account in which vulnerable children were not a priority, either in Bristol or throughout the NHS.
- 10 And it is an account of a system of hospital care which was poorly organised. It was beset with uncertainty as to how to get things done, such that when concerns were raised, it took years for them to be taken seriously.
- 11 The circumstances of Bristol, and the NHS, at the time, led to the system for providing paediatric cardiac surgery (PCS) being flawed. All of these flaws, taken together, led to around one-third of all the children who underwent open-heart surgery receiving less than adequate care. More children died than might have been expected in a typical PCS unit. In the period from 1991 to 1995 between 30 and 35 more children under 1 died after open-heart surgery in the Bristol Unit than might be expected had the Unit been typical of other PCS units in England at the time.
- 12 Our Report contains close to 200 Recommendations. They include the following:
- 13 *Children:* the needs of very sick children in the 1980s and 1990s were not given a high priority. For the future, children in hospital must be cared for in a child-centred environment, by staff trained in caring for children and in facilities appropriate to their needs. A national director for children's healthcare services should be appointed to lead the development of child-centred healthcare.
- 14 *Safety:* the arrangements for caring for very sick children in Bristol at that time were not safe. There was too little recognition that the state of buildings and of equipment, and the training of the staff, could cause actual harm to the children. For the future, the NHS must root out unsafe practices. It must remove barriers to safe care. In particular, it must promote openness and the preparedness to acknowledge errors and to learn lessons. Healthcare professionals should have a duty of candour to patients. Clinical negligence litigation, as a barrier to openness, should be abolished. Safe care should be promoted and led by a non-executive member of every trust board.
- 15 *The competence of healthcare professionals:* there was no requirement on hospital consultants at that time (nor is there now) to keep their skills and knowledge up to date. Surgeons were able to introduce new techniques without any formal system of

- notification. For the future, it must be part of all healthcare professionals' contracts with a trust (and part of a GP's terms of service) that they undergo appraisal, continuing professional development and revalidation to ensure that all healthcare professionals remain competent to do their job.
- 16** *Organisation:* consultants enjoyed (and still enjoy) what is virtually a job for life. Their relationship with the trust that employs them makes it difficult to bring about change. All employees should be treated in a broadly similar manner. Doctors, nurses and managers must work together as healthcare professionals, with comparable terms of employment and clear lines of accountability, in order to provide the best possible care for patients.
 - 17** *Standards of care:* parents taking their children to be treated in Bristol assumed that the level of care provided would be good. Their children were cared for in a 'supra regional centre' designated as such by the Department of Health. They trusted the system. Few had any idea that there were no agreed standards of care for PCS or for any other specialty. For the future, there must be two developments. There must be agreed and published standards of clinical care for healthcare professionals to follow, so that patients and the public know what to expect. There must also be standards for hospitals as a whole. Hospitals which do not meet these standards should not be able to offer services within the NHS.
 - 18** *Openness:* Bristol was awash with data. There was enough information from the late 1980s onwards to cause questions about mortality rates to be raised both in Bristol and elsewhere had the mindset to do so existed. Little, if any, of this information was available to the parents or to the public. Such information as was given to parents was often partial, confusing and unclear. For the future, there must be openness about clinical performance. Patients should be able to gain access to information about the relative performance of a hospital, or a particular service or consultant unit.
 - 19** *Monitoring:* the clinicians in Bristol had no one to satisfy but themselves that the service which they provided was of appropriate quality. There was no systematic mechanism for monitoring the clinical performance of healthcare professionals or of hospitals. For the future there must be effective systems within hospitals to ensure that clinical performance is monitored. There must also be a system of independent external surveillance to review patterns of performance over time and to identify good and failing performance.
 - 20** The aim of these and all our recommendations is to produce an NHS in which patients' needs are at the centre and in which systems are in place to ensure safe care and to maintain and improve the quality of care.

