

The Report of the Public Inquiry
into children's heart surgery
at the Bristol Royal Infirmary
1984-1995

Learning from Bristol



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Presented to Parliament by
the Secretary of State for Health
by Command of Her Majesty
July 2001

Foreword

It is my privilege to present this Report, as Chairman of the Inquiry. I do so in the hope that it will achieve two principal aims. First, I hope that it will allow a better understanding of what happened in relation to paediatric cardiac surgery in Bristol in the 1980s and 1990s. There were failings both of organisations and of people. Some children and their parents were failed. Some parents suffered the loss of a child when it should not have happened. A tragedy took place. But it was a tragedy born of high hopes and ambitions, and peopled by dedicated, hard-working people. The hopes were too high; the ambitions too ambitious. Bristol simply overreached itself. Many patients, children and adults benefited; too many children did not. Too many children died.

A Public Inquiry cannot turn back the clock. It can, however, offer an opportunity to let all those touched by the events, in our case Bristol, be heard and to listen to others. Through this process can come understanding. We tried to provide this opportunity. The understanding we formed is set out in Section One of our Report. It speaks of an organisation which was not up to the task; of confusion and muddle as to where responsibility lay for making sure that the quality of care provided to children was good enough; and of a system of care blighted by being split between two sites, by shortages of trained staff and by inadequate facilities.

It would be reassuring to believe that it could not happen again. We cannot give that reassurance. Unless lessons are learned, it certainly could happen again, if not in the area of paediatric cardiac surgery, then in some other area of care. For this reason we have sought to identify what the lessons are and, in the light of them, to make recommendations for the future. This is the second of our aims. It is what Section Two of our Report addresses. We offer our view of the way forward for the NHS: an NHS fit for the 21st century. The scale of the enterprise is considerable. So are the time and resources which will be needed to achieve the necessary changes. We make close to 200 recommendations. They are the recommendations of all of us. This is a unanimous Report. Our job is done. It is up to others to decide how to take things forward.

For the Panel it has been a long journey. I pay tribute to the support Rebecca Howard, Brian Jarman and Mavis Maclean have given me throughout. They have tolerated the burdens which I have placed on them with exemplary patience and goodwill. We have worked harmoniously. Throughout, we have had the benefit of a quite outstanding team. It has constituted a rich array of talents: the architects and designers who created the hearing chamber and facilities in Bristol; the teams supporting us in areas such as analysis, administration and IT; the managerial abilities of the Deputy Secretary Zena Muth; the tireless efforts of Becky Jarvis in the final stages of publication; and my personal assistants who in turn managed not only me but such things as trains and hotels with great skill and good humour. Warm thanks are also due to the Inquiry's legal team: the solicitors and paralegals led by Peter Whitehurst and Counsel led by Brian Langstaff QC. They all worked prodigiously hard. I mention also our team of Experts. They helped us enormously. Their work was of the highest standards and often groundbreaking. I single out one person for particular thanks. The Inquiry was fortunate beyond words in having Una O'Brien as its Secretary. I cannot praise her too highly. Her ability, dedication and sheer unremitting hard work represent the finest traditions of public service. Without her we could not have achieved half of what we did. She is owed a singular debt of gratitude.

I hope I can be forgiven for adding an entirely personal note. During the Inquiry's hearings my brother Stuart died. He had contracted hepatitis while operating on a patient. He was a good man and a good doctor. He taught me much. I dedicate any contribution I may make to the future of the NHS to his memory.

Ian Kennedy

July 2001

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Information about reference material, sources of evidence and footnotes

(a) Reference material

Explanation of acronyms: A list of acronyms commonly referred to in the text can be found at the end of the Report in Appendix 1.

People: A list of the full names and titles of those individuals referred to in the text can be found at the end of the Report in Appendix 2.

Further reading: A bibliography of published works which have informed the Panel's work can be found in Annex B.

(b) The Annexes to the Report

There are four Annexes to the Report. They comprise the equivalent of 12,000 pages of text and are available in CD format, attached to the back of the Report.

The Annexes are:

Annex A	A factual account of the evidence heard and received during Phase One (oral hearings) of the Inquiry.
Annex B	A variety of papers including the following:– The procedures of the Inquiry Papers by Experts to the Inquiry The Clinical Case Note Review Papers on statistics.
Annex C	The Inquiry's Interim Report: <i>Removal and retention of human material.</i>
Annex D	The transcript of the oral hearings: a verbatim account of 96 days of evidence.

A more detailed list of contents of the four Annexes is in Appendix 3.

(c) Footnotes

The footnotes in the Report refer to sources of evidence, or provide an explanation, for a particular point. The types of footnote, and the routes for further exploration, are as follows:–

WIT: the prefix WIT denotes a witness statement. WIT 0578 0003 Mr White is a reference to page 3 of Mr White’s statement.
All statements can be found on the Inquiry’s website

T: the prefix T refers to the transcript. T24 p. 16 refers to day 24, page 16. **The full transcript is in Annex D. It is also available on the Inquiry website.**

Other acronyms: A variety of other acronyms occur in the footnotes, particularly in Section One. An example would be UBHT 0065 0027. This refers to a paper given to the Inquiry by the United Bristol Healthcare NHS Trust (UBHT); the number is a unique page reference number assigned by the Inquiry. A full list of all the footnote acronyms can be found in the notes to Annex A.

Common acronyms are:–

UBHT – United Bristol Healthcare NHS Trust

DoH – Department of Health

RCSE – Royal College of Surgeons of England

The vast majority of the documents referred to in Section One are available in Annexes A and B on the accompanying CD.

(d) The Inquiry’s website

The Inquiry’s website www.bristol-inquiry.org.uk will remain available for the foreseeable future. The website includes the full text of the Summary, Final Report, Annexes A–D and all background papers for Phase Two. The website is the only route of access to the statements received from 577 witnesses and to all the formal written comments made about those statements.

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'.

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Introduction

Hugh Ross, present Chief Executive of the United Bristol Healthcare (NHS) Trust, in his closing submission to the Inquiry:

‘... on behalf of United Bristol Healthcare Trust and its predecessor bodies, I should like to say sorry to the children and families of those who used the paediatric cardiac services in Bristol in the past. It is clear to me that a substantial number of parents and children did not receive the standard of care they were entitled to expect. I have seen at first hand how painful and distressing it has been for many parents to remember and reflect again on the events of the past. I would like to pay tribute to their bravery and composure under the most extreme circumstances.’¹

Counsel for the Department of Health, in his closing submission to the Inquiry:

‘... the Department of Health accepts that it is responsible and is accountable for any failings of the systems that were in place during the period covered by the Inquiry. Ultimate responsibility rests with the Department of Health and the Secretary of State.’² ‘... it now seems clear that there was confusion and therefore systemic failings with regard to the way in which the Supra Regional Services Advisory Group dealt with the specialty of neonatal infant cardiac surgery. Sir, may we say that there is no doubt that the diligence of the Inquiry team has uncovered this confusion and the systemic failing which was previously not known to the department. All these are accepted and are a cause of great regret.’³

Janardan Dhasmana, consultant cardiac surgeon at the UBH/T,⁴ at the end of his oral evidence to the Inquiry:

‘All these things, what have they done to me? They have ruined me professionally, financially, my family life has gone and I have lost confidence in myself. This is the first time in the last two years that I have been able to speak to any audience for three days. I was not sure on Monday whether I would be able to really stand up to these questions. Thank God Almighty for giving me the courage. All this courage has really come from support which I had from my close relatives, and there are still patients and parents who have continued to support me, making me feel that I am still trusted in some corners. Again, I emphasise, whatever suffering I have gone through, and I am going through, is no match to the suffering which you had with the loss of your child, and I wish I could turn the clock back. I cannot say any more.’⁵

¹ T96 p. 131–2 Mr Ross

² T96 p. 54 Mr Pirani

³ T96 p. 56–7 Mr Pirani

⁴ We use the term ‘UBH/T’ to refer to that group of hospitals in Bristol which, prior to 1991, comprised the United Bristol Hospitals, and, since 1991, have been known as the United Bristol Healthcare (NHS) Trust. Included within this group of hospitals are the BRI and the BRHSC

⁵ T87 p. 118 Mr Dhasmana

James Wisheart, consultant cardiac surgeon at the UBH/T, at the end of his oral evidence to the Inquiry:

'I wish this evening to repeat and to offer again my deepest regret and sympathy to all parents whose children died at the time of or after their operation. In saying this, my sympathy and regret go to parents and families on all sides of this particular debate. ... the lowest point of a surgeon's life is when a child dies under his or her care.'⁶

Dr Stuart Hunter and Professor Marc de Leval in the 1995 report of their external inquiry wrote:

'It is not possible to determine the cause of these poor results [of the neonatal Arterial Switch operation]. To blame surgical skill as the sole reason would be shortsighted. It is most likely a multifactoral and multidisciplinary problem.'⁷

Susan Francombe, mother of Rebecca, at the end of her oral evidence to the Inquiry:

'... we did have a few hours of that joy that you get with your first born baby, and I think it was important for my husband and I to try and remember her like that.'⁸

Background to this Inquiry

- 1** The Bristol Royal Infirmary (BRI) and the Bristol Royal Hospital for Sick Children (BRHSC)⁹ were and are teaching hospitals associated with Bristol University's Medical School. They looked after patients with heart disease: adults, children and infants. In this Report we are concerned particularly with congenital heart disease: babies born with heart problems, and their subsequent treatment.
- 2** Many such babies are at the very edges of survival. About half of the babies born with congenital heart disease need intervention to help them survive: without treatment their outlook can be bleak. Some, tragically, are beyond help. Over the years treatment became possible; in particular, surgery. One form of surgery, and the one with which we are most concerned, is open-heart surgery. Whereas with closed-heart surgery the operation takes place whilst the heart continues to beat, with open-heart surgery the heart is stopped while the surgery takes place. The blood supply to the child's vital organs is supported by a heart-lung bypass machine.

⁶ T94 p. 195 Mr Wisheart

⁷ UBHT 0052 0268; the first of two drafts of the Hunter/de Leval Report

⁸ T68 p. 28 Susan Francombe

⁹ The BRHSC was also referred to in evidence as the Bristol Children's Hospital (BCH)

- 3 Heart surgery at any age is a risky enterprise. In babies only months old, surgical techniques are at the frontiers of skill and care. The heart, after all, at that point, is barely the size of a walnut. It is not just the operation itself, but the whole process of care, from initial diagnosis to aftercare, which is challenging and complex. Without care, the baby may die or live a short and increasingly blighted life. With care, the baby may live to adulthood and enjoy a relatively normal life, notwithstanding that further operations may be needed.
- 4 Over the decades from the 1960s, the skills and techniques involved in caring for those born with congenital heart disease have developed such that the very difficult has become almost routine, and boundaries of the possible have been continually pushed out. This is a tribute to the extraordinary skills and dedication of those working in this area of care: the surgeons, the cardiologists, the anaesthetists, the nurses, and the various technical support staff. But open-heart surgery on babies is a risky enterprise. It can never be free of risks: the more difficult the problem, the greater the risk.
- 5 Bristol had a group of clinicians who brought these developments in open-heart surgery to patients living in the South West of England and South Wales. This area historically had been neglected in terms of its share of the resources of the NHS. This neglect was reflected in the resources available for cardiac surgical care. National shortages in such specialists as paediatric cardiologists or paediatric nurses were, therefore, experienced more keenly in the South West. Moreover, shortages of resources were not only reflected in the revenue available to employ staff, but also in the capital available for buildings and equipment. But this was the NHS at that time. All who worked in it sought to transcend these difficulties.
- 6 In the early 1980s, the then Department of Health and Social Security (DHSS) established a system whereby certain very specialised services should be funded centrally. The aim was to concentrate resources and expertise. The system, establishing what were called Supra Regional Services (SRS), was intended to control the proliferation of units. This, in turn, it was hoped, would avoid the risk of too many units expending large amounts of resources doing only a few procedures. It would also mean that the clinicians involved would encounter a sufficient number of what were rare cases to acquire the necessary experience and expertise. Paediatric cardiac surgery (PCS) was one of the services deemed suitable for categorisation as an SRS. The service was, somewhat arbitrarily, limited to paediatric cardiac surgery on newborn and infant children up to 1 year of age. Bristol in 1984 was made one of the nine designated centres. At the same time, Bristol also continued to carry out heart surgery on children over 1 year old.
- 7 In 1984, therefore, at the start of the period of the years of our Terms of Reference, there was a designated service for babies under 1 year old, which involved open-heart surgery at the BRI and closed-heart surgery at the BRHSC. There was also a service funded from local sources for children over 1 year old, similarly divided between the two hospitals.

- 8** One assumption in the process of designation was that a unit should undertake a certain volume of cases to ensure good results in this very exacting field. The reasoning is readily understandable, if not proven: the more you practise, the better you become and the more likely you are, over time, to meet the complete range of what are, in any event, rare conditions. Bristol at the time of designation performed very few open-heart operations on children under 1. Over the ten years as an SRS centre, Bristol never achieved the numbers deemed appropriate.
- 9** Adverse comments about aspects of Bristol's performance surfaced from time to time. It needs to be appreciated, however, that the word 'performance' was understood in different ways over time. On one interpretation, performance was equated with throughput (the number of cases treated). This was relevant both because of the assumption of a relationship between the volume of cases treated and the development of professionals' skills, and also because funding was based on treating a targeted number of cases. Performance could also refer to the quality of care, not least the outcome, be it recovery, residual disability or death. This is the meaning which patients, parents and healthcare professionals were concerned with, although it may not have been the meaning ascribed by others concerned to measure other things.
- 10** It was recognised in Bristol and in the DHSS that the circumstances under which PCS was carried out in Bristol were capable of improvement. From the early 1980s plans were laid to consolidate the service on one site in the wholly paediatric-oriented environment at the BRHSC. This would avoid the need to carry out the open-heart surgery at the BRI in a context in which children were treated and cared for alongside (and to a degree in competition with) adults. It was also planned to appoint a paediatric cardiac surgeon, that is, a heart surgeon who would operate only on children, and not, as was the case with the cardiac surgeons in Bristol, also carry out operations on adults with acquired heart disease. These plans did not come to fruition until 1995.
- 11** Meanwhile, from the late 1980s onwards, doubts and concerns about aspects of the performance of the Bristol Unit were increasingly expressed in a variety of contexts. Some of these concerns were expressed by healthcare professionals working in the Bristol Unit. Others were expressed by individuals in a variety of contexts outside the Unit. Concerns also circulated in the form of rumour and some appeared in the form of unattributed reports in the media. An operation performed on Joshua Loveday on 12 January 1995 proved to be the catalyst for action. Joshua died on the operating table. An outside review was instituted. PCS was all but halted until the new surgeon who had already been appointed was in post.
- 12** Complaints were subsequently made to the General Medical Council (GMC) concerning the conduct of two cardiac surgeons, Mr James Wisheart and Mr Janardan Dhasmana, and of the Chief Executive of the Trust, Dr John Roylance. They were found guilty in 1998 of serious professional misconduct. Dr Roylance and Mr Wisheart were erased from the medical register. Mr Dhasmana's registration was made subject to a condition, valid for three years, that he did not operate on children.

The GMC's hearing was limited, both in terms of only examining the role of those appearing before it, and also in terms of the number of cases considered. It examined the cases of only 53 children of whom 29 had died and focused particularly on the Switch operation.

- 13 A group of parents of children who had undergone cardiac surgery at the BRI organised themselves to provide mutual support. In June 1996 the group first called for a Public Inquiry into the PCS services at the BRI.

Establishment of the Inquiry and Terms of Reference

- 14 On 18 June 1998 Frank Dobson MP, then Secretary of State for Health, announced to Parliament the establishment of this Inquiry. 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.'

Interpreting the Terms of Reference

- 15 The Terms of Reference given to the Inquiry constituted a significant challenge. First, we had to conduct a factual inquiry into events, and to reach conclusions about those events. The events took place over a period of 12 years, ending more than three years before the start of the hearings. Second, arising from the conclusions we reached, we were asked to make proposals for improving the quality of care in the NHS: to engage, in other words, in an analysis of how the lessons of Bristol might be applied to the NHS in the future. To achieve these objectives the Inquiry had to constitute itself in different forms, hence the Oral Hearings of Phase One and the Seminars of Phase Two. As well as hearing from parents, the Inquiry also had to consider two quite distinct types of evidence and be assisted by two categories of witness: those involved in caring for children in Bristol and Experts who commented on this care on the one hand, and those with expertise on the wider issues facing the NHS. The challenge was made much greater by the fact that any advice we might give on improving the quality

of care, our second task, while informed by the events in Bristol, was not limited to either Bristol or to PCS, but rather ranged across the acute sector of the NHS. We saw the requirement placed on us as being to address fundamental issues of policy going to the core of the NHS as a whole. We also had to ensure lessons could be learned and appropriate action taken promptly. This was our task.

This Report

- 16** This is the Final Report of the Inquiry. It has two sections. In Section One we set out our understanding of the events which took place at Bristol in the period 1984–1995. It begins by setting the scene, at both a national and a local level, against which the events of Bristol must be understood. There follow three chapters in which we set out the concerns which were expressed at the time and what, if any, action was taken. Finally, we respond to that element in our Terms of Reference which requires us to reach conclusions about the adequacy of care provided to children who underwent PCS.
- 17** In Section Two we look to the future and the lessons that can be learned from what happened at Bristol. This responds to our duty, set out in the final part of our Terms of Reference: ‘to reach conclusions from these events and to make recommendations which could help to secure high quality care across the NHS’.
- 18** The evidence received by the Inquiry is in the public domain. A full account is set out in Annex A. Papers by our Experts and various submissions made to the Inquiry are set out in Annex B.

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The conduct of the Inquiry

- 1 In this chapter we examine the circumstances under which a Public Inquiry comes to be established and propose guidelines for the future. We then set out the principles followed in the conduct of this Inquiry. Given that the Inquiry looked back over a decade and a half, we discuss the dangers of hindsight and how we sought to avoid them. Finally, we describe some of the more important elements of the conduct of the hearings.

Features of a Public Inquiry

Independence

- 2 A Public Inquiry is set up by a relevant government department and funded by that department. Once established, however, it is expected by the public to act independently. Moreover, it is represented, and represents itself, as being independent. Independence includes necessarily being independent of government.
- 3 While this may appear to suggest the possibilities of tension, whether in the working of the Inquiry, or in its capacity to speak its mind in its conclusions and recommendations, we experienced no such tension. When we asked for assistance, it was given promptly by government and, in the great majority of cases, by other public bodies. We pursued whatever lines of enquiry we thought important, sought whatever material we thought relevant, and reached whatever views we thought appropriate.

Statutory powers

- 4 In conducting our Inquiry we were aided by the fact that we were appointed under a statute¹ and, as a consequence, had powers which that statute conferred on us. In particular, we had the power, if necessary, to compel witnesses to attend hearings and require that documents be produced, powers which we only used once (although on two further occasions we had to remind witnesses that we could and would use them). Secondly, we had the power to take evidence on oath or affirmation. We found these powers, particularly the former, essential (if only to be held in reserve). Their existence assured us of compliance, without our having to use them. We are aware that other Public Inquiries have been conducted without such powers (Lord Justice Scott's Inquiry and the BSE Inquiry).² We take the view, however, that the powers which we enjoyed are essential for at least two reasons. First, Public Inquiries are

¹ The National Health Service Act 1977; see Annex A, Chapter 1

² The Inquiry into exports of defence equipment to Iraq, 1996 (Cmnd HC 115); The Inquiry into BSE and variant CJD in the United Kingdom. House of Commons, October 2000. In each of these Inquiries assurances were given that, if statutory powers were needed, they would be granted

almost always established to look into a matter of grave public concern. We think it most important in the process of addressing that concern to be able to show that stones will not be left unturned. In this way confidence in the Inquiry can be more readily obtained. Secondly, we are convinced that, in the circumstances which we were faced with, our having these powers, albeit in reserve, allowed us to achieve the very high level of co-operation which we believe would not otherwise have been the case.

Whether an Inquiry should be a Public Inquiry

- 5 Many Inquiries set up by government take place in private. This may be right in the circumstances. Public Inquiries, by contrast, have tended to be reserved for those matters of greatest public outcry. For the future we are persuaded that the public interest demands that the criteria which guide the decision whether an Inquiry should be held in public or private should be made more explicit. The decision should not, for example, depend on some measures of public outcry, since the public may not always know of or recognise the need for concern, yet the issue at stake may be of great public importance. Nor should the decision necessarily rest on criteria such as the need for speedy deliberation and action, or the cost involved.
- 6 In the area of healthcare, there has been a tendency to opt for holding Inquiries in private. It has commonly been thought that this best reflects the public interest, in that people's feelings would be spared. It has also been suggested that enquiring in private is more conducive to getting at the real truth. Our experience suggests that these assumptions are misplaced. Holding an Inquiry in private is more likely to inflame than protect the feelings of those affected by the Inquiry, not least because of the notion of secrecy and exclusion which it fosters. Furthermore, the public's confidence in the organisation or service under review, or indeed in government as a whole, is unlikely to be enhanced, if they, and particularly the press, are excluded.
- 7 Currently, we note that the call for a Public Inquiry when something appears to have gone wrong is becoming increasingly common. This would appear to be a consequence of there being no clear criteria or guidance, for government or the public, which analyses what Inquiries are for and about, when they are justified, and whether and why they should be in public or private. We see an urgent need for the development of such guidance.³ We welcome, therefore, the beginning of this process in the field of healthcare. The document, *'Building a Safer NHS for Patients'* proposes that a Public Inquiry may be established by the Secretary of State for Health: 'where a service failure results in serious harm to larger numbers of patients, where there is serious national concern, or where a major issue of ethics or policy is raised for the first time by an incident'.⁴

³ See the paper prepared by the Rt Hon The Lord Howe of Aberavon, CH, QC for presentation to the British Association Annual Festival of Science, Cardiff, on 7 September 1998: *'The Management of Public Inquiries'*

⁴ *'Building a Safer NHS for Patients: implementing an organisation with a memory'* London: Department of Health, 2001

Accountability

- 8** That this Inquiry was announced to be a Public Inquiry meant for us that all the evidence which we recovered should be known by and accessible to the public at large. This is because it is intrinsic in the notion of working in public that the public has a right to be as informed as the Panel and thereby be able to hold the Inquiry to account.

Suggested criteria for future decision-making about Public Inquiries

- 9** In formulating guidance, we suggest that the following criteria should be regarded as central to any decision whether to establish a Public Inquiry:
- The issue to be examined must not only be of significant public importance in its own right, but must also be such as to raise matters of wider public concern.
 - Public confidence in government, local or national, in the area under scrutiny, if it is to be restored, cannot readily be restored without an independent examination of the issue in public.
 - The issue cannot properly be dealt with in another way that is less expensive, less elaborate and more speedy. Public Inquiries are costly to organise and run and, clearly, public money spent on an Inquiry is money that cannot be spent on meeting those needs of the public which are highlighted by the fact that an Inquiry is called for: in the case of Bristol, healthcare and particularly PCS services. There must, in other words, be some added value to the public, for example in the wider lessons which can be learned, over and above the mere investigation of some particular event. The cost of an Inquiry, to a very large degree, depends of course on its scope. The terms of reference should, therefore, be drawn up with this, as well as other matters, in mind. Cost can also be reduced by the considered use of modern information technology which can greatly speed up the process.

The purposes of a Public Inquiry

- 10** Lord Justice Clarke in the introduction to his Thames Safety Inquiry report⁵ identified two principal purposes. First, a Public Inquiry should seek to restore public confidence by carrying out ‘a full, fair and fearless investigation into the relevant events’.⁶ Nothing should be swept under the carpet. Secondly, a Public Inquiry should identify lessons to be learned. We broadly agree with these two purposes but wish both to put our gloss on Lord Justice Clarke’s observations and to add what to us are other important purposes.

⁵ Thames Safety Inquiry Final Report, February 2000 (Cm 4558)

⁶ Lord Justice Clarke

- 11** Lord Justice Clarke talks of identifying ‘the truth’. We would only remark that, in the sorts of circumstances giving rise to Public Inquiries, it may be rare for there to be ‘one truth’. There are often a number of ‘truths’, all held with sincere conviction by those advancing them. This is particularly so, and particularly important to recognise, when looking back over a number of years to events which have since taken on an importance perhaps not recognised at the time. To cite one example, we heard on a number of occasions different accounts of what was said by a doctor to a parent about the risks and prospects for success of surgery. Sometimes the recollections are significantly at variance. We do not necessarily draw from this the conclusion that one person is not ‘telling the truth’. Rather, we recognise that both may be telling ‘their truth’, which they are convinced is accurate, and are doing so in all sincerity. To understand this and to communicate this notion of truth and differing but honest beliefs, both to those involved in the Public Inquiry and to the public at large, is almost as important a task for the Inquiry as to seek to uncover and set out the story as we see it. And, of course, to recognise this complexity is not at odds with taking a robust view of the evidence when this is called for. Nor does it prevent an Inquiry from saying what went wrong, why, and what we must learn.
- 12** When Lord Justice Clarke talks of restoring public confidence, we would add from our experience that a Public Inquiry of itself cannot, and perhaps should not seek to restore public confidence. The public’s confidence in any particular organisation’s, or even government’s, role in any particular area has to be won. Indeed, a Public Inquiry may reach the view that confidence is not deserved unless certain actions are taken. It is here, as Lord Justice Clarke observes, that learning the lessons of the past comes in, and, of course, the framing of recommendations to give effect to those lessons.
- 13** In addition to these purposes of a Public Inquiry outlined by Lord Justice Clarke, we draw attention to the other, more subtle, but in our view equally important, purposes referred to by Lord Howe in a paper he gave in 1998. Referring to a collection of essays published under the title *‘Inquiries after Homicide’*,⁷ he states: ‘First of the many insights offered by this book is the identification of at least four functions that can be served by the process of inquiry: learning, discipline, catharsis, and reassurance.’ He points out that ‘they can be, indeed often are, in conflict.’ He refers to the process of seeking someone to blame as serving ‘to divert attention from what could be the most important cause of all, namely some underlying or pervasive managerial, administrative or financial failure.’ He quotes Sir Cecil Clothier QC: ‘Whenever some great disaster befalls the human race, the instinctive reaction of most people is to seek its cause and try to prevent a recurrence. But behind this civilised response there lies a darker motivation as old as time – the urge to lay blame.’

⁷ Edited by Jill Peay, London: Duckworth, 1996

- 14** Whatever its particular terms of reference, a Public Inquiry should attempt to promote understanding, not only of what may have gone on, but also what led to the events which are the subject matter of the Inquiry, and what may have been the motives and intentions of those involved. In this way, the complexities that surround all events and actions can be exposed and explored. The black and white certainties advanced by some may be shown to be illusory and unhelpful.
- 15** A Public Inquiry should aim, indeed it may be as much a duty as a purpose, to be a means whereby all those affected by the events under investigation can feel that their concerns have been aired and heard and that life can move on. It is commonly the case that events leave those touched by them in some kind of personal limbo, prevented by the past from creating a future. We found this to be particularly the case in our Inquiry: not just parents and doctors, but a hospital trust and even a city were caught up in the Inquiry. Thus, one purpose we saw the Inquiry as fulfilling was to allow everyone, in their own way, the opportunity to come to terms with the events at the UBH/T. In this way, the process of healing could begin.
- 16** Further, a Public Inquiry, whatever its formal terms of reference, offers the opportunity for a form of communal catharsis. The importance of this purpose should not be undervalued. It offers an opportunity for those in authority to be held to account; it allows for the public venting of anger, distress and frustration; it provides a public stage on which this can take place. Recognising this purpose has significant implications for the way in which the Public Inquiry is conducted: the more it is designed and organised to allow these objectives to be realised in a controlled and formal context, the more the public will feel that the Inquiry is acting in their interest. The more these objectives are frustrated, the less content the public will be. The more, for example, that a Public Inquiry is made to look like a court of law, and behaves like a court of law, in which certain professionals (particularly lawyers) feel comfortable, the more likely the public will feel excluded and conclude that the Inquiry was not really for them. The Inquiry must strive to be inclusive. It must strive to avoid designating groups or individuals as ‘parties’. That is to suggest adversaries and to invite adversaries. Instead, all who can assist should be enabled to do so and should be seen as ‘participants’ in the process of seeking to understand.

Process

- 17** We set out in detail in Annex A and Annex B⁸ the process according to which the Inquiry was set up and the procedure which was followed. We draw attention here to a number of matters of particular importance.

- 18** *Openness*: a Public Inquiry must be open not merely in the sense of allowing the public to attend but in many other ways. It must be accessible in so far as what it does and how it proceeds must be explained and must be comprehensible. As we have said, the evidence which the Inquiry Panel considers must be made public, so that the public can see what the Inquiry sees. Accessibility to the public has other meanings. The physical environment in which the Inquiry is conducted must not be one which inhibits attendance, whether by its location, its convenience and comfort, or its association with activities in which the public do not feel at ease, for instance a court room or municipal council chamber. This is because a feature of openness is inclusiveness: a Public Inquiry should seek to include the public in its deliberations and, therefore, avoid that which appears to exclude.
- 19** *Respect for the needs of the public*: it must be recognised that, in the case of a Public Inquiry, there are, in fact, a number of publics, with differing, sometimes opposing, views and aims. The Public Inquiry must seek to serve them all, even-handedly and with a sensitive awareness of differences. Misunderstandings, disagreements and clashes which distract the Inquiry from its task and can occupy time and resources, can be avoided by effective liaison between and organisation by the secretariat and the various groups.
- 20** *Procedure*: a Public Inquiry is not a trial – it is an inquiry into events, which is held in public. Not being a trial, there is no need for it to appear to behave like a court, not only because this tends to exclude some who find courts inhibiting and hard to follow, but also because the procedures which may be appropriate for a court are not necessarily helpful in a Public Inquiry. Moreover, it must be made crystal clear that it is perfectly possible to conduct a Public Inquiry with the most careful attention to the legal requirements of fairness, without having to behave like a court. There is no equation which reads ‘fairness equals court’.
- 21** Of course, the procedures which are adopted reflect the Inquiry’s overall approach. We feel strongly on this matter of approach. Those whose background is the law and courts, whether they be practitioners (solicitors and barristers) or judges, will naturally tend to regard the approach adopted by the courts as being eminently transferable to a Public Inquiry. After all, are they not both engaged in the process of seeking after the truth? Well, the simple answer is that they are very different. First, a Public Inquiry has a range of purposes, as we have suggested, which go beyond those which ordinarily concern a court. Secondly, a court is asked to decide between one party and another: one must win, the other lose; one must attract some degree of blame or criticism, the other is vindicated. A Public Inquiry must cast its net much wider. Thirdly, the English legal tradition is built on the foundation of adversariness: that from the clash of opposing forces, marshalled by legal representatives, the truth will emerge. Whatever the merit of adversariness in courts of law, we were convinced it would be an entirely unhelpful approach for us to adopt. There were no parties before us. There would be no winners nor losers. We had no need for the theatre of confrontation. Indeed, we felt strongly that we, and those who followed the Inquiry, would gain much more understanding of what went on in Bristol if we were able to give those who gave

written evidence and those who came to speak to us the opportunity to do so in as calm and unthreatening an environment as we could establish.

- 22 *An inquisitorial approach:* the approach we adopted was, therefore, wholly inquisitorial. By this we mean that the Inquiry identified the witnesses it wished to hear from and that the witnesses' evidence was explored and tested by Counsel to the Inquiry on the Inquiry's behalf. This is not to say that by adopting this approach we ignored the ordinary principles of fairness and due process. Rather, we designed our procedures to meet the needs of the Inquiry, respectful of the duty at all times to show fairness to all those affected by the Inquiry. For this reason, for example, everyone who could be said to be criticised in a material way by any other witness' evidence was given an opportunity to comment in advance of that evidence being made public. In this way, evidence was always placed in a wider context. Equally, we greatly needed the assistance of the lawyers who represented the many participants and pay tribute here to the help they gave us. What was different was the role which we asked them to play. Rather than proceed in the oral hearings by way of examination and then cross-examination (sometimes by a number of parties), we formulated a procedure whereby the questioning of witnesses was carried out by Counsel to the Inquiry. All other counsel, representing the range of participants affected by or interested in the Inquiry, liaised with the Inquiry's Counsel to ensure that all lines of examination were pursued and questions put. The opportunity to cross-examine existed, but the procedure worked with such success (not least due to the co-operation of all concerned) that, in the event, no application to cross-examine was made throughout the 96 days of hearings. Not only did this save time (and expense), but also ensured that the Inquiry was conducted calmly and without rancour.

Understanding and interpreting the past: the dangers of hindsight

- 23 We recognise the dangers of retrospective vision. We recognise also that what we have examined has only been a selection of what went on. Properly to understand and take a view on the events of Bristol require that we see them in their context. Not only do we look back at the period 1984 to 1995 from a distance, but we must recognise there was much change during that period. Even to apply the view of 1995 to 1984 would be a distortion. As regards hospitals and those who worked in them, the context was one of changing knowledge and ways of behaving over time.

The reality of the time was not the picture of it which we are able to create. We reconstruct the past from the building blocks left to us. But these can only ever give a partial picture. For example, through the forensic process, events and exchanges are brought into sharp focus. At the time that they happened, however, they were part of

the blur of daily activity which characterises a large and busy organisation. By dissecting them out, we see them in isolation, distinct from the hundred and one things happening at the same time. But they never existed in isolation. We must remember that.

- 24** In addition to the formal written statements which we received, we have taken account of documents and records obtained from the United Bristol Hospitals and the United Bristol Healthcare (NHS) Trust (UBH/T)⁹ and those who worked in it, not only as evidence in themselves, but often as the basis for the oral evidence of witnesses called to help the Inquiry. It might be said that they, at least, are immune from the dangers of hindsight. They are the same now as they were then and so can reveal what was going on. Again, this is only partly true. Indeed, if pressed too far, it actually becomes untrue. Documents and records can only tell part of the story. By their clarity, they suggest an ordered and readily identifiable progression of events. But their order is an order imposed by us. We have selected them, and thus have singled them out from what Mrs Thatcher once memorably described as a ‘snowstorm’ of paper¹⁰ which busy organisations dealt and deal with all the time. By selecting them, we have given them an importance and coherence which is the product of hindsight and may not have been as evident at the time. Moreover, documents which appear to record facts may have been written in fact to advance an argument. Furthermore, documents record that which is recorded. But large organisations also function by word of mouth. Decisions are taken all over the place, in meetings, conferences and conversations. They may not always be recorded. If they are not, they become a matter of memory. It is a natural tendency, in such circumstances, to rely on the certainty of what is written down, when set against the gloss suggested by a fallible memory. But this is to produce an illusory and, to a degree, unfair picture of the reality of the time. This is particularly true in Bristol where there was a managerial commitment to what was described in evidence as an ‘oral culture’.¹¹
- 25** As regards the evidence of parents, it is equally important to recall the context. For the parents who came into contact with the organisation, the context varied hugely: there were long-term relationships, as a child was cared for through a series of procedures, contrasted with short, agonisingly sad encounters ending in the tragedy of death or disability. To each parent, these were times of the highest intensity. This was their child and their child’s life. Each moment was an eternity and yet everything passed in a dizzying whirl. Each word and gesture were noted and repeatedly weighed and assessed for significance. But, paradoxically, sometimes words might be forgotten and gestures disregarded if hope lay elsewhere. We recognise this.
- 26** Finally, in this brief recital of caveats about reconstructing the past, we draw attention to (and took account of in our deliberations) a further reality. The events which we were asked to enquire into had been subject to lengthy exposure in the media over a

⁹ We use the term ‘UBH/T’ to refer to that group of hospitals in Bristol which, prior to 1991, comprised the United Bristol Hospitals, and, since 1991, have been known as the United Bristol Healthcare (NHS) Trust. Included within this group of hospitals are the BRI and the BRHSC

¹⁰ The Inquiry into exports of defence equipment to Iraq, 1996 (Cmnd HC 115)

¹¹ See Annex A, Chapter 8

number of years, and to a major investigation by the GMC, before we began our Inquiry. While it is impossible to evaluate the impact of this degree of attention, we were aware that interpretations had long since been placed on events, which understandably would tend to become entrenched, thereby influencing the evidence which we received.

The approach of this Inquiry

- 27** In our Preliminary Statement,¹² we committed ourselves to certain values. They included openness, transparency in our working, inclusiveness, the avoidance of a confrontational approach, and fairness. By adhering to these, our task has been made easier and, we hope, the ordeal of others has been made more bearable. We are aware that from the outset there have been many sets of expectations about the outcome of the Inquiry. There are parents who hope for a clearer explanation of what happened to their child. Others seek to defend those who have been criticised in other arenas. There are also expectations, shared by many, that we will be able to suggest ways of helping to secure care of high quality in the future throughout the NHS. We are conscious that in addressing our task we may satisfy some to some degree, but inevitably disappoint others.
- 28** Conscious of the pitfalls of hindsight, we took a number of decisions from the outset of the Inquiry about the way in which we would proceed, designed to insulate the Inquiry as far as possible from looking at the past with the eyes of the present. They included:
- The order in which evidence was heard was planned so as to begin by examining the wider context in which PCS services were provided in Bristol and then gradually to focus on the events in Bristol. Some may, indeed, have been surprised that we did not wish at the outset to hear from the Bristol clinicians. Our decision to hear from them quite late in the oral hearings was deliberate. We were anxious to ensure that we appreciated and took account of the various layers of context and background, before seeking to understand the particular circumstances and events at Bristol.
 - We did not have any regard to the result of the disciplinary hearings conducted by the GMC against Dr Roylance, Mr Wisheart and Mr Dhasmana. We began with a clean sheet.
 - We established a Group who acted as Experts to the Inquiry. In this way, they gave their evidence on behalf of the public interest, rather than for any particular individual or group. Many members of the Expert Group were in clinical practice

during the period 1984–1995, and thus were able to assist the Inquiry by placing evidence in its historical context. They were also able to indicate to the Inquiry the norms of practice that prevailed at the time. The Group also contained Experts in management, audit, counselling, and statistics.

- We gathered together all the available data on PCS at Bristol, both that which was available to clinicians and the hospital at the time, and that which was available nationally, and subjected it to independent and rigorous analysis by independent experts.
 - We then commissioned an independent detailed review of a sample of these case notes. Having made it clear in our Preliminary Statement that we would take account of all operations and all children operated on at Bristol during the period of our Terms of Reference, we did so, both in the statistical analyses and so as to form the basis for the sample chosen for the Clinical Case Note Review (CCNR). The CCNR was based on an appropriately constructed sample of cases. It was designed and carried out by panels drawn from the Expert Group. After an exhaustive search by the United Bristol Healthcare (NHS) Trust (UBHT), the clinical notes of the vast majority of children who received heart surgery at the BRI and the BRHSC between 1984 and 1995 were included in the group from which the sample was chosen. The design of the sample meant that, after making proper adjustments, we were able to reach a view on the care of all of the children treated during the relevant period.
 - We sought to ensure that the process of receiving evidence remained as open and inclusive as possible throughout the Inquiry. By making public the evidence seen by the Panel as we went along, witnesses affected by any evidence were able to comment as the Inquiry went on. Thus the Inquiry might have a single statement, accompanied by several formal written comments from others, thereby lending depth and texture to the evidence. Furthermore, in keeping with our duty to obtain as extensive a picture of Bristol as possible, we continued to seek out anyone who might be able to help us until the end of the Inquiry.
- 29** In the course of the Inquiry, we adopted a number of initiatives, both procedural and practical, some of which were innovative and had not been tried before in a Public Inquiry. Full details are set out in Annex A;¹³ the initiatives included:
- the use of information technology, particularly an Inquiry website, as a means of publishing witness statements and oral evidence throughout the course of the Inquiry;
 - the live transmission of the Inquiry’s hearings to remote locations;

¹³ Annex A, Chapter 1

- the establishment of a panel of people who were available to serve as Experts to the Inquiry;
- the extensive use of academic research and review;
- the role of Counsel to the Inquiry and other legal representatives in participating in an inquisitorial approach to the evidence;
- the way in which evidence was taken from Experts, so that they could interact with each other and with the various clinicians from Bristol who we heard from;
- the provision of counselling and support for witnesses and others attending the hearings;
- the statistical analyses and the CCNR; and
- the physical environment and practical arrangement of the hearing chamber and adjoining rooms.

30 Lastly, as befitted the nature of the Inquiry which we were engaged with, we began and ended with the evidence of parents.

31 There is one thing, in particular, which we have *not* done. We made it clear at the outset that we would not seek to reach a determination as to the adequacy of care received by each individual child. We explained why at the beginning of the Inquiry. We repeat that explanation here. Our Terms of Reference required us to conduct a Public Inquiry, not a series of clinical negligence trials. We were not constituted as a court of law, nor were we capable of acting as one. Given the number of procedures and the number of children involved, and given how long it takes for a court to try a complex case of clinical negligence, it would have taken us many, many years to try every case, even had we been required to do so and capable of doing so, which we were not. Issues of blame, fault, negligence and compensation under our current system are for the courts, to be investigated with all the necessary procedural safeguards. They were not for us. We make these points again here because it is clear that, despite our best efforts, some still thought that we would provide an answer to every child's death or disability. We regret this and that they may therefore feel disappointed. We hope that they will join us in believing that, if something good, by way of changes in the care of children in the NHS, can come from this Inquiry, the death or disability of their child, whatever the cause, was not in vain.

32 As we said in our Preliminary Statement in October 1998, the Inquiry cannot put the clock back. We cannot put all the broken pieces of history back together. What we can do is offer through this Report the basis for reflection, understanding, and moving forward with concern for the interests of all. We hope that we do not aim too high in believing that our Report may serve both as a memorial and as a milestone on the way to improved care.

- 33** We add one final word. Throughout the Inquiry we were helped by parents: some who were part of the Bristol Heart Children Action Group (BHCAG), some who came together to form the Bristol Surgeons Support Group (BSSG), and some who belonged to neither group. We were helped by the co-operation of the UBHT. We were helped by our Expert witnesses. And we were helped by those doctors, nurses and others who were intimately involved in the events of Bristol. We would be failing in our duty if we did not recognise the dedication, commitment and hard work of the healthcare professionals. That things were done which should not have been done will become clear. But the Bristol story is one of a flawed organisation and systems. It is also a story of some people whose behaviour was flawed but who cared greatly about human suffering. It is not a story about bad people.

Setting the Scene

Chapter 3: The Care and Treatment of Children with Congenital Heart Disease

The care and treatment of children with congenital heart disease

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The care and treatment of children with congenital heart disease

- 1 In this chapter we describe briefly the care and treatment which children with congenital heart disease (CHD) might have expected to receive in hospital during the period of our Terms of Reference. We also introduce the other chapters which make up what we call ‘Setting the scene’, and which provide the context for understanding what took place in Bristol between 1984 and 1995. An account of developments in the UK in the diagnosis and treatment of CHD in children between 1984 and 1995, written for the Inquiry by Dr Eric Silove, a member of the Inquiry’s Expert Group, appears in Chapter 3 of Annex A. It includes an explanation, with diagrams, of specific abnormalities in the heart and the ways in which they have been diagnosed and managed over time. It takes account of all the conditions and procedures referred to in this Report.
- 2 Between six and eight in every 1,000 children born in the UK are likely to have CHD. The severity of the abnormality which constitutes the CHD can vary enormously. For some children (approximately 50%) it will be relatively mild and may even heal spontaneously as the child develops. For the others, a surgical procedure will almost certainly be necessary to enable them to have a good chance of growing into adulthood. At the extreme, some babies with very severe abnormalities may die within days if they do not have medical and surgical treatment. Some, sadly, are beyond treatment and die.
- 3 The care and treatment of children with CHD includes, but is not confined to, hospital care. Very often healthcare professionals who work in the community, such as GPs, health visitors and midwives, district nurses, physiotherapists and social workers, may contribute to their care. We acknowledge the importance of such contributions. They are not, however, the subject of this Inquiry. Our focus is on one particular part of the child’s journey of care: heart surgery in hospital. When we talk of paediatric cardiac surgical (PCS) services, however, we do not confine them merely to the surgery. We refer to the whole range of services provided by a hospital to children with CHD and to their families. Thus we include not only surgical procedures, but the full range of care and treatment offered by a hospital and its staff associated with surgery: diagnosis, pre- and post-operative care, and support for the children and their families.
- 4 In many respects there is no ‘typical’ journey of care for a child born with CHD. Every child’s condition and every family’s circumstances are unique. Yet it is possible to set down, in general terms, the stages of care and treatment which children and their families might encounter. These stages are much the same today as they would have been between 1984 and 1995. An initial diagnosis might be made by the paediatrician at the hospital where the child is born. In other cases, where there are

perhaps no immediately obvious signs of a problem, a baby's condition may be diagnosed days or weeks later, when signs are noted by parents, a midwife, a health visitor or GP. Referral to a paediatrician generally follows. The baby will then be referred to a paediatric cardiologist who will make a diagnosis and carry out an assessment of the abnormality of the heart.

- 5 The cardiologist, in many cases in consultation with a paediatric cardiac surgeon, will advise on necessary care and treatment. The management of the baby's care will depend on the nature and severity of the abnormality: an emergency operation may be required, or initial treatment may involve the use of drugs. For some children, the abnormality in their heart may be such that one operation will be sufficient to correct the defect. For others, a series of operations over a period of years may be required, during which time their care would be managed by a specialist team from the hospital. The child may need open-heart or closed-heart surgery. During open-heart surgery, the child's heart is stopped and the child is supported by a heart-lung bypass machine. During closed-heart surgery, the operation is carried out while the heart is still beating.
- 6 Post-operatively, the child will be cared for initially in the hospital's intensive care unit (ICU). After discharge from the hospital, long-term care and management of the child by a paediatric cardiologist, often in conjunction with a consultant paediatrician in the child's local hospital, will continue for many years as the child's condition is reviewed and assessed.
- 7 The child's family will be supported, both practically, for example by the offer of local accommodation where needed, and emotionally, by staff during the child's stay in hospital, and in the longer term.
- 8 If a child should die following surgery, a pathologist investigates the cause of the death. The pathologist prepares a report on the cause of death for those who were caring for the child, which serves as the basis for discussion with parents about the reason for their child's death. The pathologist's findings can assist the cardiologists and surgeons, not only in their understanding of that particular child's death, but also in shaping their approach to treatment in future cases.
- 9 These elements together make up the PCS service with which we are concerned. We now turn to developments in the diagnosis and treatment of CHD in children between 1984 and 1995.
- 10 Very little treatment for children with congenital heart abnormalities was available anywhere in the world until the late 1950s. In 1958 the first open-heart operation on a child was carried out in the UK, using a heart-lung bypass machine. Heart-lung bypass technology was a significant development which made it possible for surgeons to stop the heart, to repair the defective part of the heart, for example, the pumping chambers inside the heart, and then to restart the heart. The number of surgical procedures performed and the number of hospitals carrying them out increased during the 1960s,

and by the early 1970s cardiac surgery for children had come to be available in a small number of centres in less than half of the major regions in the UK.

- 11** The development of PCS services over the last 40 years in the UK, as with the development of any clinical service, has been an evolutionary process. It was not only the volume of operations which increased. Advances in technology, the refinement of surgical procedures and the development of new procedures took place. These, in turn, contributed to better chances of survival. Techniques for diagnosis also improved. Non-invasive methods of diagnosis using ultrasound scanning technology developed rapidly in the 1970s and 1980s, and provided a safer alternative to cardiac catheterisation which, as an invasive procedure, carried a higher risk in small infants. These non-invasive methods included echocardiography (ultrasound scanning) which was developed during the late 1970s and 1980s; the ‘Doppler’ technique, introduced in the mid 1980s; colour mapping of Doppler signals towards the end of the 1980s and into the 1990s; and the introduction of echocardiography in the operating theatre and the ICU.
- 12** Surgical techniques continued to evolve during the 1980s and 1990s. New procedures, such as the Arterial Switch and the Fontan procedure, were more widely undertaken. Surgery was carried out on children at an earlier age than previously in the case of some heart defects. It also became possible to correct some heart defects, including Ventricular Septal Defects, by one rather than a series of procedures.
- 13** Advances in equipment and technology also meant that, from about 1982, the technique of cardiac catheterisation could be used, in certain circumstances, for treatment as well as for diagnosis. Thus some children who might previously have required surgery which involved opening the chest in order to expose the heart could now be treated by passing a tube or catheter from a vein in the groin into the heart and inflating a balloon in order to stretch open a narrowed valve.
- 14** There were also significant changes in the management of intensive care. In 1984, at the beginning of the period covered by our Terms of Reference, it was generally the surgeon who assumed primary responsibility for post-operative care. In the early 1990s anaesthetists began to be more fully involved, and began taking on clinical sessions dedicated to the ICU. In some units, by the mid 1990s, full-time intensivists (clinicians specialising in intensive care, usually anaesthetists) were appointed. This was part of a development in paediatric intensive care generally, and not specific to the care of children who had undergone heart surgery.
- 15** We have described, broadly, the elements of a paediatric cardiac surgical service which might have been available to a child with CHD who was in need of surgery. We have also referred to some of the key developments which took place in PCS services during the 1980s and 1990s. At this stage in the process of setting the scene it might seem natural now to turn to Bristol and to describe how the PCS service there was organised and delivered. In fact that may not be helpful. It would leave out of the account the wider context within which the PCS service in Bristol was provided.

For it is important to remember that the PCS service in Bristol took place within the NHS. The NHS in the 1980s and 1990s was a place of significant change. These changes influenced the hospitals in Bristol. They were as affected as other hospitals by the actions and demands of government. They encountered the same pressures. Their relationship with local health authorities went through the same sort of development. Thus, before we turn to the particular circumstances of the PCS service in Bristol, we should take account of the wider context. We need to get a sense of what was happening in the NHS at the time.

- 16 The principal reason for setting out this wider context is that it is not possible otherwise to take a view on the quality of the PCS service provided to children in Bristol, how it was assessed at the time, and how it might be assessed today. Bristol did not exist in isolation. It was affected in many things that it did by the conditions which prevailed in the wider NHS. Of central importance in this wider context is how the term ‘quality’, in relation to the notion of the quality of care, was perceived at the time, and how such perceptions changed.
- 17 A further element contributing to a proper understanding of events in Bristol is that the funding for a major part of the PCS service, the care and treatment of children under 1 year, was unusual: it was funded on a national basis through a system known as the supra regional services. Thus, to make sense of the arrangements in Bristol, and ultimately to increase our understanding of what happened there, we must take account of this particular funding arrangement.
- 18 When we turn to describe the arrangements for PCS in Bristol, it will be clear that the PCS service was provided within a large, university teaching hospital, with many thousands of employees and a multi-million pound budget. The PCS service was neither free-standing nor self-contained. It was part of a wider system, part of the organisation known as the United Bristol Hospitals (UBH), and, latterly, as the UBHT. The policies and practices of the UBH/T as a whole clearly conditioned and influenced the services within it, including the PCS service. Thus it is important also to be aware of this wider, *local* context.
- 19 In setting the scene, therefore, this section of our Report addresses first the national context and then the local context within which PCS services were provided. It is arranged as follows:
 - the changing NHS 1984–1995 (Chapter 4);
 - management in Bristol (Chapter 5);
 - quality, standards and information (Chapter 6);
 - the audit and monitoring of the paediatric cardiac surgical service in Bristol (Chapter 7);

- paediatric cardiac surgical services (Chapter 8); and
- the paediatric cardiac surgical service in Bristol (Chapter 9).

Setting the Scene

Chapter 4: The Changing NHS 1984 – 1995

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The changing NHS 1984–1995

- 1 We describe in this chapter some of the principal changes which occurred in the NHS in the 1980s and the 1990s. By doing so we do not intend to offer a history of the NHS over that period. Rather we highlight certain changes which provide the necessary background to an understanding of the events in Bristol. A short historical account of the main changes to the organisation of the NHS between 1948 and 1995 is given in Annex A Chapter 2 and there are further papers in Annex B.¹

A period of rapid change

- 2 The fact that the NHS is, in essence, a value-driven, politically sensitive enterprise, means that it is always changing. It has never been free of the tinkering which shifting views on the proper role of the public and private sector and on levels of taxation inevitably bring to bear. But the 1980s and 1990s were somewhat special in both the pace and nature of the changes which took place.
- 3 It is important to bear in mind that the pace of change was not particular to the NHS. Rapid change in institutions was the order of the day. There was no reason why the NHS should have been different. Many working within the NHS, however, thought the pace of change was too great. Those in other sectors of the economy, public or private, were less sympathetic to this view. Managers and employees in the NHS, in their view, simply had to learn to cope with change since it was a given. It was not going away.² It had to be expected, accepted, managed and explained to those working in the organisation.

Nature of the change

- 4 The fundamental political driving forces of the 1980s and 1990s were the desire to transform the economy to make it more efficient and competitive and to control (and if possible reduce) public spending. The NHS, as part of the public sector, attracted attention. But it attracted attention because it was part of the public sector, not in its own right. The changes introduced, therefore, were the application to the NHS of a more general set of ideas. They were not crafted exclusively with the specific needs

¹ See paper at Annex B, 10a: Bevan G. 'National and regional resource allocation frameworks and funding availability for acute sector health services at Bristol'. Also papers 11a to 11f by Professor Charlotte Humphrey in Annex B

² Annex B, 3d Phase II Report of Seminar 4, Leadership

of the NHS in mind. Moreover, the ideas of the day were concerned with efficiency, and with the market as the economic model for delivering it. These ideas appeared to many, both inside and outside the NHS, to constitute a challenge to the internal values of the NHS. A contrast was drawn between the values of community, of social justice and social welfare, of service and selflessness on the one hand, and, on the other, those of commerce, of output and throughput, of cost control and cost-efficiencies, of managerial rather than professional direction. Whether this contrast was caricature or reality was less important than the fact that this was how many perceived the changes in the NHS.

A series of initiatives

- 5 The impression gained is that there was no great visionary plan for the NHS as such. Rather, there were a number of distinct policies, each of which constituted a further attempt to realise the general goals of efficiency and cost control in the specific context of the NHS. The broader political economic objectives of modernising the economy and containing the overall size of the public sector were important forces behind policies towards the NHS.

Efficiency initiatives

- 6 During the 1980s the Department of Health and Social Security (DHSS) introduced a series of efficiency initiatives which focused on improving and extending the services of the NHS without increasing costs. They included: efficiency savings, under the name of 'cost improvement programmes' which required health authorities to generate annual efficiency savings of 0.2% to 0.5%; Rayner scrutinies,³ investigations carried out by managers in the NHS into the efficiency of such areas as transport, and residential accommodation for NHS staff; the development of performance indicators, allowing health authorities to compare their performance against others in areas such as finance and manpower (but not, significantly, the quality of care); competitive tendering in such areas as laundry and domestic services; and income generation involving such schemes as income from private patients and car-parking charges.

The introduction of general management

- 7 The second initiative which we must refer to is the Griffiths Report and the consequent introduction into the NHS of the notion of the general management.
- 8 In February 1983 the then Secretary of State for Health and Social Security, Norman Fowler, established an inquiry into the effective use of manpower and related resources in the NHS. A team led by Roy Griffiths, Deputy Chairman and Managing

³ On the model of the scrutinies of the civil service conducted by Sir Derek Rayner

Director of Sainsburys, presented their report, which was very short (25 pages), in October 1983. Its findings are often summarised in the well-known quotation:

‘In short if Florence Nightingale were carrying her lamp through the corridors of the NHS today she would almost certainly be searching for the people in charge.’⁴

- 9 Roy Griffiths and his team took the view that the NHS had no coherent system of management at a local level. It lacked any real continuous evaluation of its performance against normal business criteria: levels of service; quality of product; operating within budgets; cost improvement; productivity; motivating and rewarding staff; research and development. Precise objectives for management were rarely set and there was little measurement of health outcomes. There was little evaluation of clinical practice and even less evaluation of the effectiveness of clinical interventions.
- 10 In June 1984 Norman Fowler announced to Parliament that he accepted the recommendations of the Griffiths Report. During the 1980s, he and his successors introduced the following:
 - *General managers*: drawn from inside and outside the NHS, were to be introduced into health authorities as soon as possible and into hospitals and units by the end of 1985.
 - *Management budgets*: were to be introduced into hospitals as soon as possible, together with a further strengthening of the processes of financial accountability, which was to be extended to hospitals and units.
 - *Value for money*: existing initiatives and audits were to be extended and the savings ploughed back into improving services for patients.
 - *Management training and education*: the NHS Training Authority was established and programmes were to be increased, particularly for doctors.⁵
- 11 The introduction of general management brought to an end the health authority’s district management team (DMT) and the philosophy of ‘management by consensus’. This approach had existed since the previous reorganisation of the NHS in 1974, but Griffiths saw it as reactive and concerned with crisis management. A general manager and line management within hospitals replaced the DMT. The general managers of hospitals were operationally and professionally accountable to their counterparts in the district health authority (DHA). General management represented a radical change to both organisation and management across the NHS. It was intended to offer active, strategic direction and to devolve responsibility through a clear structure of line management and devolved budgets.

⁴ Griffiths Report, NHS Management Inquiry Report, London: DHSS, 1983. Other members of the team were Michael Bett, board member for personnel at British Telecom; Jim Blyth, Group Finance Director at United Biscuits; and Sir Brian Bailey, Chairman of Television South West and the Health Education Council

⁵ UBHT 0236 0011

- 12 A crucial element in the introduction of general management was the recognition of the need to find a way of involving doctors, in particular senior doctors, in the day-to-day management of the NHS. Throughout the 1980s various models were tried. None was successful until the model of the 'clinical directorate' attracted interest and support.
- 13 Clinical directorates were developed in 1972 at the Johns Hopkins Hospital in Baltimore, USA. The model was championed in the United Kingdom by Professor (later Sir) Cyril Chantler of the United Medical and Dental Schools of Guy's and St Thomas' Hospitals.
- 14 The model suggested that clinical services should be organised into a series of directorates. Each directorate would have a clinical director or lead consultant, usually chosen by the other doctors within the directorate, to act on their behalf. The clinical director was expected to assume responsibility for providing leadership to the directorate and to represent the views of all the clinical specialties. The clinical director was expected to initiate change, agree workloads and resource allocation with the unit general manager, and act as the budget holder for the directorate.
- 15 The relationship between the clinical director and colleagues was not seen as one of line management. Rather, the clinical director was expected to negotiate and persuade colleagues. Equally, the relationship between the clinical director and the unit general manager was seen as one of negotiation and persuasion.
- 16 The pace at which hospitals introduced clinical directorates varied widely. By 1989, a clinical directorate system was beginning to develop in Bristol, in response to national encouragement⁶ and in preparation for the establishment of the UBHT. The model adopted by Dr Roylance, Chief Executive of the UBHT and previously District General Manager, was based on 13 clinical directorates⁷ each managed by a clinical director, who was a consultant, and by a general manager. The aim was for the clinical director to be 'in charge of' the doctors and the general manager to be responsible for everyone else.⁸
- 17 Another feature of the approach advocated by Griffiths and reflected in the new arrangements, challenged what had hitherto been basic values of the NHS: the translation into the public sector of the idea of focusing on producing satisfied consumers. Indeed, the recipients of public services began to be described as consumers, or customers. This constituted a major challenge to the notion that the standards and the outcomes (or outputs) of the NHS were the preserve of the healthcare professionals.
- 18 A fundamental difficulty in implementing the Griffiths Report lay in the simple fact that an organisation in the public sector such as the NHS is not like a commercial

⁶ T24 p.45 Dr Roylance

⁷ WIT 0079 0002 Mr Boardman

⁸ WIT 0108 0006

business. There were no major incentives available to persuade those working in the NHS to change their ways of working. Nor were the economic sanctions of the private sector available. If a business failed to perform adequately it was taken over or made bankrupt. The hospital had to continue to offer a service; it could not just be closed down.

The NHS reforms

- 19 The third initiative to which we draw attention is that represented by what were called the NHS reforms. In 1989 the Government announced a fundamental review of the NHS. This led to the publication of a White Paper, *Working for Patients*⁹ which proposed major reforms.
- 20 The programme of action set out in the White Paper aimed to secure two objectives:
 - ‘... to give patients, wherever they live, better health care and greater choice amongst the services available; and
 - ‘greater satisfaction and rewards for those working in the NHS who successfully respond to local needs and preferences.’¹⁰
- 21 *Working for Patients* confirmed the then Government’s commitment to the basic principles of the NHS: a comprehensive system of healthcare financed through taxation and free at the point of delivery.
- 22 The White Paper did not directly address the question of the perceived need for additional funding for the NHS. Instead, it concentrated on the need to make the NHS more efficient. Providing increased funding was not seen by the then Government as the answer to the NHS’s needs. Instead, what was required was a framework which would raise the performance of all hospitals to that of the best. The framework included:
 - More delegation of responsibility for the delivery of healthcare to local level: regional health authorities, health authorities, and hospitals. This was to be achieved through the introduction of the internal market.
 - The creation of NHS trusts. This would allow those units which applied to become independent trusts and, as such, to have more control over their affairs.

⁹ Department of Health. *Working for Patients*. London: HMSO (Cm 555)

¹⁰ WIT 0159 0497 – 0498 Miss Evans

- Through the internal market, money would follow the patient and go more directly to where the service was delivered. This would allow purchasers to make better use of the funds available, so as to secure a comprehensive range of high-quality services.
 - The establishment of 100 additional consultant posts to reduce waiting lists, improve the service, and reduce the long hours worked by junior doctors.
 - The introduction of general practitioner fundholding (GPFH). This allowed GPs to hold budgets with which to purchase a defined range of services for patients.
 - Reforms to the regional health authorities (RHA), district health authorities (DHA) and family practitioner committees (to be known as family health services authorities (FHSA)). The membership was to be reduced, and representation of the local authority removed. The authorities, like trusts, were to have both executive and non-executive directors. The family health services authorities were to have general managers and were to be directly accountable to regional health authorities. Community health councils (CHC) would continue to represent the interests of the patient.
 - At a national level, the Supervisory Board within the DoH was to be replaced with a Policy Board, and the Management Board became the NHS Management Executive (NHSME).
 - There were to be improved audit arrangements and the Audit Commission would in future be responsible for auditing the financial accounts of health authorities.
 - Medical audit was to be extended throughout the NHS.¹¹
- 23** The NHS reforms moved forward rapidly. The NHS and Community Care Act received the Royal Assent in June 1990. The new RHAs came into being on 26 June 1990, followed by the DHAs and FHSAs on 17 September 1990. On 1 April 1991 the *'Working for Patients'* reforms came into operation. Fifty-seven provider units (including the United Bristol Hospitals) became trusts. Three hundred and six general practices became GPFHs.
- 24** Shortly thereafter, however, the Government announced that the pace of implementing *'Caring For People'*, that part of the statute concerned with community care, would be slowed down and phased in over a three year period. This provided the NHS with much needed breathing space to accommodate the scale of change which the reforms represented.
- 25** While the language was that of the market, the reality of the relationship between trusts as providers of services and health authorities as purchasers was, in effect, that

¹¹ Department of Health. *'Working for Patients'*. London: HMSO (Cm 555)

of a managed market at best. As Professor Klein put it: ‘purchasers became commissioners: a recognition that monogamy, rather than polygamy characterised the internal market, with most purchasers and providers locked into permanent relationships in which each partner sought to modify the other’.¹²

The ‘Patient’s Charter’

26 A fourth initiative which we should note was the production in 1991 of the ‘*Patient’s Charter*’. This Charter represented again an attempt to translate into the NHS a wider policy of defining in consumerist terms the standards to which the public was entitled in the delivery of public services. The Charter spoke in terms of patients having rights, for example to be treated within a specific period of time. It made no reference to the quality of the care to be provided. As Klein suggests, its importance lay not so much in its specific content as in the ‘new rhetoric and a new set of expectations in the NHS marking precisely the kind of shift of power from providers to consumers envisaged in the Griffiths Report’.¹³ Of course, the ‘rights’ in the ‘*Patient’s Charter*’ were not enforceable rights. To that extent, if targets were not met, there was no redress. Thus, although there was some reduction in waiting times and in the way hospitals conducted themselves, the change was one of rhetoric as much as action.

Resources

- 27** As we have said, the 1980s and 1990s were characterised by a concern for efficiency and cost control. This had implications for all parts of the public sector. The NHS was not immune.
- 28** Resources include not only finance, both revenue and capital, but also material, in the form of equipment and drugs, and human resources, in the form of doctors, nurses, managers and others. It is commonly said that the NHS was, as regards the resources available to it, seriously underfunded during (and before and after) the period covered by our Terms of Reference. Before taking a view on this and assessing its impact, we need to examine more carefully what is being said.
- 29** The resources made available to a publicly funded service such as the NHS represent the conclusion of a complex process which is ultimately political. In abstract terms, the process is as follows. The government of the day determines the level of taxation and what will be funded through that taxation. It also determines what proportion of that funding will go to any particular service. The government offers itself to the electorate on the basis of the decisions made. The public, by their voting choices,

¹² Klein R. *The New Politics of the NHS* (third edition) London: Longman, 1995

¹³ Klein R. *The New Politics of the NHS* (third edition) London: Longman, 1995

endorse the decisions, or indicate that they favour the alternative choice offered by the political opposition. On this reasoning, resource allocation in the public sector is the product of a compact between public and government.

- 30** This approach would suggest that a service can never accurately be said to be *underfunded* since, within a relatively short timescale, its funding is regularly adjusted to reflect the prevailing political compact. On this approach also, it is idle to talk of a ‘proper level of funding’ or the ‘necessary level of resources’, since there is no absolute or proper level. There is only a political choice which, by reflecting the will of the electorate is, by that fact, the proper choice.
- 31** To the extent that this describes the political reality of how resources are allocated to the NHS, it is an approach with a flaw at its centre. If the government of the day opts for X resources to fund a public service and then represents that service as being able to provide services which in fact cost X plus Y, then it immediately becomes possible to use the term ‘underfunding’. And this has been the history of the NHS in the period in which we are interested and beyond. Governments of the day have made claims for the NHS which were not capable of being met on the resources made available. The public has been led to believe that the NHS could meet their legitimate needs, whereas it is patently clear that it could not. Healthcare professionals, doctors, nurses, managers, and others, have been caught between the growing disillusion of the public on the one hand and the tendency of governments to point to them as scapegoats for a failing service on the other.
- 32** Of course, if governments had claimed that the service delivered by the NHS should be judged on the basis of a comparison with a moderately successful Second World country, no complaint could be raised. But the NHS was repeatedly represented as a comprehensive service which met all the needs of all the public. Patently it did not do so.
- 33** During the 1980s, for example, there was a growing body of evidence that resources had not kept pace with demand, or with the ever-expanding range of diagnostic and therapeutic options. The House of Commons Select Committee on Social Services reported in 1988 that expenditure on hospital and community health services had been underfunded by £1.5 billion between 1980/81 and 1987/88.¹⁴
- 34** December 1987 provided a particular example. There was increasing concern about the perceived lack of funds in the NHS. This perception was borne out when, in December 1987, the Department of Health and Social Security reported that there had been a shortfall in health authorities’ income. Consequently, a further £100m in extra funds were allocated for that year as a one-off payment.

¹⁴ Sixth Report House of Commons Social Services Committee. 1987–88 Session. London: HMSO, October 1988. The figures quoted are 1987/88 prices

- 35** Shortages in healthcare professionals, particularly doctors and nurses, to provide the service which was promised were a constant factor. The public came to expect, if not accept, dirty hospitals, poor food, inadequate facilities, long waits, and an uneven quality of care. Healthcare professionals laboured to make ends meet and to care for their patients, working in circumstances which were an affront to the claims made for the NHS.
- 36** In 2000, at last, the present government acknowledged this 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 that proportion spent on healthcare in Europe. This development has been widely welcomed. It is seen as a long-overdue recognition of the need for more resources. But we add a caution. The currently announced injection of funding will do much to enable the NHS to catch up: to train and recruit the needed healthcare professionals; to refurbish the hospitals and clinics; to obtain the necessary equipment; to reconfigure the service. But it will not be enough to do more than this. It will not, in other words, allow the NHS to develop in the way contemplated in *'The NHS Plan'* and which is necessary if it is truly to meet the claims made for it. We have every reason to believe that to achieve what was set out in the *'The NHS Plan'*, which we will refer to in Section Two of this Report, there must be a sustained increase in funding year-on-year.

The NHS and cardiac surgery

- 37** Acquired heart disease in adults was (and remains) a major cause of illness and death. In addition to public health initiatives aimed at reducing the incidence of the disease, the 1980s and 1990s saw the recognition of the significant benefits of cardiac surgery, particularly coronary artery bypass grafts (CABG). A high priority was placed on carrying out CABG on adults with acquired coronary heart disease. The priority was translated into increasing pressure on cardiac units in hospitals to treat an ever-increasing number of patients. By contrast, congenital (as distinct from acquired) heart disease (CHD) in children is a relatively uncommon disease, affecting some 6–8 children in every 1,000. The numbers of children needing surgery were, therefore, small in comparison with adults. It is no surprise therefore that, as the demand for cardiac surgery on adults increased, so it attracted an increasing amount of investment and resources. Equally, health authorities responding to the national priority sought, after the NHS reforms of 1991, to purchase an increasing amount of care for adult patients.
- 38** In cardiac units which specialised only in children, the pressure from adult patients was less keenly felt. Furthermore, the creation of a supra regional service (SRS) specialising in neonatal and infant cardiac surgery provided secure funding for the treatment in specialist units of children with CHD. But Bristol's cardiac unit treated

adults and children. While designated as a supra regional centre (SRC) for heart surgery on children under 1, it was under constant pressure to treat more adults. The two cardiac surgeons in Bristol cared for both adults and children, so they were exposed to the same pressure. Paediatric cardiac surgery in Bristol represented a very small part of the total activity of the UBH/T. The context in which the events in Bristol must be understood, therefore, was one in which a small service was always under pressure.

The NHS and developments in the care of children

- 39** We refer here to developments in healthcare services for children which are relevant to an understanding of what took place in Bristol. There were not only technical and scientific advances. These were accompanied by an increasing awareness of the separate and particular needs of children as patients. There was a growing recognition in the 1980s and 1990s of the need to see children not as small adults, but as a group of patients with distinct physiological and psychological needs.
- 40** Professor David Baum, President of the Royal College of Paediatrics and Child Health 1996–1999, told us that caring for children’s needs: ‘might be very different from an adult approach to fluids, to electrolytes, to drugs, taking into account their position in the family, the health care of the parents, other siblings, educational need. ... social setting and so on.’¹⁵
- 41** An increasing emphasis was placed upon the facilities and environment in which acute healthcare services for children should be delivered. In 1991, for example, the DoH issued guidance: *‘The Welfare of Children and Young People in Hospital’*.¹⁶ It stressed the need to ensure that care in hospital was child- and family-centred. One consequence was that more attention was given to providing child-friendly facilities, to providing accommodation for parents when visiting children in hospital, to involving parents in the care of their child, and to providing a range of advice, information and support for them.
- 42** The institutional arrangements for supporting and promoting the education and training of healthcare professionals in paediatric care developed significantly from the 1970s onwards. The Association of Paediatric Anaesthetists was set up in 1973, the Paediatric Intensive Care Society in 1987, and the British Cardiology Association in 1991. The Royal College of Paediatrics and Child Health received its charter as a Royal College in 1996.

¹⁵ T18 p. 46 Professor Baum

¹⁶ HOME 0002 0001; DoH *‘The Welfare of Children and Young People in Hospital’*, HMSO, 1991

- 43** But, progress in achieving improvements in acute healthcare services for children was slow. Two particular problems were evident throughout the 1980s and the 1990s. First, there were insufficient numbers of paediatrically trained staff (nurses and doctors) to provide a fully paediatric service. Secondly, there was a national shortage of Registered Sick Children's Nurses (RSCN) during the late 1980s and early 1990s. There were only two RSCNs working at the BRI in the early 1990s in the Wards (5A and 5B) where very sick children undergoing open-heart surgery were cared for.¹⁷
- 44** There was also a national shortage of paediatric intensive care nurses, which was reflected in Bristol. The Intensive Care Society reached the view by the early 1990s, that it was essential that a senior nurse with several years of experience of paediatric intensive care be in charge of the nursing care in the Unit. They also advised that a minimum of one trained nurse to one patient should usually be required for a 24-hour period.¹⁸
- 45** This meant that the bedside establishment should be 6.4 whole-time equivalents (WTE) per patient per 24 hours, a ratio endorsed by the Paediatric Intensive Care Society.¹⁹ The staffing level at the BRI was 5.4 WTE. This reflected the mix of adults and children.
- 46** There was also a national shortage of paediatric cardiologists. In the late 1980s, the British Cardiac Society and the Royal College of Physicians of London regarded this shortage as 'very worrying'.²⁰ This national shortage was starkly reflected in Bristol. For the early part of the period of our Terms of Reference there were only two senior paediatric cardiologists. A third was appointed in 1989. There were no trainees who could support them. They bore an extremely heavy workload involving not only their patients in Bristol but the need to visit 'outreach' clinics throughout the South West and South Wales.
- 47** There was no specialist paediatric cardiac surgeon in Bristol. The two cardiac surgeons who operated on children also operated on adults.

¹⁷ WIT 0114 0012 and T32 p. 76 Fiona Thomas

¹⁸ T32 p. 41 Fiona Thomas

¹⁹ T7 p. 152 Dr Ratcliffe

²⁰ BPCA 0001 0001

Setting the Scene

Chapter 5: Management in Bristol

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Management in Bristol

- 1 In this chapter we describe the system of management of the United Bristol Hospitals (UBH), and of the United Bristol Healthcare NHS Trust (UBHT) after Trust status was acquired in April 1991. We describe the creation of the system of clinical directorates, and set out the respective roles of the Trust Board, Dr John Roylance, Mrs Margaret Maisey and Mr James Wisheart. We also consider the relationship between the University of Bristol Medical School and the UBH/T. A fuller account of the evidence which the Inquiry received on these matters is in Chapter 5 of Annex A and there is also a further paper in Annex B.¹

General management

- 2 General management, which we described earlier in Chapter 4, was introduced in Bristol during 1985. Dr John Roylance was appointed District General Manager (DGM) of Bristol & Weston District Health Authority (B&WDHA) with effect from 1 April 1985. The appointment of a doctor to this role was rare at the time. In 1986, only 15 out of 188 DGMs had a medical background. The DGM was 'directly and visibly responsible'² for the management of the district. He was the overall budget-holder and was responsible for the development of policies and for monitoring their implementation. Thus, the influence of Dr Roylance on the delivery of health services to the South West Region from 1984 to 1995 was very great.
- 3 Dr Roylance saw his role as:

'... getting rid of functional management, nurses being managed by nurses, physiotherapists by physiotherapists, administrators by administrators. It could be said at that time when I took up the District General Management role there were about 9 different health services in the District coming together only at District level. In introducing the General Management function, it was expressly required to delegate operational management decisions as near to the bedside as possible.'³
- 4 Dr Roylance said that until general management was introduced, the exercise of clinical freedom was pursued entirely independently of any consideration of resources. Management had to use: '... quite crude measures to try and prevent the major overspending of a service, things like closing operating theatres, closing wards ...'⁴

¹ 'An evaluative commentary on health services management at Bristol: setting key evidence in a wider normative context', Judith Smith and Professor Chris Ham, May 2000. See Annex B, 101

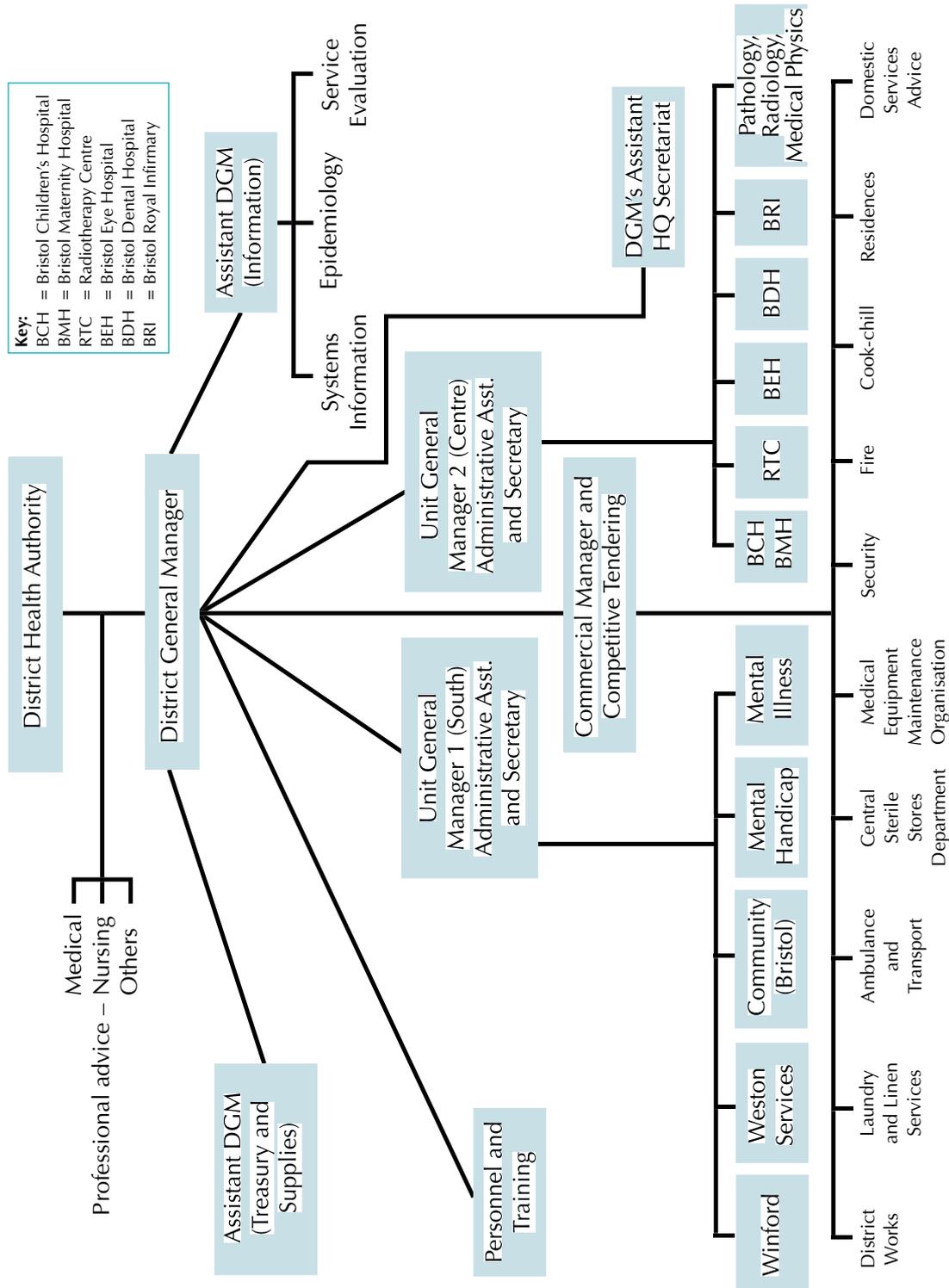
² WIT 0074 0425; from correspondence from Dr Roylance to the Regional Health Authority dated 1 May 1985

³ T24 p. 9 Dr Roylance

⁴ T24 p. 24 Dr Roylance

5 In May 1985 the District approved a management structure for the health authority and its units, as shown in the chart below:

Figure 1: Management structure of the Bristol & Weston District Health Authority, May 1985⁵



⁵ WIT 0038 0067 Ms Charlwood; a document relating to the introduction of general management in the District, prepared by Dr John Roylance, dated 1985

- 6 The District was divided into two units:⁶ the Central Unit and the South Unit. Each had a Unit General Manager who was directly responsible to the DGM. The Units had 11 sub units between them, each managed by general managers. The Central Unit (the general managers of which were John Watson and then Margaret Maisey from 1989–1991) had six sub units, of which the BRI was one. The BRHSC was incorporated into another unit (the Children’s and Maternity Unit).
- 7 All of the professional, technical and administrative staff were incorporated into this system of units and sub units, with their pre-existing hierarchies remaining only as advisory structures for the general managers. There was one exception: the consultant staff retained both their previous advisory role, through the Hospital Medical Committee (HMC) advising the DGM directly, and their clinical independence.⁷
- 8 In addition to the management structure, there were four advisory committees which gave professional advice in their particular areas of expertise to the general managers at both unit and district level. For the most part, the professional advice at district level was channelled through the Chair of the HMC who, in turn, was given advice by the chairs of the clinical divisions, of which there was one for paediatric services and one for surgical services.⁸

The system of clinical directorates

- 9 In 1989 the system of clinical directorates was in the process of being introduced across the District.⁹ Central to this system was the concept of semi-autonomous units, based on a medical specialty or group of specialties, whereby full budgetary responsibility and clinical decision-making could be combined in a single entity. Thirteen clinical directorates were established, each managed by a clinical director (a consultant) and a general manager, and each formulating its own business plans. The larger directorates were split into associate directorates, managed by associate clinical directors and associate general managers.
- 10 Clinical directors were responsible for formulating policy. They led their particular service and held budgets. General managers were responsible for implementing policy within each directorate. The system which evolved during 1990–1995 was for the clinical directors to report to the DGM (the chief executive after the adoption of Trust status) and for the general manager to report to the clinical director and to the director of operations.

⁶ Formerly there had been seven

⁷ WIT 0108 0005 Dr Roylance

⁸ WIT 0074 0010 Dr Baker. Dr Ian Baker was District Medical Officer, B&WDHA, 1984–1988, Director of Public Health and Assistant General Manager (Planning), B&WDHA, 1988–1991, and has been consultant in public health medicine, B&DHA, since 1991

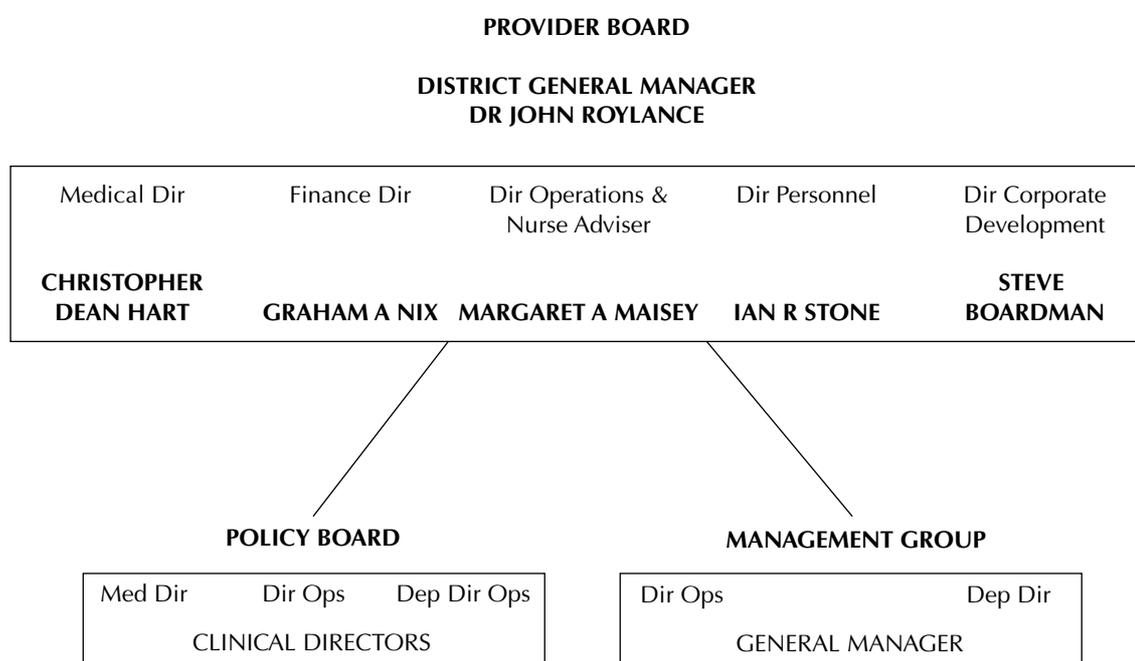
⁹ WIT 0108 0006 Dr Roylance

- 11 These changes led to an alteration in the managerial role of the medical staff. From 1985 onwards, medical staff had been involved in the management of services through the system of clinical divisions. From 1990 medical staff who became clinical directors or associate clinical directors had a greater degree of managerial autonomy and authority and were able to negotiate changes in services through planning or contracting. General managers working alongside clinical directors and associate clinical directors had a supportive role.¹⁰

The adoption of Trust status

- 12 The management arrangements put in place for the 'Shadow Trust', and subsequently for the NHS Trust, built on those that had gone before, and are shown in Figure 2 below, an organisational chart for the Bristol Provider Unit in 1990.

Figure 2: Bristol Provider Unit c. 1990¹¹



¹⁰ WIT 0074 0011 Dr Baker

¹¹ WIT 0038 0076 Ms Charlwood; an enclosure to a letter to Miss Catherine Hawkins, Regional Manager, SWRHA, from Dr John Roylance, District General Manager, B&WDHA, dated 31 August 1990

- 13 On 1 April 1991 the UBHT came into existence, with Dr Roylance as Chief Executive.¹² Under the new purchaser-provider arrangements, the UBHT became the provider of services through the BRI, the BRHSC and other hospitals, and the Bristol and District Health Authority became the principal purchaser of those services.
- 14 The role of Deputy Chief Executive in the UBHT was split between two office-holders: the Finance Director, who was responsible for general management issues, and the Medical Director, who was responsible for clinical issues. In addition, the Director of Operations, Mrs Maisey, who was also the Nurse Adviser, acted on behalf of the Chief Executive in dealings with general managers in the clinical directorates.
- 15 The system of clinical directorates remained in place. A number of clinical directors referred to the burden of carrying out both clinical and managerial work. Monthly meetings were held between general managers and the Director of Operations/Nurse Adviser,¹³ and between clinical directors and the Chief Executive and Medical Director. Clinical directors also met together on a monthly basis as the 'Management Board'.

- 16 Dr Roylance stated that:

'The aim was for the Clinical Director to be "in charge of" the doctors and for the General Manager to be responsible for everyone else, to ensure that the necessary administration and support services were in place for the Directorate to run efficiently. In the discussions which took place before this change it was agreed that the most appropriate way forward would be to view the Clinical Director and General Manager as being in a managerial "bubble", jointly sharing the managerial responsibilities; thus, neither was directly responsible to or for the other. These two were assisted in their management roles by the chief nurse of the unit, a Directorate personnel officer and a senior member of the Finance Department.

'The only other level in management was that at operational level with ward sisters or their equivalents taking full responsibility for wards or their Units.'¹⁴

- 17 Dr Roylance stated that the working relationship between the clinical director and the general manager evolved over time, from what he called the managerial 'bubble', to the position in which the clinical director was accountable to the Chief Executive, and the general manager supported the clinical director.