The adequacy of the paediatric cardiac surgical service in Bristol

- 21** We concentrate on open-heart surgery on children under 1. We adopt a ‘systems’ approach to analysis, by which poor performance and errors are seen as the product of systems which are not working well, as much as the result of any particular individual’s conduct. We acknowledge at the outset that in a number of ways the service was adequate or more than adequate. The great majority of children who underwent PCS in Bristol are alive today.
- 22** *Our overall conclusion, however, is that the PCS service for children who received open-heart surgery was, on a number of criteria, less than adequate.*
- 23** To the extent that it is based on reliable and verifiable evidence, this is the judgment of hindsight. At the time, while the PCS service was less than adequate, it would have taken a different mindset from the one that prevailed on the part of the clinicians at the centre of the service, and senior management, to come to this view. It would have required abandoning the principles which then prevailed: of optimism, of ‘learning curves’, and of gradual improvements over time. It would have required them to adopt a more cautious approach rather than ‘muddling through’. That this did not occur to them is one of the tragedies of Bristol.
- 24** We reach one conclusion which owes nothing to hindsight. There was poor teamwork and this had implications for performance and outcome. The crucial importance of effective teamwork in this complex area of surgery was very widely recognised. Effective teamwork did not always exist at the BRI. There were logistical reasons for this: for example the cardiologists could not be everywhere. The point is that everyone just carried on. In addition, relations between the various professional groups were on occasions poor. All the professionals involved in the PCS service were responsible for this shortcoming. But, in particular, this poor teamwork demonstrates a clear lack of effective clinical leadership. Those in positions of clinical leadership must bear the responsibility for this failure and the undoubtedly adverse effect it had on the adequacy of the PCS service.
- 25** The Experts to the Inquiry advised that Bristol had a significantly higher mortality rate for open-heart surgery on children under 1 than that of other centres in England. Between 1988 and 1994 the mortality rate at Bristol was roughly double that elsewhere in five out of seven years. This mortality rate failed to follow the overall downward trend over time which can be seen in other centres. Our Experts’ statistical analysis also enabled them to find that a substantial and statistically significant number of excess deaths, between 30 and 35, occurred in children under 1 undergoing PCS in Bristol between 1991 and 1995. As our Experts make clear, ‘excess deaths’ is a statistical term which refers to the number of deaths observed over and

above the number which would be expected if the Unit had been 'typical' of other PCS units in England. The term does not refer to any particular child's death. The mortality rate over the period 1991–1995 was probably double the rate in England at the time for children under 1, and even higher for children under 30 days. This higher mortality rate in Bristol was not restricted to the neonatal Switch and Atrio-Ventricular Septal Defect (AVSD) operations. Even without taking these two higher-risk groups into account, there was considerable evidence of divergent performance in Bristol. Further, differences in mortality rates in Bristol could not be accounted for on the ground of case mix (an explanation which some clinicians both then and even now have adopted). We note a failure to progress, rather than necessarily a deterioration in standards.

Particular elements of the PCS service which were less than adequate

The system and culture of management in Bristol

- 26** Bristol was not unusual in having problems. It was, after all, managing the transition from the known (the old NHS) to the unknown (Trust status). Problems arise in all institutions. But it is incumbent on senior management to devise systems which respond quickly and effectively to these problems. What was unusual about Bristol was that the systems and culture in place were such as to make open discussion and review more difficult. Staff were not encouraged to share their problems or to speak openly. Those who tried to raise concerns found it hard to have their voice heard.
- 27** We accept that Dr Roylance, the Chief Executive of the Trust, was both thoughtful and principled in his development of a management system for what was one of the newest and largest trusts in England. He also succeeded in meeting the principal obligation of balancing the books. Sadly, a system of separate and virtually independent clinical directorates, combined with a message that problems were not to be brought to the Chief Executive for discussion and resolution, meant that there was power but no leadership. The environment was one in which problems were neither adequately identified nor addressed.
- 28** Nor were there effective measures outside Bristol to monitor the approach adopted by Dr Roylance. This was a feature of the NHS reforms in 1989–1991. Senior managers were invited to take control, but little or no system existed to monitor what they did in the exercise of that control. Indeed, it did not really exist inside the Trust either. The Chairman and the Trust Board were either part of the 'club' or treated as outsiders. Referring to information about the outcome of care, Mr McKinlay, the Chairman of the United Bristol Hospital Trust (UBHT) from 1994 onwards, told us that:

'... there was no tradition or culture in UBHT that the Board or the committees of the Board should be involved ... I thought that was something that was wrong. I thought the Board should have some knowledge of statistical outcome, but there was a tightrope to be trod to find a way of easing it into place.'

The PCS service

29 The adequacy of the PCS service in Bristol was undermined by the fact that it was divided between two sites, with cardiologists in one hospital and surgeons in another. The cardiologists, who were well regarded throughout the South West, were understaffed. There was a national shortage of specialists in paediatric cardiology. Among other things this meant that the cardiologists at Bristol could not effectively participate in surgery or intensive care. In addition, the prevailing national shortage in nurses trained in caring for children was reflected in Bristol. The surgeons operated on adults as well as children; and the children were nursed alongside adults in a mixed Intensive Care Unit (ICU). While there was an effective child-centred approach to care at the Children's Hospital, this was not so in the BRI where open-heart surgery was carried out and where the management of care in the ICU was described as 'highly disorganised with conflicting decisions'. It was never really clear who was in charge.

Monitoring the quality of care

30 At a national level there was confusion as to who was responsible for monitoring quality of care. The confusion was not, however, just some administrative game of 'pass the parcel'. What was at stake was the health, welfare, and indeed the lives of children. What was lacking was any real system whereby any organisation took responsibility for what a lay person would describe as 'keeping an eye on things'. The Supra Regional Services Advisory Group (SRSAG) thought that the health authorities or the Royal College of Surgeons was doing it; the Royal College of Surgeons thought the SRSAG or the Trust was doing it, and so it went on. No one was doing it. We cannot say that the external system for assuring and monitoring the quality of care was inadequate. There was, in truth, no such system.

31 At a local level, although information arising from reviews of PCS emerged only rarely in the formal structures for audit within the Trust, or in the Trust's dealings with the District Health Authority, a good deal of activity did, in fact, take place. Moreover, it pre-dated the introduction of the formal system of medical audit in 1990. The clinicians involved in providing the PCS service collected, recorded and analysed data on procedures and deaths, set up and maintained computerised information systems, produced and circulated figures and reports, made annual returns to the national UK Cardiac Surgical Register (UKCSR) and received back aggregated data about national performance. They also held regular meetings to discuss the results of audit, and reviewed individual cases and series of cases.

The views of parents

32 The evidence of parents was mixed. To some, the staff, doctors, nurses and others were dedicated and caring and could not have done more. To others, some staff were helpful while others were not. To others again, the staff, largely the doctors and particularly the surgeons, were uncaring and they misled parents.

33 While the evidence is polarised, there is a strong sense that on many occasions communication between parents and some staff was poor. There does not appear to have been any deep thinking about how to communicate information to parents in

advance of surgery, nor any systematised approach to doing so. While some parents felt that they had been significantly helped to understand what the surgery and subsequent intensive care involved, we were also told of doctors and nurses drawing diagrams on scraps of paper, or even a paper towel. The sense is gained that informing parents and gaining their consent to treatment was regarded as something of a chore by the surgeons.

- 34** As regards the process of gaining consent to surgery, it is difficult to imagine a more stressful time for parents whose children were about to undergo surgery. Their child was facing a major operation with an uncertain outcome and, to add to their great anxiety, they had the burden of responsibility of saying 'yes' or 'no' to that operation. That being so, the sharing of information should be a process. There must be time to take in what has been said by the clinicians, to reflect on it and to raise questions. This does not seem to have been the practice at Bristol, but neither would it have been regarded as poor practice elsewhere during the relevant period. With the benefit of hindsight it is clear that much distress and unhappiness will result if parents are not sympathetically allowed to find out what they wish to know about what is facing their child. It should not be a question of the healthcare professional judging what the parent needs to know: it is the parent who should make that decision. At the time, however, the prevailing view was that parents should be protected from too much information.
- 35** Some parents told us that they were given support and counselling, and commented favourably on it. When, sadly, their child died, many parents were critical about the way in which the news was broken. Some said that they received no counselling. The United Bristol Healthcare Trust (UBHT) conceded in its evidence that the service it provided was insufficient to meet the needs of some parents. We were impressed, however, by the sensitivity and support shown by the nursing staff.