¹² Some parts of the District Health Authority did not become a first wave trust (one of the initial trusts established in 1991), but combined together in order to be managed directly for the early years of the 1990s

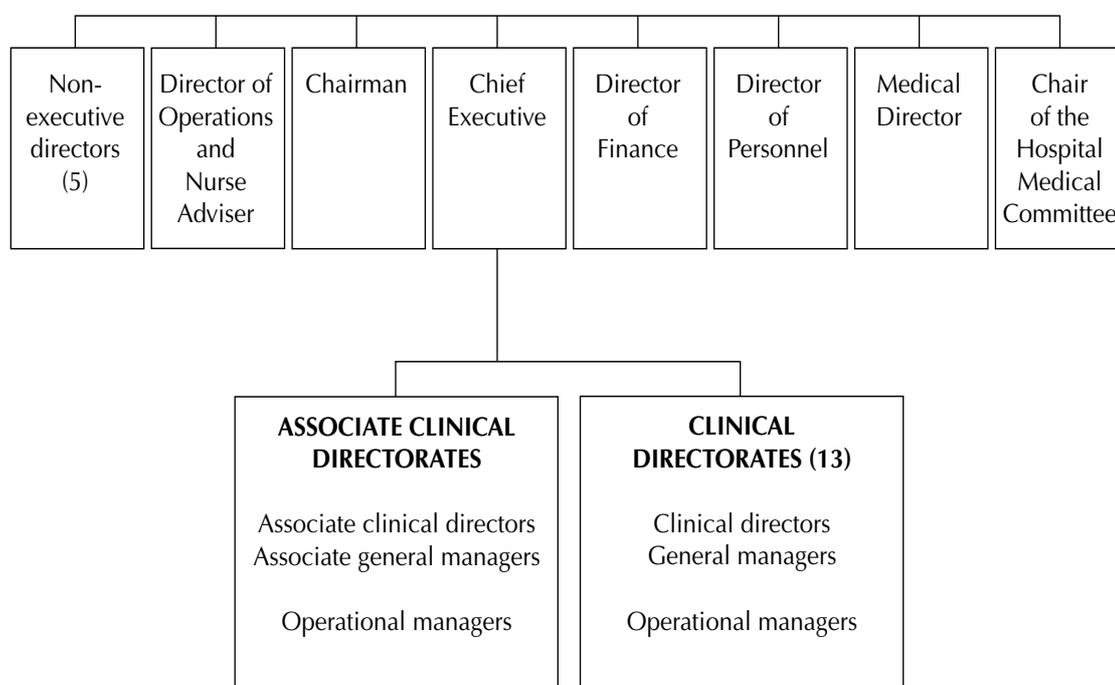
¹³ Margaret Maisey, Director of Operations and Nurse Adviser 1991–1996, Director of Nursing 1996–1997 at UBHT

¹⁴ WIT 0108 0006 – 0007 Dr Roylance

The role of the Trust Board

- 18** The Trust Board came into being in 1991 and comprised a Chair, appointed by the Secretary of State for Health, five non-executive directors, two of whom were appointed by the Regional Health Authority and the remainder by the Secretary of State, and five Executive Directors including the Chief Executive, the Director of Finance, and the Medical Director. The following table describes the arrangements:

Figure 3: The UBHT Trust Board in 1992¹⁵



- 19** Mr Peter Durie was the first Chair of the UBHT. He was succeeded in July 1994 by Mr Robert McKinlay. Mr Durie stated that the role of Chair of the Trust was ‘ill defined’,¹⁶ but neither he nor Mr McKinlay felt that they had a managerial role.¹⁷ Dr Roylance told us that the Chair and non-executive directors set policy which was then implemented by the executive directors. The NHS Code of Accountability for NHS Boards,¹⁸ which came into effect in 1994, advised that the non-executive directors were responsible for monitoring the executive management of the organisation.

¹⁵ Derived from WIT 0108 0042 Dr Roylance

¹⁶ WIT 0086 0002 Mr Durie

¹⁷ WIT 0086 0002 Mr Durie; WIT 0102 0007 Mr McKinlay

¹⁸ ‘Corporate Governance in the NHS, Code of Conduct, Code of Accountability’, Department of Health, 1994

The role of Dr Roylance

- 20** Dr Roylance was the first Chief Executive of the Trust. According to Mrs Rachel Ferris, General Manager, Director of Cardiac Services since 1994:

‘... it was accepted in management circles that Dr Roylance was known for saying “don’t give me your problems, give me your solutions”. All my peers were told that responsibility for dealing with issues must be pushed back to the Directorates. My perception was that if this did not happen, then it was seen as a failure on the part of the Manager ... I saw Mrs Maisey’s role as controlling the General Managers in order that Dr Roylance could get on with other things.’¹⁹

- 21** Dr Roylance’s management style was referred to variously as giving rise to an ‘oral culture’, in that he preferred to avoid setting things down in writing unless necessary, and as creating a ‘club culture’, to which you either belonged or not.
- 22** Dr Roylance believed that healthcare in the hospital was: ‘led by consultants’,²⁰ and that they were ‘self-teaching’ and ‘self-correcting’.²¹ Dr Roylance said that it was ‘impossible’ for managers to interfere.²² It was ‘a fact’ that only clinicians could identify defects in the performance of other clinicians.²³ He saw the role of management as being: ‘to provide and co-ordinate the facilities which would allow the consultants to exercise clinical freedom’.²⁴ He outlined to us some of the difficulties he saw in managing consultants: ‘... anybody who wishes to manage consultants should do their apprenticeship in the voluntary sector where none of the staff are paid and they can all please themselves. Unlike consultants, in that area I am told it is much easier to get rid of them without an industrial tribunal, but consultants are not manageable.’²⁵ Therefore, he said: ‘... one has to adopt a leadership style and one has to free up their abilities and recognise their culture.’²⁶ Dr Roylance’s management philosophy attached importance to: ‘management by values and not by objectives’.²⁷

¹⁹ WIT 0089 0032 Mrs Ferris

²⁰ T24 p. 14 Dr Roylance

²¹ T24 p. 14 Dr Roylance

²² T24 p. 14 Dr Roylance

²³ T24 p. 17 Dr Roylance

²⁴ WIT 0108 0018 Dr Roylance

²⁵ T25 p. 168 Dr Roylance

²⁶ T25 p. 168 Dr Roylance

²⁷ UBHT 0006 0202; minutes of Executive Committee Meeting on 21 May 1993

The role of Mrs Maisey

- 23** Mrs Margaret Maisey held the twin posts of Director of Operations and Nurse Adviser from 1991–1996. She told the Inquiry that she had influence within the Trust:

‘... certainly I had influence, I had John Roylance’s ear when I wanted it, I could speak to the Board if need arose. I do not think it ever did, particularly, but I did have influence, and I could make sure that works went up the road and ... did the work they said they would do and had not got round to doing. I could make some of these departments, lean on them to do things.’²⁸

- 24** Other witnesses also commented on her role. Mr Durie told us that she was perceived to be Dr Roylance’s ‘eyes and ears’,²⁹ and Mrs Ferris said of Mrs Maisey: ‘She herself, I think, on many occasions, described herself as the Rottweiler of the Trust, so I think her own view was consistent with that.’³⁰ While Mrs Maisey held the role of Nurse Adviser there was no Executive Director of Nursing on the Trust Board. Given the demands placed on Mrs Maisey as Director of Operations, her capacity to provide leadership and support for nurses was inevitably diminished.

The role of Mr Wisheart

- 25** In addition to his clinical commitments, Mr Wisheart had a number of other roles. From 1992 to 1995, he held the post of Medical Director of the UBHT. The role was to advise the Chief Executive and Trust Board on medical issues, and initially two sessions of time per week were allocated for this.
- 26** Initially, the posts of Medical Director and of Chair of the HMC were joined. This meant that Mr Wisheart held both. It was subsequently recognised that these two jobs were too much for one person. Thus, when Mr Wisheart’s two-year term as Chairman of the HMC came to an end in January 1994, while he continued as Medical Director, Dr Laszlo took over as Chair of the HMC. As a consequence of the position he held, Mr Wisheart was for a number of years, one (if not two) of the ‘Three Wise Men’, a system designed to respond to concerns about fellow doctors in the NHS.³¹
- 27** Mr Wisheart was also the Associate Clinical Director for Cardiac Surgery from 1990 to 1992, when he was succeeded by Mr Dhasmana from 1992 to 1995, and Chair of the Clinical Audit Committee for six months from July 1994.

²⁸ T26 p. 158 Mrs Maisey

²⁹ T30 p. 38 Mr Durie

³⁰ T27 p. 83–4 Mrs Ferris

³¹ See Annex A Chapter 8 for a description of the ‘Three Wise Men’ procedures

Relationship between the University of Bristol Medical School and the UBH/T

- 28** There seems to have been an extremely close relationship between the University and the UBH/T throughout the period of our Terms of Reference. Like other medical schools, all senior NHS clinical staff held honorary posts in the University as professors, senior lecturers or clinical teachers. Conversely, all clinical staff in the University had formal honorary contracts with the DHA, which, after 1991, were then transferred to the UBHT. There were numerous standing and ad hoc committees with representation both from the University and the UBH/T.³² Mr Wisheart told the Inquiry that there were many common responsibilities shared between the Faculty of Medicine and the Trust and that a number of committees and groups sought to encourage and promote a high degree of co-operation between the two.³³
- 29** However, there was also clearly some tension between the aspirations of the University and the UBH/T. In the case of appointing staff, Dr Roylance told the Inquiry:
- ‘The University always took the view that they wished to appoint the best applicant and were uneasy about specifying too narrowly the specialty of the potential professor.’³⁴
- 30** Dr Roylance explained that this could result in a professor in one specialty being replaced by the appointment of a professor in a different specialty, notwithstanding the hospital’s need to continue to provide a service which might not fall within the new professor’s specialty.
- 31** Mr Stephen Boardman, Director of Corporate Development at the UBHT 1991–1992, saw ‘enormous strengths’ in having a medical school alongside the hospitals because of the tendency to attract ‘the top people’ in the field.³⁵
- 32** However, he also pointed out that: ‘there are times when the core business, the core function of the hospital or the health service, has to be to deliver services which meet the local needs of the local population.’³⁶ Clearly, there were times when the needs of the University and of the NHS hospitals were in conflict.
- 33** So far as cardiac surgery was concerned, however, there was not a close relationship between the Department of Cardiac Surgery and the University prior to about 1990.³⁷

³² Dr Roylance gives a full account in his statement WIT 0108 0013

³³ T40 p. 54 Mr Wisheart

³⁴ T88 p. 76 Dr Roylance

³⁵ T33 p. 66 Mr Boardman

³⁶ T33 p. 66 Mr Boardman

³⁷ WIT 0096 0038 Mr Hutter

Mr Dhasmana put the date as later, saying: 'Up to 1992 there was no direct administrative or managerial connection with the University. ... The Academic Department of Cardiac Surgery was established in October 1992, after which relationships became closer.'³⁸

- 34** The Bristol Heart Institute, a collection of a number of academic departments of which cardiac surgery was one, was established in 1995 as a new organisation by Professor Angelini.
- 35** Mrs Ferris suggested that difficult discussions took place about whether or not the Institute was valuable to, or detracted from, the Directorate of Cardiac Services. She said that there was concern among some surgeons that the Institute would take over the Cardiac Services Directorate and that Professor Angelini would be in charge of both the academic department of cardiac surgery and the clinical service.³⁹ The consequence would be, it was feared, that the emphasis of the Directorate would lean more to research and academic concerns than to the needs of the NHS.

³⁸ WIT 0084 0046 Mr Dhasmana

³⁹ T27 p. 115 Mrs Ferris

Setting the Scene

Chapter 6: Quality, Standards and Information

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- 1 In this chapter we describe the approach to quality taken within the NHS between 1984 and 1995. We refer to the ideas and practices prevalent in the 1980s and describe how they started to change during the 1990s. Secondly, we turn to consider the way in which quality, such as it was understood, was monitored within the NHS during the period of our Terms of Reference, drawing on the examples of the South West Region and Bristol. A fuller account of the evidence received by the Inquiry on these matters is in Chapter 18 of Annex A together with expert papers commissioned by the Inquiry set out in Annex B.¹

Responsibility for the quality of clinical care

- 2 Responsibility for the quality of clinical care was regarded as lying with healthcare professionals, in the performance of their duties according to the standards of professional practice to which they had been educated and trained. Thus, for example, nurses sought to meet the standards of professional practice expected of them as nurses and doctors the professional standards expected of them as doctors. For healthcare professionals quality meant, as it always had, doing the best for the individual patient within the resources available, applying professional judgment to the particular patient's needs. There were no agreed standards as to what care the patient with a given illness or condition might expect of healthcare professionals as a team or of the NHS as a whole. There being no such standards, there were also no benchmarks against which to assess and evaluate the quality of clinical care given.
- 3 In this respect, health was no different at the time from most other public services employing professionals. In education and social care, for example, there were few, if any, national standards as to what a pupil or an elderly person could expect of the education or social services systems. Performance monitoring and a concern for the effectiveness of a service were only in their infancy. There was an unarticulated but, nevertheless, prevailing consensus which dominated thinking about public services up until at least the late 1980s: if enough well-qualified professionals could be educated and trained, they could then be relied upon to provide services of high quality throughout their working lives. Indeed, the prevailing wisdom was that policy-makers and managers should keep out of matters involving professional judgment. One such matter was the quality of the service delivered. That was the preserve of the professionals.

¹ Annex B, 10m Walshe K, Offen N. *'An evaluative commentary on systems for review and audit at the United Bristol Hospitals NHS Trust from 1984 to 1995'*. Also paper 11b Humphrey C. *'Commissioning, Purchasing, Contracting and Quality of Care in the NHS Internal Market'* and Annex B, 11c Humphrey C. *'Medical and Clinical Audit in the NHS'*

National policy towards quality

- 4 National policy towards the quality of healthcare up to the late 1980s (and beyond) focused on the effective and efficient use of resources (value for money), and on a concern for the number of patients treated, sometimes referred to as 'levels of activity', or 'throughput'. Concerns over lengthening waiting lists for treatment, and how to tackle them, became important elements in national policy. The view was generally held that the longer the waiting list, the greater the possibility that the condition of a patient on that list would deteriorate. To that extent, tackling waiting lists was an initiative linked to improving the quality of care provided. Patients were becoming less tolerant of having to wait for treatment. Thus, the need to reduce the size of waiting lists overall and, simultaneously, to reduce the length of time patients spent waiting became important elements of public policy. The quality of the care which patients would receive, however, when they were finally admitted to hospital, and the outcome of that care, were not high on the political agenda. It was assumed that care would be good.
- 5 The arrangements for managing the NHS between 1984 and 1995 reflected these prevailing attitudes. The quality of clinical care was an area into which managers ventured with trepidation. Sir Graham Hart, Permanent Secretary at the Department of Health (DoH) from 1992 to 1997, told us of 'a deeply-rooted reserve'² in government about matters to do with clinical performance. It was something traditionally thought of as being the exclusive domain of the professions.

Attitudes and policy begin to change

- 6 Attitudes and policy were not static. Whereas at the beginning of the period of the Inquiry's Terms of Reference, there was no active engagement on the part of any tier of management with the quality of clinical care, by 1995, quality had come to take on importance. A national policy on medical and later clinical audit, introduced in 1989, was beginning to have an impact by 1995. Quality of clinical care had also come to be on the agenda of management within the NHS. District health authorities (DHAs), which by 1995 had mostly given up managing hospitals directly and had become purchasers of healthcare, were showing an increasing interest in the quality of the clinical care provided by the trusts with whom they had contracts. There are four inter-related strands to the developing interest and activity in improving the quality of healthcare: audit; other quality initiatives; information; and monitoring. We deal with each in turn in the paragraphs which follow.

² T52 p. 36 Sir Graham Hart

Audit³

- 7 In the 1980s competing ideas about how to assess and improve the quality of care began to emerge, albeit tentatively. Principal amongst these was how to promote 'audit' of care. The idea of audit, that clinicians should periodically take time to review and reflect on their practice, to consider what worked well and what did not, and then to 'close the audit loop' by making any necessary improvements, was familiar before it became part of any official policy. Healthcare professionals had always had a strong interest in seeking to analyse the outcome of care for their patients. Many doctors participated in some form of review by, for example, holding meetings to consider selected cases. But, there was no structure, far less support in terms of time or resources, for such audit as took place.
- 8 Moreover, when it was carried out, audit tended to be within professional boundaries. Thus, doctors carried out audit with doctors, nurses with nurses. Further, the extent to which healthcare professionals became involved was a matter for them personally: it depended on their commitment, their enthusiasm and the time available. And, even when they did take part, as we have said, there were no agreed standards to which they could turn to help them evaluate how well they were doing for patients.

A national policy on audit

- 9 The publication in January 1989 of the Department of Health's White Paper *'Working for Patients'*⁴ set out plans for the creation of the internal market. The White Paper *'Working for Patients: Medical Audit Working Paper No. 6'*,⁵ detailed plans for a comprehensive system of medical audit within the internal market. As a result, efforts were made to encourage and to organise medical audit. Protected funding was made available, through regional health authorities, to support it.⁶ Regional and district health authorities were asked to develop strategies, to set up audit committees and to produce annual reports on audit activity within their areas. But, reflecting the 'deeply-rooted reserve' referred to earlier, it was accepted that audit should be carried out by healthcare professionals, that it should be voluntary and that the results should not be made known beyond the professional group.
- 10 The audit that was carried out was not systematic. It covered only certain services sometimes selected by the clinicians themselves and sometimes by the relevant audit committee within a hospital. Thus, information on which a view could be based as to what was adequate clinical performance nationally, so that local hospitals could assess their own performance (and be assessed by others), was virtually non-existent.

³ We take the term 'audit' to mean a systematic framework for assessing care and treatment and for introducing and monitoring improvements

⁴ HAA 0165 0145; DoH, *'Working for Patients'*, London: HMSO, 1989 (Cm 555)

⁵ HOME 0003 0130; DoH, *'Working for Patients: Medical Audit Working Paper No. 6'*, London: HMSO, 1989

⁶ Central funds for medical audit were distributed to hospitals through regional health authorities on a capitation basis (whole time equivalent consultant numbers). £28 million was allocated in 1989/90 and again in 1990/91. The allocation rose to £49 million in 1991/92

- 11 Policy on audit developed in the early 1990s and in November 1992 the first meeting of the DoH's Clinical Outcomes Group (COG) was held. It aimed to give strategic direction to the development of clinical rather than merely medical audit, aimed at encompassing a multi-disciplinary approach and to develop methodologies to identify and achieve improved outcomes. The subjects considered by the Group included: the implications of multi-professional audit; management aspects of clinical audit; producing a clinical audit handbook; and the development of audit in primary care.⁷
- 12 Anxious to allay fears that information could fall into the hands of management (a prospect which, at the time, was judged by many professionals to be unacceptable), the process of medical audit was insulated from management and put under the direction of doctors. Audit was represented as an educational tool, not a mechanism for accountability to the profession, the employer (the NHS) or to the public. As Ms Pamela Charlwood, Chief Executive, Avon Health Authority since 1994, stated to the Inquiry in relation to the early part of the period 1984–1995: 'first medical audit and then clinical audit was an area of considerable professional sensitivity'.⁸
- 13 In 1993 the scope of audit was expanded; medical became clinical audit. Healthcare professionals from different disciplines were encouraged to come together to review the care given to their patients. But healthcare professionals remained sceptical about the benefits of the audit process, and concerned both about the practical problems of undertaking effective clinical audit and the use to which information might be put by management.
- 14 In 1993 trusts were told by the DoH that while funding for medical audit, nursing and therapy audit was to continue for 1993/94, an additional sum of £3.2 million was to be allocated for the development of multi-professional clinical audit.
- 15 Subsequently, there were significant changes to the method of funding which had an impact on the overall availability of resources. In 1994/95 funding for clinical audit was included in the overall allocation to regions, who were expected to maintain and develop clinical audit and were to be held accountable for it. Consequently, funding for clinical audit became part of the contract between the purchaser and the provider.

Other initiatives concerned with quality

Quality assurance

- 16 During the 1980s, at the same time that ideas and the practice of medical audit were coming to prominence, other ideas about 'quality assurance',⁹ began to have an

⁷ WIT 0482 0222 Dr Moore

⁸ WIT 0038 0014 Ms Charlwood

impact in the NHS. One significant influence was the influx of senior managers from outside the NHS, following the introduction in the mid-1980s of general management. In 1989 a survey of quality assurance initiatives in the NHS identified 1,478 initiatives in 116 districts. The growth of such initiatives was said to have reached 'epidemic proportions'.¹⁰

- 17 Few if any of these initiatives, however, addressed quality in terms of professional competence or impinged on the exercise of clinical judgment. Most, to different degrees, borrowed and built on ideas from the quality assurance movement in industry. Involvement was voluntary and their success was limited. In a given hospital several initiatives were often pursued independently, but in parallel. Often initiatives were seen as the special preserve of nurses, or of a particularly innovative manager. For the most part, hospital doctors were not involved. The prevailing paradigm remained one in which it was left to the individual professional to define what was an acceptable standard of clinical care.

The 'Patient's Charter'

- 18 A significant national initiative which can be seen as part of the movement to improve quality was the '*Patient's Charter*', first issued in 1991. As we have seen, however, it focused attention on waiting times and on the quality of the patient's experience whilst in hospital. It did not refer directly to the quality of clinical care.

Other activity intended to promote improvements in the quality of care

- 19 Guidance was issued from different sources by the DoH, by the Royal Colleges and by other bodies. It was addressed to different audiences: nurses, doctors and other healthcare professionals. Material from these sources could be contradictory, incomplete or conflicting. It was difficult to know where or to whom to look for definitive guidance

Poor co-ordination of systems for assuring quality

- 20 While interest in quality assurance and the quality of clinical care certainly grew between 1984 and 1995, the development of mechanisms for assessing and improving quality (setting standards, gathering data, recording and reporting performance, and making improvements) was haphazard. Each strand, audit, quality assurance activity, the '*Patient's Charter*', and other initiatives, developed along separate lines. The mechanisms were not co-ordinated. Numerous organisations became involved. Their involvement was not co-ordinated. Their roles and responsibilities were ill defined. Over time, this led to a situation of increasing confusion as to who was responsible for what as between the various parties (the DoH, the regional and district health authorities, the trusts and the various bodies

⁹ We take the term 'quality assurance' to mean methods used to maintain or enhance the quality of a service, using systematic assessment of performance against predetermined standards. It involved monitoring a service and introducing improvements

78 ¹⁰ Carr-Hill R, Dalley G. 'Assessing the effectiveness of quality assurance'. *Journal of Management in Medicine*, 1992; 6:10–18

outside the NHS, such as the Royal Colleges, and healthcare professionals themselves).

Information

Systems for collecting information concerning clinical performance

- 21** The systems for collecting data in the hospital sector were numerous and fragmented throughout the period 1984 to 1995. Although there may have been rare exceptions, in most hospitals there was not one but many systems, operating in parallel. On the one hand, there was one type of system, the hospital-wide administrative system which collected data to facilitate dealing with patients as they passed through the hospital (including, for example, information on a patient's appointments, length of stay, date of discharge), and to keep track of waiting times. On the other hand, in any given hospital there was another type of system, the clinical systems which involved a plethora of free-standing clinical systems, often the preserve of an individual consultant or small groups of consultants with a shared specialty, which held data about treatments and outcomes.
- 22** The various clinical systems, many of them paper based, differed from one another and had no relationship with the administrative hospital-wide systems. The funding made available in the late 1980s and early 1990s for medical and later clinical audit helped to reinforce this separation by making available to groups of clinicians money for small local computer systems. The lack of any connection between these different systems, one administrative, the others clinical, for collecting data cannot be explained solely on the basis of some technical or technological reason. It was just as strongly a reflection of a mindset that clinical matters were the sole domain of clinicians and non-clinical matters, to do with the management of resources and with the movement of patients into and through the hospital, were the preserve of managers and administrators.
- 23** As it happens, cardiac surgery was somewhat exceptional in terms of there being information about clinical performance. There was a voluntary system for recording data which was, established in 1977: the United Kingdom Cardiac Surgical Register. The Society of Cardiothoracic Surgeons collected and distributed in aggregated form data about mortality rates in cardiac surgery, including in paediatric cardiac surgery. Anonymised data were collected from cardiac centres on the centres' activity and rates of mortality. The data were categorised by reference to diagnosis rather than the operation or procedure carried out. The data were made available to cardiac surgeon. The surgeons in turn could decide whether and how to distribute the data more widely. The data were not easy to interpret and were regarded by surgeons as a useful guide at best, rather than as reliable and authoritative.

- 24** Administrative systems were valuable in providing information relating to the management of hospitals. The DoH had always gathered data from the regions about financial performance and the extent and amount of care delivered. In the early 1990s, the collection and presentation of this information were substantially improved, providing Ministers and the regions with quarterly reports on performance in relation to key targets concerned with activity and finance.
- 25** Information about waiting times figured prominently in these quarterly reports. An important source of this information were the Patient Administration Systems (PAS) which, by the mid-to-late 1980s, had been established in most acute-care hospitals. These, in turn, contributed to a national database which produced information about the scale of activity in a hospital, the Hospital Episode Statistics (HES) database.
- 26** This information included, for example, the number of patients who came into and left the system, and the specialty in which they were treated. This national database, managed by the DoH, was intended and used for planning purposes. It was *not* designed as a system to monitor clinical performance, because the Department at the time, as we have seen, did not see its role as to be involved in matters of clinical performance. (As we shall see in Section Two, the database has belatedly been recognised as a valuable source of information on clinical performance.) Although views were changing over the period of our Terms of Reference, there was no question of the DoH itself interrogating its database with enquiries about clinical performance. Quite simply, it did not consider that such questions were for it to ask. Moreover, the mood of the times was such that, had the Department thought to use the database in such a way, it would have been seen as provocative by healthcare professionals.
- 27** Information on mortality in hospitals, which is one indicator of the quality of a service provided by a hospital, was contained in the HES database. But the quality of the data was relatively poor until after 1991. Miss Catherine Hawkins, Regional General Manager, South West Regional Health Authority (SWRHA), told the Inquiry that, in the late 1980s, there was no reliable information on how a hospital was performing in terms of the outcomes for patients. She described the situation to us graphically: ‘... at that time, you did not know when people left hospital whether they were dead or alive.’¹¹
- 28** We have set out briefly the approach to quality which prevailed during the period of our Terms of Reference and the limited systems which existed to capture information. We now move to a description of the respective roles of the DoH, the regional health authorities (RHAs) and the DHAs in seeking to secure and improve good quality healthcare.

Monitoring

The role of the Department of Health

- 29** Priorities and funding were set nationally, but it was then for each RHA to translate these into a local health service. Guidance on planning and priorities was issued by the DoH to regions each year. The Chair of each RHA annually met the Secretary of State to review priorities and to take a view of the health service in the region. Miss Hawkins told us about the focus of the reviews: 'Frequently it would be against things like health promotion and disease prevention: whether you were closing the large mental handicap hospitals and creating community care ... were your services like cardiac patients getting enough cases through units ... very wide ranging items at times.'¹²
- 30** The Chair of the relevant RHA then in turn met each of the Chair of the DHAs within the region to ensure that national priorities, and the region's interpretation of them, would be followed in the year ahead.
- 31** The meetings between the Secretary of State and the Chair of the RHA were supplemented by contact between officials. It was reported that Miss Hawkins told a BBC Television '*Newsnight*' interviewer that in 1988: 'Civil servants were hell bent on the numbers game. They were not bothered about the outcome of the operations; they just wanted to be able to quote a big increase in the number of operations being undertaken.' In her evidence to us she gave the same impression.¹³
- 32** Professor Sir George Alberti, President of the Royal College of Physicians since 1997, told the Inquiry that the DoH's focus appeared to be more on throughput and waiting lists than on outcome or quality of care and that the lack of guidance given in the area of audit was a reflection of this: 'They were not interested in results; they were interested in as many people passing through the system as possible for as low a cost as possible ... commercial considerations did seem to enter into it rather strongly.'¹⁴
- 33** In 1991, however, there was a development in approach. The Performance Management Directorate (PMD) was established within the DoH with the aim of improving NHS performance both through planning and continuous review. We were told that: 'Using taskforces PMD sought to bring together colleagues from across the Department and the NHS to tackle development and other high-priority issues. PMD consisted of multi-disciplinary teams containing administrators, doctors, nurses and economists.' Its fundamental role was to improve 'the quality, quantity and effectiveness of services of the NHS by liaising strategically with the Regions.'¹⁵

¹² T56 p. 25–6 Miss Hawkins

¹³ T56 p. 61–2 Miss Hawkins

¹⁴ T9 p. 44 Professor Sir George Alberti

¹⁵ WIT 0482 0220 Dr Roger Moore

- 34** The idea at the time was that regions, in turn, would apply the same approach of ‘performance management’ to their relationships with DHAs which, by 1991, were ‘purchasing’ health services, rather than directly providing them. Throughout the period, however, assessing and assuring the quality and performance of clinical services in particular hospitals were regarded by the DoH as being matters for the hospital, or for the health service in that locality.
- 35** Until 1991, the DoH relied upon the regions as the main means of access to the districts which managed acute healthcare services. Thereafter, with the creation of trusts, a new system was put in place, that of the regional outposts (also known as trust outposts of the NHS Management Executive). There was no longer a direct managerial link between hospitals which became trusts and regions. Instead, a deliberately unobtrusive system (called at the time a ‘light touch’ approach) was adopted.
- 36** The trust outposts reported to officials concerned with finance in the DoH and were responsible for ensuring that trusts met their statutory financial duties, and for approving capital schemes. The outposts were not required to pay attention to clinical matters, nor to other areas of performance, although by default they could become involved in issues relating to the provision of services if, for example, a trust had a serious financial problem or a capital scheme was proposed. The Secretary of State had no power to direct trusts in respect of the quality of care that they provided.
- 37** Sir Alan Langlands, Chief Executive, NHS Executive from 1994 to 2000, summed up the state of affairs. He described the situation after the establishment of trusts as one which relied on professional self-regulation, the development of processes of audit, a rudimentary internal market where purchasers held providers to standards set out in contracts, and a hierarchical relationship between the DoH, DHAs and trusts. Even if these were all perfectly aligned, he said, there was no certainty that any of the parties would be in a position to identify or respond to issues of clinical performance.¹⁶

The role of the regional health authority

- 38** Miss Hawkins told the Inquiry that the main function of the RHA was the strategic planning of services. Asked by Leading Counsel to the Inquiry whether her role as the RGM involved her in directly supervising the various different districts within the Region, she replied:

‘It was a very difficult system because the Regional Health Authority had monitoring and a degree of control, in italics, of its districts without the actual authority to affect them directly, because each district had its own Chair and non-Executive Board who actually managed the districts. So it was a situation where you had accountability and responsibility without true authority.’¹⁷

¹⁶ T65 p. 59 Sir Alan Langlands

¹⁷ T56 p. 22 Miss Hawkins

- 39** Miss Hawkins was asked whether she or the Regional Medical Officer tried to get figures from the BRI about the performance of the Cardiac Unit, particularly as regards adult cardiac surgery. She stated:

‘I would have to say no, because I would not have had the evidence to go in and demand such figures. A reluctance on the part of districts who were very content to refer out of region and not to the BRI, without being able to identify what they meant – what did they mean by unsatisfactory outcomes – was not a reason to put in two or three people to try and identify and collate statistics by hand, which is what it would be. There was no computerised record at that time.’¹⁸

- 40** She said that there was, after 1991: ‘a shift of emphasis on monitoring which would move away from the providing of the service to the purchasing of the service, because we would be working through the purchasing DHAs, whereas the performance monitoring of the provider was the DHSS [*sic*] if they were a Trust.’¹⁹
- 41** In addition to its monitoring role, the Region also had an important role in implementing the national policy on medical and later clinical audit. Following the publication of *Working for Patients; Medical Audit Working Paper No. 6*²⁰ in January 1989, arrangements to support medical audit were to be made at regional level, with funds allocated centrally. The Regional Hospital Medical Advisory Committee (RHMAC) took on the responsibility for these funds and for reporting on progress to the DoH. The RHMAC accepted the prevailing view that audit was essentially a professional educational activity and that: ‘Health authorities and managers ... are not competent to make judgements on the technical quality of medical care.’²¹

The role of the district health authority

- 42** Ms Pamela Charlwood, commenting on the approach to judging quality in the period 1984–1995, stated: ‘the criteria chosen, and their indicators, were mostly of a general nature and on a large scale, so did not draw attention to concerns about surgical outcomes in a particular specialty at a particular hospital’.²²
- 43** Ms Charlwood stated that ‘from the outset B&WDHA ... tried to concern itself with qualitative issues’.²³ In the early 1980s a number of reviews were held. In 1985 a Performance Assessment Committee (PAC) was formed to monitor the care of patients. The PAC received statistical information from a Medical Information Working Group (MIWG) which consisted of clinicians and managers.²⁴ Following the January 1989 White Paper *Working for Patients*, the MIWG evolved, in 1991, into the District Audit Committee (DAC), by which time the UBH had become the UBHT and service agreements were in place between the UBHT and the District.

¹⁸ T56 p. 65 Miss Hawkins

¹⁹ T56 p. 125 Miss Hawkins

²⁰ HOME 0003 0124

²¹ UBHT 0068 0011

²² WIT 0038 0022 Ms Charlwood

²³ WIT 0038 0022 Ms Charlwood

- 44** Miss Deborah Evans, Director of Contract Management, B&DHA, 1991–1995, stated that: ‘For the first year in which the service agreements ... were in use nationally, 1991–92, Bristol and Weston Health Authority drew up a service agreement ... which included the quality standards that were felt to be appropriate ... This ... included performance monitoring requirements.’²⁵
- 45** During 1991–1995 the DHA was able to monitor some aspects of trusts’ performance directly, through a shared clearing-house system which processed data from the computerised Patient Administration System (PAS) of local hospitals. However, the ability to monitor other items of performance and quality was very limited. The systems were not amenable to more in-depth monitoring of such things as rates of mortality and morbidity.²⁶ The DHA did not have the capacity to monitor all aspects of the quality of the service and relied on each trust to report on selected aspects of quality.
- 46** The 1991–1992 service agreement between the District and the UBHT for cardiac services (which excluded children under 1) required that the cardiac surgical unit would set up an audit group, part of the function of which was to provide the B&DHA with sufficient information to ensure that adequate audit was taking place.²⁷
- 47** Occasionally, information about mortality rates in the PCS service came to the attention of those within the district and the region, but no particular significance was attached to the figures. For example, in October 1988, when the DHA still directly managed the UBH, the District’s PAC considered the mortality rates for PCS for 1987. Members of the committee noted that there were no national performance indicators against which to assess the data. In March 1993 Mr Wisheart presented data for 1992 to the Directors of Public Health network of the South West Region. There is no record of the outcome of the presentation.²⁸
- 48** From the perspective of the B&DHA after 1991, the emphasis in audit was on adult cardiac care, not PCS. Ms Charlwood stated: ‘Within Bristol there was a consistent interest in auditing aspects of adult cardiac care. The adult service covered large volumes of activity and expenditure and in some cases there were “standards” offered by national organisations – for example, thrombolytic therapy in acute coronary heart disease.’²⁹

²⁴ WIT 0038 0023 Ms Charlwood

²⁵ WIT 0159 0027 Miss Evans

²⁶ WIT 0159 0034 Miss Evans

²⁷ WIT 0159 0037 Miss Evans

²⁸ WIT 0038 0040 Ms Charlwood

²⁹ WIT 0038 0014 Ms Charlwood

- 49** In terms of promoting and encouraging audit activity Ms Charlwood stated that: ‘From April 1993 onwards, Health Authorities were given a more explicit role in promoting clinical audit and funding audit through allocations and from 1995 through the service agreements.’³⁰ In 1993 the DHA discussed a joint strategy for clinical audit with the UBHT and other local trusts. An agreement was reached that audit should take place in a small number of areas of shared concern. PCS was not identified by the UBHT or by the DHA as an area of shared concern.³¹ Ms Charlwood added that the District’s draft specification for adult and children’s cardiac services for 1993–1994 included a number of quality standards. One of those standards stated that: ‘the quality of investigations and interventions will keep case fatality and morbidity to the minimal levels according to National Standards and will be the subject of monitoring and of clinical audit.’³² Ms Charlwood went on, however, that in February 1994: ‘a report to the B&DHA on quality and effectiveness of care included a paper on clinical audit; “A significant problem was the feeling of clinical professions that clinical practice was not the concern of the purchaser”’.³³ She added: ‘It was only later in 1995 that decisions to audit pcs openly and mutually arose when the Health Authority learned of the quality issues around the service ...’³⁴
- 50** Dr Trevor Thomas, Chair of the Medical Audit Committee (MAC), UBHT, stated that he was under the impression that the District was receiving mortality statistics for the whole of cardiac surgery. Dr Ian Baker, Consultant in Public Health Medicine, B&DHA since 1991, told us that such data were never received.³⁵
- 51** The B&DHA, therefore, as purchaser, was anxious to receive information on audit and, in particular, the reports (and data on which they were based) of the UBHT’s MAC. However, this committee was reluctant to provide this because it was seen as ‘commercially sensitive’³⁶ in the context of the new internal market. In fact, the MAC reports were not seen even by the UBHT’s Board until October 1995.

³⁰ WIT 0038 0014 Ms Charlwood

³¹ WIT 0038 0015 Ms Charlwood

³² WIT 0038 0034 Ms Charlwood

³³ WIT 0038 0034 Ms Charlwood

³⁴ WIT 0038 0015 Ms Charlwood

³⁵ T62 p. 115 Dr Thomas

³⁶ T62 p. 115 Dr Thomas

Setting the Scene

Chapter 7: The Audit and Monitoring of the Paediatric Cardiac Surgical Service in Bristol

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Introduction

- 1 In this chapter we describe the way in which the national policy for medical and later clinical audit (as described in Chapter 5) was implemented in Bristol. Secondly, we turn to paediatric cardiac surgery (PCS) in particular and set out in broad terms the types of activity undertaken by the clinicians in Bristol to audit their work. A fuller account of the evidence received by the Inquiry on these matters is in Chapter 18 and 19 of Annex A. Further papers commissioned by the Inquiry from experts are set out in Annex B.¹
- 2 As we have seen, from the inception of the NHS, individual clinicians have reviewed the quality of the care given to their patients and the clinical outcomes of such care. Such reviews might take place within a specialty, or at meetings held regionally, nationally and internationally, or as part of the process of writing an article for a professional journal. With the emergence of audit the emphasis moved from a situation in which individual clinicians decided whether and how to participate in a review of the care provided, towards a more formal, systematic approach. Local audit committees were established, audit was encouraged and supported financially, and information about the range and impact of audit activity in a given hospital or area was collected.
- 3 Notwithstanding the national endorsement of medical and then clinical audit, the approach adopted was educational. The aim was to encourage review. Audit was not seen as a tool systematically to identify problems or to monitor the outcome of care for all patients. As Dr Roylance put it, referring to the requirements placed on trusts in 1991: 'At that stage, it was simply required that there be audit activities in which every doctor participated and that general results be reported. Audit was still said to be primarily an educational activity: its monitoring potential was very much underplayed at this stage.'² He also stated '... I was aware of a strong feeling within the medical profession that audit was going to be used as yet another management tool and I felt that its introduction to the formal structure of Bristol and Weston Health Authority as it was at that time, and then the UBHT, needed to be handled very carefully in order to encourage doctors to participate.'³

Audit in the UBHT

- 4 The UBHT took over the District's role with respect to audit in 1991. The Medical Audit Committee (MAC) of the UBHT was established soon after the Trust came into being. The MAC was a sub-committee of the Hospital Medical Committee (HMC) and its membership was almost wholly medical. The MAC's remit was to follow the regional strategy and to promote, facilitate and co-ordinate audit within the Trust.

¹ Annex B paper 10m Walshe K, Offen N. 'An evaluative commentary on systems for review and audit at the United Bristol Hospitals NHS Trust from 1984 to 1995'. Also paper 11c Humphrey C. 'Medical and Clinical Audit in the NHS'

² WIT 0108 0046 Dr Roylance

³ WIT 0108 0043 Dr Roylance

It did not manage the audit activity within the various hospitals nor did it have any formal powers or resources.

- 5 Between 1991 and 1995, on average, £250,000 a year was provided to the UBHT to spend on audit activities. These funds were allocated directly from the Region through the Regional Medical Officer (RMO). They were allocated to the consultant medical staff, not to the MAC. Management took no part in the distribution or allocation of these funds. The funds were spent mostly on local IT systems and on the salaries of audit assistants. The MAC did not have any control over these funds nor was it in a position to monitor how they were used.
- 6 The MAC produced annual reports that included general information about audit and examples of audit activity within the UBHT over the previous year. It was for each specialty to decide on audit topics and on how the audits were to be arranged. Specialties and departments within the trust were asked to supply regular returns to the MAC about their audit activity. Some specialties, such as oncology and ophthalmology, responded; others did not. The information in the annual reports, therefore, was drawn from such information as the MAC had been able to gather. It had no powers to require that it be given information about audit activities where none was forthcoming.
- 7 The annual reports of the MAC were given by the UBHT to the Region. Dr Roylance stated, however, that *detailed* results of audit were not communicated to either the Region or the District. Dr Roylance was not personally involved in the process or the detailed arrangements, since, in his view, to have become involved might have threatened the process of audit and the co-operation of the clinicians.⁴ The Trust Board did not see the reports of the MAC.
- 8 The annual reports of audit activity within the UBHT offer insights into the way audit was perceived at the time and the manner in which it was carried out in the UBHT. The 1992 Annual Report, for example, stated that medical audit: '... must continue to be seen to be a confidential and independent educational process – not merely the inquisitorial arm of purchasers under the auspices of the Regional Health Authority.'⁵ An extract from the 1993 Annual Report shows the difficulties encountered by members of the MAC. As responsibility for audit was devolved by management to clinical directorates, the MAC was of the view that it was: '... quite difficult for the Audit Committee to influence and record audit activities ... the Audit Committee has no budget and is not made up of clinical directors.' It was pessimistic about the future unless: '... some agreement can be made between senior management and the [new] Clinical Audit Committee (CAC) as to the future of audit in the UBHT.'⁶
- 9 A further insight into audit at the UBHT can be gained from the annual reports about audit activity in the South West produced by the Region. Its report for 1992/93 noted

⁴ WIT 0108 0043 – 0044 Dr Roylance

⁵ UBHT 0032 0080; MAC Annual Report 1992

⁶ UBHT 0058 0309; MAC Annual Report 1993

that there was only a small amount of information about the UBHT's audit activity because very little had been received from the Trust, and that which had been received was in a form which meant that it could not be used. A similar picture appeared in the Region's annual audit report for 1993/94.

- 10** In terms of the role of management, Dr Roylance saw it as being to ensure that audit was being carried out whilst: 'the actual audit figures were to remain confidential to those providing the service i.e. the clinicians.'⁷ It was not envisaged at the time that management would be given the data underlying or produced by audit. Dr Roylance was of the view that any such involvement of management would, in fact, inhibit the development of the audit process.
- 11** The MAC was reconstituted as the CAC in early 1994, reflecting the change from medical to clinical audit. A number of non-medical clinicians became members. The CAC reported via the Medical Director and the Patient Care Standards Committee, to the Trust Board. Mr Wisheart took over as Chairman of the CAC from Dr Thomas in July 1994 and held that position for six months. The CAC was responsible for encouraging and monitoring the introduction of the process of audit but with the emphasis now being on the shared care of patients by a range of healthcare professionals. As with the MAC, the CAC's reports were seen by Dr Roylance and the Region. From 1995, they were also seen by the Trust Board.
- 12** There was no mention of PCS in the annual reports of the MAC of 1992 or 1993/94. Audits of cardiac surgery (although not specifically of PCS) are mentioned in the reports of 1990 and 1994/95. Dr Thomas told us, however, that he knew that audit meetings and activity were occurring within the specialty of PCS, and that returns were being made to the UK Cardiac Surgical Register (UKCSR).⁸

How the clinicians in Bristol reviewed paediatric cardiac surgery

- 13** 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 (DHA), a good deal of activity did, in fact, take place. Moreover, it predated 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 UKCSR, held meetings to discuss the results of audit, and reviewed individual cases and series of cases.

⁷ WIT 0108 0019 Dr Roylance

⁸ T62 p. 140 Dr Thomas

The sources of data

- 14** The surgeons, anaesthetists and perfusionists kept separate logs of their clinical activity, and the paediatric cardiologists maintained their own computerised information system known as the South West Congenital Heart Register. Basic demographic data and data on diagnoses, procedures and outcomes were recorded for each child seen or operated on.
- 15** Mr Wisheart stated that he kept a log of his open-heart operations from 1975 until the end of his career. The log contained information about each patient and in particular about the outcome of the procedure(s) carried out. Mr Wisheart stated that he used his logbook to monitor his own performance: 'It had the advantages of being within my possession (i.e. in my hospital office), accessible, highly reliable and because of the way that it was set up it was both functional and effective.⁹ ... I believe that the quality of the data in the log is high but I would never claim that it is perfect. ... I would regard entries concerning death and autopsies as extremely reliable.'¹⁰ Mr Dhasmana described his surgeon's log: 'The main purpose of the logbook was to provide a quick reference for the personal audit of the open-heart procedures carried out by me in the Hospital, as an ongoing process. This helped in recognition of problems at an early stage. The logbook provided figures, which helped with preparation of various audits, reports including compilation of data in the U.K. Cardiac Surgical Register.'¹¹
- 16** The cardiac surgeons used their logs and the South West Congenital Heart Register as their chief sources of statistical data. A variety of statistics were produced, including annual statistical summaries, annual reports on paediatric cardiology and cardiac surgery, figures for audit and other meetings, and the annual returns made to the UKCSR.
- 17** From 1990 the cardiac surgeons introduced their own computerised information systems, the METASA system and later the Patient Analysis and Tracing System (PATS), for the purpose of local audit and research, although these never functioned effectively during the period of the Inquiry's Terms of Reference.
- 18** The paediatric cardiologists kept records of all children seen by them with a congenital heart defect. Dr Jordan stated that the recording system had a long history. Records had progressed from books to various early computer systems, until the Bristol and South West Children's Heart Circle purchased a computer which was capable of holding a database of information. Dr Jordan engaged his son to write a software application to make the system more 'user friendly'.¹² A small research grant from the Regional Health Authority paid for a part-time secretary to put in the data. Some 96 items were recorded for each patient. Dr Jordan explained: 'In general, while the system probably sounds amateurish and was by no means perfect, it was better than most units had in place. Clearly it would have been better if we had had more

⁹ WIT 0120 0255 Mr Wisheart

¹⁰ WIT 0120 0259 Mr Wisheart

¹¹ WIT 0084 0001 Mr Dhasmana

¹² WIT 0099 0002 Dr Jordan

clerical and computer staff, but we had no finances to pay for this¹³ ... Even with the system as it was, I could have made much more use of it if I had had more time.¹⁴

- 19** As regards the anaesthetists, they each kept personal logs. Professor Prys-Roberts told the Inquiry that he regarded the keeping of such a log as 'proper medical practice.'¹⁵ Referring to the data in her log, Dr Sally Masey, consultant anaesthetist UBH/T stated: '... The data are, as far as I am aware, complete for my practice except for 1988 ... The record of in-hospital deaths may not be complete, as some deaths may have occurred about which I was unaware.'¹⁶
- 20** The perfusionists also kept logbooks. Mr Richard Downes, a clinical perfusionist at the BRI from 1992, stated that: 'The function of the Perfusionist's log was to provide a record in the form of lists of the type and number of open-heart surgery cases the perfusionists had carried out over the years. That information was limited to the cumulative number of patients operated on, surgeon's initials, patient name, age, operation type and date of operation ...'¹⁷ Additional sources which contained data about heart operations on children included: the Post-Mortem log kept by Professor Berry, consultant paediatric pathologist, BRHSC; the Operating Theatre Register; Helen Stratton's (Cardiac Liaison Nurse, UBHT) register of the cases that she dealt with; and the Ward Admission Books kept by the ward nurses.
- 21** Apart from all the sources of information kept by healthcare professionals, administrative staff in the UBH/T also collected and kept data on patients: the UBH/T's Patient Administration System (PAS). This was a computerised system maintained for administrative purposes. It included demographic data (such as name, address and date of birth), administrative data (such as dates of hospital appointments and dates of admission), and clinical data (diagnoses and procedures) for all patients treated by the UBH/T. This information formed the basis of returns to the national Hospital Episode Statistics (HES) database, held by the Department of Health (DoH). From the early 1990s the UBHT also sent PAS data for analysis to a private consultancy called CHKS Limited. This company provided reports on the Trust's performance in selected specialties, comparing UBHT with a group of similar hospitals. CHKS Limited produced a report on the cardiology and cardiac surgery services dated 1992. PCS was not separately identified in the report. Given that it was regarded as a distinct, administrative system, there is no evidence to suggest that the clinicians providing the PCS service would have referred to or taken account of the data on the UBHT's PAS system.
- 22** Referring to PAS systems in general, Ms Ann Harding, then Acting Director of the NHS Information Authority, told the Inquiry: '... I think this is one of the problems that we have, the data is collected for the purposes which clinicians believe is managerial and

¹³ WIT 0099 0003 Dr Jordan

¹⁴ WIT 0099 0004 Dr Jordan

¹⁵ T94 p. 5 Professor Prys-Roberts

¹⁶ WIT 0270 0001 Dr Masey

¹⁷ WIT 0169 0015 Mr Downes

therefore is not relevant to them. ... the level of detail at which a clinician would want the information for the purposes of audit is not readily encompassed within the levels of diagnosis and operative coding that we currently have.'¹⁸

Statistics relating to the clinical performance of specialist centres elsewhere in the UK

- 23** Statistics relating to PCS at other specialist centres, for the purpose of comparison, were available to the clinicians in Bristol from a range of external sources. Principal among these were the annual reports from the UKCSR, distributed by the Society of Cardiothoracic Surgeons of Great Britain and Ireland. These contained aggregated data on numbers of operations and numbers of deaths, derived from the returns made to the Register by each of the specialist centres in paediatric and adult cardiac surgery in the UK. These figures were used by the clinicians in Bristol to draw comparisons between their clinical performance and that of specialist centres elsewhere. Mr Dhasmana stated that: 'The [UKCSR] provided annual figures in the form of averages compiled from the returns to the Society of Thoracic and Cardiovascular Surgeons of Great Britain and Ireland. All cardiac centres in the UK, including supra-regional centres, would be providing data for the register. ... The UKCSR annual figures were the only known comparator during this time.'¹⁹
- 24** It is less clear whether the Bristol clinicians saw reports emanating from the Supra Regional Services Advisory Group (SRSAG). In particular, it is unclear whether they saw either of the two Working Party reports, commissioned by the SRSAG and produced respectively in 1989 and 1992. These showed the relative performance in terms of mortality of the different units carrying out paediatric cardiac surgery on children under 1. Dr Joffe told the Inquiry that he had not seen the 1989 report until he gave oral evidence to the Inquiry in 1999. Mr Dhasmana said he did not receive any regular feedback regarding other centres from the SRSAG. Mr Wisheart, when asked by Leading Counsel to the Inquiry about these reports, stated: 'I have more difficulty with my recollections there because I certainly saw some reports but I have seen other documents, through this Inquiry chiefly, which I had never seen before.'²⁰
- 25** Statistics on clinical outcomes at specialist units elsewhere in the UK were also available to the clinicians from professional meetings, other professional contacts, and professional journals. Mr Wisheart referred to sharing data with other centres: 'This took place through communication and publication of data within the context of peer reviewed scientific meetings and journals, including the informal meetings of paediatric cardiac surgeons in Great Britain from 1990.'²¹ Mr Dhasmana stated: '... there was some scepticism attached to information received in conversations with colleagues from other centres, as people did not normally like to talk about problems faced during operations.'²²

¹⁸ T 39 p. 26 Ms Harding

¹⁹ WIT 0084 0051 Mr Dhasmana

²⁰ T94 p. 85 Mr Wisheart

²¹ WIT 0120 0292 Mr Wisheart

²² WIT 0084 0052 Mr Dhasmana

Paediatric cardiology and cardiac surgery: annual statistical summaries

26 The numbers of cardiac operations carried out and the numbers of deaths, of both adult and child patients, were compiled by Mr Wisheart into an annual statistical summary. He explained: ‘... This did not happen right at the beginning, but it began early on and evolved to the point where each year I published an annual – what I have called a “statistical summary”. ... The summaries that I am referring to were aggregated and I continued to produce those up until, I think, 1992.’²³ A copy of the data was sent to individual consultant cardiac surgeons working in the cardiac unit. The figures also appeared in the three Annual Reports of the paediatric cardiology and cardiac surgery services which were produced for the years 1987, 1988 and 1989/90 respectively. Mr Dhasmana stated that, for the years 1993/94 and 1994/95, copies of the annual data were also submitted to the directorate’s audit co-ordinator for the particular year.²⁴

The Annual Reports on paediatric cardiology and cardiac surgery

27 As we have said, there were three Annual Reports on paediatric cardiology and cardiac surgery (for the years 1987, 1988 and 1989/90). The reports contained tables of the results of open and closed surgery for congenital heart disease in patients under and over 1 year of age, and showed the numbers of deaths and the rate of mortality. Dr Joffe, speaking of the 1988 report, told the Inquiry: ‘The idea was to send the reports to the then District Health Authority, both the local one and the peripheral centres, particularly to the paediatricians around the region with whom we were related. ... It was freely available to members of the cardiology team.’²⁵ Dr Jordan’s recollection was: ‘The consumption [of the 1987 report] was basically internal and it went I think to the management of the Children’s Hospital and to the various people concerned. ... I think we did actually send the one in 1987 out much more widely ... but my recollection is that we did not send subsequent ones out.’²⁶

The anaesthetists: Dr Bolsin

28 Dr Bolsin began to gather data about the PCS service in 1989. In 1991 he showed them to Professor Prys-Roberts, Professor of Anaesthesia at the Bristol University Medical School (and later President of the Royal College of Anaesthetists 1994–1997). Professor Prys-Roberts advised him to collect more data before reaching any view. In the summer of 1991 Dr Bolsin circulated minutes of a meeting between the anaesthetists, the surgeons and the cardiologists, which included reference to an audit of the outcomes in children undergoing PCS. Later that same year, Dr Bolsin was helped by Dr Black, a senior lecturer in anaesthesia from the University of Bristol and they began to compile and collate data. In early 1992 Dr Bolsin again saw Professor Prys-Roberts with handwritten data. Dr Bolsin was advised to get further data which could then be shared with others. Dr Bolsin then worked with Dr Black to

²³ T41 p. 63 Mr Wisheart

²⁴ WIT 0084 0024 Mr Dhasmana

²⁵ T90 p. 16 Dr Joffe

²⁶ T79 p. 11 Dr Jordan

produce data which were shown to colleagues in the Department of Anaesthesia in the spring of 1993 in the form of a report²⁷ '*Analysis of Paediatric Cardiac Mortality Data from UBHT 1990–92*'. Dr Bolsin then showed his data to an ever-widening group, but not to Mr Wisheart or Mr Dhasmana.

Meetings for audit and review of the PCS services

- 29** The clinicians held a variety of meetings to discuss and review statistics relating to their clinical performance. These meetings fell into four main categories: Cardiac Surgical Audit; Departmental Audit; Clinico-Pathological Conferences; and Evening Meetings. They were held on a regular basis and variously attended by those involved in paediatric cardiac surgery and paediatric cardiology, and other clinical disciplines. Mr Wisheart stated: 'The practice of audit within paediatric cardiac surgery was set up by the clinicians in that area and it was done on the basis of their interest, enthusiasm and commitment, not because of any management requirement.'²⁸
- 30** Mr Wisheart explained that: 'Cardiac Surgical Audit was formally instituted in 1990–91 in response to the White Paper. However it evolved from pre-existing activities which had been labelled educational but which did involve a significant element of audit.'²⁹ The meetings focused on the review of individual cases, although series of patients were reviewed when particular 'topics' were audited, or annual statistics presented. Reviews of series of cases also took place with a view to presenting research findings to scientific meetings and publication in professional journals.
- 31** Regular departmental audit meetings, convened by the paediatric cardiologists and bringing together those involved in paediatric surgery and cardiology, commenced in 1990. These meetings were held monthly at the BRHSC and were open to all members of staff concerned with the care of children with congenital heart disease (CHD). Sometimes nursing staff and technical staff from the catheter laboratory attended. Mr Dhasmana stated: 'Others like anaesthetists and junior members of surgical staff were not able to attend these meetings on a regular basis because of their clinical commitment elsewhere in the same hospital or at the BRI.'³⁰ These particular meetings lapsed in 1992 for a period of time, as we shall explain in the subsequent chapters on concerns.
- 32** Clinico-pathological meetings were held when a patient died. These meetings were organised by Professor Berry and were scheduled to take place once a month. Mr Dhasmana stated that the aim of such meetings was to review individual cases: 'in order to confirm the pre-operative diagnosis and to re-examine the operative procedure.'³¹ Mr Wisheart told us that the meetings were open to cardiologists, surgeons, radiologists, and anaesthetists, as well as pathologists. He went on:

²⁷ UBHT 0061 0080

²⁸ WIT 0120 0392 Mr Wisheart

²⁹ WIT 0120 0392 Mr Wisheart

³⁰ WIT 0084 0020 Mr Dhasmana

³¹ WIT 0084 0022 Mr Dhasmana

'Up until the arrival of Dr Ashworth³² in 1993 no record whatsoever was kept of these meetings and in particular there were no minutes or definitive reports of findings. As far as I am aware the occurrence of these meetings were [*sic*] not reported to the Trust Audit Committee.'³³

- 33** Informal evening meetings were held at the homes of consultants beginning in the early to mid-1980s. Mr Wisheart described these as 'multi-disciplinary evening meetings' and explained that they were attended 'by cardiologists, surgeons, anaesthetists, radiologists and pathologists'³⁴ and took place two to four times a year. Mr Dhasmana referred to them as meetings of the 'paediatric club'.³⁵
- 34** Mr Wisheart stated that the agenda of these meetings: '... was not limited to audit, but it did include review of the annual statistical summaries and occasional series of patients, particularly before the more formal audit activities began in 1990–1991. The clinical series reviewed included Fallois's Tetralogy repair in 1991, VSD closure in 1988 or 89 and the prevention and management of pulmonary hypertension.³⁶ Thus the emphasis was on a series of patients rather than the individual patients.'³⁷ We were told that no minutes were taken of these meetings. As Dr Joffe told us: 'We had a very small, close-knit group of five or six people and I think our thorough airing of the situation with a conclusion that we had come to at the end of it was sufficient for all of us to then take on whatever policy changes we had decided upon, and all of us would stick to them. So there was no problem in not having minutes for that kind of discussion.'³⁸

³² [Dr Michael Ashworth, consultant paediatric pathologist, UBHT]

³³ WIT 0120 0395 Mr Wisheart

³⁴ WIT 0120 0396 Mr Wisheart

³⁵ WIT 0084 0023 Mr Dhasmana

³⁶ See Chapter 3 of Annex A for an explanation of these clinical terms

³⁷ WIT 0120 0396 Mr Wisheart

³⁸ T90 p. 130 Dr Joffe

Setting the Scene

Chapter 8: Paediatric Cardiac Surgical Services

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The planning and funding of paediatric cardiac surgery for children under 1 year of age (neonatal and infant cardiac surgery)

- 1 In this chapter we describe the way in which the paediatric cardiac surgical (PCS) service for children under 1 year of age, neonatal and infant cardiac surgery (NICS),¹ was planned and funded during virtually all of the period of the Inquiry's Terms of Reference, as part of the national system of supra regional services (SRS). We set out the criteria whereby specialised services, including NICS, were designated for inclusion in the system, Bristol's designation as a supra regional centre (SRC) for the provision of NICS, and the subsequent decision to de-designate NICS as an SRS. A fuller account of the evidence received by the Inquiry on these issues is in Chapter 7 of Annex A.

The system of supra regional services

- 2 The vast majority of hospital services in England between 1984 and 1995 were funded through allocations of money from the Department of Health (DoH) to regional health authorities (RHAs). However, in the 1970s, policy-makers in the NHS were faced with the problem of how to fund and support the development of a number of specialised services, including PCS. In 1974 a Joint Working Party was set up between the DoH's Medical Policy Division and representatives of the medical profession to consider how specialised clinical services should be delivered. This Working Party met regularly and, in 1983, it was agreed between the DoH, the RHAs and the Joint Consultants Committee that new arrangements would be introduced for what were to be called 'supra regional services' (SRS).²
- 3 The SRS system was intended to protect, nurture and support the development nationally of highly specialised and financially vulnerable services. The services were vulnerable in the sense that there was a relatively low volume of patients who required particular clinical expertise or experience and on occasions particular facilities and equipment for which the cost was high. The disparity between cost and demand was such that they could not economically be provided even on a regional basis in each of the then fourteen NHS regions in England. The SRS system worked, therefore, by designating certain centres (SRCs) at which the particular service would be provided as part of the SRS system.
- 4 It was thought that by providing a special funding system which would aim to ring-fence money for the designated services, any proliferation of these services could be

¹ NICS is PCS on children under the age of 1. The term 'neonates' refers to children aged up to 28 days, and 'infants' to children under 1 year of age

² 'Supra regional' means covering more than one region

limited. Thus, they would develop in controlled and protected conditions until they were strong enough to be integrated into the mainstream of the NHS.

- 5 In one sense, the SRS arrangements should not greatly occupy the Inquiry. They were to do with protecting funds so that very specialised areas of care could be developed. We devote attention to them here because they are an essential element in setting the scene for what went on in Bristol. This is because the SRS arrangements created certain assumptions and conditions which in turn affected the way PCS services were provided in Bristol. First, there was a real sense in which the process of designation was perceived as a recognition of the designated centre as a place of excellence. In the minds of parents of children needing care this was undoubtedly the case. In the minds of the clinicians, it was a feather in their cap to be sought and won. Second, and following on from that, designation as an SRC constituted a green light to the clinicians in the UBH/T to continue and seek to develop its PCS service. Third, designation brought a secure stream of funding, so that senior management might come to the view that the service was taken care of financially and could be left to get on with things. These are some of the reasons why we must attend to the system of SRS in some detail.

- 6 Dr Norman Halliday, Medical Secretary to the Supra Regional Services Advisory Group (SRSAG) from 1983 to 1994 and one of the ‘architects’ of the SRS system, told the Inquiry that:

‘The reason for setting up the supra-regional service and the reason for selecting any particular service was principally funding ... But of course from the Department’s point of view, we recognised that there was also a benefit in that. There was a benefit in that we could control the development of the services, which would be beneficial in terms of cost, but also beneficial in terms of benefits to the patients, because the experience worldwide was that the more a doctor does a particular form of treatment, the better are his results. So by controlling the development of these services, we would be giving benefits to the patients.’³

- 7 The SRS arrangements came into effect at the beginning of the financial year 1983/84 and applied initially to four designated services:
 - paediatric haemodialysis and transplantation;
 - spinal services;
 - services for the management of chorioncarcinoma; and
 - the National Poisons Information Service.

³ T13 p. 12–13 Dr Halliday

Over time it extended to 16 designated services, including a particular subdivision of PCS termed NICS.

The consequences of designation as a supra regional centre for a local health service

- 8 The importance of the designation of a particular centre as an SRS should not be overstated. Crucially, it did not constitute any permission or authorisation on the part of the SRSAG that the particular service could be carried out at the particular centre. Still less did it constitute a prohibition against providing that service in other centres. The SRSAG could not prevent developments elsewhere. All that it could do was foster developments in the centres it chose and, to the extent that patients might not benefit from treatment in non-designated centres, hope that others would not offer the service.
- 9 In practical terms, the designation of a particular service as an SRS meant that it was funded by ‘top-slicing’ a levy each year from the funds allocated by Parliament for Hospital and Community Health Services. Those funds were then administered directly by the DHSS/DoH and distributed to the designated SRCs on the advice of the SRSAG. The funding was protected, and a hospital with an SRC thus obtained a guaranteed source of funding. This mattered during the period 1984–1995 when funding of the NHS generally was under very great pressure. Although accounting mechanisms at the time did not permit the money received to be specifically traced to expenditure on the particular SRS (it simply went into the hospital’s overall income), SRS funding did give protection to the service concerned, if only because a hospital could not readily receive the SRS funding and at the same time fail to provide the service.

Paediatric cardiac surgery for the under-1s as a supra regional service

- 10 PCS service for children under 1 year of age (NICS) was selected for inclusion in the SRS system from the start of the financial year 1984/85.
- 11 Guidance on the selection of specialised services which were to be funded supra-regionally had been issued by the DHSS in a Health Notice dated December 1983.⁴ The criteria to be followed were:
 - the service should be an established clinical service, not a research or development activity (for which alternative sources of funding existed);
 - there should be a clearly defined group of patients having a clinical need for the service;
 - the benefits of the service should be sufficient to justify its cost when set against alternative uses of NHS funds;

- the cost should be high enough to make the service a significant burden for the providing regions;
 - supra regional funding, as opposed to regional or sub-regional development, should be clearly justified either (a) by the small number of potential patients in relation to the minimal viable workload for a centre, or (b) by the economic or service benefits of concentrating the service in fewer and larger units shared between regions, or (c) as an interim measure by the scarcity of the relevant expertise and/or facilities; and
 - the units to be designated should be capable of meeting the total national caseload for England and Wales.
- 12** The decision to designate NICS as an SRS was taken following years of discussion among healthcare professionals. In 1967 the Joint Cardiology Committee (JCC) of the Royal College of Physicians of London (RCP) and the Royal College of Surgeons of England (RCSE) prepared a report on the need for special cardiac centres for diagnosis, treatment and research.⁵ In the same year, the British Paediatric Association (BPA) argued that operations to remedy congenital heart defects in young children should only be carried out in a limited number of centres. In 1979 the BPA followed up its 1967 report with the recommendation that six centres for NICS (including one in the South West) should be established.⁶ In 1980 the London Health Planning Consortium recommended that three centres be established in London.⁷
- 13** It was with this background that, in 1980, the second report of the JCC of the RCP and the RCSE was published. Amongst other things, that report indicated that: the size of a centre should depend on the population served; there should be a close connection between where diagnosis and treatment were carried out; it was to be expected that the greater the number of operations performed the lower the rate of mortality; the number of units should be ‘certainly under ten’; and the selection of SRCs should be based on present workload, geographic location and quality of work.⁸ In 1982 the regional medical officers suggested nine centres (being exactly those that were subsequently designated in 1984).⁹
- 14** The recommendation of the JCC in 1980 in relation to PCS that the selection of SRCs should be based, in part, on geographic location was not reflected in the criteria set out in 1983. Nor does it appear to have been endorsed by the SRSAG in their further

⁵ ‘*British Heart Journal*’ 1968; 40:864–8

⁶ BPCA 0001 0014; BPA report, 1967

⁷ ES 0002 0007; London Health Planning Consortium report, 1980

⁸ RCSE 0003 0017 – 0025; second report of JCC, 1980

⁹ ES 0002 0007; minutes of a meeting of representatives of the designated SRCs, 5 December 1984

guidance issued in September 1988.¹⁰ This stated that certain quantitative criteria were being used in handling bids for designation of a service as an SRS, namely:

- that the rarity of the condition to be treated must be such that the population served *by each unit* (emphasis added) is a minimum of 5 million and the total national caseload should normally be capable of being treated in fewer than ten units; and
 - that the cost [should] be high enough to make the service a significant burden for the providing regions had been taken as being at least £250,000 per unit.
- 15** The September 1988 guidance also stated that the units providing all SRS would be those which not only fell within the definition of a ‘centre of excellence’, but also met all of the criteria set out in the December 1983 DHSS Health Notice.¹¹
- 16** The professional view, accepted and endorsed by the SRSAG, was that the provision of NICS should be concentrated into relatively few centres so as to ensure a high standard of diagnosis and treatment. It was also noted that there were too many small units receiving funding that would be better directed towards developing the larger and more efficient ones.
- 17** NICS was designated as an SRS and the following centres were designated for its provision during 1984/85:
- The Freeman Hospital Newcastle;
 - The Royal Liverpool Children’s Hospital;
 - Killingbeck Hospital, Leeds;
 - Southampton General Hospital;
 - Birmingham Children’s Hospital;
 - Brompton Hospital, London;
 - Great Ormond Street Hospital for Sick Children, London;
 - Guy’s Hospital, London; and
 - the BRHSC/BRI in Bristol.
- 18** Supra regional funding of PCS related only to *neonates* and *infants*. The PCS service for children over 1 was not within the SRS system. Thus, throughout the period of the Inquiry’s Terms of Reference, the arrangements for organising and funding cardiac

¹⁰ Centres of excellence and supra regional units (DOH 0002 0025)

¹¹ HN (83) 36 and DOH 0002 0022 – 0023

surgery for older children were the same as those which applied to children's and adults' acute healthcare services generally.

- 19** The SRSAG drew a distinction between children under and over 1 in designating NICS as an SRS in order to meet the criteria of low volume and high cost. Since PCS was carried out on children up to their teens, the overall volume of PCS could not be categorised as low. Only by restricting PCS to the under-1s was this criterion met.
- 20** Dr Halliday accepted that the drawing of a distinction between under-1s and over-1s, with the former included but the latter excluded in the SRS arrangements, was 'somewhat artificial'.¹²

The designation of Bristol

- 21** Dr Barry Keeton, a consultant paediatric cardiologist at Southampton General Hospital since 1978, and a member of the Inquiry's Group of Experts, described his recollection of the process of selecting centres for inclusion in the SRS for NICS. He said:

'... I recall that prior to the setting up, there were eight centres that had been nominated for supra regional designation, and then my next recollection is that the Regional Medical Officers commissioned a report. I had some personal knowledge of this because the lady who did it came round to visit me and I gave her some help in the data, the statistics from Southampton. Following that Regional Medical Office report, there were then nine centres and that was the point at which Bristol was added on, I think in 1984, to the supra regional list.'¹³

- 22** The clinicians in Bristol were aware that centres were to be designated for NICS. Dr Joffe told the Inquiry he was 'appalled' that those selecting centres for designation made: 'no attempt ... to visit Bristol and see the centre and find out what it had to offer.'¹⁴
- 23** The clinicians, Dr Joffe, Dr Jordan and Mr Wisheart, wrote a joint memorandum to the Chairman of the SRSAG expressing their view that: '... Bristol has an irrefutable claim for recognition as a supra regional cardiac centre for neonates and infants. ... redirection of these [cardiac] patients to a centre elsewhere must result in a demise of meaningful paediatric cardiology in Bristol.'¹⁵
- 24** They argued:

'The paediatric cardiology service already functions as the de facto Regional and Supra Regional Centre (although not yet officially recognised as such), drawing 28% of new referrals to the unit from Avon, 48% from the rest of the SW Region and 24% from South Wales, North Wessex and elsewhere. ... The long-term

¹² WIT 0049 0015 Dr Halliday

¹³ T51 p. 112 Dr Keeton

¹⁴ T90 p. 70 Dr Joffe

¹⁵ JDW 0001 0152; Memorandum on the Designation of Bristol as a SRC in NICS, July 1982

management of patients is supervised near their homes through a system of Consultant Cardiac Clinics developed over many years and probably more comprehensive than in any other paediatric cardiology service in England. Regular peripheral clinics are held in Bath, Swindon, Cheltenham, Gloucester, Taunton, Barnstaple, Exeter, Torquay, Plymouth and Truro, and patients are referred by paediatricians in South Wales. Close liaison exists with paediatricians in all these centres, who would resist any curtailment in the services they and their patients receive.'

25 Further, they argued that it was:

'... unrealistic to base any such decision simply on current surgical volume in infants, without taking cognisance of other important factors such as geographical position and communications, association with a University Department of Child Health, historical evolution and ties with paediatricians in the region and adjacent areas of other regions, anticipated expansion and development, and standards of associated paediatric and neonatal services.'¹⁶

26 As set out above, a number of criteria were set for identifying appropriate centres for SRS. We heard evidence that Bristol did not meet the criteria set out in the 1983 Health Notice, but was nonetheless designated, mainly on the basis of geography. Sir Terence English, President of the RCSE, and a member of the SRSAG from 1990 until 1992, told us that it was also thought that Bristol had 'the capacity to develop ... if the will were there'.¹⁷

Caseload

27 Prior to designation, the South Western Regional Health Authority was of the view that '... Bristol is not necessarily large enough to fulfil the criteria [for an SRS] of a catchment population of 5 million ...'¹⁸

28 NICS referred to both open- and closed-heart operations. We are particularly concerned with open-heart surgery. A paper prepared for the SRSAG in 1988 stated that, based on a unit with two surgeons: '... the minimum [appropriate] open-heart workload is likely to be at least 80 cases per year'. Three of the designated units, Guy's, Bristol, and the Freeman in Newcastle, at that time, four years after designation, were described by the paper as falling 'far short'.¹⁹ Sir Terence English agreed with the 1988 paper. He told us that the minimum caseload necessary for a centre to maintain sufficient expertise was regarded as 40 or 50 open-heart operations performed by a single surgeon per year in the under-1-year age group and that there should be at least two surgeons in the unit, giving a total of 80–100 open-heart operations per year.²⁰

¹⁶ JDW 0001 0150; Memorandum on the Designation of Bristol as a SRC in NICS, July 1982

¹⁷ T17 p. 76 Sir Terence English

¹⁸ HAA 0095 0071; draft report (this document appears to be dated 14 November 1983: see HAA 0095 0073)

¹⁹ DOH 0002 0242 Paper SRS(88)2

²⁰ T17 p. 69–70 Sir Terence English

- 29 In the year before designation, the Bristol Unit carried out a very few (three, four or 11)²¹ open-heart operations on children under 1 year of age. In 1991, seven years after designation and the year before de-designation, the two surgeons providing the NICS service in Bristol carried out 46 open-heart operations between them on children under 1 year.
- 30 Dr Halliday told us that, in terms of caseload, Bristol ‘certainly did not perform anything like on a par with the other units’.²²

Quality

- 31 A paper produced by the DHSS in 1988²³ stated that centres suitable for designation had to qualify as ‘centres of excellence’: ‘Units which might qualify for this title are those where a special expertise had been developed in a particular area of medicine. ... All supra regional services will be provided in units which would fall within the “centres of excellence” definition.’
- 32 There was no evidence in the documentation available to the Inquiry that Bristol was regarded, either at the time of designation or subsequently, as a centre of excellence for NICS. In fact, Dr Halliday said that ‘Bristol did not actually shine as a star’, whereas many of the other units did stand out.²⁴

Geographical location

- 33 While referred to in the second report of the JCC of the RCP and RCSE in 1980, geographical location was not formally a criterion for designation of an SRC. Bristol’s geographical location, however, was clearly a deciding factor in its designation. Dr Halliday said: ‘In the case of Bristol, the case was weak, but there was an important point and that was the geographical cover, because all the other units covered the country well, but the South West was deprived in terms of cardiac surgery, especially for neonatal and infants. So the Advisory Group was concerned to see that part was covered. Indeed, many of the professional reports identified that there was a need for cover in that area ...’²⁵ and ‘... if you are designating a service for the first time and you are endeavouring to cover the country, you may well have to identify a unit which at that moment in time is not performing as well as some of the other centres which may have been established for many years, but the intention is to develop that service, nurture that service.’²⁶

²¹ The figures differ depending on whether they refer to the financial or calendar year

²² T13 p. 27 Dr Halliday

²³ DOH 0002 0025 – 0027; DHSS Paper EL(88)P/153 ‘Centres of Excellence and Supra Regional Units’, dated 12 September 1988

²⁴ T13 p. 28 Dr Halliday

²⁵ T13 p. 26 Dr Halliday

²⁶ T13 p. 31–2 Dr Halliday

The de-designation of neonatal and infant cardiac surgery as a supra regional service

- 34** The PCS service for children under the age of 1 was de-designated as an SRS in July 1992, although funding was maintained until the end of March 1994. It was taken out of the protected funding system because the proliferation of centres around the country providing the service became steadily more obvious. While the SRS system had, in part, been designed to control proliferation, the DoH did not in fact have the power to *prevent* centres which were not within the supra regional funding arrangement from offering the relevant services. Throughout the period that Bristol was designated, other centres which were not designated and, therefore, were not funded under the SRS system, began to carry out PCS on children under 1. For example, by September 1990 Cardiff, Oxford and Leicester were all performing NICS.²⁷
- 35** Indeed, Dr Halliday agreed that designating PCS for children under 1 as an SRS was ‘doomed from the start’,²⁸ in that the decision to limit the service to the under-1s was arbitrary, there was already an existing and established service in centres other than those designated, and that the criteria for SRSs did not appear ever to be met, at least in some of the designated SRCs. Moreover, the proliferation of centres made it inevitable that if there were too many centres, the criterion based on volume of cases could not be met. Given that the incidence of congenital heart disease was a constant 6–8 per 1000, there would not be enough throughput in at least some of the centres.
- 36** There were discussions about the continued designation of SRCs for NICS, and about the continued designation of particular centres, from at least 1988. These discussions, however, were focused on the *number of units* providing the service, rather than on any consideration of the *quality of the service* provided in any particular unit.
- 37** The possibility of de-designating NICS as an SRS was first raised as early as 1988 in a paper prepared for the SRSAG.²⁹ Sir Terence English told us that, subsequently, the de-designation of particular units, identified as ‘non-viable’ and operating at ‘sub-optimal’ levels, was discussed at a meeting of the SRSAG in September 1989. However, at a meeting of the SRSAG in July 1990, Sir Terence reported that he considered that NICS should remain a designated service, but with no more than nine units.³⁰

²⁷ SCS 0004 0026; minutes of meeting on 20 September 1990

²⁸ T13 p. 128 Dr Halliday

²⁹ DOH 0002 0242; Paper SRS(88)2

³⁰ DOH 0002 0196; minutes of meeting on 26 July 1990

38 In October 1990 the SRSAG stated that NICS should 'ideally be concentrated in no more than 6 or 7 centres, and that proliferation occurred to the detriment of patients'.³¹ The difficulty which the SRSAG identified was that, whilst the generally accepted view was that there should be a reduced number of designated centres, no clinicians were willing for their particular centre to be the one to be de-designated. Nor, it seems, was the SRSAG prepared to make the decision and earmark one or two units for de-designation. Dr Halliday told us:

'... almost from day 1 we were facing a situation where we might have to de-designate this service, or units within the service. The problem was that however much we tried, and however much advice we got from the various medical organisations, no-one recommended de-designating particular units, so we were faced with the situation where the only option was to de-designate the service. That is why we talk about the importance of geography, the problems about de-designating on expertise, or referral problems. Unless someone could provide us with the evidence which would allow us to take that decision, we had no alternative but to de-designate the service.'³²

In addition, as we have said, the DoH had no power to prevent centres outside the SRS system from providing an NICS service. Indeed, as we have seen, by 1990 the SRSAG was aware that three centres outside the SRS system, Cardiff, Oxford and Leicester, were also performing NICS.³³

39 In February 1992 the SRSAG considered a report entitled '*Designation Issues. Neonatal and Infant Cardiac Surgery*', which recorded that there were by that time 13 units in England undertaking NICS, whereas the epidemiological evidence suggested that the number of units required to provide the service was no more than seven and probably nearer five. The report considered and rejected the possibility of de-designating Bristol:

'Members accepted the conclusions set out in the paper SRS(90)15 that in general terms, all other factors being equal, there is a strong case for Bristol and Newcastle in terms of geographical spread. They agreed that it would be difficult if not invidious to de-designate the centres in question on the basis of surgical expertise, and doubted whether it was possible to do so on the basis of referral pattern.'³⁴

40 In the event, the entire NICS service was de-designated in 1992. Its funding, however, was protected for a further two years until March 1994 under a funding arrangement with Regional General Managers.³⁵ The SRSAG stated that the decision to de-designate the whole of the NICS SRS, rather than just certain units, was: 'a fairer

³¹ DOH 0002 0168; minutes of meeting on 3 October 1990

³² T13 p. 106–7 Dr Halliday

³³ SCS 0004 0026; minute dated 20 September 1990

³⁴ DOH 0002 0044; Report on Designation of NICS, SRS(92)2

³⁵ T89 p. 170 Dr Halliday; DOH 0002 0156; minutes of a meeting on 29 September 1992

decision in terms of medical and surgical rights of patients than to restrict designation to a few surgical units.’³⁶

- 41** Funding for cardiac surgery on the over-1s and on adults had continued throughout the period in the normal way. After protected funding came to an end, it was then a matter for the DHAs, under the purchasing arrangements already in place, to purchase PCS services for the under-1s along with the existing cardiac services. None of the centres which had been designated ceased to provide PCS after this change in funding arrangements.
- 42** Sir Michael Carlisle, the then Chair of the SRSAG, told the Inquiry that he found the reason given by the SRSAG for de-designation of NICS, namely that it was ‘a fairer decision in terms of medical and surgical rights of patients’, to be ‘slightly ambiguous’.³⁷ The advice previously had been that it was in a patient’s best interests that there should be a *designated* service. Similarly, Sir Terence English commented that he was unable to understand the logic of the reference to ‘fairer in terms of medical and surgical rights’ of patients.³⁸ Sir Michael said that, had the Working Group recommended a greater reduction in the number of designated centres, it was highly likely that the SRSAG would have continued to designate the service, and that the real cause of de-designation of the service was proliferation.³⁹

Monitoring by the Supra Regional Services Advisory Group

- 43** In the early years, any monitoring carried out by the SRSAG, based on annual figures submitted by the designated centres, was for the purposes of producing recommendations on funding for the next financial year. The introduction of service agreements, or ‘contracts’, in 1991 was accompanied by the submission to the SRSAG of quarterly activity figures as well as an annual report from the unit.
- 44** Professor Gareth Crompton, the then Chief Medical Officer (CMO) for Wales, told the Inquiry that:

‘I would have expected from the beginning, when they established the supra-regional centres, that there would have been a system of data capture and analysis and publication from each of the centres, distributed freely to the Department of Health and to Regional Health Authorities who were sending patients there from

³⁶ DOH 0002 0099; minutes of a meeting on 28 July 1992

³⁷ T15 p. 78–9 Sir Michael Carlisle

³⁸ T18 p. 168 Sir Terence English

³⁹ T15 p. 42–3 Sir Michael Carlisle

Wales or wherever and that the Supra Regional Services Advisory Group would have been in full knowledge of all the facts relating to this important initiative. If that was not the case, then I am surprised.⁴⁰

- 45** But Dr Halliday made clear in his evidence that the SRS was a funding arrangement.⁴¹ Whoever might be responsible for monitoring the quality of the service, in his view it was not the SRS.⁴² Sir Kenneth Calman, CMO for England 1991–1998, however, considered that: ‘it would be the responsibility of the Supra Regional Services Advisory Group to ensure that there was a process for monitoring’.⁴³ No such process existed. The SRS system, at least in the case of NICS, was not used to monitor the quality of the service provided.

⁴⁰ T21 p. 72 Professor Crompton

⁴¹ T89 p. 134–5 Dr Halliday

⁴² T13 p. 112–13 Dr Halliday

⁴³ T66 p. 98 Sir Kenneth Calman

Setting the Scene

Chapter 9: The Paediatric Cardiac Surgical Service in Bristol

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The organisation of paediatric cardiac surgical services in Bristol

- 1 In this chapter we describe the place of the paediatric cardiac surgical (PCS) service within the United Bristol Hospitals and the United Bristol Healthcare (NHS) Trust (UBH/T). We then set out elements of the PCS service, from initial diagnosis, through referral to and management of care in Bristol, the information made available to parents and the process of obtaining their consent to their child's operation, to counselling and support services available to parents. A much fuller account of the evidence on these issues can be found in Annex A Chapters 8, 10, 11, 13–17.

The place of PCS in UBH/T

- 2 It is important to stress that the PCS service was only a very small part of the overall service provided by the UBH (a large hospital group), and later by the Trust. Moreover, it was only a small part of the cardiac surgical service. It was always an adjunct to the service provided for adults.¹ Dr Bolsin, consultant anaesthetist at the BRI, said that: 'The major throughput of cardiac surgical cases on the BRI site was related to adult cardiac surgery. In 1988 3 paediatric cardiac surgical cases each week would be undertaken compared to twelve adult cases'.² Mr Wisheart explained that during the 1980s the number of cardiac operations at the BRI increased, but pointed out that the greater increase was in adult surgery. He stated: 'The sessions which Mr Dhasmana and I did devote to children amounted to three operations a week — I do not mean three half days; there were three operations a week of whatever length, which were children ...'³
- 3 The PCS service was a split service provided over two sites until October 1995.³

¹ Table 1 later demonstrates the growing disparity in the proportion of children and adults receiving open-heart surgery

² WIT 0080 0002 Dr Bolsin

³ See Figure 1: Location of relevant Bristol Hospitals during the period of the Inquiry's Terms of Reference

Figure 1: Location of relevant Bristol hospitals during the period of the Inquiry's Terms of Reference

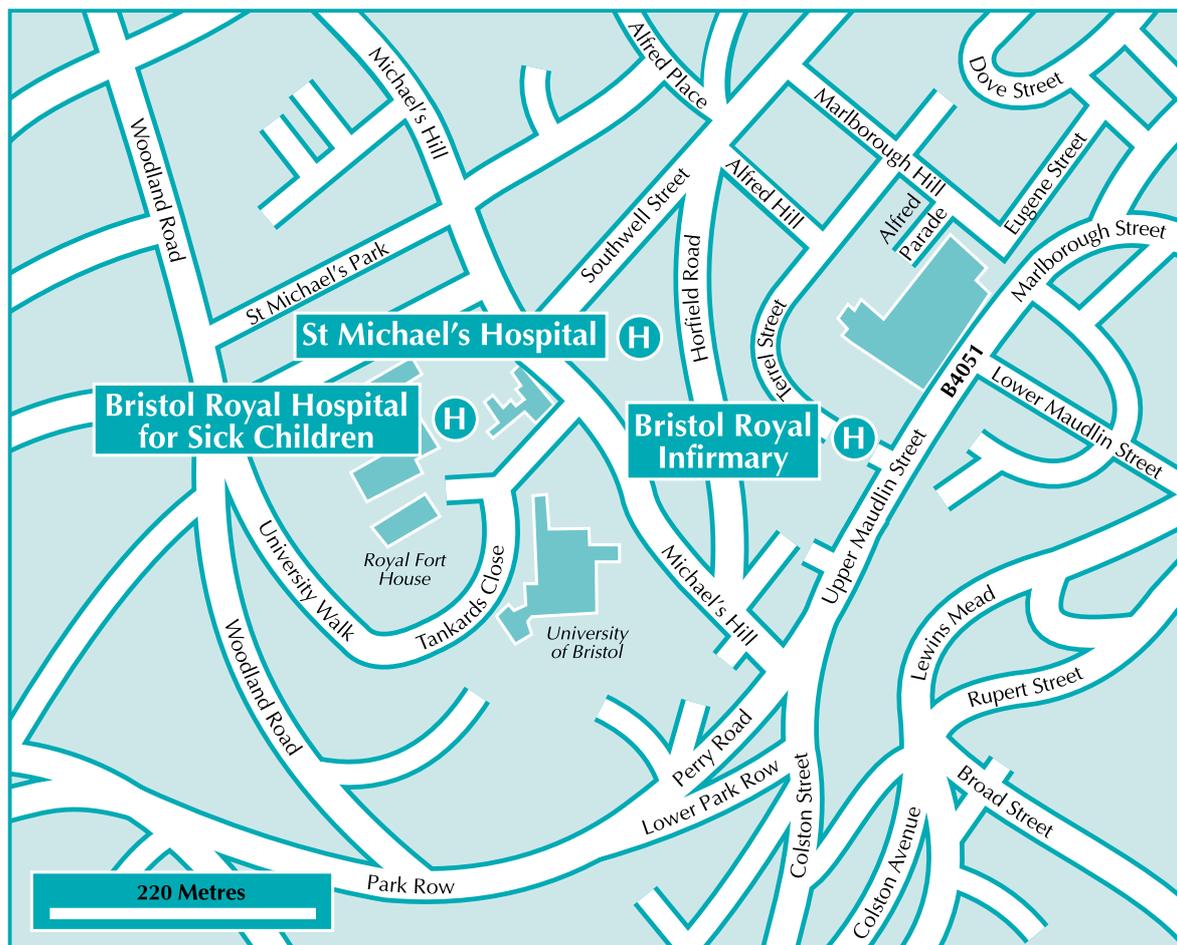


Figure 2: Services provided at the BRHSC and BRI from 1984 until October 1995

Services and facilities at the BRHSC	Services and facilities at the BRI
<ul style="list-style-type: none"> ■ the cardiologists were based at the BRHSC ■ cardiac catheterisation laboratory opened in 1987 ■ layout: Paediatric ICU (1st floor); wards (1st floor); operating theatres (1st floor); paediatric cardiology department (basement) ■ Paediatric ICU was opened in April 1982, prior to which there had been no formal ICU and cubicles alongside Ward 37 had been used for this purpose ■ Ward 37 Baby Unit; Ward 33 low dependency unit ■ 2 operating theatres for closed-heart surgery ■ playroom ■ 10 bedsitting rooms for parents 	<ul style="list-style-type: none"> ■ the surgeons were based at the BRI ■ facilities for cardiac catheterisation until 1987 ■ layout: Ward 5 (level 6); operating theatres (level 4); cardiology department (level 2) ■ Ward 5A Admissions and Continuing Care beds; Nursery ■ Ward 5B ICU and HDU beds ■ 3 operating theatres for open-heart surgery ■ play facilities ■ family meeting room ■ 2 bedsitting rooms for parents

- 4 The two surgeons, Mr Wisheart and Mr Dhasmana operated on patients suffering from both acquired and congenital heart disease, both adults and children. Open-heart operations were undertaken at the BRI, closed operations at the BRHSC, and were carried out by both surgeons. However, there was always pressure to care for the increasing volume of adult patients not least because of national and regional priorities given to reducing heart disease in adults and, after 1991, the income generated by increased numbers of adult patients. Dr Joffe told us that developments in the care of children, such as the transfer of the catheterisation laboratory to the BRHSC in 1987 and ultimately the move of open-heart surgery to the BCH in 1995, were achieved ‘on the back of adult developments’.⁴ As regards paediatric cardiac surgery (PCS), the UBH/T offered children the whole range of operations expected of a centre providing this service, although in the case of the Switch operation, this was offered at Bristol for non-neonates from 1988 and for neonates from January 1992⁵ some years after it became available at other centres.
- 5 The annual returns made by the cardiac surgical service in Bristol to the UK Cardiac Surgical Register (UKCSR) provide an indication of the volume of paediatric and adult open-heart surgery respectively carried out at the BRI over the period of the Inquiry’s Terms of Reference. These annual returns were divided into two parts, the first part relating to open-heart operations for acquired heart disease and the second relating to open-heart operations for congenital heart disease (CHD). To a large extent, adults fell into the first category and children into the category of CHD. The following table based on the figures returned to the UKCSR by Bristol for the years 1987, 1991, and 1994–1995, illustrates the growing volume of adult patients (‘open acquired’) compared with the smaller and static numbers of child patients (‘open congenital’).