Conclusions on the adequacy of the service

- 36** The system for delivering PCS services in Bristol was frankly not up to the task. What we observed amounts to a failure of PCS services to thrive. There is real room for doubt as to whether open-heart surgery on the under-1s should have been designated a supra regional service in Bristol. With the benefit of hindsight, designation has all the qualities of a Greek tragedy: we know the outcome and yet are unable, from our point in time, to prevent it unfolding. Once designated, however, it simply never developed sufficiently well. We observe a paediatric open-heart service with high aspirations (including at one stage the ambition to become a centre for heart transplantation) simply overreaching itself, given its limitations, and failing to keep up with the rapid developments elsewhere in PCS during the late 1980s and early 1990s. In summary, opportunities were not taken. Exhaustion and low morale led to stagnation and an inability to move forward in response to new developments, despite the stimulus provided by a new generation of consultants.

- 37** The split site and consequent split service were clearly major factors affecting the adequacy of care. Unifying the site did not attract sufficient priority in the struggle for resources: the claims for the PCS service made by some of the clinicians were not seen as important enough. But this did not cause the clinicians to cease to offer the service. There seems to have been an overriding sense of pressing on and hoping that one day the service would be moved onto one site, that the new hospital for children would be built, that the new surgeon would arrive, and that all would then be well.
- 38** Throughout the Inquiry we heard evidence of underfunding in Bristol meaning that a gap had developed between the level of resources needed properly to meet the stated goals of the PCS unit and the level actually available. There were constant shortages in the supply of trained nursing staff, both for the operating theatre and the ICU. The complement of cardiologists and surgeons was always below the level deemed appropriate by the relevant professional bodies. The consultant cardiologists lacked junior support. They were expected to care for children in the Children's Hospital, and in the BRI operating theatre and ICU several hundred yards away down a steep hill, and to hold outreach clinics all over the South West and South Wales. The care of children undergoing PCS was split between two separate sites. Facilities for parents, and necessary medical equipment for children, had to be funded through the good offices of a charity, The Heart Circle.
- 39** It is crucial, however, to make clear the following. The inadequacy in resources for PCS at Bristol was typical of the NHS as a whole. From this, it follows that whatever went wrong at Bristol was not *caused* by lack of resources. Other centres laboured under the same or similar difficulties. For example, the shortage in qualified nurses and in cardiologists was a national phenomenon, affecting all centres. We therefore emphasise the point again that, while under-funding blighted the NHS as a whole, it does not alone provide the explanation for what went wrong in Bristol.
- 40** We note that in 2000, at last, the present Government acknowledged the gap between claim and reality in the NHS. A significant boost in funding was announced. A further commitment was made to align spending on the NHS with the average amount spent on healthcare in Europe. This development has been widely welcomed and is seen as a long-overdue recognition of the need for more resources. But, we add a caution. We have every reason to believe that to achieve what was set out in '*The NHS Plan*' and is contemplated by our Report, there must be a sustained increase in funding year-on-year.