Table 1: The balance between open operations for acquired and congenital heart disease carried out in Bristol in 1987, 1991 and 1994–1995¹

Operation category	1987	1991	1994–1995
Open acquired	389	564	862
Open congenital	135	139	134

1. These illustrative figures are extrapolated from the returns made to the UKCSR by Bristol for the years 1987, 1991 and 1994–1995, which can be found at UBHT 0215 0077 – 0086, JDW 0005 0234 – 0243, and JDW 0005 0264 – 0273 respectively.

- 6 Notwithstanding the provisos as to the quality of the UKCSR data (which are set out in the statistical evidence in Annex B and Chapter 19 of Annex A), these figures seem to illustrate that the total number of open-heart operations carried out on children in Bristol was relatively small in proportion to the total numbers for adults and that the disparity increased with time.

⁴ T90 p. 32 Dr Joffe

⁵ Mr Dhasmana suspended the neonatal Switch programme for several months following a series of deaths. After changes in practice, the Switch programme was resumed briefly in Bristol in July 1993. Following a further death of a child the neonatal Switch programme was ended until the appointment of Mr Pawade, a specialist paediatric cardiac surgeon, in May 1995

- 7 To understand this disparity further, it is important to realise that to carry out PCS, not only is a slot required in the timetable for the operating theatre, but also a bed in the Intensive Care Unit (ICU), nursing staff, and theatre technicians. Moreover, the surgeons' three sessions per week dedicated to PCS must be co-ordinated with the availability of the paediatric cardiac anaesthetists. Since adult and child patients used the same facilities and were cared for by the same staff, this state of affairs constantly created a tension between caring for adults and for children. This tension was exacerbated further by the fact that children needed to stay in the ICU for a significantly longer time after surgery than adults.

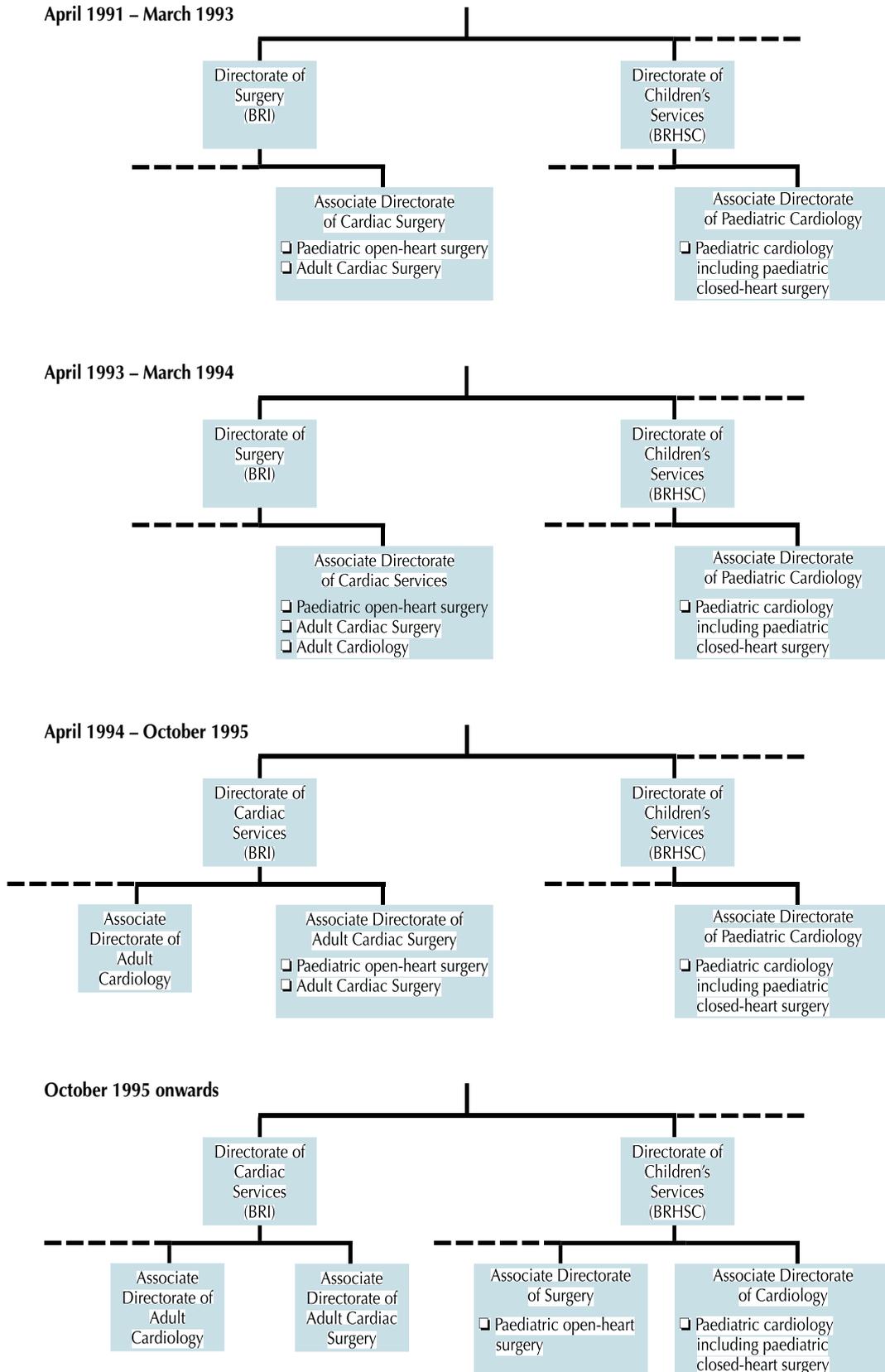
The place of PCS services in the system of clinical directorates⁶

- 8 Throughout the period of our Terms of Reference, there was a Division, and from 1991 a Directorate, of Children's Services which covered all services provided at the BRHSC, including all paediatric cardiology and closed-heart surgery.
- 9 That said, all of the components of the PCS service – paediatric cardiology and open- and closed-heart surgery – were only grouped together in terms of management for the first time in October 1995. Prior to that time, the various components were managed separately. These separate managerial arrangements principally reflected what was provided in the two buildings: the BRHSC on the one hand, and the BRI on the other.⁷
- 10 Until March 1993, paediatric open-heart surgery was included in one of the associate directorates of the Directorate of Surgery. In April 1993 new 'disease-based' (and, in effect, building-based) rather than 'profession-based' directorates were introduced. A new Associate Directorate of Cardiac Services was created, covering adult cardiology, and adult cardiac surgery and paediatric open-heart surgery.
- 11 It was not until October 1995, as has been said, with the move of paediatric open-heart surgery to the BRHSC, that PCS services were finally united in one directorate: the Directorate of Children's Services. (A counterpart for adult cardiology and cardiac surgery – the Directorate of Cardiac Services – was created at the same time.)

⁶ See Figure 3: How the paediatric cardiac service fitted into the clinical directorate system

⁷ See Figure 1: Location of relevant Bristol Hospitals during the period of the Inquiry's Terms of Reference

Figure 3: How the paediatric cardiac service fitted into the clinical directorate system



The paediatric cardiac surgical service in Bristol

Referrals and cardiology clinics

- 12** Generally, a child would be referred by a GP or a paediatrician within the catchment area to a Bristol-based cardiologist, with the request for an opinion or investigation. The referral might come from the paediatrician at the hospital where the baby was a patient. Or, in cases where there were perhaps no immediately obvious signs of a problem at birth, the referral could be made once the baby's condition was diagnosed days or weeks later, when signs were noted by parents, a midwife, a health visitor or a GP.
- 13** The UBH/T provided a PCS service to a large geographical catchment area, encompassing much of the South West of England and South Wales.⁸ During the 1970s joint outreach clinics⁹ with local consultant paediatricians were established throughout the South West Region. Dr Ian Baker¹⁰ explained the concept of outreach clinics in his statement: "Outreach" clinics were clinics where paediatric clinicians from Bristol practised way from their base facilities at BRHSC and BRI in facilities of other Health Authorities'. These were conducted thereafter by the Bristol-based cardiologists, Dr Stephen Jordan and Dr Hyam Joffe and, from February 1989, by Dr Robin Martin. A great deal of time was spent by the cardiologists in travelling to and from these clinics. Outreach clinics were held in over a dozen hospitals across the South West and South Wales such as Gloucester, Torbay, Carmarthen and Swansea.
- 14** During the late 1980s, as we have seen, a national shortage of paediatric cardiologists developed which a joint working party of the British Cardiac Society (BSC) and the Royal College of Physicians of London regarded as 'very worrying'.¹¹ The situation was described as 'unacceptable' in the British Medical Association's report for 1988 and 'perilous' in the report for 1992.¹²
- 15** This national shortage was reflected locally in the South West, but it was particularly felt because there were few large hospitals in the area – Truro, Plymouth (for part of the time) and Bristol, and because there were no paediatric cardiologists in the whole of Wales. Additionally, the PCS service in Bristol was not recognised by the Royal Colleges as suitable for the allocation of a training post, with the result that the cardiologists lacked the support of trainees.

⁸ The two PCS centres closest to Bristol were at Birmingham and Southampton

⁹ See Annex A, Chapter 10 for a detailed description of outreach cardiology clinics

¹⁰ Formerly the DMO for B&WDHA from July 1984 to October 1991, and subsequently a consultant in public health medicine for the B&DHA from October 1991 onwards

¹¹ BPCA 0001 0001

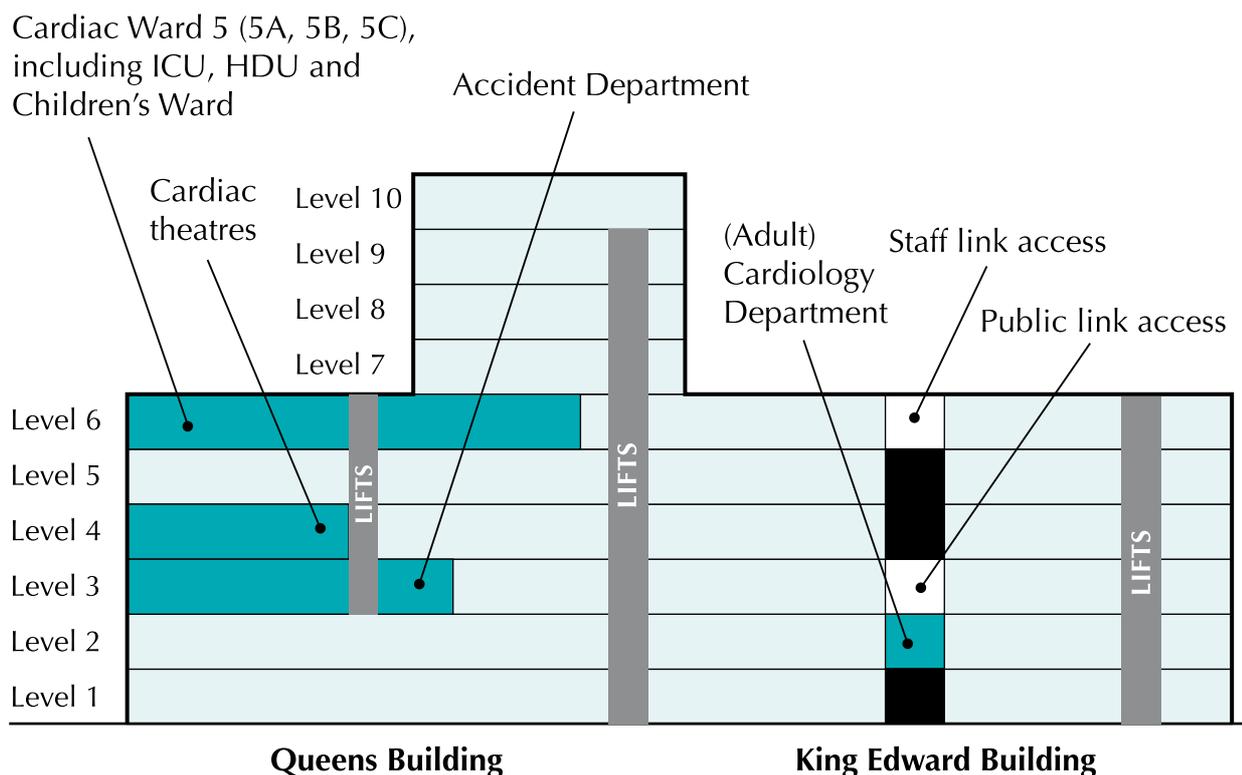
¹² BCS 0001 0017 and BCS 0001 0096; Chamberlain, et al. 'BMA report on staffing in cardiology in the UK in 1988' and 'BMA report on staffing in cardiology in the UK in 1992'

16 The Bristol cardiologists would first see the child either at an outreach clinic or at the BRHSC. After 1987, cardiological investigations, including catheterisation, would take place at the BRHSC (before then cardiac catheterisation took place at the BRI). If the cardiologist considered surgery was required, the child would be referred to a paediatric cardiac surgeon. Usually a child needing surgery who had been referred to a cardiologist in Bristol would be referred by the cardiologist to one of the cardiac surgeons in Bristol, Mr Wisheart or Mr Dhasmana. On rare occasions, the cardiologist in Bristol, by himself or in conjunction with the surgeon(s) in Bristol, would refer a child to another centre for surgery.

Surgery

17 PCS, as indicated earlier, was provided on two sites throughout the period of our Terms of Reference: open-heart surgery at the BRI and closed-heart surgery at the BRHSC. The usual pattern in the case of open-heart surgery (except in the case of emergencies) was that the child was admitted to the BRHSC for a few days prior to the operation and was then transferred to Ward 5 at the BRI as shown in Figure 4. This was a ward which concentrated on cardiac surgical patients. It was mixed, in that it accommodated both adults and children. The operation would be carried out in an operating theatre at the BRI and the child was then cared for in the ICU two floors above, before being returned to Ward 5 or to the BRHSC.

Figure 4: Location of the elements of cardiac care at the Bristol Royal Infirmary between 1984 and 1995



Intensive care at the BRI

- 18** Both children and adult cardiac patients were cared for in the ICU at the BRI. Children were separated from the adults to the best of the staff's ability by using the two beds that were between a side wall and the nurses' station. This was not always possible, however, due to the pressure on beds.
- 19** Nationally, until the early 1990s, it was not unusual for children and adults to be cared for in the same ICU. Dr Susan Jones, President of the Association of Paediatric Anaesthetists (APA), 1997–1999, told the Inquiry that it was fairly common as late as 1993 for children to be admitted to a part of an adult ICU ward. She went on: 'I think that it has been changing gradually, anyway, as big paediatric tertiary referral centres, mainly at children's hospitals, have actually expanded their intensive care unit and, indeed, provided retrieval teams so that they can actually go to a DGH, or wherever, to actually pick up these children and transfer them back.'¹³
- 20** Professor David Baum, then President of the Royal College of Paediatrics and Child Health and Professor of Child Health, University of Bristol, told us about the approach of healthcare professionals in 1984 to caring for children on such mixed wards: 'At that time, if one were looking at or were preparing a policy document, I have no doubt that the conclusion would have been very firmly, these should be separate entities. That would apply if one was talking about the mix from adolescence and adult, let alone younger children and babies, let alone if they were profoundly ill. In the ten to fifteen years since the time that you are addressing, we have regressed somewhat, but it has only been in the last two or three years that under the heading of paediatric intensive care services, as you know, the Government has come down on the side of not only having a policy, but actually implementing a policy, so that in all parts of the land we are still at the implementation phase, there should be a separate fully equipped fully staffed paediatric intensive care unit. That has still not been totally achieved for the nation in May 1999.'¹⁴
- 21** The UBHT acknowledged that since the publication of the report '*Welfare of Children and Young People in Hospitals*'¹⁵ in 1991, it had been the policy in the NHS that wherever possible, children should be nursed separately from adults, in dedicated children's units by Registered Sick Children Nurses (RSCN). The UBHT stated that: 'The policy of UBHT in the 1980s to move children's cardiac surgery to the Bristol Royal Hospital for Sick Children was in accordance with this policy, but in practice it was thwarted by lack of capital funding.'¹⁶

¹³ T8 p. 28 Dr Jones

¹⁴ T18 p. 40–1 Professor Baum

¹⁵ DoH. '*Welfare of Children and Young People in Hospitals*', London: HMSO, 1991

¹⁶ WIT 0030 0013 Phillip Wagstaff

Anaesthesia at the BRI

- 22** The anaesthetists in the cardiac unit, under the leadership of Dr Christopher Monk, the Clinical Director, anaesthetised both children and adults at the BRI. They also contributed to care in the ICU. From 1993, with the appointment of two intensivists, Dr Stephen Pryn and Dr Ian Davies, the paediatric cardiac anaesthetic caseload was carried largely by Dr Sally Masey, Dr Susan Underwood and Dr Pryn. Dr Bolsin reduced his paediatric caseload from 1993 onwards, but did not entirely give it up.

Nursing care at the BRI

- 23** There was a national shortage of RSCNs¹⁷ during the late 1980s and early 1990s. There were only two RSCNs who worked at the BRI in Wards 5A and 5B.
- 24** From April 1992, Ms Catherine Warren, who had trained as an RSCN while at the BRI, rotated between Wards 5A and 5B on those days when children underwent surgery. Otherwise, she worked in the nursery with the other RSCN, caring for children pre- and post-operatively.¹⁸

In the operating theatres

- 25** The nurses in the operating theatres were Registered General Nurses (RGN) or State Enrolled Nurses (SEN). In 1994 it was decided to create two distinct groups: anaesthetic nurses and scrub nurses. The aim was to provide continuity by ensuring that the anaesthetists were working with the same staff.¹⁹ Prior to this the staff were multi-skilled and worked both as scrub nurses and in the anaesthetic room.²⁰
- 26** The nursing team for each operating theatre ordinarily comprised an anaesthetic nurse assistant, a scrub nurse and a circulating nurse. In addition there would be an allocated sister-in-charge who would not be supernumerary and would often have an active role in the theatre.²¹
- 27** Staff numbers were decided by the theatre manager in accordance with the guidelines of the National Association of Theatre Nurses.²² In 1984 there were approximately 11 nursing staff who covered the three Level 4 operating theatres of the BRI.²³ After the expansion of cardiac care in 1988, staff numbers increased, although Ms Kay Armstrong, then a theatre sister, stated that '... it was very hard to find out from management what our staffing allocation should have been.'²⁴

¹⁷ Registered Sick Children's Nurse (RSCN), formerly part 8 of the UKCC register. Following the implementation of Project 2000, nurses educated in the care of sick children are registered as 'R.N. Child', now part 15 of the register

¹⁸ WIT 0114 0012 and T32 p. 76 Fiona Thomas

¹⁹ Ms Armstrong enrolled on the anaesthetic course in 1993 in preparation for this split

²⁰ WIT 0132 0006 Ms Armstrong

²¹ WIT 0132 0041 Ms Armstrong

²² WIT 0132 0011 Ms Armstrong

²³ WIT 0132 0002 Ms Armstrong

²⁴ WIT 0132 0003 Ms Armstrong

- 28** Ms Armstrong commented that: ‘The sisters were responsible for the day-to-day running of the theatres but did not hold the budget or have any control over the staff numbers allocated to each theatre. This was very frustrating as we were frequently understaffed without the power to do anything about it.’²⁵

In the ICU

- 29** The Intensive Care Society was of the opinion that, in relation to paediatric intensive care during the period covered by our terms of reference, it was ‘essential’ that ‘a senior nurse with several years experience of paediatric intensive care [be] in charge of the unit ... a minimum of one trained nurse to one patient is usually required throughout the entire 24 hour period.’²⁶ This meant that the establishment at the bedside should be 6.4 whole-time equivalents per patient per 24 hour period. This 6.4 to 1 ratio was endorsed by the Paediatric Intensive Care Society.²⁷
- 30** Despite national staffing shortages, Julia Thomas, Sister in charge of cardiac surgery ICU 1982–1988 and Clinical Nurse Manager of the Cardiac Unit 1988–1992, told us that the staffing level was 5.4 whole-time equivalent per bed, reflecting the case mix of adults and children being cared for.
- 31** Fiona Thomas, Clinical Nurse Manager of Cardiac Surgery between 1993 and 1996, told us that when she took over in 1993 the whole-time equivalent nursing ratio for the whole ICU was ‘about 5.4 full-time equivalent per intensive care bed.’²⁸
- 32** The evidence which we received was that it was common for there not to be an RSCN on duty in the ICU at the BRI,²⁹ and that it was ‘extremely uncommon’ for there not to be a skilled ICU nurse above E Grade level with considerable experience caring for children in this setting.³⁰

Parents at the BRHSC and the BRI

Parental involvement in care

- 33** Sister Julia Thomas explained that at the BRI:

‘The ward philosophy was to promote family-centred care throughout the child’s stay. We encouraged parents to be involved with their child’s care at all times. This included full care pre-operatively and post-operatively in the nursery, washing,

²⁵ WIT 0132 0003 Ms Armstrong

²⁶ T32 p. 41 Fiona Thomas

²⁷ T7 p. 152 Dr Ratcliffe

²⁸ T32 p. 40 Fiona Thomas

²⁹ T32 p. 44 Fiona Thomas

³⁰ T32 p. 136 Ms Disley

dressing, feeding, and generally caring for their child. In the ITU the amount of participation varied depending on the parents and the severity of the illness. Some parents found the whole intensive care experience extremely upsetting and could not visit for long. Others were there all the time and were very keen to do as much as possible for their child. We encourage parents to wash their babies, change nappies, and give eye and mouth care. Naso-gastric feeding was taught to parents, especially if their child was in ITU for a long time.³¹

34 She continued:

‘We were very careful to keep the parents fully informed about their child’s progress. The nurses explained all the procedures they were carrying out, and what drugs and treatment the child was receiving. The parents were able to read the care plans for their child, and were involved in discussions about any treatment changes required.’³²

35 She stated that the parents themselves often required considerable support, which was time consuming. She also stated that to encourage the parents to participate in their child’s care equally took time, as did teaching them about naso-gastric feeding, and about eye and mouth care.³³

Information made available to parents and the process of obtaining consent

36 The parents would be seen by various members of the medical staff following admission. Mr Dhasmana and Mr Wisheart would see the child and parents before surgery,³⁴ as would the anaesthetists. Dr Pryn, as anaesthetist and intensivist, said that he always visited the patient on the afternoon or evening prior to surgery. He attempted to make sure that his visit coincided with the presence of the child’s parents or guardians, although that was not always possible.

37 However, Dr Jordan told the Inquiry that a further assessment, following admission, was not always easy as far as the cardiologists were concerned, as the children were sometimes admitted directly to Ward 5 at the BRI.³⁵ He stated that he tried to see all patients on the day before their operation. However, because there was no formal arrangement for this to take place, he stated that he often arrived at Ward 5 to find that the child had been sent off with the parents into the town, once the routine tests had been carried out. The physiotherapists would also have their own conversations with parents and families.

38 The Counsellor in Paediatric Cardiology, Mrs Helen Vegoda, a qualified social worker, who took up her post in January 1988, told the Inquiry that on occasions she would sit

³¹ WIT 0213 0046 Julia Thomas

³² WIT 0213 0047 Julia Thomas

³³ WIT 0213 0042 Julia Thomas

³⁴ WIT 0084 0066 Mr Dhasmana; WIT 0120 0359 Mr Wisheart

³⁵ WIT 0099 0040 – 0041 Dr Jordan

in on the meetings when details of the surgery were explained to parents. She said that she would usually try to ascertain whether parents had understood the explanations given to them by the surgeons or cardiologists and, if not, would arrange for a further explanation to be given by a consultant, registrar or nurse.³⁶ The Cardiac Liaison Nurse, Miss Helen Stratton, who was in post from November 1990 until February 1994, said that she had wished to attend the BRHSC to provide support to parents at the time of diagnosis. As a nurse she felt that she would be in a better position than Mrs Vegoda to explain clinical matters to parents. However, she was essentially prevented from doing so by issues of 'territory' arising between her and Mrs Vegoda.³⁷ Following her qualification as RSCN in 1992, Ms Warren attended outpatients' clinics so that parents could talk to her after they had seen the consultant.

- 39** At the BRI, the admitting nurse was responsible for welcoming the child and family to the Unit prior to carrying out a pre-operative screening for infection.³⁸ On admission, the nurses talked to the parents and families about the child's operation, about intensive care and other aspects of the treatment.³⁹
- 40** The experience of parents differed according to the urgency of the operation. For urgent operations, parents were told when they could expect surgery to take place, and asked to telephone closer to the time to find out if the operation was on schedule.⁴⁰ For elective operations, arrangements were made to see the family in the outpatients department, and if the family accepted the advice offered, the patient's name was placed on the surgeon's waiting list. The parents were informed when the operation was expected to take place, enabling them to plan ahead. In practice, these estimates sometimes proved inaccurate.
- 41** While their child was in the ICU, parents might be given different information by nurses about their child's treatment within a relatively short space of time, due to the fact that different consultants conducted their ward rounds at different times.⁴¹ Advice given at 8 a.m. could sometimes be changed at 9 a.m., or countermanded by someone from a different specialty.

Support, counselling and bereavement services for parents

- 42** We use the term 'support' to encompass all activities or arrangements which help to meet the psychological and social needs of parents whose children are receiving care. It covers a wide range of activities, from practical arrangements for parents to stay in hospital and assist in their child's care, to the giving of information, encouragement, advice and sympathy. Such support may be provided in the hospital or surgery, or away from these, for example, by self-help groups or facilitator-led support groups. We take 'counselling' to mean the more formal activity of a trained counsellor,

³⁶ WIT 0192 0003. Mrs Vegoda said that she would never try to explain the medical aspect of any procedure as she was not qualified to do so

³⁷ In January 1992 it was agreed that Miss Stratton would work at the BRI, and Mrs Vegoda at the BRHSC

³⁸ WIT 0213 0032 Julia Thomas

³⁹ WIT 0120 0150 Mr Wisheart

⁴⁰ WIT 0084 0067 Mr Dhasmana

⁴¹ T93 p. 92–3 Mr Wisheart

psychologist or psychotherapist. Whilst support skills are generally expected of all those working as healthcare professionals, counsellors are expected to have specialised training and undergo continuing supervision.⁴²

- 43 Something of a patchwork of support, counselling and, in the case of the death of a child, bereavement services was available to parents at the UBH/T throughout the period 1984–1995. In addition to staff who provided these services as ancillary to their jobs, they were specifically provided by the Bristol and South West Children’s Heart Circle, the UBH/T chaplains, the Social Services Department of Bristol City Council, Mrs Vegoda, and Miss Stratton.
- 44 When a child died, it was not only those staff specifically designated to do so who came into contact with distressed and bereaved families. The surgeon sought to talk to the bereaved parents as soon as possible after the operation, assisted by a nurse or the hospital counsellor. The parents were invited to meet the surgeon again some six weeks later when they might feel more able to discuss matters.⁴³ When a child had sustained some disability, the parents were again encouraged to meet the surgeon on a later occasion when information as to the extent of injury and any permanent disability would be known.⁴⁴
- 45 The Patient Affairs Officer at the BRI, Mrs Diane Kennington, assisted parents with such practical matters as arrangements for a post-mortem, the registration of death and the funeral.
- 46 At the BRHSC these functions were the responsibility of the portering staff.
- 47 The parents of deceased children were also given a leaflet called ‘*After your Child has Died*’, which was specific to the BRI’s Ward 5.⁴⁵

Training in counselling

- 48 As was almost universally the case in the period of time under review, the surgeons and other clinicians received no formal training in counselling or in providing support.

⁴² See the advice of the Inquiry’s Experts in Annex B: Jean Simons ‘*Giving Information to Parents with an Unwell Child*’, 2000 at 10k and Valerie Mandelson ‘*Comments on selected parents’ experience of communication with clinicians in Bristol*’ at 10n

⁴³ WIT 0120 0234 – 0235 Mr Wisheart; WIT 0084 0103 Mr Dhasmana

⁴⁴ WIT 0084 0103 – 0104 Mr Dhasmana

⁴⁵ See further the Inquiry’s Interim Report, ‘*Removal and retention of human material*’, May 2000

- 49** The nurses were the members of staff most heavily involved with the children and their families throughout their care. Unlike the clinicians, they did receive some training. From around 1980, a two-day course in counselling and a five-day course concerned with caring for dying children was available for nursing staff, and from 1984 a specific course for nursing staff was run by the UBH/T's training department entitled 'Talking to Relatives'.⁴⁶ Many of the senior ICU nurses had taken one or both of these courses. In addition, in 1985 training sessions for BRHSC nursing staff were introduced to explain the impact of different customs and religious beliefs on the care of patients and the treatment of the families. Every intake of nurses subsequently undertook this training session.⁴⁷

The Bristol & South West Children's Heart Circle

- 50** Mrs Jean Pratten founded the Bristol & South West Children's Heart Circle in 1972 'to help parents of children with heart disease help one another'.⁴⁸
- 51** The importance of the role of Mrs Pratten personally and of the Heart Circle was considerable. From 1972 Mrs Pratten attended the cardiac unit at least once a week to offer support to families and staff.
- 52** Before 1978 families of children undergoing surgery who were from outside Bristol stayed in bed and breakfast accommodation. However, in 1978 a small house belonging to the hospital was made available and was refurbished and furnished by the Heart Circle. A year later the house next door was taken over, followed a short time later by a third house, making 12 rooms available in all. One of the houses was for the use of families whose children were in the Cardiac Surgery Unit. The Heart Circle also financed the provision of two bedrooms along the corridor from the Cardiac Surgery Unit for the use of parents.
- 53** The Heart Circle gave grants of money to families with significant need when, for example, their child was in intensive care for a prolonged period of time; provided furniture for a nursery; negotiated the conversion of a store room into a quiet room for parents and provided the furniture; set up a kitchen for parents and provided a washer-dryer; and within the Intensive Care Unit, made a designated area for children, and provided cots and other furniture and portable telephones; published an information booklet for parents with the support of the BBC's Children in Need; provided two caravans at Burnham-on-Sea to allow parents or families to take subsidised free holidays; and made a video for parents to introduce them to the Unit.
- 54** Between 1984 and 1995, the Heart Circle contributed £708,000 towards providing items of medical equipment to the hospital. For example, they contributed £25,000 towards the purchase of a Doppler echocardiography machine at the request of Dr Jordan in 1992.

⁴⁶ WIT 0234 0026 – 0027 Ms Sherriff, Assistant General Manager, BRHSC since 1992

⁴⁷ WIT 0273 0013 Canon Mann, Chaplain, BRHSC 1985–1994

⁴⁸ WIT 0269 0001 Mrs Pratten

- 55 The Heart Circle also played a major role in the development and funding of the posts of Mrs Vegoda and Miss Stratton.

The Chaplaincy at the UBH/T

- 56 The Spiritual Adviser to the UBH/T, the Reverend Yeomans, with a team of full- and part-time chaplains of various denominations who serve the BRI and the BRHSC, responded to the spiritual and religious needs of patients, their families, carers and staff.
- 57 In 1992 one of the chaplains, Canon Charmion Mann, together with Helen Vegoda, set up a Bereavement Support Group for parents, and from 1994 Canon Mann, and later her successor, the Reverend Helena Cermakova, assisted at annual remembrance services for children who had died following cardiac surgery.⁴⁹

Counsellor in Paediatric Cardiology

- 58 In January 1988 Mrs Helen Vegoda was appointed Counsellor in Paediatric Cardiology (she was also referred to as a family support worker). Between 1988 and 1990, she was based at the BRHSC and also worked at the BRI and Bristol Maternity Hospital with families whose children had congenital heart defects. She often visited Ward 5 at the BRI to see families and to be available at key times such as surgery and admission.
- 59 Mrs Vegoda's position was rather isolated, as there was no peer support. Nor did her position fit into any formal managerial structure until 1991.⁵⁰

The Cardiac Liaison Nurse

- 60 Miss Helen Stratton was appointed as Cardiac Liaison Nurse at the BRI in 1990. She was a qualified registered nurse and had taken the English Nursing Board's (ENB) course in intensive care at the BRI.⁵¹ She had no training in counselling.⁵²
- 61 There was no formal job description to determine whether Miss Stratton's post involved her working only at the BRI or also at the BRHSC, or to differentiate between her work and that of Mrs Vegoda.
- 62 Miss Stratton's understanding of her role was that she was to support parents and, where necessary, ensure a smooth transition for parents and children from the BRHSC to the BRI. This could include corresponding with the child's health visitor and GP and ensuring that parents had accommodation and practical information about their child's admission to the BRI. When a child was in surgery or in intensive care, she,

⁴⁹ WIT 0011 0031 Sharon Peacock, mother of Andrew; WIT 0461 0005 – 0006 Carol Kift, mother of Steven

⁵⁰ T47 p. 113–14 Mrs Vegoda

⁵¹ WIT 0256 0001 Miss Stratton

⁵² T46 p. 35 and WIT 0256 0002 Miss Stratton

as the liaison nurse, would spend time explaining aspects of post-operative treatment, because the nurses caring for the child often did not have the time to do this.⁵³

- 63** In relation to bereavement she understood that she would notify the health visitor and describe how the parents had reacted and their plans for returning home.⁵⁴
- 64** Miss Stratton saw her job as evolving by bringing ideas and initiatives into the BRI from centres such as Great Ormond Street Hospital for Children (GOS).⁵⁵ A book produced by GOS called *'Heart Children'*, which had concise and easy-to-understand explanations of the most common cardiac conditions, with diagrams,⁵⁶ was made available by her to parents at the BRI.
- 65** In her second year, Miss Stratton wrote and published an information pack for parents. It outlined the process of admission to the BRI for surgery, provided details of accommodation and useful telephone numbers, and described what would take place during the pre-surgery preparation. She also produced a leaflet for bereaved parents, giving the name of the Patient Affairs Officer, together with useful telephone numbers and information.⁵⁷

⁵³ WIT 0256 0002 Miss Stratton

⁵⁴ WIT 0256 0008 Miss Stratton

⁵⁵ WIT 0256 0006 Miss Stratton

⁵⁶ WIT 0256 0006 – 0007 Miss Stratton

⁵⁷ WIT 0256 0009 Miss Stratton. Bristol City Council's Social Services Department provided a social worker who was responsible for Ward 5. Her role was to ensure that patients and their families were referred to the Social Services Department, and then to offer such help as the family wanted. Due to changes in the structure and accountability of social services in 1974 and 1987, the role of social workers ceased to be a counselling role. WIT 0487 0008 Dr McMullen, Principal Medical Social Worker (Teaching), BRI 1975–1987, Social Work Team Manager, BRI 1987–1992

Concerns

Chapter 10: Introduction to Concerns

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- 1 In this section of the Report we respond to that element of our Terms of Reference which requires us ‘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 ...’. We set out later in Chapters 13–20 our conclusions on the adequacy of the system and the paediatric cardiac surgical service. In this chapter we are concerned with the conduct of individuals. We have set out in Annex A, Chapters 20 to 30, a year-by-year account of the concerns raised, as indicated by the evidence received by the Inquiry. We begin here by identifying what we regard as the most significant events raised in that extensive account. Once we have set them out, we will then be in a position to express a view: to reach the conclusions asked of us.
- 2 We begin by acknowledging at the outset that it is the concerns of parents whose children died or suffered harm after cardiac surgery in the UBH/UBHT which have played a large part in bringing the issues in this Report into the public arena, and that these concerns are both heartfelt and longstanding. Those concerns were expressed and emerged after the end of the period of our Terms of Reference. They are dealt with in detail in later chapters. They relate, for example, to the split service, and the quality of communication, informed consent and counselling. The concerns dealt with in this chapter are those raised *at the time* by clinicians, managers and in the media, or those which, in the light of the information available, *should* have been raised *at that time*.

The range of concerns

- 3 We do not interpret our responsibility under our Terms of Reference narrowly, as referring only to what happened in the operating theatre at the BRI. We include: concerns which were raised about the organisation of the service, particularly the provision for monitoring quality of care and making clear who was responsible and accountable for providing a safe service; concerns expressed about pressures on resources and waiting times; and concerns about the ways in which issues raised could be communicated and dealt with by the UBH/UBHT. These matters provide the context within which to consider the concerns which arose about the care of the children prior to surgery, particularly their cardiological care, their care in the operating theatre, their care after surgery in the Intensive Care Unit, and the outcome.

Defining a concern

- 4 Raising ‘concerns’ has been stated by the Inquiry from the outset to mean expressions of view that the quality of the paediatric cardiac surgical service was unacceptably poor and that action must be taken. Concerns in this context does not mean expressions of view that the service was capable of improvement but nevertheless acceptable. We regard a practice as unacceptable when reasonably competent practitioners in this specialist area would advise that it exposes the patient to risks beyond those ordinarily to be expected in the time and context. Although our Terms of Reference, by referring to ‘concerns raised’, would appear to restrict us only to considering those circumstances in which a concern was expressed, we regard such a restriction as inappropriate. Thus, where relevant, we also include in the notion of concerns matters which could or should have been raised but were not.

Assessing the response to concerns

- 5 We are charged to ‘establish what action was taken’. This includes, of course, a consideration of whether any action was taken at all, and, if not, whether not taking action was justified. We are also charged with establishing whether any action taken was ‘appropriate’ and ‘prompt’.
- 6 We are further charged with establishing what action was taken ‘both within and outside the hospital’. We take ‘hospital’ to mean United Bristol Hospitals and United Bristol Healthcare (NHS) Trust, such that ‘outside’ refers to action or inaction at the level of the health authority, or the region, or by the Department of Health, or by organisations and institutions such as the Supra Regional Services Advisory Group, the Royal Colleges, and the General Medical Council.

The approach adopted

- 7 Analytically, the approach we adopt involves the following sequence:
 - Were there grounds for concern?
 - Was a concern raised, or should one have been?
 - Was the concern raised recognised as such by the person to whom it was expressed?
 - With whom was it (or should it have been) raised?

- Did the concern reach the person or body who could take action?
- What action, if any, could or should have been taken?
- What action was taken?
- If no action was taken, was this justified?
- If action was taken, was it appropriate and prompt?

- 8** While this analysis describes our task, we do not allow it to dictate what follows. We bear it in mind and seek to pay due regard to it, but do not follow it slavishly. This is because, as we have made clear from the outset, we were not conducting a trial. We must, therefore, avoid an approach which has the hallmark of a criminal indictment, with particular charges to be established. This is not how we conducted the Inquiry, nor is it how we propose to respond to the issue of concerns. And, this is not just a point about procedure. It goes to the essence of our approach to the Inquiry as a whole. We have referred frequently to the illusory picture of events which can be created by an Inquiry of the kind we have been asked to conduct. The blur of activity in a busy organisation is reduced to a series of ordered documents which appear to leave no room for doubt. Discussions among healthcare professionals and between them and parents and others are represented as if they were fully reproduced in a note in a file or a minute of a meeting. Recollections across years of time are represented as if they were accurate and complete accounts of what transpired. We must guard against this illusion.
- 9** To follow too closely the analysis suggested by one approach to our Terms of Reference would, therefore, prevent us from fulfilling what we see as our real duty. Thus, in what follows we will first set out the evidence which we received about concerns: to whom they were expressed, and in what way, for example, by letter or in conversation, and what action, if any, followed. In some instances there are differences in the various accounts which cannot be resolved. In such cases, we accept that there may be honestly held but differing recollections and interpretations of events. In the final section we will express our views on the appropriateness of these responses. Finally, we reiterate that we are required to focus on concerns expressed at the time, not on those which individuals have come to have with the benefit of hindsight.

Concerns

Chapter 11: The Expression of Concerns by Individuals and Reaction to Those Concerns

- 1 Here we set out in outline the evidence on concerns raised, identifying by whom and to whom, and in what way (for example, by letter or conversation) they were raised.¹ We also set out any response to the concern raised, where this, in effect, involved passing on (and thereby raising) the concern to another, or not doing so. This section is descriptive. Differences of view are noted when they occur. The evidence is set out in chronological form. What is recounted may from time to time appear confusing or disorganised. We could, of course, impose some order on the events we describe. But that would be to impose order which did not exist at the time. *There was confusion.*
- 2 In 1984, as regards the inclusion of the UBH's paediatric cardiac surgical (PCS) service in the supra regional service (SRS), Bristol 'did not actually shine as a star' and performance was not on a par with other units in terms of numbers of operations performed,² according to Dr Norman Halliday, Medical Secretary to the Supra Regional Services Advisory Group (SRSAG).
- 3 In 1986–1987, concerns were raised in Wales, where the development of a more comprehensive cardiac service in Cardiff was under discussion.
- 4 In October 1986, Professor Andrew Henderson, then Professor Emeritus, University of Wales, distributed a letter at a meeting of the South Glamorgan Health Authority (SGHA) stating 'it is no secret that their [UBH's paediatric cardiac] surgical service is regarded as being at the bottom of the UK league for quality'.³
- 5 Professor Gareth Crompton, Chief Medical Officer (CMO) Wales, in the light of Professor Henderson's letter, raised the matter with Professor (later Sir) Donald Acheson, CMO, England. Professor Acheson referred him to Dr Halliday, with whom he had a meeting. Professor Crompton felt that, at the meeting, the issue of quality was not addressed.⁴ Dr Halliday described how he saw the meeting as dealing with questions of volume of cases rather than quality of outcome. Dr Halliday told the Inquiry that he could not take Professor Henderson's points further as no supporting evidence was attached. Further, he said that he was cautious in view of the Welsh ambitions to develop their own centre for cardiac services in Cardiff.⁵ He also stated that monitoring performance was not part of the SRSAG's role.⁶

¹ A fuller chronology can be found in Annex A Chapter 31

² T13 p. 27–8 Dr Halliday

³ WO 0001 0006; letter from Professor Henderson and others to the SGHA

⁴ WIT 0070 0003 Professor Crompton

⁵ T89 p. 125 and 130–1 Dr Halliday

⁶ See Chapter 14

- 6 In autumn 1986 Dr Jennifer Lloyd, Senior Medical Officer (SMO), Welsh Office, reported on behalf of the group from the Welsh Office that had visited⁷ the UBH to follow up the concerns expressed by Professor Henderson. Dr Lloyd stated in her report that the standard of the equipment for paediatric radiology was ‘impressive’⁸ and in the paediatric Intensive Care Unit ‘high’. Dr Stephen Jordan, consultant cardiologist, however, speaking of the ‘facilities generally for cardiac surgery [adult and paediatric]’ told the Inquiry: ‘... ever since I was appointed in Bristol, [they] lagged far behind centres elsewhere’.⁹
- 7 In 1987 the Children’s Heart Circle in Wales published ‘*Meanwhile our Children are Dying*’ by Neil Hall, referring to long waiting times before receiving care in Bristol.¹⁰ Mr Peter Gregory, Welsh Office, advised his Ministers that the report was inaccurate.¹¹
- 8 In June 1987, BBC Wales broadcast the programme ‘*Heart Surgery – The Second Class Service*’.¹²
- 9 The surgeons Mr Wisheart and Mr Dhasmana and the paediatric cardiologists Dr Joffe and Dr Jordan wrote to the editor at the BBC who was responsible for the programme, refuting the criticisms. They described the outcomes for paediatric cardiac surgery at Bristol for 1984–1986 as: ‘equivalent to the UK national results for 1984 ... and better for certain conditions’.¹³
- 10 In August 1987 Mr Wisheart, Mr Dhasmana, Dr Joffe and Dr Jordan also wrote to the Chair of the Cardiology Committee of the Royal College of Physicians (RCP), who had been asked to report on the development of services in Wales. They spoke of ‘a campaign of vilification’ and described the results in Bristol as: ‘at least equal to those achieved by other paediatric units’.¹⁴ In evidence to the Inquiry, Dr Joffe said that ‘that was a partial overstatement’.¹⁵
- 11 In 1987 Miss Catherine Hawkins, Regional General Manager (RGM) for the South Western Regional Health Authority (SWRHA), reported informal expressions of concern from various district general managers (DGMs) about waiting times and outcomes in the cardiac surgical service, but not specifically the paediatric service. She approached Dr John Roylance, DGM of the Bristol and Weston District Health Authority (B&WDHA) 1985–1991, and was reassured. She told us that Dr Roylance

⁷ The precise date of the visit is unclear

⁸ WO 0001 0265; Welsh Office Report, 10 December 1986

⁹ T79 p. 56 Dr Jordan

¹⁰ WO 0001 0361 ‘*Meanwhile our Children are Dying*’, Neil Hall

¹¹ WO 0001 0315; minute dated 18 August 1987

¹² Broadcast 16 June 1987

¹³ UBHT 0194 0022; see letter apparently dated 25 June 1987

¹⁴ UBHT 0133 0029 – 0031; letter dated 3 August 1987. Mr Peter Gregory was, from 1986 to 1990, Head of Health Services Planning Division in the NHS Directorate in Wales. From 1994 to 1999 he was Director of the NHS in Wales

¹⁵ T90 p. 103 Dr Joffe

attributed the problem to an individual who shortly afterwards retired.¹⁶ Dr Roylance stated in his evidence that this was not the explanation he would have given.¹⁷

- 12 In 1988 concerns began to be raised within the UBH. Dr Stephen Bolsin, consultant anaesthetist, told the Inquiry that following his appointment in September 1988 as a consultant anaesthetist at the BRI, he was concerned at an early stage about the conduct of open-heart surgery. He was particularly concerned about the duration of operations, and the length of time children were on bypass, in comparison with what he had observed at the Brompton Hospital,¹⁸ and the consequent effect on outcomes.
- 13 In 1988 the Paediatric Cardiology and Cardiac Surgery Annual Report of the Bristol Unit for 1987 gave little indication of cause for concern. The 30-day mortality rate for open-heart surgery for children over 1 was within a percentage point of the UK Cardiac Surgical Register (UKCSR) rate for 1984–1986. For children under 1, it was 26.5%, close to the UK figure of 21.8%. There was also an increased volume of work.
- 14 The Annual Report for 1988 gave a mortality rate for PCS in the under-1s in Bristol for 1988 of 37.9%, and 27% for the period 1984–1987. The most recent UKCSR figure covering 1984–1987 was 22%.¹⁹ In the autumn of 1989, after completing a report on his first year of work at the BRI, Dr Bolsin approached Professor Cedric Prys-Roberts, Professor of Anaesthesia in Bristol, about his concerns. He was advised to keep a record.²⁰
- 15 In 1989 Dr (later Professor) Peter (Jem) Berry, consultant paediatric pathologist at the UBH/T, published a paper with a colleague at Bristol in which he described post-mortem examinations performed on 76 children who had undergone surgery for congenital heart disease. He found that ‘despite intensive investigation during life, there was a high rate of unsuspected abnormalities at necropsy (80 per cent): 29 cases had undiagnosed additional cardiac anomalies or surgical flaws, which contributed to death in 13 cases.’²¹
- 16 The Annual Report of the Unit for 1989/90 gave a mortality rate of 37.5% for PCS on children under 1. The UK figure was 18.8%.²² The disparity, according to Mr Wisheart, lay in a small number of complex procedures.²³ The clinicians in Bristol were also aware that the figures in each Annual Report might not be noteworthy on their own, because of the small numbers involved. We received evidence that for that reason they aggregated data over a number of years. By 1989 these data showed a consistent

¹⁶ T56 p. 66–9 Miss Hawkins

¹⁷ T88 p. 56 Dr Roylance. It should be noted that the contemporaneous correspondence is somewhat equivocal

¹⁸ WIT 0080 0107 Dr Bolsin

¹⁹ UBHT 0055 0039 – 0040

²⁰ T94 p. 5 Professor Prys-Roberts

²¹ Russell GA and Berry PJ. ‘Postmortem audit in a paediatric cardiology unit’. *J. Clin. Pathol.* 1989; 42:912–18

²² UBHT 0133 0085 – 0086 ‘Annual Report on Paediatric Cardiology and Paediatric Cardiac Surgery at Bristol Royal Hospital for Sick Children and Bristol Royal Infirmary, 1989/1990’. For a fuller discussion of these data and the implications which can be drawn from them see Chapter 19

²³ JDW 0003 0081 – 0082

pattern of poor outcome when compared with the reported national average performance.

- 17 The Annual Reports were circulated within the BRI. There was no obligation on anyone to respond to or act on them.²⁴
- 18 In 1989 the Society of Cardiothoracic Surgeons was asked by the Department of Health (DoH) to report on units carrying out neonatal and infant cardiac surgery (NICS). In September 1989 the report to Dr Halliday showed that two units, one of which was Bristol, had a higher mortality rate than the others.²⁵ Sir Terence English, a cardiac surgeon and, from 1989 to 1992, President of the Royal College of Surgeons of England (RCSE), acknowledged that, as a member of the SRSAG, he should probably have taken more account of these data.²⁶ Dr Halliday visited the BRI in 1990. At the July meeting of the SRS, Sir Terence is recorded in the minutes as saying: '... this unit should retain designation but [the Royal College of Surgeons of England] recommended they should be pressed to increase the workload'.²⁷
- 19 In the summer of 1990 Dr Bolsin spoke of his concerns to Dr Brian Williams, Chair of the Division of Anaesthesia at the BRI. Dr Williams stated that Dr Bolsin had no data at the time.²⁸
- 20 On 7 August 1990 Dr Bolsin wrote to Dr Roylance about what he considered to be a misleading statement in the appendix to the application for Trust status submitted by the UBH. In his letter, he also referred to mortality for open-heart surgery for under-1s as: 'one of the highest in the country, and the problem should be addressed'.²⁹ He told the Inquiry that he expected this letter to be treated as raising a concern and that he expected a response.³⁰
- 21 Dr Trevor Thomas, Chair of the Medical Audit Committee at UBH, had advised Dr Bolsin on the drafting of this letter. He advised that a copy should be sent to Mr Geoffrey Mortimer, then Chair of the Health Authority. A copy was also sent to Mr Christopher Dean Hart as Chair of the Hospital Medical Committee (HMC) at the BRI. Mr Dean Hart stated that he saw the letter as concerned with the application for Trust status.³¹ Dr Roylance also told the Inquiry that he saw the letter as being about Trust status, and that he telephoned Dr Bolsin to respond on that issue. Dr Roylance said that he did not see the letter as requiring an investigation of open-heart PCS on the under-1s.³²

²⁴ UBHT 0055 0008. It is not clear to whom the Annual Reports were circulated. Dr Joffe claimed that they (or at least that for 1987) were also sent to district health authorities (the local DHA and those at peripheral centres). T90 p. 16

²⁵ DOH 0002 0233; Figure 3, Interim Working Party report, July 1989

²⁶ T17 p. 123 Sir Terence English

²⁷ DOH 0002 0196; minutes of meeting on 26 July 1990

²⁸ WIT 0352 0026 Dr Williams

²⁹ UBHT 0052 0290; letter dated 7 August 1990

³⁰ T80 p. 118–19 Dr Bolsin

³¹ T62 p. 144 Mr Dean Hart

³² T88 p. 73 Dr Roylance

- 22 Dr Bolsin stated that he was called to Mr Wisheart's office and rebuked for taking information about PCS to 'outsiders'. According to Dr Bolsin, Mr Wisheart included Dr Roylance in that category.³³
- 23 Mr Wisheart told us that he was not told about the letter from Dr Bolsin to Dr Roylance and that the meeting referred to by Dr Bolsin between himself and Dr Bolsin did not take place.³⁴
- 24 A copy of Dr Bolsin's letter was also sent to Dr Brian Williams who stated: '... when I met with Mr Wisheart he expressed annoyance at the content, style and distribution of Dr Bolsin's letter'.³⁵ Dr Williams stated that: 'No one supported the way in which Steve Bolsin had raised the issue but all were fully supportive of his efforts to obtain appropriate data to assess the problem more accurately in an endeavour to improve results'.³⁶
- 25 Mr Wisheart told the Inquiry that he did not recollect any conversation with Dr Williams taking place.³⁷
- 26 In January 1991 Dr Elliot Shinebourne, paediatric cardiologist, visiting the UBH on behalf of the Joint Consultants' Specialist Advisory Committee (JCSAC) of the Royal College of Physicians, recommended that the BRHSC should not be accredited for a training post in paediatric cardiology, essentially because of the split site.³⁸
- 27 Also in 1991 there was a meeting between the cardiac anaesthetists at UBHT, the Clinical Director of the Directorate of Anaesthesia, Dr Christopher Monk, and Dr Peter Baskett, then President of the Association of Anaesthetists of Great Britain and Ireland (from 1990 to 1992) and a consultant anaesthetist at the UBHT, at which Dr Bolsin's concerns were discussed. Dr Bolsin told the Inquiry that at this meeting Dr Baskett said that Dr Bolsin should not be the vehicle for criticism of the PCS service, and should 'keep his head down'.³⁹ Dr Monk told the Inquiry that he and Dr Williams were asked at the meeting to speak to Mr Wisheart and Mr Dhasmana.⁴⁰
- 28 On 28 July 1991 an audit meeting was held jointly between the cardiologists, cardiac surgeons and anaesthetists. Dr Bolsin drafted minutes, referring to a problem with mortality which he expressed as having been 'thought to be reaching crisis proportions', based on the differences between the figures in the Annual Reports and the national figures, but which had been averted. Dr Bolsin said: 'I thought I was reflecting what the unit told me, but I was subsequently told after producing these

³³ WIT 0080 0109 Dr Bolsin

³⁴ T94 p. 128 Mr Wisheart

³⁵ WIT 0352 0027 Dr Williams

³⁶ WIT 0352 0037 Dr Williams

³⁷ T94 p. 132 Mr Wisheart

³⁸ T90 p.26-7 Mr Wisheart

³⁹ T80 p. 139 Dr Bolsin

⁴⁰ T73 p. 88 Dr Monk

minutes that they were not representative and I was not to produce them ever again.’⁴¹ Dr Bolsin also said: ‘I was told “these minutes will not be circulated, this is not how we do things, I do not want you keeping minutes again.”’

- 29** Dr Bolsin was asked by Leading Counsel to the Inquiry: ‘We have been told by Dr Masey⁴² that it was she who said that to you, and we have been told by Mr Wisheart ... that he did not say that to you. Are they right or are they wrong?’ He replied: ‘I think Dr Masey is right, she did say it. Mr Wisheart may be wrong. I believe he also said that to me as well.’⁴³
- 30** A table prepared within the UBH/T by the cardiac surgeons, available in mid-1991, indicated a mortality rate in Bristol between 1984 and 1989 of 32.2% for open-heart surgery on under-1s, compared with the rate according to the UKCSR for the same period of 21.2%. The table then gave the rate for 1990 in Bristol as 12.8%.⁴⁴
- 31** In October 1991 Dr Bolsin again met Professor Prys-Roberts and showed him data on mortality. Professor Prys-Roberts advised him to continue to keep accurate records.⁴⁵ By this time Dr Bolsin had been elected the first National Audit Co-ordinator for the Association of Cardiothoracic Anaesthetists of Great Britain, responsible for the collation of data on outcomes in cardiac surgery on adults.
- 32** In October 1991 Professor John Norman of the Department of Anaesthesia, University of Southampton, wrote to Professor Prys-Roberts saying that he had been approached by young anaesthetists from the BRI with their concerns, and offering help through his colleague Dr Thomas Abbott.⁴⁶ Professor Prys-Roberts discussed this with Dr Baskett, as a senior cardiac anaesthetist, and thought that Dr Baskett had followed up this offer. Professor Prys-Roberts told the Inquiry that all the cardiac anaesthetists had expressed concerns about PCS at some stage.⁴⁷
- 33** Dr Andrew Black, Senior Lecturer in Anaesthesia, University of Bristol, was by this time helping Dr Bolsin in the analysis of data. He stated that he discussed the desirability of informing Mr Wisheart and Mr Dhasmana of the intention to collect and analyse data. Dr Bolsin argued, according to Dr Black, that this would impede their task.⁴⁸
- 34** In the autumn of 1991 Dr Bolsin spoke to Dr John Zorab, Director of Anaesthesia and Medical Director of the Frenchay Hospital, Bristol, about his anxieties. Dr Zorab told Dr Bolsin that he would informally appraise Sir Terence English and did so by letter in July 1992.⁴⁹

⁴¹ T80 p. 160 Dr Bolsin

⁴² Dr Sally Masey, consultant anaesthetist, UBH/T

⁴³ T80 p. 14 Dr Bolsin

⁴⁴ UBHT 0055 0082

⁴⁵ WIT 0382 0002 Professor Prys-Roberts

⁴⁶ WIT 0382 0006; letter dated 11 October 1991

⁴⁷ T94 p. 30 Professor Prys-Roberts

⁴⁸ WIT 0326 0013 Dr Black

⁴⁹ WIT 0296 0002 – 0003 Dr Zorab

- 35** Having spoken to DGMs about their concerns relating to the process of contracting with the UBHT, on 20 November 1991 Miss Hawkins wrote to Dr Roylance about: ‘... how poorly Bristol Trust is now performing on Cardiac Surgery contracting ... I am sure Mr Wisheart would like to be made aware of the gross dissatisfaction Region-wide’.⁵⁰ These concerns related largely to the treatment of adults and did not relate to NICS since NICS was contracted for through the SRSAG. Miss Hawkins’ concerns do, however, identify the tension between engaging in NICS and treating adults who were sometimes kept waiting for treatment.
- 36** The reply from Dr Roylance, drafted by Mr Wisheart, addressed only the issues of contracting and ignored what, according to Miss Hawkins, she considered ‘the real issue’: that there was a general dissatisfaction in a major part of the Region with the cardiac unit, which the Medical Director was disregarding.⁵¹ Miss Hawkins visited the BRI and spoke to Mr Wisheart and was reassured that the problems would be addressed.⁵²
- 37** In October 1991 Dr Bolsin saw Professor Prys-Roberts again about the PCS results. Professor Prys-Roberts agreed to speak informally to Dr Roylance. Professor Prys-Roberts having seen preliminary data, spoke to Dr Roylance. Professor Prys-Roberts told us: ‘I was seeing soft evidence that gave me concern’.⁵³
- 38** A table prepared in the UBHT and supplied to the Inquiry disclosed a mortality rate in 1991 of 30% for open-heart surgery on under-1s. The UKCSR figure for 1990 was 15.8%.⁵⁴
- 39** On 3 January 1992 Mr Martin Elliott, consultant cardiothoracic surgeon, Great Ormond Street Hospital, wrote to Mr Wisheart saying that he had decided not to apply for the Chair in Cardiac Surgery at Bristol because: ‘I have lingering doubts about the security of the paediatric volume [and] a worry about the separation of cardiology from cardiac surgery...’.⁵⁵ He had also met Mr Peter Durie, Chairman of the UBHT 1991–1994, and expressed his concerns about the split site. In a separate paper written at Mr Wisheart’s request, he stated that:
- ‘The separation of open and closed paediatric cardiac surgery must be inefficient, and is potentially dangerous.’⁵⁶
- 40** Following a site visit by the SRSAG in February 1992, data on Bristol’s death rates in PCS on the under-1s were passed by Mr Steven Owen, Administrative Secretary to the

⁵⁰ UBHT 0038 0430; letter dated 20 November 1991

⁵¹ T56 p. 97–8 Miss Hawkins

⁵² T56 p. 105 Miss Hawkins

⁵³ T94 p. 21 Professor Prys-Roberts

⁵⁴ UBHT 0055 0144

⁵⁵ JDW 0003 0102; letter dated 3 January 1992

⁵⁶ WIT 0467 0013; Mr Elliott’s paper ‘The Chair of Cardiac Surgery in Bristol’

SRSAG, to Dr Halliday.⁵⁷ Dr Halliday told the Inquiry that he often received data, but that they were difficult to interpret in isolation.⁵⁸ He said:

‘The difficulty is, as I have said, having figures in isolation without the machinery to analyse it, is of no particular value. ... I was not given any figures with the suggestion that there was a problem here. I was given figures as I was on many visits. ... If, however, we were given the data and told that there was a problem with that data, that would be a different matter.’⁵⁹

This contrasts with the previously mentioned response by Dr Halliday to Professor Henderson’s points: that he could not take Professor Henderson’s expression of concern further because he had no supporting evidence.

- 41 Professor Prys-Roberts stated that in ‘early February or March 1992’,⁶⁰ he met Dr Roylance and told him that Dr Bolsin had data that he would show Dr Roylance. Professor Prys-Roberts stated that Dr Roylance said that he would deal with it.⁶¹ Dr Roylance does not recall this, but recalls discussing with Professor Prys-Roberts the need to appoint a cardiac surgeon.⁶²
- 42 In the spring of 1992 Dr Bolsin went to see Mrs Kathleen Orchard, General Manager, Directorate of Surgery, UBHT 1991–1993. She recalled that he expressed a ‘worry’ rather than a serious concern about PCS.⁶³
- 43 In 1992 *‘Private Eye’* published six articles (14 February, 27 March, 8 May, 3 July, 9 October and 20 November) criticising the PCS services at the BRI.
- 44 Mr Durie told the Inquiry that the articles in *‘Private Eye’* were raised informally at a meeting of the Trust Board, but the minutes do not record this.⁶⁴
- 45 On 22 June 1992 Dr Roylance received a letter from Ms J Binding, an official in the Corporate Affairs Department of the NHS Management Executive, about concerns raised by a parent who had read articles in *‘Private Eye’* and whose child was about to have surgery at the BRI.⁶⁵ Mr Wisheart drafted the reply which indicated that results at Bristol were good.⁶⁶
- 46 In April 1992 Dr Bolsin met Dr Phil Hammond and showed him ‘very provisional’ logbook data.⁶⁷ Dr Bolsin told the Inquiry that he regarded Dr Hammond as a

⁵⁷ T13 p. 113–14 Dr Halliday

⁵⁸ T13 p. 113 Dr Halliday

⁵⁹ T13 p. 113–14 Dr Halliday

⁶⁰ T94 p. 12 Professor Prys-Roberts

⁶¹ T94 p. 33 Professor Prys-Roberts

⁶² T88 p. 117–21 Dr Roylance

⁶³ WIT 0170 0044 – 0045 Mrs Orchard

⁶⁴ T30 p. 36–7 Mr Durie

⁶⁵ JDW 0003 0134; letter dated 22 June 1991

⁶⁶ JDW 0003 0157; letter dated 23 July 1992

⁶⁷ WIT 0080 0111 Dr Bolsin

concerned trainee GP. Dr Hammond told the Inquiry that he was also the author of the articles in *'Private Eye'*.⁶⁸ Dr Bolsin said that he did not know in 1992 that Dr Hammond wrote the articles⁶⁹ and may not have known until 1995.⁷⁰

- 47 In mid-1992 after being unsuccessful in an application for a post in Oxford, Dr Bolsin again spoke to Professor Prys-Roberts about collecting data. Professor Prys-Roberts had had no further discussion of the matter with Dr Roylance.⁷¹
- 48 In June 1992 the Report of the Working Party of the Royal College of Surgeons, commissioned by the SRSAG, was delivered to Sir Terence English as President of the RCSE. It recommended the designation of nine centres including Bristol.⁷² Sir Terence thanked the Chair, Professor David Hamilton, by letter on 2 July, describing the Report as 'balanced and authoritative'.⁷³
- 49 On 15 July Dr Zorab wrote to Sir Terence at the RCSE about 'great anxieties' being expressed by colleagues at the BRI, brought to a head by the articles in *'Private Eye'*.⁷⁴ Sir Terence had been succeeded as President of the RCSE on 8 July by Sir Norman Browse, who forwarded the letter to Sir Terence. Sir Terence described how the letter acted as a stimulus to him to revisit the figures on mortality in Table 1 of the Working Party's report.⁷⁵ These figures showed the results in Bristol as being worse than those at any other centre.
- 50 Sir Terence asked for the report of the RCSE's Working Party to be withdrawn for amendment. Professor Hamilton initially agreed but then withdrew this agreement. Sir Terence then spoke to Dr Halliday and asked for his reservations about Bristol to be conveyed to the next SRSAG meeting, which he would be unable to attend. Sir Terence told the Inquiry that he specifically raised the mortality figures with Dr Halliday.⁷⁶ It is Dr Halliday's recollection that he understood Sir Terence's reservations about Bristol to be the long-standing concerns about the volume of work being carried out.⁷⁷ At the meeting of July 1992 the SRSAG decided to de-designate the entire PCS service.⁷⁸
- 51 Sir Michael Carlisle, Chairman of the SRSAG 1989–1994, and the other members of the SRSAG were not shown, nor told of, Dr Zorab's letter to Sir Terence English,⁷⁹ nor were they told by anyone of the nature of Sir Terence English's reservations.

⁶⁸ WIT 0283 0001 Dr Hammond

⁶⁹ WIT 0080 0111 Dr Bolsin

⁷⁰ T80 p. 65 Dr Bolsin

⁷¹ T94 p. 49 Professor Prys-Roberts

⁷² RCSE 0002 0167; Working Party Report

⁷³ RCSE 0002 0179; letter dated 2 July 1992

⁷⁴ RCSE 0002 0188; letter dated 15 July 1992

⁷⁵ T17 p. 124 and T18 p. 150 Sir Terence English

⁷⁶ T18 p. 184 Sir Terence English

⁷⁷ T89 p. 157 and T89 P. 157 Dr Halliday

⁷⁸ DOH 0002 0099; minutes of meeting on 28 July 1992

⁷⁹ T15 p. 74–5 Sir Michael Carlisle

- 52** In July 1992 Dr Bolsin and Dr Black began to tabulate the data on 233 children who had undergone open-heart surgery at the BRI in 1991 and 1992. They became concerned about high mortality in patients with Ventricular Septal Defect (VSD), Tetralogy of Fallot, and Atrio-Ventricular Septal Defect (AVSD).⁸⁰ Dr Bolsin and Dr Black showed their data to Professor Gianni Angelini, Professor of Cardiac Surgery, University of Bristol, and Professor Prys-Roberts.⁸¹
- 53** Ms Mona Herborn and Mrs Kay Armstrong, Sisters in the operating theatres at the BRI, stated in their evidence to the Inquiry that by 1992 they were concerned about mortality rates in PCS and discussed the matter with Dr Bolsin.⁸²
- 54** No annual reports from the Unit were produced after the 1989/90 report as Dr Joffe, on his appointment as Clinical Director of the Children's Services, told us that he did not have the time to devote to continuing them, which he 'very much regretted'.⁸³
- 55** Because, as Mr Dhasmana put it, 'the neonatal switch programme ended in failure' involving the deaths of five babies, it was halted in September 1992.⁸⁴ Mr Dhasmana sought the advice of Mr William Brawn, consultant paediatric cardiac surgeon at Birmingham Children's Hospital.⁸⁵ On 1 December 1992 he visited Mr Brawn at the Children's Hospital, Birmingham together with Dr Masey. He talked about the procedure with Mr Brawn, observed an operation and took away the video of the operation for further reference.⁸⁶
- 56** Also in December 1992 the minutes of the Trust Board record that Dr Roylance advised that dissatisfaction had been expressed about the quality and cost of cardiac services for adults and children over 1 in Bristol, and that Dr Roylance would discuss this with Mr Wisheart.⁸⁷
- 57** Early in 1993 Dr Bolsin saw Professor John Farndon, Director of the Division of Surgery at the University of Bristol since 1988, about his concerns. Professor Farndon advised him to validate and then share the data with those providing the service.⁸⁸ Professor Farndon recalls being approached by Mr Alan Bryan, consultant cardiac surgeon, Dr Monk, Professor Prys-Roberts and Dr Sheila Willatts, consultant in anaesthesia and intensive care, about their concerns about open-heart PCS.⁸⁹

⁸⁰ See Annex A, Chapter 3, for an explanation of these clinical terms

⁸¹ WIT 0326 0015 Dr Black

⁸² WIT 0255 0014 Ms Herborn; WIT 0132 0055 Mrs Armstrong

⁸³ T90 p. 14 Dr Joffe

⁸⁴ WIT 0084 0112 Mr Dhasmana

⁸⁵ WIT 0084 0110 Mr Dhasmana

⁸⁶ WIT 0084 0113 Mr Dhasmana

⁸⁷ UBHT 0005 0226; minutes of meeting on 7 December 1992

⁸⁸ T69 p. 89–90 Professor Farndon

⁸⁹ WIT 0087 0007 Professor Farndon

- 58** Dr Masey was shown their data by Dr Black and discussed the data with Dr Bolsin. She advised Dr Bolsin to share the data with the surgeons. Dr Bolsin's reply was that he thought this might limit his access to data.⁹⁰ In 1993–1994, Dr Willatts recalls prolonged discussions among the anaesthetists of the results of PCS. She stated that she had hoped that they could be examined by a joint meeting of surgeons and anaesthetists which Professor Farndon volunteered to chair.⁹¹
- 59** In July 1993 Mr Dhasmana again went to Birmingham for training. He remained '... very concerned that something is probably a little different in neonates which I have not still been able to transfer'⁹² and decided to stop carrying out the neonatal Switch procedure.
- 60** In the autumn of 1993 Dr Bolsin presented statistics on outcomes in open-heart PCS for specific diagnoses to Mr Bryan who said he found them disturbing. Mr Bryan, senior lecturer in Cardiac Surgery, University of Bristol, and consultant cardiothoracic surgeon, UBHT, was also aware of concern being expressed by senior colleagues: Professor Angelini, Professor Prys-Roberts, Professor Farndon and Dr Monk.⁹³
- 61** Dr Monk stated that he was shown data. He stated further that he did not take the data to Mr Wisheart or Mr Dhasmana because the data were not verified.⁹⁴ He said that he spoke to them both about his concerns.⁹⁵
- 62** In November 1993 Professor Angelini talked to Mr Jaroslav Stark, consultant cardiothoracic surgeon at Great Ormond Street Hospital, about Dr Bolsin's data. Mr Stark advised Professor Angelini to go to see Professor Farndon.
- 63** Also in November 1993 Dr Bolsin saw Professor John Vann Jones, first Clinical Director of the newly created Directorate of Cardiac Services, with data on four specific conditions.⁹⁶ Professor Vann Jones questioned the data on VSDs, asked Dr Bolsin to check his figures and expected him to return.⁹⁷ (These figures were later found to contain an error and ultimately Dr Bolsin apologised to Dr Roylance.)⁹⁸
- 64** Dr Bolsin does not recall expecting to return to see Professor Vann Jones. He told the Inquiry that he believed that he had explained his view that there was a need for a full investigation.⁹⁹

⁹⁰ WIT 0270 0014 Dr Masey

⁹¹ WIT 0343 0002 Dr Willatts

⁹² T85 p. 50 Mr Dhasmana

⁹³ WIT 0081 0023 Mr Bryan

⁹⁴ WIT 0105 0025 Dr Monk

⁹⁵ T73 p. 119 Dr Monk

⁹⁶ In evidence, Professor Vann Jones referred to these conditions as Tetralogy of Fallot, VSD, AV Canal, and single ventricle. T59 p. 104

⁹⁷ WIT 0115 0019 Professor Vann Jones

⁹⁸ UBHT 0061 0053; letter from Dr Bolsin to Dr Roylance (undated)

⁹⁹ WIT 0115 0025 Professor Vann Jones

- 65** Mr Wisheart visited Professor Vann Jones a day or two later to present his own figures after learning that Dr Bolsin had spoken to Professor Vann Jones and Professor Paul Dieppe, Dean of the Faculty of Medicine, University of Bristol.¹⁰⁰
- 66** In December 1993 Dr Bolsin spoke to Dr Jane Ashwell, SMO at the DoH, about outcomes in PCS. She then spoke and wrote to Professor Farndon, as Director of the Division of Surgery at the BRI.¹⁰¹
- 67** On 23 December 1993 Professor Angelini and Professor Farndon went to see Mr Wisheart about their concerns about PCS and the need to appoint a consultant paediatric cardiac surgeon.¹⁰² Data were placed on the table.
- 68** Mr Wisheart recalls the discussion of the need for the appointment, but not of concerns nor of data.¹⁰³
- 69** Late in 1993 Professor Peter Keen, Dean of the Faculty of Medicine, University of Bristol, agreed that Professor Angelini should take matters forward concerning the PCS service.¹⁰⁴
- 70** On 20 January 1994 a special meeting of cardiologists, surgeons and anaesthetists involved in paediatric care was called. Mr Dhasmana was absent. Dr Bolsin did not present any data. There was no Chair, nor an agenda. (Mr Dhasmana described it as a meeting of the 'paediatric cardiac club'.¹⁰⁵) Dr Stephen Pryn, consultant in anaesthesia and intensive care, presented some data and Mr Wisheart presented the surgeons' data, which was unchallenged. Dr Pryn recalls:

'Whilst Mr Wisheart was presenting his data, I was looking down through my very rough workings and was trying to count in my mind.

'I particularly chose the AV canals, because I think Mr Wisheart had said, "Here are the realities for the AV canals; they are not good but they are tolerable", and I wanted to cross-check that with my data. So I was counting the AV canals and I got a little confused between children who were aged over 1 and under 1, and at the end I made some comment about, I do not know, mortality in children with AV canal over 1, and both Mr Wisheart and Alison Hayes, the cardiologist, actually said to me, "Your data must be rubbish because we do not do AV canals in the over 1s". So that was it. So I sat down again; basically, I had not prepared for a presentation.'¹⁰⁶

¹⁰⁰ WIT 0115 0207 Mr Wisheart

¹⁰¹ WIT 0338 0005 Dr Ashwell

¹⁰² T61 p. 85 Professor Angelini

¹⁰³ WIT 0073 0104 Mr Wisheart

¹⁰⁴ WIT 0413 0001 Professor Keen

¹⁰⁵ T86 p. 145 Mr Dhasmana

¹⁰⁶ T72 p. 147–8 Dr Pryn

- 71** In March 1994 Dr Peter Wilde, the senior radiographer at the UBHT, distributed a discussion document on ‘Echocardiology on the Cardiac Unit’. In a covering letter he said: ‘The system is certainly unsatisfactory at present and could potentially be very much better if we had an organised strategy. I feel sure that a high quality supporting echo service would undoubtedly lead to improvements in cardiac outcomes.’¹⁰⁷
- 72** Early in 1994 Dr Bolsin wrote to Dr Ashwell at the DoH thanking her for her support and advising her that: ‘There is now in place a programme for the appointment of a new paediatric cardiac surgeon and a commitment from the highest levels of the Trust to improve and maintain performance. There would seem to be little benefit from any further investigation from your end at this stage although this should not be ruled out if words are not converted speedily into actions.’¹⁰⁸
- 73** In March 1994 Professor Angelini again met Dr Roylance, having previously seen him in December 1993 with Professor Farndon. On this occasion Dr Monk went with him to discuss their concerns over the mortality data for PCS. No written materials were presented nor discussed at the meeting.¹⁰⁹
- 74** At the instigation of Dr Monk and with the aim of discussing concerns, he and Mr Wisheart took Dr Bolsin and Professor Angelini to a private dinner on 5 April 1994 at a restaurant in Bristol (Bistro 21). Dr Monk asked whether there were any concerns regarding PCS. Neither Dr Bolsin nor Professor Angelini replied.¹¹⁰ No discussion of the matter took place. Three days later Mr Wisheart reported to the Trust Board that the Unit was obtaining excellent results with children.¹¹¹
- 75** On 18 April 1994 Dr Bolsin went to see Mrs Janet Maher, General Manager of the Directorate of Surgery 1993–1998, about his concerns. She advised him to talk to Dr Monk and the surgeons.
- 76** Mrs Maher spoke to Dr Monk, Dr Roylance and Mr Wisheart, and formed the view that Mr Wisheart found Dr Bolsin’s comments about data confusing, as these comments did not tie in with his own data.¹¹²
- 77** In April 1994 Professor Vann Jones was asked by Ms Lesley Salmon, Associate General Manager, then General Manager 1991–1994, to convene a meeting for non-medical staff to inform and reassure them about the PCS service, in view of the rumours which were circulating.¹¹³
- 78** In May 1994 Professor Angelini was visited by Mr Peter Durie, Chairman, UBHT, and Mrs Margaret Maisey to talk about the quality of PCS. Professor Angelini suggested as

¹⁰⁷ UBHT 0146 0050; letter dated 3 March 1994

¹⁰⁸ UBHT 0061 0270; letter dated 10 February 1994

¹⁰⁹ T61 p. 108 Professor Angelini

¹¹⁰ WIT 0105 0023 Dr Monk

¹¹¹ UBHT 0020 0015; minutes of meeting on 8 April 1994

¹¹² WIT 0153 0023 – 0025 Mrs Maher

¹¹³ T59 p. 155 Professor Vann Jones

a solution the appointment of a new paediatric cardiac surgeon.¹¹⁴ Mr Durie asked Professor Angelini to write him a letter dealing with the point and also suggested that Professor Angelini see Professor Vann Jones. This he did and he and Professor Vann Jones then wrote to Mr Durie.

- 79** Mr Durie went on leave at this time and does not recollect seeing the letter. He presumed that it would have been ‘given to the Chief Executive [Dr Roylance] to work on’¹¹⁵. Mr Durie stood down as Chairman of the Trust Board on 30 May. The new Chairman, Mr Robert McKinlay, took up office on 1 July 1994. Dr Roylance told us that he, Dr Roylance, did not see the letter.¹¹⁶
- 80** On 12 May 1994 a draft report was circulated for consideration by the UBHT’s Cardiac Expansion Working Party. The draft report referred to the ‘perception that the quality of paediatric cardiac services in the UBHT does not match the standards of the Trust’s major competitors ...’.¹¹⁷
- 81** Towards the summer of 1994 Professor Angelini and Mrs Maher had a conversation about the move of the children’s service to the BRHSC. Their respective recollections of this conversation differed. Professor Angelini explained that he was ‘trying to understand ... the reticence of the management to have the paediatric service moved to the Children’s Hospital’,¹¹⁸ whilst Ms Maher recalled that the move to the BRHSC was taking place and that it was happening ‘despite [Professor Angelini], and not because of him’, as he seemed to her to be taking credit for something he had not been involved in.¹¹⁹
- 82** In early June 1994 the six paediatric anaesthetists met to review the results of the Arterial Switch operations. On 21 June they drafted a letter expressing concern about PCS. According to Dr Bolsin and Dr Masey, the first draft was intended for Dr Roylance. Dr Monk was to be a co-signatory. However, subsequent drafts or versions seen by the Inquiry were addressed to Dr Monk. This alternative version was taken by Dr Monk to Dr Roylance. It referred to ‘unacceptably high mortality’ in the neonatal Arterial Switch operation and requested a review. Dr Davies, Dr Baskett, Dr Pryn, Dr Bolsin, Dr Masey and Dr Underwood each signed a draft, although all six of them did not all sign any one draft.
- 83** In July 1994 Dr Monk saw Dr Roylance twice on the matter. He told us that Dr Roylance told him that the issue was clinical and therefore for clinicians to resolve.¹²⁰ Dr Roylance does not recall the discussion nor the letter,¹²¹ which he

¹¹⁴ T61 p. 127 Professor Angelini

¹¹⁵ T30 p. 94 Mr Durie

¹¹⁶ T89 p. 19 Dr Roylance

¹¹⁷ UBHT 0275 0139; draft report ‘Options for Development of Adult and Paediatric Cardiac Services in UBHT’, May 1994

¹¹⁸ WIT 0153 0028 Professor Angelini

¹¹⁹ WIT 0153 0061 Ms Maher

¹²⁰ T73 p. 164 Dr Monk

¹²¹ WIT 0108 0128 Dr Roylance

told us he did not see until he had retired.¹²² However, he did tell us that if he had been shown the letter: 'I would have acted very quickly and very strongly.'¹²³

- 84** In July 1994 the anaesthetists' concerns were brought to Mr Dhasmana's attention when they asked him to notify and consult them before arranging any further Switch procedures¹²⁴ (he had already stopped the neonatal Switch operation).¹²⁵
- 85** On 19 July 1994 Dr Peter Doyle, SMO, DoH, attended an audit meeting at the BRI. On his way back to the railway station in a taxi, he was given an envelope which Dr Bolsin told him contained data about PCS. Dr Doyle told the Inquiry that he did not look at the data. He filed the document. He wrote to Professor Angelini indicating that concerns had been expressed to him over mortality rates in children undergoing PCS and seeking to be reassured that steps were being taken to remedy the problem.¹²⁶
- 86** In August 1994 Professor Angelini replied, referring in his letter to the plan to appoint a new paediatric cardiac surgeon, and eventually to move open-heart surgery to the BRHSC.¹²⁷ Dr Roylance wrote to Dr Doyle in September confirming these two steps had been decided on by the Trust Board.¹²⁸ Dr Roylance was advised by Mr Wisheart to indicate in his letter to Dr Doyle that the problem was limited to one procedure.¹²⁹ No minutes informing the UBHT's Board of the decisions referred to by Dr Roylance in his letter to Dr Doyle have been found. The letter also confirmed the Trust Board's 'awareness of this problem'.¹³⁰ In fact, the Board was not aware, and had never been told, of the problem.
- 87** In September 1994 Mr Ashwinikumar Pawade was appointed as consultant paediatric cardiac surgeon, with effect from May 1995. Professor Farndon, Mr McKinlay and Professor Angelini met to discuss this appointment. Professor Angelini and Mr McKinlay recall a discussion of poor results in PCS at the meeting.¹³¹
- 88** In November 1994 at a meeting of consultants, Professor Angelini suggested to Mr Dhasmana that the PCS 'should be rationalised'¹³² prior to Mr Pawade's arrival.
- 89** On 17 November 1994 Professor Farndon discussed the concerns about PCS with Mr Wisheart, and kept a note of the meeting.¹³³ The note recorded an agreement to tabulate results and hold an open discussion to discuss the data relating to operations

¹²² T88 p. 152 Dr Roylance

¹²³ T88 p. 148 Dr Roylance

¹²⁴ T87 p. 38–9 Mr Dhasmana

¹²⁵ T86 p. 164 Mr Dhasmana

¹²⁶ UBHT 0052 0287 – 0288; letter dated 21 July 1994

¹²⁷ DOH 0001 0012; letter dated 19 August 1994

¹²⁸ UBHT 0061 0278; letter dated 12 September 1994

¹²⁹ UBHT 0061 0276; letter dated 4 September 1994

¹³⁰ UBHT 0061 0278

¹³¹ WIT 0073 0016 Professor Angelini; WIT 0073 0055 Mr McKinlay

¹³² T61 p. 176 Professor Angelini

¹³³ T69 p. 170 Professor Farndon

on both adults and children. Professor Farndon described himself as ready to act as an honest broker. He was not asked to do so by anyone.

- 90** On 8 December 1994 there was a meeting of the ‘paediatric cardiac club’ at Dr Joffe’s house. The non-neonatal Switch operation was discussed. It was agreed that Mr Dhasmana should continue to carry out this procedure. Dr Bolsin was not present.¹³⁴
- 91** Mr McKinlay stated that by Christmas he told Dr Roylance that he wanted an independent external inquiry into the unit as a whole and he agreed. Dr Roylance, however, denied that before Christmas he had agreed to an Inquiry.¹³⁵ On balance we prefer Mr McKinlay’s account.¹³⁶
- 92** In late December 1994 18-month-old Joshua Loveday (who had been seen in the Joint Cardiology Clinic by Dr Martin on 21 November 1994) was scheduled to be admitted for a Switch operation to be performed by Mr Dhasmana. On 6 January Professor Angelini saw Mr Wisheart to seek to persuade him that it would be unwise to proceed. This was the first occasion on which Mr Wisheart recalls an open expression of concern about PCS.¹³⁷ Professor Angelini put his views in writing to Mr Wisheart on 10 January,¹³⁸ after speaking to Dr Roylance, Dr Doyle, Dr Willatts and Professor Farndon.
- 93** On 11 January Dr Bolsin contacted Dr Doyle to inform him that a Switch operation was listed for the next day.¹³⁹
- 94** A clinical meeting was held on 11 January at which Dr Joffe, Dr Hayes, Dr Martin, Mr Dhasmana, Mr Wisheart, Dr Masey, Dr Monk, Dr Bolsin and Dr Pryn were present. The purpose of the meeting was to discuss whether to proceed with the operation on Joshua Loveday. It was decided that only clinical factors should be considered. Dr Martin advised that the case was urgent. All those present agreed that there were no clinical reasons for not proceeding with the operation, as Mr Dhasmana’s non-neonatal Switch results were within the acceptable range.¹⁴⁰ While not objecting on clinical grounds, Dr Bolsin dissented on the basis of what Mr Wisheart remembered as ‘institutional reasons’ with ‘political consequences’.¹⁴¹ Mr Wisheart was aware that Dr Roylance was minded to call for an independent review of PCS but Mr Wisheart did not reveal this to others. Mr Wisheart told the Inquiry that he felt it might have added to the pressures on Mr Dhasmana.¹⁴² There was also a joint discussion in a side meeting, involving Mr Wisheart, Mr Dhasmana

¹³⁴ WIT 0120 0455 Mr Wisheart

¹³⁵ T88 p. 23 Dr Roylance

¹³⁶ WIT 0102 0028 – 0029 Mr McKinlay

¹³⁷ WIT 0120 0455 Mr Wisheart

¹³⁸ WIT 0120 0455 Mr Wisheart

¹³⁹ DOH 0001 0009; memorandum dated 16 January 1995

¹⁴⁰ WIT 0120 0456 Mr Wisheart

¹⁴¹ WIT 0120 0456 – 0457 Mr Wisheart

¹⁴² T77 p. 127 Mr Wisheart

and Dr Martin, as to whether it was clinically appropriate to proceed with Joshua's operation.¹⁴³

- 95 On 12 January, Mr Wisheart informed Dr Doyle of the death of Joshua Loveday following surgery. Dr Doyle wrote to Dr Roylance stating that 'it would be extremely inadvisable to undertake any further neonatal or infant cardiac surgery' (Joshua was in fact 18 months old and his operation did not fall into the category of NICS). He also urged Dr Roylance to expedite the proposed independent inquiry.¹⁴⁴
- 96 Dr Roylance replied expressing concern about the way in which Dr Doyle had been informed.¹⁴⁵
- 97 Later in January 1995, Mr Wisheart was asked as Medical Director by Dr Roylance to set up the independent external inquiry previously discussed. Professor Marc de Leval, Professor of Cardiothoracic Surgery, Great Ormond Street Hospital, and Dr Stewart Hunter, consultant in paediatric cardiology, Freeman Hospital, Newcastle upon Tyne, were invited to undertake it.¹⁴⁶
- 98 Dr Hunter recorded in his notes at the time that Dr Roylance offered them a free hand, and expressed his concerns about the PCS service¹⁴⁷ and the existence of conflict between professional groups. When he met Dr Hunter and Professor de Leval, Dr Roylance identified three questions which he wished to have answered: whether the appointment of a new paediatric cardiac surgeon was a proper solution to the problem; whether moving to the BRHSC was proper; and what the service should do between the time of reporting and the arrival of Mr Pawade?¹⁴⁸
- 99 On 10 February 1995, Professor de Leval and Dr Hunter visited Bristol. Mr Wisheart told the Inquiry that it was at the open meeting at the end of the day that he heard for the first time about the existence of audit data collected by Dr Bolsin.¹⁴⁹
- 100 The Hunter/de Leval Report described a degree of confusion in the organisation of the Intensive Care Unit, and identified the need for better communication and trust and a monthly morbidity and mortality conference with open discussion. The report stated that the critical factor in solving the overall problem was the appointment of the new surgeon with a proven track record in a major centre.¹⁵⁰ Professor de Leval told the Inquiry¹⁵¹ that although the data available to them were weak, there was a problem with the outcomes in PCS, and that the surgeons had been reticent in recognising and confronting this in the past. The first draft of the report, prepared in confidence for

¹⁴³ UBHT 0340 0350; Dr Martin's minute of the meeting

¹⁴⁴ UBHT 0061 0282 – 0283; letter dated 25 January 1995

¹⁴⁵ PAR2 0001 0027; letter dated 26 January 1995

¹⁴⁶ UBHT 0061 0337; letter dated 25 January 1995

¹⁴⁷ WIT 0319 0013; Dr Hunter's notes

¹⁴⁸ T89 p. 75 Dr Roylance

¹⁴⁹ T94 p. 163 Mr Wisheart

¹⁵⁰ WIT 0322 0007 Dr Hunter

¹⁵¹ T60 p. 5–6 and T60 p. 59 Professor de Leval

Dr Roylance, described one of the surgeons (Mr Wisheart) as being among the higher-risk surgeons, but the other (Mr Dhasmana) as comparing favourably with the best in other UK units. The report was discussed with all consultants at two meetings in March and modified in a second draft when it became clear that it would have a wider readership than originally anticipated by its authors.

- 101** In Dr Roylance's absence, Mr Graham Nix, as acting Chief Executive, consulted Mr McKinlay concerning a response to the report. After discussion with Dr Gabriel Laszlo, Chairman of the HMC, Dr Joffe, Dr Monk and Dr Vann Jones an agreed report and response was issued which accepted the recommendations. A protocol was agreed whereby complex PCS would either await the arrival of Mr Pawade or, if urgent, be referred elsewhere. Mr Wisheart was to cease PCS, except in cases where he had treated a child previously and the parents asked him to continue caring for the child.

Concerns

Chapter 12: Responses to Concerns and Actions Taken, and Whether Such Actions were Appropriate and Prompt

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Fairness

- 1 We stress at the outset 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 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 that we identified, 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 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.

Responses outside the UBH/T

- 2 Concerns about the paediatric cardiac surgical (PCS) service in Bristol were raised with the Supra Regional Services Advisory Group (SRSAG), the Department of Health (DoH) and the South West Regional Health Authority (SWRHA). Concerns were raised with the DoH culminating in the request for help from staff at the UBHT in connection with the decision to operate on Joshua Loveday in January 1995.

The Supra Regional Services Advisory Group

- 3 We accept that, although there was only a qualified endorsement of PCS at Bristol in 1984, the arguments in favour of designation were defensible. These were the need for coverage in the South West, and the potential for development in Bristol, provided that the service was supported and monitored. But, as time passed and the results, both in terms of throughput and outcome, failed to improve, we would have expected a greater degree of vigilance in considering the progress made and the options for the future. One of these options would have been to discontinue support by de-designating the service in Bristol. While we accept that this, of itself, would not necessarily have brought PCS to an end in Bristol, since the SRSAG had no power to prevent PCS being undertaken, we take the view that such a step would have attracted sufficient attention to cause the service to be evaluated carefully before being supported further by the UBH/T.
- 4 The 1989 report commissioned by the SRSAG from the Society of Cardiothoracic Surgeons of Great Britain and Ireland (SCS) (discussed at the SRSAG's July 1989 meeting) included information about poor outcomes in Bristol. While not in itself sufficient to require immediate action, this information might have been expected to

lead to vigilant monitoring of the service in Bristol by the SRSAG, through which it was funded. Dr Halliday visited Bristol in 1990, and sub-optimal results were noted. But these were attributed to the low volume of work. Whether accurately or not, increasing volume was at the time widely held to be associated with improving results.¹ Thus, to look for higher volumes as a way of achieving better outcomes was not unreasonable. But the focus on throughput may with hindsight be thought to have distracted attention from further inquiry, as the Bristol results, with the exception of the figures for 1990, showed no real improvement as regards outcomes in PCS on the under-1s. The final events leading to de-designation of the service in 1992 reveal a lack of effective communication between expert advisors, DoH officials and the Chair of the SRSAG. It is regrettable that, in the light of evidence in existence over time (up to 1992) Sir Terence English, President of the RCSE and member of the SRSAG, holding the position he did as a leading cardiac surgeon, did not advise the SRSAG that he was concerned about the poor outcomes of the Bristol Unit and that they deserved investigation or action. We acknowledge that he drew these matters to the attention of Professor David Hamilton, Chair of the RCSE Working Party, and it is common ground that he mentioned that he had reservations about Bristol to Dr Halliday, but regrettably he did not inform members of the SRSAG and particularly the Chair, Sir Michael Carlisle, of the nature of his concerns. We add that we were particularly impressed by the frankness with which Sir Terence gave his evidence and by his willingness to admit to error or misjudgment in this regard.

- 5 It is important to remember, however, that, at this time, responsibility for monitoring the quality of care of PCS in the under-1s, in the sense of reviewing the outcomes, had no clear place in the system, whether locally in Bristol or centrally in the DoH. Dr Halliday did receive some mortality data from Bristol but said that he did not have the 'machinery to analyse it'.² Professor Farndon told us there was no effective system for monitoring the quality of care in PCS in Bristol. Sir Alan Langlands told us that the DoH had a responsibility for setting up a system for monitoring matters such as finance and volume of cases, but that quality of care was a matter for the employer. The Royal Colleges regarded the task as one for the employer, or the DoH. Others regarded it as the duty of the individual doctor to ensure the quality of care. Equally, audit for a large part of the time covered by the Inquiry's Terms of Reference was an educational tool rather than a device for ensuring quality. Measures described at the time as indicators of quality were still predominantly concerned with indirect clinical aspects of care, such as waiting times. The choice of topics to be audited remained with clinicians. Moreover, audit did not take place across the boundaries between specialties, making it even more difficult to get a clear picture of a complex, multi-specialty team activity like PCS.
- 6 In short, there was no effective national system for monitoring outcomes. This situation was compounded by the assumption by a number of the respective

¹ T7 p. 75–6 Dr Michael Godman. (We note that the Joint Working Party of the Royal College of Physicians and the Royal College of Surgeons of England in 1987, DOH 0002 0223, had noted the link between low numbers of patients treated and higher mortality, and that Bristol had low numbers of cases)

² T13 p. 113 Dr Halliday

organisations that it was not their responsibility but that of some other body. This meant, in turn, that the absence of, and need for, a national system was not recognised nor acknowledged at the time.

The Welsh Office and the Department of Health

- 7 In 1986–1987 concerns which had arisen in Wales about the quality of care in Bristol came to the attention of the DoH. In our view, the expression of these concerns was (or could at the time have been judged to be) affected by the plans to establish a Welsh Centre for Cardiac Services in Cardiff. Professor Henderson's (Professor Emeritus, Honorary Consultant Cardiologist, University of Wales, College of Medicine) concerns lacked supporting evidence. Nevertheless, they were taken by the Chief Medical Officer (CMO) for Wales, Professor Gareth Crompton, to his English counterpart, Professor Sir Donald Acheson, who referred him to the Medical Secretary of the SRSAG, Dr Halliday. At the meeting between Professor Crompton and Dr Halliday, there seems to have been a failure of understanding. We are of the view that Dr Halliday failed to respond adequately to the concerns being raised. Dr Halliday should have acted on Professor Crompton's concerns by, for example, taking steps to try to obtain further data to ascertain whether the allegation that Bristol was at the 'bottom of the UK league for quality'³ was a real cause for concern, or by informing the CMO for England of his discussion with Professor Crompton. Several of the reasons advanced by Dr Halliday for not taking Professor Crompton's expressions of concern further were inadequate. In particular, the fact that the meeting with Professor Crompton was not a formal minuted meeting with an agreed agenda, or that Professor Crompton did not set out his concerns in writing to Dr Halliday should not have affected how Dr Halliday responded.⁴ Moreover, it was wrong not to give sufficient weight to Professor Crompton's expressions of concern because of Dr Halliday's view that 'allegations from Wales [were] nothing to do with the supra-regional arrangements in England',⁵ especially since Wales did not have a PCS centre of its own at the time and was dependent on centres in England. Dr Halliday was also in error in discounting what Professor Crompton told him because he (Dr Halliday) assumed:

'that had the CMO [Wales] or anyone else in authority in the Welsh Office believed that there was substance to the allegations Professor Henderson was making they would have reviewed their policy and raised the matter formally with the Department. ... that the Welsh Office was not apparently taking seriously the allegation of one of their medical advisers rather undermined the credibility of such claims.'⁶

³ T21 p. 26 Professor Crompton

⁴ T89 p. 123 Dr Halliday

⁵ T89 p. 141 Dr Halliday

⁶ WIT 0049 0035 Dr Halliday

The Welsh Office did, in fact pursue the matter with a visit to the BRI, but were reassured by the Bristol surgeons' presentation, which attributed their results in the complex procedures to case mix.⁷ We received no independent evidence to support the Bristol surgeons' contention.

- 8** Subsequent concerns about waiting times and outcomes in Wales, which were raised (in June 1987) and taken up by the media, were rejected by the cardiologists and the surgeons in Bristol.⁸ The information available to the surgeons at this time included the mortality rate for open-heart surgery in under-1s in their Unit's 1987 Annual Report. The figure for 1984–1986 was 26.5%, compared with the most recent national data available at that time of 21.8% (UK Cardiac Surgical Register (UKCSR) 1984 data). Given the small numbers of cases in Bristol, and the surgeons' views that there was a higher level of complexity in the cases coming to them, there was no immediate reason in our view for the Bristol Unit to take action, other than to continue to monitor and discuss outcomes. It should be noted, however, that the clinicians' letter of rebuttal to the BBC at the time included a statement that their outcomes were 'at least equal to those achieved by other paediatric units.'⁹ This claim was later acknowledged by Dr Joffe in evidence to be a 'partial overstatement.'¹⁰

The Department of Health and Dr Bolsin

- 9** Dr Bolsin was in contact through his work on audit with Dr Ashwell and Dr Doyle, both Senior Medical Officers at the Department of Health. He approached Dr Ashwell, who responded by advising Dr Bolsin about the formal procedures for dealing with disputes between doctors and by raising the matter with Professor Farndon, who was the Director of the Division of Surgery at the University of Bristol. It is difficult to see what Dr Ashwell she could have been expected to do.
- 10** When Dr Doyle was given data by Dr Bolsin which he was told related to Dr Bolsin's concerns, he did not read it but put it away in a filing cabinet without further scrutiny. In our view this was a seriously inappropriate response. Knowing that the data related to concerns about PCS, Dr Doyle should have examined it. If Dr Doyle had found that he was not able to assess the data himself, he could have sought advice. Dr Doyle was inappropriately reluctant to get engaged in what he saw as a dispute between doctors. In our view, Dr Doyle, by not examining the contents of the envelope given to him by Dr Bolsin, allowed himself to avoid considering whether to urge suspension of the service. It is true that, ordinarily, the DoH sought not to become involved in local clinical issues, taking the view that such matters are best dealt with locally. But this situation was different. Dr Doyle, by not looking at Dr Bolsin's data, simply chose not to have to make a decision. However, Dr Doyle did write to Professor Angelini to seek

⁷ The Inquiry's Experts advised us that the term 'case mix' refers to 'underlying cardiac anomalies of the patients' who are treated, which consequently must be taken account of in any comparison between centres or clinicians. See Annex B (4a), 'Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres during the period 1984 to 1995', September 2000, Dr Spiegelhalter et al. See also Annex A Chapter 19

⁸ See Annex A Chapter 22

⁹ UBHT 0133 0031

¹⁰ T90 p. 103 Dr Joffe

reassurances.¹¹ By opening up a dialogue with the BRI, the DoH did become aware of the concerns in Bristol, which led Dr Doyle subsequently to seek reassurances from Dr Roylance. Dr Doyle's later response to Professor Angelini and his insistence on a review after the Joshua Loveday case were entirely appropriate.

The South West Regional Health Authority

- 11 We heard from Miss Catherine Hawkins, Regional General Manager, SWRHA, of the concerns expressed to her by purchasers about their contracts for cardiac surgical services. She passed on these concerns to Dr Roylance, indicating that the information would be of value to Mr Wisheart.
- 12 These concerns, however, were about the service in general of which PCS services for children over 1 was only a small part (PCS on the under-1s was funded through the SRSAG). This meant that Dr Roylance was able to interpret, or did interpret, them as concerns about the contracting process, not about the quality of care and therefore not indicative of a need for any inquiry into PCS.

The Royal Colleges

- 13 The Inquiry heard no evidence of concerns about the quality of care in PCS in Bristol being raised with the Royal Colleges. Given his position as a consultant in the hospital where junior anaesthetists were raising questions, Professor Prys-Roberts in his capacity as President of the Royal College of Anaesthetists may be considered to have been in a strong position to support junior colleagues. But this additional responsibility also meant that Professor Prys-Roberts was focused on national issues and perhaps distracted from events in Bristol.
- 14 The most direct involvement of the Royal Colleges with the Bristol hospitals was through their assessment of whether a hospital should be designated as suitable to have posts for training. In 1991 the Children's Hospital was refused such designation for a training position in paediatric cardiology because of the disadvantages associated with the split site and service. We heard from Sir Barry Jackson, President of the Royal College of Surgeons of England (RSCE), that there was no means at the time whereby information collected by the Royal Colleges through individual accreditation procedures could be brought together and thus learned from. This position, we were told, has not altered. We also heard from Sir Barry about the distinction drawn between assessing suitability for training and assessing quality of care.¹² Regrettably, therefore, for a number of reasons, the Royal Colleges were

¹¹ The decision of the judicial committee of the Privy Council in the case of *Roylance v GMC AC* (1999) 139 might suggest that, by virtue of his being a doctor, Dr Doyle should have involved himself even more directly, given that the safety of care for children was at issue. We do not hold this view, and if the case of *Roylance* could be said to have decided that a doctor's duty extends that far, we regard the decision as unhelpful. Dr Doyle was a full-time official of the DoH. To suggest that simply by virtue of being a doctor he always owes a duty to any patient about whom he learns would make the performance of his role impossible. We discuss in Section Two possible variations in the registration, and consequently the duties, of a doctor working in a non-clinical setting

¹² T28 p. 6 Sir Barry Jackson

not equipped to respond adequately to any concerns which may have been raised, far less to identify concerns for themselves.¹³

- 15** The Royal Colleges were also involved in giving advice to the SRSAG, both directly through the membership of Sir Terence English, and through the Working Parties which were asked to report to the Group on PCS. The Royal Colleges' contribution was, however, that of advice. They had no power to require that action be taken on their advice. On one view, therefore, there was involvement without responsibility: the liberty to comment without the duty to do anything. The RCSE, for example, through Sir Terence, had developed in the 1970s a new and potentially important system for monitoring outcomes in cardiac surgery in the form of the UKCSR. Unfortunately, it was not possible to resolve the ensuing ambivalence among surgeons about passing these data to the DoH. There was reluctance to make individual unit returns available to the DoH before 1991, but at the same time, there was a presumption that the DoH had access to them. Professor Sir George Alberti, as President of the Royal College of Physicians of London (RCP), spoke of hoping that his College in the future would 'nudge everything up a bit',¹⁴ but that the Colleges had no power to make things happen. The result was most unsatisfactory.

Responses within the UBH/T

Dr Bolsin's actions

- 16** By the late 1980s concerns about outcomes in PCS began to develop within the BRI. They arose initially from Dr Bolsin's observations. These were gradually supported by his collection of data that was shown to some colleagues, but not to Mr Wisheart or Mr Dhasmana. It may be helpful to set out step by step the actions taken by Dr Bolsin.
- In 1988 he approached the issue as a clinical problem through his own division, seeing first the Professor of Anaesthesia, Professor Cedric Prys-Roberts, and then the Chairman of the Division of Anaesthesia, Dr Brian Williams.
 - In 1990, after consulting the Chair of the Medical Audit Committee (MAC),¹⁵ he approached the senior management of UBH and raised the question of the results in PCS in a letter to the Chief Executive-designate, Dr Roylance. He told the Inquiry

¹³ In Chapter 16, in the section of our Report dealing with the adequacy of care, where we refer to monitoring of quality, we make the points that the Royal Colleges: did not include information on the quality of care received by patients in their criteria of assessment of suitability for training; varied in the thoroughness of their visits (Dr Shinebourne's visit to the Children's Hospital can be compared with the two visits from the RCSE. Both visits suggested a less than rigorous attention to the detail of the PCS service at the BRI); did not exchange information between each other, thereby preventing a full picture of the quality of a hospital's care from emerging; did not have any powers other than to grant or deny designation of training posts; and did not assess the ability to train the consultants to whom training posts were designated. All of these add up to a very unsatisfactory state of affairs

¹⁴ T9 p. 4 Professor Sir George Alberti

¹⁵ Dr Trevor Thomas

that, as a consequence, he was rebuffed by both Dr Roylance and Mr Wisheart. Dr Williams confirmed that Mr Wisheart was annoyed by the content of the letter to Dr Roylance.¹⁶

- In 1991 Dr Bolsin raised his concerns in a meeting of cardiac anaesthetists. His colleagues and the Clinical Director, Dr Monk, were supportive of his concerns, though critical of the manner of his approach. In 1991 he referred to matters having been thought to have reached crisis proportion in the preceding year. This was in writing, in the form of minutes of a meeting made available openly to paediatric surgeons and cardiologists.
 - Late in 1991 it seems that his views became known to colleagues in anaesthesia outside the UBHT (in Southampton and in Frenchay Hospital in Bristol).
 - In Spring 1992 Dr Bolsin again approached the management at the BRI, but this time at the level closest to the service, the General Manager of the Directorate of Surgery.
 - In April 1992 he took his concerns outside the hospital and spoke to Dr Phillip Hammond.
 - In 1993 he spoke to surgeons other than those whose work gave rise to the concerns: Professor Farndon, Mr Bryan, and Professor Angelini, to Dr Willatts, the intensivist, and to the cardiologist Professor Vann Jones, head of the new Directorate of Cardiac Services.
 - In late 1993 Dr Bolsin approached the DoH through Dr Ashwell and in July 1994 and January 1995 through Dr Doyle.
- 17** Throughout this period Dr Bolsin's raising of concerns was coupled with his involvement in audit, first within the practice of anaesthesia and intensive care (in relation to intubation and inotropics in 1989), and later with Dr Black, working across the boundaries of specialties, looking also at the work of perfusionists and surgeons.
- 18** Dr Bolsin's role has been lionised by those critical of the PCS service, and attacked by those who support the Bristol surgeons. The path he followed in raising concerns did not follow the route advised by the DoH, known as the 'Three Wise Men' procedure. This is not surprising, however, as this procedure was perceived as dealing primarily with individual clinicians whose performance was affected by problems, such as ill health. Furthermore, his concerns involved the work of Mr Wisheart, who at one time occupied two of the three positions from which the 'Wise Men' were selected, in his roles as Chair of the Hospital Medical Committee (HMC) and Medical Director of the Trust. In addition to the contacts Dr Bolsin made, there was no other obvious route for raising questions about quality of care, other than by discussing results with

colleagues at audit meetings and making comparisons with available national data. In our view, the possibility of such open discussion was barred by the firmly held view of Mr Wisheart, in particular, that the explanation for their poor results in complex procedures lay in the condition of the patients treated rather than the care provided. Mr Bryan described in the BRI:

‘a culture ... of explaining or justifying ... mediocre or poor results on the basis of case severity rather than directing attention to producing better results’.¹⁷

He went on, tellingly:

‘... if you are confronted with a result which is not very good, then there are two responses ... either ... “the results are not very good and they should be better, we must be doing something wrong, we have to get this right and improve things”, or ... “actually the results are not very good but it is because they are bad patients ... and we are doing our best”’.¹⁸

- 19** This avoidance of open discussion was compounded by what we regard as the uneasy relationship between anaesthetists and surgeons,¹⁹ which made it difficult for any anaesthetist to appear critical of a surgeon and particularly of a surgeon such as Mr Wisheart who was a senior figure in the hospital and worked closely with the Chief Executive. The path followed by Dr Bolsin in seeking acknowledgement of, and support in raising, his concerns was, therefore, understandable. His initial, rather oblique, approach to Dr Roylance in his letter of 1990 was rebuffed by both Dr Roylance and Mr Wisheart. Thereafter, he spoke to colleagues within his specialty, moving on to anaesthetic colleagues outside the hospital, to his hospital peer group among the newly appointed consultants in a number of specialties including surgery, and finally to the management of the UBHT and the DoH. The difficulties he encountered reveal both the territorial loyalties and boundaries within the culture of medicine and of the NHS, and also the realities of power and influence. After all, as we have said, his concerns related to one of the most senior and long-serving surgeons in the BRI, Mr Wisheart, and had to be addressed by Dr Roylance, who was a long-standing colleague of Mr Wisheart. The manner of Dr Bolsin’s approach was criticised by his colleagues, and he seems to have antagonised both senior management and senior medical figures at an early stage. Thereafter, he felt that he had to take a more circuitous route to arouse awareness of what was troubling him. It is also clear that he was not alone in having difficulty in approaching the senior figures, Dr Roylance and Mr Wisheart. For example, Mr Bryan described Professor Angelini’s telling him that when he (Professor Angelini) and Professor Farndon tried to raise concerns with Mr Wisheart in December 1993, the latter spoke to them ‘like a couple of schoolboys’.²⁰

¹⁷ T63 p. 33 Mr Bryan

¹⁸ T63 p. 39 Mr Bryan

¹⁹ Dr Bolsin, for example, said: ‘... there is a particular rivalry between surgery and anaesthesia because probably they work so closely together. Surgeons do not like to be told what to do by anaesthetists and anaesthetists do not like to be told what to do by surgeons and it is legendary and it exists.’ T82 p. 132

²⁰ T63 p. 66 Mr Bryan

- 20** It is worth noting here that the Public Interest Disclosure Act, passed in 1998 to give protection to ‘whistleblowers’, would not have protected Dr Bolsin, had it been in force, if he had sought to make his views known publicly. This is because the Act, as currently drafted, would only have protected Dr Bolsin if, in good faith, he had made a ‘qualifying disclosure’ to his employer, or his legal adviser or the Minister of State or a prescribed official. The disclosure which Dr Bolsin made would not have qualified in this way.²¹
- 21** Collecting and validating data is not a simple task (Mr Bryan told us that retrospective clinical data is very difficult to collect²²). Definitions varied depending on whether classification by diagnosis or procedure was used, records were incomplete or the numbers of procedures were small, and to achieve any sophistication in statistical analysis required that categories be collapsed to a point at which the validity of the clinical information could be challenged or even compromised. Risk stratification²³ in PCS is still problematic today. That said, Dr Bolsin’s data was broadly accurate. He made a significant error in the misclassification of four VSD deaths, an error he later accepted. The Inquiry is mindful of the fact that Dr Bolsin was not preparing data for publication, but to raise questions for discussion and review. Professor de Leval told us that if queries of this kind had arisen at Great Ormond Street Hospital, he would not so much have relied on particular figures but would have initiated an open discussion.²⁴ It is one of the greatest matters of regret that, for a number of complex and interlocking reasons, such discussion did not take place at the BRI.
- 22** Dr Bolsin was advised and encouraged by a number of colleagues to share the information which he collected with Mr Wisheart and Mr Dhasmana, and to be open about collecting information about clinical work outside his specialty of anaesthesia. We accept his difficulty about approaching Mr Wisheart, a senior figure of whom he was in some awe, and perhaps even in fear. It is less clear why he did not approach Mr Dhasmana, who was willing to acknowledge and seek to correct his imperfections. We are aware that traditionally anaesthetists see themselves as providing a service and working across disciplines and are thus comfortable with looking at the work of others. But this view was not shared by surgeons. At this time cross-disciplinary audit was not common. Mr Dhasmana could have regarded an approach from Dr Bolsin as acceptable, in which case things might have been different. It is unfortunate that Dr Bolsin did not approach him.
- 23** In summary, while Dr Bolsin’s actions may not always have been the wisest, and sometimes he gave mixed signals, such as his assurance to Dr Ashwell that all was well,²⁵ he persisted and he was right to do so.

²¹ It is for this reason we propose, in Section Two, that the Act be amended

²² T63 p. 56 Mr Bryan

²³ The Inquiry’s Experts advised that ‘risk stratification’ can refer to two distinct types of risk: that arising from case mix and that arising from the operation itself in the light of the patient’s ‘age, previous medical history and current clinical condition at the time of operation’. See Annex B (4a), ‘*Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres during the period 1984 to 1995*’, September 2000, Dr Spiegelhalter et al. See also Annex A Chapter 19

²⁴ T60 p. 43 Professor de Leval

The context

- 24** How do we view the action or inaction of those whom he approached? At no stage, and to us this is important, was he told that he was wrong or mistaken in seeking to gather information. Rather, he was told that he should take great care to verify his information, and that he should seek to discuss it openly with colleagues, including those whose work gave rise to his concern. From senior colleagues, he received assurances that the matter would be raised with Dr Roylance or Mr Wisheart, but none of the attempts to do so succeeded in achieving the open discussion or action desired. Perhaps Professor Farndon came closest after his meeting with Mr Wisheart in November 1994, after which he told us that Mr Wisheart accepted that the results were not good, and agreed that all five cardiac surgeons (i.e. including those who operated only on adults) should tabulate their results and discuss them with the cardiologists and anaesthetists. Professor Farndon offered to chair such a meeting, as 'honest broker',²⁶ but was never approached to do so. The events surrounding Joshua Loveday's operation brought matters to a head shortly afterwards.
- 25** A number of questions arise at this point: Was this apparent failure to respond to Dr Bolsin's concerns the full story, or was action on the PCS service being taken through other routes as part of wider plans for development at the UBHT? Was there a wider context in which the concerns raised by Dr Bolsin need to be understood?
- 26** In one sense, the senior clinicians and management of the UBH/T had fundamentally resolved, in their own minds at least, by the early 1980s how to deal with the issues relating to the split site and consequent split service. The aims were to unify, so far as possible, the care of children on one site and, as regards PCS, to recruit a surgeon specialising in PCS (and presumably build up the team associated with PCS accordingly). This is so, notwithstanding the fact that when the UBHT came into being in 1991 formal proposals to implement these aims were not initially put to the Trust Board.
- 27** These twin aims remained the long-term objective with regard to the PCS service. Despite the rapid and extremely complex changes of the late 1980s and early 1990s, the management in Bristol eventually realised their objective. It took about 14 years. In terms of comparable developments (for instance, the agreement to plan and construct a major hospital) this is by no means a long time. Furthermore, all the elements of the plan were agreed and in place before 'the story' of the PCS service in Bristol broke in the national press in 1995; that is to say, the plans were not a response to concerns expressed. They were in response to a recognition that change was needed: a recognition that the problem was identified and a solution settled upon if not formally agreed, which, in time, would come about. But therein lay a danger. Because change had been agreed upon and was on the way, at least in the minds of

²⁵ UBHT 0061 0270; letter dated 10 February 1994

²⁶ T69 p. 193 Professor Farndon

senior clinicians and managers, the danger existed that the expression of concerns would be interpreted merely as complaints that matters were less than ideal, rather than that they were unacceptably poor. Those raising concerns were of the latter view. The more senior of those with whom the concerns were raised took the former view.

28 Thus, there was a mindset *among senior managers* that:

- the solution to the care of children, including the PCS service, had been identified and was in train, albeit that things moved slowly in the NHS;
- meanwhile, everyone had to manage within the constraints of limited resources, as was typical in the NHS (and remains so today);
- the clinicians, led by Mr Wisheart, could be trusted to get on with things. Mr Wisheart would let other members of senior management know if there were problems; and
- the PCS service was, in any event, a small part of the UBH/T's overall activity and was not a prominent item in the managerial range of concerns. Professor Vann Jones said in his evidence: 'I think the total has been calculated; the whole GMC Inquiry was based on 4 per cent of the paediatric workload, and not only that, but these surgeons were also doing a lot of adult work as well.'²⁷

29 At the same time, there was a mindset among those *long-serving clinicians* who had been at the BCH/BRI for some years that:

- a long-term solution to the PCS service was ultimately going to be achieved. As early as 1981 Dr Joffe and Dr Jordan had advocated 'the eventual performance of open-heart surgery in children at the BCH' in their joint paper '*The development of Paediatric Cardiology in Bristol*'.²⁸ Mr Wisheart stated that, around 1990–1991, detailed plans were drawn up to transfer open-heart PCS to the BRHSC. But the Trust's proposal to build a new children's hospital took priority and again set back plans to effect the move;²⁹
- in the interim, they would seek to do their best and gradually develop their expertise;
- as part of a teaching hospital, they should aspire to be at, and be seen to be at, the leading edge of developments. This was a form of professional hubris. No question could arise of withdrawing from any activity. It was a matter of 'onward and upward'. Designation as a supra regional service (SRS) was a feather in Bristol's cap. (Indeed, Dr Joffe's stated goal in 1990 was that the BRI should become a

²⁷ T59 p. 108 Professor Vann Jones

²⁸ WIT 0097 0203 Dr Joffe

²⁹ WIT 0120 0106 Mr Wisheart

designated centre for heart transplants ‘within a year or two’,³⁰ a view that Mr Wisheart endorsed);³¹

- they were actively collecting and discussing data. They were quick, however, to deny any adverse inferences drawn from the data, by resort to plausible justifications such as case mix. To some, this could be seen as wilful blindness; to others, a justifiable reaction in the context of difficult procedures with low numbers performed under less than ideal circumstances; and
- the younger consultants in anaesthetics and cardiology (taking up positions in a provincial hospital after training in major international centres) did not always behave in an ‘appropriate’ manner, meaning that they were less deferential and more questioning of existing practice than was expected by the ‘old guard’.

30 Among the *younger clinicians* there was a mindset that:

- the older, established consultants had been left behind by recent developments, were slow and reluctant to change and were in something of a backwater;
- there was a degree of resentment and defensiveness among the older consultants if practices were challenged;
- the senior management was close to the ‘old guard’ and supported them. There was a sense of a club, to which one belonged or from which one was excluded. This meant, for instance, that it was difficult to raise what were considered to be legitimate concerns. The style of management had a punitive element to it; and
- there was no properly effective system for dealing with concerns: everything depended on people rather than systems. Also, the environment was not such as to make ‘speaking out’ or ‘openness’ safe or acceptable.

31 Mr Dhasmana does not fit readily into any of these camps. He was deferential to Mr Wisheart. He saw himself as a progressive, modernising surgeon. His surgical skill, except in performing the neonatal Switch operation, was commended by Professor de Leval in the first of the two drafts of the Hunter/de Leval Report.³² The subsequent statistical analysis carried out for the Inquiry, however, concluded that there was ‘no evidence to suggest that there was any marked difference in the mortality rates of the two surgeons for similar operations.’³³ He was disengaged from management, even of his own surgical team, despite having had to be a manager. He was, however, self-critical and aware of his shortcomings. He showed himself ready to seek training, and to withdraw from a procedure. The Inquiry takes the view that he was wrong not to inform the parents of Joshua Loveday about the clinical meeting that preceded the

³⁰ WIT 0097 0025 Dr Joffe

³¹ Mr Wisheart T94 p. 120

³² UBHT 0052 0263

³³ INQ 0012 0033 Professor Stephen Evans; and Chapter 19

operation and seek their views as to whether they wished the surgery to proceed in the light of the meeting. He was, in short, wholly caught up with his surgery. He should have displayed a wider vision and told Joshua's parents about the meeting. This is the particular criticism we make of Mr Dhasmana. However, we acknowledge and appreciate the regret expressed by Mr Dhasmana when he gave evidence to the Inquiry.

- 32 This is the context within which we can consider the actions taken in the hospital and the Trust in response to concerns raised. We concentrate first on the management of the UBH/T.

Dr Roylance

- 33 We reached the following views as regards the actions of Dr Roylance:

- Dr Roylance did not act upon Dr Bolsin's observation in the letter of July 1990. It is doubtful, however, whether the message Dr Bolsin claimed that he intended to signify in his letter was sufficiently clear and strong to prompt Dr Roylance to take the matter further.
- Dr Roylance relied on Mr Wisheart, whether in his role as Medical Director, Clinical Director, or the senior cardiac surgeon, to advise him when the PCS service surfaced as an issue. On one view, this could be said to be appropriate. It could also be said, by contrast, that Mr Wisheart's advice was inevitably tainted by personal involvement, such that Dr Roylance should, as a manager, have obtained a second opinion. Dr Roylance did not agree to a review of the PCS service until December 1994. On any view of the evidence, this was excessively late. Furthermore, it was not appropriate in the circumstances to ask Mr Wisheart to organise the review.
- Dr Roylance's style of management was to insist on a clear demarcation between clinical and managerial issues (notwithstanding the fact that the distinction cannot be sustained).³⁴ It would be in keeping with this style that clinicians might be reluctant to approach him about matters of concern to them, and that he, for his part, would make it clear that he did not wish to hear or get involved in them. Concerns were raised with Dr Roylance in exchanges with Dr Bolsin, Professor Prys-Roberts, Professor Angelini and Dr Monk (although Dr Roylance does not accept this). He failed to respond to them. This managerial approach could be categorised as wilful blindness, but this is the judgment of hindsight. If, by seeming to insist that clinicians solved problems for themselves, he empowered doctors to get on with looking after patients, it was clearly reasonable. Moreover, it was entirely within the spirit of the reforms proposed by the Griffiths Report.³⁵ But the Inquiry regrets that Dr Roylance lacked sufficient awareness of the potential

³⁴ In an exchange with the Chairman, Dr Roylance said: 'I was in the habit ... of telling people whether they were talking to John Roylance, whether they were talking to Dr John Roylance, or whether they were talking to the Chief Executive.'; T89 p. 37 Dr Roylance

³⁵ See Annex A Chapter 2

problems associated with this style of management, particularly with regard to the barriers it created to effective communication. In particular, the organisational structure created in the UBH/T, while providing for communication *within* a particular unit or directorate, was not at all suited to allow communication *across* units and directorates. This made it difficult to envision or carry out any overall strategy. Furthermore, Dr Roylance failed to appreciate that if clinicians were to be involved in management, there was a significant need for training and support for them.

- This management style, plus Dr Roylance's preparedness to rely on Mr Wisheart, meant that he refused to engage with Dr Monk and read the anaesthetists' letter in the summer of 1994 when Dr Monk showed it to him and tried to get him to read it. This could be said to be an over-rigid adherence to non-involvement in clinical matters. Any notion that his involvement would undermine the doctors' sense of empowerment could be discounted, since it was they who were asking him to get involved. This incident speaks of an inappropriate degree of rigidity. A good manager should retain the flexibility to contemplate varying his approach to management, particularly when the safety of patients is, or is said to be, at stake.
- Dr Roylance's decision not to become involved in what he saw as a matter for the clinicians to decide, namely whether to proceed with the operation on Joshua Loveday, conforms with his style of management. He was, as a manager, anxious to see that a system was in place whereby the clinicians could reach an informed view. However, while his approach is consistent with his style of management, it also illustrates the rigidity of Dr Roylance's thinking.
- When approached by Dr Doyle in late 1994, Dr Roylance did not share the relevant correspondence promptly or fully with the Trust Board or the Chairman, Mr McKinlay. He was, however, misled by Mr Wisheart's memo of 4 September 1994,³⁶ which unjustifiably described the problems referred to by Dr Doyle as relating to one procedure only, the rest of the work being said to be acceptable or better. That said, Dr Roylance also misled the DoH by implying in his letter to Dr Doyle that the Trust Board were aware of the problem when they were not.
- Once it was known that Joshua Loveday, sadly, had died, Dr Roylance instigated the independent review of the PCS service. Albeit belated, this was an appropriate response. It was not appropriate, however, to assign the organisation of the review to Mr Wisheart, given his central involvement in the PCS service and the need for the review to be seen to be independent.
- Dr Roylance secured the appointment of Mr Pawade and the move of PCS to the Children's Hospital (together with the start of the construction of a new Children's Hospital). By these achievements, he could be said to have resolved the long-running problems of the split site and service. That it took many years is to be

³⁶ UBHT 0061 0276

regretted but cannot be a ground for criticism of Dr Roylance. What is of concern is the management and conduct of the PCS service in the years between the decision and its fulfilment.

- 34** We conclude that Dr Roylance's behaviour was characterised initially by inaction. He relied too heavily on Mr Wisheart and was persuaded that action was not required. In the context of the care and safety of children, Dr Roylance, as the senior manager, had two options: he could insist that he would only do something if his close colleague Mr Wisheart could be proved wrong; or he could agree to look into the matter more thoroughly. The weight of the evidence and argument is that he should have done the latter. Thus, his inaction was not appropriate. He lacked awareness of and insight into the potentially negative effect his 'silo' style of management had on lines of communication between directorates within the hospital; he also was unaware of the potentially negative effects of the concentration of power and influence in the hands of a small elite group within the hospital. To this extent he can properly be criticised. We stress that we make these criticisms of Dr Roylance in his role as a manager.
- 35** We are aware that Dr Roylance was also a doctor. We do not, however, regard this fact alone as warranting an assumption of responsibility for the care of every child (or children generally) admitted to the UBH/T. There must be circumstances (and becoming involved in senior management to the exclusion of clinical practice must be one), in which someone who is a registered medical practitioner can put aside his duty to any particular patient (because he has none) and take up his managerial duty on behalf of all patients under his responsibility. We are aware that Dr Roylance continued to maintain a clinical session and that this complicates matters. But we hold generally to our view. To this extent, it follows that we do not agree with the decision of the Privy Council in *Roylance v GMC*,³⁷ to the extent that it decides otherwise.

Mr Wisheart as Medical and Clinical Director

- 36** We reached the following views as regards the actions of Mr Wisheart:
- Mr Wisheart could be said to have been too close to the issues to act objectively as a manager and director, since he was the senior surgeon in the area and an important focus of the concerns. He would have had great difficulty separating the personal from the professional. It is no surprise that his response was denial and inaction. He lacked the insight to understand or admit the inherent conflict of interests in which he found himself. Otherwise, he would have advised Dr Roylance to seek advice from as wide a spectrum of opinion as possible, both within the hospital and beyond.
 - Given that Mr Wisheart knew that the solution to the problem of the PCS service (consolidating all aspects of care at the BRHSC and appointing a new paediatric

cardiac surgeon) had been agreed in principle for some time, he chose as a surgeon to believe that things would gradually get better, as regards increasing the numbers of patients treated and generally improving outcomes. He also persuaded himself that plausible justifications existed to explain the poor results obtained at Bristol. Indeed, he would not admit that the results generally, or his own in particular, were poor until, very late in the day, he accepted as much as regards his operations to correct Atrio-Ventricular Septal Defect. He adopted an approach based on optimism rather than reality, but this is a judgment of hindsight. At the time, there was enough room for doubt for him to persuade himself that things would improve, whatever others might think.

- Mr Wisheart's management style was perceived by some of those around him as autocratic. He was part of the 'club culture' which fostered a sense of 'them and us'. The consequence was that Mr Wisheart was not likely to be approached by colleagues, especially 'junior' colleagues who might have concerns. Nor would he pay great attention to what he would regard as unsubstantiated rumour, or to what he might have felt was insubordination in the case of Mrs Ferris, when she questioned him about his figures on PCS.³⁸ Again, this was a regrettable barrier to the sort of open communication which should characterise the management of a unit or directorate in a large hospital.
- As a manager, he was far too busy with far too many responsibilities. Although Mr Wisheart claimed that he was able to carry out all his many responsibilities without difficulty, we take the view that this suggests a lack of insight. It may also have reflected a regrettable lack of willingness to relinquish authority and power. In particular, communication, continuity of care and leadership are crucial to the successful organisation and delivery of the post-operative intensive care of PCS patients. But, there was a failure to achieve this, due in large part to the system whereby Mr Wisheart retained overall control of the care of children in intensive care, while undertaking his surgical and other responsibilities.
- As a manager, Mr Wisheart did not show leadership in creating teamwork or co-operation. His style of leadership was ill-suited for such an essentially co-operative activity as PCS.
- As a manager, he misled the Trust Board as to the results achieved in paediatric cardiac work, in particular in the report of 8 April 1994.³⁹ This was wrong and warrants strong criticism.
- As a manager and colleague, he failed to tell the extraordinary meeting called to discuss the care of Joshua Loveday that Dr Roylance had in mind to commission an independent review of the PCS service, which we conclude Dr Roylance had discussed with Mr Wisheart. We recognise that Mr Wisheart's reason for not doing so was to avoid putting greater strain on Mr Dhasmana. We regard this as wrong-

³⁸ T87 p. 183 Mrs Ferris

³⁹ UBHT 0020 0015

headed. When the question of whether to proceed or not was in the balance, we have little doubt that if the meeting had learned of the proposed review, the clinicians would have decided not to proceed with surgery but to make other arrangements. Mr Dhasmana told us as much in his evidence,⁴⁰ although this is the judgment of hindsight. Whatever his motive, Mr Wisheart's failure to tell the meeting was a serious error of judgment.

- 37** Mr Wisheart's actions *as a manager* were characterised by seeking to reassure Dr Roylance and the Trust about the PCS service on the one hand, while, on the other hand rejecting or denying concerns brought to him by others. By adopting this approach, he inhibited any proper examination of the PCS service from taking place. During the discussion of Joshua Loveday's treatment, his actions as a manager were characterised by ambivalence. He recognised the level of concern being expressed, but he, Dr Joffe and other, senior, long-serving clinicians were excessively defensive of the performance of the PCS service. It may be that this defensiveness was reflected in deciding, collectively, to support the plan to proceed with the operation rather than acknowledging that the team, and the surgeon at the centre of it (Mr Dhasmana), might not be the best team to perform the surgery. Mr Wisheart's preparedness, albeit reluctant, to let the operation go ahead showed a lack of appreciation of the effect that the surrounding stress could have on Mr Dhasmana and the rest of the team. His failure to advise Dr Roylance to seek to stop the operation was inappropriate.
- 38** Mr Wisheart's actions, as a manager, after the tragic death of Joshua Loveday, were characterised by a degree of denial and self-justification (which remained his approach when giving evidence to the Inquiry in December 1999). This added to the poisoned atmosphere at the BRI and was inappropriate.

Mr Wisheart as a clinician

- 39** We emphasise that we are not concerned here with the technical skills of a surgeon in the operating theatre. To the extent that we are commenting on Mr Wisheart as a doctor, we are referring to his inability to reflect on his practice.
- 40** We conclude that, *as a clinician*, Mr Wisheart's failure to act in response to the outcomes he was achieving would be justified by him on the basis that he made his data available for scrutiny, as did Mr Dhasmana, and that the results were explicable in terms other than poor performance. He believed further that the outcomes would improve as experience improved. Also, he recognised that he should withdraw from PCS as soon as a replacement could be appointed. That said, we take the view that he should have recognised his own lack of objectivity and instituted some check on PCS, whether by colleagues within Bristol or from outside. Further, as a senior consultant he should have recognised the need for, and provided, better clinical leadership, communication and teamwork, particularly in the management of the Intensive Care Unit. In not doing so, he failed to act appropriately and promptly. This failure led to the creation of a number of the conditions giving rise to poor outcomes in PCS.

- 41 On all of these grounds, in his conduct as a manager and a clinician, we are critical of Mr Wisheart.

Mrs Maisey

- 42 We were struck by the evidence we received about Mrs Maisey. She was clearly a very influential figure in the UBH/T, in effect Dr Roylance's adjutant, 'his eyes and ears',⁴¹ as it was put to us. She was very much part of the management culture of the UBH/T, a culture which we have described as one of fear. We heard that she described herself as 'the Rottweiler of the Trust'.⁴² We were told the general managers feared her.⁴³ Others, particularly nurses on the ward, did not see her as a person to turn to despite the fact that she was the Trust's Nurse Adviser.⁴⁴ She gave too great a priority to her responsibilities as Director of Operations. Her ability to carry out her role as Nurse Adviser, so as to provide leadership and support for the nursing staff was thereby significantly and damagingly diminished.
- 43 We conclude that the nursing staff were let down by Mrs Maisey. As Nurse Adviser to the UBH/T, she should have provided them with support and leadership at Board level and ensured that any concerns that they had were taken seriously. Mrs Maisey failed in her duty to provide this essential leadership. Indeed, her whole approach to management was characterised by seeing herself, and being seen as, a member of 'the club', rather than someone charged with nurturing and representing the interests of nursing.

Clinicians as managers

- 44 We interrupt our commentary at this point because our observations concerning Mr Wisheart go beyond Mr Wisheart to all those who found themselves as clinicians in positions of management. While, as we have said, the Griffiths Report called for the involvement of clinicians in management, to which Dr Roylance responded positively, no thought or attention seem to have been given to the fact that management requires particular skills and training. Merely being a senior clinician does not mean that the clinician has these skills. They must be acquired and clinicians must be given the time and opportunity to acquire them. It is clear that a number of the Inquiry's observations about the way in which concerns raised about the PCS service were handled at the BRI have arisen out of decisions taken by clinicians on the borderline between managerial and clinical loyalties and practice. For example, Mr Wisheart, *as a clinician*, may have thought it inappropriate to intervene in Mr Dhasmana's decision to operate on Joshua Loveday because of a long-standing tradition that one consultant does not interfere in the clinical judgment of another. But, *as Mr Dhasmana's Medical Director*, he had a duty to do so. Mr Dhasmana, *as a clinician*, decided to operate but, *as the manager of the surgical team*, Mr Dhasmana had a responsibility to consider the impact which the calling of an extraordinary

⁴¹ T30 p. 38 Mr Durie

⁴² T27 p. 83 Mrs Ferris

⁴³ T27 p. 81 Mrs Ferris

⁴⁴ T32 p. 29 Julia Thomas

meeting to discuss Joshua's operation would have on the team and to reconsider the decision. All the tasks to be performed in any hospital should be carried out by those who have both the necessary skills and resources, with clear lines of accountability to ensure that a good job is done. This should be self-evident. Clinicians at the UBH/T, at the time in question, were being asked to undertake managerial responsibility for which they were untrained, unprepared, and under-resourced. To choose one example, it was instructive to hear Mr Baird describe how his duties as Clinical Director of Surgery occupied 'five or ten minutes'⁴⁵ of his time twice a day. This may be understandable, given the other range of duties he had, but it is not a recipe for good management.

- 45** In the future, if, as we argue in Section Two, *all* who work for the NHS are collectively categorised and come to see themselves as healthcare professionals (albeit with differing responsibilities), the dividing line between the managerial and the clinical may be less clear cut. All managers will be seen as caring for patients. All clinicians will be seen to be carrying out managerial tasks, even if only within their own clinical teams. To do this effectively, clinicians will need to be supported by training and resources, and especially an adequate allocation of time.

Action by the Chair of the Trust Board

- 46** Mr Geoffrey Mortimer, the Chair of the Bristol and Weston District Health Authority who had not been enthusiastic about the application for trust status, resigned in September 1990. He had been sent a copy of Dr Bolsin's 1990 letter to Dr Roylance concerning what Dr Bolsin saw as an inaccuracy in the application for trust status. We have no evidence of any response.
- 47** In April 1991 Mr Peter Durie became the first Chair of the UBHT. In late 1991 Mr Martin Elliott, Consultant Cardiothoracic Surgeon, Great Ormond Street Hospital, was invited to apply for the Chair of Cardiac Surgery at the University of Bristol. He visited Bristol on a number of occasions to discuss the position and to acquaint himself with the facilities. On one of these visits Mr Elliott met Mr Durie. Their discussion included the problem of the split site, the solution of which was 'a fundamental requirement'⁴⁶ for Mr Elliott if he was to apply for the Chair. However, Mr Durie's suggestions (particularly that the person appointed to the Chair would have to generate income to resolve the problem) were regarded as 'totally unacceptable'⁴⁷ by Mr Elliott. He declined the invitation to apply, writing to Mr Wisheart subsequently with an explanation.⁴⁸
- 48** The Inquiry found no evidence of any response before 1994 from the non-executive members of the Board or the Chair of the Board to any raising of concerns about the PCS service. They relied heavily on the Chief Executive for advice, who in turn relied upon Mr Wisheart.

⁴⁵ T 29 p. 62 Mr Baird

⁴⁶ WIT 0467 0007 Mr Elliott

⁴⁷ WIT 0467 0007 Mr Elliott

⁴⁸ JDW 0003 0102

49 In May 1994 Mr Durie asked Professor Angelini to write him a letter setting out the situation, after a meeting at which the poor results in PCS, and the need to appoint a dedicated paediatric surgeon, were discussed. Mr Durie was to leave office at the end of that month. The confusion over Mr Durie's failure to ensure that a system was in place to record that the letter had been received from Professor Angelini following the meeting, so that any necessary action could be considered, indicates the need for there to be a foolproof system to cover periods of time when responsibility is handed over and there is some hiatus before the successor assumes office, so as to ensure that there is continuity in dealing with correspondence. His successor, Mr McKinlay, took up office in July 1994, and was a more active Chair of the Trust Board. Having been approached by Professor Angelini and Professor Farndon in September 1994, he saw them about the need for a second paediatric cardiac surgeon and their concerns about the poor results in PCS. At some point during the 1994 Christmas period he discussed with Dr Roylance the need for an external review of the service. Subsequently, the Hunter/de Leval review was commissioned. Their report was accepted by the Board in March 1995, after revision, it was said, to make it more suitable for a wider audience, and a protocol for action was promptly agreed. In all these respects Mr McKinlay's actions were appropriate.

Other clinical staff

The anaesthetists and intensivists

- 50** In addition to the long-standing efforts of Dr Bolsin, which we have referred to already, the other anaesthetists discussed and shared his concerns. A number of attempts were made to bring those concerns to the attention of Dr Roylance and Mr Wisheart by the anaesthetists' Clinical Director, Dr Monk, who acted with care and forethought. He spoke to the surgeons concerned, Mr Wisheart and Mr Dhasmana, in the autumn of 1993 (albeit that he did not show them any data), to the Chair of the Division of Surgery, Professor Farndon, in 1993, and in March 1994 saw Professor Angelini and Dr Roylance. With Professor Angelini, he invited Mr Wisheart and Dr Bolsin to an informal dinner at Bistro 21, intending to facilitate an informal and open discussion of the PCS results. Sadly, the dinner represents in microcosm the inability of these colleagues to communicate on the questions at issue, and the conversation turned to football. Dr Monk's handling of the anaesthetists' joint letter, his asking junior staff to collect data for discussion, and his determined attempt to involve Dr Roylance, by redefining the issue as managerial rather than clinical, was a well-thought-out attempt to get a response, which Dr Roylance failed to provide. It is difficult to see what more Dr Monk could have achieved within the existing power structure and management culture.
- 51** Dr Pryn had put together some figures at short notice to present to the special meeting of cardiologists, surgeons and anaesthetists in January 1994. But, through no fault of his own, he was not sufficiently prepared to make a formal presentation. Mr Wisheart presented his own data and Dr Pryn's figures were rejected.⁴⁹ As a result of his own concerns about the organisation of the Intensive Care Unit (ICU), Dr Pryn had tried to

⁴⁹ T72 p. 147–8 Dr Pryn

get 'single form' recording in the ICU, in order to improve the co-ordination of care. Unfortunately, he had to abandon the attempt when clinical colleagues did not co-operate. Dr Pryn, supported by Dr Masey, was also asked to prepare data for the meeting to discuss the operation on Joshua Loveday. It is difficult to see what more Dr Pryn could have done.

The surgeons

- 52** Professor Angelini took action on his own initiative to remedy the problem of the lack of a resident anaesthetist to be on call for the ICU. He succeeded in securing an appointment within a month of his arrival in 1992. He approached Dr Roylance and Dr Martin about the concerns expressed to him by Dr Bolsin, which he came to share, and went to Great Ormond Street Hospital to seek expert advice from Mr Stark who worked there as a Consultant Cardiothoracic Surgeon. Finally, he corresponded with Dr Doyle at the DoH, and was instrumental in bringing the DoH's awareness of the concerns to the attention of Dr Roylance. It is unfortunate that he did not feel able to discuss Dr Bolsin's concerns when he went to dinner with Mr Wisheart at Bistro 21, but, as has been said, this was not so much a failure to act properly as a symbol of how difficult communication had become by then.
- 53** Professor Farndon, by 1994, offered to act as honest broker, saw Mr Wisheart, but, despite his efforts, could not take things forward.
- 54** Mr Wisheart, throughout the period, in his role as a clinician, kept records, encouraged audit meetings, and presented data. In response to queries, he continually repeated his arguments that poor results were due to the particular condition of the patients he treated. The Clinical Case Note Review carried out by the Inquiry as a retrospective exercise in 1999, did not, in fact, reveal major problems in surgical technique, but rather with the overall organisation of care, particularly in the ICU. But we take the view that Mr Wisheart should have realised that the poor results that were being discussed could have their origin in the overall organisation of care, particularly in the ICU. We do not have evidence of a prompt or effective response to the concerns identified to him by individuals (by Mr Elliott in 1991, and by colleagues at the BRI, for example, Professor Angelini and Professor Farndon, in December 1993, Ms Maher in April 1994, Dr Monk and Professor Farndon, again, in November 1994, and Dr Monk in 1993 and 1994). We do have evidence (for example, from Dr Bolsin, Mr Bryan and Mrs Ferris) that Mr Wisheart was not an easy man with whom to raise concerns, particularly about his own work.
- 55** Mr Dhasmana, by contrast, was acutely aware of the difficulties he was encountering with the neonatal Switch. He made efforts to undergo retraining for himself and his team (although the cardiologists did not go with him to Birmingham when invited) and he stopped operating when his results failed to improve. He took part in collecting and presenting data and was open to discussion. Indeed, on occasions, he

was strongly self-critical. But he could not see the impact of stress on himself or the surgical team before Joshua Loveday's operation. This was a product of his over-concentration on his responsibilities as surgeon and a less than complete awareness of the importance of the whole team.

- 56** By way of conclusion, we take the view that the other surgeons either felt dominated by Mr Wisheart, or were unable to find a way around his insistence that matters were under control.

The paediatric cardiologists

- 57** The Inquiry heard no evidence of action taken by the cardiologists in response to the concerns about the PCS service after their rebuttal of the questions raised in Wales. We heard evidence instead about their isolation from the surgery being undertaken at the BRI, the impact of the split site on cardiological input in both the operating theatre and the ICU, and their heavy programme of work both in Bristol and in a number of outlying and distant clinics. Their workload was further exacerbated by the fact that the refusal of accreditation for training posts meant that they had no junior doctors in training who could support them. They might have been expected to have picked up any concerns about referral to the BRI, but we have no evidence that such concerns were expressed to them.⁵⁰ They took part in audit meetings with their surgical colleagues, and in the 'paediatric club', but found no reason to question the data or comments on it made by their surgical colleagues. They regularly pressed for a long-term solution to the problems posed by the split site by suggesting that care be united on a single site. In all of these respects, therefore, we make no adverse comment on the conduct of the cardiologists, even though we recognise that Dr Joffe's ambitions for the cardiac unit at the UBH/T were somewhat out of line with the reality of the actual situation.

- 58** We do, however, make one adverse comment as regards Dr Joffe. We find it regrettable that, in his position as a manager, namely the Director of Children's Services from 1990 to 1994, he failed to enquire more diligently into the quality of care received by the children undergoing open-heart surgery at the BRI, when concerns began to be raised more widely in 1994.

Nurses

- 59** We regard it as significant that we did not hear concerns being brought to senior figures at the UBH/T by the nursing staff. We do not infer from this any lack of concern on the part of nurses. Rather, we see it as illustrating a larger truth. The hierarchical system common at the time (and regrettably still too prevalent now) made it difficult for the nursing staff to voice concerns and to be heard. It is revealing that only when independent experts from outside the UBHT, Professor de Leval and Dr Hunter, came to carry out their Review, did Fiona Thomas feel able to express her concerns about the lack of proper organisation in the ICU. It is also indicative of the state of affairs that the only way which Kay Armstrong and Mona Herborn felt was open to them to make

⁵⁰ T79 p. 141–2 Dr Jordan

known their dissatisfaction with aspects of PCS was to withdraw their services from the operating theatre when a Switch operation was to be performed.⁵¹ Nursing staff were let down by a culture that excluded them.

Concluding observations

- 60** Concerns were expressed and data were collected and discussed, though not all data were discussed by all those involved. Indeed, it could be said that Bristol was awash with data but was, at the same time, singularly uninformed. Procedures existed for review, although there was no agreement as to what was meant, or even what was being referred to, as ‘high-quality care’, nor where the responsibility lay for ensuring that it was provided. At the time covered by our Terms of Reference, surgeons were powerful, and cardiac surgeons associated with, and part of, senior management particularly so. ‘Management’ stayed out of what were defined as ‘clinical matters’. There was no clear focus of responsibility for the care of patients. Audit was still an educational tool rather than a means of assessing and assuring quality. A central misfortune was that a key figure in the centre of the web, Mr Wisheart, was a man who worked hard and long for PCS, but was not able to reflect effectively or critically on his work. As Mr Baird said, when asked how the system dealt then with the competence of a consultant, ‘the difficult area arises where the individuals lack insight’.⁵²
- 61** In Bristol too few people had too much power. Unhappily, if the people have flaws, the organisation becomes vulnerable. An organisation offering a service must, of course, have dedicated staff. But that is not enough. It must also have in place within it systems that allow it to learn, develop and prosper, quite apart from any external mechanisms. A key feature of such systems is that all involved must feel able to be open about their work and the work of colleagues. This is a central message which emerges from Bristol. This is what we must take into Section Two of our Report in due course.

⁵¹ Ms Armstrong, for example, said she ‘dreaded’ the scheduling of complex cardiac surgery (T59 p. 37) and ‘could no longer bring myself to go and scrub for those cases’ (T59 p. 40)

⁵² T29 p. 41 Mr Baird

Adequacy of Care

Chapter 13: Introduction to Adequacy of Care

- 1 We are required by our Terms of Reference to reach conclusions on the adequacy of care provided at Bristol for those children undergoing paediatric cardiac surgery (PCS). We begin by drawing attention to some important points.
- 2 First, we concentrate on one particular aspect of the PCS service: care surrounding open-heart surgery on children under 1. It is this care which is the principal focus of concern about Bristol.
- 3 Secondly, while we may in what follows concentrate on aspects of the care which were less than adequate, because clearly Bristol did have a number of failings, we would not wish the impression to be gained that the PCS service at Bristol was always and in every regard of poor quality. While even now it is not possible to be absolutely certain about how many children received paediatric cardiac surgical care in Bristol between 1984 and 1995, the UBHT was able to identify at the Inquiry's request in 1999, the records of 1,827 children who had either open- or closed-heart surgery. The great majority of those children are alive today. We are anxious to record that, in a number of ways, the service was adequate or more than adequate.
- 4 The nursing staff, with few exceptions, were praised by witnesses for their dedication and caring attention. When this is set against a background of extremely constrained resources and a national shortage at the time of trained paediatric nurses, this is an achievement to be acknowledged.
- 5 Thirdly, we heard of the willingness to treat children whom other units seemed less inclined to treat. There is indirect support from the statistical evidence for this view in the case of children with Down's syndrome.¹
- 6 Finally, we acknowledge the hard work, dedication and commitment of all those involved in the PCS service at Bristol.
- 7 In particular, we were sometimes amazed at how the paediatric cardiology service could have been maintained at all. The number of consultants was well below the recommended level² (indeed, for most of the period of our Terms of Reference, there was no paediatric cardiologist in the whole of Wales), they held clinics across a very large area, in the South West and South Wales, and they had no trainee posts to support them and provide cover.
- 8 Of course, dedication and commitment are sometimes not enough. This is one of the most important observations that we will make, such that it significantly informs what we say about the future in Section Two of our Report. As we have already said, this is not an account of bad people, nor of people who did not care. It is certainly not an

¹ Mr John McLorinan, father of Joseph, told the Inquiry that he moved back to the area as the BRI, unlike some other hospitals, was prepared to operate on his son, who had Down's syndrome. T2 p. 2 and T2 p. 160. See also Annex B. Papers 6b and 7c by Dr Aylin et al

² See the evidence of Drs Swanton and Godman, regarding recommended levels in the late 1980s and early 1990s. At Bristol, until Dr Martin began cardiology work in February 1989, Drs Joffe and Jordan carried the whole of the paediatric cardiology workload between them. T7 p. 25 and T7 p. 80

account of people who wilfully harmed patients. Rather, it is an account of how people who were well motivated, failed to work together effectively for the interests of their patients, through lack of insight, poor leadership, and lack of teamwork. It is an account of a hospital where there was an imbalance of power, with too much control in the hands of a few individuals. It is an account of a service offering PCS which was split between two sites, had no dedicated PCS nurses, had no dedicated paediatric intensive care beds at the BRI, and had no full-time paediatric cardiac surgeon. And it is an account of a system of hospital care which was poorly organised and beset with uncertainty from top to bottom as to how to get things done, such that when concerns were raised, it took years for them to be taken seriously.

- 9 In keeping with our Terms of Reference, we separate our consideration of the adequacy of the PCS service at Bristol from the discussion of the concerns which were raised at the time about the care, and the responses to them. In the 'concerns' section, we concentrated on the actions of those who formed the view that the service was not merely poor, or less than adequate, but *unacceptable*, such that something needed to be done. We also considered the responses to those actions. Here, however, we examine the extent to which the PCS service was adequate, or less than adequate, both as perceived at the time, and with the benefit of later analysis and hindsight.
- 10 In our consideration of adequacy, we focus on the care provided by the UBH/T to children over a period of 12 years. We are concerned with making findings about the overall pattern and quality of care, as provided at the BRI and the Children's Hospital, not to examine on an individual basis the care which each and every child received over time from the NHS.
- 11 We make no findings as to the care of individual children. We take account of particular cases, but as exemplars of patterns of conduct. This is how we approach the notion of adequacy, as we now explain in greater detail.
- 12 We turn now to what we mean by adequacy. The term 'adequate' does not just refer to common practice. It is ultimately a judgmental term. Thus, it is not open to someone to say that a practice was adequate, as we use the term, simply because it conformed with what everyone else did. Otherwise, adequacy would lose any real meaning or force, since it could come to represent the lowest common denominator of practice. Equally, however, adequacy must not be confused with best practice. While all may strive to be best, by definition not all can be best.
- 13 To be adequate, therefore, a practice or service must meet some standard of quality, without necessarily being the best. To say that care, to be adequate, must meet some standard of quality invites the question, where does that standard come from? If there are standards set out by some body or group, the task is made much easier. A practice or service is adequate if it meets those standards, provided (and it is an important proviso) that the standards themselves are reasonable and not merely designed to serve the interests of the particular group. If there are no such agreed standards, the standard of quality comes from the input of two groups in particular: those providing

the service and those receiving it. It represents an assessment of what, from their differing perspectives, they would regard as acceptable. Where technical skill is involved, it represents not what an individual professional may do or would have done, but what, in the view of professionals generally, they should do or should have done at the time. In reaching that view, they must take account not only of their own professional opinion but also of the opinion of the wider community. Where no technical skill is involved, the approach is different. No technical skill is required in, for example, treating people with respect. Yet it may be a crucial ingredient in the adequacy of a practice or service. Whether a service is adequate or not then depends on what parents, patients and the public are entitled to expect of those who serve them: not what they do expect.

- 14** We have sought to ensure that our views are grounded in the conduct and the reality of the time covered by our Terms of Reference. We have asked ourselves whether, at that time and according to the standards of the time, from the perspective of clinicians, managers, parents and the public at large what was done in Bristol would have been regarded as acceptable. That things were done differently elsewhere, for the better or worse, while not conclusive, may help us reach a view.
- 15** A central question which arises in the case of the clinicians is how does an Inquiry, looking at the care offered by a hospital over a period of 12 years ending some six years before the publication of this Report, establish whether others at that time would have regarded what was done in Bristol as acceptable? If adequacy is, as we have said, a judgmental term, the judgment is that much more likely to be accepted if it is made against the background of a set of agreed national standards of care. Clearly, as regards matters of technical expertise, if all professionals had agreed on what was best practice, what was unacceptable, what was poor and, by implication, therefore, what was adequate, it would be easier to assess the adequacy of care at Bristol, at least from this point of view. But, during the whole of the period of our Terms of Reference, and even today as we write this report, no such standards exist as regards paediatric cardiac surgical services.
- 16** Professionals in the various specialties in Bristol, of course, have their views as to what constituted adequate care from the point of view of technical skills during the relevant period. Indeed, we have looked to some of them to advise us as our Experts. But, the absence of any agreed, established and monitored standards, meant that at that time any particular clinician had no real benchmark against which to judge technical skill and performance. There was very probably a sense of what amounted to good practice. And, there were, of course, approximations of such benchmarks in the form of reports based on the information held in local and national databases, and results presented at professional meetings and published in journals. But, these were universally regarded with some scepticism as not representing a true picture of performance. It was acknowledged that when a unit encountered poor results, these were rarely published. Moreover, not every unit submitted regular returns of its performance to the Register kept by the Society of Cardiothoracic Surgeons of Great Britain and Ireland.

- 17** One option open to us was to examine, for the purpose of comparison, paediatric cardiac surgical services as provided in hospitals in England at that time. We deliberately chose not to take that route. It would have been a very difficult undertaking: it would have involved taking evidence from those hospitals; it would not have been possible to complete such an examination within a reasonable timescale, and it would have been quite unjustifiable in terms of the burden of cost it would have placed on the respective hospitals.³ We opted instead to draw extensively on the views and assessments of experts who were in practice at the relevant time in all parts of the country. In the absence of agreed standards of care in place at that time, we sought to try to create a notion of such standards through the experience and knowledge of a wide cross-section of experts who could reflect on practice at that time. In short, we have sought to bring a true sense of comparative judgment, by hearing the views of a wide range of experts as to what they think was acceptable during the time covered by the Terms of Reference. We accept, of course, that this is a poor substitute for having agreed standards. But, we repeat, none existed.
- 18** We need now to remind ourselves that adequacy is not concerned only with the exercise of professional skills and the existence of professional standards dealing with technical skills. It is also about common standards of behaviour. It is about how people behave and what parents, patients and the public experienced. These are of no less importance in guiding us to our conclusions. We need, therefore, to get a sense of what happened to the children and parents in Bristol and ask ourselves whether their experience was such as to brand the paediatric cardiac surgical (PCS) service less than adequate by the standards of the time. That parents may not have complained at the time is not conclusive on this question. What we need to ask is whether, according to the standards of the time they would have been entitled to do so. This discussion of what adequacy may mean makes it clear, as we recognised from the outset, there could be no single template against which the adequacy of the service at Bristol could readily be assessed. Equally, we recognised there was unlikely to be one source of evidence which on its own would produce an answer. So, we have had to build up a picture of adequacy based on evidence from a variety of sources: the clinicians involved and their professional bodies, the UBH/T, the Department of Health (DoH) and the health authorities, from the parents of children who died and children who survived, and from our Experts. At all times we have had to distinguish between that which was known (or knowable) at the time, and that which it has only been possible to see and understand with the benefit of hindsight. For example, we could come to the view that, with the benefit of hindsight, the PCS service in Bristol was poor and should never have been encouraged or developed. But coming to that view *now* is not the same as saying that it could have been reached at that time. We are concerned with how the PCS service was viewed during the time of our Terms of Reference and how it may be viewed now.
- 19** Some may say that we could reach a view on the adequacy of care at Bristol simply and conclusively by comparing statistically the outcomes, in terms of mortality rates,

³ See Annex B, 5e Inquiry paper 'Note on supplementary analytical work – March 2000'

at Bristol with those of other centres. But this ignores the fact that, in relation to such data as were available at the time, there were no agreed standards against which to judge it. That another unit was at some point in time several percentage points better or worse than Bristol says little unless the data are properly comparable and there is some agreement as to what percentage outcome is unacceptable or poor.

- 20** We did commission our own statistical analyses and the Clinical Case Note Review. But these, of course, inform us from the perspective of hindsight. The conclusions were not known at the time. Thus, while they allow us to reach a clearer view of the adequacy of PCS services in Bristol at that time, they cannot, *on their own*, be the basis for criticism of what was done between 1984 and 1995.
- 21** Finally, we must raise here one further aspect of our approach to adequacy. We have to decide whether care was adequate. As part of this process, we have to decide what were the elements or factors which made it more or less so. We have to identify what went wrong, since clearly there was something wrong. The traditional, widely held, but crude notion is that when something goes wrong, it does so because it is caused by and is the fault solely of the people directly involved. In our context, it would suggest that if a patient were to suffer harm while undergoing surgery, the surgeon would be the person at fault. In this traditional, 'person-focused' approach, the response when something goes wrong is usually to seek to identify who can be blamed as causing the event, and then to apply a suitable sanction. The difficulty with this traditional approach is that it ignores the fact that individuals work within systems. Merely to adopt a simplistic approach to causation and, as a consequence, to sanction or remove an individual, without addressing the need to review and change the system, virtually guarantees that the error will be repeated. We have avoided this approach. Instead, we have been guided throughout by what has come to be known as the 'human factors' approach, as a means of understanding how systems which are concerned with preventing harm in fact work and why they break down. The human factors approach has been defined as the study of the interrelationships between humans, the tools they use, and the environment in which they live and work.⁴ It is more subtle, sophisticated and comprehensive than the 'person-focused' approach. Human factors (or systems) analysis adopts an approach in which lapses in safety, in the form of errors and poor performance, are seen as the product of systems which are not performing well. Remedial action, therefore, lies in analysing the system and identifying all those factors which led to, or contributed to, the error. In other words, a much more comprehensive approach to causation is adopted. This does not mean to say that the performance of individuals is excused or overlooked. Rather it means that understanding all the factors which lead to an individual's performing in a particular way makes it more likely that the error will not be repeated. In our context, it means that we will obtain a more rounded and informed understanding of the extent to which the care in Bristol was not adequate and where the inadequacies lay.

- 22** When systems analysis is applied to any situation in which performance is poor, or where things go wrong, there are two elements which need to be considered: active failures and latent factors. Active failures are the more obvious events closely and directly connected to the error. They include slips, lapses and mistakes. An example is leaving a swab in a patient after an operation. This is traditionally what is regarded as ‘the error’, and thus the sole cause of the problems that follow. But systems analysis suggests that behind the active failure sit what are known as latent factors, the systems and circumstances which, in our example, led to the swab being left behind. These factors, each of which plays a role in causation, may range from the working arrangements within the operating theatre, to communications between members of the team in the theatre, to the long hours worked by some or all of the staff, to the morale of the team. The thrust of the approach is that it is these systemic factors which must be understood and addressed. If they are not, the pattern of unsafe factors which led to the swab being left behind will continue to be repeated.
- 23** We endorse and adopt this approach for a number of reasons. We find it intellectually persuasive. We believe it is right to move away from an approach built exclusively around focusing on a single particular event and naming and blaming individuals. We say this not because we wish to shirk an unwholesome task but because such an approach does little to improve the safety and quality of care. Moreover, we regard systems analysis as offering critical insights both into understanding what happened in Bristol, and what we should learn from Bristol for the future.
- 24** Our approach to adequacy, therefore, is multi-factorial. There is a range of factors which, *taken together*, allow us to reach a view about the adequacy of care in Bristol. As we said during the Hearings, we liken our task to piecing together a jigsaw. Each factor is part of the jigsaw puzzle, but it is only when all the factors are put together that the full picture emerges.
- 25** To build up the picture of what happened in Bristol, we have divided the evidence which we received into a number of strands. Most of these strands relate to what was or could have been known contemporaneously during the period of our terms of reference. This evidence allows us to take a view on the extent to which those in Bristol at the time could form a view as to whether the service which was provided was adequate. Other strands of evidence reflect the perspective of hindsight. They include the comments of our Experts and the research commissioned by the Inquiry. They allow us to reach a view *now* about the adequacy of care in Bristol, but a view that was not known at the time. The evidence that we will examine relates to the following:
- the approach, nationally and locally, to the notion of clinical quality;
 - the management of the UBH/T;
 - the organisation of the PCS service in Bristol;

- the experience of parents;
- the views of the healthcare professionals in Bristol;
- reports and advice from the Inquiry's Group of Experts;
- the statistical analyses of clinical performance; and
- the Clinical Case Note Review.

26 We do not analyse each of these separately. That would be to produce a disjointed account which would obscure the interlocking nature of the various strands of evidence. Rather, in what follows, we group the evidence under a series of more general headings.

The Adequacy of Care

Chapter 14: External Assessment and Monitoring of the Quality of Care in Bristol

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- 1 We ask in this chapter about what mechanisms existed outside Bristol to assess and monitor the adequacy of the care provided to children under 1 undergoing open-heart surgery. We offer our conclusions as we proceed.
- 2 We have already set out the approach adopted by various organisations at national and local level to monitoring and assessing the quality of care generally. What we are concerned with here is the effect which the approach adopted had on the adequacy of the care which children undergoing paediatric cardiac surgery in Bristol received. Clearly, the assumption is that one method of ensuring a good quality of care is to have mechanisms or systems in place to assess and monitor care, with a view to identifying matters of concern and the need to take remedial action. We ask here whether there were any such mechanisms outside the UBH/T. If there were not, the adequacy of care was clearly put at risk.

The Department of Health

- 3 We have set out earlier the role which the Department of Health (DoH) ascribed to itself in relation to the NHS during the period of our Terms of Reference. It was a role in which the factors which were set out and monitored were focused on finance and the volume of patients treated. The quality and performance of clinical services were regarded as matter for the local hospital or health service, not the DoH. Information which was gathered concentrated on performance in relation to the scale of activity in hospitals, and on finance. Waiting times figured prominently. The national database which was built up was intended to be used for planning services, not to monitor clinical performance. This was how the DoH saw its role. As we noted earlier, Sir Alan Langlands, Chief Executive, NHS Executive 1994–2000, described the situation after the establishment of trusts as one which relied on professional self regulation, the development of processes of audit, a rudimentary internal market where purchasers held providers to standards set out in contracts, and a hierarchical relationship between the DoH, health authorities and trusts. All these things would need to be perfectly aligned, he said, to ensure that failure did not occur.¹
- 4 Given this context, it is possible now to see that it would have been unusual for a civil servant in the DoH to become directly involved in a particular clinical issue; in our case, in response to the approaches of Dr Bolsin, consultant anaesthetist, UBH/T, about the quality of the paediatric cardiac surgical (PCS) service at the BRI in 1994 and 1995. It is also possible to see how difficult it would have been for anyone in the BRI to know to whom in the DoH they should take matters of concern about a clinical service. Neither Dr Doyle nor Dr Ashwell (both Senior Medical Officers at the DoH), with whom concerns were raised informally by Dr Bolsin, belonged to any system of communication which existed between trusts and the DoH, or between regions and

the DoH. Indeed, the main point of contact between the trust and the DoH was the 'outpost'² which focused principally on financial performance. Dr Doyle was by then (April 1994) the Medical Secretary to the Supra Regional Services Advisory Group (SRSAG), but by 1994 the SRSAG was no longer involved in funding paediatric cardiac surgical services for children under 1. He also had responsibility in the DoH for the development of policy on cardiac services and it was in that capacity that he was in Bristol when Dr Bolsin gave him data in an envelope. When what appeared to be a particular clinical problem to do with PCS services in Bristol was separately brought to the attention of both Dr Doyle and Dr Ashwell, each, in a way, sought to refer it back to the hospital concerned. The prevailing ethos of the time was that such matters should be resolved locally. There seemed to be no alternative means of responding to clinical problems. Dr Ashwell did, in fact, offer Dr Bolsin a vague reference to some forthcoming work of an internal group in the DoH (the Clinical Outcomes Group) which was considering general issues to do with audit. But she was unsure about the role and remit of the Group. For his part, Dr Doyle referred to a quite different Group within the DoH, the Performance Management Directorate, as a possible source of assistance. In short, there was confusion among Departmental officials themselves. The DoH, for historical and structural reasons, was simply unable adequately to respond when an issue of the quality of care was being raised. This is profoundly unsatisfactory. There needs to be a mechanism somewhere to handle such problems. Bristol showed that there was no mechanism, anywhere. The assumption by the DoH was that problems would be dealt with elsewhere. Sadly, this assumption was also the assumption of all the other bodies who might otherwise have been able to act.

- 5 We conclude, therefore, that the DoH stood back from involvement in the quality of clinical care. It had not created systems to detect or act on problems of clinical care, other than by referring them back to the district or hospital concerned. The focus of the DoH was strategic and not operational. And to the extent that it was concerned with the 'operational', its interpretation of what was operational was rooted in matters to do with funding, financial viability and levels of activity. It had systems designed to support these objectives. There were no systems effectively concerned with the adequacy of clinical care. This was a product of the DoH's historical relationship with the NHS, with healthcare professionals, with how the NHS had developed and, latterly, with concerns for cost control. It is not adequate for the future.

The Supra Regional Services Advisory Group

- 6 Established as a funding mechanism, the SRSAG gathered data on the number of operations performed, but this was with a view to fixing funding levels for future years.

² The NHS Management Executive established, in 1991, regional outposts to carry out financial monitoring of trusts and to undertake appraisal of strategic capital investment

While information on the performance of units (in the form of mortality rates) reached the SRSAG, it did not see its role as being to assess or monitor clinical performance.

- 7 Thus, when Dr Halliday, Medical Secretary, SRSAG told the Inquiry that he was 'without the machinery to analyse'³ data on mortality, his comment goes to the wider point, that the SRSAG did not see itself as having a role in this respect. The difficulty is that while this may have been obvious to the SRSAG, it was bewildering to others. Confusing impressions arose and were given. The SRSAG certainly requested data on mortality from supra regional centres (SRCs). By so doing it gave the impression that mortality rates had some bearing on its decision-making. Indeed, it may well have given the impression that it was monitoring performance and was in a position to do something about performance if there were concerns. The lack of clarity about the SRSAG's role was compounded when, in 1991, the SRSAG began to act as a 'purchaser' mimicking the emerging relationships between DHAs and trusts. Annual service agreements (contracts) were established between the units providing neonatal and infant cardiac surgery (NICS) and the SRSAG. These included references to quality, but the expectation in the service agreement was that it was a matter for individual units, not the SRSAG, to ensure that the service was satisfactory from a clinical point of view.⁴
- 8 The picture is made more obscure by the discussions⁵ which the SRSAG had in 1992 concerning the possible de-designation of the whole of NICS because of the proliferation of units carrying out such work. One option considered was to de-designate particular units, based on the low volume of open-heart operations carried out. Bristol was one of the two units describes as being 'at risk'. After discussion, it was agreed by the SRSAG that designation of all the units should continue. One reason given was that 'it would be difficult if not invidious to de-designate the centres in question on the basis of surgical expertise'.⁶ This is an important observation. If it means that the SRSAG had data demonstrating that the surgeons in Bristol were obtaining good results which were comparable to those obtained by others, so that choosing between them was invidious, it means that the SRSAG was monitoring performance and the quality of care (and was mistaken since the data did not support such a view of Bristol's performance). But, as we have seen, Dr Halliday consistently stated that this was not part of the SRSAG's role. There could be another meaning: that the SRSAG did not wish to make hard choices concerning designation which might offend the clinicians concerned. But the SRSAG was there to make hard choices. The proper care of patients demanded it, whether or not clinicians and colleagues were offended.

³ T13 p. 113 Dr Halliday

⁴ The service agreement between the SRSAG and the UBHT, for example, provided that the unit: 'will ensure that the quality of services will be clinically and socially satisfactory, and will seek constantly to improve it.' The BRI was to monitor regularly: 'all relevant aspects of the service, and make the results available to the purchaser'. It was also *the unit* which was to provide an annual report dealing with such matters as 'quality of service' and 'statistics', as well as information on waiting lists and copies of the agreement on quality reached with the major purchasers (see DOH 0004 0004)

⁵ DOH 0002 0044

⁶ DOH 0002 0044

- 9 The role played by the SRSAG seems to have been, therefore, to concentrate on its primary task of safeguarding and nurturing financially vulnerable services. Monitoring volume was part of this task in the case of NICS. But the quality of care provided was seen as something for others to assess and monitor.

The South West Regional Health Authority

- 10 Miss Hawkins, Regional General Manager, SWRHA, 1984–1992, told us that in the 1980s the SWRHA was ‘not responsible for the performance of the unit [at the BRI]; we were responsible for monitoring it, but the BRI was responsible for the performance of the unit.’⁷ After the NHS reforms of 1991, the role of the SWRHA changed to that of supervising and managing the various districts in their role as purchasers of services in the internal market.
- 11 It is fair to conclude, therefore, that over the whole period of our Terms of Reference, the SWRHA never had any effective role in assessing or monitoring the quality of clinical care. It might have been thought to have had. But it did not. Another link in the chain was weak.

The District Health Authority⁸

- 12 Until the creation of the Bristol & District Health Authority (B&DHA) in 1991, the relevant district had since 1982 been the Bristol & Weston District Health Authority (B&WDHA). Ms Charlwood, Regional General Manager, SWRHA (1993–1994), Chief Executive, Avon Health Commission and Avon Health Authority (since 1994), provided us with a full and helpful account of the District’s activities in the area of monitoring standards of quality.⁹ She stated that from the outset ‘B&WDHA appears to have tried to concern itself with qualitative issues.’ But she made it clear that the criteria for judging quality changed over time to reflect changes in the Government’s priorities. More importantly, she stated that ‘The criteria chosen, and their indicators, were mostly of a general nature and on a large scale, so did not draw attention to concerns about surgical outcomes in a particular specialty at a particular hospital.’ Moreover, ‘... much of the ... information did not differentiate paediatric from other cardiac surgery.’

⁷ T56 p. 64 Miss Hawkins

⁸ Bristol & Weston District Health Authority was established on 1 April 1982. Bristol & District Health Authority formally came into existence 1 October 1991 and remained until 1 April 1996

⁹ WIT 0038 0022 Ms Charlwood

- 13** In 1985 a Performance Assessment Committee (PAC) was set up by B&WDHA ‘to monitor patient care’, but it was noted that: ‘... no separate routinely available information is recorded for the outcomes of neo-natal care in relation to neo-natal surgery both cardiac and non-cardiac.’ Paediatric cardiac surgery was not one of the services reviewed by the PAC in 1986. In 1987 a sub-committee of the PAC, together with Dr Roylance as District General Manager, set up a review of the Central Unit (BRI and BRHSC). PCS was not identified as a concern. In September 1988 the PAC received a report from its Medical Information Working Group (MIWG) concerning cardiothoracic surgery. The report noted the lack of comparative figures in the form of performance indicators. It was also minuted that Mr Wisheart referred to the ‘national register of cardiac cases’. This appears to have been taken as an indication that some external form of monitoring was taking place in the case of PCS. The PAC received the 1987 Annual Report on the PCS services.¹⁰ Ms Charlwood noted that ‘Mortality rates in the Report were described as virtually identical to those obtained nationally as published in the UK cardiac surgical register ... but the Minute ... says “Members ... noted that there were no national performance indicators”.’¹¹
- 14** Ms Charlwood concluded that up to that point the B&WDHA had:
- ‘... recognised the need to monitor performance in terms of outcomes for patients; acknowledged the impracticability of assessing all outcomes in specialities [*sic*]; opted to monitor specific services each year; ... [and had] not seen or heard anything about paediatric cardiac surgery to warrant selecting it for scrutiny.’¹²
- 15** The B&DHA took an interest in the quality of care provided by the UBHT, from the moment that it was set up in 1991 in succession to the B&WDHA. In 1991 it set out provisions relating to the quality of care in the service agreement with the UBHT. The agreement also anticipated that units within the UBHT, including the PCS service, would set up an audit group. But a distinction was made, at least on the part of the UBHT, between reporting to the B&DHA that a mechanism for audit was in place, and informing the District of the actual audit information. The latter was not forthcoming. Thus, although the service agreement contemplated that there be an audit of outcome, including measures of 30 day mortality, one year morbidity and one year symptomatic state, the District did not obtain this information.¹³ It could not, therefore, monitor the quality of care provided.
- 16** Over time, purchasers increasingly sought to set standards of quality and to obtain audit information from trusts, but there remained a gap between aspiration and reality. In the B&DHA’s draft specification for Adult and Children’s Cardiac Services for 1993/94, the District listed amongst standards of quality: ‘the quality of investigations and interventions will keep case fatality and morbidity to the minimal

¹⁰ ‘Annual Report on Paediatric Cardiology and Cardiac Surgery at the Bristol Royal Hospital for Sick Children and the Bristol Royal Infirmary, 1987’. See Annex A Chapter 19

¹¹ WIT 0038 0023 Ms Charlwood

¹² WIT 0038 0023 Ms Charlwood

¹³ See T62 p. 115 Dr Thomas and WIT 0108 0019 Dr Roylance

levels according to National Standards and will be the subject of monitoring and clinical audit'.¹⁴ This may be described as a valiant effort, particularly since there were no accepted national standards on levels of mortality and morbidity. Quite whether and how the District monitored the service is not clear. In early 1994 a B&DHA paper on clinical audit stated: 'A significant problem was the feeling of clinical professions that clinical practice was not the concern of the purchaser'.¹⁵

- 17** We conclude therefore that the District, between 1991 and 1995, sought to use the tool available to it, the service agreement, to get some grip on monitoring and securing the quality of clinical care. The agreement's lack of legal force, the continued reluctance of healthcare professionals to release audit information and the fact that information was considered a commercial confidence meant that the District's efforts were frustrated. Another element in the system, with the best will in the world, was not up to the task.