Concerns raised and failures to take appropriate action promptly

- 41** Concerns about the PCS service in Bristol were first raised as early as 1986–1987. From 1988, concerns began to be raised in the BRI. Dr Bolsin first wrote to Dr Roylance in 1990 and, thereafter, Dr Bolsin collected data and took them to an increasing number of colleagues. No one ever said he was wrong to do this; rather he was told to take care to verify his information and discuss it with colleagues, including those whose work gave rise to his concern. A member and an official of the SRSAG had evidence by 1992 that Bristol was performing badly in terms of mortality, yet did not share this information with the Group as a whole. The clinicians in Bristol at least by 1990 had data on their own poor performance relative to that in other centres in the UK which could have caused them at least to pause and reflect. Instead, in keeping with the mindset of the time, they pressed on, drawing false comfort from their figures for 1990 (which proved to be an exception), and only belatedly ceasing to carry out certain operations on children under 1. An opportunity was not taken in July 1994 by an official of the Department of Health to investigate more closely the outcomes of PCS in the under 1s. It was only in 1995 that PCS was formally stopped (although some operations were still carried out after then) until a newly-appointed paediatric cardiac surgeon took up his appointment.
- 42** From the start of the 1990s a national database existed at the Department of Health (the Hospital Episode Statistics database) which among other things held information about deaths in hospital. It was not recognised as a valuable tool for analysing the performance of hospitals. It is now, belatedly.
- 43** We stress again that, to a very great extent, the flaws and failures of Bristol were within the hospital, its organisation and culture, and within the wider NHS as it was at the time. That said, there were individuals who, in our view, could and should on occasions have behaved differently. In the final stages of the Inquiry, each was advised that the Inquiry was minded to comment adversely on some particular aspect of his or her conduct or behaviour, whether a particular incident or a pattern of behaviour, and was told of the evidence on which the Inquiry relied. Each had an opportunity to make representations. Those representations were taken account of by the Inquiry in reaching its conclusions. We emphasise that it would be unfair to those named to seek to set out in a Summary a condensed version of the evidence supporting our adverse comments. The relevant evidence can be found in Section One of the Report and in Annex A. We also emphasise that such adverse comments as we make must be seen against the background of the Report as a whole in which we also have occasion to make favourable comments.

Within the Bristol hospitals

- 44 The Inquiry concluded that in *certain respects* adverse comments should be made regarding certain individuals, some of whom displayed flaws in their approach to management. Others showed a lack of leadership and insight. And some failed to treat parents with appropriate respect and candour.
- 45 Such comments are made in respect of the following as regards the roles they held at the time: Dr Roylance (Chief Executive, UBHT), Mr Wisheart (Cardiothoracic Surgeon and Medical Director, UBHT), Mr Dhasmana (Cardiothoracic Surgeon and Associate Clinical Director in Cardiac Surgery, UBHT), Dr Joffe (Clinical Director Children's Services, UBHT) and Mrs Maisey (Director of Operations and Nurse Adviser, UBHT).

Outside the Bristol hospitals

- 46 In the general confusion as to who was responsible for monitoring the quality of PCS services, there were occasions on which action could have been taken by a member and an official of the Supra Regional Services Advisory Group and an official of the Department of Health.
- 47 The Inquiry concluded that *in certain respects*, when concerns were raised, the following individuals, in the roles they then occupied, should have behaved differently: Dr Halliday (Medical Secretary, Supra Regional Services Advisory Group), Dr Doyle (Senior Medical Officer, Department of Health) and Sir Terence English (Member of the Supra Regional Services Advisory Group and President of the Royal College of Surgeons).

The future:

- 48** We are required to ‘make recommendations to secure high quality care across the NHS’.
- 49** We must learn the lessons of Bristol. Even today it is still not possible to say, categorically, that events similar to those which happened in Bristol could not happen again in the UK; indeed, are not happening at this moment.
- 50** That said we must not lose a sense of proportion. Every day the NHS provides a service to hundreds of thousands of patients, with which patients are satisfied and of which healthcare professionals can justifiably be proud.
- 51** In making our recommendations our guiding principles were:
- The complexity of the NHS as an organisation must be recognised.
 - Patients must be at the centre of the NHS, and thus the patient’s perspective must be included in the policies, planning and delivery of services at every level.
 - The dedication and commitment of NHS staff is and must remain at the core of the service.
 - The quality of healthcare must include all aspects of care: clinical and non-clinical.
 - Patients’ safety must be the foundation of quality.
 - Systems of care, and facilities, as well as individuals, affect the quality of healthcare.
 - Learning from error, rather than seeking someone to blame, must be the priority in order to improve safety and quality.
 - Openness and transparency are as crucial to the development of trust between healthcare professional and patient, as they are to the trust between the NHS and the public.
 - The particular needs of children’s healthcare services must be addressed.

The care of children

Children and their healthcare needs must be given higher priority in the NHS

- 52 Healthcare services for children are still, generally, fragmented and uncoordinated. While well-established guidance on such matters as standards of care and staffing levels exists, the extent to which it is implemented varies widely. Had it been implemented in Bristol a good number of shortcomings in care would have been addressed much earlier.
- 53 The announcement by the Government of a separate National Service Framework for Children is to be welcomed. The healthcare needs of children are different from those of adults and this must be recognised. As Liz Jenkins, Assistant General Secretary of the Royal College of Nursing, told us: 'I do think that the majority of adult qualified nurses and doctors see children as small adults, who simply need smaller beds and smaller portions of food'.
- 54 There must be greater integration of children's health services. We were particularly impressed by the approach of the Philadelphia Children's Hospital. A pilot project based on it should be launched whereby a large children's hospital takes responsibility for the management of children's healthcare in hospitals in a particular area.
- 55 The optimal arrangement for children's acute hospital services is in a children's hospital, close to an acute general hospital. Specialist care must be concentrated in a limited number of centres where the staff have the necessary skill and experience.
- 56 There must be standards for the care of children, some of which must be mandatory. There must be incentives to improve children's care. There must be plans for the publication of information about the quality and performance of children's healthcare services.
- 57 There must be a voice for children's healthcare. At a national level, there should be a national director for children's healthcare services in the NHS. In the trust, an executive member of the board should be responsible for the protection of children's interests.
- 58 All healthcare staff who treat children must have training in caring for children. They should also be trained in communicating with young people and parents.

The culture of the NHS

- 59 The culture of the future must be a culture of safety and of quality; a culture of openness and of accountability; a culture of public service; a culture in which collaborative teamwork is prized; and a culture of flexibility in which innovation can flourish in response to patients' needs.

Respect and honesty

Patients in their journey through the healthcare system are entitled to be treated with respect and honesty and to be involved, wherever possible, in decisions about their care

- 60 The quality of healthcare would be enhanced by a greater degree of respect and honesty in the relationship between healthcare professional and patient. Good communication is essential, but as the Royal College of Surgeons of England told us: '... it is the area of greatest compromise in the practices of most surgeons in the NHS and the source of most complaints'.
- 61 Future doctors, nurses and other healthcare professionals must be adequately trained in communication skills during their initial education.
- 62 Partnership between patient and healthcare professional is the way forward. The exchange and provision of information is at the core of an open and honest relationship between healthcare professionals and patients. There are four fundamental principles which should in future underpin any policy aimed at meeting patients' needs for information. First, trust can only be sustained by openness. Secondly, openness means that information be given freely, honestly and regularly. Thirdly, it is of fundamental importance to be honest about the twin concerns of risk and uncertainty. Lastly, informing patients, and in the case of young children their parents, must be regarded as a process and not a one-off event.
- 63 Hospitals must have an integrated system of support and counselling for patients and carers, staffed by well-trained professionals with links to systems outside. Such a system is central to care, not an add on.
- 64 There should be a clear system in the form of a 'one-stop shop' in every trust for addressing the concerns of patients about the care provided or the conduct of a healthcare professional.

- 65 When things go wrong hospitals and healthcare professionals have a duty of candour: to be open and honest. Not only does this show respect to patients; an error, once acknowledged, also allows lessons to be learned.

A Health Service which is well led

Patients are entitled to expect that both the NHS and the hospital in which they are cared for is well led

- 66 The highest priority still needs to be given to improving the leadership and management of the NHS at every level.
- 67 The role of government as regards the NHS in relation to the quality of care is twofold: to manage the NHS, and to organise good, comprehensive and independent systems to regulate the quality of healthcare.
- 68 Chief executives of trusts, particularly now that they are legally responsible for monitoring and improving the quality of healthcare, must be supported and enabled to carry out this duty. In particular, all employees, including consultants, must have a similar employment relationship with the trust.
- 69 Trust boards must be able to lead healthcare at the local level. Executive directors should be selected on agreed criteria and appropriately trained. Non-executives should play an active role in the affairs of the trust.
- 70 The quality of healthcare should be regulated through bodies such as the National Institute for Clinical Excellence and the Commission for Health Improvement. These bodies should be independent of government. There should be an independent overarching body, the Council for the Quality of Healthcare, to co-ordinate and integrate the activities of these bodies. This Council would report both to the Department of Health and to Parliament.