The NHS generally

- 18** The story of how the quality of clinical care generally and the PCS service in particular was monitored externally, therefore, is one of muddle and confusion. Witnesses pointed in a bewildering variety of directions. Some said the responsibility lay, to some extent, with the SRSAG or the DoH: including Sir Kenneth Calman, Chief Medical Officer 1991–1998,¹⁶ Professor Crompton, Chief Medical Officer for Wales 1978–1989, Dr Ian Baker, Consultant in Public Health Medicine, B&DHA, Sir Terence English, former President, RCSE, Sir Michael Carlisle, former Chairman, SRSAG,¹⁷ and Dr Norman Halliday, former Medical Secretary, SRSAG (in relation to the period after Trust status, although he qualified this by emphasising that he relied on the views of medical personnel rather than any system of formal monitoring). Moreover, Dr Halliday stated: '... the statutory duty for provision of health services rests with the Health Authorities ... The Supra Regional Services Advisory Group did not alter the statutory arrangements.'¹⁸ Dr Halliday also said that the supra regional service (SRS) was a funding arrangement, and that the SRSAG did not have responsibility for monitoring the quality of the care provided by SRCs:

'I was the architect of the Supra Regional Service arrangements. It was I who drafted all the papers, made all the proposals and negotiated with the profession. At no time did we consider that the Advisory Group which would eventually be set up would have responsibilities for any of the services. Their role was to advise the

¹⁴ WIT 0038 0034 Ms Charlwood

¹⁵ WIT 0038 0034 Ms Charlwood

¹⁶ Sir Kenneth accepted that at least the SRSAG should ensure that systems of monitoring were in place: but if not the SRSAG, then the DoH had a responsibility

¹⁷ T15 p. 3 Sir Michael thought that the DoH had an accountability as a contractor

¹⁸ T13 p. 112 Dr Halliday

Secretary of State on which services would be centrally funded. It was a funding arrangement.’¹⁹

19 Witnesses also suggested that responsibility lay with the Royal Colleges, or, more locally, with the health authority, or the hospital or trust, or the treating clinicians. Dr Halliday at one point or another in his evidence told us that responsibility lay with each of these.

20 As we have seen, Sir Alan Langlands commented:

‘... there was confusion ... the distinctive roles and responsibilities of each of the players was not adequately clarified. I think that the Department of Health, the NHS Executive in particular, must take some responsibility for that. It falls into my category of systemic failure. You cannot expect people to behave sensibly in this position unless they are absolutely clear where they fit in.’²⁰

21 The confusion, was not, however, just some administrative game of ‘pass the parcel’. What was at stake was the health, welfare, indeed the lives of children. What was lacking was any real system whereby any organisation took responsibility for what a layperson would describe as ‘keeping an eye on things’. The SRSAG thought that the health authorities or the Royal College of Surgeons were doing it; the Royal College of Surgeons thought that the SRSAG or the trust were 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.

The Royal College of Surgeons of England

22 During the period of our Terms of Reference, the Royal College of Surgeons of England (RCSE), in keeping with other Royal Colleges, visited teaching hospitals on a regular basis to inspect the training of those intending to make a career in surgery. The purpose of the visits was to ensure that the training was appropriate such as to warrant the designation of the hospital as suitable for training. Whatever the quality of the visits, and we have cause to criticise visits made to the BRI,²¹ the RCSE was most anxious to make it clear that they did not have responsibility for assessing or monitoring the quality of the care provided at the hospitals which were visited. Mr Dussek, consultant cardiothoracic surgeon, Guy’s Hospital, together with Professor David Hamilton visited the BRI in July 1994, on behalf on the Specialist

¹⁹ T89 p. 134–5 Dr Halliday

²⁰ T65 p. 103 Sir Alan Langlands

²¹ See later Chapter 16

Advisory Committee of the RCSE in Cardiothoracic Surgery. He informed us in a written statement that:

‘The standard or quality of clinical services was a matter that was not usually addressed on any SAC visit and on this visit we did not address the issue. In retrospect of course this appears bizarre but it is only since the Bristol case came to light at the GMC [General Medical Council] hearing that attitudes have changed. It does seem obvious now that the quality of the surgery carried out would affect the quality of the training. However at that time, no SAC visit in any specialty to the best of my knowledge, ever looked at clinical outcome.’²²

Thus, while others may have looked to the Royal Colleges to assess and monitor the quality of care, the College did not see its role as such.²³

Assuring and monitoring the competence of healthcare professionals

- 23** The issue here is whether there were mechanisms in place at the relevant time to provide any assurance as to the competence of healthcare professionals, and thus as to the adequacy of the care provided.
- 24** As regards hospital consultants, once specialist training was completed, there was no system for ensuring that they remained competent. Once qualified, the prevailing view was that it was up to them to maintain their competence. They did not answer to anyone, save in exceptional circumstances such as to involve the GMC or the employing health authority or trust. The hospital consultant effectively had a job for life. For the employer, the process of responding to issues of alleged incompetence was, and until very recently remained, very time-consuming and complex. The adequacy of the care provided to patients could not, in other words, be effectively addressed through regulatory or employment mechanisms. It is out of this state of affairs and a series of much-publicised examples of incompetence and bad professional behaviour,²⁴ that the current pressure for appraisal and revalidation has grown. In the thinking of today, therefore, the mechanisms in existence in 1984–1995 were less than adequate. In the thinking of the time, they were taken for granted and barely changed over the period in question.
- 25** As regards nurses, once qualified they were subject to a system of quality assurance, in that they were required to go through a regular, if not particularly rigorous, process

²² WIT 0067 0011 Mr Dussek

²³ T 28 p. 13–14 Sir Barry Jackson

²⁴ See, for example, J Ritchie, 2000; *The Report of the Inquiry into Quality and Practice Within The National Health Service Arising from the Actions of Rodney Ledward*

of re-registration. Further, both the employer and their professional body (the United Kingdom Central Council (UKCC), now the Nursing and Midwifery Council (NMC)) have always had considerable authority to respond to issues arising from poor performance by nurses.²⁵ Mechanisms of quality assurance were, therefore, in place. The difficulty throughout the period of our Terms of Reference (and until today) was that shortages in trained nurses meant that employers routinely required nurses to undertake responsibilities for which they had not been fully trained. The problem in relation to the adequacy of care received by patients was not, therefore, one of assuring and monitoring competence, but of employers cutting corners, for wholly understandable reasons.

- 26** As regards managers, no systems existed (or exist even now) stipulating the criteria which a senior manager must satisfy so as to be appointed to and remain in office. Thus, insofar as senior managers contributed to the healthcare of patients in Bristol (and their contribution was significant), the absence of any such systems undoubtedly gave rise to the risk that the adequacy of care provided could be compromised.

The Adequacy of Care

Chapter 15: The Culture and Management at the UBH/T

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- 1 We set out in this section the extent to which the culture and management at the UBH/T affected the adequacy of the care received by children undergoing paediatric cardiac surgery (PCS). First, we address the various aspects of management which we regard as of particular importance. Then, at the end of the section, we offer our conclusion.

The approach to management

- 2 We have already set out in Chapter 7 what we take to be the style and culture of management which dominated the UBH/T from the late 1980s until 1995: a clinician-management divide; an excessively devolved system of management; an oral culture; a commitment to turning questions back on the questioner. While adopted with due consideration and considerable dedication by Dr John Roylance, we take the view that this approach to management resulted in a concentration of power combined with a fragmentation of responsibility. This militated against the provision of an adequate standard of care. Not least, it meant that early warning signals of problems were less likely to be picked up if the care provided by some unit of the organisation were to become less than adequate.
- 3 We focus here for the most part on the period from 1989 onwards, as the move towards trust status began. But we point out that Dr Roylance was District General Manager (DGM) of the UBH from 1985 onwards and then Chief Executive of the UBHT, and had been a senior figure in the healthcare community for a number of years before 1985. Moreover, many others who occupied positions of influence in the UBH/T had been in place for a long time: Mr Wisheart, Mrs Maisey, Mr Nix and Dr Joffe. This undoubtedly brought the advantage of continuity and camaraderie. It also, however, posed the risk of creating a 'club culture' whereby some belong and others are excluded: a risk which in our view became a reality.
- 4 The move to trust status and the internal market, begun in 1989 and completed when UBHT became a 'first wave' trust in 1991, was welcomed by Dr Roylance. He saw it as an opportunity to resolve the conflicts over scarce resources which had traditionally existed between managers and clinicians, by bringing clinicians into management. In this way, as presaged in the Griffiths Report, clinical expertise would be brought to bear directly in the making of hard decisions. As a corollary, clinicians would also bear some of the responsibility for those decisions. But for this responsibility to be acceptable to the clinicians, it was recognised that it would need to be accompanied by assurances to clinicians that they would be free from interference in the exercise of their clinical activities. 'Clinical freedom' was not to be trespassed upon by management. Dr Roylance considered himself ideally suited to this approach. He took the view that, as a doctor, he understood the boundary between the clinical and managerial, and could be trusted by his fellow doctors

not to cross it. This view was not shared by all. Miss Catherine Hawkins, Regional General Manager (RGM) of the South and West Regional Health Authority (SWRHA), 1984–1992, told the Inquiry that she felt that it was difficult for Dr Roylance to perform the DGM role: ‘It was more difficult for him as a doctor managing doctors, and ... because he had been there for quite some time, it was very hard for him to appreciate the real role and function of a manager as opposed to being one of the colleagues in a set up of a teaching hospital.’¹ On the other hand, Dr Ian Baker, a clinician, described Dr Roylance as ‘a reassuring District General Manager’.²

- 5 Dr Roylance had worked in Bristol since 1963 (beginning as a senior registrar in diagnostic radiology at the BRI). In 1985 he was one of only 15 clinicians among the 188 district general managers appointed to a DGM post, following the Griffiths Report.³ He provided a valuable element of continuity during the transition to trust status. His experience equipped him well to develop a management system based on clinical directorates, each led by a clinical director to whom the directorates’ general managers were to be accountable. The system of clinical directorates was set up in 1989. Such a system was not unusual at the time, although the size of the Trust may have added to the difficulty of devising an appropriate management structure. Thirteen directorates were established.⁴ Even taking account of the size of the Trust, this was a large number of distinct, separate units. We consider that the UBHT might have benefited from an additional tier of management for this large group of directorates.⁵ Unfortunately, but perhaps predictably, the clinical directorates at the UBHT in practice became isolated from each other. This led in turn to a lack of effective means of communication between them. We have described this as the development of ‘silos’, channelling activities into separate and distinct compartments which did not effectively communicate with each other. This ‘silo’ effect created the environment in which it was difficult for managers at the centre to learn of developments, and particularly of problems, in the different parts of the organisation at an early stage before they became intractable.

Clinicians as managers

- 6 Clinicians taking up managerial duties lacked the training, experience and time to recognise and respond to problems which might exist in their area of responsibility. They were not equipped to identify the need to develop lines of communication nor how to introduce good managerial practices. Perhaps even more significantly, it was not recognised by senior management that they should be given the opportunity to

¹ T56 p. 123 Miss Hawkins

² T36 p. 38 Dr Baker

³ See Annex B, 101 Smith J and Ham C (2000): *An evaluative commentary on health services management at Bristol*

⁴ They were anaesthetics, community services, dentistry, medicine, mental health, medical physics, obstetrics and gynaecology, oncology, ophthalmology, paediatrics, pathology, radiology and surgery

⁵ See Figure 3 in Chapter 5 showing a diagram of the structure of the UBHT

acquire the necessary managerial skills. For example, we heard from Mrs Rachel Ferris about Mr Dhasmana's lack of skill as a manager. She told us that he: '... found it difficult to chair meetings and ensure that decisions got made'⁶ and that: '... he found it difficult to understand some of the concepts which I as General Manager had to work with'.⁷ Mr Roger Baird as Clinical Director for Surgery told us that he used to fit his work as Clinical Director into his normal working week without allocating sessions to it. He explained: 'I would pop in for a few minutes and see how they were getting on. I was there, maybe twice a day just for five or ten minutes.'⁸

Teamwork

- 7 The lack of managerial expertise at the level of clinical director and, as important, the lack of training to acquire expertise, led to a further problem: the failure to develop effective teamwork within directorates. One particularly striking example of this failure was the Intensive Care Unit (ICU) at the BRI. It also contributed to the deterioration of relationships between some groups of professionals which generally lowered morale. Dr Bolsin, consultant anaesthetist, UBH/T, referred to differences between anaesthetists and surgeons,⁹ and Fiona Thomas, clinical nurse manager, UBH/T, referred to some of the theatre nurses refusing to 'scrub in' for operations.¹⁰
- 8 It should be noted that at the time the consultants, particularly the surgeons, saw themselves as having very effective teams. But they saw these as their teams, which they *led*. They were not *part* of the team, other than as leaders. Also, the teams were teams of 'like professionals': consultant surgeon leading surgeons, consultant anaesthetist leading anaesthetists. The teams were not organised primarily around the care of the patient, they were not cross-specialty nor multidisciplinary, and they were profoundly hierarchical.

Strategic vision

- 9 From 1990 onwards Dr Roylance's delegation, as DGM and then Chief Executive, of large areas of responsibility to the clinical directors was accompanied by a reluctance to develop corporate responsibilities or priorities. Moreover, overall strategic vision or direction was lacking at Board level. The Trust's non-executive directors and even

⁶ WIT 0089 0017 Mrs Ferris

⁷ WIT 0089 0018 Mrs Ferris

⁸ T29 p. 62 Mr Baird

⁹ T82 p. 114 Dr Bolsin

¹⁰ T32 p. 71 Fiona Thomas

Mr Peter Durie, the Chair until 1994, were not encouraged by Dr Roylance to develop this approach. In Dr Roylance's view, with the creation of trusts, planning had passed from the Trust and the Board to the various purchasers of healthcare services, particularly the Bristol and Weston District Health Authority (B&WDHA), later Bristol and District Health Authority (B&DHA). He told the Inquiry that: '... the people who decided [what] the pattern of cardiac services should be ... were the purchasing health authorities not the providers, not the Trust Board'.¹¹

- 10** In our view, this was far too rigid and literal an approach to the idea of the purchaser-provider split. It effectively absolved the Trust from any strategic responsibility and cast it in an entirely reactive role. By its own logic, of course, it would leave the provider high and dry if the purchaser's priorities changed, albeit that the Department of Health's (DoH's) guidance or policy at the time was for the maintenance of a 'steady state'. Crucially, in the context of the concerns of our Inquiry, this approach militated against the identification of clear goals for the development of cardiac services. In particular, it left unresolved a central problem: the determination of the priority to be given to paediatric, as distinct from adult, patients needing cardiac surgical services.

Cardiac services

- 11** Waiting times for adult patients needing cardiac care were unacceptably long. Deborah Evans, Director of Contract Management, B&DHA, 1991–1995, informed the Inquiry that waiting times were the biggest single issue in contract negotiations between the B&DHA and the UBHT. They related largely to adult rather than to children's services.¹² Children could be treated, but only at the cost of not treating adults. Moreover, paediatric patients stayed in hospital and, particularly in the Intensive Care Unit (ICU), for a longer period of time on average and their treatment cost more. A tension clearly existed. Even treating children, let alone developing the paediatric cardiac surgical (PCS) service, therefore, was, to that extent, in competition with the increasing demand for treatment of adults, particularly as adult cardiac care was designated as a national priority. Thus, for those seeking to reduce the adult waiting times and to increase revenue by caring for more adult patients,¹³ there was no incentive energetically to seek the development of the PCS service. The picture which emerges is that, in the case of Bristol, the cardiac surgical service was an adult service. PCS in the form of open-heart surgery was tacked on to it, rather than being a dedicated service in its own right.

¹¹ T24 p. 152 Dr Roylance

¹² WIT 0159 0023 Miss Evans. She told the Inquiry that 'In children's cardiology and cardiac services ... waiting times were rarely if ever an issue.'

¹³ WIT 0114 0029 Fiona Thomas

Resources

- 12** Poor resourcing in terms of equipment and staffing for the PCS service was tolerated. Although resources generally were constrained and there were national as well as local shortages of cardiologists and properly trained nurses, effective measures to ameliorate the difficulties were not taken. The PCS service simply did not have the necessary priority for the UBHT to provide the service which could legitimately be expected of a supra regional centre. For example, on 31 January 1992 Mr Arthur Wilson, Deputy RGM of the SWRHA, offered advice on how to lift the pressure on the service for adults, by suggesting that open-heart surgery be moved to the Children's Hospital. He wrote to Dr Roylance inviting him to produce a proposal for capital funding for cardiac services taking into account a) increased capacity; b) unification of children's services; and c) steps to meet quality and cost concerns of purchasers.¹⁴ Thus, albeit as a side-wind of the need to meet the demands of adult patients, the service for children was being offered a way forward. Dr Roylance's initial response dated 12 February¹⁵ stated that he welcomed the approach, and the Trust responded with a full proposal developed by the Clinical Director and the General Manager for Cardiac Surgery by the 9 March deadline set by Mr Wilson.¹⁶ But nothing came of the bid.
- 13** Mr Graham Nix, UBHT Finance Director, clearly believed that resources for open-heart cardiac surgery should be found by expanding the adult service. But, if everything else stayed constant, this meant placing limits or constraints on the paediatric service.¹⁷ Eventually, as Mr Nix conceded, open-heart surgery was moved to the BRHSC, so as to meet the increased demand for adult surgery at the BRI, not out of any recognition of the legitimate needs and claims of PCS. In other words, while it had long been contemplated that open-heart surgery would move to the BRHSC, it was not until the pressure to meet the needs for adult surgery, and gain the financial benefits which would follow, that in fact action was finally taken.
- 14** There is a pervading sense of PCS being in the way, preventing the UBHT from increasing its income from the care of adult patients. The extremely high workload and dedication of staff were taken advantage of, rather than mobilised towards achieving any clear objectives. For example, perhaps with more managerial expertise the shortage of paediatric experience among the nurses in the ICU at the BRI might have been improved by encouraging the initiatives of Helen Stratton, Cardiac Liaison Nurse, UBH/T, 1990–1994 to bring the paediatric nursing expertise of the BRHSC to the BRI. Instead, the attempt came to a halt as a result of turf wars between the two

¹⁴ UBHT 0038 0410; the letter was dated 31 January 1991 but was received in February 1992, therefore should have been dated 31 January 1992

¹⁵ UBHT 0038 0408; letter dated 12 February 1992

¹⁶ UBHT 0038 0369; letter dated 9 March 1992

¹⁷ WIT 0106 0044 Mr Nix

counsellors at the BRHSC and the BRI respectively. Similarly, the provision of essential equipment from charitable sources might have been better planned to ensure compatibility and cost-effectiveness.

Delegation and accountability

- 15** Mr Hugh Ross, Chief Executive of the UBHT from October 1995, told us that when he succeeded Dr Roylance he found that: ‘there were not sufficient mechanisms and information systems in place for me to assure myself that all of the Directorates were operating in a proper manner’.¹⁸ Mr Stephen Boardman, Director of Corporate Development, UBHT, 1991–1992, put it more bluntly: ‘Dr Roylance did not appear to have control over the Clinical Directorates’.¹⁹ Dr Roylance’s view was that it was his role to recognise and go along with the culture of consultants, which he characterised as being grounded in clinical freedom. He saw it as his role to free them to do their job. He told the Inquiry that he was not in the business of ‘herding cats’.²⁰ Clinicians at the bedside were to make decisions and it was not for management to interfere.²¹
- 16** The degree of delegation operated by Dr Roylance would be a matter for concern in any large institution, if there were no appropriate systems for accountability and review in place. But, in the UBHT, the potential for problems to develop and remain unresolved, arising from this *system* of management was compounded by the *culture* of management which prevailed. Power was concentrated in the hands of the Chief Executive and his close colleagues. Mr Wisheart, at various times, was Medical Director, a Clinical Director and Chair of the Hospital Medical Committee (HMC), and in 1992 he held all of these positions. Mrs Margaret Maisey, the Director of Operations, as we have seen, combined this role with that of Nurse Adviser to the detriment of the duties associated with the latter. In Mr Wisheart’s case, the extent of the responsibilities held makes it difficult to see how the roles could all be performed adequately. He was also carrying out heart surgery on adults and on children. Dr Roylance made the final decision on who became a clinical director, from among senior clinicians with whom he had worked for some years.²² The scene was set for the development of the ‘club culture’ expressly encouraged by Dr Roylance. Mr Boardman²³ told the Inquiry that a career depended on someone’s ‘fit’ within the ‘club’, rather than performance, and that any challenge to policy was perceived as disloyalty. This approach was neither conducive to self-assessment or reflective criticism in some nor confidence in others. Indeed, we heard of a culture of fear.²⁴

¹⁸ T19 p. 23 Mr Ross

¹⁹ WIT 0079 0281 Mr Boardman

²⁰ T25 p. 168 Dr Roylance

²¹ T24 p. 15 Dr Roylance

²² T30 p. 32 Mr Durie

²³ WIT 0079 0014 Mr Boardman

²⁴ WIT 0089 0025 Mrs Ferris referring to Mrs Maisey

Dr Susan Dopson²⁵ reported Dr Roylance as saying to her: 'I have enormous power which I'm not prepared to use except in very specific situations ... I can hire and fire anybody, I don't need to ask anybody's permission for anything.'

- 17 The managerial culture at the UBHT was one which took too great a pride in and placed too great a reliance on its 'oral culture'. Claiming to avoid unnecessary paperwork, communication was oral rather than written. In the circumstances, this only added to the uncertainty and insecurity in decision-making, as those who were outside the 'club' found it hard to discover what was going on and those to whom responsibility was delegated sought to read the minds of the senior executives.

Conclusion

- 18 The UBHT was not unusual in having problems. It was, after all, managing the transition from the known (the old NHS) to the unknown (trust status). We understand that 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 the UBHT was that the systems and culture in place were such as to make open discussion and review more difficult rather than more easy. As we have said, we were told by Mrs Rachel Ferris, General Manager, Directorate of Cardiac Services, UBHT, that Dr Roylance told his staff: 'don't give me your problems, give me your solutions'.²⁶ This approach was generally unhelpful. It was counterproductive as a means for securing improvements in the quality of care. It ignored the growing realisation that problems are better understood as offering valuable opportunities for learning. It failed to encourage staff and patients to share their problems and to speak openly. The most dangerous management style of all is that of the exercise of power without strategic vision, accompanied by 'divide and rule'. Dr Roylance's style of management could be so characterised.
- 19 We accept that Dr Roylance was both thoughtful and principled in his development of a management system for what was one of the newest and largest trusts in England, and that he succeeded in putting in place stringent financial controls and in balancing the books. Sadly, a system of separate and virtually independent clinical directorates, combined with a powerful message that problems were not to be brought to the centre for discussion and resolution, meant that there was power but no leadership. An environment was created in which problems, which we repeat are likely to arise in all institutions, were not adequately identified or addressed in Bristol.

²⁵ Dr Dopson is a university lecturer in management studies and a Fellow in organisational behaviour, Templeton College, Oxford

²⁶ WIT 0089 0032 Mrs Ferris

- 20** Nor were there effective measures outside Bristol to monitor or change the style or system of management adopted by Dr Roylance. This was a feature of the NHS reforms in 1989–1991. Trusts were to be allowed to get on with things. 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, as Bristol suggested. The Chair and the Trust Board were either part of the ‘club’ or treated as outsiders. Referring to information about the outcome of care, Mr Robert McKinlay, the Chair of 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.’²⁷
- 21** Thus, in our view, there were a number of elements in the system and culture of management in Bristol which were conducive to the provision of less than adequate care. It may be true, as Mr Wisheart argued in his evidence to the Inquiry, that the fact that the managerial system was less than adequate may not have affected directly the adequacy of care received by any particular patient. Nevertheless, contrary to Mr Wisheart’s view, the inadequacies of management were an underlying factor which adversely affected the quality and adequacy of care which children received.

²⁷ T76 p. 8–9 Mr McKinlay

Adequacy of Care

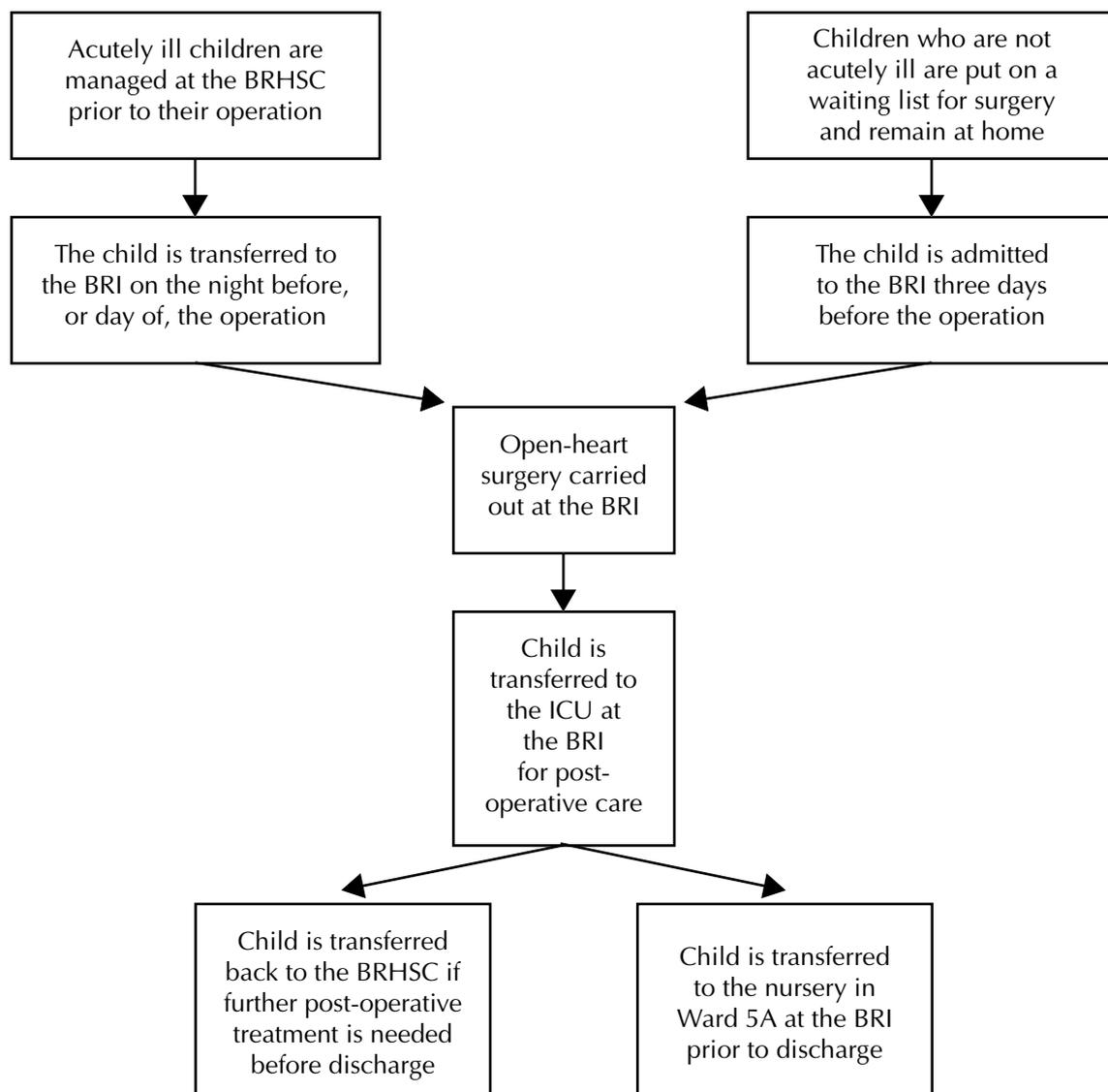
Chapter 16: The Organisation of the Paediatric Cardiac Surgical Service in Bristol

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The patient's journey

- 1 In this section we comment on aspects of the organisation of the paediatric cardiac surgical (PCS) services in Bristol which in our view affected the adequacy of the care provided to children and their families. As throughout, we concern ourselves with open-heart surgery. We describe first the physical environment and the UBH/T. We then follow the family's journey through the process of care from their first contact with the PCS services. We offer our conclusions as they arise.

Figure 1: The typical journey through the BRHSC/BRI of a child undergoing open-heart surgery



The physical environment

- 2** We visited the BRI and the BRHSC (in St Michael's Hill) on 22 July 1999.¹ We make here some general comments. First, we emphasise that our visit was already 14 years after the beginning and four years after the end of the period covered by our Terms of Reference. Children undergoing open-heart surgery are all now cared for in the BRHSC.² There are no longer children in Ward 5 of the BRI. That said, we were told that the physical arrangements had not greatly changed.
- 3** We were shocked by what we saw at the BRI. There was a sense of delapidation. The corridors were dirty, with an array of discarded equipment and bric-a-brac pushed against walls and in corners. The Intensive Care Unit (ICU) was cramped and crowded. Large items of equipment were 'stored' in the middle of the room, making the space even more crowded. The area previously allocated for children was small and would have allowed little space for family members. The room set aside for parents to await news was small, cramped and windowless. The main lift used to transport children to and from the operating theatre, two floors below, was cramped and old. The space in the alternative lift was so limited that on occasions staff who should have been accompanying a child had to run up the two flights of stairs to meet it. Our overall, lasting impression was that Wards 5A and 5B were cramped, overcrowded, overheated, dirty and neglected. It was a tribute to the staff that they were prepared to work there. Although we did not see other wards, it may also represent a comment on the relative importance given to these wards by the Trust. We have no doubt that this state of affairs could only have had an adverse effect on the morale of staff and parents and, to that extent, would have affected adversely the quality of care provided to children.
- 4** As regards the Children's Hospital, we were struck by the steep hill which divided it from the BRI, making the distance between the hospitals feel much greater than the actual 150–200 metres it is.³ We were shown the casualty area and resuscitation room. We were impressed by the sense of space in what was a busy outpatients department. After seeing the cardiac catheter unit and echo room, we were shown Ward 3B. This Ward was used for admissions of some cardiac patients. We found it old, crowded and cramped. The ICU was rebuilt in 1994 at which time it was significantly enlarged. The main surgical ward was crowded but organised and had a play area with a play leader. The overall impression was one of crowding and some dilapidation, but also a sense of energy and direction.

¹ An account of our visit is set out in Annex B at 1e

² The brand new Bristol Royal Hospital for Children was opened in April 2001

³ Dr Joffe's estimate. He also said 'But the hill, when you were walking up it, felt as if it was almost half a mile, rather than 200 metres.' T90 p. 65–6

Referral to the cardiologists in Bristol

- 5 The patient's journey to the BRI begins at the point of referral, by local paediatricians through outreach clinics and by GPs, to the cardiologists in Bristol. The cardiologist would first see the child either at the BRHSC or at one of the outreach cardiology clinics, for an opinion or investigation. If the cardiologist considered that surgery was likely to be required, the child would be referred to a paediatric cardiac surgeon, usually one of the Bristol cardiac surgeons.
- 6 To assess how the Bristol Unit was regarded by doctors who referred on children with heart disease, the Inquiry contacted consultant paediatricians and cardiologists who had been based within the Bristol catchment area during the period of the Inquiry's Terms of Reference, seeking their comments on their referral practices. We received replies from 72 consultant paediatricians who were based in hospitals in the South West of England and in South Wales during the period 1984–1995. Many (29) stressed that their referrals were to the Bristol cardiologists, not to the Bristol surgeons, and thus the important relationship was with the Bristol cardiologists. We found no indication in their evidence of any lack of trust or lack of confidence in the Bristol cardiologists. Indeed, a number of the referring paediatricians told the Inquiry that they held the Bristol cardiologists in very high regard.
- 7 Professor David Baum, then President of the Royal College of Paediatrics and Child Health, told us:

'I would say there are competent consultant trained cardiologists on this corridor who are my colleagues whom I trust through their training and I trust them as individuals, and that I will refer the care of this baby... It was not a part of the mindset of the time to inquire into the quality of surgical outcomes.'⁴

The split site and the split service

- 8 As has been explained, until October 1995 the PCS services were provided on two sites. The cardiologists were based at the BRHSC, where closed-heart surgery and investigations were carried out. Open-heart surgery was performed at the BRI, where post-operative care was also provided. The ICU cared for both adults and children. Until 1987, when a new catheter laboratory opened at the BRHSC, cardiac catheterisation was also carried out at the BRI.

- 9** The service was not only divided physically, by a ten minute walk including a steep hill, but also in its organisation. There was, in other words, not merely a split site, but, much more significantly, a split *service*. After the creation of the Trust, the organisation of the PCS service was divided. Paediatric cardiology lay within the Directorate of Children's Services, based at the Children's Hospital, under the direction of Dr Joffe, consultant paediatric cardiologist. Paediatric open-heart surgery lay within the Directorate of Surgery. Although all cardiac services were brought together under the clinical direction of Professor John Vann Jones, consultant cardiologist, in 1994, paediatric cardiology remained part of the Directorate of Children's Services at the BRHSC. It was only in October 1995 that paediatric open-heart surgery and paediatric cardiology were brought under the same Directorate, the Directorate of Children's Services at the BRHSC. These divisions in responsibility for what was a small specialist service within a large Trust clearly militated against a clear focus on what was needed for the children being treated and on the standards of care to be and being achieved.
- 10** Crucially, the organisation reflected the buildings where the children were treated and where the healthcare professionals were based. It did not reflect the needs or interests of the children. Thus, there were both physical and organisational impediments to the adequacy of the service provided. As regards the split site arrangement for the PCS service, Dr Jane Ratcliffe, Honorary Secretary of the Paediatric Intensive Care Society 1991–1998, told us she could not think of another PCS unit in the 1980s and early 1990s where the cardiologists were on one site and the surgeons on another: 'I find it very worrying, because you need somebody to consult very rapidly. I know that the geography of the Royal Infirmary and the Bristol Children's Hospital is not across town, but even so, I think I would find it very difficult in working practice to try and work and do justice to both sides.'⁵ As a result of the split, we also heard that for their part, the cardiac surgeons were not readily available on the ward at the BRHSC, although they did visit 'sometimes after midnight'.⁶
- 11** A number of parents described to us their confusion and distress at having to move from one hospital to the other, particularly when they feared that the move was not well planned and prepared. Michelle Cummings⁷ told us that on moving her daughter, Charlotte, back to the BRHSC after surgery at the BRI: '... they didn't even know we were coming ... there was no intensive bed for her, no life support machine, and they were still hand ventilating her'.
- 12** Charlotte's medical notes state that she was: 'Transferred from Ward 5. Arrived unannounced as usual.'⁸ Joyce Woodcraft, a former nurse and Senior Sister at the BRHSC, told us that she thought that the comment in the record was 'harsh', but that such a transfer did happen 'occasionally'.⁹

⁵ T7 p. 162–3 Dr Ratcliffe

⁶ WIT 0532 0041 Ms Chinnick

⁷ T3 p. 149 Michelle Cummings

⁸ MR 0722 0063

⁹ T57 p. 37–8 Ms Woodcraft

- 13** We also heard evidence of separate sets of medical notes being prepared and kept on the two sites. On occasions, the notes from the BRHSC would not accompany the child on transfer to the BRI. This clearly was a most unsatisfactory way of caring for very ill children. In fact, the Inquiry has direct experience of the implications of this split service because, for each child who had open-heart surgery, in 1999 (in preparing for the Inquiry) we had to obtain two sets of notes, one for the time spent at the BRHSC and another for the time spent at the BRI. The notes are kept in separate buildings. This is a particularly symbolic demonstration of the way in which the care provided was organised according to the building rather than according to the child.
- 14** The care provided at the BRHSC, where results were good for closed-heart procedures, was in the main commented on favourably by parents. The dominant theme was of appreciation for the family-centred atmosphere and the specialist paediatric nursing skills provided. John McLorinan, father of Joe,¹⁰ told the Inquiry that: ‘... in the children’s ward one feels cushioned and cradled ... BRI was not really geared for children and families’. There were some dissenting voices. For example, Penelope Plackett, whose daughter Sophie was disabled after undergoing surgery, was distressed to find her with nappy rash after leaving her for the weekend at the BRHSC at Mr Dhasmana’s suggestion to take a much-needed break. As regards the BRI, however, although many parents told us how much they appreciated the dedication of the staff, a number also spoke of their distress on finding their child being cared for at the BRI in an intensive care unit which looked after both adults and children. Helen Johnson, mother of Jessica, called it ‘limbo land’.¹¹ For mothers of newborns it was particularly difficult to be without the care of trained maternity nurses at this time of great stress. Kathleen Tilley, mother of Lauren, indicated that she was:
- ‘... back and forth between the Bristol Royal Infirmary and the Childrens Hospital all night because I was breast feeding Lauren. I have to say that the two sites were extremely inconvenient. Although I was able to walk, it did mean that I had virtually no sleep that night and when I returned in the morning I was expecting to be met and told when the operation on Lauren was to proceed.’¹²
- 15** Susan Francombe, mother of Rebecca, stated that: ‘Rebecca came through the operation [at the BRI] but in the time it took us to reach her from the Bristol Maternity Hospital she had deteriorated considerably.’¹³
- 16** The process of transferring children between the BRHSC and the BRI had been recognised by the South West Regional Health Authority (SWRHA) to be dangerous as long ago as 1984: ‘... at the present time, patient’s lives are frequently being put at risk by the need to transfer very young children between the Bristol Children’s Hospital and Bristol Royal Infirmary every time a catheter investigation is needed’¹⁴ and ‘The

¹⁰ T2 p. 173 John McLorinan

¹¹ T44 p. 144 Helen Johnson

¹² WIT 0230 0004 Kathleen Tilley

¹³ WIT 0349 0005 Susan Francombe

¹⁴ UBHT 0295 0418

transportation of critically ill infants must be avoided. This current practice has given considerable concern to the Paediatric Cardiologists for some time.¹⁵ We heard evidence from one of the Experts to the Inquiry, Dr Duncan Macrae,¹⁶ that the process of preparing and stabilising a child is as demanding and important for a ten minute journey as for one of hundreds of miles. He also described how poorly specialist transfer was conducted in the early 1990s. This being so, the need to transfer patients between the two sites was a persistent underlying factor giving rise to a risk of adversely affecting the care of the child.

- 17** On arrival at the BRI, further problems arose because of the lack of a permanent cardiological presence there. The Bristol surgeons were without cardiological support in the operating theatre, and to a large extent in the ICU. This dislocation of essential cardiological services from the surgical and other services at the BRI was, in our view, one of the most significant adverse factors affecting the adequacy of the PCS services overall. At the same time, the cardiologists were also without full surgical support at the BRHSC.¹⁷
- 18** Mr Martin Elliot, consultant cardiothoracic surgeon, Great Ormond Street Hospital, decided not to proceed with an application for appointment as a paediatric cardiac surgeon at the UBHT in 1991 largely because of his concerns about the split service. In his written evidence to the Inquiry he stated: 'I thought it inefficient, archaic, inhibitory to progress and potentially dangerous. I made this clear in verbal and written communication to the team in Bristol.'¹⁸
- 19** Dr Elliott Shinebourne, acting on behalf of the Specialist Advisory Committee on Cardiovascular Medicine of the Royal College of Physicians, was sufficiently concerned about the split site to advise in 1992 against the BRHSC being designated as suitable for a training post in paediatric cardiology.
- 20** We acknowledge that throughout the period of our Terms of Reference the clinicians in Bristol wished to consolidate all aspects of the PCS service onto one site. But this was not achieved until 1995. Until then, we have no doubt that the PCS service was adversely affected by being a split service and that, as a consequence, the adequacy of the care provided was constantly compromised. Indeed, of all the factors affecting the adequacy of the PCS service, this was perhaps the most serious. Mr Elliot, as we have seen, described the split service as '... potentially dangerous'. It was in fact actually dangerous.

¹⁵ UBHT 0295 0420

¹⁶ T51 p. 119 Dr Macrae

¹⁷ WIT 0532 0041 Ms Chinnick

¹⁸ WIT 0467 0005 Mr Elliott

The paediatric cardiologists' role

- 21** The children were admitted to the BRHSC under the joint care of cardiologists and surgeons.¹⁹ On admission to the BRI, Mr Wisheart told us that a child would be reassessed not only by a surgeon, but also by a paediatric cardiologist from the BRHSC, as well as being seen by the anaesthetist for the first time.²⁰ Dr Jordan, consultant paediatric cardiologist, and Dr Joffe, however, both told the Inquiry that the role of the cardiologist in immediate pre- and post-operative care was limited because of their heavy workload, the absence of support from junior staff, and the need to visit the outreach clinics which extended across the South West and South Wales.²¹ There was, it will be recalled, a significant national shortage of paediatric cardiologists at that time. Dr Jordan told us that the cardiologists' attempts to meet the surgeons to look at the results of the various tests carried out on the child, in preparation for the following week's operations, fell by the wayside. They were, he said, just too busy.²²
- 22** As has been said, the meetings between cardiologist and surgeon were a casualty of the cardiologists being overstretched. Dr Houston, one of our Experts in paediatric cardiology, told us, however, that it was *imperative* for the cardiologists and surgeons to meet before an operation to review the notes and examine the test results together.
- 23** Similarly, and more importantly, given that open-heart surgery was carried out at the BRI, there were difficulties for the cardiologists in becoming involved in care at the BRI, either on the ward or in the operating theatre. Dr Joffe, consultant paediatric cardiologist, found it difficult to get actively involved. He told us that: 'Dr Jordan specifically made a point of going to the BRI every day and often twice a day, and found it slightly easier than I [Dr Joffe] did because earlier on he was still involved in adult cardiology, [and] had an office at the BRI.'²³
- 24** Dr Joffe initially had an office at the BRI and Dr Jordan had an office there until the late 1980s. Thereafter, both were based at the BRHSC. Dr Joffe said that the physical separation between the BRI and BRHSC, although only about 150 to 200 metres, was: 'real although of course not insurmountable' because the BRHSC was up an 'extremely steep' hill. Dr Joffe told us that: 'the separation made a difference in terms of the ordinary communication that exists in a unit where consultants and various doctors can meet with each other and bump into each other in a corridor, and so on, which facilitates overall management.'²⁴

¹⁹ WIT 0120 0126 Mr Wisheart

²⁰ WIT 0120 0127 Mr Wisheart

²¹ WIT 0097 0297 Dr Joffe and WIT 0099 0040 – 0041 Dr Jordan

²² T78 p. 99 Dr Jordan

²³ T90 p. 65 Dr Joffe

²⁴ T90 p. 65–6 Dr Joffe

The operating theatre

- 25** We heard critical comments from staff about the organisation of work in the operating theatre at the BRI. In particular, Mr Wisheart was criticised for his tendency to arrive late, having to be called even after the patient had been made ready to go on to bypass.²⁵ We heard of Mr Dhasmana's impatience with staff in the theatre, itself an indication of poor training and teamwork.²⁶ Criticism was also made of the absence of anaesthetists during surgery, who would leave to make their ward rounds.²⁷ Dr Pryn, consultant anaesthetist, told us: 'I found it difficult to look after sick patients on the CICU [Cardiac ICU]. When I was at the same time anaesthetising for cardiac operations. Often I would have to leave my patient in theatre with a trainee anaesthetist while I went to the CICU to assess patients'.²⁸ Difficulties with equipment were also mentioned, such as the fact that use of the diathermy machine interfered with monitors.²⁹ Echocardiography was not available in operating theatres or in the ICU. Dr Jordan stated that the Heart Circle provided funds for the purchase of an echocardiograph machine, which could be kept on the ward.³⁰ Mrs Pratten, founder of The Bristol & South West Heart Circle, confirmed that in 1992 the Heart Circle was approached by Dr Jordan and asked to provide £25,000 towards the cost of a Doppler/echocardiograph.
- 26** Perhaps the most significant deficiency was the lack of availability of cardiological advice and assistance to the surgeons in the operating theatre. We heard from our Experts about the problems which can arise as a consequence.
- 27** We were told of the case of Marc Stevens, who, having had a shunt operation in May 1986, was admitted to the BRI in April 1991 for a corrective operation. We heard that during the course of the operation the surgeon, Mr Wisheart, encountered a further complication and took the decision to put in a second shunt. One of our Experts, Mr Philip Deverall, a retired consultant paediatric cardiothoracic surgeon, commenting on this decision, told us:

'It is not easy to think on your feet under those pressures on bypass and under considerable stress, and under optimal circumstances, it is nice under those circumstances to be able to ask your paediatric cardiologist, your fellow surgical consultant, your anaesthetist, to stand back, if necessary, in my experience, to actually leave the operating room and cool down and decide what to do.'³¹

²⁵ T59 p. 63 Sister Armstrong

²⁶ See exchange between Mr Dhasmana and Leading Counsel to the Inquiry T85 p. 14 Mr Dhasmana. T59 p. 31 Sister Armstrong

²⁷ As early as 1987, Mr Keen had complained in a letter that there was not always 'consultant anaesthetic cover' in the operating theatre. UBHT 0138 0022

²⁸ WIT 0341 0030 Dr Pryn

²⁹ T72 p. 76 Dr Pryn

³⁰ WIT 0099 0041 Dr Jordan

³¹ T78 p. 109 Mr Deverall

- 28 Acknowledging the difficulties in contacting the cardiologists in such a situation due to the split site and their other commitments, Dr Jordan told us: ‘I would have liked to think if I had been there in theatre, discussing this, I would have ... said “The last thing you want to do, I am afraid, is to do another shunt”.’³²
- 29 Once again, there emerges a picture of less than adequate care, with the principal factor being the split site, and the consequently split service and a lack of the presence of the cardiologists.
- 30 Ultimately, teamwork and collaboration among the healthcare professionals working in the operating theatre was put under particular strain by the growing sense among some that the results in surgery on the under-1s were poor. The anaesthetists sought a veto over the performance by Mr Dhasmana of neonatal Switch operations and two of the theatre sisters, Ms Kay Armstrong and Mrs Mona Herborn, refused to scrub for such work.

Post-operative care

- 31 We heard from our Experts that the transfer from the operating theatre to the intensive care unit is one of the most difficult stages in the care of a child. The principal reason is that the child passes through the care of three distinct groups. The levels of skills available to monitor the patient go from those of the consultant surgeon and anaesthetist in the operating theatre, to those of the porter, the nurse and the anaesthetic assistant who move the child, and then to those of the nursing staff and the surgical senior house officer who receive the child in the ICU.
- 32 At the BRI the stress, and the opportunity for things to go wrong at this critical stage, were exacerbated by the need to travel in a small lift between two floors from the operating theatre up to the ICU. We heard from one of our Experts, Dr Barry Keeton, consultant paediatric cardiologist, that Southampton General Hospital also faced this problem in the 1980s. But, in contrast to Bristol, he told us that at Southampton they commandeered one of the hospital lifts and made it into a dedicated lift for the purpose of transfer between the operating theatres and ICU. The lift itself was equipped with resuscitation and monitoring equipment in order to reduce the risk to the child.³³ No such arrangements were in place in Bristol. As we have said, not only was the lift very cramped when it had to accommodate a bed, a nurse and an anaesthetic assistant, but it had no emergency equipment installed, and, most remarkably, was at risk of being summoned and stopped or sent to another floor, if the lift button was pressed while in transit. If ever there were an environment conducive to error and danger this was it. Yet when the BRI was twice inspected as a centre suitable

³² T78 p. 110 Dr Jordan

³³ T51 p. 12–13 Dr Keeton

for training surgeons by representatives of the Royal College of Surgeons of England,³⁴ no adverse comment was made. Indeed, on both occasions, the visiting team appear from their report to have thought that the operating theatre and the ICU were on the same floor! This is an extremely worrying comment on the rigour and reliability of the process of inspection, as a precursor to approval of a hospital for training purposes.

- 33** It was a particular feature of the ICU, as we have seen, that there were no dedicated beds for children. They were nursed with adults. Professor John Vann Jones told us:

‘... when I did paediatric cardiology, having been an adult cardiologist and thrown into these unusual circumstances, I felt very uncomfortable with it because these youngsters have many metabolic problems that develop very quickly. They are tiny little things. They become acidotic very easily: they have their ventilation suppressed very easily. If you do not actually have general paediatricians in the building and you do not have a paediatric cardiologist in the building all the time, and you do not have dedicated paediatric anaesthetists you are going to have more morbidity. That problem needed to be resolved.’³⁵

- 34** Post-operative management at the BRI was criticised by Dr Hunter and Professor de Leval in the first draft of their report as ‘highly disorganised with conflicting decisions’.³⁶ The fundamental problem, which was unresolved throughout the period of our Terms of Reference, was the stark question: who was in charge? Anaesthetists and surgeons carried out separate ward rounds. Mr Wisheart told us that he did not regard conducting ward rounds at different times as posing a particular difficulty.³⁷ We heard that, as a consequence, nursing staff felt that they received conflicting instructions.³⁸ A course of action indicated by one clinician might be changed by another on a later ward round. For example, Dr Pryn told us that ‘relatively frequently’³⁹ complex decisions had been taken at the earlier ward round by registrars with which he, as the intensivist, disagreed. Mr Wisheart expressed the view that this only occurred ‘occasionally’ when ‘a difficulty might arise if one party instituted a course of action, for whatever reason, without discussing it with the other party and the second party then comes along and may not agree with what has been done’.⁴⁰

- 35** There was no clear line of command to indicate who could take decisions about changes in treatment with the urgency required in the case of very young babies, whose condition changes far more rapidly than that of adult patients. The doctors physically present in the ICU for most of the time were junior doctors training in general surgery. They were not authorised to make decisions without consulting the senior surgeons, but the latter were often either in the operating theatre or in a clinic. Moreover, the junior doctors, while knowing something about surgery, might well

³⁴ UBHT 0038 0187

³⁵ T59 p. 165 Professor Vann Jones

³⁶ This was subsequently changed in the second draft to ‘less organised with multiple decision making process’; see Annex A Chapter 30

³⁷ T40 p. 142 Mr Wisheart

³⁸ T27 p. 111 Mrs Ferris

³⁹ WIT 0341 0011 Dr Pryn and T72 p. 50 Dr Pryn

⁴⁰ T40 p. 142–3 Mr Wisheart

have no expertise in cardiac care, paediatrics, or intensive care. Yet they were the medical presence in the ICU, caring for seriously ill children. Dr Pryn told us that: 'it was a unit run by trainees ... quite familiar with the cardio-vascular system ... but relatively poor at integrating that with other systems, for instance the respiratory system'.⁴¹ Even when two intensivists at consultant level were appointed in 1993, they were only present for part of the week on a rota system, such that the difficulty of who was in charge remained unresolved. When Dr Pryn took it upon himself to try to resolve the matter by introducing a single clinical report form, others did not co-operate. Professor Baum referred to the need for paediatric input because the 'physiological needs of children ... might be very different from an adult approach to fluids, to electrolytes, [and] to drugs'.⁴²

- 36** We pause to notice that it was at two key points in particular in the care of a child that there was a degree of confusion, or lack of agreement, as to who was ultimately in charge of care, and considerable shortcomings in the practical arrangements. These were when the cardiologist handed over care to the surgeon, and later when the surgeon handed over care to the ICU. In neither of these situations were the arrangements clear and smooth. It is not surprising that difficulties at these two crucial points significantly contributed to making the care of the child on occasions less than adequate. Simply put, the system for maintaining continuity of care was flawed.
- 37** The situation was made worse by the fact that, until 1992, when a registrar in anaesthesia was appointed, there was no *resident* anaesthetist in the BRI on call for the ICU. This meant that at night and on weekends, if an anaesthetist was needed in the ICU, he or she would have to be contacted and drive in from home. It was only on Professor Angelini's insistence, shortly after he arrived, that a room was found so that an anaesthetist could be accommodated and be on call for the ICU at the BRI. We were also told of the recurring shortages of trained nursing staff. Over and above the national shortage, there were difficulties in recruiting trained paediatric intensive care nurses, because at the BRI they had to care for adults as well as children. This was not a good career move for them. Sister Fiona Thomas told us of her continuing concern about staffing levels.⁴³ The ratio in the ICU at the BRI from 1992 was 5.4 whole-time equivalent nurses per patient. The national standard in 1992, to which Sister Fiona Thomas referred us, was 5.1 to 7.8 qualified nurses per patient to provide 24-hour cover per bed. The standard published by the Paediatric Intensive Care Society in 1992, however, recommended 6.4⁴⁴ because the nurse must not only nurse the patient, but also support and care for the family.
- 38** The evidence is compelling that the care provided in the ICU to the children who had just undergone open-heart surgery was less than adequate in a variety of ways. Fundamentally, these failings led back to one principal flaw: a lack of effective leadership.

⁴¹ T72 p. 20 Dr Pryn

⁴² T18 p. 46 Professor Baum

⁴³ WIT 0114 0010, 0019 Fiona Thomas

⁴⁴ WIT 0060 0011 Dr Ratcliffe

The Adequacy of Care

Chapter 17: Parents' Experiences

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Generally

- 1 As the child was prepared for surgery, we heard distressing evidence from some parents about problems with administering pre-medication, and having to say good-bye to their child at the door of the operating theatre. Michael Parsons told us how he had to carry his daughter, Mia, to the operating theatre awake because the pre-medication had not taken effect. He described how Mia screamed as she was taken from him to be given her anaesthetic.¹ At the same time, we also heard warm testimony as to the kindness and efficiency of staff at all stages of treatment. In essence, the evidence of parents was mixed. To some, the staff, doctors, nurses and others were dedicated, 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 misled parents.
- 2 It is important to make clear that we do not rely on the evidence of parents as to the relative skill and technical competence of the doctors and nurses, because these are not matters on which the parents themselves have expertise. Some parents referred in their evidence to the views of experts whom they had consulted in the context of litigation. This, of course, was the experts' evidence, not their own. By contrast, the evidence of parents about their experience in human terms, and in terms of being helped to understand and participate in their child's journey through treatment, carries great weight with us.

Involvement in care

- 3 Parents' reactions to 'child-centred care' differed. Some were pleased to be able to assist in their child's care. Others felt that their involvement in looking after their child was as much a reflection of a lack of staff at the UBH/T as of any actual policy of involvement.
- 4 Michelle Cummings, mother of Charlotte, told us: 'I found it a great help to feel I was included in Charlotte's care, that I was able to do basic things like wash out her mouth and wash her down, not do huge amounts, but it made me feel included. I think that is quite a help for parents.'²
- 5 Karen Welby, mother of Jade, said of another parent: 'While Jade was in for her second operation in 1984, a little boy who was admitted whose mother could not cope at all, she delivered [him to] the hospital and then left a few hours later and said she would

¹ T2 p. 73–5 Michael Parsons

² T95 p. 88 Michelle Cummings

be back after his surgery and after his intensive care. The nurses were very, very busy and they did not have time to play with him, or feed him. Obviously they would have made the time to feed him, but I took over his care, as well as Jade's. ... he was a bit younger than Jade and I had two, both in a high chair, feeding them both at the same time.'³

Parents' experiences: the cardiologists

- 6 We heard from the parents about their initial meetings with the cardiologists. Some recall being told that they had a choice of where to take their child for surgery⁴ while others did not.⁵ The kind of information given by the cardiologist to parents may sometimes have been unduly optimistic. We heard Dr Joffe, consultant paediatric cardiologist, for example, express the view that it was his duty to try to maintain hope.⁶ Such an approach was not unusual for the time. But, by being not wholly truthful, it ran the risk of putting parents in a false position and of sowing the seeds of distrust later on. In particular, such an approach added to the distress of parents if, subsequently, a more pessimistic assessment was made by the surgical team, due to the passage of time or because more information was available. Equally, it made the task more difficult for the surgeon who was put in such a position and potentially damaged relations between the parents and the surgeon.⁷

Parents' experiences: communication

- 7 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 it.⁸ 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.⁹ The sense is gained that informing parents and gaining their consent to treatment was something of a chore. Indeed, Mr Dhasmana, consultant cardiothoracic surgeon, indicated that 'traditionally' the junior doctors used to get parents to sign the consent form after the admission of their child on to the

³ T95 p. 102 Karen Welby

⁴ WIT 0238 0003 Caroline Jones, mother of Matthew

⁵ WIT 0302 0004 Samantha Harris, mother of Kimberley

⁶ T91 p. 35–6 Dr Joffe

⁷ T83 p. 19 Diana Hill; Maria Shortis

⁸ In 1991 Helen Stratton introduced a booklet which she gave to parents

⁹ T6 p. 13–14 Douglas Bwyne, father of Jason

ward 'as a part of their clerking procedure in routine cases'.¹⁰ It certainly did not appear to have attracted the careful thought and attention which might have been expected of a unit also designated a supra regional centre.

- 8** In particular, we heard a great deal of evidence from some parents who were unhappy about the risks and survival rates which were quoted to them before surgery. To the extent that many of the parents' accounts are disputed by the clinicians, we accept that there may be genuine differences in recollection, all honestly held, as to what was said. But this allows us to return to the wider point. It is difficult to imagine a more stressful time for parents. 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. That being so, the sharing of information should be a process. There must be time to take in what has been said, 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. Thus it is largely with the benefit of hindsight that the clear conclusion can be drawn 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 is not a question of the 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. A further point is worth making. It is clear from what we heard that references to percentages, for example, that an operation has an 80% chance of success, is not necessarily helpful for at least two reasons. First, a parent understandably may put a gloss on the figure which plays down the fact that 1 in 5 operations will end in failure. Secondly, a parent may not know whether the clinician is referring to his own, his unit's or some national figures. Indeed, in the absence of agreed reliable data, clinicians have tended to be somewhat less than clear on this matter. If our proposals in Section Two are accepted, this issue will diminish, since data on surgical outcomes will be available to the public.
- 9** Finally, we acknowledge that the clinicians in Bristol as elsewhere were managing an extremely delicate process of communication, and dealing with parents who, quite reasonably, held differing views as to what they wished to be told. For example, Paul Bradley, father of Bethan, told us that he would have wished to be told at the outset as much as possible, even if it was distressing.¹¹ Sharon Tarantino, on the other hand, told us that information, for example, about post-mortems as her daughter Corinna was awaiting surgery, would have been the last thing that she would have wished to hear about¹². As we said in our Interim Report,¹³ information comes at a price. To know is to have to face what has been revealed. What we conclude is to repeat that

¹⁰ WIT 0084 0123 Mr Dhasmana

¹¹ T53 p. 35 Paul Bradley

¹² T53 p. 74 Sharan Tarantino

¹³ 'Removal and retention of human material' 2000. A copy of the Interim Report and Annexes can be found in Annex C

there is a clear need for much greater attention to be given to communication. We take the view that there were occasions when the communication between clinicians and the parents in Bristol was less than adequate. But, against the standards of the time, the practice was probably not greatly different from that which clinicians elsewhere thought appropriate.

Facilities and support available to parents

- 10** We turn now to the facilities available to parents as they waited for their child to recover. Parents were able to stay at the BRI overnight. Although the arrangements were somewhat less than ideal, they do appear to be comparable with those of other hospitals. Parents were also shown the Intensive Care Unit (ICU) so as to prepare them for when they visited their child after surgery. The great majority of parents found this helpful, although some were distressed at realising that adults were also cared for in the same ICU.
- 11** As for support, the Directorate of Surgery at the BRI stated in its document *'Services for Patients'* that counselling of patients and their relatives before and after surgery is a priority.¹⁴ We heard, however, that actions did not always match the words. The view was expressed that funds often only became available to the paediatric cardiac surgical (PCS) service at the BRI in response to a crisis, and that the funding by the hospital of support and counselling was seen as inadequate, reflecting its being given an extremely low priority.¹⁵ By contrast, some stated that, whatever funding difficulties existed, counselling was given a high priority in respect of the training given to nursing staff to enable them to support and counsel the families who were in their care.¹⁶
- 12** Mrs Jean Pratten, founder of the Bristol & South West Children's Heart Circle, stated that a lack of support and co-ordination by management often hindered and complicated the support that the Heart Circle was able to make available.¹⁷ Furthermore, the cardiac surgeons took the view that the development of the medical service, was a better use of resources than meeting the emotional and psychological needs of families.¹⁸

¹⁴ HAA 0097 0009 *'Services for Patients'*, July 1991

¹⁵ WIT 0269 0011 Mrs Pratten; WIT 0534 0005, 0007 Dr Gardner

¹⁶ WIT 0180 0037 Ms Hale; WIT 0150 0043 Miss Gerrish

¹⁷ WIT 0269 0011 – 0012 Mrs Pratten

¹⁸ WIT 0120 0238 Mr Wisheart; WIT 0084 0104 Mr Dhasmana; T47 p. 169 Mrs Vegoda

- 13 Some parents who gave evidence to the Inquiry told us that they were given support and counselling. Others felt that they had received none. Some went so far as to describe their experience as appalling,¹⁹ and as giving the impression the staff were covering up for some mistake.²⁰
- 14 Some parents also gave evidence that they were offered no counselling at all after the death of their child,²¹ and some that they were not even offered a cup of tea or coffee.²² The UBHT conceded in its evidence to us that the service was insufficient to meet the needs of some parents.²³
- 15 In 1993 a survey²⁴ conducted into the level of information and support being given to families attending for catheterisation at the BRHSC²⁵ found that, at the time of initial diagnosis, 45% responded that they did get support from the hospital, 53% said that they did not, and of those who did not get support, 25% said they would have liked to receive it. Thus, at that time, the majority of parents were still not gaining access to, or were unaware of, the support that could be obtained at the BRHSC.
- 16 As with all other matters, there were mixed views about the support services that were available. Mrs Helen Vegoda, Counsellor in Paediatric Cardiology 1988–1996, and Miss Helen Stratton, Cardiac Liaison Nurse 1990–1994, each attracted both praise and criticism. That said, there was ample evidence of a degree of confusion as to the respective roles of the two of them, and the consequent uncertainty it created in the parents. As David Charlton, father of Hannah, put it: ‘We felt we were into “territory issues” between them’.²⁶ There were clear issues of ‘territory’ between Mrs Vegoda and Miss Stratton. We heard evidence, for example, of Miss Stratton being made to feel unwelcome when she visited parents at the BRHSC, and of Mrs Vegoda being told that it was inappropriate for her to visit a family on Ward 5 at the BRI.²⁷ It is not clear whether these difficulties affected the care of patients.²⁸
- 17 Discussions were held in an attempt to resolve the problems. A division of their areas of responsibility was agreed, but it did little to help the working relationship between them.²⁹ The corrosive turf war between Miss Stratton and Mrs Vegoda was never adequately addressed by management and seriously undermined the service which both were able to deliver.

¹⁹ WIT 0260 0004 Erica Pottage, mother of Thomas

²⁰ WIT 0291 0015 Antonio Chiarito, father of Maria

²¹ WIT 0229 0020 Paul Bradley, father of Bethan; WIT 0016 0014 Jean Sullivan, mother of Lee

²² WIT 0458 0013 Rosemary Walker, mother of Ryan

²³ WIT 0291 0022 UBHT

²⁴ WIT 0192 0065 Mrs Vegoda

²⁵ WIT 0192 0072 Mrs Vegoda

²⁶ WIT 0539 0008 David Charlton

²⁷ WIT 0256 0004 Miss Stratton; WIT 0192 0248 and WIT 0192 0250 Mrs Vegoda’s note, ‘Areas of Concern’

²⁸ WIT 0269 0005 Mrs Pratten

²⁹ T47 p. 127–8 Mrs Vegoda

When a child died

- 18** When, sadly, their child died many parents were critical about the way in which bad news was broken. We were told of occasions when there was a lack of privacy, of a perception of being hurried out of the way. Some parents told us that staff appeared anxious for them to leave the hospital and not speak to other parents on the ward.³⁰ At the time, the UBHT's policy was for the parents to be encouraged to return home as soon as possible, and for their general practitioner (GP) to be informed of the situation immediately so that appropriate support could be given locally.³¹ Unhappily, the effect of this on some parents was that they felt that, once their child had died, the hospital ceased to behave as if it had any other responsibilities by way of care.³² We note that, here, perceptions are everything. Philippa Shipley, mother of Amalie, was told that she would have to leave the hospital as 'our presence there would upset other patients and their families'.³³ Malcolm Curnow, father of Verity, recalled that: 'both my wife and I felt under pressure to leave the hospital ... I felt as if we were on a conveyor belt. One of the nursing staff asked us to clear our room, as it was needed by another family'.³⁴
- 19** Other parents, by contrast, commented very favourably on the counselling and support which they received on the death of their child, and indeed for many years after, in the form of cards, telephone calls, and remembrance services.³⁵ Justine Eastwood, mother of Oliver, told us: 'We had the news of Oliver's death broken very gently and privately to us. Privacy, at times like these, was uppermost on the minds of the staff. We were given the option to clean Oliver up and prepare him after his surgery which I declined. We were then allowed as much time as we required just to be with him alone. I remember being spoken to about the necessity of a post-mortem and inquest because of the circumstances under which Oliver died. We did speak with the coroner at a later date about the findings of the inquest'.³⁶ John Mallone, father of Josie, reported how: 'On the morning of Friday 11th January, it was clear that Josie was going to die'. He said the staff put up screens to give them privacy and Josie was taken out of her incubator and placed on a pillow.³⁷ The support provided by staff for parents was complicated by the fact that some nurses and doctors found it very difficult to deal with their own emotions on the death of a child. In such a case, a more senior nurse or counsellor could take over the task of supporting the parents.

³⁰ WIT 0421 0012 Rosemary Riddette-Jones, mother of Luisa

³¹ WIT 0421 0019 Rosemary Riddette-Jones

³² WIT 0415 0009 Karen Meadows, mother of Sarah

³³ WIT 0392 0020 Philippa Shipley

³⁴ WIT 0004 0009 Malcolm Curnow

³⁵ WIT 0184 0012 Robert Langston, father of Oliver; WIT 0288 0011 Tracey Morgan, mother of Daniel; WIT 0244 0014 Alison Havenhand, mother of Victoria; WIT 0225 0011 Lynne Lloyd, mother of Kate; WIT 0229 0023 Paul Bradley, father of Bethan

³⁶ WIT 0022 0015 – 0016 Justine Eastwood

³⁷ WIT 0155 0016 John Mallone

- 20** Our overall impression was that, in circumstances that were harrowing for all concerned, the nursing staff showed considerable sensitivity and support throughout.³⁸ Indeed, the demands, the experience and the skills needed on Ward 5 were recognised to be so exacting that the usual chaplaincy volunteers, who assisted elsewhere at the hospital, were not asked to work there.³⁹
- 21** We heard from some parents of a lack of sensitivity about the process for dealing with the body of the child, especially in terms of information about post-mortem examination and burial. We commented on this issue at length in our Interim Report.⁴⁰ There was also evidence of poor communication between the hospital and the families' health visitors or GP,⁴¹ and even letters sent to parents to bring their child to outpatient appointments, when, in fact, the child had died. On the other hand, we also heard praise for the work of Miss Stratton in offering photographs and handprints when a child had died, and great appreciation for the annual service of remembrance for bereaved parents of children who had died. We acknowledge that finding the least distressing way of breaking bad news to families, particularly immediately following surgery, is a challenge to any hospital system. We also acknowledge that Bristol made some effort in the area of support and counselling. But these services were not given a high priority: indeed, they had to be funded initially from charitable contributions, and they were poorly managed. We regret the low priority attached to what we regard as an essential feature of a service involving high-risk procedures on young children. Moreover, we note that the provision of information to bereaved parents about post-mortems was made the responsibility at the BRI of Mrs Diane Kennington. Mrs Kennington told us that she never received any training to enable her to carry out this role. She was merely assigned the task having previously worked at the BRI as a cashier. At the BRHSC, advice to bereaved parents was the responsibility of the portering staff under Mr Frank Long. They did their best, but without training they cannot be described as the appropriate professionals.

³⁸ WIT 0274 0009 Rev. Yeomans; WIT 0401 0006 Mr MacIntosh, social worker, BRI, since 1997; WIT 0385 0007 Ms Appleton, social worker, BRI, 1989–1994

³⁹ WIT 0274 0005 – 0006 Rev. Yeomans

⁴⁰ *'The Removal and retention of human material'* 2000. A copy of the Interim Report and Annexes can be found in Annex C

⁴¹ WIT 0222 0021 Maria Shortis, mother of Jacinta

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Chapter 18: The Designation of Bristol as a Centre for Neonatal and Infant Cardiac Surgery

- 1 Before we conclude this section on the organisation of paediatric cardiac surgical services (PCS services) in Bristol, it is proper to stand back and ask whether Bristol should ever have been designated as a supra regional centre (SRC) for open-heart paediatric cardiac surgery (PCS) on the under-1s. This, after all, is the area of surgery which is of such concern to us. We must remember that designation took place in 1984. Thus, we can only take account of those factors which were known (or knowable) at the time. But, of course, these include the split site, the shortage of paediatric cardiologists, the lack of a full-time paediatric cardiac surgeon, and the low numbers of open-heart operations being carried out on children under 1. Before we look at what happened, we need to make one point very clear: designation was not the same as permission. Bristol could have carried out open-heart surgery on the under-1s without designation. Indeed, it was the fact that some hospitals did and that there was a proliferation of PCS services which ultimately led to de-designation. But, while designation did not connote permission, it did mean financial support and, more subtly, recognition.

- 2 On one view, given that it was designated, questions of adequacy should focus on how Bristol performed once designated. Alternatively, it could be said that Bristol should not have been designated in the first place. It could be said that problems about adequacy of care were built into Bristol from the start to a greater or lesser extent and were bound to emerge if designation took place. On this view, once designated, these problems and others began to appear. The reason for Bristol's designation is something of a mystery (the evidence is silent as to what *precisely* happened). Certainly, on the criteria which were supposed to guide the process of designation, Bristol did not appear to meet them.¹ Two additional criteria were offered in evidence as explanations: geographical location and the capacity for development. As regards the latter, the evidence showed only very gradual development in Bristol as regards the numbers of children operated on. Moreover, Sir Terence English agreed in evidence that if the capacity for development were a criterion, it should have been closely monitored to see whether in fact it was taking place. On this view, continued designation should depend on an increase in the number of operations carried out. In fact, lack of progress in achieving this increase was reported. But this was taken by the Supra Regional Services Advisory Group (SRSAG) as a ground for urging Bristol to redouble its efforts rather than for insisting on de-designation. We may well regard this as a triumph of hope over experience.

¹ DOH 0002 0023. The criteria were: '1 The service should be an established clinical service. 2 There should be a clearly defined group of patients having a clinical need for the service. 3 The benefits of the service should be sufficient to justify its cost when set against alternative uses of NSH funds. 4 The cost should be high enough to make the service a significant burden for the providing regions. 5 Supra regional funding ... should be clearly justified either a) by the small number of potential patients in relation to the minimal viable workload for a centre or b) by the economic and service benefits of concentrating the service in fewer and larger units shared between regions ... or c) as an interim measure, by the scarcity of the relevant expertise and/or facilities. 6 The units to be designated should be capable of meeting the total national caseload for England and Wales'

The other criterion advanced, geographical location, served both as a ground for justifying the original designation and for the subsequent perseverance. But geography on its own was not a formal criterion as set out by the Department of Health (DoH) in September 1983.² It had been advanced by earlier working parties but was not formally adopted by the DoH.³ In the case of Bristol, however, it became *the* criterion. The argument was twofold. Given that family-centred care was appropriate, it was wrong to ‘disenfranchise’ parents over a wide sweep of the South West and South Wales by causing them to have to go to Southampton (which was awkward to get to), or Birmingham. Secondly, care did not cease once surgery had been carried out. Outpatient care from visiting cardiologists and repeated return trips to the supra regional services centre were on the cards. To travel to Bristol (it was thought) was less onerous for those in the South West and South Wales than to travel further. Set against these arguments is the simple proposition that if it had been put to parents that by travelling 80 miles further up a motorway, the chances of survival of their child could well be doubled (or more), the parents would probably have opted for elsewhere. Nor would the number of operations necessarily have swamped the other centres. Bristol never operated on very many patients in any given year. And the funds allocated to Bristol could have been allocated more efficiently elsewhere to meet the need created by the extra volume of cases. We should also bear in mind that children in Norway were routinely flown for surgery from Bergen in Norway to Leeds with no apparent ill-effects, and children from Germany were flown to Great Ormond Street Hospital.

- 3 There is a case for arguing, therefore, that Bristol was designated for reasons which were wrong: geographical location and potential (the capacity to develop), coupled with the ‘background noise’ of the ambitions of a provincial medical school. It may be too strong to say that the establishment of the PCS service at Bristol was ‘doomed from the start’. It may be fair to say that the designation of Bristol was not a decision which was really in the interests of the child patients. Furthermore, 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. One last counter-argument can be raised: that a lot of children did very well after being cared for in Bristol. But this misses the point. More children died than should have been the case.

² DOH 0002 0023

³ RCSE 0003 0017. ‘*The Second Report of the Joint Cardiology Committee of the RCP/RCSE*’ in 1980 referred to ‘geographical location’

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Chapter 19: Observations on the Organisation of the PCS service

- 1 In the past three chapters, we have examined a number of aspects of the organisation of the paediatric cardiac surgical (PCS) service at Bristol. We now set out our view so far, before proceeding further. The picture we have is of hard-working and dedicated clinicians committed to an area of practice which was demanding, complex and difficult. As Mr Roger Baird, consultant general surgeon and Medical Director, UBHT, 1997–1999, put it: 'I think one of the features about cardiac surgery is that the intervention and the outcome are so closely related to each other that they are quite easily linked in people's minds.'¹
- 2 To cite one of many examples of hard work and commitment, John Mallone, father of Josie, recalled meeting Mr Wisheart on the ward at 3 a.m., knowing that he would be back at work at 8 a.m.² The staff were doing their best as they saw it, within the system at the time. But, in the absence of good, clear, overall organisation and management of the clinical care of the children, it is this dedication which may paradoxically have contributed to the problems of performance. Mr Wisheart, the man at the centre of the PCS service, may simply have been too busy to see the big picture. He concentrated on his surgery rather than on the total range of care, and he lacked sufficient insight into how far he was stretched. The senior consultant surgeons and cardiologists seem to have been unable to find a way out of their difficulties. They simply pressed on, even when things did not improve. There was resistance to the fresh ideas of the new generation of consultants appointed³ and little interest shown by some, or success by others, in improving the management of the Intensive Care Unit (ICU).
- 3 In addition, during the period of our Terms of Reference, the approach to caring for children in acute care hospitals made rapid advances. It became increasingly accepted not only that children are not (in the time-worn cliché) little adults, since they have different physiology and need different technical care, but also that they need to be looked after within a paediatric, family-centred environment. Mixing adults and children in the same ICU was coming under criticism, although it was not uncommon in many hospitals, and it was only from the mid 1990s that a major effort was made to provide sufficient *paediatric* intensive care beds to meet demand. Equally, in the late 1980s and early 1990s there was a rapid development in the concept of intensive care. The idea of the specialist intensivist emerged, usually coming from a background in anaesthesia, with the ability to look across body systems to provide comprehensive care. There were also important developments in the management of ICU, with a consensus developing in favour of the 'closed' ICU, in which all the patients are the responsibility of the clinician in charge who can co-ordinate care, rather than the 'open' ICU in which each patient remains the responsibility of the admitting clinician.
- 4 There is little evidence of Bristol's seeking systematically to embrace these developments, at least at the BRI. Indeed, the evidence is of a conservative, increasingly outdated approach to care, coupled with resistance to those who argued

¹ T29 p. 15 Mr Baird

² T95 p. 161–2 John Mallone

³ e.g. Dr Pryn's records system T72 p. 27, T72 p. 35–6

for, or tried to introduce, change. There was little indication of the development of an understanding in all of the professionals, and particularly the surgeons, of belonging to a team in any sense of the term involving shared responsibilities and consultation across specialties. There was a poor understanding of the importance of teamwork, most particularly in the case of collaboration between cardiologists, anaesthetists and surgeons in the management of the ICU: that teams are necessarily multidisciplinary.

- 5 Nothing effective was done about the difficulties which were identified and recognised. Reference is made now to the unusually complex anatomical difficulties encountered during the surgery, and the less than adequate cardiological support. It could be replied, however, that no attempts by way of practical steps were taken to respond to the problem of lack of cardiological support. Mr Wisheart as Medical Director might, for example, have insisted on mechanisms to improve the cardiological input in the operating theatre and the ICU. Alternatively, he could have said, that without it, the PCS service was not safe. He did neither. Equally, the absence of a sufficient number of nurses trained in paediatric care in the BRI ICU did not cause anyone in a position of responsibility to act.
- 6 The split site and consequent split service were clearly major factors in affecting the adequacy of care. Unifying the site did not attract sufficient priority in the struggle for resources. The claim of the PCS service was 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, and that the new surgeon would arrive, and then all would be well.
- 7 The overall problems which we have identified relate to an inadequacy in the system for providing care rather than in any particular individual. The system for delivering PCS services in Bristol was frankly not up to the task. Things were only made worse by the fact that there was insufficient reflection on, and insight into, the overall care experienced by the children concerned.
- 8 What we observe amounts to a failure of paediatric open-heart surgery to thrive. There is real room for doubt as to whether open-heart PCS on the under-1s should have been designated a supra regional service in Bristol. Once designated, however, it simply never developed sufficiently well. We observe a unit with high aspirations (including at one stage the ambition to become a centre for cardiac 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 the new generation of consultants.

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Chapter 20: Understanding and Assessing the Quality of Clinical Care in Bristol

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Introduction

- 1 We have described how aspects of the management, organisation and delivery of the paediatric cardiac surgical service (PCS service) in Bristol militated against the service's developing towards the standard of care which may have seemed a possibility in the early 1980s. We have also seen how some aspects of the service, notwithstanding our recognition of the difficulties and circumstances of the time, did not consistently reach an adequate standard.
- 2 In this section, we are concerned to determine what, during the period covered by our Terms of Reference, the clinicians in Bristol knew, or should have known, about the quality of care which they were providing: specifically, how they were performing in terms of outcome.
- 3 It is important for what follows to understand what 'outcome' (in the context of surgery) meant to anyone who might be concerned with outcome in Bristol at that time. For clinicians in Bristol, as elsewhere, the main guide to measuring outcome which they used was the rate of mortality following surgery, based on deaths recorded as having occurred in hospital within 30 days of undergoing surgery. This mortality rate was used to assess outcome for the unit as a whole and for particular procedures. By no means does it give a full account of outcome. It says nothing about how well the children fared if they did not die within 30 days: whether they thrived or failed to do so. Thus, even in the context of concerns about outcome, death within 30 days of surgery is, at best, a crude measure.

Audit and information

- 4 To assess outcome, there need first to be standards. Then, there needs to be a system of audit, both at local and national level, which can allow the assessment of performance and outcome in relation to these standards. We have already described how audit developed in the 1980s and 1990s. We are led to the view that, during the period of our Terms of Reference, although there were pockets of activity, and although the Department of Health's (DoH) thinking about audit was developing into a search for mechanisms of quality assurance, no clear national standards of care emerged against which clinicians could confidently expect to compare their performance, and that, even by the end of the period, it is unlikely that any clinician would be expecting to do so.
- 5 Turning to Bristol, Dr Roylance took what can be seen now to be a modern and far-sighted view of audit. He did not regard the activities which went by the name of audit

as being 'truly' audit. Rather, they merely involved the intermittent collection of data. For Dr Roylance, such data could only have meaning, and become part of a true process of audit, if, first of all, there were standards of care against which to evaluate current practice and so give meaning to the data. Then, secondly, he recognised that it was necessary to 'close the audit loop' by improving those aspects of care where standards were not being met. Regrettably, however, despite his being clearly ahead of his time in general terms, his decision to delegate responsibility for audit to the directorates was effectively counter-productive. It reflected his overall approach to management, on which we have commented earlier. It had the effect again of channelling activities into separate and distinct compartments which did not effectively communicate with each other (which we have called the 'silo' effect).

- 6 The consequence of the arrangements for audit was a lack of coherent organisation and co-ordination. In particular the role of the Medical Audit Committee (MAC) was uncertain. For example, following a visit to the UBHT in March 1994, the Regional Audit Team produced a report which noted that power in relation to audit lay with the directorates, whose directors were not members of the MAC. The Regional Audit Team report said that the MAC was bypassed by managers when they addressed audit issues and that there was 'confusion for the Audit Committee over its role'.¹ Because audit was assigned to directorates, funding for audit went to them too, leaving the MAC without resources to do its job. Moreover, Dr Roylance said that he considered it to be the responsibility of the Chair of the MAC to be satisfied that the process of audit was being carried out² and that he should be told by the Chairman if any management action was needed.³ But he also said that if a unit failed to carry out the audit process that would not be a management issue which would involve him.⁴
- 7 The net effect of these various arrangements was that they clearly militated against the development of a strong body of information and analysis that would have enabled healthcare professionals to look across the boundaries of the various specialties to assess the care provided by multidisciplinary teams, of which the PCS service was a particularly obvious example.⁵ Senior management, which could have helped to bring this about, stood back from involvement in audit, in keeping with Dr Roylance's commitment to the autonomy of the clinicians and the need for senior management to avoid 'interference'. But this reluctance on the part of senior management to be involved was common and accepted practice until the early 1990s.⁶ It may well have hindered the development of any effective 'audit loop', but this is a criticism of audit as it was introduced and operated, and of the general absence of standards, rather than a particular comment on Bristol.⁷ In Bristol, there was no survey of the clinical work of the hospital as a whole, and thus no way to gauge its performance in the complete range of its activities. The Annual Reports of the UBHT's Medical (later

¹ UBHT 0024 0076. Dr Thomas rejected the idea that there was confusion; T62 p. 111 Dr Thomas

² T88 p. 136 Dr Roylance

³ T88 p. 137 Dr Roylance

⁴ T88 p. 137 Dr Roylance

⁵ WIT 0108 0019 Dr Roylance

⁶ T28 p. 98 Sir Barry Jackson

⁷ T62 p. 63–4 Dr Walshe

Clinical) Audit Committee, while they were sent to the Region and to the Chief Executive, did not go to the District, nor (before late 1995) to the UBHT Board. Moreover, the audit process addressed only a small selection of topics, all of which were chosen by the clinicians. But this was a product of the system and not something peculiar to Bristol. Audit in the 1990s had simply become a system principally driven by concerns to maintain funding and hampered by the imperatives of the internal market. It is no surprise that the current Chief Medical Officer (CMO) for England commented in a paper in 1998:

‘Although the concept of peer review is well established in the United Kingdom, the implementation of clinical audit in the NHS is not a complete success. Concerns have focused on the failure of audit processes to detect and moderate significant clinical failure; on incomplete participation... on the lack of connection and flow of information to those responsible for managing services; substantial decline to the amount of regional audit; and on the value for money for what amounts to a significant annual investment.’⁸

- 8 It will be recalled that in Bristol topics for audit were selected by the clinicians. There was no mention of the PCS service in the Annual Reports of the Trust’s Audit Committee of 1992 and 1993/94. In other words, the PCS service was not identified by the relevant directorate as a topic to be included in the Trust’s report of its audit activity. Nor was there pressure from the District, since it disclaimed responsibility for requiring audit of paediatric cardiac surgery (PCS) on the under-1s, as this care was funded by the Supra Regional Advisory Service (SRSAG) until 1994.⁹
- 9 As regards the monitoring of the quality of performance of PCS on children under 1, we have seen that there was a significant confusion or lack of clarity about which, if any, body was responsible, which left a hole right at the centre of any efforts at quality assurance. In keeping with the assumptions of the time, no questions were raised about the ability of the Bristol Unit to undertake the surgery. It was simply assumed that the volume and throughput of cases would increase to some appropriate level, and that the quality of care would correspondingly improve. This was because there was a prevailing, although unproven, assumption that quality was directly related to volume. Retrospective statistical analysis commissioned by the Inquiry indicates that this assumption was not entirely unwarranted in that there is an association between mortality rates and volume. For open-heart operations on the under-1s, and for arterial Switches and Atrio-Ventricular Septal Defect (AVSD) operations in particular, centres undertaking a higher volume of operations had lower rates of mortality in the period 1991 to March 1995.¹⁰
- 10 Notwithstanding the lack of audit generally and of any systematic mechanism for monitoring performance, there was information about PCS available to the clinicians in Bristol. There was the data from the UK Cardiac Surgical Register (UKCSR). There

⁸ Scally G, Donaldson LJ. ‘Clinical Governance and the Drive for Quality Improvement in the New NHS in England’ *BMJ* 1998; 317:61–65

⁹ T31 p. 6 Miss Evans

¹⁰ See Annex A Chapter 19

were the surgeons' logs and the data collected by the cardiologists (the South West Congenital Heart Register). Meetings were regularly held: the Clinical Pathology Conference to review the care of any patient who had died; the Surgical Audit meetings to review data on mortality and morbidity; the Paediatric Club to discuss detailed statistical summaries; and the Paediatric Cardiology meetings where results in PCS generally and in specific procedures were discussed. But all the data were seen in isolation. First, there were no agreed standards. Secondly, while data were compared with the UKCSR, as we have seen this was regarded as of limited value as a tool for benchmarking.¹¹ Furthermore, crucially as regards the neo-natal Switch operation, the UKCSR used categories based on diagnosis rather than procedure, so that meaningful comparisons were difficult.

- 11 Moreover, the difficulty in obtaining any reliable data from which conclusions could be drawn was further compounded by the small number of paediatric open-heart operations carried out in Bristol in each of the various diagnostic categories. This meant that, to obtain a large enough series of cases for statistical testing, results from a number of years had to be run together. But by doing this it could be claimed for some considerable time that no trend in outcome could be discerned.
- 12 The inevitable conclusion, therefore, is that, while there may have been a considerable amount of data around, indeed as we have said that Bristol was awash with data, these data offered little by way of real information whereby the BRI surgeons could assess their performance. Certainly, it would have been difficult at the time unequivocally to assess their performance against national figures. It follows that it would have been difficult, *purely on the basis of statistical evidence*, to reach an unequivocal view on the adequacy of the PCS service. It is true that, as our Experts comment,¹² by applying 3-year rolling chi-squared tests¹³ to their own data on open-heart surgery on the under-1s and comparing it to the UK figures, the Bristol clinicians would have identified significant statistical differences had they run together their data into groupings covering 3 years. Such aggregation would have been necessary as the figures for any one year would not have been sufficient to allow any conclusion to be drawn. But they did not have the mindset to undertake such analysis, preferring to believe that things would get better. The Unit also produced a series of three Annual Reports (for 1987, 1988 and 1989–1990) on paediatric cardiology and cardiac surgery at Bristol and made them widely available within the UBH, and, at least as regards the 1987 Report, within the District. The Reports contained figures on open and closed procedures and deaths at Bristol, broken down by age group. The 1989–1990 Report also gave the UK figures for 1988, derived from the reports in the UKCSR, for comparison. The figures on mortality for open-heart surgery in under-1s contained

¹¹ WIT 0085 0052 Mr Dhasmana

¹² See Annex B, 4a: Spiegelhalter D, et al. 'Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995'. September 2000

¹³ The chi-squared test is a standard procedure for comparing two proportions, for example mortality rates at two different units. It is possible to assess how likely it is that any observed difference between the two proportions could have arisen by chance, in a situation where the true underlying rates are identical. Once chance has been eliminated then conventionally this is interpreted as evidence of a genuine difference between the true underlying proportions

in the 1989–1990 Report, when compared with the national data, showed Bristol’s performance to be noticeably worse.

- 13** We asked a group of our Experts to advise us about the Annual Reports of 1987, 1988 and 1989–1990. We asked specifically: ‘What, if any, course(s) of action would you reasonably expect a clinician at Bristol to have taken in the light of these clinical audit data and statistical analyses?’ Mr Leslie Hamilton in his reply¹⁴ made the point that ‘... no clinician would have used the mortality figure from the UK Register as being an accurate model, recognising that deaths are likely to be underreported.’ He stated that while he would not have expected the clinicians in Bristol to focus solely on ‘the absolute mortality rate ... I would expect that the team would look at the management of the patients who died particularly carefully and see if any particular diagnostic group was implicated.’ As regards any course of action to be taken, he stated that the ‘... most realistic option is for the surgeon (and other staff) to go and visit another unit to observe practice and hopefully pick up “tips” that can be used to improve practice.’ He continued that ‘... in 1999 a unit whose results did not improve with these attempts would stop carrying out that procedure. However in the late 80s I believe that the mindset in all units would have been to persevere in making changes in the hope that things would improve.’ Dr Bull¹⁵ advised us that ‘... once the 1989 report was published it could have been formally discerned that the mortality rate for open-heart surgery in infancy in 1988 was excessive in comparison to UKCSR.’ This, in her view, meant that ‘... further exploration of the numbers was necessary internally within the department.’ Dr Macrae¹⁶ took the view that ‘... the failure of the Bristol annual reports to demonstrate an improving mortality should have raised concerns and led to discussions within the unit about the reason for this, and any necessary remedial action, given that in the wider UK context (I note that the UK figures are appended to the 1988 – ‘90 reports) mortality for open heart surgery under one year of age was approximately half of that reported in Bristol.’ Dr Houston agreed with Mr Leslie Hamilton that the individual types of procedure should have been examined and that any further response should have depended on the outcome.
- 14** It could be said that the clinicians in Bristol did take action of the kind suggested. In time, Mr Dhasmana, as we have seen, went to Birmingham with his anaesthetists to observe Mr Brawn’s surgery. Meetings were held at which results generally and in specific procedures were discussed. Both Mr Wisheart and Mr Dhasmana ultimately, albeit much later, ceased to carry out particular procedures (AVSD in Mr Wisheart’s case and neonatal Switch in Mr Dhasmana’s). But the Unit continued to carry out PCS. We come back to mindset, which Mr Leslie Hamilton stressed. The data even when examined still needed a judgment to be taken. That judgment, as Mr Hamilton indicated, was to behave according to the mindset of the time, ‘to persevere ... in the hope that things would improve.’¹⁷

¹⁴ Hamilton L. ‘Expert Comment on the Bristol PCS Annual Reports for 1987; 1988 and 1989/90’, Annex B, 10f

¹⁵ Bull C. ‘Expert Comment on the Bristol PCS Annual Reports for 1987; 1988 and 1989/90’, Annex B, 10i

¹⁶ Macrae D. ‘Expert Comment on the Bristol PCS Annual Reports for 1987; 1988 and 1989/90’, Annex B, 10g

¹⁷ Hamilton L. ‘Expert Comment on the Bristol PCS Annual Reports for 1987; 1988 and 1989/90’, Annex B, 10f

- 15** The Bristol clinicians might also have compared their work with that reported in scientific meetings and publications (for example, Professor de Leval told us that, at a conference in Boston in 1991, he learned that intervention at an earlier age than had previously been the practice in cases of AVSD increased the likelihood of a successful outcome. Subsequently, he changed his practice at Great Ormond Street Hospital and the mortality rate for AVSD fell dramatically). But it was well known that professional journals and meetings tended to report the good results from the larger centres, such that these statistics might not give a true picture of the range of results encountered in practice. One publication in a journal, however, which was relevant to the PCS service was the paper written by two pathologists actually in Bristol. They had identified problems in surgery associated with cardiac anomalies not diagnosed prior to surgery. Their work appeared to go unremarked.¹⁸ Professional meetings did, however, serve other purposes. It was at a meeting of the British Paediatric Cardiac Association (BPCA) in November 1992 that Mr Dhasmana mentioned his problems in relation to the neonatal Switch operation to one of the paediatric cardiologists at the meeting who recommended Mr William Brawn at Birmingham as someone who might help him. Mr Brawn and Mr Babulal Sethia were also at the meeting; Mr Dhasmana spoke to them both there and subsequently went to watch Mr Brawn operating at Birmingham.
- 16** A further source of data throughout the period of our Terms of Reference should be mentioned. This was the hospital administrative system, Patient Administration System (PAS), from which data were fed into the national system, Hospital Episode Statistics (HES). PAS was seen by clinicians generally as a system produced by clerical staff for administrative purposes. The clinicians thought that it was unreliable, not least since the coding¹⁹ was carried out by administrators rather than clinicians. Clinicians only trusted their own data. Thus it did not appear to occur to clinicians to use the HES data as a means of developing views on standards and performance. That said, it would have been difficult to do in any event, since access to the HES data was controlled by the DoH, and the use of large databases such as HES requires specialist skills which most clinicians would not have had. But, as our Experts point out, these data could have served as a good source of information.²⁰
- 17** In the light of our examination of audit generally and of the data available at that time to the clinicians in Bristol, we reach the following view. The surgeons were working in a relatively new and developing field of highly complex surgery. They were dealing with small numbers of disparate congenital cardiac anomalies. Perhaps unsurprisingly, they tended to turn to their own logs of operations as the most detailed, relevant and reliable sources of data. In these logs they saw a pattern of complex cases. In this hard-pressed service, which was attempting to offer the full range of specialist care to these children, as well as meeting all the other needs of a cardiac surgical unit, the poor results achieved were believed then, and are still believed, by

¹⁸ Russell GA, Berry PJ Postmortem audit in a paediatric cardiology unit. *J Clin Pathol* 1989; **42**: 912–918.

¹⁹ Coding is a procedure whereby information from patients' clinical records is recorded according to agreed codes

²⁰ See Annex B, 6a: Evans SJW. *'A report on local data relating to children who received cardiac surgery under the terms of reference of the Bristol Royal Infirmary Inquiry'*, October 1999

Mr Wisheart to be the result of this pattern of complex cases, the result of caring for an unusually high proportion of unusually difficult cases.²¹

- 18** Despite what has been said, it could be argued that, by around 1990, simple statistical comparisons with the available national data for 1988–1989 and 1989–1990 might have suggested, at the very least, that the clinicians in the Bristol Unit should have been asking themselves questions about the Bristol Unit’s performance in open-heart surgery on the under-1s. An analysis could have suggested a pattern of less than adequate performance. This was certainly the case as regards the comparison between the Annual Report on PCS for 1989–1990 and the UK figures. But, given the time lag in the distribution of this national data and in the preparation of the Annual Reports on PCS, the national data would have reached Bristol towards the end of 1990. This was just the time when the first sense of the results in Bristol for 1990 suggested that things were improving: that a corner had been turned. This was confirmed when the results in Bristol became known in mid-1991. As our Experts advise in their ‘Statistical Overview’:

‘... it is not until the data for 1988 were included that the divergence from the national rates became statistically significant, and this was reinforced by the data for 1989. Given that there was a delay of the order of 18 months before the UKCSR data were fed back to centres, it would have been 1990 before the data from the UKCSR might have given any reason for concern, and the independent reinforcement for the 1989 data, which would become available during 1991, would have heightened this concern. However, the data for 1990 then came back into line with national figures ... which might have been taken as reassurance that any problems which might have existed previously had been resolved.’²²

Thus concerns arising in 1990 were understandably assuaged by the good results for that year. Sadly, these good results turned out to be the exception. But even thereafter, other explanations, particularly low numbers from which statistically significant conclusions could not be drawn and what was thought to be a run of unusually complex cases, were called upon.

- 19** We point out again that the PCS service in Bristol was subjected to review. Data were available and they were discussed. They lent themselves, however, to a variety of interpretations, not all of which pointed to poor performance. It is a failure in the system which existed in Bristol, as well as a matter of the greatest regret, that the data were rarely considered by all members of the team together. This could well have led to a more rounded assessment of whether there were problems and where they lay. Moreover, there was a reluctance to challenge interpretations of the data and to look for alternative explanations, both of which attitudes militated against any better understanding of what was happening. This reluctance, while at one level human and understandable, at another level constitutes a further factor contributing to make the PCS service less than adequate. It highlights the fact that there were no effective

²¹ WIT 0120 0298; T92 p. 104–5 Mr Wisheart

²² See Annex B, 4a: Spiegelhalter D, et al. ‘Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995’, September 2000,

systematic mechanisms within the UBH/T as a whole, or beyond Bristol, to evaluate and assess performance. Thus the clinicians, having satisfied themselves that matters were improving, or that there were what to them were good reasons why they were not improving, were not accountable to anyone else.

The Inquiry's independent assessment of the quality of the PCS service in Bristol

- 20** So far, we have looked at data which were known (or knowable) by the clinicians in Bristol at the time. To the extent that mortality rates were one indicator of the adequacy of the care provided, the data we have considered so far were all available at the time. Our concern was whether they were adequately addressed. Now we turn to what can be known with hindsight. We turn to the studies which the Inquiry commissioned from our group of Expert advisers. There were two types of study: the first consisted of a retrospective statistical analysis of all the relevant sources of data on clinical performance; the second was the Clinical Case Note Review (CCNR).

Mortality

- 21** As regards the statistical analysis, the Experts' principal finding was that:

'The single most compelling aspect of the data is the magnitude of the discrepancy between the outcomes observed at Bristol and those observed elsewhere. For children aged under one year undergoing open surgery between 1988 and 1994, the observed mortality rate at Bristol was roughly double that observed elsewhere in 5 out of 7 years. While the national trend over this period was for mortality rates to fall substantially, no such trend was seen in the Bristol results. In spite of the many flaws in the data sources, we do not believe that statistical variation or any systematic bias in data collection can explain a divergence of this magnitude. We therefore conclude that there is strong evidence of divergent performance at Bristol in the areas identified above, and we believe that the imperfections of the data do not cast serious doubt on these conclusions.'²³ They concluded further 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 is clear in their report, 'excess deaths' is a statistical term which refers to the number of deaths observed over and above the number that 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 'excess' mortality over the period 1991–1995

²³ See Annex B, 4a: Spiegelhalter D, et al. 'Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995.' September 2000. Dr Spiegelhalter, et al. state: 'Particular emphasis was placed on the analysis of data from 1991 to 1995, since data were available for that period from both of the national data sources'. See also Annex A Chapter 19

was probably double the rate in England at the time for children under 1, and even greater for children under 30 days. We accept our Experts' conclusions.

- 22** This higher mortality rate in Bristol was not restricted to the neonatal Switch and AVSD operations. As our experts told us, even without taking these two higher risk groups into account, there was considerable evidence of divergent performance in Bristol. Moreover, differences in mortality rates could not be accounted for on the ground of case mix. Importantly, 25% of the excess mortality was accounted for by those whose operations were concentrated just prior to the first birthday. The statistical evidence which we received suggests that surgery may have been delayed, and this observation is supported by other evidence. Witnesses told us that children were not always treated when they needed to be.²⁴ We have come to the view that, having been delayed, children were scheduled (or squeezed in) just before they fell outside the qualifying age group, so as to maintain Bristol's designation as an SRS, in other words for reasons of status as much as for any financial reason. We note further our Experts' observation that in other centres there was a trend over time towards a reduction in the rate of mortality. This did not happen in Bristol. We note a failure to progress, rather than necessarily a deterioration in standards. Such a failure is much more difficult to identify and, if identified, far easier at the time to explain away.
- 23** Despite this objective, retrospective evidence, our Experts were anxious to caution that:

'Clearly there is a consistent and on-going pattern of poor outcomes (from the CSR data) but it is difficult to know what weight should have been put on these data *at the time* (our emphasis), with there being questions over the data quality and with inadequate statistical tools to adjust for case mix and to analyse accumulating data from many different centres.'²⁵

There was no one, nor any group, with the specific responsibility of examining such data and making known any findings, either within the UBHT or outside. The Society of Cardiothoracic Surgeons of Great Britain and Ireland certainly did not perceive that it had any such responsibility. We note that Mr Julien Dussek told the General Medical Council that in his capacity as Secretary to the Society from 1990 to 1995:

'I rarely made any check on the forms other than to ensure that the columns were correctly filled in. On one occasion I did write back to a particular unit to check that their mortality figure was low (and it was) although I never wrote to confirm that a mortality rate was particularly high.'²⁶

He stated that: '... at no time did the subject of Bristol ever come up at our Executive meetings or our Annual Business Meetings.'²⁷ We note that the approach of the

²⁴ See Annex A Chapter 12 on waiting times

²⁵ See Annex B, 6c and 7f

²⁶ GMC 0014 0093 Mr Dussek

²⁷ WIT 0067 0011 Mr Dussek

Society has since changed. The Society decided that from April 1997 'surgeon-specific outcome data' would be returned and that the 'President of the Society will seek clarification from any surgeon whose performance lies outside pre-defined limits. ... If concerns persist ... the Medical Director of the Trust will be contacted and the Society will provide, in conjunction with the Royal College of Surgeons, a discrete and supportive external review.'²⁸ At the time, however, the explanations offered by the clinicians to themselves and others went unchallenged. Mr Wisheart thought that his bad results in AVSD were explained by a run of unusually complex cases. As regards the neonatal Switch, Mr Dhasmana thought the explanation lay in a combination of the learning curve, surgical technique, organisation of the staff in the operating theatre and pre- and post-operative management.²⁹

Morbidity

24 As well as examining rates of mortality, our Experts also examined the available statistical data on levels of morbidity following PCS in Bristol in relation to other specialist centres. Their overall conclusion was that the sources of routine data which are available do not serve as an appropriate basis for drawing any firm conclusions concerning morbidity rates in Bristol. While there was an apparently high rate of neurological complications in Bristol compared with other centres, our Experts considered it likely that there was under-recording of complications in all centres, with Bristol being slightly more full in its reporting. They also noted that the numerous sources of data in Bristol were not greatly in agreement with each other. Dr Kate Bull, one of our Experts, described some of the difficulties involved in examining morbidity following PCS, and in particular in determining the prevalence of brain damage following surgery. She drew attention to the importance of the need to conduct long-term cohort studies involving a range of disciplines, and to the relevance of the pre-operative condition of the child. She explained, further, that morbidity in the form of brain damage following children's heart surgery tended to involve a chain of causation, and that 'seeking out a single cause of a complication is often not realistic'.³⁰ Dr Ted Sumner, one of our Experts in paediatric intensive care, was asked whether a higher incidence of post-operative morbidity could be expected in a unit with a higher incidence of mortality. He told us of studies relating to cardiac surgery in adults in the USA: 'I could not find any from this country ... I think there were more than 50 centres involved in the data collection. It transpired that centres with a low mortality, good centres, had the same complication rate as centres with the higher mortality. But the difference was that the better centres, that is, centres with a lower mortality in adult cardiac surgery, had a better record of rescue of the complications, that is, they recognised them earlier and treated them better, for the same severity score.'³¹

²⁸ WIT 0163 0002 Mr Keogh

²⁹ WIT 0084 0113 Mr Dhasmana

³⁰ INQ 0049 0007 Dr Bull

³¹ T81 p. 83 Dr Sumner

The Clinical Case Note Review

- 25** Statistical data are only one way of assessing performance. At the very least they should give rise to questions as to whether there is a problem concerning the outcomes of care. They can tell us little, however, about the reasons for these outcomes. Thus, to examine in detail the clinical care provided, we commissioned a further retrospective analysis, the Clinical Case Note Review (CCNR).³² A random stratified sample of 80 cases was selected from the case notes of 1,827 children who underwent open- or closed-heart surgery at Bristol between 1984 and 1995. The sample was weighted so as to reflect the concerns which gave rise to the Inquiry. Thus it was weighted towards younger children, towards those who had open-heart surgery and towards those who died. The case notes of each of the 80 cases were reviewed by multidisciplinary teams of clinical Experts (doctors and nurses). Each group of Experts was asked to assess the adequacy of care provided to the child, both in overall terms and at various stages in treatment. Where they reached the view that a child had received less than adequate care, the Expert team was asked to assess whether this might have had an impact on the outcome for that child. The results of the CCNR suggested that for 70% of the children, care was thought, overall, to have been adequate, but for 30% care was thought to have been less than adequate to varying degrees. In 9% of cases, the less than adequate care might have, or could reasonably be expected to have, affected the outcome for the child.
- 26** We acknowledge a number of possible caveats. First, our Experts were anxious to point out that their study did not involve comparison with other centres performing PCS at that time. We take the view, however, that the wide range of expertise among the reviewers does offer an indirect comparison with practice at other institutions. Moreover, the adequacy of the care in Bristol falls to be judged on the basis of our Experts' views as to what could properly have been expected of clinicians at the time, wherever they were. Secondly, our Experts also accept that the case notes cannot tell the whole story of a child's care. There are many discussions and actions which do not appear in the notes. That said, the notes convey a sufficiently clear picture of the care provided to allow a view to be taken. Thirdly, it must be true that all centres are likely to have cases where treatment was less than adequate and that such shortcomings might have affected outcome. But we are concerned with the adequacy of care in Bristol. Thus we accept our Experts' findings that for three in ten of the children care was less than adequate to varying degrees.³³
- 27** In reaching this conclusion, it is extremely important to understand what the CCNR actually found. Problems rarely arose, according to the CCNR, from the particular activity of any individual clinician. In most cases, the case notes suggest that problems arose from the management of care *as a whole*. Our Experts identified a number of

³² The full report by Mr Hamilton and Dr Silove is in Annex B, 12a

³³ We also accept that we can validly extrapolate from the sample of 80 cases. Details of the process of selecting and weighting the sample are given in the annexes to the CCNR Report. See a supplementary technical note from Professor Stephen Evans, Annex B, 12d

factors. They included: delays between diagnosis and treatment; shortcomings in the cardiological input both before and after surgery; some weaknesses in surgery; shortcomings in the organisation of intensive care; and difficulties in delivering care across two sites. Their findings are validated by the degree of agreement among and between the various teams of Experts reviewing the cases.

- 28** Among the detailed comments made by the Experts who conducted the CCNR were the following.³⁴ Professor John Deanfield wrote that his team had identified as a common feature that: 'There was often considerable delay between primary referral and appropriate investigation by the cardiologists. In some cases, despite adequate diagnosis, surgery was delayed to an extent which jeopardised outcome (e.g. AVSD). Furthermore, further delays often occurred between referral to the surgeon and conduct of the surgery itself.' He went on that: 'Intensive care at the Bristol Royal Infirmary appears to have been fragmented and insular in approach. For example, failure to anticipate clinical problems, delayed response to post-operative problems and failure to involve other team members (eg. cardiology, surgery and other disciplines) contributed to poor overall performance.' Dr Barry Keeton drew particular attention to the concern: 'about the lack of evidence of regular input and involvement by members of the paediatric cardiology team in the post-operative management of the patients'. The team of which he was a member felt: 'that the split nature of the sites for care of children's cardiology was clearly hampering the communication between the various professionals within the team and perhaps the co-ordination of the child's care'. Dr David Hallworth's team wrote that: 'the feeling is of children being cared for by staff who are much more used to dealing with adult patients'.
- 29** In addition, in his evidence during the hearings in Phase One, Professor de Leval told us of the impact on the outcome of surgery of multiple minor errors. He told us that, taken together, and without the technique or experience to develop defensive mechanisms against them, they were far more likely to endanger the success of any procedure than a single major error.³⁵ The arrangements at Bristol were almost calculated to produce such minor errors, given the split site, the lack of cardiological input in the operating theatre and ICU, the lack of trained nurses, and the lack of co-ordination in the ICU. Mr Dhasmana described the benefits of a dedicated paediatric cardiac surgical assistant or well-trained theatre nurses, as he saw in place in Birmingham.³⁶ Moreover, it was clear from disagreements among our Experts that some of the problems identified were not unique to Bristol and still remain to be resolved. For example, Dr Eric Silove and Dr Alan Houston disagreed about the relative responsibilities of the surgeon and the cardiologist in the care of a child at various stages.³⁷ Furthermore, on the question of who is in charge in the ICU, our Experts showed that confusion still appears to be the order of the day. The nurse identified the intensivist, the cardiologist said that no one is in charge but everyone is responsible, the intensivist said that there must be one person in charge without

³⁴ See Annex B, 12b: Letters from team leaders of the review on general observations arising from undertaking the CCNR, October 1999

³⁵ T50 p. 69 Professor de Leval

³⁶ T85 p. 12 Mr Dhasmana

³⁷ T49 p. 117 Dr Silove and Dr Houston

identifying whom, and the surgeon while suggesting a procedure identifying the cardiologist as the person in charge pre-operatively, the surgeon during surgery and the intensivist post-operatively, indicated that fundamentally the surgeon remained in charge, even in the ICU.

Conclusions

- 1 With regard to the systems in place to seek to secure the provision of adequate care, there were elements both in the arrangements at Bristol, particularly aspects of management, poorly developed teamwork, and split service, and more widely beyond Bristol, for instance, the respective roles of the SRSAG, the Royal Colleges, the Regional Health Authority, the District Health Authority, the Trust (after 1991), and the DoH in quality assurance, that were conducive to the PCS service being less than adequate on occasions. But it is crucial to recognise that, at that time, some of these factors, in particular the split service, which was heavily implicated in affecting adversely the quality of care, were regarded as a challenge to be overcome rather than as an obstacle or barrier warranting the cessation of the PCS service. The thinking seems to have been that things would get better in time, once the plans to consolidate the service at the BRHSC were realised. In the interim, the tradition in the NHS of overcoming the odds drowned out any messages that things were worse than they should be.
- 2 In addition to the shortcomings in the systems underpinning the PCS service, there is the separate question of whether there was sufficient evidence at that time that the service *as a whole*, whatever the outcome in particular cases, was less than adequate. On balance, we take the view that, had there been a mindset to carry out the necessary analysis, the figures for 1987, 1988 and 1989 could have alerted the clinicians in Bristol by 1990 that there was a need to stop and take stock of their results. The absence of such a mindset may have allowed them to wish away their poor results because of the improvements shown by the 1990 data. But certainly, at least by 1992, notwithstanding the false assurance of the 1990 data, there was evidence sufficient to put the Unit on notice that there were questions to be answered as regards the adequacy of the service.
- 3 At the time, however, there was a temptation for the clinicians to persuade themselves, even in the face of such evidence, that any poor outcome could quite plausibly be explained away. They could equally plausibly speak in terms of an expectation of improvement over time, notwithstanding the failure of Bristol's performance to improve in comparison with improvements reported in other units. Indeed, Mr Dhasmana spoke in terms of the 'inevitability' of a 'learning curve', by which it was meant that results could be expected to be poor initially, but would improve over time with experience.¹ They could argue that the small numbers of children who were treated meant that their figures looked worse when expressed in percentage terms, that they treated children who were more sick (albeit that there was no evidence to support this assertion) and that, once the hoped-for new surgeon was appointed, the pace of improvement would quicken. All of these arguments had sufficient plausibility at that time that they could be believed, and they could not readily be refuted, though they might be doubted.

¹ WIT 0084 0115 Mr Dhasmana

- 4 It could be argued that there was a duty on the clinicians to challenge their own rather easy explanations. But they were working in a tradition and against a background in which, sadly, there was no system in place which could provide reliable and meaningful information which could be analysed and which could not be explained away. Only they could effectively challenge their results. They did discuss their data: Mr Dhasmana did seek help from the team in Birmingham. But, with hindsight, they were too easily persuaded that their poor results were a run of bad luck or that things would improve. To some in Bristol the cup was dangerously empty, to others it was half full, and neither could be proved wrong.
- 5 Turning to the concerns expressed by parents, parental dissatisfaction with the PCS service may well have existed throughout the period of our Terms of Reference. It only really surfaced, however, in any significant sense after 1995. Indeed, we note that during the entire period of our Terms of Reference the UBHT records show only two formal complaints regarding PCS.² Certainly, any parental dissatisfaction did not, at that time, serve as a reason for stopping all or some PCS, or even for re-evaluating the programme. Of course, this is no surprise since parents could never get an overall perspective, concentrating as they naturally were on their own child. Furthermore, there was no system in existence to discover their feelings and views so as to respond to them.
- 6 *We conclude that the PCS service for children who received open-heart surgery was, on a number of criteria, less than adequate.* The statistical evidence allows us to reach this conclusion as regards children under 1 who had open-heart surgery between 1988 and 1994. The rest of the evidence, including for example that of the parents, the clinicians in Bristol and the Clinical Case Note Review, allows us to go further and say that the service was less than adequate over the whole period of our Terms of Reference and as regards open-heart surgery on all children, whether under or over 1. But this judgment, to the extent that it is based on reliable and verifiable evidence, relies heavily on hindsight. At the time, while the PCS service was less than adequate, it would have taken a different mindset from the one which 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, and adopting what may be called the precautionary principle. This did not occur to them. This is one of the tragedies of Bristol.

² The Inquiry asked the UBHT to check all complaints made by patients (or carers) between 1984 and 1995. The UBHT received a total of 1,703 complaints. Of these, two related to concerns of patients following the death of their child admitted for paediatric cardiac care, one in 1986 and the other in 1993. UBHT 0345 0001

- 7 We reach one conclusion which owes nothing to hindsight. It relates to what we described earlier: the problem of poor teamwork and the implications this had 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 UBHT. There were logistical reasons for this: for example, the cardiologists could not be everywhere. But the point is that, knowing this, they carried on. Also, relations between the various professional groups were on occasions poor. All the professionals involved in the PCS service must bear responsibility for this. But, in particular, it demonstrates a clear lack of effective clinical leadership. Those in positions of clinical leadership must therefore bear the responsibility for this failure and the undoubted adverse effect it had on the adequacy of the PCS service.

Chapter 21: Introduction

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The Inquiry's Task

- 1 The final part of the Inquiry's Terms of Reference asked the Panel, in the light of findings from Bristol, to '*make recommendations which could help to secure high quality care across the NHS.*'¹ It was the philosopher George Santayana who remarked that 'those who cannot remember the past are condemned to repeat it.' The aim of this section of our Report, therefore, must be to build a bridge between the lessons of the past and the NHS of the future and, in so doing, our aspiration is that Bristol will be remembered not merely as a synonym for tragedy but also as a turning point for the NHS.
- 2 This is a daunting and a challenging task. A good deal has changed in the NHS since 1995, the cut-off point for our examination of the events in Bristol, not least the very significant improvements in paediatric cardiac surgical services in Bristol itself. The quality of healthcare is currently high on the agenda of healthcare professionals, the wider public and government. It is central to '*The NHS Plan*'² and to the purpose of such recently created bodies as the Commission for Health Improvement (CHI) and the National Institute for Clinical Excellence (NICE). In responding to our Terms of Reference, we have taken account of these initiatives aimed at improving the quality of healthcare. We have not seen it as our role to overturn them. Where recent changes are likely to help address the messages from Bristol we shall say so. But we believe that the lessons of Bristol must be applied at a more fundamental level. The question which we seek to address is this: what needs to be done, in terms of the needs of patients, the culture of healthcare, the role of healthcare professionals and the role of the NHS locally and nationally for the quality of care to improve, and to keep improving? Or, to put it another way, what was it that was absent from the healthcare system as a whole during the 'Bristol years', and is still absent today? For, despite the recent changes and initiatives, it is not necessarily the case that all of the lessons of Bristol have been learned. Even today, it is still not possible to say, categorically, that events similar to those which happened at Bristol could not happen again in the UK: indeed, are not happening at this moment.
- 3 Clearly, the Inquiry's brief is extremely broad. In addressing it, we wish to make one prior point of the utmost importance. It is inevitable that in this Inquiry the emphasis has been on failures and shortcomings in the NHS. This should not cause us to 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. This must never be forgotten or overlooked, and it forms the essential backdrop to all that we say in this section of the Report.
- 4 While the events in Bristol are our starting point, we do not confine ourselves to recommendations relating only to paediatric cardiac services or to services in Bristol.

¹ We take our Terms of Reference as applying to the NHS in England

² '*The NHS Plan*', London: Department of Health, July 2000

As the evidence in Phase One made clear, while some problems were specific to Bristol, in many ways the Bristol experience exemplified what were and are national issues within the NHS. Thus, in considering our recommendations for the future, we look across the spectrum of the NHS: at its resources; at its culture; at the professionals who deliver healthcare (which we take to include doctors, nurses, other healthcare professionals *and* managers).³ We also look at the systems and organisations which support healthcare, as well as at the external environment of policy, governance and regulation. Given the context of the Inquiry, the focus is necessarily on acute and children's hospitals.⁴ It may well be, however, that many of the recommendations can be applied more widely to other parts of the NHS. We do not lose sight of the fact that it was a concern for the care of children which led to the Inquiry. Thus we also address the particular needs of children and their families in the NHS. We ask whether any further recommendations are called for to meet these particular needs and, if so, what they should be.

- 5 We believe that there is an enormous desire across the country, amongst the public, patients and healthcare professionals, to renew our commitment to the NHS and make it work for everyone. The recent injection of substantially increased funding into the NHS means that, for the first time in many years, there is now the opportunity to broaden the debate about what needs to change in the health service. We can begin to move beyond an exclusive focus on the level of funding, to embrace more fundamental issues about the culture of healthcare, the safety of medicine, and how to improve the quality of care for patients. That said, the recent injection of funding does not mean we can be complacent about resources: healthcare of good quality comes at a price. Increases in funding need to be sustained. Furthermore, if we are to continue to have a state-funded system of healthcare, the government must care about and take care of the NHS.

Phase Two of the Inquiry

- 6 Phase One focused on the evidence of what happened in Bristol. It served to identify problems that need to be addressed. After hearing the Bristol evidence, we turned to Phase Two of the Inquiry. In response to the requirement in the Inquiry's Terms of Reference to make recommendations to '*help to secure high quality care across the NHS*', we asked questions as to what was currently working well within the NHS and what was working less well and why. We decided to seek an answer to the deceptively simple problem: what are the determining factors which enable a large complex organisation to meet its objectives? We sought ideas, submissions and argument on seven topics from over 150 experts and more than 50 organisations. We chose the

³ We concentrate throughout on those who provide and manage care and treatment. By so doing we do not ignore the contribution to healthcare made by others who work in the NHS

⁴ We recognise, of course, that there is more to health than acute healthcare in hospitals, not least health promotion, preventative care and other social strategies

seven topics because the evidence we heard during Phase One suggested that they were of central relevance to the quality of healthcare. The seminar topics were as follows:

- what factors influence an organisation's performance, and what factors influence the performance of the NHS;
- the culture of the NHS;
- leadership;
- people: education, training, development and regulation of professionals;
- systems: safety, risk and information;
- empowering the public and patients; and
- children and children's healthcare services.

7 On each topic, the Inquiry's Panel sought written submissions from a wide range of interested organisations and subsequently held a seminar, in public, with 20 or so invited participants. All of the written contributions, plus an account of each seminar, were published on the Inquiry's website during the course of spring and summer 2000.⁵ We heard from people working within or close to the NHS, as well as from those who hold senior positions in entirely different walks of life, elsewhere in the public sector, and in the private sector. Other large organisations, both public and private, face challenges similar to those confronted by the NHS, in terms of pursuing quality and safety, leading and managing a workforce of professionals, working within tight financial constraints, while subject to a variety of regulatory frameworks. We were struck by how frequently it was asserted in the Inquiry's seminars that the NHS is unique and yet how often, on examination, the similarities to other organisations became apparent.

8 To illustrate the point, there are many other organisations which employ professionally qualified people who give a service direct to the public. We heard from schools and local authorities, and from law and accountancy firms. Other industries face issues of quality and safety, not least the nuclear, chemical and airline industries. We invited contributions from participants from these sectors also. On the issue of safety, we were very struck by the way in which the airline industry has been active over the years in improving safety. By way of illustration, in a recent pilot study, Professor Charles Vincent and colleagues wrote that: 'Although we cannot extrapolate with any precision, our findings strongly suggest that adverse events are a serious problem in the NHS, as they are in the United States and Australia. We estimate that around 5% of the 8.5 million patients admitted to hospitals in England and Wales

⁵ See Annex B for a summary report of each seminar. See Inquiry website www.bristol-inquiry.org.uk for the discussion points and the position papers submitted by individuals and by organisations to each seminar

each year experience *preventable* [our emphasis] adverse events ...'⁶ Professor Vincent was not able to say, at this stage, what proportion of these preventable adverse events result in death. Studies in the USA suggest that the numbers are high. Estimates vary, but it is said that between 44,000 and 98,000 Americans die in hospitals each year as a result of preventable medical errors, some of which are due to accidents, others to negligence.⁷ If the rate were similar in the UK, then as many as 25,000 people could be dying each year from preventable adverse events. Whether the result of accident or negligence, all are, by definition, avoidable. This scale of human loss is the equivalent of the avoidable crashing of one jumbo jet a week. If air travel were so unsafe, it is unlikely that airlines would survive more than two or three weeks. Something would be done. Of course, air travel is an extremely safe form of transport. Systems and procedures have been put in place to ensure this. The question which demands an answer is why, in the face of the evidence of avoidable deaths (and ignoring for the moment the undoubtedly larger incidence of avoidable injury), this is not so in the case of the NHS. One of the challenges for the future becomes, therefore, what can the NHS learn from other large organisations which have confronted and addressed issues such as safety which are of major concern to the NHS.

Guiding principles underlying our approach and recommendations

- 9 We take some principles as given, in so far as they are central to the NHS and served as the guiding principles in its creation. They are reasserted in *'The NHS Plan'*. They include that the NHS be a publicly-funded service, free at the point of delivery, that it provide a comprehensive service and that there be equity in people's access to its services. To these we add certain principles which have guided us in our Inquiry and which underpin our recommendations. Whatever the uncertainties of the future, they are the underlying conditions which are essential to ensure that the quality of care is improved and sustained over time. The principles are as follows:
 - 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 policy, planning and delivery of services at every level.

⁶ Vincent C, Neale G, Woloshynowch M. 'Adverse events in British hospitals: preliminary retrospective overview.' *BMJ* 2001; **322**: 517 – 519. www.bmj.com Professor Vincent defines an adverse event as: '... unintended injuries caused by medical management rather than the disease process'

⁷ Kohn L. et al., eds. *To Err is Human: Building a Safer Health System*, Washington DC: National Academy Press, 1999; p. 26 gives details of two studies, one in New York state and the other in the states of Utah and Colorado, where the percentages of adverse events resulting in death were, respectively, 13.6% and 8.8%

- 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 and mistakes, 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.

Recognising the complexity of the NHS

- 10** One of the key messages from Bristol which has guided us is the profoundly complex nature of healthcare and of hospitals, and the unbalancing effect of adopting at any given time an approach to improvement which concentrates on one specific, single issue. Not only is the NHS highly complex in its processes and its organisation, but healthcare and medicine are constantly changing, as are patients' needs and expectations. It follows that this Inquiry's Panel cannot anticipate all the challenges which the NHS may face ten or even five years from now. Therefore, our recommendations are intended to be realistic and workable in the near to medium term.
- 11** There is no 'quick fix' to the challenges which we identify. Change needs time and patience. In an organisation as large and complex as the NHS, which has deeply entrenched patterns of behaviour, forged over the 50-plus years of its existence, sustained change for the better will take years, not months. This calls for political nerve. It calls for consistency of direction. It calls not for one-off injections of funds but a significant and sustained increase in resources. It calls for sympathetic understanding, since little of lasting value can be achieved without consent and co-operation. And it calls for a reaffirmation of the values and mission which are ultimately what the NHS is about. Thus we are wary of suggesting what may be seen as grand or iconic gestures whereby the pressure for change can be bought off, but

little of substance actually changes. Our approach is more to work with the grain, and to make proposals which are likely to be capable of implementation. Thus our recommendations are a mixture of longer-term 'directions of travel' and a series of particular measures which are 'bite-size' in nature. Taken together, over time, they can begin the process of reshaping the NHS in the manner which, we are convinced, all those who use and who work in the service would wish.

Patients must be at the centre of the NHS

- 12** The NHS exists as a service to patients. Those whom it exists to serve are all of us, since we are all patients at some point in our lives. The legitimate needs of patients must be at the centre of the NHS and thus they are at the centre of our recommendations. There may have been times when it has appeared that the NHS was organised more in the interests of those who work in it than of those for whom it exists. It was the General Medical Council (GMC), in its contribution to Phase Two, which described the NHS as 'too heavily provider-oriented and too unresponsive to the people it serves.'⁸ This approach must be consigned to history. It is not the way forward. But a patient-centred service does not mean, and should not be taken to mean, a patient-dominated service, in which doctors, nurses, managers and other healthcare workers are regarded merely as functionaries. This would be to devalue, indeed ignore, the professionalism of those who work in the NHS. This professionalism must be respected and given its proper place.

Recognising the dedication of NHS staff

- 13** Whatever the changes in the NHS in the course of its history, there have been certain constants. Principal among these is the dedication and commitment of those who work in and for the NHS. We acknowledge and wish to harness these qualities. What we are seeking is an NHS which will marshal these qualities fully in the service of the public and of patients: to create a partnership in which all respect the needs and claims of others. The changes which we recommend, therefore, are intended both to be in tune with the values of public service and to allow professionals in the NHS the opportunity, the time and the space to fulfil the commitment they have chosen to undertake. Furthermore, the changes must be backed in large part by incentives, since, in our view, the carrot always works better than the stick. Of course *incentives* in the public sector are not easy to fashion. But as soon as incentives are understood as not being confined solely to financial rewards for individuals, creative approaches can be adopted. We have sought to reflect this need for incentives in all that we propose.

A comprehensive approach to quality with safety as the foundation

- 14** We are convinced that the only definition of quality in the context of healthcare which can be of real value has to be one which is all-embracing. A first condition for achieving quality in healthcare is that the service is safe. Once safety, as a fundamental prerequisite, has been addressed, attention must turn to the pursuit of

⁸ Seminar 3. General Medical Council. Position Paper

quality. In essence, this involves identifying what will enable the NHS to meet its own high objectives and values. For us, this translates into the following concrete requirements. The quality of healthcare can only meet levels of which the NHS can be proud, if healthcare first encompasses the notions of respect for and honesty towards patients. It must recognise the emotional as well as the physical needs of patients (and their families). It must be delivered by competent staff who have suitable facilities and are always striving for improvement. It must be informed by up-to-date medical knowledge, including mechanisms for assessing the effectiveness and value of treatment. It must be safe, avoiding error and accident as far as is possible. It must be appropriate for and responsive to the needs of the patient, including being available when needed, in good time and accessible. Finally, responsibility for the quality of healthcare services must rest with some identifiable person. That person now is the chief executive of each trust.⁹

- 15 A particular feature in our approach should be noted. Traditionally, analyses of the quality of healthcare have concentrated largely on the skills of the healthcare professionals who work in the NHS. More recently, attention has turned to the systems by which healthcare is delivered, focusing on such systems as those concerned with safety, standards, and the ‘pathway’ of patients’ care as they move between GP and hospital. We go further. We are also concerned with the *attitudes* which those in the NHS bring to their work: how they relate to and respect the interests of patients. We are saying, in effect, that to secure care of high quality across the NHS, we can no longer overlook those elements of the service which go beyond technical skills and competence and beyond the systems in which they are practised. We have to care about attitudes, about respect and honesty, indeed about a partnership between patients and professionals.

Systems affect the quality of healthcare

- 16 The skills of healthcare professionals are only one component of the quality of care. As we learned from Bristol, an individual clinician’s effectiveness is significantly influenced by other matters, such as the physical arrangements for healthcare, the availability of equipment, the members of the team, whether there are standards and protocols for practice and the extent to which these are followed and monitored.
- 17 As we set out in the introduction to Section One of our Report, throughout the Inquiry, both in its conduct and in framing our recommendations, we have been convinced of the value of what is known as the ‘human factors’ approach to understanding how people behave and function in complex systems. According to this approach, the performance of an organisation must be understood in terms of the complex interaction of factors which, only when taken together, explain success or failure. Thus, whatever the temptation to focus on the actions of individuals and to seek to blame someone when things go wrong, it is as important to pay attention to the system(s) in which those individuals find themselves.

⁹ Throughout we use the word ‘trust’ to refer to an NHS acute hospital or healthcare trust. We do not intend it to refer to any other type of trust. Whenever we wish also to include primary care trusts we specifically say so

- 18** The human factors approach suggests that, in any particular example of failure, there will have been a set of underlying factors which set the scene for the failure, as well as the more obvious direct factors which were the immediate cause. Thus, for example, if we are *to learn* how to avoid repeating it in the future, a surgeon's error must be understood not as a single, isolated occurrence, but as part of a system in which a host of other factors may well have played a part. These may be more or less visible, ranging from the surgeon's own skills to, for example, the training and competence of the theatre nurses, the quality of the equipment, the morale of the unit, or even of the hospital, and the pressures of time and resources. Using this example, to concentrate on the surgeon's error *in isolation* is to misdiagnose the problem and thus run the risk of it being repeated on another patient.

Learning from mistakes

- 19** The history of the NHS is littered with the reports of Inquiries and Commissions: most have soon been consigned to gather dust on shelves. There must be many reasons for this. Perhaps one significant reason is the prevailing culture of blame and stigma. A serious failure of some sort occurs somewhere in the NHS. An Inquiry is set up. Months, or years, later, a report is published. Almost always, the report singles out an individual, or group, who are held to have been responsible. The individual is condemned. The NHS proceeds on its way, assuming that the matter is resolved: until the next serious failure.
- 20** The flaw in this approach is obvious. While it may be appropriate to criticise some individual(s), it is often too easy a response to stop at that point. Crucially, it deflects attention from the context in which that individual was working. The individual may be replaced, but the underlying environment, which gave rise to the problem, goes unchanged. It will only be a matter of time, therefore, before the same, or a similar, set of problems arise again in the same place or elsewhere in the NHS.
- 21** Throughout our Inquiry we have adopted an approach which looks beyond individuals to the systems within which they work. We do not reject the concepts of blame, or of individual accountability. When individuals are held accountable and shown to be guilty of misconduct, blame is both necessary and appropriate. What we reject is recourse to blame as a necessary, almost a reflex action, as if it were a solution in itself. What we also reject is the assumption that if individuals have been blamed, this is proof that an organisation has been held to account. Accountability is a complex notion, calling for a variety of mechanisms, as much active as reactive. Singling out individuals for blame after the event is an entirely different exercise. Its contribution to the effective performance of an organisation is at best limited and it can sometimes be counterproductive. It certainly is not a proxy for a proper, rigorous process of accountability.
- 22** One important lesson from Bristol is how, by concentrating on this or that person, by seeing things simply in terms of people, even those in Bristol who wanted action left the larger issues unaddressed. This is crucially important. Our aim is to encourage

change, with a view to empowering and assisting professionals within the NHS to serve those for whom it exists: the public. In doing so, criticisms may be made. But they are made constructively, to clear the air, to offer a prospect of healing divisions, of rebuilding trust and starting again.

Developing an open and transparent NHS

- 23** A further principle which has guided us is the need for an ethos of openness and transparency in the NHS of the future. The NHS must let in and work with the public: it must celebrate its successes and make known its shortcomings. Of all our guiding principles, this is perhaps the most significant and the most difficult to put into action. But, if it is not translated into practice, little progress can be made. Celebrating success appears unproblematic, even if there will always be sceptics (and rivals) who challenge the criteria. Admitting shortcomings, however, is a wholly different matter. It constitutes an immense challenge. Most important, it calls for maturity, and since we emphasise partnership between patient and healthcare professional, we point out that the maturity must come from both. Patients and the public must understand that not everyone can be the best and that data need careful understanding. Healthcare professionals must face up to possible underperformance and be prepared to demonstrate how they aim to improve it.

The need to address the particular requirements of children's healthcare services

- 24** It has been clear for a long time that healthcare services for children need to be improved. What is shocking is how hard it seems to be to bring this about. Fundamentally, it has to be accepted that children have particular healthcare needs which are indisputably distinct from those of adults. While there are many examples of good healthcare services for children, there are still too many circumstances in which children have to make do with services designed for adults which are quite simply unsuitable and inappropriate for children. We cannot say too loudly that this is wrong. As a society we can do better for our children; we must do better. While we believe that children will benefit from the more general recommendations in this Report, more needs to be done, and done urgently, to address the particular needs of children. Thus we devote a separate chapter of the Report to this crucial area of healthcare.

The structure of the NHS: understanding management and regulation

- 25** We have said that our approach is patient-centred. The future of the NHS lies in a realignment of services so that they are organised around the patient. And it lies

more fundamentally in an understanding of the distinct roles of regulation and of management. Regulation must ensure that the NHS works in patients' interests. Once it is grasped that it is the interests of patients which should determine the future form of the NHS, what we say here acquires its context. In approaching our task we have found it essential to address what may be described as the architecture of the NHS. In particular, we have asked ourselves what should be the role of government, principally through the Department of Health, and how should systems concerned with the safety and quality of healthcare be organised. We recognise that the NHS is a state-run organisation with a virtual monopoly in the provision of healthcare. As such, responsibility for the NHS can and will always be traced back to the Secretary of State for Health as the person responsible to Parliament. It is right that the Department of Health should be the headquarters for the NHS, at the apex of a hierarchical system of management. But *management* of the service is quite distinct from *regulation*. By regulation, we do not refer to the various economic approaches, such as through the market. Instead, we mean the totality of the processes and systems for assuring and improving the safety and quality of healthcare, including the regulation of healthcare professionals and the regulation of the institutions in which they work.

- 26** The regulation of the NHS in this broad sense must not, in our view, be in the day-to-day control of the Department of Health. While it is the proper role of government to establish the regulatory framework, to ensure safety and promote quality, that framework must be as independent as possible of the Department of Health. This is quite simply because it is not in the interests of the public or of patients that the monopoly provider should also set and monitor the standards of care. Instead, these functions must be carried out by independent bodies within a statutory regulatory framework. The regulatory bodies, embracing, as we have said, matters to do with safety, quality and standards as well as the competence of healthcare professionals, must themselves be co-ordinated and their efforts aligned by some overarching system. Duplication must be reduced. Equally, holes in the system must be stopped. Only in this way will the fragmentation and lack of clarity about responsibility for regulating the quality of healthcare, which was such a feature of Bristol, be addressed. And by insisting on independence from government, the systems to ensure safety and promote the quality of healthcare will be made secure from the vagaries of passing political pressures.
- 27** Let it be clear what we are saying. We are not saying: management bad; regulation good. We are saying that each has its role. Management must be for the Department of Health and exercised in every trust but, from the perspective of patients, regulation is a different enterprise. It is there to protect them against all political weathers. We admit that one way forward is to proceed as in the past through a subtle blend of regulation and management. This distinction could remain blurred as could the precise identification of who is responsible for what. The difficulty lies in the fact that this is the traditional 'insiders' fix. Those running things know what's what. Everyone else remains unsure and unclear and thus excluded. Only by making explicit that which has been implicit, will the interest of the patient and public be served, because *they* will then know what's what. This is the process which government has already

begun. It should go further, towards a gradual realignment of management and regulation.

The structure of the Report

- 28** As we have said, a patient-centred approach informs the whole of our analysis and the recommendations which flow from it. In the chapters which follow, we consider the journey taken by a patient in need of healthcare, looking at the quality of the care received from the patient's perspective, and not from the perspective of what may meet the requirements of any healthcare organisation, any professional group or part of a profession, or the government of the day. We ask what the patient may properly expect of the NHS. To the extent that expectations may not currently be met, we seek to identify the problem and to make recommendations as to possible solutions.
- 29** Whether a patient's 'journey' through the NHS consists of a telephone call to NHS Direct, a consultation with a GP, a visit from the community health nurse, a visit to an NHS walk-in centre, a visit to an outpatient clinic, or a stay in hospital, every patient is entitled to expect:
- respect and honesty;
 - care in a setting which is well led;
 - competent healthcare professionals;
 - care which is safe;
 - care of an appropriate standard; and
 - inclusion and involvement in the NHS, both as a patient and as a member of the public.

These form the themes of the chapters which follow. They are preceded by a chapter on the culture of the NHS. For it is the culture of an organisation that sets the conditions in which any proposed change must occur. Only if the prevailing culture of the NHS develops and grows in the direction which we advocate, will it be possible to achieve and sustain the long-term improvements to the quality of healthcare which we all seek.

Chapter 22: The Culture of the NHS

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Introduction

- 1 At the centre of the patient's experience is an encounter with the culture of the NHS. This culture, by which we mean the attitudes, assumptions and values of the NHS and its many professional groups, conditions the patient's journey and thus the quality of care received. We believe it essential to explore the prevailing culture of the NHS ('the way things are done around here'), to understand its strengths and its problems and to consider how it may need to develop and grow.
- 2 As *'The NHS Plan'* put it, the NHS bears too many of the hallmarks of the 1940s: '... the whole culture is more of the last century than of this'.¹ We agree. However well we are able to meet our Terms of Reference in recommending systems and policies to 'secure high quality care', such systems and policies will never succeed if the deeper, underlying culture of the NHS remains the same.
- 3 To speak of the culture being outmoded or in need of change is not to say that it is uniformly negative. Indeed the culture of the NHS has many strengths. They include the values of public service and social solidarity which have been at the core of the NHS since its foundation. They also include the commitment to access and equity on which the NHS was founded and which *'The NHS Plan'*, when implemented, should help to reinforce. The dedication and commitment of all who work in the NHS is a further, some would say defining, strength.
- 4 We recognise and celebrate these features of the culture of the NHS. Yet it is clear that there are also aspects of that culture which have acted, and continue to act, as a barrier to improving care for patients. By drawing attention and giving emphasis to these less positive aspects of the culture of the NHS, we aim not so much to criticise, as to understand them and how they came about and thereby to suggest where change may be needed.
- 5 Before considering these cultural barriers to improving care in more detail, we need to refer to two particular influences. The first is the role of resources. We are not of the school that argues that any problem can be solved if enough money is thrown at it. Indeed, the evidence of Bristol demonstrates that without, for example, proper leadership, good communication, good relations between professional groups, and agreement on such crucial issues as who is in charge of the Intensive Care Unit (ICU), more resources on their own would not have made the difference. Thus, we must put any reference to resources in context. It is one of a number of factors influencing the culture of the NHS. In the NHS healthcare professionals and patients have been consistently asked to participate in and tolerate a service which has been increasingly underfunded *in terms of what has been asked and expected of it*. Underfunding, of course, is not a neutral or objective term. It means the provision of a lower level of

funding than others would argue for. The NHS, like any other public service, is funded to a level arrived at in a fragile compact between government and governed. Moreover, this is a compact at the mercy of the nation's economy and the delicate balance involved in decisions about taxing and spending. This is how a parliamentary democracy works. What marks out the NHS, is that successive governments have made claims of excellence which simply have not been realisable, given the funds allocated. Patients have been led to have high expectations, only to be disappointed too often. Those working in the NHS have become increasingly frustrated that they are unable to give patients the service which they joined the NHS to provide. They have found themselves battered from all sides: taught what is the best, but expected to practise in circumstances in which 'getting by' is prized as success, and make excellence very difficult to attain.

- 6 A second influence of great importance on the culture of the NHS is that the NHS historically has been seen as more than a health service. It was seen as a national icon: a commitment to a particular set of values. This commitment and these values were challenged, particularly in the 1980s and 1990s. It is little wonder that, collectively or in groups, healthcare professionals have felt beleaguered and have reacted in ways that others might see as unhelpful. It is no surprise that many withdraw into a kind of professional bunker and view everything outside as a threat. For instance, many professionals saw the introduction in 1991 of the purchaser-provider split, trust status and contracting, as offending against the concept of public service by reducing healthcare to a commodity rather than a right. To protect patients, as they saw it, clinicians fought a rearguard action against what was termed 'management'. Suspicion became the order of the day, particularly among doctors and nurses, a mentality which some feel still pervades these professions: suspicion of government, suspicion of trust managers, suspicion generally borne of years of genuine frustration that the NHS was failing to provide them with the tools they needed. As they saw it, and with justification, they were not able properly to care for the patients they were there to serve. Managers for their part also felt a sense of frustration. They struggled to deliver the service which they aspired to give. The workforce was disenchanted and blamed them. The government, as they saw it, constantly bombarded them with initiative after initiative. It was no surprise, therefore, that some managers felt that they equally had neither the tools to manage the workforce nor the wherewithal to meet the targets imposed on them by successive governments. Little wonder too that the public started to question the NHS and to question healthcare professionals, as the dissonance between what the NHS had claimed to offer them and their own experience became apparent. The public became more consumer-minded. They came to demand more and better care and to show a greater readiness to complain if care fell short of what they expected.
- 7 This is the context in which the cultural problems within the NHS need to be properly and honestly addressed. Seen in context, it becomes clear that the problems are not intrinsic to a system of a publicly funded, national healthcare service, far less insuperable. Rather, they should be seen as responses to circumstances. Change the circumstances and there is the prospect of resolution. Make the patient the centre of

the service. Set standards for the safety and quality of care. Support professionals. Liberate and empower the professionals, *all* the professionals, to do their jobs, within clear and agreed frameworks. Give them decent resources, equipment and facilities, and care of a high quality, delivered consistently across the service, will then be a realistic goal.

- 8** What this discussion of culture means for us here is that new models of patient-centred care for securing quality cannot simply be grafted on to the existing attitudes and ways of working within the NHS. The new models have to be accepted, endorsed and embraced by all who must make them work. They have to find their way into the very grain of the NHS. They must not be seen as a threat or challenge to fixed professional power bases. The way forward for everyone involved in the NHS and particularly for those who lead and manage the service, is to generate a new and different culture: one that builds on and reinforces the historic values of the NHS, but one which ensures that the actions taken in the name of those values truly reflect the interests of patients, now and in the future. In short we must begin the patient's journey by identifying the organisational culture and values which are necessary for the quality of care to improve and flourish.

The complexity of culture

- 9** It is important to avoid caricature when referring to 'culture' and to be clear what the word is intended to convey. We take it to refer to those attitudes, assumptions and values which condition the way in which individuals and the organisation work. It is also helpful to bear in mind Professor Robert Dingwall's view² that organisational culture is a complex notion and something which is often resilient to change. One reason for this may be that its complexity lies in the coexistence of competing cultures. This is very much the case within the NHS, where the cultures, for example, of nursing, medicine and management are so distinct and internally closely-knit that the words 'tribe' and 'tribalism' were commonly used by contributors to the Inquiry Seminars on this subject.
- 10** The positive aspects of tribalism are clear. Tribalism engenders a sense of belonging, a set of common goals, a sense of mutual support. Moreover, competition between various tribes may be beneficial if it creates an environment of creative tension within the organisation. The danger of tribalism, of course, is that where there are numerous tribes it can threaten to undermine the capacity of a large organisation to adhere internally to a set of agreed core values and to represent these values to the outside world. Moreover, when tribal groups fall out, or disagree over territory in an organisation such as the NHS, the safety and quality of the care given to the patient is put at risk.

- 11 The way forward must lie in creating an environment of mutual understanding among the groups rather than attempts by one group to gain dominance over others. If one group dominates in a service which calls on the skills of many groups, the interests of patients are not served. Indeed, as Dr Terry McNulty argued, the creative management of the tension between competing cultures involves finding the common ground amidst the diversity of values, accepting this diversity as a given.³

Some important features of culture

- 12 Organisationally, a sense of collective solidarity among the various groups of professionals in the face of what is seen as considerable adversity has been a cultural strength which has served the NHS well. We heard references to this type of 'Dunkirk spirit' during the evidence in Phase One and Phase Two. The General Medical Council (GMC) referred to 'a national "make do and mend" culture'⁴ in the NHS: adverse circumstances seem to tap a particular quality in the national psyche. Objectively, of course, such an approach is ultimately hopeless. It exploits the preparedness of the professionals to sacrifice themselves, while exhausting them. As a recipe for the future, it is useless. What needs to be cultivated is a new sense of collective effort based on opportunity, rather than frustration.
- 13 A further cultural strength has been the capacity of the NHS to absorb change at a pace which would defeat many other organisations. The political nature of healthcare has meant that legislation, circulars, guidelines, targets and demands for data have rained down on those who work in the NHS. Amazingly, the NHS has kept going. But again, this has been at a significant cost to the energy and morale of those who work in it, and thus to the quality of healthcare.
- 14 In the face of the pace of change, and while treating ever more patients with constant pressure on resources, healthcare professionals have continued to fight for their patients' interests as they see them. This is a further strength of the culture of the NHS: the commitment of healthcare professionals to doing the best for their patients. This must not be overlooked, far less undermined, in any changes that take place.
- 15 Whatever the strengths, it is clear to us that there are certain negative features which also characterise the present culture of the NHS. To change a culture takes time; it takes a sense of direction and it takes determination. There are no short cuts. Patience is required. And, during this process of change, understanding *by all of all* is essential. If a way forward is to be charted, the first stage must be an open and honest appraisal of the culture in which healthcare is practised and an acceptance that it must develop. This process is not free from pain, particularly when those who work in the NHS

³ Seminar 3. Dr Terry McNulty, Senior Lecturer in Organisational Behaviour, University of Leeds Business School. Position Paper

⁴ Seminar 3. General Medical Council. Position Paper

already feel bruised and hurt. But it is a process which must be negotiated, for change depends on a recognition of the need to change.

- 16** Part of this process of understanding involves acknowledging an apparent contradiction. It is that professionals as individuals or as a group within the NHS can, as we saw in Bristol, be enormously dedicated and caring, yet, *at the same time*, form part of, or represent, elements that need to change. We cannot state this point too emphatically: healthcare professionals are virtually universally dedicated as individuals. But, as members of separate professions and of a large organisation, the NHS, they may not always act in the interests of patients as a whole. Their particular culture may even work against these wider interests. This is not because the professionals involved, be they managers, doctors, nurses or others, are bad people. It is merely that they have come to view the world in a particular way and, as a consequence, are unable to see the wider interests of patients as a whole (rather than the patient before them) and the wider picture of the NHS.
- 17** One prominent feature of NHS culture, which still persists in parts of the NHS, lies in what one contributor to our Seminars referred to as the ‘... built-in traditional attitudes of some healthcare professionals ...’.⁵ Such attitudes discourage patients from asking questions, and lead to their being given only limited access to information, thereby preventing patients from participating fully in their care. In relation to medicine, Sir Donald Irvine has spoken of what he calls ‘The cultural flaws in the medical profession [which] show up as excessive paternalism, lack of respect for patients and their right to make decisions about their care ...’.⁶ We heard in our Seminars that these flaws are evident in all parts of the NHS. They are not confined to one professional group but may be found at every level of the patient’s encounter with the service. Yet it hardly needs to be said that such attitudes are redolent of a time now past, where those with professional expertise were automatically deferred to as ‘knowing best’. Today, patients increasingly want to have more information about, and to be involved in, their care. This does not mean that they do not respect or value professional expertise. Rather, it means that such expertise has to be used in a different, sharing and more open way.
- 18** This old-style paternalism is evident in the adherence to the idea of hierarchy. As was revealed in the course of the Seminars and by the evidence in Phase One, the continued existence of a hierarchical approach within and between the healthcare professions is a significant cultural weakness. While the situation has changed somewhat over the past decade or so, the problem remains. Even today, in some places, it is assumed that a doctor’s view is inevitably superior and that nurses are there to carry out a doctor’s orders. This continues despite the very great efforts made by the nursing profession to create a relationship of mutual dependence and respect between doctors and nurses.⁷ Many nurses in hospitals and elsewhere still do not feel

⁵ Seminar 3. Association of Community Health Councils for England and Wales. Position Paper

⁶ Sir Donald Irvine. ‘*The changing relationship between the public and medical profession*’. Lloyd Roberts Memorial Lecture. Royal Society of Medicine, 16 January 2001. www.gmc-uk.org

⁷ Seminar 3. The Royal College of Nursing. Position Paper

valued by their medical colleagues or by managers. A sense of hierarchy also persists within medicine. The role of a hospital consultant, for example, is regarded as of higher status than the role of a general practitioner. Indeed, Sir Donald Irvine, himself a GP and President of the GMC, has spoken of how, at the start of the NHS, general practice had a very low status with no impact on the culture of medicine.⁸ Much has changed since then, but the resonance of these assumptions about ranks within medicine persist. More persistent still, perhaps, is the sense of hierarchy between different medical specialties within hospital medicine, such that, for example, as the evidence in Phase One indicated, if a surgeon is in the room, it is he, at least in his eyes, who is 'in charge'. Of course, if he is the person with the most appropriate skills to be in charge this is not a problem. It becomes a problem if status or title can be used automatically to supersede the authority of another more qualified to be in charge. Clearly, these aspects of the current culture of the NHS are simply inappropriate. They are a product of dated professional self-images which are already on the wane. Where they persist, they affect behaviour; they are a powerful force militating against teamwork, particularly among younger staff, anxious not to fall foul of those with power or authority.

- 19** Subservience or deference to a perceived superior can be a particular barrier when issues arise among healthcare professionals about a colleague's performance.⁹ Although there is now a duty on doctors and nurses to protect patients from risk and not to suppress concerns about a colleague's performance, very many in practice today were educated and trained in a culture in which there was a reluctance to criticise or comment upon the conduct of colleagues, particularly those who were more senior or practised in the same team or specialty. This is the negative side of the tradition of group loyalty which has been a strength in times of relative adversity. It continues to be a negative aspect of NHS culture. Not only does it make it difficult for an individual to summon up the courage not to conform, but this sense of hierarchy also influences who gets listened to within the organisation when questions are raised.
- 20** A further cultural problem arises from the strong claim made by some doctors to 'clinical freedom.' The weakness is as much symbolic as actual, signifying as it does some claim to an autonomy which sits uncomfortably in a large, complex organisation seeking to adhere to agreed standards within limited resources. In essence, an appeal to 'clinical freedom' is a claim that in the care of a patient, the doctor's decision is the determining decision and may not be challenged. On one level, of course, this approach reassures patients that the doctor is 'in their corner' and puts their interests first. But, there is an all-too-real danger that the doctrine becomes merely code for 'doctor knows best' and will brook no argument. In a modern, managed healthcare system, where healthcare professionals must work in teams, such an approach may be counterproductive. It does not serve the interests of the patient. Equally, against a background of constrained resources, it may not always be right for the individual doctor treating a particular patient to insist on having his or her way,

⁸ Sir Donald Irvine. *The changing relationship between the public and medical profession*. Lloyd Roberts Memorial Lecture. Royal Society of Medicine, 16 January 2001. www.gmc-uk.org

⁹ Some would see Dr Bolsin as having been in that position. See chapters on Concerns in Section One

if the price to be paid is to limit or impair the care available for other patients. It was for this reason that Sir Alan Langlands described clinical freedom as ‘... romantic notions ... in a bygone age’, and ‘... not a phrase I have heard for a very long time in the National Health Service’.¹⁰

- 21** Also problematic is the friction between clinicians on the one hand and managers on the other, akin, in places, to a type of guerrilla warfare. We have made it clear that, for us, *all* are healthcare professionals. They are all involved in different ways in serving patients and the public. The frustrations and difficulties of the past two decades, not least the changes in 1991, and the different perspectives of these two groups of professionals, have led to a degree of struggle and conflict, as unnecessary as it is unhelpful. This is not a struggle where one side is ever going to triumph over another: nor should it be. But, while it has existed, it undoubtedly has affected the quality of the care which patients have received. We have little doubt that once there is a real understanding of the various roles and responsibilities each must play in the NHS, this cultural barrier to change will begin to disappear. There will be a recognition that just as nurses and doctors work hard and that we need them to be highly skilled and caring, so the same is true of managers. They are hard-working, theirs is real work, and we need them to be good at their job. As the NHS Confederation put it in one of their papers for Phase Two:

‘A relationship that in the past has suffered from much mutual mistrust must be rebuilt on a foundation of mutual respect. Managers and doctors each have very high levels of expertise that will serve the NHS far better if they are understood by all to be separate but equally beneficial. Tribalism must be eliminated and replaced by far better mutual understanding.’¹¹

- 22** As with everything, there is a history to what the NHS Confederation calls ‘mistrust’. In the period after the creation of the NHS, clinicians looked after all aspects of clinical care and ‘administrators’ were there to support. There was, as we have seen, a ‘deeply rooted reserve’ about becoming involved in clinical matters which went right to the top of government. The change in the 1980s and 1990s was dramatic. Managers were expected to manage, and that included all aspects of the NHS. They were understandably perceived by some clinicians, however, as being the people who limited or rationed the care which they were trying to deliver to their patients, or who asked for ever greater ‘efficiencies’. This history must be put behind us. The quality of clinical care is self-evidently the responsibility of all who work in a trust (and is now explicitly so according to the principles of clinical governance). As the NHS Confederation put it:

‘Doctors see themselves as accountable to their patients, their Royal Colleges, the GMC and their consciences. ... From the Manager’s point of view there is a higher imperative; to balance the twin pressures of limited supply of resources ... with the

¹⁰ T65 p. 5 and T65 p. 106 Sir Alan Langlands

¹¹ Seminar 3. NHS Confederation. Position Paper

ever increasing local demand for more and better healthcare. Both views are legitimate.’¹²

We would interject that the manager’s imperative is not necessarily ‘higher’: it is merely different and that is the point. Sir Donald Irvine expressed well the need to move forward in his Lloyd Roberts Lecture when he said:

‘... it [the medical profession] needs to develop better communication with and respect for managers, to understand the pressures and constraints upon them. Doctors and managers together have to make the system work for patients. Only by working together and helping each other can they start to do so.’¹³

Looking to the future

- 23** The implications of our analysis are that necessary changes in the culture of healthcare can only be brought about if, *at the same time*, the root problems of resources and the capacity of managers to manage are comprehensively addressed. We have already referred to resources. We will address the issues of management in detail later. What we concentrate on here are the developments in aspects of the culture which we see as essential to allow the NHS to serve patients. We focus on the need to develop a culture of safety and of quality; a culture of openness and one 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.

A culture of openness

- 24** We have already referred to that aspect of the culture of the NHS which tends to be defensive and secretive, and to old-style attitudes of paternalism and self-protection. This is not fertile ground for a patient-centred service in which communication, openness and honesty are essential to the restoration and maintenance of trust. We have no doubt that, as an organisation, the NHS and those who work within it must embrace a culture of openness. Equally, we are aware of how difficult this is to achieve. On the face of it, the recent past may suggest that circumstances are not propitious. Stories of scandal and malpractice seem to dominate the media coverage of the NHS. A complex, but accurate (and more fair), analysis based on systems and an understanding of how people function inside organisations is much more challenging to portray. Sometimes it can seem as though NHS problems all boil down to questions of individual responsibility and blame. Meanwhile, dissatisfied and damaged patients, frustrated by poor communication, having failed in their search for

¹² Seminar 3. NHS Confederation. Position Paper

¹³ Sir Donald Irvine. *The changing relationship between the public and medical profession*. Lloyd Roberts Memorial Lecture. Royal Society of Medicine, 16 January 2001. www.gmc-uk.org

explanations, defeated by the culture of defensiveness, resort to the media or the law, or both. And, of course, this requires that someone be singled out for blame.

- 25 It may be objected by some within the NHS that asking them to be open is to give ‘the invaders the keys to the city’. But this is too pessimistic. If trust is to be established and maintained, there is only one choice available to those who work in the NHS. They must let in those currently kept outside. They must accept that the public are not ‘invaders’ and that, once let in, they will behave with the maturity which being an insider demands.
- 26 The process of embracing openness involves taking very many small steps. One such step is to make available to patients information on measures taken to safeguard safety. Another is the regular publication of information on the quality of care: in particular, on the outcomes of particular treatments at particular hospitals. Another is the prompt acceptance of responsibility when things have gone wrong, accompanied by an appropriate apology. All of these take courage. All may well, initially, attract hostile criticism. But, we are convinced that they must be done. As Professor Marc de Leval noted: ‘... physicians must become more open and comfortable with their fallibility and the patients must accept their own vulnerability.’¹⁴ Some may object that, if the public had more information about clinical performance, they would not want to go to those hospitals which perform less well, and those hospitals which perform best of all would be overwhelmed with demand. In this regard the experience of New York state is instructive. In the early 1990s, information was made public showing mortality rates following coronary artery bypass grafts. The data referred to individual hospitals and individual surgeons. In fact, the net result of this greater openness was not a mass desertion of the poorly performing hospitals, quite the opposite. There was a rapid improvement in their mortality rates. The information, therefore, was used to improve outcomes for patients.¹⁵
- 27 For a culture of openness to succeed, those who work in the NHS must be confident that they will be supported by the organisation at all levels. Openness must be valued and rewarded. Otherwise, healthcare professionals will understandably be reluctant to embrace it. What this means, crucially, is that blame and stigma should not be the response of managers or colleagues. Adopting the words used by Professor Marc de Leval: while regretting them, we must all learn ‘to treasure mistakes’, because of what they can teach us for the future. This calls for an extremely mature organisation and, equally, a mature society. It means an abandonment of the easy language of blame, in favour of a commitment to understand and learn. It calls for significant leadership. It calls for practical action geared to being more open about error and mistakes and it calls, as we will argue later, for the removal of one of the greatest of all barriers to openness: the fear of clinical negligence litigation.

¹⁴ de Leval M. The Edgar Mannheimer Lecture, 1996

¹⁵ Chassin MR. ‘Improving the quality of care’. *N Engl J Med* 1996; **335**:1060–3. Centres with high mortality rates took radical action to improve their performance including temporarily suspending their coronary artery bypass programmes and restricting hospital admission privileges of some surgeons who performed a low volume of surgery and whose risk-adjusted death rates were found to be well above the state average

- 28** If the culture of openness between the NHS and the public has to change, so too does the internal culture within the NHS, so as to allow for greater openness with and between staff. Currently, there continues to be a sense among the workforce that they cannot discuss openly matters of concern relating to the care of patients and the conduct of fellow workers. There is a real fear among junior staff (particularly amongst junior doctors and nurses) that to comment on colleagues, particularly consultants, is to endanger their future work prospects. The junior needs a reference and a recommendation; nurses want to keep their jobs. This is a powerful motive for keeping quiet.
- 29** The workforce must feel that they will be safe if they wish to raise and have discussed matters of concern. Managers must put in place mechanisms to facilitate this process. We were much impressed during our Seminars by the way the airline industry has approached the issue by providing a neutral reporting system to which staff can report errors, near misses or concerns about safety. There is much here for the NHS to learn.
- 30** The editor of the *'British Medical Journal'* summed up the challenge well:

‘We need a culture that allows doctors to express fears, doubts and vulnerabilities; identifies and helps those in difficulties; refuses to condone inappropriate delegation; values teamwork and continuous learning and improvement; and genuinely puts the interests of the patients first.’¹⁶

We agree. We would add that such a culture is needed not only for doctors but for all who work in the NHS.

A culture of accountability

- 31** Along with a commitment to a culture of openness should be a commitment to accountability. By accountability, we do not mean a system which relies exclusively on an approach where an individual or group is picked out and blamed, as if that was enough to remedy a particular problem.
- 32** The prevailing culture within the NHS is a culture of uncertainty. There is an obscurity, intentional or otherwise, from the point of view of the patient, as to who is responsible for, and thus accountable for, what. Two particular problems flow from this. First, in a large and complex organisation, which operates on very many levels, from national to local, it is not difficult for responsibility to be attributed to others. It can be laid at the feet of an amorphous Department of Health, or a particular technician working ‘at the coal-face’, or at a myriad of points in-between.
- 33** The second problem is that this state of affairs is simply unfair to those who work in the organisation. They do not know to whom they should go, with what problem. The frustration builds up and the organisation, and the patient, suffer.

¹⁶ Smith R. ‘Managing the clinical performance of doctors’. *BMJ* 20 November 1999; **319**: 1314–15 www.bmj.com

- 34** It follows that for the future, there needs to be a clear articulation as to who has responsibility for what and thus is accountable for it. This is not intended as a device to tighten the mechanisms for blame. It is a necessary prerequisite for an organisation to function effectively, to be able to assess its performance and respond accordingly and thereby to serve the interests of patients.

A culture of quality and safety

- 35** The safety of patients must be a paramount consideration in determining the way forward for the NHS. Safety is fundamental to achieving a high-quality service. As is apparent from the lessons of Bristol, it must be the responsibility of all staff in their various roles to create a culture of safety within the NHS. Standards, guidelines or protocols exist to indicate what the requirements of safety demand. It follows that to fail to meet or comply with them necessarily compromises patients' safety. In all organisations, however, not only in the public sector, corners are cut from time to time. One response is to seek to ensure that standards are adhered to. This approach is typified by the airline industry. The aim is to limit the exercise of discretion by individual operators, and eliminate a 'patch and mend' mentality. According to this approach, the standards themselves set the limit of safe conduct. If they are not complied with, the conduct is unsafe. Equally, if they cannot be complied with because of, for example, a shortage of resources, it cannot be safe to proceed.
- 36** There is much to recommend this approach, but it is not without disadvantage. Safety, in part, depends on the capacity of individuals to adapt and, listen to others, when faced with a problem. Too great a dependence on guidelines stultifies this creative capacity and is, thus, counterproductive in terms of safety. We accept this argument. It serves to show how complex the issues are. The argument does not address, however, but merely restates the central question: is there a point beyond which the exercise of creative discretion is inappropriate?
- 37** In the NHS, the question is made even harder, not least by the cultural assumption, born of long experience, that nothing would ever be done if the nurse or doctor waited until the relevant standards were set, or where they do exist were met. From one view, this is an anti-safety culture. From another, it is the mend-and-make-do culture which we saw earlier, a necessary pragmatism that keeps 'the show on the road'. The challenge historically has been the extent to which the NHS will compromise the culture of safety in favour of the culture of pragmatism. We will examine the issues raised in detail later [Chapter X- Safe Care]. Here we merely point out, by way of illustration, that the answer is that the culture of safety is more complex than it first appears. Pragmatism, it might be thought, must give way to observing the appropriate safety standards. In fact, both of the apparent responses to the fact that standards cannot be met have implications for safety. The first response may be to cease activity until remedial action can be taken. If the remedy is, for example, a new operating theatre, this means a long-term cessation of activity. This means, in turn, that fewer patients will be treated, or patients will have to wait longer, or they will have to travel further for treatment. All of these results have adverse consequences for the

safety of the patients affected. This was one of the dilemmas of Bristol. Alternatively, the hospital can carry on offering the service, recognising that safety is being put at risk, but also recognising that those who are successfully treated without extra waiting and travel have gained in terms of safety.

- 38** Thus, where the culture of safety is compromised hospitals are in a 'lose/lose' situation. They put their patients at risk whichever course they adopt. The way forward depends, therefore, on an understanding by all of the nature of this problem, that it often cannot be solved quickly, and that the process of solution requires a series of co-ordinated steps. This is a process, not something to be achieved overnight. Questions of safety must be discussed in an open and transparent manner, so that all, particularly current and future patients, can make suitably informed decisions, not least in the light of the fact that in the process of moving to safer systems, compromises may have to be made along the way if the NHS is to continue to function.
- 39** It may be objected that to talk of a culture of pragmatism and compromise is to countenance and reinforce unacceptable levels of care. We would reply that, if the measures which we propose later concerning safety are put in place, the problem will be far less significant in the future. And, meanwhile, patients should be entitled to make choices, provided they have honest information.

A culture of public service

- 40** We referred earlier to what is seen by some as the tribalism of the various groups which make up the NHS workforce. Here we address a particular aspect of this tribal culture which seems peculiar to many consultants. It can be expressed by quoting the words used by Dr Hugo Mascie-Taylor who, in one of his papers submitted for Phase Two, wrote:

'It is interesting to observe the language that consultants use when describing where they work – they say they work at "St X's", or in London, they may say that they are "on at St Y's" but they rarely, if ever, say "I work *for* St X or St Y NHS Trust".'¹⁷

It needs to be said at once that there are consultants who do feel and profess a strong loyalty to their hospital. We do not quote Dr Mascie-Taylor's words, therefore, as constituting a literal truth. Rather, we ask, as does he, about the consultants' sense of belonging and to what or whom they feel greatest identity. The suggestion made is that there are degrees of identity or loyalty, beginning with their patients, peers and the relevant Royal College, then professional bodies, then the hospital and ultimately, at some distance removed, the NHS, as an organisation rather than an idea.

- 41** The issue is one of self-identity and belonging. The current education and training of the doctor inculcates a strong sense of loyalty and belonging to the professional

¹⁷ Seminar 4. Dr Hugo Mascie-Taylor. Position Paper (emphasis added)

group. This is by no means a bad thing: indeed, it has its advantages, in terms, for example, of the influence, advice and support of peers. The difficulty begins if the sense of belonging goes no further than merely the professional group. For with a sense of belonging goes a commitment to the wider enterprise, in this case the NHS and a sense of identification in its success, together with a desire to prevent its failure. If, on the other hand, the enterprise is 'nothing to do with me: I just work in it', a vital element in building a culture of high performance is lacking.

- 42** The problem is exacerbated if the other part of the medical workforce, the junior doctors, are only in any particular hospital for a short period of time, as they move from rotation to rotation. Notwithstanding their obvious dedication and hard work, it must be difficult to develop loyalty to any particular institution, or the larger NHS, save as a set of abstract ideas. Moreover, it could be said that the problem is further exacerbated if different professionals are employed on different contractual bases whereby, for example, nurses are treated differently from doctors.
- 43** For the future, duties and allegiances to professional bodies and groups must be aligned with the duties and responsibilities owed to employers (NHS trusts) and to the public. Now that chief executives have an overall responsibility for the quality of care delivered by the trust, it follows that they must have the necessary authority to carry out that responsibility. It is senior managers' responsibility to see that all healthcare professionals do their job properly. For this to be achieved, local arrangements for accountability need to be strengthened. Not least of these are the relevant contractual arrangements. As we shall say in greater detail later, the contractual relationship of all NHS healthcare professionals to their local employers should be on a similar basis. This will have particular implications for consultants. But, as the NHS Confederation put it in its evidence to Phase Two:

'The employer is accountable for the quality of care ... and a framework which enables the employer to change the practice of employees must underpin that accountability.'¹⁸

A culture of teamwork

- 44** Teamwork is of crucial importance in its own right; its continued development will serve to break down the tribal barriers referred to earlier. Collaboration between professionals is the core of what we mean by teamwork. Many healthcare professionals will believe that they have always worked in teams, such that there is nothing new here. In the past, the 'team', more often than not, consisted of individuals from only one group of professionals, with the most senior person being in charge and the rest following, like it or not. Such historical arrangements may have suited administrative convenience or the niceties of professional etiquette but they did not necessarily suit the patient.

- 45** Teamwork as a means of serving the patients implies a multi-professional team and a sharing of responsibility. The team leader may not necessarily be the most senior member of the group and, crucially, may not be a clinician, if the circumstances are such that some other professional should take the lead. Leadership is based on ability and function in the context, rather than some title or professional qualification. Moreover, teams must cross the boundaries of profession and discipline. We note the efforts on the part of professional bodies to promote multi-professional teamwork. The GMC, for example, in January 2000 issued guidance on teamwork in medicine. It is, however, a sign of how much things need to change, and singularly ironic, that such advice about professions working together is issued by a single professional group. Multi-professional teamwork needs multi-professional guidance and multi-professional leadership. Teamwork is the collective collaborative effort of all those concerned with the care of the patient. Patients do not belong to any one professional; they are the responsibility of all who take care of them.
- 46** We conclude as we began. The culture of healthcare, which so critically affects all other aspects of the service which patients receive, must develop and change. Fundamentally, this will be achieved through education, through learning new ways to work and through forging new links within and between professional groups. It is instructive to recall the words of Professor Lucian Leape during one of our seminars: 'Culture is not amorphous, nor immutable; we are not powerless to change it. It is in some respects no more than the sum of the actions and attitudes of many individuals. Thus, if in some crucial areas of practice we can change the rules, the regulations and incentives, behaviour and, ultimately, attitudes will follow.' We agree. We now turn to a consideration of what the patient is entitled to expect from a changed NHS. We begin with respect and honesty.

Chapter 23: Respect and Honesty

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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 treatment.

Messages from Bristol

- The service in Bristol was based on a paternalistic approach to families and to the care and support they needed.
- The culture in Bristol was not one which encouraged openness and honesty in the exchange of information between and amongst healthcare professionals and between them and families.
- Support and counselling particularly at the time of bereavement did not have a sufficiently high priority.
- Communication was too often left by senior clinicians to nurses or junior doctors because it was time consuming and could be emotionally taxing.

Introduction

- 1 For a health service to be truly patient-centred, it needs to embrace a commitment to, respect for, and honesty towards, those it serves. Respect for others encompasses the need to see people as thinking, feeling, interacting beings for whom contact with the NHS will be different in each and every case. This means that patients must be seen first as people who live complex lives, rather than as clinical problems with a collection of symptoms. Respect for others also acknowledges difference and responds to individual needs without prejudice or assumption. Honesty implies openness and an exchange of information on all relevant matters. It means being open about risks, uncertainties and alternatives, as well as about the possible benefits of treatment. And it means clinicians being able to say that they do not have all the answers.
- 2 This chapter is about the relationship between the patient and the healthcare professional. We suggest how the quality of healthcare would be enhanced by a greater degree of respect and honesty in that relationship. We argue that the relationship needs to be based on partnership rather than on outmoded paternalism, and we stress the importance of involving patients, wherever possible, in decisions about their treatment and care. We suggest that much greater attention must be given

to patients' needs for information and for support for them and their families. We stress that the communication skills of healthcare professionals are of fundamental importance in enabling patients to participate as partners in their care. We consider the need for a culture of openness and honesty within the hospital as a whole, and we argue for a duty of candour towards patients when things go wrong or concerns are raised.

Respect

- 3 Perhaps one of the most important features of a patient's experience when going into hospital is a sense of powerlessness and loss of control over personal decisions. Of course, patients are usually ill, and more than content to let others take care of them. But this should not be read as implying a readiness to have all decisions made for them, nor a willingness to be kept in partial or complete ignorance of what is going on. Good practice now demands better communication with the patient, and seeks to involve the patient, wherever possible, in decisions about treatment. Yet we were told, by a wide cross-section of patient groups during Phase Two, that there is still an image of patients as passive recipients *for* whom rather than *by* whom decisions are made. As one patients' group put it:

'Medical practice is essentially an intellectual pursuit. Being ill is a highly emotional experience. ... patients are deemed incapable of deciding what is in their medical interests. They become clinical material to which things are done.'¹

- 4 The imbalance of power between professional and patient arises for a variety of reasons. For example, patients generally have less knowledge about the healthcare system, its organisation and institutions than those who work within it. They possess a justifiable need to believe in the competence of the professionals caring for them. They may perceive themselves to be different in status from the professional, in terms of expert knowledge, class, gender or ethnicity. Structural factors can also inhibit patients' confidence: physical circumstances such as the patient being confined to a bed; or an awareness of the constrained amount of time for consultations whether on the ward, or visiting an outpatient clinic. We have no doubt that this sense of vulnerability is perhaps even more acute in the case of the parents of an unwell child. This feeling was expressed by a group which includes Bristol parents, as follows:

'The majority of parents who enter the NHS with a child who has a life threatening condition enter a world which is unfamiliar. A world of high tech machinery, a place where clinicians are making serious decisions which affect life and death

¹ Seminar 7. Patient Concern. Position Paper

outcomes. ... The effect of being in such an alien environment can leave a parent feeling disempowered, scared, vulnerable and anxious.’²

- 5 If a sense of powerlessness is a common experience, and engenders feelings of frustration or worse, ways must be found to empower the patient, and, in the case of unwell children, their parents. We emphasise that we are *not* concerned to empower patients *at the expense of* healthcare professionals. The aim should be to foster an environment in which both patients and professionals feel that they are playing a mutually supportive role in the patient’s care.

Honesty

- 6 A relationship based on respect will only flourish if there is a foundation of honesty in the exchanges between patient (or parent) and professional. During Phase Two, we heard that the honesty and openness of nurses and doctors makes a significant and positive difference to the patient’s, or their carer’s, ability to cope. For example, one mother wrote of a neurologist who had treated her daughter: ‘Although what he had to tell us was so bleak, we appreciated his very direct approach. We wanted the truth as he saw it, and he respected our wish to be fully informed.’ She went on to express her appreciation also of her daughter’s cardiologist’s ability to respond in ‘... a normal, human way ...’ and the nurses’ willingness to ‘... share part of themselves on a human mother-to-mother level.’³

- 7 We also received evidence of the importance of honesty in maintaining trust between parents of a sick child and clinicians. Richard Lunniss, father of William, told us:

‘You cannot trust people if you do not think they are being honest, even if they are being nice. Once you think that they might not say the thing as it is, then you can never believe quite — there is no working relationship from that point on.’⁴

- 8 Justine Eastwood, mother of Oliver, also spoke of the need for honesty, particularly in the most difficult of circumstances when a child is very sick:

‘I think you need to know. It hurts ... It hurts to hear it, but you need to know the truth. I do not want to be told everything is going to be jolly and fine. It is a fact of life. ... You do not want people to be cruel to you but you need honesty in a situation like that.’⁵

² Seminar 7. Constructive Dialogue for Clinical Accountability. Position Paper

³ Seminar 7. A mother’s perspective on support for families when things go wrong in children’s healthcare. Joanna Richards. Position Paper

⁴ T95 p. 81 Richard Lunniss

⁵ T95 p. 80 Justine Eastwood

- 9 We were equally struck by one of the submissions to Phase Two from the Royal College of Surgeons which acknowledged the importance of good communication but stated, starkly, that practice still falls short of theory:

‘Proper communication between a patient and the surgeon responsible for their care is essential so that the patient can develop trust and is sufficiently informed to be a true partner in the decision making process. Unfortunately, this is the area of greatest compromise in the practice of most surgeons in the NHS and the source of most complaint by patients.’⁶

Partnership: involving patients and parents in decision-making

- 10 Many patients now wish to have a greater level of involvement in decisions about their care. One clear message from Bristol is that this is certainly true for parents who, almost always, want to be closely involved in their child’s care. Even those who say that they would prefer not to know too much are entitled to be given the opportunity to be involved, to the extent that they would feel comfortable. An editorial in the *‘BMJ’* captured the point well: ‘For doctors the trick will be to determine which patients want to be offered choice and which prefer a passive role.’⁷ That patients should be more active partners in decisions about their care is already acknowledged as public policy. The NHS Executive’s Patient-Partnership strategy, relaunched in 1999, states clearly:

‘Achieving [patient partnership] will require that patients are given the information that they want about themselves and their care and ensuring they are treated with respect and as partners in their care.’⁸

- 11 Partnership is also reflected in professional guidance. The GMC’s guidance, *‘Seeking patients’ consent: the ethical considerations’*, for example, states: ‘It is for the patient, not the doctor, to determine what is in the patient’s own best interests. ... you may wish to recommend a treatment or a course of action, but you must not put pressure on patients to accept your advice.’⁹

⁶ Seminar 7. The Royal College of Surgeons of England. Position Paper

⁷ Editorial; ‘Paternalism or Partnership?’, *‘BMJ’* 18 September 1999; **319**: 719 – 720. www.bmj.com

⁸ Department of Health. *‘Patient and Public Involvement in the New NHS’*, London: Department of Health, 1999. (Health Service Circular: HSC (99) 210) available from www.doh.gov.uk

⁹ General Medical Council. *‘Seeking patients’ consent: the ethical considerations’*, November 1998. www.gmc-uk.org

- 12 It was suggested to us in Phase Two that involvement in decisions about care can also significantly improve a patient's prospects for recovery. Angela Coulter, a contributor to one of our seminars, wrote:

'Patients with hypertension benefit if they are allowed to adopt an active rather than a passive role in treatment, patients with breast cancer suffer less depression and anxiety if they are treated by doctors who adopt a participative consultation style, and patients who are more actively involved in discussions about the management of their diabetes achieve better blood sugar control. Patients whose doctors are ignorant of their values and preferences may receive treatment that is inappropriate to their needs.'¹⁰

- 13 This notion of 'partnership' between doctor and patient featured in a number of submissions to Phase Two, including one from the Royal College of General Practitioners (RCGP). The RCGP acknowledged that many doctors in practice today have been trained along the lines of a traditional model of consultation, in which the patient's only active contribution to the conversation is the presentation of symptoms. For many years now, however, the approach used in the training of GPs has differed from this traditional model. Instead, a model of partnership is advocated, in which: '... the patient and doctor meet as equals with different expertise. The doctor has the medical knowledge and skill, but the patient has personal knowledge and skill. ...'¹¹ In this model of partnership, the whole structure of the consultation changes and the power in the relationship becomes more evenly shared. The RCGP also stated that partnership: '... is not to deny ... that the professional has expertise. ... for this partnership to work patients need information about the problem presented to them in a language that they understand. They may need time to consider. Patients may prefer a particular treatment. ... The professional needs to respect the patient's perspective and the patient needs to respect the professional and the service.'¹² The '*BMJ*', in its editorial, argued similarly:

'Partners work together to achieve common goals. Their relationship is based on mutual respect for each other's skills and competencies and recognition of the advantage of combining these resources to achieve beneficial outcomes. Successful partnerships are non-hierarchical and the partners share decision making and responsibility. The key to successful doctor-patient partnerships is therefore to recognise that patients are experts too. The doctor is, or should be, well informed about diagnostic techniques, the cause of disease, prognosis, treatment options, and preventive strategies, but only the patient knows about his or her experience of illness, social circumstances, habits and behaviour, attitudes to risk, values, and preferences. Both types of knowledge are needed to manage illness successfully, so both parties should be prepared to share information and take decisions jointly.'¹³

¹⁰ Coulter A et al. 'Sharing decisions with patients: is the information good enough?', *BMJ* 30 January 1999; **318**: 318–322. www.bmj.com

¹¹ Seminar 7. The Royal College of General Practitioners. Position Paper

¹² Seminar 7. The Royal College of General Practitioners. Position Paper

¹³ Editorial; 'Paternalism or Partnership?', *BMJ* 18 September 1999; **319**: 719–720. www.bmj.com

- 14** The importance of partnership was also emphasised by a submission to Phase Two from the Royal College of Nursing.¹⁴ In it, the College argued that the development of skills to enhance partnership is vital for the professions, for example, in aiding patients to participate in making informed decisions about their care. The Royal College of Surgeons also recognise the trend towards partnership. It argued, as in fact did the RCGP, that patients will differ in their preferences and that this should be acknowledged. That said, in a patient-centred health service, a consistent approach to involving patients is needed. It can no longer be acceptable for patients, having been treated, as they are now for the most part, as equal partners by their GP, then to go into hospital and be confronted with old-style paternalistic attitudes from some consultants.
- 15** Many parents who gave evidence to the Inquiry commented in their statements, or through their representative groups, on the improvements which they felt were needed in the attitudes shown by healthcare professionals towards patients and particularly parents. Overwhelmingly, they emphasised the need for parents with a child in hospital to be involved in their child's care and for parents' expertise, as the people who know the child best and who care for the child, to be fully acknowledged and appropriately engaged. This approach is now regarded as good practice when children are in hospital. We believe that it should be standard, routine practice. We have no doubt that this approach, whereby parents and patients are alongside and in partnership with the professional, rather than following and doing what they are told, is the way forward for modern care in hospital.