Competent healthcare professionals

A patient is entitled to be cared for and by healthcare professionals with relevant and up-to-date skills and expertise

- 71 The education of healthcare professionals in communication skills, the principles and organisation of the NHS, the development of teamwork, shared learning across

- professional boundaries, clinical audit, and leadership should be given greater priority.
- 72 Medical schools, schools of nursing and management schools should be encouraged to develop joint courses. Future healthcare professionals must work in multidisciplinary teams; shared learning should therefore begin as soon as possible. A common curriculum for the first year of undergraduate education of all healthcare professionals should be developed through a pilot project.
 - 73 A system of regulation should be in place to ensure that healthcare professionals acquire and maintain professional competence. Regulation includes education, registration, training, continuing professional development, revalidation and discipline.
 - 74 Medical schools must ensure that the criteria for selecting future doctors include the potential to be versatile, flexible and sensitive. They must also ensure that healthcare professionals are not drawn from too narrow an academic and socio-economic base.
 - 75 Continuing Professional Development (CPD), periodic appraisal and revalidation must be compulsory for all healthcare professionals. There should be an overarching mechanism to co-ordinate and align the activities of the various bodies (the General Medical Council (GMC), the Nursing and Midwifery Council (NMC) and others) to ensure that they serve patients' interests. This mechanism should be a new independent Council for the Regulation of Healthcare Professionals (in effect, the body currently proposed in '*The NHS Plan*'). This Council too should report to the Department of Health and to Parliament.
 - 76 Senior managers in the NHS should be subject to CPD, periodic appraisal and revalidation.
 - 77 There should be positive incentives to encourage senior clinicians to take on senior managerial roles, including special categories of registration with professional bodies and the ability to move out of and back into clinical practice after suitable retraining. There should be appropriate training for senior clinicians before taking on these roles.
 - 78 Where surgeons or other clinicians undertake an invasive clinical procedure for the first time, they should be properly trained and directly supervised, if the procedure is already established. In the case of a new, untried invasive clinical procedure they must seek permission from the local research ethics committee for permission. Patients are entitled to know what experience the surgeon or clinician has before giving consent.
 - 79 It must be the employer first and foremost who should be able to deal with poor performance and misconduct. Professional Codes of Conduct should be incorporated into healthcare professionals' contracts. It is for the relevant professional regulatory

body to decide whether the healthcare professional's registration should be affected. For doctors, this body should be the GMC, for nurses the NMC.

The safety of care

Patients are entitled to care that is safe

- 80** Around 5% of the 8.5 million patients admitted to hospitals in England and Wales each year experience an adverse event which may be preventable with the exercise of ordinary standards of care. How many of these events lead to death is not known but it may be as high as 25,000 people a year.
- 81** The components of safe care are much more than the actions or competence of healthcare professionals: they include the physical environment, equipment, working arrangements, teamwork and good communication.
- 82** The NHS is still failing to learn from the things that go wrong and has no system to put this right. This must change.
- 83** A culture of safety in which safety is everyone's concern must be created. Safety requires constant vigilance. Given that errors happen, they must be analysed with a view to anticipate and avoid them.
- 84** A culture of safety crucially requires the creation of an open, free, non-punitive environment in which healthcare professionals can feel safe to report adverse events and near misses (sentinel events).
- 85** The Government's proposed National Patient Safety Agency should be an independent agency to which certain sentinel events are reported so as to be analysed with a view to disseminating lessons throughout the NHS.
- 86** The culture of blame is a major barrier to the openness required if sentinel events are to be reported, lessons learned and safety improved. The system of clinical negligence is part of this culture of blame. It should be abolished. It should be replaced by effective systems for identifying, analysing, learning from and preventing errors and other sentinel events. An expert group should consider alternatives to clinical negligence, including an alternative administrative system of compensating those who suffer harm arising from medical care.
- 87** Incentives for reporting sentinel events should be introduced, whereby healthcare professionals' contracts would provide that they would be immune from disciplinary action from their employer or professional regulatory body if they were to report a

sentinel event within 48 hours. Confidential reporting should be provided for. Failure to report would attract possible disciplinary action.

- 88 An approach to safety based on designing safer systems and equipment should be encouraged. The National Patient Safety Agency should bring together interested parties to tackle some of the more persistent causes of unsafe practices.
- 89 At trust board level, an executive director should be responsible for putting into operation the trust's strategy and policy on safety and a non-executive director should provide leadership to promote a culture of safety.