Information

- 16** The exchange and provision of information is at the core of an open and honest relationship between healthcare professionals and patients. It is *also* an inextricable part of the caring for the patient. As the Royal College of Surgeons told us:

'The better informed and more involved a patient is, the more likely it is that they will: be better able to weigh up the pros and cons of treatment and make decisions about their care; be better prepared for what to expect of surgery; adhere to treatment regimes; be satisfied with their care – which has a positive impact on the outcome of treatment; be less likely to complain or sue should a complication occur.'¹⁵

- 17** One of the principal ways of empowering the patient is to ensure that they have the necessary information to allow them to understand and participate in their care to the extent desired. The ability to assess patients' needs for information requires the ability to listen, combined with a willingness to avoid second-guessing what they will want to hear, or be able to understand.

¹⁴ Seminar 7. The Royal College of Nursing. Position Paper

¹⁵ Seminar 7. The Royal College of Surgeons of England. Position Paper

- 18** In the light of the contributions to our seminar on empowering patients, we identify 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.
- 19** Translated into practical action, we believe that these principles should influence both the form and the content of information, and the process by which it is communicated:
- information should be given in a variety of forms (written, oral, audio-visual), it should be given in stages and be reinforced over time;
 - information should be tailored to the needs, circumstances and wishes of the individual;
 - information should be based on the current available evidence, and include a summary of the evidence and data, in a form comprehensible to patients and their carers;
 - various modes of conveying information, whether leaflets, tapes, videos or CDs, should be regularly updated and developed and piloted with the help of patients and carers;
 - patients and, where appropriate, carers, should always be given the opportunity and time to ask questions about what they are told, to seek clarification, and to ask for more information;
 - patients and, where appropriate, carers, should also be given the sense of freedom to indicate when they do not want any (or more) information: this requires skill and understanding from healthcare professionals;
 - before embarking on any procedure, patients and, where appropriate, carers, should be given an explanation of what is going to happen and, after the procedure, should have the opportunity to review what has happened;
 - patients and carers should be supported in dealing with the additional anxiety sometimes created by greater knowledge; and
 - patients should be told that they may have another person of their choosing present when receiving information about a diagnosis or a procedure.¹⁶

- 20** These principles and practical proposals are deliberately more comprehensive than is usual. They go further than most current guidance. By being more comprehensive, they serve to provide a protocol on which partnerships can be built and patients can know what to expect, rather than having to rely on the discretion of the professional to part with information. We note that the need for change in this direction is recognised. For example, the new edition of the GMC's code for doctors, '*Good Medical Practice*', gives a higher priority than was previously the case to the importance of good communication between patients and doctors.¹⁷
- 21** What these principles make clear is that the issue is no longer *whether* to inform a patient, but *how* to do so effectively. There is a voluminous literature on the mechanics, as well as the principle, of informing patients. It has been argued that, because it is unclear what patients may wish to know or impossible fully to inform them (i.e. to the level of the professional), it is unwarranted, if not cruel, to impose information on them. We are not persuaded. We believe that healthcare professionals have a duty to empower patients: providing information is one means of such empowerment. We accept that each patient is different and may wish for varying amounts of information at various times, with the constant ability to say 'enough'. But this fact does not serve as a reason for not setting off on the information journey. Rather, it indicates how carefully the journey must be travelled and that healthcare professionals need good, all-round communications skills, if the patient's needs are to be respected and met.
- 22** In the particular case of children, their needs for information should also be assessed by listening to them and being led by their questions. Children will ask about what they want to know and must be answered truthfully and clearly. For those healthcare professionals who are inexperienced or lack confidence in talking to children, there are a number of people within the healthcare team who can advise and guide, for example, play specialists, social workers, psychologists and teachers. A reluctance by any professional to consult team members, for whatever reason, is counterproductive, as an holistic approach to the needs of the child within the family, combined with a multidisciplinary, multi-professional approach, is likely to be most effective.¹⁸

Improving ways of giving information

- 23** We have seen that the provision of adequate information is an essential prerequisite to the development of trust. It underpins the honesty between professional and patient. Thus it is essential that such information be clear, factual, and that it empowers the patient. We recognise that there are undoubtedly examples all around the country of good information being provided for patients, as the creative use of a range of media, such as leaflets, books and interactive videos and the Internet grows. Nevertheless, we heard in Phase Two that much of the current information for patients about treatment is out of date, or of poor quality. Criticism was particularly levelled at information

¹⁷ General Medical Council. '*Good Medical Practice*', July 1998. www.gmc-uk.org

¹⁸ We note the call for further research in Dixon-Woods M. et al. 'Partnerships with Children', '*BMJ*' 18 September 1999; **319**: 778–780. www.bmj.com

which is excessively optimistic, and that which has a tendency to downplay, or omit mention of, side effects, risks, uncertainties and controversies. We would add that too often the information given to patients seeks to encourage compliance with what is proposed, rather than to engage patients with the choices which are theirs to make, and thereby empower them. Much more creative thought needs to be given to ways of improving the quality and timeliness of information for patients. It is not just a question of the media that are used, although that is important. The quality of the content is also crucial. This is a much neglected area where the new NHS Modernisation Agency could play a role in identifying and disseminating good practice. Angela Coulter and her colleagues made a similar plea to the NHS Executive before *'The NHS Plan'* appeared. It still is relevant. They argued:

'The goals of the government's patient partnership strategy, which aims to promote shared decision making, will not be met unless patients are provided with good quality information about diseases and treatments. We call on the NHS Executive to:

- 'Fund the development and evaluation of high quality patient information materials covering common clinical problems.
- 'Commission patient information materials to accompany each of the evidence based guidelines to be commissioned by the National Institute for Clinical Excellence.
- 'Establish a system for accrediting patient information materials and websites to help patients and health professionals identify reliable information.
- 'Establish a system for disseminating good quality materials to patients, where appropriate making them available in general practitioners' surgeries, hospital departments, community pharmacies, consumer health information services, healthy living centres, public libraries, etc.
- 'Ensure that each NHS Trust and primary care group [and now, primary care trust] has a designated senior member of staff responsible for ensuring that patient information meets high quality standards.'¹⁹

24 One of the recommendations in *'The NHS Plan'* was that, in future, patients should receive a copy of any letter about their illness or care which was written by one clinician to another. We support this recommendation wholeheartedly. We believe it will do much to empower individual patients. (Of course, patients are already entitled to see their medical notes, although some may not be aware of this.) We add, however, that, to the extent that technical matters may not be written about in a way that can be understood by the patient, the patient should be able to seek help from NHS Direct or from their GP. We add further that this practice must extend to parents

¹⁹ Coulter A, Entwistle V, Gilbert D. 'Sharing decisions with patients: is the information good enough?', *BMJ* 1999; **318**: 318–222.
www.bmj.com

of those too young to take decisions for themselves. At some point, of course, the child's right to confidentiality will displace the claim of the parent. This is but a further example of the need to manage these conflicting claims and will need to be carefully addressed.

- 25** There is one additional, particular practice which we would commend for the future, especially in the case of parents whose children are ill. Patients, when meeting their doctor for an important consultation, to discuss a diagnosis, a course of treatment, or prognosis, should have an option to tape-record those discussions, so that they can listen again later to what was said. Tape recording facilities should be provided by the NHS to enable patients to make a recording. The patient would be able to take the tape home. If necessary a copy of any such tape could be kept with the medical record. We were told repeatedly by parents in the Phase One hearings that they remembered very little of what was said to them, on those particularly significant and hence very stressful occasions when their child's diagnosis or treatment was being discussed. We also heard that when two parents met the clinician, they often remembered different and sometimes conflicting messages. A simple measure such as enabling patients to tape-record a consultation, something already done in a number of places, could bring significant benefits to patients, families and professionals in terms of partnership and mutual understanding.
- 26** We should also notice here the increasing influence of the Internet.²⁰ Patients now have access to a great deal of information and data. The public's and patients' desire for more information is not going to go away, nor can it be readily managed or contained by professionals. It is particularly important that professionals should not perceive this development as an implicit attack on their expertise. Rather, they must adopt new strategies based on partnership. They must seek to explain and give meaning to what patients may have come across, and guide patients in their continuing search.²¹ At the same time, and separately, efforts to guide the public towards those sources of information which can be properly relied upon and are of good quality should be pursued by professionals and the government. This has started to happen, to a degree, through NHS Direct Online, various hospital websites and the National Electronic Library for Health, but there is much more that could be done to provide patients and professionals alike with access to sources of information which both can trust.²²

²⁰ In 1999, there were, according to the *'BMJ'*, at least 100,000 health-related websites. Eysenbach G et al. 'Shopping around the internet today and tomorrow: towards the millennium of cybermedicine'. *'BMJ'* 13 November 1999; **319**: 1294. www.bmj.com

²¹ See Sheppard S et al. 'Helping patients access high quality health information', *'BMJ'* 18 September 1999; **319**: 764–766. www.bmj.com

²² See further Eysenbach G et al. 'Shopping around the internet today and tomorrow: towards the millennium of cybermedicine'. *'BMJ'* 13 November 1999; **319**: 1294. www.bmj.com

Communication skills: overcoming the barriers to effective communication

- 27** Patients are entitled to expect that those who care for them, doctors, nurses and others, will be able to listen, to explain and to communicate with them. Patients are also entitled to expect that healthcare professionals will be able to communicate effectively with each other. Whatever the circumstances, the need for good communication is constant and is integral to good care.

Time

- 28** Undoubtedly, pressures of time are a factor inhibiting good communication. This applies to all healthcare professionals whatever their skills. There is no escaping the reality that it takes time actively to listen, to assess a patient's need for information and to develop understanding of the patient's circumstances. We heard repeatedly that pressure of time means that patients often get a strictly limited amount of time to talk, particularly when seeing a consultant. This means that there is often no time for patients to ask questions or to take any real part in discussions about their care. The National Federation of Consumer Groups summed up the problem in a contribution to a Phase Two seminar:

'Lack of time is the problem that so often leads to thoughtlessness and lack of adequate information.'²³

- 29** We were interested to note that in recent research into how hospital consultants in the Oxford region respond to patients' complaints, communication problems figured prominently in these complaints. 'Circumstances and work conditions' were cited by some of the consultants as factors which prevented them from communicating effectively. One surgeon is quoted in the study as commenting:

'Communication is an expensive luxury. I have never yet had a complaint from one of my private patients because in my private practice I have the time to handle all aspects of a case ...'²⁴

The point being made is clear: there is a relationship between the time to communicate and the resources available to the NHS. Time is a resource like any other resource. In the context of an NHS which has endured decades of constrained resources, the allocation of time to communicate with patients, though readily

²³ Seminar 7. National Federation of Consumer Groups. Position Paper

²⁴ Mulcahy L. *Disputing Doctors; a socio-legal analysis of doctors' responses to being called to account by patients*. (just in press), Open University Press. Chapter 5. She also describes in the same chapter a consultant as saying 'When you know that something has gone wrong, that's when you pull out all the stops and over compensate by listening to the patient and making them feel you really care'

recognised by healthcare professionals as important, has been consistently squeezed. NHS trusts must ensure that the working arrangements of healthcare professionals allow them the necessary time to communicate with patients.

Awareness

- 30** Time, however, is not the only factor. The attitude which the clinician brings to an encounter with the patient also matters greatly. As we were told in Phase Two by the Royal College of Surgeons:

‘Whilst the pressures on time undoubtedly contribute in some instances [to poor communication], the style of practice, sensitivity and personality of the surgeon are equally important.’²⁵

- 31** This point was developed in an expert opinion commissioned by the Inquiry from Jean Simons, Head of Bereavement Services at Great Ormond Street Children’s Hospital. Drawing on extensive research into parents’ and patients’ experience of the communication skills of healthcare professionals, she wrote:

‘It was most patients’ experience that although doctors thought in their interviews they were giving time and space for the patient to express their feelings, they were on the whole preventing the patient from doing so by their own need to give information (as they thought the patient needed to hear), changing the subject, offering premature and inappropriate reassurance, and insisting on their own agenda prevailing in the interview rather than partnering the patient in the discussion.’²⁶

- 32** Thus, a further problem which needs to be recognised is that communication is not easy. The patient may be apprehensive. The doctor may be anxious to do a good job and may not be sure how much the patient wants to know or how much he or she should be told. Breaking bad news and dealing with bereavement is always hard, for the doctor as much as for the patient. Nowhere was this more evident in Bristol than in relation to communication about post-mortems. As Mr Dhasmana told the Inquiry:

‘This used to be a most difficult period ... I was always emotional during this meeting and the only way I could really, just, you know, express it was quickly get to the point. ... It used to be very difficult for me to communicate very well at that time.’²⁷

Humanity

- 33** We were told by participants in both Phases of the Inquiry that patients often expect the doctor to be touched by their plight. They do not feel that it is professionally inappropriate for the doctor to be uncomfortable or to be visibly moved by what he or

²⁵ Seminar 7. The Royal College of Surgeons of England. Position Paper

²⁶ 10k Simons J. ‘Giving Information to Parents with an Unwell Child’, Annex B

²⁷ T87 p. 97–8 Mr Dhasmana

she is trying to say. It is obvious to us, therefore, that the ability to communicate on a number of levels, in a variety of situations, with people who feel both vulnerable and anxious should be regarded as one of the most fundamental and essential of the healthcare professional's responsibilities. This point was made forcefully by the Bristol Heart Children Action Group in its submission to Phase Two:

'The [medical] profession are removed from the needs of the users on an emotional level and because of the very difficult job they do, communication often only stays at a clinical level ... The patient needs to be listened to in whatever form they express themselves ... Gone are the days where the patient needs to be protected by the profession. Far more account should be taken about what patients want and feel they need to know ...'²⁸

Improving the capacity to communicate

- 34 Given all the various difficulties in communicating effectively, it is no surprise that there has emerged among healthcare professionals a mentality of compartmentalising communication into specific tasks, for example, gaining consent to an operation, giving bad news, gaining consent to a post-mortem. In fact, of course, this approach is the very antithesis of communication. It proceeds on the basis of there being a discrete, single matter to discuss, all other matters being off the point. This may appear to be cost-effective in terms of professionals' time. Also, it allows them to control the exchange, if such it is, and thereby limit their exposure to that which is discomforting. But ultimately it is not effective because it falls short of meeting the legitimate needs of the patient.
- 35 There is evidence that nurses are exposed, in their education and training, to a range of communication techniques and skills. The same cannot be said consistently of medical education and training which, even today, does not give sufficient significance to communication skills. In many medical schools they are still regarded as soft 'add-ons' to what is, in essence, a scientific education. The extent to which education in communication skills, such as it is, is carried through into post-registration training is also highly variable. Whereas for trainee GPs, communication skills form an integral and significant part of their training, this is not so for most doctors training to be hospital specialists. The result is that, all too often, senior hospital medical staff opt out of the job of communicating adequately with their patients. The point we seek to make is that virtually every encounter with a patient involves communication, and thus it should be *good* communication. It is not enough for the consultant to rely on the nurse or the GP 'to do all the talking'. Crucial as they are, nurses and GPs should not be used as a means whereby a consultant can avoid engagement. That said, healthcare professionals do not act alone; we were persuaded by the submission from the Royal College of Nursing that, in addition to those 'in the front line' who communicate with patients and serve as 'the companion on what is often a difficult and lonely journey', there should also be others who can provide

support. Counsellors, patients' friends and others can play an invaluable role in giving and explaining information in a non-technical manner.²⁹

- 36** The way forward lies in understanding that two quite distinct developments must take place. The first challenge is to foster, encourage and shape the attitudes of healthcare professionals, both as they enter and as they progress through the profession. The second challenge is to reinforce the attitudes of openness and preparedness to communicate by offering appropriate training in the relevant skills. As regards the development of what we might call the 'right attitudes', the starting point must be the selection of young people to be educated as healthcare professionals and then the education which they receive. The challenge is to maintain and build upon the attitudes which those starting out on a career in the NHS undoubtedly possess or aspire to: the values of caring, of comforting, of supporting and of truthfulness and honesty. So far from being blunted or lost, these qualities must be cherished and shown to be the true cultural tradition of healthcare. Equally, the challenge is to allow professionals already in the NHS to reclaim these attitudes by having the time, space and resources properly to care for their patients.
- 37** As regards training in communication skills, future doctors, nurses and all other healthcare professionals must be prepared adequately during their education and training. Priority must also be given to appropriate training in and the regular development of skills for those currently in practice. A comprehensive approach is called for. Communication skills are generic: they should no longer be packaged as though communicating was a series of discrete tasks which can be rehearsed and repeated with limited personal engagement. Communication skills go much wider than just the giving of factual information, the giving of bad news, or the obtaining of consent. They include listening skills, an ability to understand, to elicit and to assess how much information a patient wants, and not least the capacity to engage 'in a normal human way'. Communication skills are crucial to enabling healthcare professionals to fulfill their professional duties: without such skills they are left ill-equipped to care for patients, in the fullest sense.³⁰

Support for patients and for families

- 38** A further feature of a patient-centred health service which respects patients' needs is the provision of support to patients and relatives by the NHS. We regard this as of very great importance. It should not be limited to the time actually spent in hospital but should extend to the time before admission and after discharge. We recognise that difficult questions arise as to the proper, and indeed effective, reach of the hospital, given its resources. Thus, we do not see the provision of the sort of support referred to

²⁹ Seminar 3. The Royal College of Nursing. Position Paper

³⁰ See Chapter 25 on Competent Healthcare Professionals

here as being the exclusive responsibility of the hospital. A period in hospital is only one element along a continuum of care. Rather, we argue for the development of a more integrated approach to the provision of support services, whereby the respective roles of the hospital, the GP and local primary care team, the local Social Services Department and the various volunteer organisations are clarified and organised around the needs of the patient. We were struck by a strong theme which emerged consistently from parents' evidence in Phase One: that they felt abandoned, both in the hospital and later, after the discharge, or the death of their child. Very often, their need for support was closely linked to a need for information about their child's care, particularly when a child had died. Support is a subtle and complex process. It requires skill. Some patients may reject it. For others, it is a lifeline. What matters is that the hospital (with other organisations) has a system whereby information which addresses the needs of parents and patients on leaving hospital is communicated swiftly and that efforts are made to integrate a process of continuing care and support.³¹

- 39** To meet these needs for an integrated system of support, a hospital must have a well-developed system and a well-trained group of professionals whose task it is to provide counselling and support and to make the links to the various other forms of support (such as that provided by voluntary and social services) which patients may need. (We use the generic term support to include counselling, while conscious of the fact that counselling is distinct and calls for different training and skills.) The support which may be required is wide ranging. It can include, for example, information about disability benefits and the various other forms of help that may be available after discharge from hospital. It can include talking to someone who has had a similar experience. It can include factual information about what to do when someone has died, and longer-term support after bereavement. Crucially, this wide-ranging set of needs must not be regarded as an optional 'add-on', to be provided solely by untrained volunteers or untrained administrative staff; or in an 'ad hoc' way by healthcare professionals, according to whether they happen to be available at the time. It is integral to care and should be regarded as such. It is what patients (and others) are entitled to.
- 40** Support at a time of bereavement warrants special attention. In England about half of all deaths take place in a hospital.³² For children, this figure is higher. When a child dies it is always traumatic and often unexpected. We believe that the provision of a professional bereavement service within hospitals is absolutely essential. This is especially so for families whose child has died.
- 41** Many families find emotional and social support from others who themselves have gone through similar experiences. They value the exchange of information and mutual understanding which such support groups offer, often long after they or their child left hospital. It is not necessary for each and every hospital to create such groups; what

³¹ A number of recommendations on this matter were made in the *'Report of the independent inquiries into paediatric cardiac services at the Royal Brompton Hospital and Harefield Hospital'*. April 2001. www.rbh.nthames.nhs.uk

³² See this Inquiry's Interim Report *'Removal and retention of human material'*, 2000. Annex C

matters is that such groups, wherever they develop, particularly in the voluntary sector, are supported, and that means funded, as an important part of the healthcare process. Within the hospital, patients and families need to be told that such support exists and how to call upon it. Equally, healthcare professionals must be made aware and must be active in directing patients towards it. The proposed Patient Advocacy and Liaison Services could play an important role here; it is vital that these services are visible within each trust, that staff are familiar with what they can offer, and that these services are properly funded. NHS Direct and NHS Direct Online can and should also serve as a gateway to such groups.

Consent to treatment

- 42** We are concerned here with the process of obtaining consent. We do not intend to review the enormously complex legal and ethical issues raised and the extensive literature on them. We touched on some issues relating to consent in the context of post-mortems and the removal, use and disposal of human material in our Interim Report.³³ Here, we intend to make only some very general points.
- 43** We noted earlier that, when patients are in need of surgery or some other intervention, far too great an emphasis seems to be placed on the isolated act of obtaining written consent to the surgery on a form, rather than on the process of communicating, to which the signing of a consent form is just the end point. By this we mean that too great a regard is paid to the symbolic act of signing a piece of paper, rather than to the real task. The real task is a process which involves explaining what is to take place; setting out what is known about the risks, uncertainties, and possible negative consequences, about the specific performance of the trust, of the specialty and of the consultant unit (as that information becomes available), about any alternatives and about the likely outcome; considering and explaining how the patient will be affected; and seeking and answering questions. Such a process is the only proper way to gain the patient's informed authority to proceed.
- 44** We were saddened to hear a recently-qualified doctor describe, at one of the Phase Two seminars, how, as part of his training, he was sent 'to consent' patients. The very words used illustrate how fundamental is the lack of understanding of what should be going on in the guidance which he had received from those instructing him. A doctor seeks permission. Patients are being asked whether they want to give it. Before doing so they have the right to be told anything that may be material to the decision. The doctor has the duty to do this. Patients are not there to be 'consented'. They are there to be informed and asked if they wish to go ahead. Moreover, consent should be seen as an ongoing process of informed decision-making, permeating the whole process of

³³ We acknowledge that the Department of Health has published new guidance on consent: *Reference guide to consent for examination or treatment*. London: Department of Health, April 2001

care, rather than a one-off event associated with obtaining formal agreement to specific procedures. This is all the more important when parents are making this decision on behalf of their child.³⁴

- 45** Equally, the process of consent should not be seen as applying only to surgical procedures. It seems extraordinary that a surgical operation is surrounded with the formal trappings of written consent forms, yet when carrying out other clinical procedures, such as a physical examination, or an X-ray, it is not routine to advise a patient of what is going on, far less to seek permission. It is an ethical, as well as a legal, principle that a patient's consent is required for even the most routine of examinations which involve any form of touching. In this way, the patient's (or parents') right to choose is respected. This indeed is the essence of respect. By insisting on this, we would not wish to see a further bureaucracy of form-filling. Indeed forms are something of a distraction. We do not advocate more forms. We advocate more communication. As we have said, forms are of almost secondary importance, merely providing evidence of agreement. What we are emphasising is the primacy of the patient's choice; the right of patients to be asked if they wish to undergo the procedure, to be informed about the procedure and to be asked to agree.

The need for openness and honesty within the hospital

- 46** For respect, honesty and openness to flourish between healthcare professionals and individual patients there must be a culture of openness and honesty within the healthcare system as a whole. The hospital as an institution must be open with patients as to what they can expect, where and to whom they can go if they do not understand something, and what they may do if they wish to pass on suggestions or comments. During our oral hearings, we heard the frustration of parents at not being able to discover what was happening as regards the care of their child. A hospital committed to openness would involve and integrate the parent (or patient) into the pattern of care, rather than exclude them.
- 47** One example of an organisation which has chosen to pursue the goal of greater openness in the delivery of its services is provided by Brighton Healthcare NHS Trust. The Trust's 'Patient's Advocate' acts as 'friend within the system' for patients, their relatives or carers. She sees her role as being to improve communication. Penny Dunman, the current Patient's Advocate, recently stated: 'Almost always, lack of communication is at the root of people's anxieties'.³⁵ The service is designed to help

³⁴ We consider the particular issues arising when parents must give their consent on behalf of their children later in Chapter 29 on Children's healthcare services

296 ³⁵ 'Nursing Standard' August 16–22 2000; vol 14 (48) p. 13

patients and their carers to deal with problems which they encounter in relation to their care within the Trust. The aim is to increase the level of satisfaction with the Trust's services while reducing the incidence of complaints. The advocacy service now includes induction and other training for hospital staff at all levels. Significantly, the advocacy service has had the support of the Trust's Chief Executive since its inception, demonstrating that cultural change and strong leadership go hand in hand. The Brighton example is significant because it shows what can be achieved with a 'one-stop shop' for patients: a place that both provides information to smooth the patient's journey, and acts as a source of support for early help and intervention to resolve patients' questions and concerns.

- 48** The Government's announcement in *'The NHS Plan'* of its intention to set up a Patient Advocacy and Liaison Service in every NHS trust and primary care trust is to be welcomed. The establishment of this service should be implemented in full as quickly as possible. Had such a service existed in Bristol, parents would have had a further place to turn to for advice and support when they needed more information or had unresolved questions about their child's care. We add, however, that such a service must be integral to the care of patients, not an optional extra. It is what patients and relatives are entitled to expect as they negotiate the unfamiliar and sometimes frightening environment of the hospital. And, as such, it follows that, as with other aspects of healthcare service, it must be given secure funding to enable it to provide an effective service to patients.
- 49** But this is only a part of a much wider approach which is needed. NHS trusts and primary care trusts must have systems which ensure that patients know where and to whom to go when they need further information or explanation. It is equally important that trusts themselves provide access to a wide range of sources of information, not limited to resolving concerns or complaints, which will guide and assist patients in the course of their care. The key is to ensure that the sources of information which are intended for patients, for example, the hospital's website, the liaison service and the various contact points throughout the hospital, are integrated and complementary. Moreover, there will be real opportunities in the future for the Patient and Advocacy Liaison Services, in a given geographical area, to collaborate so as to provide an effective, efficient and seamless service for patients. The provision of information for patients and the public would be a key area where such collaboration would benefit a local population. This opportunity must be grasped.
- 50** It is also vital that healthcare services routinely seek direct feedback from patients. This is not something to be feared but to be embraced. To hear, as we did during the oral hearings, the many comments and ideas that parents had about how they felt the care for their child could have been improved, and to know that there was no system at the time for capturing that rich vein of concern and advice, was to witness an enormous lost opportunity. The old culture of waiting until someone complains, then behaving defensively and changing reluctantly, has no place in a modern health service. That is why we strongly endorse the proposal in *'The NHS Plan'* that patients on leaving hospital be asked for their feedback. Further, rather than what we regard as

old-style 'satisfaction surveys', formal, systematic structured surveys of patients' full experience of their care should be routinely conducted across the NHS and the results made public. Very often in the past, patients have had no alternative but to use the complaints system, simply because there was no other way to convey their views about the service which they had received. Used, as it must be, and used wisely, information from patients and their relatives should help the hospital, and the NHS generally, to identify emerging problems and to anticipate matters that might become the source of complaint in future if not resolved. The contrast which we seek to draw is between a system in which all interaction with patients becomes routed through a complaints system, such that comments become complaints, even if they did not begin as such, and a system which allows multiple opportunities for communication between the hospital and those it serves. The future lies in the latter.

When things go wrong

- 51** While by no means inevitable, it is likely that, despite the best efforts of the hospital's staff, there will be occasions when things go wrong. We need immediately to separate two matters: what happened and what the hospital should do about it. As regards what happened, distinctions derived from the law are commonly made between mistakes or errors on the one hand, and accidents on the other. These distinctions are concerned with the conduct of the hospital or its staff. They are not concerned with what has happened to the patient. They also ignore what we all know, that there are many factors which contribute to an event, not just the one that directly gives rise to it. In a patient-centred healthcare system, however, it is the effect on the patient which matters. Thus, we do not distinguish here between various kinds of events. We group them together as adverse events, meaning an unplanned event which results in harm to the patient.³⁶ We turn now to what the hospital should do in the case of an adverse event. Historically, of course, while hospitals may have been willing to disclose and discuss accidents, they have been unwilling to do so in the case of an error or a mistake because of the legal repercussions. We discuss this later in detail in Chapter 26 on Safe Care. What we say here is that even in the case of a mistake which might bring legal liability there is a duty of candour. This duty is part of and grows out of the culture of openness which we have called for. It is also a duty that is implicit in the notions of respect and honesty in dealings with patients.
- 52** With specific regard to an unplanned event which results in harm to the patient, the duty of candour should still apply even when mistakes are not immediately apparent and come to light later. This is so particularly when the patient may otherwise be unaware. There is already evidence that such an approach is being adopted within the NHS, for example in circumstances of misdiagnosis. We were also impressed by the policy of some US hospitals in this regard. For example, the Veterans Affairs Medical Center in Lexington, Kentucky, has a policy whereby, if it discovers an error of which

³⁶ We propose later in Chapter 26 that the term 'sentinel event' be used. This term embraces adverse events *and* near misses and prevents disputes as to whether an event was one or the other

the patient and family are unaware, they disclose this to the patient, even if it involves error on the part of the hospital or its staff.³⁷

- 53** During Phase Two, we heard from Professor Lucian Leape. He said that when things go wrong, patients generally want three things: someone to tell them what has happened; a clinician to say s/he is sorry that it has occurred; and action to ensure that the event will not happen to anyone else. He said that in his experience patients do not want punitive action; they want responsible action. We would add that saying sorry has nothing necessarily to do with admitting any fault. Rather it is an expression of concern for the situation in which patients find themselves. We note also the research by Linda Mulcahy and others, reported in the National Audit Office's report on clinical negligence.³⁸ It stated that when serious problems occur, patients may want compensation, but they also want an admission; the prevention of future incidents; an explanation; and an apology. When things go wrong, patients should not have to struggle against the system and raise formal complaints. Thus, we believe that hospitals have a responsibility to be active and to investigate adverse events. Whenever it is clear that what went wrong is the result of action or inaction on the part of the hospital or its staff, they should be under a duty to be open and honest and to acknowledge this as early as possible, ensuring that any compensation due is paid swiftly. Difficult and uncomfortable though it will be, we are convinced that this degree of openness by hospitals and healthcare professionals is essential to the maintenance of patients' trust. It is the essence of respect for and honesty towards patients. And, as we argue later, the more that is known and understood about adverse events generally, the more it will become possible to address their causes and to prevent them in the future.
- 54** We draw attention to the fact that compensation for harm arising from adverse events is an enormously complex subject. Currently, patients may obtain financial assistance from a variety of unrelated sources, including state and employment related benefits and, where available, legal action. Some patients receive none. The system (if such it be) needs radical re-examination. We propose later, in Chapter 26 on Safe Care, that clinical negligence litigation be abolished. We accept that there must be a review of the implications of this proposal not least as regards compensation which arises from litigation. We favour an administratively-based system of compensation based upon the needs of patients rather than on the circumstances which gave rise to those needs.

The future of the NHS complaints systems

- 55** It will be clear from what we have said that an NHS which has respect for and honesty towards patients is not one which hides mistakes or waits for patients to complain. It is for this reason that we advocate openness when things go wrong and an active approach to seeking feedback and comments from patients. The more that difficulties can be addressed early on, by, for example, being open about error, by helping to resolve patients' concerns at an early stage and by the effective use of patients'

³⁷ Wu AW. 'Handling hospital errors: is disclosure the best defense?', *Annals of Internal Medicine* Dec 21 1999; 131(12):970-2

³⁸ 'Handling clinical negligence claims in England', Report by the Comptroller and Auditor General. HC403. Session 2000-2001: May 2001

feedback, the more it should be possible to reduce the extent to which the great variety of patients' concerns and questions coalesce into a generalised notion of 'a complaint'.

- 56** Of course, there will be times when a patient wishes to complain, or is justified in doing so. Thus, there also needs to be an open and easily accessible system for the patient or carer to follow in such circumstances. Currently, the complaints system operated in trusts is widely acknowledged to be cumbersome and bureaucratic. Despite efforts to reform it in the mid-1990s the system has too many layers and lacks a sufficient element of independence. The Government has committed itself to further reform of the system. The decision to establish Patient Advocacy and Liaison Services within trusts is a first and important component of a broader system to identify and respond to problems as early as possible. While we make no comment on the detailed operation of any new system, we offer the following observations. There should be a clear system in the form of a 'one-stop shop' in every trust, for addressing the concerns of a patient about the care provided by, or the conduct of, a healthcare professional. The Patient Advocacy and Liaison Service should be part of this system. The system must be kept as simple as possible. It must follow a well-established principle in handling complaints, that a complaint is best resolved as close as possible to the time and place it arose. The system must be easy to use and accessible. It must be integrated with other policies and systems (such as feedback from patients) and not be off to one side, so to speak, of the mainstream of the hospital's activity. It must also be understood to be part of a pattern of exchanges between healthcare professionals and their patients, and between the trust and patients. When serious complaints arise, which are not easily resolved, they should be dealt with swiftly and thoroughly, keeping the patient (and carer) informed along the way. There should be a strong independent element, not part of the trust's management or board, in any body considering serious complaints which require formal investigation. For this category of complaints, we support the Government's proposal to establish an independent advocacy service to assist patients (and carers).
- 57** Patients, for the most part, as we heard in our seminars, do not want to complain. Often they feel forced to because their concern has been ignored or not properly addressed. The message is clear: improve communication generally, be more open with patients, and complaints will go down. For the complaints which remain, the system in place must be open, minimally bureaucratic, receptive, and appropriately independent.

Chapter 24: A Health Service which is Well Led

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

Messages from Bristol

- The national leadership of the NHS, as between government and professional organisations, was confused and fragmented. No one was really clear about who was ultimately responsible for standards and the quality of care.
- Accountability of the UBH/T to local health authorities and to the Department of Health was confused. Within the hospital, mechanisms of accountability between the central management and the clinical directors, and between clinical directors and clinicians, were unclear and ambiguous. In particular, no one was entirely clear who was responsible for maintaining and improving the quality of care for patients.
- Leadership in Bristol was fragmented: clinical leaders were expected to take responsibility for discrete areas of clinical care; managers were expected to focus on non-clinical matters. A separation was created which was hard to sustain. Delegation of authority from the Chief Executive to clinical directorates created 'silos' (discrete organisational units with very little communication between them) within the Trust. These were almost separate organisations. Strategic leadership from the centre was weak. Communication was up and down the system but not across it.
- There was a contradiction at the core of the organisation in Bristol: a rigid formal system of management, which separated clinical and non-clinical issues, coexisted with an actual system in which the Chief Executive and a small group around him really managed all aspects of the hospital. Those working in the hospital found this difference between the declared system and the actual system confusing and unsettling. The workforce felt alienated if they did not belong to the 'inner circle'.
- There was an insular 'club' culture, in which it was difficult for anyone to stand out, to press for change or to raise questions and concerns.
- The Trust Board, from its inception, was remote from the main activity of the hospital, which was, caring for patients. The Chair of the Board and non-executive directors were not routinely or systematically involved in formulating policy or monitoring the performance of clinical care.

- 1 In this chapter we argue that the highest priority still needs to be given to improving the leadership and management of the NHS, at every level. By this we mean that there needs to be a consistent effort from government and from the top of every NHS organisation to ensure that the NHS is organised for and works in the interests of patients, and to ensure that the quality and safety of care are central. It also means that there must be clarity as to who is responsible and accountable for the quality and safety of care. This applies at the level of organisation and at the level of individual healthcare professionals. In what follows, we address the issue of leadership in stages. First, we review, briefly, the recent history of how quality of care has been regarded in the NHS, including the changes introduced in the last three years. Secondly, we consider what further changes may be needed, in the light of Bristol, to the strategic framework for the quality of care provided by the NHS. Thirdly, we consider the arrangements for management and accountability *within* the NHS and ask whether these are such as to enable those directly responsible for managing NHS organisations to be able to deliver care of a good quality to patients. Fourthly, we examine in more detail the *external* checks and balances that are required to ensure that patients can have confidence in the quality of care.

The 1980s and early 1990s – national leadership in relation to the quality of healthcare

- 2 In the decades after the establishment of the NHS (in fact right up until the late 1980s) central government, through the Department of Health (and formerly the Department of Health and Social Security), interpreted its responsibility for the NHS largely in terms of planning and of allocating resources. It did not see itself as being responsible for, and thus accountable for, the quality of clinical care, either in terms of setting standards or of monitoring clinical performance.¹ Quality was regarded by government as a matter for individual healthcare professionals. For their part, healthcare professionals, particularly hospital doctors, had deeply embedded in their culture the notion of professional autonomy, often expressed in the form of ‘clinical freedom’. This translated as the autonomy of professionals to manage the care and treatment of patients by reference only to what they considered appropriate for the individual patient. This did not mean that healthcare professionals thought of themselves as unaccountable. Rather, they saw their accountability as being to their profession and professional bodies and (to a lesser extent) the hospital as employer.
- 3 During Phase One of the Inquiry we received evidence from Sir Graham Hart, former Permanent Secretary at the DoH. Looking back to the 1980s he wrote:

¹ See also Section One, Chapter 6

‘There was a deeply-rooted reserve on the part of the Department – shared by the professions – about Departmental involvement in clinical performance. This was in general seen as the preserve of clinicians individually and, to some extent collectively.’²

This ‘reserve’ was reflected throughout the 1980s in the priorities which were set by government for those in charge of local acute hospitals. These priorities, reflected in targets, related only tangentially to the quality of clinical care received by the patient. Financial targets, targets to reduce waiting lists, and targets to increase the numbers of patients to be treated were predominant. These were, after all, the priorities of a Secretary of State answering to those concerned with spending tax revenue. The experience of patients, how well patients were treated, or how effectively, and with what impact on their health, were only at the margins of policy. Unsurprisingly, these issues in turn, did not rank high among the priorities of those who were in charge of hospitals providing acute care.

- 4 Over time, pressures grew on government to become involved in the quality of clinical care, no doubt reflecting the growth of consumerism generally. But the ‘deeply-rooted reserve’, whereby government and those who led and managed the NHS avoided involvement in issues of clinical quality, still exerted a powerful influence. Medical and later clinical audit were introduced, but very gradually and participation was voluntary. The *‘Patient’s Charter’*, when it was introduced in 1991, confined itself, in relation to quality of clinical care, to setting limits on waiting times for treatment. The reforms of the NHS in 1991 were partly driven by the view that the discipline of the market would lead to improvements in the quality of care. But the market was imperfect and fragmented. There were few standards. And such information as was generated about the quality of care was not routinely shared. Certainly very little was made public. Purchasers (health authorities and GP fundholders) had few real financial or other levers to bring about improvements in the quality of care, and in reality they had little choice of provider hospital.
- 5 While government played only a minimal role, those at the centre of the healthcare professions endeavoured to provide a degree of leadership. From the early 1990s onwards, a number of the Royal Colleges and other professional associations began to develop standards for the care of people with certain illnesses and conditions. This represented the translation of the notion of clinical freedom into a sort of collective professional approach. But it was leadership without authority. They had only very limited formal powers. The curious situation existed in which the right to lead in areas of clinical quality was claimed by the Royal Colleges, as a natural extension of clinical freedom, but the authority which ordinarily would accompany such leadership was absent.
- 6 Thus, as we saw in Section One, when serious concerns about the quality of paediatric cardiac surgical care in Bristol percolated through to the national level,

an organisational form of 'pass the parcel' was played out. Each organisation which might have been able to do something, passed the problem on, thinking it was some other organisation's or individual's responsibility. Hardly anyone involved had a clear sense of whom they should turn to, what action to take, or whether, indeed, it was their place to take any action. The situation was compounded by the fact that, in any event, there was no reliable way of evaluating the quality of the service, in the sense of outcomes of the care received by patients. This is what happens when national leadership on the issue of the quality of clinical care is weak: that, regrettably, was the way things were at the time.

- 7 Reference to Bristol allows us to re-emphasise that leadership at a national level, most particularly through the DoH, crucially sets the context within which leaders of trusts at the local level are able to carry out their responsibilities. With hindsight, it is possible to see that the absence, up to the late 1990s, of national leadership from government on the subject of the quality of clinical care had a role to play in the way in which events unfolded in Bristol. The quality of clinical care did not rank highly in the overall management of the NHS. Nor, until the Audit Commission was given a limited remit for the NHS in 1990, were there organisations external to the NHS which commented authoritatively upon matters touching on the quality of healthcare.³ But we should stress again that this was no conscious abdication of responsibility on the part of successive governments. Rather, it was an aspect of the unstated compact between government and the healthcare professions, particularly the medical profession, which had helped to see the NHS established in the first place.

Recent changes

- 8 For a long time then, responsibility for clinical standards and for clinical performance was simply not thought to be a matter for government in its role of leading the NHS. This began to change when, in 1997, the Government started a programme of reform to bring matters concerning the quality of care into the mainstream of NHS management. We will examine in more detail the impact of these changes, but, briefly, we acknowledge here a significant change to the internal management of the NHS, namely the decision to place a legal duty on trusts and health authorities in relation to the quality of care. Whereas before 1999 a trust chief executive and trust board were not *required* to pay attention to the quality of healthcare, that has since changed. The 1999 Health Act states that each health authority, trust and primary care trust has a duty '... to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care which it provides to individuals'.⁴

³ The Audit Commission's remit with regard to the NHS was to ensure the proper stewardship of public finances and to help those responsible for the NHS to achieve economy, efficiency and effectiveness

⁴ *Health Act 1999 s18(1)*. London: The Stationery Office, 1999

This duty falls effectively on the chief executive. We also note the decision to create, for the first time, at some distance from government, institutions respectively to set and to monitor standards of care. These institutions, the National Institute for Clinical Excellence (NICE) and the Commission for Health Improvement (CHI) thus mark a further break with the past. The introduction of these changes is intended to have an impact on the role of government at the centre of the NHS. In *'The NHS Plan'*, the role and responsibility of leadership from central government was spelled out in clear terms: '... the centre will: set standards, monitor performance, put in place a proper system of inspection, provide back up to assist modernisation of the service and, where necessary, correct failure.'⁵ The DoH, it went on, will also have a role in championing the interests of patients by applying both pressure and support.

- 9 These developments contain an implicit recognition that government has two key roles in relation to the NHS. It has a role in terms of leading and managing the NHS to ensure that it delivers that which taxpayers and patients want: care of good quality. It also has another role, one which government quite properly holds in many areas of society where there is one or a few very large suppliers of a service, namely to establish a system to protect the interests of the people who receive that service. Such a system, in essence, is a system of regulation. In the past, in relation to the NHS, it was thought that a system of regulation aimed at healthcare professionals alone would be enough. Bristol has taught us that this is not enough. It is also necessary to have a system for regulating the institutions which provide healthcare.
- 10 Thus, the approach of government is changing, and changing, we believe, in the direction which the lessons of Bristol would suggest is necessary. We would argue however, that for the future the change must be clearly analysed and focused. What is required is much more explicit recognition on the part of government that, as regards quality of care, it has two separate but related roles: good management of the NHS, and the organisation of good, comprehensive regulation of the quality of healthcare. In the past, as the example of Bristol so clearly demonstrates, neither of these roles was properly understood or performed.
- 11 For the future, it is clearly the responsibility of government to *establish* the systems both for good management and for regulation. But it does not follow that government should do both of them. Indeed, there is a clear conflict of interest were government to perform both of these roles. As we shall see later, regulation of the NHS cannot be for government. It must be independent of government. It must involve and reflect the interests of all, patients, public and healthcare professionals, as well as the NHS and government.
- 12 This delineation in the roles that government should play is both simple and clear: serving through the DoH as the strategic headquarters of the NHS, and establishing the system of regulation, of both institutions and healthcare professionals, by independent bodies. We will set out the detailed implications of this approach in the

pages and chapters which follow. We admit that to pursue this direction will take political nerve. But if trust in the proper regulation of the NHS is to be regained and then maintained, it is a step which government must take.

- 13 We turn now to examine as the two separate but related elements of a well-led NHS: (a) leadership and management of the service, and (b) regulation to ensure, on behalf of patients and the public, that standards for the quality of care are set and implemented.

The leadership and management of the NHS

- 14 We recognise that, so long as the NHS remains a publicly funded service and that healthcare continues to be provided primarily through trusts, NHS primary care trusts and through staff employed by the NHS, the NHS is a state-run organisation with a virtual monopoly in the provision of healthcare. It follows from this that how resources are used within the NHS is subject to Parliamentary scrutiny through the accountability of the Secretary of State. This being so, we accept that management of the NHS must be the responsibility of the DoH. This is not to say that the Department should manage every detail of activity. Historically, as was set out in *'The NHS Plan'*: 'The relationship between central government and the NHS has veered between command-and-control and market fragmentation. Neither model works. The NHS cannot be run from Whitehall'.⁶ Nor, we would add, can it be run like a commercial organisation in which the values of public service and of the healthcare professionals are replaced by a culture of commodity and commerce, if it is to keep faith with its founding principles.
- 15 *'The NHS Plan'* recognises that the quality of care provided for patients will have the best chance of improvement when clinicians and managers have the freedom to lead and manage local services within a national framework. The Plan emphasises that, progressively, there will be less central control and more devolution as standards improve and services become more focused on patients' needs. The challenge will be to make that a reality.
- 16 We are in no doubt that intervention from the centre should only be contemplated when it adds value. Such value can most effectively be added at the strategic level, by establishing and monitoring national systems, rather than by direct intervention or directing the management of individual trusts or individual professionals. We recognise that this shift will take time, that a process of change is involved, but would argue that there needs to be progressively much greater self-discipline on the part of central government. The prime focus should be on supporting local management and on helping health authorities and trusts to deliver care which is safe and of a good

⁶ *'The NHS Plan'*. London: Department of Health, 2000. Para 2.31

quality. We understand, as we have already made clear, that if Ministers are accountable to Parliament they will be inclined to want to direct. Furthermore we recognise that there are, and should be, occasions on which central government must have the power to intervene and take action. But this must be carefully judged if a sense of local leadership is not to be undermined. The answer lies in a gradual understanding of what the centre is responsible for, together with the parallel development of local mechanisms whereby institutions and managers at the local level can be held accountable. And, in between, there is the necessary development of a middle tier of leadership and management able to see beyond the individual trusts and take account of the interests of the wider community. On this account we welcome the creation of the new health authorities which will take on this role.

Resources

- 17** We have noted the increases in the funding of the NHS since 1999. We have also made the point that if the NHS is to meet the claims made for it, the level of funding must increase yet further. This is because the various initiatives concerned with the safety and quality of care are not cost-free. Indeed, it is suggested that the cost of implementing the modernisation agenda will require significant additional funding, over and above that which is already planned. The point is simple yet crucial. If staff are to be properly trained and then motivated to continue in public service, this will cost money. If the ratio of healthcare professionals to patients is to improve, as it must if safety and quality in healthcare are to improve, this will cost money. If healthcare professionals are to have the necessary time and space, for example, to participate effectively in audit, to engage in continuing professional development, and to communicate properly with patients, this will cost money. If healthcare professionals are to have available the necessary equipment and facilities, this will cost money. If buildings are to be built, this will cost money. It would be the cruellest irony if it were demanded of chief executives that they deliver a healthcare service fit for the twenty-first century, while not giving them the necessary resources. Of course, government could change its mind and downgrade its commitment to what the NHS should provide and how good the service should be in terms of safety and quality. If it did, however, this would probably mean the end of the NHS. What government cannot do is to renew its commitment to a comprehensive, accessible healthcare service for all and then fail to fund it to the level of the demands government makes of it. Governments have got away with this in the past, but not now. Expectations have been raised and the public is watching.

Leadership at the level of the health authority

- 18** As we have indicated, there needs to be leadership at a level between the national and the local. The DoH cannot descend to the detailed needs of individual trusts and trusts need more guidance and, on occasions, control than can be exercised through general strategic direction. The history of the NHS over the past decades is one of wrestling with this problem without ever entirely resolving it. The recent decision to rationalise the intermediate tier and to have only 30 health authorities between the trusts and the DoH is, in our view, the right way forward. It allows the concerns and

needs of a wider population than that served by any trust to be taken account of. It also allows national strategic goals to be translated into, and adapted to, the circumstances of a particular area and then passed down to the individual trust. Perhaps most importantly, in terms of the lessons of Bristol, it means that the actions and ambitions of trusts (including primary care trusts) can be co-ordinated according to some rational and cost-effective plan which serves the interests of all within the health authority. For example, a proposal by a trust to embark on a new area of healthcare service will have to be agreed by the health authority. If it is judged inappropriate, as not meeting or responding to the needs of the local population, funding would be denied. This is a powerful tool in the development of a better planned and more coherent NHS.

Leadership at the level of the trust

- 19** The chief executive: We have already indicated that the leadership exercised by central government and, to a degree, at the level of the health authority, conditions what may be done at the level of the trust. Equally, we have argued that it must be the role of the centre to establish an appropriate framework, including certain general principles applicable to all trusts, and then let the chief executive in the respective trusts get on with the job. From the perspective of the patient, the job of the chief executive is to ensure that patients receive care which is safe and of good quality.
- 20** Since 1999, as we have seen, it has been the duty of each health authority, trust and primary care trust to put and keep in place arrangements for the purpose of monitoring and improving the quality of healthcare which it provides to individuals.⁷ We applaud this development, not only because it finally gives proper prominence to the quality of the care provided by the trust, but also because it identifies that responsibility and therefore accountability rest with the organisations which provide healthcare services. The game of 'pass the parcel' is no longer an option at local level. This is the way forward and we support it.
- 21** But there is another side to the coin. If trusts are to have this responsibility, they and their chief executives must be supported in carrying it out. The NHS at the centre must reinforce the duty to secure quality in healthcare and the message which the imposition of such a duty sends, by establishing and maintaining the framework necessary for chief executives to do what is asked of them. In short, they must given the tools for the job. We single out two of these 'tools' for special attention; they are:
- appropriate contractual relationships with trust employees
 - support for the role of trust chief executive.

We also comment on the role of the trust board and of non-executive directors.

⁷ *Health Act 1999 s18(1)*. London: The Stationery Office, 1999

Contractual relationships with trust employees

22 Participants in our seminars who came from organisations other than the NHS frequently commented on the complexity of employment relationships in the NHS and on the extent to which it appeared that a chief executive and a trust's board can be disempowered by strong professional groupings, apparently beyond the chief executive's control to manage. We heard that there continue to be differences in the nature of the employment relationship between different groups of healthcare professionals and their employer, the trust. Specifically, hospital consultants have a unique employment status within the NHS. Even today, consultants would not necessarily consider themselves accountable or answerable to a clinical director, and clinical directors would not necessarily consider themselves accountable or answerable to the medical director. Nor would they see themselves as necessarily answerable or accountable to the chief executive. There continue to be uncertainties and ambiguities about accountability: the same general uncertainties as existed in Bristol in the 1980s and 1990s.

23 Consultants have an odd position in terms of the ordinary norms of employer-employee relations. They enjoy a job effectively for life. It is extremely difficult to remove them. The hours they spend actually dealing with patients are not regulated. They see themselves as largely autonomous, with their duty being owed to the patient and their sense of identification being to their professional peer-group. To that extent, they do not see themselves as employees at all. This point was brought out by Dr Hugo Mascie-Taylor, the Medical Director of the Leeds Teaching Hospitals NHS Trust. In a paper submitted to the Inquiry he wrote:

'... it is fair to say that consultants are not managed like other NHS employees. Indeed, some would say that in some ways the consultant body still stands at the edge of the NHS rather than at the centre of it.'⁸

24 We are convinced of the need to restate the relationship between the consultant and the hospital. The principal means of doing so must be through the contract agreed between them. As in all such agreements, there should be a recognition on both sides of the other's interests. The trust must agree to provide the consultant with the time, space and the necessary tools to do the job. The trust must be enabled to provide suitable incentives to consultants and to other hospital doctors to encourage them to achieve high quality in the care of their patients. One means of so doing is to extend the system of Distinction Awards beyond the changes made in the late 1990s. These changes reflected a recognition that distinction in the care of patients, as well as in the performance of research, should be rewarded. This could be taken further and the system extended beyond hospital consultants to include junior doctors.

25 The trust must also underwrite its commitment to an open, fair and non-punitive environment, in which all employees feel safe to voice views and concerns. For their

⁸ Seminar 4. Dr Hugo Mascie-Taylor. Position Paper. The quotation is extracted from Dr Mascie-Taylor's chapter in *'Managing Medicine – a Survival Guide'* (1997) London: Financial Times Healthcare

part, consultants must accept that the time spent in the hospital and what they do in that time must be much more explicitly set out. They must also accept that failure to comply with contractual obligations places them at the same risk of some form of disciplinary action as any other employee. There is no reason why the consultant should be immune from such processes, or be protected by the current labyrinthine procedure, involving sometimes an interminable period of time of suspension on full pay (which is the near equivalent to immunity). We note the emergence of primary care trusts. We also note that GPs associated with these trusts have historically enjoyed a different relationship with the NHS from that of the hospital doctor. Our concern is with the acute hospital sector, but if systems of accountability and regulation are to be introduced effectively across the NHS, careful consideration will need to be given to the relationship between the GP and the primary care trusts.

- 26** We emphasise the importance of the contract because we see it as crucial that the hospital, through its chief executive, be able to manage itself. This is one of the most important tools which chief executives need if they are to be able to meet their obligations regarding the safety and quality of healthcare. It is a tool which any chief executive in any other organisation would take for granted. Moreover, in a patient-centred system of healthcare, it is clearly in the interests of patients that the chief executive be able to respond to any complaint that a consultant has not met his or her contractual duties as promptly as possible. Moreover, by enabling the chief executive to respond by reference to the contract between the consultant and the trust, the response is closer to the event, is more informed as to local circumstances and action can be taken more promptly. The process is thus made more effective and patients' interests are better served.
- 27** It must not be thought that we see a change in the employment relationship of the consultant as a panacea to all the difficulties faced by chief executives in leading and managing a trust. Nor, importantly, do we see it as some instrument for control. This is because the contract is part of a much larger picture. As we have said, that larger picture must be one of openness and, over time, increasing understanding and trust. The contract serves to facilitate the performance by both parties, employer and consultant, of their respective duties to the NHS. Indeed, one particular feature of any new contractual relationship must be that it sets out clearly the lines of accountability and responsibility within the hospital. Consultants must be able to know what is expected of them and to whom they should turn if they wish any particular matter to be dealt with. We were impressed by evidence that while a formal structure of management might exist in a hospital, some consultants might choose to regard it as a matter for others and not something of direct interest or concern to them. Equally, others felt unsure about their place in the organisation of the hospital and uncertain as to whom they should turn with regard, for example, to matters relating to the safety of patients. Setting out such matters in the employment contract would serve to reduce these difficulties.
- 28** Any discussion of the consultant's contract must address the question of the relationship between the powers of the employer and those of the body concerned

with maintaining the register of medical practitioners. We will set out our views in due course on the wider issues of the regulation of healthcare professionals in general. Here, we focus on one matter of importance.

- 29** The General Medical Council (GMC) currently sets and publishes a Code of Professional Practice on how doctors should conduct themselves.⁹ Breach of the Code can bring disciplinary action by the GMC, concerned with whether the doctor should remain on the register. This process is independent of the employer-employee relationship. But we think that there is good reason why the doctors' Code, as currently set down in the GMC's *'Good Medical Practice'*, should be incorporated into the contract between the trust and all doctors, not just consultants. Nor should this be limited to doctors. The relevant Codes of Practice should be incorporated into the contract made between the trust and all other healthcare professionals. Breach of the Code would then be an employment issue, to be dealt with by the hospital in appropriate and agreed ways. This would mean that breaches could be dealt with, as we have already said, close to the event and in the light of local circumstances. If action is required in the interests of patients (this being the first and paramount priority), it could be taken with all due speed. What the relevant professional body (for example, the Nursing and Midwifery Council) might wish to do concerning the wider question of the healthcare professional's fitness to continue in practice would be a matter for it to resolve. We add that in circumstances in which the safety of patients is or may be at risk, the employer should be required to notify the relevant professional body of any action taken. The relevant professional body in turn, being concerned not just with discipline but all aspects of performance, can then take appropriate action.

Support for the role of chief executive

- 30** A feature of trusts since their appearance in 1991 has been the difference between the chief executive and many of the healthcare professionals, particularly the senior staff, in relation to their employment. While the latter have what amounts to security of tenure for life, the chief executive (and senior managers) have a far less secure status. Just as we suggest some paring down of the status particularly of consultants, so we see the need to develop a culture in which chief executives (and senior managers) may feel more secure in their employment. Currently, there is a sense in which the NHS is too greatly politicised and too closely managed from the centre. As a participant in one of our Seminars, with experience of life in the public sector, put it: '... the life of a Chief Executive is nasty, brutish and short'. In such a climate, the danger exists of demanding the head of the chief executive (or a senior manager) if some problem affecting a trust attracts sufficient adverse attention. To us, this is no different from the reflex of demanding that some healthcare professional should be 'struck off' when something has gone wrong. It is the culture of blame and it is unhelpful, as we have repeatedly asserted. It may satisfy an immediate desire for some punitive action but it rarely addresses the underlying issues. The same is true as regards a chief executive (and senior managers). There is a danger that they can be treated as sacrificial lambs, to achieve some quick political fix. This does nothing to

ensure good leadership and management in the NHS; it does the opposite. It deters those who are otherwise capable and committed. For this reason, we are concerned that chief executives (and senior managers) receive appropriate support and enjoy the same degree of security of tenure as other senior professionals in the NHS. They must be allowed to lead and manage, and be supported in this. They must not be at the mercy of the government's anxieties about the headline of the day. The trust's board should be left to make its own decisions on the future of the chief executive, according to clear and agreed criteria.

The trust board

- 31** Leadership at the local level also depends on the trust board. The board consists of executive and non-executive directors. As regards the executive directors, in particular the medical and nursing directors, it is of crucial importance that appointments are based on real ability and commitment to leadership and management. Trusts should make training and preparation for the role of executive Director part of their overall strategy and seek to identify and support those who may be suitable for appointment. The NHS Leadership Centre, in conjunction with trusts, should develop programmes of training and support for clinicians and others who seek to become executive directors. The criteria and process for selection must be clear and open. Appointments must be made on the basis of ability. They must not be made on some notion of 'muggins' turn'. In one of our Seminars Hugo Mascie-Taylor pointed to the tendency to appoint the most senior consultant to the role of manager, and remarked that seniority does not necessarily guarantee managerial ability: 'In some cases the most senior consultants were actually those least likely to take a corporate view, and making them the manager simply allowed them to exercise their individualistic powers more easily.'¹⁰ And, just as there must be a clear process for appointment, so there must be systems to support executive directors while in office and to review, periodically, their performance.

Non-executive directors of trusts

- 32** As for the non-executive directors, a very clear message to emerge from Bristol is how readily the board's non-executive directors (and even to an extent the chairman) can be prevented from exerting the authority expected of them, simply by not being let in on issues. A strong chief executive, with support from executive directors, can seek to control what comes to the board and in what way. Once this approach takes hold, it is hard to overcome. Its consequence is that the board cannot effectively serve the public interest.
- 33** We were struck by the views expressed in our Seminars about the variation in the roles played by and the expectations held of non-executive directors. An overriding sense of lack of clarity and direction emerged. And, without sound knowledge of what might be happening in the trust, non-executive directors were often unable to challenge the views of the chief executive, or the executive directors. In our view,

¹⁰ Seminar 4. Dr Hugo Mascie-Taylor. Position Paper

non-executive directors have a crucial role to play as representing the public interest in the conduct of the trust's affairs. They must be people with a high level of ability and experience in the leadership and management of organisations. They should not all have a background in healthcare, since the views in organisational terms of those with differing experience can be of great importance. They should, however, have a commitment to public service. Given the importance of their role, the process of appointment must be open and transparent. As recommended in *'The NHS Plan'*,¹¹ there should be an NHS Appointments Commission responsible for the appointment of non-executive directors of trusts, health authorities and primary care trusts. The criteria for appointment must also be open and clear. We were pleased to note that *'The NHS Plan'* included a proposal to develop training for non-executive directors and to issue a standard job description. These are long overdue. There should also be a programme of induction which should refer to the principles and values of the NHS and the duties and responsibilities of non-executives with regard to the quality of care provided by the trust. This programme should be provided through the NHS Leadership Centre. The non-executive directors must be allowed to become thoroughly involved in the affairs of the trust. They must be let in and then assert the authority which is properly theirs. This is particularly so in the case of the Chairs of trust boards. They must be supported to exercise their authority and independence of mind, That is why we believe that the Chairs of trust boards should have a source of independent advice (or mentor) during their period in office drawn from a pool of experts assembled by the NHS Leadership Centre. We note here also, and endorse, the views expressed in a recent report from the Cabinet Office: that all non-executives members of boards in the public sector should receive suitable training, including best practice on recruitment, on performance management for leaders and on holding leaders to account.¹²

The future framework for the regulation of the quality of healthcare

- 34** We turn now to the second of the two fundamental elements required for a well-led NHS: regulation. First, we need to make clear what we mean by regulation. It is a broad term. It describes all those processes by which the safety and quality of healthcare are assured. It can be divided into two categories: the regulation of healthcare professionals and the regulation of healthcare institutions (hospital trusts, health authorities and primary care groups/trusts). The regulation of healthcare professionals, historically largely associated only with discipline, involves all matters affecting the performance of the professional. It covers, therefore, initial education, training, appraisal, continuing professional development and, where relevant,

¹¹ *'The NHS Plan'*. London: Department of Health, 2000. Para 6.54

¹² Cabinet Office, Performance and Innovation Unit, *'Strengthening Leadership in the Public Sector'*. April 2001. www.cabinet-office.gov.uk

disciplinary action. The regulation of institutions is equally broad, addressing those systems which set, monitor and enforce standards and disseminate information on performance. This approach to regulation allows us to capture the whole varied range of activities which are concerned with safety and quality under one heading. What is currently a mass of ill- or uncoordinated activities can be reanalysed once it is recognised that they are part of a common process.

- 35** Once regulation has been properly defined, we need to ask who is going to be responsible for the two categories of regulation which we have identified. We begin with our conclusion. Regulation, as we have defined it, is not properly a task for central government, through the DoH. As a monopoly provider, it cannot be in the public interest for it also to set and monitor the required standards of performance. Its role must be to ensure that the standards of care once established are delivered. In our view, regulation must reside in bodies which are not directly under the control of government. The role of the Department should be to create the necessary regulatory framework and then stand back, only becoming involved when significant changes in the policy of regulation are involved.
- 36** As regards the regulation of institutions, we have noted that government, through the creation of bodies such as NICE and CHI, has gone some way to creating the sort of system which we regard as essential.¹³ But two further steps are required. First, these bodies must be given greater autonomy and independence from central government's control. Second, there must be some overarching body which can integrate and co-ordinate the activities of all the various individual bodies concerned with safety and quality. Only if such a body exists will the risk which we identified in Bristol be avoided: the fragmentation of responsibility among a plethora of organisations and the danger that concerns fell through the cracks between organisations. This overarching body must be created by government to be at arm's-length from and independent of government. It could be called the Council for the Quality of Healthcare. We point out that this is the only *new* body which we recommend should be created. All the other bodies to which we refer already exist or are proposed in *'The NHS Plan'*.
- 37** We adopt the same approach as regards the other area of regulation, that of healthcare professionals. Currently, there are a large number of bodies involved in the activities which together constitute regulation. They include the new Nursing and Midwifery Council, the GMC, the proposed new body which will regulate the professions allied to medicine, the Royal Colleges, the various professional associations, the DoH, health authorities and trusts. Each operates in its own sphere, with, historically, little collaboration or co-operation. The various activities must be brought together and properly co-ordinated. The role of the various bodies must be clearly identified. And all of the bodies should be brought under the overall leadership of one overarching body. This body in turn must be independent of the DoH. It could be called the Council for the Regulation of Healthcare Professionals. (In effect this is the body

¹³ We note, however, the current difference in status of these bodies. NICE is a Special Health Authority of the NHS; CHI on the other hand is not part of the NHS but is a non-departmental public body allied to the DoH

currently proposed in *'The NHS Plan'*, referred to there as the Council of Healthcare Regulators.)

The regulation of healthcare institutions

- 38** We turn now to consider in greater detail the co-ordination of the regulation of healthcare standards and of the standards of healthcare institutions. We will deal in the next chapter with the regulation of healthcare professionals. Our starting point is to repeat that currently the state is virtually the monopoly provider of health services in this country. The public and patients are entitled, therefore, to expect that (a) there are systems in place to ensure that this monopoly is able to achieve its prime objective, healthcare of high quality for patients, and that (b) there are systems in place to ensure that this state monopoly is publicly accountable in this regard. Furthermore, such systems, if they are properly to do their job on behalf of patients, must be trusted both by the public and by healthcare professionals. This means, in our view, that they must be independent. They must be at one remove from party political debate. They must be seen to have a life and status of their own, free from changes in political fashion. Standards and quality in healthcare must be the sole priority of the body responsible for them, not one of a number of competing priorities. The NHS is quintessentially a statement of political values. Thus, it is inevitable and right that central government should seek to lay down the parameters of the NHS's activities, particularly in the realm of finance and priorities. But, once this is done, the systems for monitoring the extent to which it is meeting its stated aims must, in our view, be de-politicised, so as thereby to rekindle and maintain public confidence in the NHS. We believe that the framework which is gradually emerging could and should be made stronger and more independent in a number of respects.
- 39** To illustrate our point that there is some way to go, we refer to the system so far developed for the setting of standards in healthcare. The DoH remains very closely involved in the process, despite having set up an organisation, NICE, to carry out this task.¹⁴ Sir Donald Irvine, Chairman of the GMC, recently asked, 'Can a centralised bureaucracy, led by a Minister of the Crown, be both standard setter and near monopoly provider?'¹⁵ The tension between being a monopoly provider and setting standards needs careful analysis. On one view (Sir Donald's) there is a conflict of interest. The monopoly provider will always be tempted to interfere to make the standards match the needs of the day, or, more worryingly, the political priorities of the day. But, at the level of abstract analysis, it is perfectly plausible to take the opposite view from Sir Donald. Who better than the monopoly provider to set the standards? The monopoly provider knows what resources are available and can seek to tailor standards to resources. The same arguments could also be applied elsewhere: to the conduct of national audits of performance and to the publication of information about healthcare performance on a national scale. Who better than the monopoly

¹⁴ The DoH sets standards in 'priority' areas of healthcare through National Service Frameworks; it also determines annually the list of conditions in relation to which NICE should develop standards

¹⁵ Sir Donald Irvine. *'The changing relationship between the public and the medical profession'*. Lloyd Roberts Memorial Lecture. Royal Society of Medicine, 16 January 2001. www.gmc-uk.org

provider to report on its own progress? It has access to all the data and can analyse and present it.

- 40** But we are not engaging in some abstract analysis of how best to organise the NHS. We are talking about how best to persuade those affected by it and those working in it to rebuild and retain their trust in the NHS. In our view that trust can best be rebuilt and sustained by central government continuing the process it has already begun of establishing an independent framework for quality assurance. This means in practice that the organisations which have been set up to support, sets standards for, and monitor the NHS must be given greater authority and independence. It also means that the organisation and funding of these organisations may have to be revisited to ensure that they are able to fulfil their respective roles. It means that in the regulation of healthcare institutions, the Department's role should be increasingly strategic: to establish 'offshore', as it were, a system of regulation; to support its authority; and to review its functioning over time with a view to improving it. This is a crucial lesson from Bristol. As we have said, adopting this role will take nerve and political courage. But it is the right way to secure the future of the public's trust in a national health service.
- 41** How should government go about this task? Our vision of the DoH's role in the future, in relation to regulation rather than to the management of the NHS, is that its responsibility lies in ensuring that a proper system is in place and that the various bodies are able to make their contributions to the overall framework of improving the safety and quality of healthcare. This is the extent and limit of the Department's responsibility. The issue here, and it is a complex and demanding issue, is how to set the proper bounds of the political on the one hand and the expert and the public on the other in a national health service. We take the view that the only system which will enjoy public trust and confidence is one in which the political responsibility is limited to creating the overall framework and monitoring it thereafter.
- 42** There are already organisations charged with bringing about improvements (CHI and NICE). These are not new bodies. We would incorporate them into the framework we propose. But they would have to be differently constituted. They should be made fully independent of the DoH. Indeed, that CHI and NICE are not sufficiently independent, is *already* creating a sense that both are limited in their powers to act. Neither body, for example, has the powers to enforce compliance with its reports, and both bodies look primarily to the DoH (the monopoly provider) for their membership, their resources, and to set their detailed agenda. By way of illustration, CHI's independence cannot be manifested or enjoyed as long as it is the Department rather than CHI itself which sets the targets for the number of trusts which must be inspected each year.
- 43** The type of model which we favour for CHI, NICE and the proposed National Patient Safety Agency is that of a body such as the Foods Standards Agency. The FSA is at arm's-length from government and while its overall general objectives and practices must be approved by government, the government's power to direct its activities is otherwise limited. Moreover, it has an explicit duty to ensure that members of

the public are kept adequately informed about and advised in respect of matters which the FSA considers significantly affect their (i.e. the public's) capacity to make informed decisions.¹⁶

- 44 But, as we have made clear, we do not stop there. A plethora of organisations, all with their own ambitions and anxious to defend their 'territories', was one of the defining features of what happened in Bristol. To bring together the various activities of these agencies, to ensure that issues are not missed, and to give some kind of strategic direction, some further mechanism is needed.
- 45 Such a mechanism would ensure that the activities of the various parts are co-ordinated and integrated. This is the role central government currently presumes to play, but it does so unconvincingly. In particular, it tends to an extent to see the creation of the agency or organisation as a solution in itself, while retaining real control at the centre. Furthermore, as we have said, one of the principal lessons of Bristol is how various organisations can become blind to the activities of each other.
- 46 Thus, as mentioned earlier, we see the need for an overarching body to monitor and co-ordinate the activities of all the various agencies concerned with standards and quality. The Council for the Quality of Healthcare would have an independent status, once established by government. The various agencies would be required to report to it and would derive their authority from it. Its terms of reference would be laid down by statute and it would report both to the DoH and to Parliament. It would provide the much-needed leadership to ensure that patients receive care of a proper standard and quality. While the Secretary of State for Health would be responsible to Parliament for its activities, it would be understood that the Department's role was one of establishing and funding the Council, and setting and periodically reviewing its strategic framework, rather than being involved in its operational activities.

The Regulatory Councils

- 47 We see two Councils as the future framework for the regulation of the quality of healthcare: one to bring together and co-ordinate all those processes by which the safety and quality of healthcare are assured in healthcare institutions, and the other (already in *'The NHS Plan'*) to bring together and co-ordinate the various bodies concerned with all aspects of the regulation of healthcare professionals. It could be objected that the NHS is not short of organisations and bodies already. While we understand this possible objection, we reject it. First, there is a very great need to resolve the problem of fragmentation of responsibilities for assuring the quality of care within the NHS. The overarching organisations which we propose will achieve this. Secondly, the functions which would be undertaken by the Councils are purportedly already carried out by the DoH. We have suggested that they are not carried out with appropriate vigour, efficiency or independence. That they need to be carried out, however, is clearly recognised. The system we propose would simply do it in an appropriate manner. It may well be that, in time, the separate activities of the two

Councils could be combined in just one organisation with two branches: one to cover the regulation of professionals and the other to cover the regulation of healthcare institutions. In the interim, we have no doubt that there should be close collaboration between the Councils.

Chapter 25: Competent Healthcare Professionals

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

Messages from Bristol

- There was no requirement on hospital consultants to keep their skills and knowledge up to date nor to demonstrate to anyone other than their peer group that they remained sufficiently skilled.
- Surgeons were able to introduce new techniques without any formal system of notification and without the need to demonstrate the necessary level of skill.
- Patients were cared for by distinct groups of health professionals. Collaboration and inter-professional teamwork were poorly organised.
- Appointments of clinicians to managerial positions on occasions were filled on the basis of seniority or ‘muggins’ turn’ (next in line), rather than the ability to do the job.
- Clinicians undertaking managerial roles did not receive the necessary formal training or support.
- The communication skills of the healthcare professionals varied greatly.
- The systems in existence were not capable of assuring the competence of healthcare professionals.
- Poor or diminishing competence could not be adequately addressed until it became manifestly bad.

Introduction

- 1 We learned from both Phases of our Inquiry that what we heard about in Bristol, in terms of attitudes and in terms of competence, broadly defined, was not unique to Bristol. Nor was it limited just to the period of our Terms of Reference. Indeed, anyone reading the recent review into the Oxford Cardiac Services¹ would find uncanny similarities to what we describe in Section One in the case of Bristol. Yet it referred to

events between 1995 and 1999. The report into paediatric cardiac services at the Royal Brompton and Harefield Hospitals² only appeared in April 2001, yet it too has echoes of the events and circumstances of Bristol. The continued existence of shortcomings in professional competence clearly undermines the capacity properly to care for patients.

- 2 This chapter looks at the range of skills of healthcare professionals. We argue that, in the case of doctors and nurses, technical clinical skills are a necessary but not a sufficient qualification to practise as a healthcare professional. For the future we must expand our understanding of what constitutes professional competence. Attitudes and interpersonal skills must be recognised as having value alongside clinical skills. This has consequences for the way in which future healthcare professionals are selected and educated. In the second part of this chapter we consider the systems for ensuring that competence is acquired and then maintained throughout the professional's working life. We identify areas where these systems need to be strengthened. We give particular attention to the way in which professionals acquire *new* clinical skills. Some of our observations relate to particular professions but most relate to *all* healthcare professionals (managers, doctors, nurses and other healthcare workers).

Professional competence

- 3 When we talk of professional competence, we refer to patients' expectations that the professional they come into contact with will be up to the job. Professionals should be able to do that which they profess they can do. From the patient's point of view, it is shocking to think that this might not be the case. Indeed, the need for healthcare professionals to acquire and maintain appropriate levels of competence is so obvious that it would seem unnecessary to refer to it. The patient simply expects that the healthcare professional has up-to-date knowledge and skills. A healthcare professional's competence from the patient's point of view is not negotiable. Moreover, when we talk of professionals, we repeat that we mean all of the professionals who make the NHS work: doctors, nurses, the professions allied to medicine,³ managers and other healthcare workers.
- 4 Levels of competence quite properly will vary. A consultant or a nurse ward manager will have a wider and deeper level of competence than the junior doctor or newly qualified nurse. Yet, even at the start of a professional life, competence should meet a critical minimum level. Competence will also vary at the level of specialist expertise. Consultants working in a highly specialised field, by declaring themselves to be

² 'The Report of the Independent Inquiries into Cardiac Services at the Royal Brompton and Harefield Hospitals', April 2001. www.rbh.nthames.nhs.uk

³ The term 'professions allied to medicine' is usually taken to include professionals working in the fields of physiotherapy, occupational therapy, speech and language therapy, audiology, dietetics, podiatry, counselling and orthoptics

specialists, profess that they have (and thus should have) a greater level of competence in the particular area than a consultant who is a generalist.

- 5 Professional competence requires a firm educational grounding, followed by a period of formal training to acquire the relevant knowledge and skills in the workplace. Thereafter, continued competence rests on a combination of education, continuous development, confidence and experience.⁴ It depends on the motivation of individual professionals to learn and develop and the extent to which their employer supports them and enables them to do so. It also depends on the professional standards which they are required or expected to meet, and on the wider systems for ensuring that those standards are adhered to.
- 6 Thus, acquiring and maintaining professional competence involves collaboration between the individual, the educational institutions, the employer, and those who set and enforce standards of professional competence. Individual healthcare professionals, once qualified, need to be sufficiently motivated and have sufficient incentive to maintain and develop their competence. If the process of keeping knowledge and skills up to date is neglected, the professional's level of competence will diminish. It is crucial, therefore, that the working life of healthcare professionals be so structured as to allow them to meet these requirements. This means that the employer must provide professionals with sufficient time and opportunity to maintain existing skills, and to acquire and consolidate new skills. Thus, the work environment in the NHS must support and enable the process of continuous learning, through well-planned strategies for continuing professional development. As for those who set standards, they must ensure that their frameworks of professional standards are and remain appropriate to the needs of patients and professionals and are, in fact, observed.
- 7 Professionals' competence also depends upon professionals themselves having an honest understanding of their abilities. It is crucial that errors in practice, or gaps in skill or knowledge, are acknowledged as early as possible and used as an opportunity for learning, rather than being suppressed or hidden out of fear of blame or sanction. Learning through mistakes can often be a very effective way of improving competence and understanding. But to acknowledge errors and shortcomings, professionals must feel safe to do so. Employers, therefore, must create an environment which enables this to happen.

⁴ The term 'education' usually refers to the undergraduate period when prospective healthcare professionals are working towards an initial qualification; the term 'training' usually refers to that period after qualification when the professional is acquiring further specialist skills; the term 'continuing professional development' generally refers to activities undertaken by a qualified and trained professional to maintain their skills, during the course of a working life

Broadening the notion of competence

- 8** Clearly, healthcare professionals must be technically competent to do the task they profess to do, but technical competence is no longer sufficient, if indeed it ever was. A major lesson of our Inquiry is that there are a number of non-technical, non-clinical skills of doctors, nurses and managers which are crucially important to the care of patients. We have identified six key areas. They appear to have been relatively neglected in the education and training of healthcare professionals in the past. They must not be in the future. They are:
- skills in communicating with patients and with colleagues;
 - education about the principles and organisation of the NHS, how care is managed, and the skills required for management;
 - the development of teamwork;
 - shared learning across professional boundaries;
 - clinical audit and reflective practice; and
 - leadership.
- 9** Clinical skills are essential, but patients are entitled to expect that the healthcare professionals caring for them will also possess these non-clinical skills. Education and training in them must be accorded a greater priority in the future and this should apply at all stages of a professional's career: education, training and continuing development. Healthcare professionals cannot fulfil their responsibilities without having these skills. In the case of doctors we are aware that ever since the Todd Report in 1968⁵ a range of non-clinical subjects have been taught in medical schools. But, with notable exceptions, it is sadly the case that these subjects (for example, communications, medical sociology, or health and society) have not been accorded the importance they require. Whereas students are increasingly examined in them, the problem remains that they are dismissed as having a low status by those who teach basic sciences and this attitude rubs off on the students.
- 10** Education in the areas which we have highlighted must become fully integrated into the undergraduate curricula of relevant courses. They must be much more than mere 'add-ons', tolerated as extraneous burdens on what some might see as the 'real' clinical curriculum. It is in the formative years of undergraduate education that attitudes are forged and skills imparted which shape the quality of engagement with patients for years to come. Efforts to improve and expand professional competence

⁵ Lord AR Todd. *The Todd Report* (1968). Royal Commission on Medical Education. (Cm. 3569)

through undergraduate education, however, will only succeed if the skills of newly qualified professionals are reinforced throughout professional life and also valued by those currently in senior positions. That is why we argue that these six areas must also be given a high priority at all levels of professional preparation and training. They should also form part of the plans and practices of NHS employers for the continuing professional development of their employees.

Communication skills

- 11 We are concerned here with attitudes – the frame of mind which the professional brings to the job. The pre-eminent attitude must be that the NHS is a service for the public. The needs of the patients must be the driving concern. This calls for a recognition of the need to establish and maintain good communication with patients and with fellow professionals. It calls for a commitment to respect patients, and to be honest and open towards them. And here, honesty includes the obligation of professionals to be honest with themselves about their abilities. An attitude of public service also calls for the ability to convey uncertainty without fearing that it will appear weak. It calls for retaining and conveying a sense of open-mindedness in the dialogue which is the patient's journey. Perhaps most important of all, it calls for a sense of shared humanity, sympathy, understanding, an ability to engage with the patient on an emotional level, an ability to listen, an ability to assess how much patients wish to know about their condition and treatment, and an ability to convey information with clarity and sympathy. Caring is not just 'what nurses do'. It is what all healthcare professionals should do. In our view, therefore, the attitude of public service which we describe is the essence, the affirmation, of professionalism, not its antithesis.
- 12 There is already evidence that medical schools are developing their curricula to reflect the importance of personal and interpersonal skills. Largely in response to the General Medical Council's (GMC's) 1993 document, *'Tomorrow's Doctors'*,⁶ most courses now include modules on communication skills. Medical schools also recognise that doctors, in addition to acquiring a core of clinical knowledge and skills, must develop attitudes appropriate for professional practice. But the extent to which education in these non-technical, non-clinical areas is integrated into the curricula, and the relative weight given to them, varies considerably. The GMC's reports of recent visits to medical schools⁷ demonstrate this. We commend the curriculum of Southampton University's Medical School as one where very great efforts have been made to integrate the education and training in personal and interpersonal skills into all parts of the curriculum.⁸

⁶ We note that, as this Report goes to press, a newer edition of *'Tomorrow's Doctors'* is in preparation. It includes a renewed emphasis on the importance of communication skills in undergraduate medical curricula

⁷ See the GMC's website www.gmc-uk.org where these reports are published

⁸ We note the considerable emphasis placed on communication skills in the training of GPs, in the course of their professional training, over the past three decades

Education about the principles and organisation of the NHS, about how care is managed, and the skills required for management

- 13 One of the most surprising features of the current approaches to the education of healthcare professionals, particularly in medical schools, is the relatively low priority accorded to teaching in two areas which are central to a career in the NHS. We refer to an understanding of the NHS, its values and how it operates, and to the way in which the NHS's services are managed. The consequence is that many future healthcare professionals graduate with a lamentably insufficient awareness and understanding of the organisation in which the vast majority will spend their working lives. We welcome the recognition of the problem in *'The NHS Plan'*, in which it is proposed to provide new, joint training across professions in the principles and organisation of the NHS.⁹
- 14 The importance of such education and training cannot be overstated. An understanding of the values and principles on which the NHS operates has a profound bearing on such intangible but crucial factors as the future professional's sense of belonging and identity. If, for example, a doctor's or a nurse's education is geared to encouraging identification first and foremost with a professional group, the interests of which may not always coincide with those of the wider NHS, the seeds of tension and conflict are sown. If the organisation of the NHS is explained, a signal is given that it is important to the professional's life. By learning about the NHS, future healthcare professionals become aware from the outset that the NHS is a service *both* for the *particular patient* currently needing care, *and* for the *generality of patients*. This opens the way to an understanding of the challenges and dilemmas faced by those who are responsible for running and managing the service for the benefit of all and who, therefore, must serve both *patient* and *patients*.
- 15 As regards management, it is increasingly the case that healthcare professionals are involved in decisions about the management of services. Indeed, many individuals may take up specifically managerial roles at different points in their careers. But an understanding of management is not just about preparation for a role as a 'manager'. This is because all healthcare professionals are involved in management, in the sense that any patient is exposed to a process of care, which should be a managed process involving professionals working together. Thus, we regard it as imperative that future healthcare professionals preparing for a career in clinical care, as early as possible in their education, be made aware of what management of healthcare processes and organisations entails, the type of decisions which those specifically designated as managers must make and the skills which management requires. This should include an understanding of the management of resources, and an awareness of the choices to be made in organising and delivering services for people with widely different needs and in greatly different circumstances. To the extent that some healthcare professionals, not least hospital doctors, who are not involved in management in its usual sense, currently continue to view managers with less than outright affection,

⁹ *'The NHS Plan'*. London: Department of Health, 2000. Para 9.18

some education in management could also serve to change the relationship between the two groups.

- 16 Indeed, we consider that there would be considerable advantage if both medical schools and schools of nursing were to collaborate more closely within and across universities with the various centres of management and policy which teach about the health service and about public sector management. Such collaboration would strengthen the opportunities for those developing careers as healthcare professionals to learn at an early stage about the principles of management and leadership. It would also give those with a non-clinical background who are working towards a qualification in management, the opportunity to gain exposure to some of the clinical and ethical issues which they will subsequently face in a career in health service management. Indeed, after completing their initial education, there should be many more opportunities than at present for managers and clinicians to 'shadow' one another for short periods, to learn about their respective roles and work pressures. This is but one of a number of possible initiatives that should be developed to help to break down the artificial and negative barriers which have grown up between managers and clinicians.

The development of teamwork

- 17 Healthcare professionals in hospitals have always worked in teams of one sort or another. These teams, however, have tended to be somewhat rigid and hierarchical. Until recently, an example would have been the team called the 'firm' of a particular consultant. With the introduction of what are known as 'care pathways' for patients suffering from certain illnesses, care is increasingly being organised around the needs of the patient, rather than around the institutional arrangements of the hospital, or of a group of professionals. This is undoubtedly the way of the future. Teamwork, therefore, will have to become increasingly more flexible, involving varying groups of professionals from a variety of disciplines and from a variety of specialties and organisations, all working together. And this will be so, as much in hospitals as in community and primary healthcare. All prospective healthcare professionals, therefore, must receive education and training in the meaning of teamwork, how to work effectively in multidisciplinary teams, how to deal with the issues of accountability which arise in teams, and the role of teams in providing healthcare. We owe this both to the professional and the patient. This education and training should not be confined only to the early years of preparation. Issues related to teamwork must also be included in specialist training. We note the comments during Phase One of Sir Barry Jackson, President of the Royal College of Surgeons:

'... there is teamworking ... between different specialties with similar interests for the patient ... But the concept of a formalising of that team approach between anaesthetists and surgeons and pathologists and radiologists per se so far as training purposes are concerned, has not been something that has been addressed by my College hitherto, or currently... and it may be that this is something which needs addressing in the future'.¹⁰

A similar point was made by the NHS Confederation in one of its papers to Phase Two: 'Doctors are rarely trained to work in a multidisciplinary manner within a whole system ...'.¹¹ In our view, this is something which must be addressed.