Care of an appropriate standard

Patients are entitled to care and treatment of an appropriate standard informed by current knowledge

Clinical standards for the care of patients

- 90 Until well into the 1990s, the notion that there should be explicit standards of care which all healthcare professionals should seek to meet and which would apply to patients across the NHS, simply did not exist. It is now widely accepted that this state of affairs has to change. Patients are entitled to expect that their care will be of such quality as is consonant with good practice, based on sound evidence. Recent developments give cause for optimism. These include statutory responsibility of trusts for the quality of healthcare, the development of clinical guidelines through the National Institute for Clinical Excellence, and the monitoring of performance through the Commission for Health and Improvement.
- 91 There remains insufficient co-ordination in setting standards. Guidelines appear from a variety of bodies giving rise to confusion and uncertainty. Moreover, there are weaknesses in monitoring performance in relation to these standards, whether at the level of the trust or nationally. In particular there is no mechanism for surveillance to ensure that patterns of poor performance are recognised and addressed.
- 92 For the future, standards for clinical care must be set by the National Institute for Clinical Excellence. In doing so, it must draw on the expertise particularly of the Royal Colleges. Standards must be patient-centred. They must not be the product of individual professional groups talking to themselves. They must incorporate the concept of teamwork and the respective responsibilities of members of the team. Some standards should be obligatory, some to be achieved over time.

Generic standards for healthcare institutions

- 93 All hospitals must meet certain standards (generic standards). Those which do not should not be permitted to provide NHS services. Generic standards relate to such matters as the state of the buildings and of equipment, the quality of leadership and the trust's policies and procedures for ensuring that care is safe and of good quality.
- 94 Trusts must periodically undergo a process of validation and revalidation (akin to licensing), to ensure that they meet these standards. Revalidation would mean that the trust could continue to offer healthcare services. The Commission for Health Improvement would be responsible for the process of validation. In time the process of validation should be extended to discrete, identifiable services within a trust. A pilot project involving children's acute hospital services and paediatric cardiac surgery in particular should be carried out.
- 95 Information about performance in the NHS is the basic building block of any system of standards and quality. In the past, there have been great difficulties in collecting information. There has also been a separation between administrative and clinical systems which our Experts described as 'wasteful and anachronistic'.
- 96 For the future the multiple methods and systems for collecting data must be reduced. Data must be collected as the by-product of clinical care.
- 97 At a national level, the monitoring of clinical performance should be brought together and co-ordinated by one body, an independent Office for Monitoring Healthcare Performance which would be part of the Commission for Health Improvement. It could also carry out a surveillance role.

Public involvement through empowerment

The public are entitled to expect that means exist for them to become involved in the planning, organisation and delivery of healthcare

- 98 A patient-centred service is one that is designed and planned to address the needs of the particular sectors of the public it exists to serve. Strategic planning at national level, and decisions at local level must involve the public.
- 99 In its everyday working the NHS must take account of and respond to the interests and needs of the public.
- 100 The public must be involved in those processes designed to secure the competence of healthcare professionals, particularly in those bodies charged with setting standards for education, training and Continuing Professional Development.

101 The principles which should inform future policy about involving the public and patients in the NHS include:

- Patients and the public are entitled to be involved wherever decisions are taken about care in the NHS.
- The involvement of patients and the public must be embedded in the structures of the NHS and permeate all aspects of healthcare.
- The public and patients should have access to relevant information.
- Healthcare professionals must be partners in the process of involving the public.
- There must be honesty about the scope of the public's involvement, since some decisions cannot be made by the public.
- There must be transparency and openness in the procedures for involving the public and patients.
- The mechanisms for involvement should be evaluated for their effectiveness.
- The public and patients should have access to training and funding to allow them fully to participate.
- The public should be represented by a wide range of individuals and groups and not by particular 'patients' groups'.

102 The priority for involving the public should be that their interests are embedded into all organisations and institutions concerned with quality of performance in the NHS: in other words, the public should be 'on the inside', rather than represented by some organisation 'on the outside'.