Professionals learning together

- 18** We have said that one of the most effective ways to foster an understanding about and respect for various professional roles and the value of multi-professional teams is to expose medical and nursing students, other healthcare professionals and managers to shared education and training. We add some further detail here.
- 19** We believe that the process of shared learning must begin as early as possible. As we have said, the benefits of bringing together undergraduate students from different disciplines to be educated together should be explored with vigour. Our preference, in time, would be to go further. While recognising the challenge it represents, we urge that thought be given to creating an undergraduate first year of entry which is common to all, whatever discipline they may wish ultimately to pursue. In this year, there would be a common core curriculum, aimed not so much at inculcating technical knowledge but at a broader understanding of health, healthcare and the NHS. This would involve the creation of an educational framework in which aspiring healthcare professionals could initially take a range of courses which would equip them to work in the field of health and healthcare, although not necessarily as a nurse or doctor. Thus, students could come to the view that, rather than practise medicine, it is management or nursing or another healthcare profession which they prefer, and thus go on to specialise in courses which are wholly geared to those careers. Equally, a student contemplating nursing may wish to switch to studying medicine. It may immediately be objected that there is such a disparity in the educational qualifications of the various groups of students that it would be impossible to teach them all together. Our reply is simple. They will have to work together later.
- 20** One enormously beneficial result of this approach would be to engender mutual understanding and respect among those starting out on the road to becoming healthcare professionals. It would help to address the damaging inter-tribal rivalries, which we identify as a weakness in the current culture of the NHS. We recognise that this approach would have significant implications for the organisation of the initial phases of the healthcare professional's education, but we do not think that they are insurmountable. To this end, the Council for the Regulation of Healthcare Professionals (which we referred to in the last chapter and discuss in greater detail later) should make it a priority to promote common curricula and shared learning across the professions. We think, therefore, that the right approach would be to pilot such courses in three or four universities, and to evaluate their impact before any larger scale changes were introduced.

¹¹ Seminar 3. The NHS Confederation. Position Paper

- 21** Throughout professional life there must be more opportunities than exist at present for healthcare professionals to learn and develop together. Some examples undoubtedly already exist, such as the scheme whereby young doctors, about half of whom go on to a hospital career, can spend some of their pre-registration year as house officers working in general practice. But such examples are relatively rare. At the level of specialist training for doctors, while the quality of such training has improved, there is now almost too great an emphasis on expertise in a single specialty. This is too narrow an approach. In their 20s and 30s, many young hospital doctors training to be specialists need to have regular opportunities to train with others in other areas of medicine, and with other healthcare professionals with whom they will share the membership of a team later on. This is equally true of established healthcare professionals for whom, we believe, there should be more opportunities to train and learn together in areas of shared concern. For example, it should be the norm for surgical teams (the surgeon, anaesthetist, theatre nurses, operating department assistants) to have time together, and with other teams such as those in the Intensive Care Unit, to review and develop their performance as a team. We also believe that there should be many more courses within the curricula of continuing professional development which are open to professionals from a variety of disciplines and backgrounds. The days when courses were designed exclusively for doctors, or exclusively for nurses, should be behind us. What matters is that those caring for patients with a particular condition or illness learn and develop their skills together to provide the best possible care for their patients.

Clinical audit and reflective practice

- 22** Clinical audit, the process whereby healthcare professionals reflect on and improve their and the team's clinical practice is fundamental to improving the quality of care received by patients. The NHS is already committed to the notion that participation in clinical audit will be compulsory. It is essential, therefore, that those entering the healthcare professions are given a good grounding in the basic skills of clinical audit: what it is; how it should be conducted; what is meant by team-based audit; how to understand and interpret data; how to use published material and evidence of effective practice; how to use national standards and guidance; how to understand the nature of error and mistakes; and how to learn from them. We see this as an area that cries out for a common core curriculum for the professions. If we expect multi-professional team-based clinical audit, it makes no sense at all to educate nurses, doctors and other healthcare professionals about clinical audit along separate lines. Equally, those already in practice should be able, as part of their continuing professional development, to gain access to further training in clinical audit, and there must be opportunities for clinical teams, who carry out shared audit, to train together.

Leadership

- 23** We heard in our Seminars about the characteristics of leadership best suited to the NHS. Arguments were put to us that the NHS needs a more 'transformational' style of leadership, a style which emphasises setting a direction, motivating people and managing significant change. This was contrasted with a more conventional style,

referred to as 'transactional', which focuses on planning, organising and problem-solving. While it is not for us to adjudicate on the value of one style over another (indeed skills of both types are probably essential for senior managers and for the chief executive of a trust), what matters is that there should be a place within the NHS to consider such questions and to offer advice. The Centre for Leadership, announced in *'The NHS Plan'*, must be that place. A priority for the Centre should be to offer guidelines as to the leadership styles and practices which are acceptable and are to be encouraged, and those which are not.

- 24** We have referred earlier to the need for better education in communication and listening, interpersonal skills, and trust and respect for others. These skills are the essence of good leadership. The task of developing them, as we have seen, starts at the very beginning of a healthcare professional's education. Furthermore, we have pointed to the value of different professional groups developing the necessary skills together. Indeed, in the specific area of leadership training, in developing and funding programmes in leadership skills, the NHS should focus its investment in supporting joint education and multi-professional training open to nurses, doctors, managers and other healthcare professionals. As the NHS Executive told us in one of its papers for Phase Two: 'It ... makes sense for doctors, nurses and managers to learn together about what makes for effective leadership and to do this earlier in their careers'.¹²
- 25** We emphasise that leaders of the calibre needed by the NHS at all levels do not just emerge. It is also a mistake to expect that those who are skilled in one aspect of healthcare, or those who have risen to a certain level of seniority in their profession, will by that fact alone automatically make good leaders. Leaders must, to a large degree, be made. The skills of leadership can be taught, acquired and developed, although of course individuals will vary in the extent to which they are able to deploy these skills effectively. Thus, given the continuing and pressing need in the NHS for people with leadership skills, we believe that active steps must now be taken to identify and train people within the NHS who have the potential to take on leadership roles. This must not be confused with old-style succession planning: making sure that there is always someone to replace a person in a given post. What we are referring to is a more comprehensive investment in developing the skills and talents of leadership, so that professionals can exercise those skills at whatever level they work within the NHS, be it leading a small clinical team, a larger directorate, or a major trust.
- 26** Given the need for programmes to develop skills in leadership at all levels of the NHS, an early task for the NHS Leadership Centre must be to take a firm grip on the myriad of existing programmes. It should develop a framework which would better reflect the values and purpose of the NHS. We heard that the many existing leadership schemes include: the NHS Leadership programme; the NHS Nurse Leadership programme; the British Association of Medical Managers (BAMM) Leadership programme for medical managers; the Royal College of Nursing (RCN) Leadership programme; and the NHS Development programme for finance managers. Further, much money is spent by the

¹² Seminar 4. The NHS Executive. Position Paper

NHS on leadership programmes provided by non-NHS bodies, such as the King's Fund and various business schools. We are not advocating a single leadership programme, or that the NHS should no longer use providers of such programmes who are outside the NHS. Instead, what is needed is some proper assessment of the relative value of the many programmes offered, with a view to deciding which and what to support. Moreover, there clearly must be a greater emphasis on multi-professional programmes. In an NHS which puts the patient first, and seeks to integrate all aspects of care around this goal, the rationale for separate leadership programmes for nurses, for doctors, and for managers, looks increasingly anachronistic.

- 27** It should be clear that we believe that the NHS Leadership Centre should not be regarded as a luxury. It must receive a proper and sustained level of funding. The Centre should be involved in all stages of the education, training and continuing development of all healthcare professionals. The Centre should invest in developing leadership skills from within the NHS and support those who are already in positions of leadership. This makes sense for the patient. We note the recent publication of a Cabinet Office report on leadership in the public sector. We believe that all our observations on leadership in the NHS are consistent with the key findings of that report.¹³
- 28** By way of conclusion to this part of the chapter, we also believe that competence in *all* of the non-clinical, non-technical areas which we have identified must be formally assessed, with results counting towards professional qualifications, whether as a doctor, nurse or other healthcare professional. Only in this way will the signal be sent that these are important matters, going to the heart of concern for patients.

The systems for assuring competence

- 29** Just as we are concerned with the patient's journey, we are also concerned with the journey taken by the person who seeks to be a healthcare professional. At each step in that journey, in the interests of patients and the public, systems must be in place to ensure that the aspiring professional (and subsequently the qualified professional) has and maintains the requisite competence.
- 30** We turn now to the question of regulation. As we have said, this is a broad term. It is not merely concerned with discipline and poor performance. To be effective in the service of patients, professional regulation should be understood as encapsulating all of the systems which combine to assure the competence of healthcare professionals: education, registration, training, continuing professional development and revalidation, as well as disciplinary matters. It should be concerned to promote good

¹³ The Performance and Innovation Unit of the Cabinet Office. 'Strengthening Leadership in the Public Sector' (March 2001). www.cabinet-office.gov.uk

practice at all stages of a professional's career. It should include control of access to relevant professions through setting educational standards and ensuring that they are met. It should assure competent performance, through the setting of professional standards. It should require measures such as appraisal, continuing professional development and revalidation. It should also include the capacity to deal with poor performance and misconduct, although if appropriate efforts are made to assure good performance in the course of a professional's working life, the incidence of poor performance requiring some form of disciplinary action should be significantly reduced. There are clear indications that the body which currently regulates some aspects of a doctor's career, the GMC, is moving towards this notion of regulation as a more comprehensive and active process. The proposals to reform the regulation of nurses and midwives, and the regulation of the professions allied to medicine are also moving in this direction.¹⁴ In addition, we do not overlook the role of the employer-employee relationship in the overall framework of regulation: it must complement other mechanisms of regulation by fostering good performance. Thus, the employer should have in place systems and resources to enable and support healthcare professionals to maintain and develop their competence, as well as systems to identify and act on failing or poor performance as early as possible.

- 31** In the paragraphs which follow we consider in greater detail the systems for assuring competence. We do so against the background of the need which we have identified to create an independent council for the regulation of healthcare professionals, at arm's-length from government. The task of this council will be to co-ordinate and integrate in the interests of patients the activities of the various bodies currently involved in what we call Professional Regulation. We will return to this overarching professional regulatory body once we have examined the various elements which together constitute professional regulation. We start with the system which applies at the outset of professional life when young people are first selected to be educated as healthcare professionals, and later we look at the systems in place to assure competence during a professional's working life.

The selection of future healthcare professionals

- 32** If the future healthcare professional, to be adjudged competent, must, in addition to technical and clinical skills, be able to display appropriate attitudes and competence in such areas as communication, the question inevitably arises as to the criteria for selecting those who are to become healthcare professionals. Are the criteria sufficiently broad to take account of the need for the full range of qualities and attributes which patients are entitled to expect? Is there a system for ensuring that the criteria are applied? Of course, much can be done in shaping the future healthcare professional by improving the undergraduate curricula. But this alone will not be sufficient. The task begins at an earlier stage: the attributes, attitudes and skills which form the criteria for initial selection also need to be appropriately broadly based.

¹⁴ See: *'The New Nursing and Midwifery Council: A consultation document'*, August 2000. www.doh.gov.uk/nmconsult; and *'Establishing the New Health Professions Council'*, April 2001. www.doh.gov.uk/hpcorder

We concentrate on entry to medical school. But the points we make apply to aspiring entrants to all healthcare professions.

- 33** We heard during Phase Two of the Inquiry that selection for medical school has been criticised for its superficiality. It is generally based on the information contained in a university application form and on an interview which, where it takes place, in some cases lasts no more than 15 minutes. Heavy reliance is placed on high academic achievement, in particular on achieving top A level grades in scientific subjects. We heard that, in the past, medical schools have also been accused of elitism, a lack of fairness and transparency in the process of selection, and of not selecting from a diverse range of social and ethnic backgrounds. Moreover, and remarkably since the NHS both contributes a substantial amount of the funding of the education and employs most graduates, the selection process is conducted with very little input from the wider NHS or from the public.
- 34** There is some evidence that the GMC's guidance to medical schools *'Tomorrow's Doctors'*, published in 1993, has begun to influence selection. Medical schools are beginning to take account of the applicants' personal qualities, interests, communication skills and relevant work experience in an attempt to select those who have the potential to be versatile, flexible and sensitive professionals. This is only a beginning. And, to the extent that many medical schools would say that they have done this for years, a somewhat greater commitment may be called for. We note that the GMC is in the process of revising *'Tomorrow's Doctors'* so that it incorporates the GMC's thinking about the qualities of a good doctor, as set down in *'Good Medical Practice'*. *'Good Medical Practice'* is a sensitive account of the duties and qualities of a doctor and crucially espouses a patient-centred approach to healthcare. Thus to match the attributes of a 'good doctor' with those of young people seeking admission to medical school is a significant development – in the past, to the extent there has been any such match, it has been coincidental.
- 35** There is also evidence, at the margins, of diversification of routes into medical education. There is at least one successful 'access' course for nurses and other healthcare professionals to prepare for entry to medical school. A small number of medical schools, including two which have recently been established, encourage, or intend to encourage, applications from those currently working in other healthcare professions. Some medical schools, such as that at Newcastle University, are seeking to widen access to medical education by reintroducing a pre-medical programme for those who do not possess a predominantly scientific background. Others, such as Guy's, King's and St Thomas's School of Medicine in London, have developed a scheme to target and give special access to students from local schools who would not normally either consider applying, or be considered qualified to apply, to medical school.¹⁵

¹⁵ See *'Performance Indicators in higher education. Higher Education Funding Council'*. HEFC 00/40. 1998/99. www.hefce.ac.uk
For example, whereas 25% of all young full-time first degree entrants in 1998/99 came from Social Class III, IV or V, the equivalent figures for the group including medical students was only 12%

- 36** We regard this diversification as important. We need to guard against future generations of doctors and other healthcare professionals being drawn from too narrow an academic and socio-economic base. Patients want doctors to be clinically competent, and thus doctors must be able to understand scientific method and principles. But, as we have said, this is not all that being a doctor entails. An understanding of science may be a necessary condition for entry to medical school, but it cannot be sufficient. The future doctor must also have demonstrated other qualities, not least a capacity to be open-minded, comfortable with uncertainty, free of preconceived views and capable of recognising and responding to ethical issues.
- 37** We heard arguments during our Seminars that it would be desirable to make medical education an entirely postgraduate course of study. Postgraduate entry, it was suggested, would ensure that the student would be more mature, more widely educated, and more likely to have chosen to study medicine after careful reflection, something that may not be true of applicants who are still in their teens. Leaving aside the financial implications of such a change (on which we heard no evidence and thus make no comment), we are not persuaded that a wholesale move to a graduate-only entry is justified. What is important is not the age at which the student begins, but what the student has previously studied and been exposed to, the criteria guiding selection, and the way in which the curriculum is thereafter organised and delivered.¹⁶
- 38** We referred earlier to the GMC's publication *'Tomorrow's Doctors'*. Although the GMC has a statutory responsibility for the standards of undergraduate medical education, entry to medical school is governed by the regulations of the particular university, which is an autonomous body. The GMC states that it seeks to influence the criteria for selection through the Council of Heads of UK Medical Schools. The Council for its part has indicated that the attributes they seek in applicants to medical school are similar to those set out in *'Tomorrow's Doctors'*. But we have not seen evidence to convince us that such indications are systematically being translated into practice. The current state of affairs is far from satisfactory. There is no formal means whereby medical schools can be required to follow the GMC's or any other body's advice. We take the view that the criteria for the selection of entrants to medical school are a matter for discussion and agreement in a community wider than the individual university's medical school and the GMC. At the very least the public and the NHS should be involved.
- 39** The selection of those who wish to become nurses has equally been subject to re-examination recently. Nurses are selected for pre-registration programmes by reference to the UKCC's baseline entry criteria. The institutions of higher education which provide these programmes may impose their own criteria, but these can only be more, not less, demanding than those required by the UKCC. The Royal College of Nursing told us that it supports the philosophy of widening access to nursing education programmes. It advocates an openness towards older applicants and an

¹⁶ We note that a number of medical schools have introduced courses that admit graduates in non-medical subjects to a course which enables them to qualify as doctors in four years instead of five

acknowledgement of 'existing life skills' when considering applications. There is also support for a process of interview and selection which is not only transparent, but also includes representatives from the universities and from the prospective employers, the NHS trusts. The logic behind this approach is one of 'joint ownership' of student nurses, paving the way for support for students throughout the three-year pre-registration programme and into employment as qualified nurses.¹⁷ We add our support to this approach and point out that it is compatible with, indeed it can be dovetailed into, the approach to multidisciplinary education to which we referred earlier.

Postgraduate medical training

- 40** Historically, for doctors, the GMC has set the outline of the curriculum for undergraduate medical education. Medical schools have then stipulated, by virtue of students' having passed the required examinations, that they were sufficiently competent to be registered as medical practitioners. Responsibility for the organisation of the next stage, the training of specialists and GPs, rests with the various postgraduate deans. Their job is to ensure that the training complies with the requirements laid down by the various Royal Colleges. Thus, ultimately responsibility lies with the Royal Colleges. This responsibility in relation to hospital doctors includes, among other things, setting the curricula and examinations to qualify as a specialist, and visiting individual trusts as part of a process to accredit them as suitable for the training of specialists. Postgraduate medical training is specific to doctors, as being a necessary prerequisite to being appointed to a career (specialist) post, although, of course, further training is also required of nurses and others before they may take up certain specialist positions.
- 41** Clearly the patient is entitled to expect that the Royal Colleges, in carrying out their responsibilities for the supervision of postgraduate training, will place the wellbeing of the patient at the centre of their concerns. In this way the public can be confident that the system for assuring professional competence is secure.
- 42** The evidence which we heard about the BRI in Bristol suggested that, in the past at least, this was not always the case. Visits to inspect the BRI as suitable for training purposes were sometimes less than rigorously conducted.¹⁸ Moreover, the relationship between approval as a training hospital and the consequent ability of the hospital to attract staff and provide a service, meant that decisions on training took on a significance which went much further than issues of training. If approval was withheld, a hospital could not attract junior staff. The service provided, therefore, either had to be curtailed (rarely seen as an available option), or offered with overstretched staff. This latter consequence is what happened as regards paediatric cardiology in Bristol. In general terms, the likely impact of withdrawing training recognition was all too evident to visiting inspectors from the Royal Colleges, but they faced a genuine dilemma. It is not hard to imagine circumstances in which approval

¹⁷ Seminar 5. The Royal College of Nursing. Position Paper

¹⁸ See Section One, Chapter 16

of a hospital for training purposes was as much driven, for good reasons, by the idea of maintaining the viability of a service as by the need to guard standards of training on the public's behalf.

- 43** We are not persuaded that to leave the crucial task of approving and supervising postgraduate medical training to the Royal Colleges alone is in the public interest. We believe that to obtain and maintain public confidence, ways must be found to involve others in the process, through some appropriate body. We note the proposal in para 8.28 of *'The NHS Plan'* to create a Medical Education Standards Board (MESB). The aim is to replace the existing, somewhat fragmented and, as has been suggested, less than ideal system, and to provide a co-ordinated, coherent, robust and accountable approach to postgraduate medical education (which we take to mean training). We believe that this is the right way forward. Crucially, the new Board will include members from the NHS and the public, as well as from the Royal Colleges. The Royal Colleges do have a legitimate role and one which perhaps only they can carry out, in assessing elements of professional competence. But the force of the proposal is that they should be brought into a larger and more accountable system. We agree. We agree further with the principle stated in *'The NHS Plan'* that the Board's task will be to 'ensure that patient interests and the service needs of the NHS are fully aligned with the development of the curriculum and approval of training programmes'.¹⁹
- 44** The MESB, although an important and welcome development, will, despite the Board's title, touch on only one element of the continuum that comprises a doctor's education, training and professional development, namely, the training element. Supervision of undergraduate medical education, as we have said, is a matter for the GMC and the universities. Supervision of continuing professional development for doctors, as we shall see, is shared between the Royal Colleges and the employer. This degree of fragmentation does not serve doctors well; it makes it difficult to ensure that the principles of good medical practice are embedded into all aspects of a professional's lifelong education. Such fragmentation also makes it difficult to introduce changes which apply to all doctors currently in practice, and not just the newly qualified. For this reason, we support greater co-ordination of all the activities which make up the continuum of doctors' education, training and development. The GMC is probably best placed to do this, with its responsibility to ensure that doctors meet generic standards of professional practice throughout their working life. By taking the lead in co-ordinating these efforts, the GMC could ensure that expertise is shared, and crucially, help to ensure that all the policies on training of the various bodies are in alignment and capable of adjustment to meet the changing demands that society places upon doctors. It follows that the MESB should be a subgroup of and report to the GMC.
- 45** Just as there is a case for vertical integration of responsibility for the components of a doctor's lifelong education, the same case, we believe, applies to nurses and midwives, and to the professions allied to medicine. In each case there should be one

¹⁹ *'The NHS Plan'*. London: Department of Health, 2000. Para 8.28

body charged with oversight of all aspects of education, training and professional development, to ensure that the respective components are appropriately integrated.

- 46** So far, we have addressed the need for proper systems for each of the respective groups of healthcare professionals. It is crucial now to point to the fact that there is no single body which stands above the detail to provide consistency and overarching strategic direction for all professional groups. The Government has announced its intention, in *'The NHS Plan'* (para 10.15), to establish a UK Council of Health Regulators. The Council's role, on which we comment more in detail later, will be to help to co-ordinate activities and to act as a forum in which common approaches across the professions could be developed. Developing common approaches to education, training and development should be one of its priority areas. This is a particularly necessary and relevant role for the future of the NHS, as the boundaries between the various professions in a number of respects have started to merge and to overlap. It would also provide leadership and direction for the implementation of the common themes for education and training which we referred to earlier.
- 47** So far, we have considered the initial education and training of healthcare professionals. But assuring competence does not stop there. Other systems are needed to help to assure their competence at other points in their careers, and to ensure that the interests of patients and the needs of the NHS are taken into account.

Maintaining professional competence during a working life

- 48** The arrangements to ensure that healthcare professionals maintain and develop their competence whilst working in the NHS are currently fragmentary and apply differentially to the various groups of professionals. As far as professional requirements are concerned, for some healthcare professionals, for example nurses, the pursuit of continuing professional development has long been required as a condition of continued practice. It may be thought surprising, however, that as we write this Report this is not so in the case of hospital consultants. Once they have acquired the necessary qualification, they can currently practice for life without any formal requirement to undergo any further professional development as a condition of continuing practice. Schemes do exist in some of the Royal Colleges. But currently, as an indication of the fragmented approach we referred to earlier, whether professional development is required by the College of a doctor depends on the relevant Royal College. For instance for members of the Royal College of Surgeons and the Royal College of GPs, it is compulsory. For members of the Royal College of Paediatrics and Child Health and the Royal College of Physicians, although continuing professional development (CPD) is expected, it is not compulsory. But whether or not the College requires CPD affects only the relationship between the doctor and the College. It currently has no wider implication for working in the NHS. A number of proposals and indeed changes have been made, particularly since this Inquiry was set up. But it is important to remember that it remains a matter for individual doctors whether and how they maintain their skills and knowledge during a working life of 30 or more

years. Patients have no assurance that the doctor they see has the appropriate level of knowledge and skill. This cannot continue.

- 49** It does not require much reflection to see that *from the patient's point of view* this state of affairs is unsatisfactory. Of course, in practice, the vast majority of consultants are constantly developing their skills and knowledge, but the patient's wellbeing should not depend solely on the individual hospital doctor's motivation. It is not enough to argue, as has been the case in the past, that the hospital doctors can be left to recognise their own needs and limitations. Furthermore, it is very often those who do not feel the need to submit themselves to further development and training, who, in the absence of some formal system, may pose the greatest threat.
- 50** Similar issues arise as regards the system of appraisal. Whereas it has been commonplace for nurses and for junior hospital doctors to undergo annual appraisal, it has not been so for hospital consultants. Only now, in the middle of 2001, for the first time, is a system of appraisal for consultants being introduced. Many consultants have never undergone an appraisal in their working lives. Furthermore, in the case of GPs since technically they are independent contractors and have no employer, no system of appraisal for them has been developed. Without regular appraisal, the NHS has no formal means of assisting systematically with professional development nor any means of monitoring an individual professional's performance.
- 51** It is important to note that some of the shortcomings we point to are widely acknowledged, by the Government and by the GMC, and that, for example, important changes concerning appraisal and revalidation are under discussion. We believe that the formal systems and resources to support professionals in maintaining their competence need to be part of a comprehensive framework whereby the NHS *and* all the healthcare professions, jointly, embrace three separate but interconnected practices: *continuing professional development, periodic appraisal and revalidation*.²⁰ These three activities are not, and must not be seen as, oppressive activities, as just another burden on healthcare professionals. Nor should they be seen as activities from which one or other professional group is wholly or partly exempt. Rather, as most healthcare professionals now recognise, participating in CPD, appraisal and revalidation represents the affirmation of their professional status: that they are willing to keep themselves professionally fit on behalf of patients, and that they are accountable for so doing. Historically, compared with nurses and GPs, hospital doctors have been slow to develop systems to assure competence during working life. That has started to change, but in the interests of patients, the pace of change must quicken. In what follows, therefore, we use the specific example of hospital doctors, but the general points we make apply equally to all the healthcare professions.

²⁰ Revalidation, in general terms, is a mechanism whereby healthcare professionals are required regularly to demonstrate to external assessors that they remain fit to practise, and thus are entitled to continue to be registered or recognised as a doctor, nurse or other healthcare professional

Continuing professional development (CPD)

- 52** CPD must be part of a process of lifelong learning for all healthcare professionals. Its purpose is to help professionals to care for patients. A secondary purpose, but one which must not be ignored, is to help professionals to be fulfilled in their work. It is crucial that CPD is supported by both the NHS and the professions. Within the NHS, CPD must be underpinned by a commitment to make available the necessary resources in terms of time, funding and assistance with career development. The contract between the trust and the healthcare professional should provide for the funding of CPD and should stipulate the time which the trust will make available. The incentives, in other words, must be in place. The culture of the workplace has to be one which values learning and acknowledges the benefits it will bring for the organisation as a whole, particularly as it affects patients.
- 53** CPD is not just a case of attending courses and conferences, albeit that these have their place. There should equally be a strong element of professional development within the workplace, since this is where skills and competence are put to the test. ‘Shadowing’ the work of others, visits to centres of excellence, having a ‘mentor’ and undertaking clinical and professional supervision are amongst the strategies which can be used as part of work-based professional development. Moreover, if doctors, nurses and others must keep up to date with developments, knowledge about developments must be readily accessible. This, in turn, means access to information technology and the skills to use it. This may well call for training and funding for which employers will need to make provision.
- 54** Clearly, allocating sufficient time and resources to CPD in a planned and organised manner is of crucial importance for all healthcare professionals. They are equally important to those who manage hospitals. When staff shortages are common and all resources are stretched, there is a constant temptation to limit in one way or another the ability of professionals to take time to study and train. It was put to us by the Royal College of Surgeons, for example, that the methods employed by surgeons for maintaining standards range from traditional lectures and practical skills training in a laboratory to a proposed process of external peer review as part of revalidation. However, they pointed out that there are financial considerations for all forms of CPD. Anatomical workshop sessions are particularly expensive and this can limit the opportunities for trainees to participate.²¹ We welcome the fact that, since April 2000, all trusts have been required to have in place a training and development plan. Such plans seek to ensure that the resources devoted to continuing professional development meet the needs of patients as well as the aspirations of individual professionals. We believe that such plans must be backed with sufficient resources. CPD, as well as being good for patients, provides an incentive for professionals and thereby helps to attract and retain highly motivated individuals.

Appraisal

- 55** Appraisal is a common feature in most large organisations. The annual appraisal of all healthcare professionals should, in our view, be the norm. For most, it is. For hospital consultants and general practitioners, however, it is the exception. This must change. We are pleased to note from *'The NHS Plan'*²² that the Government has agreed in principle with the British Medical Association (BMA) that annual appraisal and effective job plans will be made compulsory in the new consultants' contract. We believe this commitment must be kept and be implemented in full as soon as possible.
- 56** We see annual appraisals as an essential part of an overall strategy aimed at maintaining competence and thereby securing safe care and improving the quality of care in hospitals. The obligation to participate in appraisal is of such importance that we take the view that it should apply to all NHS employees and be incorporated into employment contracts, including, as we have said, consultants' contracts with the trust. Indeed, we regard appraisal as sufficiently important that it should extend to GPs and a requirement to undergo periodic appraisal should therefore be incorporated into the terms of service of GPs' contracts with the NHS. Some doctors have expressed concern at what they see as a mechanism for judging or even victimising them. But this is to misunderstand the exercise. Appraisal itself is a neutral activity: what matters is the principle on which the appraisal proceeds. We believe that appraisal in the NHS should be constructive and facilitative, with a particular emphasis on what the employer can do to enable healthcare professionals to do their job well and to fulfil themselves in the workplace. For this reason, it is vital to distinguish between appraisal and revalidation. They are separate exercises with different purposes, even though appraisal may well inform the process of revalidation. Appraisal should focus on past performance, on the maintenance and development of skills as they touch on competence, and on job fulfilment. Revalidation, by contrast, is concerned with ensuring that the appropriate levels of skill necessary for continued competence have been and are maintained.

Revalidation

- 57** Revalidation in general terms is a mechanism whereby healthcare professionals are required regularly (for example every three or five years) to demonstrate that they remain fit to practise. It involves the submission of evidence to external assessors of continuing competence. In the case of the system proposed for doctors, it is linked to registration in that, if they cannot demonstrate evidence of continuing competence, their registration, and thus their right to practise as doctors, may be called into question and, ultimately, may be withdrawn. A form of revalidation already exists for nurses and for many of the professions allied to medicine. In fact, the practice in the case of nursing is closer to re-registration and is not the same as the revalidation process proposed for doctors. Essentially, every three years, nurses have to submit evidence of the CPD that they have undertaken in order to maintain their registration. There do not appear to be arrangements whereby the individuals are visited in the

²² *'The NHS Plan'*. London: Department of Health, 2000. Para 8.21

workplace by a group of assessors. We take the view that external assessment is a very important feature of the process and that methods should be devised to implement it in the case of nurses and others. In the case of senior healthcare managers, no system of registration or formal recognition currently exists. It would need to be developed alongside the introduction of revalidation for other healthcare professionals. We acknowledge that proposals for a system of revalidation for doctors are at an advanced stage of development. Thus we make our comments about the need for the revalidation of healthcare professionals, aware that the potential value of this mechanism is already coming to be widely recognised, by the public, as well as within most of the professions.

58 The call for the revalidation of healthcare professionals marks a significant break with the past. Until very recently, at least in the case of medicine, it was regarded as a sufficient assurance of competence that young, newly qualified healthcare professionals had passed the relevant examinations, and had received guidance and support from more senior colleagues. Thereafter, throughout the whole of their working life, there were no mechanisms, whether within or outside the professions, whether from employers or bodies concerned with registration and discipline, to assess and check a professional's competence. Of course, most professionals developed and improved their competence through experience. And, many have seen it as part of their professional duty to undertake continuing professional development. This is still the case today. For some, however, competence did (and does) not grow with experience. Others did (and do) not pay much attention to continuing professional development. And others tried their best but their competence diminished with time. Remarkably, there was no system in place to spot waning competence, to support these professionals and to protect patients. Only when things went dramatically wrong was action taken, and then, too often, it was too late for the patient and the professional. Thankfully, this state of affairs has been recognised as unacceptable. Both government and the various professional bodies have begun to develop systems of retraining and revalidation, whereby any shortcomings in a professional's competence can be identified and addressed at a much earlier stage than would have been the case in the past.²³

59 We believe that regular revalidation must be mandatory for all healthcare professionals, and that a requirement to undergo revalidation should be incorporated into the contract of employment between the professional and the relevant body within the NHS. Every effort must be made to develop and implement systems of revalidation as soon as possible. We recognise that some current proposals do not have the wholehearted support of some healthcare professionals. We do not see this as a reason for delay, far less for not proceeding. The public is entitled to this form of protection. Revalidation will assure the public that the doctor, nurse or other healthcare professional caring for them meets agreed levels of competence. Healthcare professionals will benefit also. Revalidation offers them the opportunity to address any shortcomings that they may have in an environment of learning and

²³ The GMC's performance assessment procedures, introduced in 1995, represented a first tentative step albeit limited, in that it is a system which is reactive and insists upon performance being 'seriously deficient'. See www.gmc-uk.org

support, rather than in a context of sanction and blame. It also offers healthcare professionals some protection against unfounded criticism of their professional competence. We find very helpful the observations made by Professor Darzi (Professor of Surgery at Imperial College School of Medicine) and colleagues in relation to the skills of surgeons:

‘A specific and sensitive test of operative competence could also detect important problems and might improve surgical outcome. Revealing underperformance early would allow for further training or career guidance towards other less practical specialties. The surgical profession needs a reliable and valid method of assessing the operative skill of its members. A driving test may not be a guarantee against accidents but it makes it less likely that you career off the road. Surgeons, the public, and politicians need reassurance.’²⁴

- 60** We do not comment on detailed aspects of current proposals of the GMC. There are, however, two important issues to which we must draw attention. Revalidation, as one of its aims, offers protection to the public. For it to gain and retain public trust and confidence, it cannot be a mechanism which is entirely controlled by the professions themselves. We believe that there must be some external perspective in the periodic review of a healthcare professional, that is, a person or organisation external to the professional’s own profession and external to the employer. We do not contemplate that this external involvement should take the form of a ‘patient’s representative’. Indeed, we doubt the existence of such a generic entity. Rather, it should be someone with an understanding of the public interest. To the extent that the person’s view may be informed by the views of patients, so much the better. We note that the GMC is conducting research into how they might capture the views and experiences of a range of patients for use in a doctor’s revalidation. We commend this approach. It should, however, be in addition to, and not in place of, an external presence on the revalidating team.
- 61** Our second point relates to the wider context in which revalidation of healthcare professionals is conducted. Currently, each of the healthcare professions, to the extent that they are establishing a system of revalidation, are doing so on their own. Thus, for example, a system for doctors is being developed by the GMC; a system for nurses, developed by the UKCC, is already in place; and each of the professions allied to medicine have their own requirements for regular re-registration of their members. As we have said, no system currently exists for senior managers. No single body is responsible for ensuring that these various systems are sufficiently rigorous and robust to protect the public. There is no mechanism of review to consider whether the systems are consistent and aligned. There is no mechanism for ensuring that the systems for revalidation of healthcare professionals are integrated into other initiatives for protecting patients, such as the inspection by the Commission for Health Improvement (CHI) of NHS trusts, or the publication of national data on clinical outcomes. This is in the tradition of the ad hoc, fragmented approach which has

²⁴ Darzi A, Smith S, Taffinder N. ‘Assessing operative skill’. Editorial: *BMJ* 3 April 1999; **318**:887–8. See also Smith SG et al. ‘Objective assessment of surgical dexterity using simulators’. *Hosp Med* 1999; **60**(9):672–5

characterised the management of the NHS for too long. It is not in the interests of patients. There must be an overarching mechanism to co-ordinate these many systems to ensure that they are properly aligned, and capable of protecting patients. This should be a further priority for the Council for the Regulation of Healthcare Professionals.

Managers

62 Clearly those formally designated as managers, whatever their background, must be prepared adequately for management roles within the NHS. Moreover, they must also be required to participate in continuing professional development, appraisal and revalidation on a basis similar to that proposed for other healthcare professionals. Just as with other healthcare professionals, these obligations should be incorporated into the contract between the manager and the trust. We recognise that currently, while the appraisal of managers is common, CPD and revalidation are significantly underdeveloped. We would expect to see the Council for the Regulation of Healthcare Professionals, together with organisations such as the Institute of Healthcare Management and the British Association of Medical Managers, collaborating to draw up proposals as a matter of urgency. It is inappropriate that one group of healthcare professionals should be excluded from this process of maintaining competence. We note here the strong support for this idea expressed by the Institute for Healthcare Management in a paper for Phase Two:

‘... this Institute believes that managers should be subject to the same constraints and regulations on behaviour as those imposed by clinicians’ professional bodies. ... The Institute is exploring whether a Code of Professional Conduct should become part of an IHM “fitness to practice” certificate incorporating initial management training, adherence to the Code and evidence of CPD.’²⁵

Clinicians who hold managerial positions

63 The events in Bristol teach us that when clinicians hold positions with formal managerial responsibilities, such responsibilities cannot properly be undertaken in the clinician’s spare time. Where clinicians take on too many managerial roles in an unstructured way it is not good for patients and not good for the service which the clinicians are supposed to manage. Bristol also teaches us that management cannot properly be undertaken by clinicians who do not have the requisite skills in leadership and management. We heard during Phase Two that there continues to be a tendency to appoint the most senior consultant to the role of clinician-manager, even though seniority clearly does not necessarily guarantee managerial ability. This is not to suggest in any way that clinicians should not move into managerial roles on either a part-time or a full-time basis, nor to say that they should become disengaged from the issues of managing trusts and the NHS. On the contrary. We believe that the Griffiths Report (1983)²⁶ was right in advocating a much greater involvement of clinicians in management. The problem has been the implementation of this philosophy. We

²⁵ Seminar 5. Institute for Healthcare Management. Position Paper

²⁶ Griffiths R. *NHS Management Inquiry*. DHSS, 1983

discovered that the situation of clinician-managers in Bristol, where they lacked time and support for their managerial roles, was commonplace at the time, and that it still persists today, despite incremental improvements to protect more time for managerial duties. We also discovered that there was nothing unusual about the practice of senior clinicians taking turns to hold managerial roles. For the future, however, where a clinician holds managerial responsibilities which go beyond immediate clinical practice, sufficient time in the form of allocated sessions must be made available and protected to enable the clinician to carry out that role. Furthermore, the clinician, before appointment to a managerial role, must have the essential skills to undertake that role, with access to training and support made available by the trust. In the hospital sector, this applies particularly but not exclusively to the role of clinical director and to other roles where the individual is expected to be part clinician and part manager. The roles of medical director and director of nursing are now, for the most part, full-time posts.

- 64** Not only do we endorse the views expressed in the Griffiths Report, we would go further. We believe that there should be positive incentives to encourage senior clinicians to take on senior managerial roles. These incentives should be professional as well as financial. A significant barrier to this at present is the difficulty of returning to full-time clinical practice having once become involved in management. One way in which clinicians holding senior managerial posts currently attempt to resolve this problem is by maintaining some modest involvement in clinical practice of perhaps one or two sessions per week. We see a real dilemma here. Many clinicians who hold managerial roles understandably may wish to return to full-time clinical practice, which is their vocation. Thus, they wish to maintain their clinical skills. But, from the patient's point of view this may not be satisfactory. The safety and quality of clinical practice may be compromised by the fact that the clinician's modest involvement is simply not enough to maintain the necessary clinical skills. This is not a matter on which we can be prescriptive, because safe levels of clinical practice will vary according to clinical specialty. Our aim is to point out the possible negative consequences for the patient. We believe that experts in each specialty, together with managers from the NHS, should consider this matter with a view to setting down the minimum level of regular clinical practice necessary to enable a clinician to provide care of a good quality. Clinicians not maintaining this level of practice should not be entitled to offer clinical care. This rule should also apply to all other clinicians who, for whatever reason, are not in full-time practice, and not be limited to those in part-time managerial roles. Attention should also be given to creating incentives so that clinicians who are sufficiently skilled and motivated to become managers are able to do so while retaining a prospect of returning to clinical practice. This should include incentives such as training and support whilst in the managerial role, and training and assistance to return to a clinical role subsequently, should the clinician so wish. The proposed system of revalidation for doctors, and the re-registration systems of other healthcare professionals, need to be sufficiently flexible to allow for these movements out of and back into clinical practice. Perhaps one way of enabling this would be to have special categories of professional registration which are for clinicians who are

currently serving as managers, as indeed there might be categories for clinicians undertaking other types of non-clinical work.

Acquiring and developing new skills to an appropriate level of competence

65 We turn now to an issue which was a central feature of the Bristol story: how is a healthcare professional to acquire competence in a new clinical activity so as to enhance skills while at the same time safeguarding the interests of patients? Given its prominence in the Bristol story we concentrate on surgery. What we say, however, is not limited to surgery, but applies to any circumstance in which the healthcare professional proposes to carry out a clinical procedure with which he is unfamiliar and which, by its nature, exposes the patient to a risk of significant harm.²⁷ The issue we refer to is sometimes characterised as the problem of ‘the learning curve’. The implication of this expression is that, as regards carrying out new procedures, competence is acquired gradually: that there is an upward gradient of success, with, and this is crucial, an implicit assumption that failure initially is inevitable and, by that token, justifiable. The common example is the surgeon attempting a new procedure, but this issue applies equally to any doctor or nurse who embarks on a new procedure, wherever it is performed on the patient (hospital, GP practice or other clinic). There are, in fact, at least three different sets of circumstances which require consideration:

- the procedure is known and already carried out in the trust, but the particular healthcare professional is performing it for the first time;
- the procedure is known, but is being done for the first time in the trust; and
- the procedure is being done for the first time anywhere.

66 From a patient’s point of view, there is a paradox. Innovations are desirable and should be introduced, but they should be tried out on someone else first! Three guiding principles may offer a way around the paradox. The first is the need for supervision; the second is the need for openness and honesty with the patient; the third is the need for an agreed and established system within the hospital for managing innovation.

Supervision

67 If a procedure has already been carried out in the trust, it is both possible and, indeed, essential, that the surgeon carrying out the procedure for the first time should be suitably trained and be directly supervised by colleagues who have the necessary competence and proficiency, until the relevant degree of expertise has been acquired; that is, the patient is not exposed to a risk greater than the norm.²⁸ If the procedure is

²⁷ There is a difference between a planned departure from current surgical practice, and doing something which could not be planned but is a response to a situation which arises. The latter is not included within our definition of innovation. We are concerned instead with the circumstances in which the doctor decides *in advance* to innovate

²⁸ For an example of ‘a surgical teaching initiative’ which ‘had a major effect on ... outcomes’ see Lehander Martling A et al. ‘Effect of a surgical training programme on outcome of rectal cancer in the County of Stockholm’. *Lancet*, 2000; **356**: 94–6

one which has not previously been performed in the trust, the surgeon carrying it out must have obtained appropriate training in a place where expertise in the procedure is established. He must further ensure that, initially, he is supervised within his own trust by someone who has the necessary expertise. This is the process which Sir Barry Jackson, President of the Royal College of Surgeons of England, described in Phase One as mentoring. We see a further role for the Royal College of Surgeons. It already has a unit for the training of surgeons. With appropriate assistance from the NHS, this unit should be developed to provide training in new technologies and procedures. It should also explore the question of whether there is an age beyond which surgeons, specifically in areas such as paediatric cardiac surgery, should not attempt new procedures or even should not continue in a particular field of surgery.

- 68** If a procedure is being carried out for the first time anywhere, a distinction should be drawn between undertaking a variation of an existing procedure and carrying out a genuinely new innovation. Of course, these are not polar opposites: any particular procedure may lie somewhere along a spectrum. In our view, when any new and hitherto untried invasive clinical procedure is attempted, the surgeon concerned should inform the trust's or the local research ethics committee.²⁹ The committee, the composition of which may need to be re-formed so as to consider such matters, will need to be satisfied that the surgeon has undertaken all necessary preparation (for instance, through the use of simulation). The committee will then decide where, along the spectrum of innovation, the proposed procedure lies, and on what matters it needs to be satisfied. It may be objected that this approach is unnecessarily burdensome and will hamper innovation. We make two observations. Healthcare professionals intending to introduce innovations in other areas of diagnosis or drug treatment are expected and expect to seek the approval of the local research ethics committee before embarking on what is, in effect, an experiment.³⁰ We see no reason why new surgical treatments should be treated differently. Secondly, there is intrinsic value in the act of making an application to the local research ethics committee. The applicant (the surgeon in our case) will have to set down the arguments and reasons for proceeding. This will cause reflection on a wide range of matters, not least the interests of patients, before embarking on any innovation. We accept that surgeons, undoubtedly, already go through a process of reflection. Some surgeons may object that, to go a step further and present a proposal to the local research ethics committee, is unwieldy and bureaucratic. However, to the patient it is a desirable, indeed necessary, safeguard.³¹ The lesson of Bristol is that when it comes to innovation it may not always be enough to leave the decision to the professional. Some system of reflection and accountability is essential.

²⁹ It may be that only complex procedures should attract this requirement. This is a matter properly for consultation

³⁰ We acknowledge that a considerable amount of standard practice is on one level experimental since its efficacy has not been demonstrated, but we do not see this as a reason for dispensing with the need to demonstrate efficacy and competence in new procedures. See Chalmers I, Lindley R. 'Double Standards on Informed Consent to Treatment', which appears in *Informed consent in medical research: respecting patients' rights in research and practice*. Tobias J. (Ed). London: BMJ Books, 2000

³¹ See de Leval M. 'Lessons from the arterial-switch operation.' *Lancet*. Vol 357, 9 June 2001. Professor de Leval writes that the 'dilemma of scientific progress and clinical application of new treatments must be addressed by society at large.'

Openness

69 A further safeguard for patients is the requirement that the surgeon be open and honest with them, or, in the case of children, with their parents. Patients are entitled to know what experience the surgeon has, how experimental or innovative a procedure is, and that this may be the first occasion on which the surgeon has carried out the procedure. This knowledge is essential if patients' consent to treatment is to be valid. Conversely, not to inform patients about a matter of such significance in terms of their healthcare is a violation of their rights. Furthermore, it is not open to surgeons to say that they would not be able to innovate if the patient always had to agree. This is to put the surgeon's desire to innovate above the patient's right to choose. It also fails to acknowledge the willingness of patients to participate actively in the development of medical care, provided their interests are respected.

Managing innovation

70 Trusts should have a system in place to manage innovation. Such a system should recognise the need for training and ensure that it is made available; it should ensure the involvement of the research ethics committee and see that local protocols reflect the need for openness and real consent from the patient. Clearly, there must be someone within the trust whose task it is to see that a system is in place and it is observed. This responsibility should rest ultimately with the chief executive, since, in our view, it is part of the statutory responsibility for quality of care.

Disciplinary action

71 We now come to the final element in the process of the regulation of healthcare professionals. If it begins with regulating entry into the profession, it ends, for some, in disciplinary action because of poor performance or misconduct. Of course, as more effort is focused on supporting healthcare professionals to develop and maintain good performance, the incidence of poor performance may decline. But it will happen from time to time. Our concern is how it should be dealt with.

72 We have already made it clear (in Chapter 24, A Health Service which is Well Led) that it must be the employer first and foremost who should be able to deal with poor performance and misconduct. We have proposed that the professional Codes of Conduct be incorporated into the contract between the healthcare professional and the relevant NHS employer. If this approach is accepted, the employer will be able to act not only in the case of breaches of duty owed as an employee but also when the professional has failed to observe the profession's Code of Conduct. In both circumstances, there would be a breach of contract enabling the employer to take appropriate action. Moreover, by empowering the employer in this way, issues can be resolved promptly and fairly, taking proper account of local circumstances, rather than be left to drag on through some lengthy process as is so often the case now.³²

³² One approach worthy of consideration is that represented by the Code of Practice published by ACAS in 1997 and brought into force by the Employment Protection Code of Practice (Disciplinary Practices and Procedures) Order 1998, SI 1998/44

- 73 Whatever the employer may do, there is also the question whether the healthcare professional should be entitled to continue to practise or whether a limit on the individual's practice, including removal of recognition or registration, is called for. This aspect of regulation of professionals historically has been the responsibility of various professional bodies: the GMC, the UKCC for Nursing, Midwifery and Health Visiting and the Council for the Professions Supplementary to Medicine. As has been said, no professional regulatory body currently exists in the case of managers but we urge that it should.
- 74 We are aware that there are continuing discussions about the disciplinary role of the GMC in particular. We wish to make the following observations. All professional bodies charged with responsibility for disciplining their members must constantly keep in mind that they do so on behalf of the wider public. The trust granted to them is that they act in the public interest to preserve and maintain the safety and quality of healthcare provided to patients. To acquire the public's confidence and trust, these professional regulatory bodies must let the public in, to a degree not hitherto contemplated. The old binary approach to discipline – serious or nothing; removal from the register or nothing – is beginning to be dismantled. But the pace of change is not fast enough and the public's patience is running out. The professional bodies must be more flexible in their approach to what constitutes misconduct and practice that warrants disciplinary action; they must deal with cases as far as possible at a local level and they must have available a range of actions to meet the problem before them which both serve the interests of the public and the needs of the professional.

The Council for the Regulation of Healthcare Professionals

- 75 Regulation, as we have defined it, therefore, extends from entry into a profession, to continuing in it, to ensuring that competence is up to date through revalidation, to processes of support for improvement and, if that fails, to removal from the register. The purpose of the system of regulation must be to assure the public of the competence of healthcare professionals and, when necessary, to protect them. As such it needs the widest involvement of professionals, of the principal employer and of the public. It cannot achieve its purpose if it is a system which is designed and operated solely by particular professionals for their professional peers. Nor can it achieve its purpose if it is solely a matter for employers within the NHS. An effective system of professional regulation must be owned collectively. Further, it needs an independence from the professions and from government which allows it to act in the public interest. In short, we see a need for a single overarching view to be taken of education, training, development and discipline of *all* the healthcare professions. This role as we suggested earlier could and should be played by the body proposed in

'The NHS Plan' (the Council of Healthcare Regulators), which we believe should be more accurately named the Council for the Regulation of the Healthcare Professions. Thus, for *each* group of healthcare professionals (doctors; nurses and midwives; the professions allied to medicine; and managers) there should be one body charged with overseeing *all* aspects relating to the regulation of professional life: education, registration, training, continuing professional development, revalidation and discipline. The bodies should be: for doctors, the GMC; for nurses and midwives, the new Nursing and Midwifery Council; for the professions allied to medicine, the reformed professional body for those professions; and for senior healthcare managers, a new professional body. Each of these bodies would be represented on the new Council, as would representatives of the NHS and the general public. It should be established as soon as possible with a broadly based membership as we have indicated. All of the existing bodies which regulate the healthcare professions in one respect or another would be members. It would provide the unifying principles and the co-ordination necessary to ensure that the various bodies, and there are many, all serve the needs of the public. The Council will of course draw on the skills and the expertise of these bodies, the Royal Colleges, the professional organisations, the trusts and the NHS. But it will be independent of all and have a strong element of public participation. We believe that the Council should have statutory powers to require the various bodies to act in the interests of patients and conform to principles of good regulation. It should also seek to ensure that in practice the bodies regulating healthcare professionals behave in a consistent and broadly similar manner. The Council should, in our view, report to and be accountable itself to Parliament. In the future, regulation of the healthcare professions must be seen in the round and organised accordingly.

Chapter 26: The Safety of Care

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Patients are entitled to receive care which is safe and which exposes them to as little harm as possible.

*'... we understand you do not come to work to make errors and we want to minimise the risk that you will do so.'*¹

Messages from Bristol

- The absence of a culture of safety and a culture of openness meant that concerns and incidents were not routinely or systematically discussed and addressed and thereby unsafe practices continued unchecked.
- The physical environment and working arrangements were as important to the safe care of patients as the technical skills of clinicians.
- The absence of systems for monitoring the safety of clinical care at national or local level put the care of patients at risk.
- The absence of a systematic approach to learning from things that went wrong prevented effective remedial action from being taken.

Introduction

- 1 In this chapter we are concerned with safety: that the care which patients receive will be safe. This is not just something which patients are entitled to; it is something they take for granted. But Bristol teaches us that this trust may be misplaced. Care may not be safe. Thus in what follows we examine: what safe care involves; what action is needed to ensure a higher and more consistent degree of safety for patients in the future; and what barriers stand in the way of achieving this.
- 2 The complexity of modern medical care makes it an increasingly risky enterprise. While the vast majority of patients receive safe treatment, it comes as a surprise to many to know that errors, mistakes or accidents occur every day in every corner of the NHS. These have become known collectively as adverse events.² They are often grouped together with another category of event called 'near misses', a term which is self-explanatory and is borrowed from the airline industry. So as to avoid the

¹ James Bagian, engineer and former astronaut, head, US National Center for Patient Safety, Veteran's Administration

² We take the term 'adverse event' to mean the occurrence of an untoward and an unplanned event which results in harm to a patient

distractions associated with allocating an event to one or other of these categories we propose, later in this chapter, that a single term, 'sentinel event', be used in the future. In describing current practice, however, we use the term 'adverse event'. We referred in Chapter 21 to the recent pilot study carried out by Professor Vincent. It suggested that around 5% of the 8.5 million patients admitted to hospitals in England and Wales experience an adverse event which may be preventable with the exercise of ordinary standards of care.³ We accept the authors' caveat about the difficulties of generalising from a pilot study. But let us be clear about what the study's findings suggest: up to 425,000 patients a year, over 1,000 patients a day, suffer an adverse event *which is avoidable*. How many lead to death we do not know, but, as we suggested in Chapter 21 it could be as high as 25,000 people a year. Full-scale studies in the United States⁴ and in Australia⁵ indicate that a similar incidence of error or mishap occurs in both of these countries. If the estimate for Britain is broadly accurate, and further work is urgently needed to establish the full extent of the problem, then we face a profoundly alarming state of affairs.

- 3 The issues which lie behind these figures are complex. Safety is a relative, not an absolute term. What constitutes safe care can change over time as known risks are better understood and managed, and new risks emerge with new procedures and forms of treatment. Furthermore, the extent to which a treatment or a procedure is safe, or risky, or unsafe can vary according to a patient's condition and state of health. Some procedures and treatments, such as open-heart surgery, are inherently risky, whatever the patient's condition. Others, such as the administration of aspirin or a routine injection, might on the face of it, appear to carry a low risk. Yet, if the wrong drug is inadvertently administered, or the wrong dose or concentration given to a patient, so narrow may be the margin of safety that the consequences can be catastrophic.

The components of safe care

- 4 The individual healthcare professional's ability to do what is proposed with proper competence and skill is, of course, crucial in ensuring safe clinical care. But professional competence is only part of the picture. Good people, with good skills and good intentions, sometimes make mistakes. How can this happen? To begin to answer this question, we need to understand that healthcare professionals work in a system. They work in NHS buildings and make use of equipment and drugs provided to enable them to care for patients. Any number of these surrounding factors, or latent conditions, can give rise to error. A misalignment of switches on a ventilator, an

³ Vincent C, Neale G, Woloshynowych M. 'Adverse Events in British Hospitals: Preliminary Retrospective Record Review'. *BMJ* 2001; **322**: 517–19. www.bmj.com

⁴ Brennan TA, et al. 'Incidence of Adverse Events and Negligence in Hospitalised Patients. Results of the Havard Medical Practice study I'. *New England Journal of Medicine* 1991; **324**: 370–6

⁵ Wilson RM, et al. 'The Quality in Australia Healthcare Study'. *Med J Aust* 1995; **163**: 458–71

instrument which shows a false reading, or the unclear labelling of drugs, can have grave consequences for the safety of patients. As we saw in Bristol, the organisation of care in two separate buildings for seriously ill children undergoing high-risk surgery had serious consequences for the safety of the children and the outcomes of their care.

- 5 Working arrangements, as well as the physical environment, also influence healthcare professionals' performance. Most now work in teams of varying kinds. To function effectively in support of patients, teams need to be well led and there must be good communication, both within and beyond the team. If the team does not work well together, if it is not well-led or if communication is poor, the safety of the patient is compromised. Healthcare professionals also work under the pressure of long hours and heavy demands. Evidence from other sectors in which professionals handle complex information and make decisions under pressure, such as in the nuclear and airline industries, suggests that such pressures, if not properly managed, can affect an individual's judgment even when faced with routine tasks, thereby jeopardising the safety of others. All of these factors can have a bearing on the safety of clinical care, no matter how dedicated or competent the healthcare professional may be. The potential impact of these surrounding factors, when combined together, was summed up well by Professor Lucian Leape, drawing on Professor James Reason's work:

'... accidents in complex systems occur primarily through the concatenation of multiple small factors or failures, each necessary but only jointly sufficient to produce the accident. Often these small failures or vulnerabilities are present in the organisation long before an incident is triggered.'⁶

To translate this general principle into something recognisable to all: what airline would ask a co-pilot to be in the cockpit, let alone have to land the plane after being on duty continuously for 24 or more hours? Yet, hospitals routinely still expect junior doctors to be on call (or on duty) and to care for ill patients in such circumstances, notwithstanding, indeed by virtue of, the current arrangements made in light of the European Working Time Directive.⁷

Pressure for change

- 6 Thankfully, a number of factors are forcing change. Knowledge and understanding of how multiple causes contribute to things going wrong is increasing all the time. Major inquiries in other areas of public life have played an important part (notably the inquiries into the sinking of the *Herald of Free Enterprise*⁸ and the fire on the

⁶ Leape L, et al. 'Promoting Patient Safety by Preventing Medical Error' (editorial). *Journal of the American Medical Association* 1998; 280 no. 16

⁷ 93/104/EC. And see HSC 1998/240

⁸ Mr Justice Sheen, '1987 *mv Herald of Free Enterprise*' (formal investigation). London: HMSO, Report of Court No 8074

Piper Alfa platform).⁹ The work of academics has been influential,¹⁰ as have the major studies already referred to on the incidence of error in the USA and Australia. All of these have begun to influence thinking about safety, and about the possible extent and causes of avoidable error, in the complex system of the NHS.

- 7 Within the NHS itself, a major pressure for change is the duty of care recently imposed by law on trusts to ensure that the quality of care delivered to patients is of a proper standard. This is helping to focus attention on the risks to which patients are exposed and on risk management. Another pressure is the rapidly growing awareness of the cost of adverse events, in both human and financial terms. Professor Vincent's study suggests that the cost may be as high as £1 billion a year. The mounting bill for clinical negligence arising from claims against the NHS is part of that cost. The National Audit Office reported recently that the liability in March 2001 for clinical negligence settlements could be as high as £3.9 billion.¹¹ The report also stated that the total annual charge to NHS income and expenditure accounts for provisions for settling claims has risen sevenfold since 1995/96. Of course, it must always be remembered that the cost of error has a direct effect on the resources available for the care of patients. The funds to meet claims for clinical negligence in hospital (which includes the cost of dealing with claims that are ultimately abandoned), are drawn from taxpayers' money. This money could otherwise be available for healthcare services. Moreover, to the extent that adverse events cause moderate or permanent impairment to the health of those affected, such events have a further direct impact on health services. The NHS and the social services have to bear an extra burden of care of the NHS's own making. All this is quite aside from the human toll exacted by unsafe and careless systems and practices, in terms of the impact on the individuals themselves, their families and their livelihoods.
- 8 Pressure for change is also growing out of a greater understanding of the nature of adverse events: that many are avoidable and rooted in the systems of care. Patients and healthcare professionals see that it is possible to do something about them. The starting point must be the realisation that such is the potential for the occurrence of adverse events in these times of ever more complex care, that a concern for the safety of patients must be both constant and active rather than sporadic and reactive. The implications of the words of Sir Cyril Chantler, former Dean, Guy's, King's and St Thomas's Medical and Dental School, must be grasped. He wrote: 'Medicine used to be simple, ineffective and relatively safe. Now it is complex, effective and potentially dangerous.'¹² Of course, with very rare, notorious exceptions, healthcare professionals and healthcare organisations seek to help patients. They do not *intend* to harm them. But, we now know that safety is not just a matter of what an individual

⁹ The Hon Lord Cullen. *The Public Inquiry into the Piper Alfa Disaster* London: HMSO, 1990

¹⁰ See particularly the work of Professor James Reason, University of Manchester, and, in relation to healthcare, that of Dr Charles Vincent, University of London; Professor Donald Berwick, President, Institute for Healthcare Improvement, Boston MA, USA and Professor Lucian Leape, Adjunct Professor, Harvard School of Public Health, Cambridge MA, USA. See also the seminal work of the US Institute of Medicine, particularly *To err is human*. Washington, DC: National Academy Press, 1999. www.nap.edu/readingroom

¹¹ The figure of £3.9 billion comprises 'provisions to meet likely settlements for up to 23,000 outstanding claims ... £2.6bn' and 'a further £1.3bn to meet likely settlements for claims expected to arise from incidents that have occurred but have not been reported.' *Handling clinical negligence claims in England*. Report by the Comptroller and Auditor General. HC 403 Session 2000–01, 3 May 2001. www.nao.gov.uk

¹² Chantler C. 'The Role and Education of Doctors in the delivery of Healthcare'. *Lancet*, 3 April 1999; **353 (9159)**: 1178–81

‘at the sharp end’ of care and treatment may do. Indeed, a professional can be as competent as possible, and yet a patient’s safety may still be at risk. What the NHS corporately, and each individual trust, must do is engender a culture of safety, by putting in place systems which maximise safety. Equally, healthcare professionals must ensure that, in caring for patients, the safety of the patient is their paramount consideration. Care will only be safe when a concern for safety is recognised and embraced by the individual *and* the organisation.

Past and present approaches to clinical safety

- 9 Until the recent past, very little attention within the NHS was given to the wider, organisational context of clinical safety, or to the relationship between a healthcare professional’s actions and the work environment. The tendency was, and to a large extent still is, to see safety in negative terms. The focus was on those adverse events which had the most serious outcomes – death and disabling injury – and on the more egregious examples of a healthcare professional’s conduct: in other words, to look at individual cases and for singular causes, for which someone could be found to blame. There was no place in this approach for seeking to understand the cause of the event, to learn from it, and to share that learning so as to avoid similar events in the future. Instead, there was the false assumption, that, when something went wrong, invariably it was caused by a negligent or incompetent individual. What we now know, and must understand for the future, is that adverse events in healthcare, as elsewhere, are very often caused by a much wider range of factors.
- 10 At the level of the hospital, again until the recent past, ‘safety’ as an issue would not commonly have been understood as being concerned with clinical care. It had much more to do with non-clinical matters, such as the means of escape in the event of a fire; the safety of procedures to deal with hazardous materials; and the protection of patients from such harm as slipping on wet floors, or falling out of bed. In this regard, the evidence from Bristol is striking. Throughout the whole of the period of the Inquiry’s Terms of Reference, the guidance in force on the reporting of accidents and untoward incidents was still that issued by the Ministry of Health in 1955. The majority of all of the incidents recorded in the incident logbooks for the cardiac wards in Bristol relate to non-clinical events, such as falls and inadvertent self-harm. This is how the safety of patients was regarded, and to a degree still is, not just in Bristol but generally. We were informed by Mr John Gray, Manager of Legal Services at the UBHT, that there was no formal policy or mechanism which required incidents to be reported or investigated, far less for the lessons to be learned and shared. For serious ‘near misses’ or major accidents, the UBH/T did, however, have an informal system for reporting based on professional judgment. In adopting this approach to patients’ safety, the UBH/T, according to Mr Gray, was not unusual. It was doing no more than following standard practice at the time. Mr Gray stated that there was ‘... much less emphasis on written procedures than there is today, but it would be wrong to interpret lack of a formal record as indicating lack of attention or lack of action where these were obviously necessary.¹³ ... In effect, staff operated to unwritten protocols where

matters such as the reporting of accidents and untoward occurrences were standard practice and fundamental.’¹⁴

- 11 One relatively recent initiative, at least as regards adverse events which amount to clinical negligence, is the clinical negligence scheme for trusts put in place by the NHS Litigation Authority (NHSLA).¹⁵ The aim of the clinical negligence scheme is to reduce the incidence of events leading to claims for compensation, by pressing trusts to develop their systems concerned with clinical risk and safety. Trusts now pay annual premiums to the NHSLA. They are offered financial incentives in the form of discounts on premiums if certain standards are met (such as standards in relation to the trust’s policies on risk management, on health records and on its response to major clinical incidents). While this arrangement is undoubtedly sensible, in that it constitutes an incentive for trusts to be more active in protecting patients, we note that the incentives, in terms of the discounts on premiums, are relatively small. We note further that the bulk of payments for clinical negligence are still met directly by the NHSLA, thus insulating trusts from the full financial impact of error. We also note that, to the extent that there are incentives for improvement, they are purely financial. While these are of concern to those involved in senior management, it is unlikely that such signals are relevant to those healthcare professionals involved in the day-to-day care of patients.

- 12 In their recent report the expert group chaired by the Chief Medical Officer (CMO) stated that: ‘The NHS is failing to learn from the things that go wrong and has no system to put this right.’¹⁶ The NHS is only now at the early stages of creating a systematic mechanism for identifying, analysing, and learning from adverse events, with a view to reducing or preventing errors in the future. Much of the information required to help to prevent adverse events, as a result of which patients are harmed, is either not collected at all, or is to be found in a patchwork of over 1,000 unconnected and different systems. The very few national systems which do exist, such as the National Confidential Enquiries, and the reporting systems of the Medicines Control Agency and the Medical Devices Agency, work in isolation from each other and are limited in their scope. Thus, the capacity of the NHS to analyse the causes of adverse events, to make known the lessons learned and to embed those lessons within the systems and practices of care, is extremely limited.

- 13 Clearly this must change. The CMO’s report was a seminal and important step along that road. We strongly support and endorse the thrust behind the expert group’s recommendations, principally that there should be: a unified system for the reporting and analysing of adverse events; a more open culture in which errors can be brought to light; and a system for ensuring that lessons are learned and practice is changed to reduce the incidence of errors in the future. We note the decision to implement the

¹⁴ WIT 0137 0029 Mr Gray

¹⁵ The NHSLA was set up in 1995. Through its clinical negligence scheme for trusts, it pools the costs of trusts’ liabilities for clinical negligence arising from incidents occurring after 1 April 1995

¹⁶ Department of Health. *An Organisation With a Memory: Report of an expert group on learning from adverse events in the NHS*. London: DoH, 2000

report's recommendations through the creation of a National Patient Safety Agency.¹⁷ Since the agency is not yet in operation, we confine ourselves here to commenting on the CMO's report, not least since the agency's purpose is to act on the report. We will, however, make one point of general importance. We note the tendency of government to respond to issues by creating new bodies or institutions. While sometimes justified, there is always the danger that the creation of the institution is seen as an end in itself; that by its creation the problem is solved. Furthermore, it is a central message of this report that in the past the NHS has suffered from too many bodies acting independently, with no overarching integration and co-ordination. We agree with the main direction of the CMO's report. We believe, however, that its recommendations should go further. If the full implications of Bristol are to be grasped, more change and of a more radical nature will be needed. In the remainder of this chapter, we set out what form that change might take:

- We believe that more attention must be given to establishing a proper baseline of knowledge about the extent and nature of adverse events and near misses in the NHS; without this we will never know in the future if improvements have been made.
- We make some observations on the Department of Health's (DoH's) proposed new system for reporting of adverse events and near misses.
- Reporting of error is crucial to the improvement of safety. We consider in depth how to tackle two major barriers which stand in the way: the current focus on blame and the recourse to clinical negligence litigation. The experience of reporting systems used in some US hospitals and in the aviation industry are instructive.
- We argue for a higher profile to be given to design-led solutions to tackle some of the underlying causes of error.
- We consider the importance of fully integrating safety into clinical governance and the external review of trusts.
- We emphasise that the starting point must be the need to create a culture of safety, so we consider this first.

Creating a culture of safety

- 14** Placing the safety of patients at the centre of the hospital's agenda is *the* crucial first step towards creating and fostering a culture of safety. This means that safety must be

everyone's concern, not just that of the consultant, or the nurse in charge. Even less should it be represented as being solely the concern of a person bearing a title such as 'Safety Officer' or 'Clinical Risk Manager'. That merely succeeds in giving the impression that safety is for 'someone else' to look after and that, somehow, the issue has been appropriately dealt with. The safety of patients, the safety of their clinical care, is a matter for everyone, from the trust boardroom to the ward assistants. Safety requires leadership from the highest level of management. It requires constant vigilance. It should be considered in everything that the organisation does. It is not a short-term project but a commitment for 365 days a year. A culture of safety can only really be created when a concern for patients' safety is embedded at every level of the organisation.

- 15 Central also to a culture of safety is an understanding that adverse events occur and that people and the organisations of which they are part *do make mistakes*. To err is human. A culture of safety, therefore, is one that seeks not so much to eliminate as to analyse and thereby anticipate adverse events including errors and, in the light of that analysis, to organise systems and practices which, as far as possible, prevent them. Some types of adverse event can be eradicated, of course, and when this is possible it must be done. Others cannot, but their impact can be substantially reduced. Barriers or defences can be built into systems so as to help avert them, or to contain and mitigate their potential for harm. As Professor James Reason suggested at one of our seminars: 'Though we cannot change the human condition, we can change the conditions under which humans work.'
- 16 Constant vigilance is, therefore, a feature of a culture of safety. This point was made forcibly by Professor Marc de Leval, Professor of Cardiothoracic Surgery, Great Ormond Street Hospital for Children NHS Trust. There is, he said, a need for a pervasive mindset of chronic unease, or intelligent wariness.¹⁸ This is not the same as encouraging fearfulness. The line between them is fine, but the latter must be avoided. It raises defences and can easily lead to paralysis. Organisations which adopt an attitude of vigilance do not assume that 'no news is good news'. They recognise that 'no news is in fact no news'. They are thus more likely to be on the lookout for errors and consequently are better prepared to respond when an incident does occur. On this analysis, it is important that people are aware of what they do not know, are aware of where danger may lie, know what should not happen and what is unacceptable, know what to do when problems are identified and know that these will be handled quickly. As the Secretary of the US Anaesthesia Patient Safety Foundation wrote recently: 'The price of patient safety is eternal vigilance'.^{19,20}
- 17 Perhaps the most fundamental feature of a culture of safety is the need for the hospital to create an open and non-punitive environment in which it is safe for healthcare professionals to report adverse events, safe to admit error, safe to admit when things

¹⁸ See report of Seminar 6, Annex B

¹⁹ Gaba DM. 'Anaesthesiology as a Model for Patient Safety in Health Care'. *BMJ* 2000; **320**: 785–8. www.bmj.com

²⁰ The metaphor of the 'squirrel on the lawn' was suggested at a Phase Two Seminar: even at the time when all appears safe, the squirrel remains ever vigilant

have almost gone wrong, and safe to explore the reasons why. Adverse events, especially clinical errors, very often go undetected and unreported because of fear: the fear healthcare professionals have of being blamed and perhaps more fundamentally, the fear of what it will mean for them to acknowledge that through their conduct a patient has actually been harmed, the last thing they intended. This goes beyond a fear for job or reputation. The sense of apprehension was captured by Albert Wu, writing in the special edition of the *'BMJ'* on medical error:

'... although patients are the first and obvious victims of medical mistakes, doctors are wounded by the same errors; they are the second victims. Nurses, pharmacists and other members of the healthcare team are also susceptible to error and vulnerable to its fallout. Given the hospital hierarchy, they have less latitude to deal with their mistakes: they often bear silent witness to mistakes and agonise over conflicting loyalties to patient, institution and team. They too are victims.'²¹

Without a culture of safe reporting, it will be impossible systematically to collect information about the incidence of adverse events, especially errors. Without knowing what is going on, no organisation can take a valid view on how safe it is for the patient to be there, far less take any necessary corrective action. Without knowing, there can be no learning. Without learning, there can only be the risk that it will happen again.

18 The essential features of a culture of safety are, therefore:

- Concern for the safety of patients should be embedded in the NHS as a whole, and be the responsibility of everyone who works in a trust.
- There must be an awareness and understanding of safety and an appropriate means of managing issues relating to safety at all levels of the NHS.
- Human fallibility is an inescapable reality: thus, systems are needed to anticipate all types of adverse event, to eradicate them where possible and mitigate their effects.
- A mindset of constant vigilance is crucial.
- Fear is the enemy of safety: an open and non-punitive environment, in which it is safe to admit and report adverse events, especially errors, is fundamental.
- Adverse events offer an opportunity to learn and to make changes for the better, not an occasion merely to punish and forget.

The extent of adverse events and near misses – the urgent need to establish a baseline

- 19** There is a pressing need for research into some of the central questions about the type and extent of adverse events and near misses in the NHS. We need to be able to answer such fundamental questions as: What is the current scale of adverse events and (to the extent that it can be discovered) near misses? How do they arise? Can they be classified? How can they be guarded against? The Australian and US studies are of value, but they are some years old, and relate to different systems of healthcare. There are almost certainly issues of specific relevance to the NHS which need to be identified. The study of British hospitals by Professor Vincent, while extremely important, is a pilot study. We believe that major studies of the NHS, along the lines of those undertaken in Australia and the US, must be carried out in the UK. Such studies would be an invaluable source of information against which to measure progress. They are an essential part of the task of developing a coherent approach to safeguarding patients. They should be made a priority.²²

A national reporting system

- 20** We fully support the principles behind the recommendation of the CMO's expert group and reflected now in the creation of the National Patient Safety Agency that there be a national system for reporting adverse healthcare events and certain specified near misses. Assuming such a system could be made to work, we have no doubt that it would provide an excellent means for identifying patterns of behaviour, for learning and for disseminating lessons throughout the NHS. We make the following comments and suggestions regarding the proposed new national reporting system:
- The national system must be rooted in sound, standardised local reporting systems. There should be clear protocols as to the categories of information which must be forwarded to a national database. It is vital to have good reporting systems locally, so that an event or near miss can be understood in the circumstances in which it arose, and appropriate action taken. It is no less important to have a first-class national system, because of the need to identify patterns, and to share lessons quickly and effectively throughout the NHS. The national and local systems are interdependent and mutually supportive.
 - We believe that the national database would be best managed by an independent organisation, outside the NHS and the DoH. This would ensure that a high degree of confidence would be placed in the system by the public; they would see that it was outside the ambit of political influence or control. The managers of the national database should be required to publish summary reports on patterns of adverse events and near misses at least every quarter (and, if necessary, monthly) together with any proposed remedial action.

²² We note in this respect the research proposals contained in 'Building a Safer NHS for Patients', Department of Health. www.nhs.org.uk April 2001

- To prevent the system's becoming bureaucratic and preoccupied with definitions of what constitutes an 'adverse event' or a 'near miss', we propose the adoption of the more inclusive term, 'sentinel event'. This has been defined as 'any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof'.²³ The phrase 'or the risk thereof' includes any variation in procedure, a recurrence of which *would* carry a significant chance of a serious adverse outcome. We endorse the principles reflected in this definition but accept that it may require further refinement. We use the term 'sentinel event', as understood here, for the remainder of this chapter.
- The national reporting system should operate broadly in the following manner. It should receive its information from trusts. It should indicate those *categories* of sentinel event as regards which it requires to be informed, for example, failures in equipment or medication errors. The national system should also make provision for recording information from individual healthcare professionals who, for whatever reason, do not feel confident in informing their local trust. The opportunity should exist to report a sentinel event in confidence. In any case where the safety of patients is in question, those who manage the national reporting system must inform the trust concerned. There must be guarantees in place to ensure that no disciplinary or discriminatory action may be taken against the relevant healthcare professional for the act of reporting. To the extent that a disclosure of such information by a healthcare professional to the national reporting system could not correctly be said to come within the Public Interest Disclosure Act, the Act should be amended.²⁴
- The NHS has the unique advantage of being a single organisation with one headquarters. Once a good reporting system is put in place, there is every chance that it will be able to identify and disseminate the lessons to be derived from a particular sentinel event. What is needed is the will to make this happen, the acknowledgement that safety really does matter and, crucially, the resources to put in place good, efficient, standardised and accessible systems for reporting.

Reporting sentinel events: the barriers to openness

21 As we have said, a national reporting system requires there to be effective systems of reporting at a local level. We turn now, and in some detail, to the question of how to ensure the local and national systems for reporting sentinel events can work effectively. It is one thing to set up a reporting system, quite another for people to use it. At a recent summit on Medical Errors and Patient Safety Research in the USA, the Joint Commission on Accreditation of Healthcare Organisations stated:

'Today, the blame-and-punishment orientation of our society drives errors underground. Indeed, we believe that most medical errors never reach the

²³ Seminar 6. The term 'sentinel event', and this definition, were drawn to our attention by the Royal College of Nursing; the term is widely used in the USA by the Joint Commission for the Accreditation of Healthcare Organisations

²⁴ Or, perhaps more simply, the Secretary of State should, by order under s.43F of the PID Act designate to whom, including the National Patient Safety Agency, disclosure in respect of patients' safety may be made. We deal later with healthcare professionals' reporting to local systems

leadership level of the very organizations in which they occur. Therefore, although there is much rumination over the statistics published about medical errors, we believe that no one has a real handle on the actual numbers because all the incentives to report are negative.²⁵

Although written about the USA, this aptly describes what we believe to be the state of affairs here. We have already referred to the lack of openness in the NHS which acts as a major barrier to obtaining information about the incidence of sentinel events, particularly error. We need now to understand more clearly what causes this lack of openness, so as to be able to overcome it and move forward.

- 22** There are a number of causes which must be confronted. The first can be called the myth (or imperative) of infallibility. The idea of the healthcare professional as giver of life, restorer of health, or as one who does not make mistakes, is a dominant theme in the culture of healthcare. This makes it extremely difficult, particularly given the expectations placed upon professionals by the patient, for them to speak up and point out that things have not gone as expected. To admit this is to fail the myth and thus appear a failure. Professionals assume that the patient expects infallibility and consequently find it very hard to admit that they are fallible.
- 23** Secondly, in the particular case of errors, quite apart from any errors of their own, healthcare professionals find it difficult to speak up about the errors of others. There is what can be called a code of silence – that aspect of professional culture which causes ‘tribal’ groups to close ranks and keep problems within the group. There is a real sense of ‘There but for the grace of God go I’. The pressure of hierarchy within the professional group also plays a part. As a consequence, junior staff, or those from other specialties or disciplines, are inhibited from speaking out. We were struck by the evidence of a recent study to evaluate the reporting of adverse incidents in an obstetrics unit, quoted by the Royal College of Nursing (RCN) in one of its papers to the Inquiry. Of 196 adverse incidents, as defined by relevant protocols, identified as arising during the delivery of 500 babies, fewer than a quarter were reported by the staff. The RCN told the Inquiry that:
- ‘... the main reasons put forward for the non-reporting of errors were fears that junior staff would be blamed, high workload and the belief (even though the incident was designated as reportable) that the circumstances or outcome of a particular case did not warrant report.’²⁶
- 24** Thirdly, fear of exposure and blame, whether in the press or through litigation, with the consequent loss of standing, career prospects, or even livelihood, is a further powerful inhibiting factor. As a society we are still trapped in a culture which, when things go wrong, is one of blame. The assumption is often made that there has been an

²⁵ ‘National Summit on Medical Errors and Patient Safety Research’. September 2000. ‘Statement of the Joint Commission on the Accreditation of Healthcare Organizations’. Available at www.jcaho.org

²⁶ Stanhope N, Crowley-Murphy M, Vincent C, O’Connor A, Taylor-Adams SE. ‘An evaluation of adverse incident reporting’. *J Eval Clin Pract* 1999; **5(1)**: 5–12. See also Seminar 6. The Royal College of Nursing. Position Paper

error. Moreover, errors are personalised to an individual, the better to find ‘the person responsible’, who can then be dealt with. And of course, the media, eager for a name, and lawyers, needing someone’s ‘fault’ for their client to point to, reinforce this approach. Errors in the NHS, as elsewhere, are seen not as matters to learn from, but as moral lapses deserving of blame.

- 25** Blame and fault find their expression most strongly in the system of clinical negligence litigation. We regard the impact of clinical negligence litigation to be of such importance that it warrants scrutiny here. To state our conclusion first, we believe that both the threat and the reality of litigation to claim damages for clinical negligence serve as barriers and disincentives to openness within the NHS. Moreover, we consider that they are perceived as such across the NHS. Currently, it is open to patients to bring a legal action if injury is wrongfully done to them in the process of receiving medical care (if, indeed, they are aware that such an injury has been done, for very many patients never become aware of it).²⁷ The legal action is based on an allegation of negligence on the part of a healthcare professional or an NHS trust: that their conduct fell below the standard which the law requires, and that this failure caused the damage of which the patient complains.
- 26** The system of clinical negligence litigation in England and Wales forms part of what is known as tort liability.²⁸ The theory behind the system, as it has evolved, is that by bringing a legal action for damages, the claimant is not only seeking financial compensation for the injury which has been suffered, but is also seeking to achieve two further objectives. The first is to hold the NHS to account. The second, through the combination of public exposure and the award of damages, is to help to prevent similar incidents from occurring again by creating an incentive for trusts and healthcare professionals to act more carefully.
- 27** We referred earlier to the issue of financial compensation: how best to address the financial needs of those who are harmed in the course of healthcare. What concerns us here is whether the system of clinical negligence litigation achieves its other stated aims: accountability and deterrence. If it does, then it may be justified as a system, even if at the same time it operates as a barrier to openness. If it does not, and in our view it fails on both counts, it clearly works against the interests of patients’ safety.
- 28** Taking accountability first, clinical negligence litigation requires that there be someone (or some organisation) to blame for having been at fault. Thus, it institutionalises the notion of blame as the ultimate remedy. Accountability, on the other hand, suggests a system in which performance is assessed and reviewed against standards; blame may follow or be part of that process, but it cannot *be* that process. Clinical negligence litigation does not represent a systematic approach to accountability, far less to the proper analysis of error. Rather, it is an entirely

²⁷ We note in this respect a finding from research in the USA, which showed *inter alia* that very few victims of negligent injury filed malpractice claims. Weiler PC et al., ‘*A Measure of Malpractice. Medical Injury, Medical Litigation and Patient Compensation*’. London: Harvard University Press. 1993

²⁸ A tort is a civil wrong giving rise to liability and a remedy ordinarily in the form of financial compensation

haphazard process. Furthermore, any system of accountability, to be effective, requires that there be openness about who is accountable and for what. There is no such parallel in the system of clinical negligence litigation. Few cases ever actually see the light of day in court. Indeed in many of the more obvious cases of error, where it is clear to the trust, the NHS Litigation Authority, or a defence society, that a hospital or a particular professional was at fault, the claim is settled and no public airing of the issues ever takes place.²⁹ What might be learned from such cases cannot thus be shared across the NHS. Other hospitals and healthcare professionals, indeed even those in the same institution, may not learn of, and thus from, the case. Paradoxically, those cases which are not settled, and thus become publicly known, tend to be those in which it is less certain that a hospital or a particular professional was at fault. Thus, at its extreme, we have the bizarre situation under the current system of clinical negligence litigation, in which the worst excesses rarely come into view, while the more borderline cases attract the attention of the press and public. This is a far cry from any system for holding the NHS to account for its conduct and its errors.

- 29** What about deterrence: does clinical negligence litigation act as a form of deterrence? Patients who suffer harm through some kind of clinical error commonly express the view that the one goal which they seek to achieve through litigation is to prevent what happened to them from happening to others. According to this approach, for deterrence to work, there must first be a way to convey to the NHS the relevant information about the particular error. Secondly, there must be some sort of systematic approach, whether by sanction or incentive, to securing a change in the behaviour of healthcare professionals and of trusts, so that the causes of the error are identified and eradicated, or that their effects are mitigated. As regards deterrence through the dissemination of relevant information, we have already seen that the system of clinical negligence litigation operates against this aim. Many cases are handled locally and not widely known about. Of those that do reach the NHS Litigation Authority, many are settled without attention to any notion of learning the wider lessons. The scale of the opportunities lost by the NHS to learn from litigation is described in the CMO's report '*An organisation with a memory*'. One source of information alone, the NHS Litigation Authority's database, has the details of some 14,000 claims. It is an indictment of the current system (if such it can be called) that none of the sources described in the CMO's report has ever been used systematically to analyse the causes of error and to suggest lessons for the future.
- 30** The system of clinical negligence litigation could be said to fare equally poorly in terms of the second point we raised earlier: the deterrent effect of the types of sanction or incentives which it invokes. On one level, since the NHS and healthcare professionals historically have had access to little systematic information about the incidence of error across the NHS, they can hardly have been expected to resort to some systematic approach to deterrence, so as to tackle the root causes of error. At another level, clinical negligence litigation does have a significant deterrent effect on

²⁹ Around 800 new claims are settled annually by the NHS Litigation Authority arising from incidents in trusts; a further 700 new claims are settled annually by the medical defence organisations arising mainly from incidents in primary care. See '*An Organisation With a Memory*', p. 61

behaviour, but the effect is almost entirely perverse. By institutionalising blame it breeds defensiveness. The instinct is to cover up and deny. Errors cannot be treasured if, by acknowledging them, the healthcare professional or hospital may be sued. As Professor Troyen Brennan of Harvard University Medical School said recently, clinical negligence litigation frustrates monitoring, slows the movement to overcome the incidence of error, and feeds a cycle of public anxiety, more litigation and more secrecy.³⁰

- 31** It is crucial for healthcare professionals and the hospital to discuss in an appropriate audit meeting what may have gone wrong. If a record is kept of such a meeting the records could later be acquired by legal representatives, through a process known as 'disclosure', should a patient wish to pursue a legal claim against the hospital. What can be learned if nothing can be recorded and analysed? The incentives in practice, therefore, are not so much to manage and reduce error as to cover it up when it happens. So much may be at stake for the individual healthcare professional that, on balance, it still seems the easier course to stay quiet than to speak up, whether about their own conduct or that of a colleague. That is not to say that healthcare professionals invariably take the easier course. It is just that we must be clear and honest about which way the incentives drive behaviour.
- 32** Notwithstanding all these other arguments, perhaps the strongest argument against the assertion that clinical negligence litigation promotes deterrence is the most obvious one: errors continue to take place on a very significant scale. Indeed, the scale and the nature (particularly the multiple causes) of error are such that the system of clinical negligence litigation barely scratches the surface. At best, it could be characterised as sweeping up, occasionally, after the event.
- 33** It is our view, therefore, that the culture and the practice of clinical negligence litigation work against the interests of patients' safety. The system is positively counter-productive, in that it provides a clear incentive not to report, or to cover up, an error or incident. And, once covered up, no one can learn from it and the next patient is exposed to the same or a similar risk.

Overcoming the barriers to openness

- 34** Having considered the barriers to openness, we turn now to the changes necessary to overcome them, always bearing in mind the objective we seek to achieve: to ensure that the maximum effort and energy is spent to improve safety across the NHS. This can only be achieved when we have created an environment of openness so as to give rise to a systematic flow of information.

Replacement of clinical negligence litigation

35 The system of clinical negligence litigation is now ripe for review. It is over 20 years since it was last considered as part of the review carried out by a Royal commission under Lord Pearson.³¹ Much has changed in the NHS and in the practice of medicine since then. The system is now out of alignment with other policy initiatives on quality and safety: in fact it serves to undermine those policies and inhibits improvements in the safety of the care received by patients. Ultimately, we take the view that it will not be possible to achieve an environment of full, open reporting within the NHS when, outside it, there exists a litigation system the incentives of which press in the opposite direction. We believe that the way forward lies in the abolition of clinical negligence litigation, taking clinical error out of the courts and the tort system. It should be replaced by effective systems for identifying, analysing, learning from and preventing errors along with all other sentinel events. There must also be a new approach to compensating those patients harmed through such events. The abolition of recourse to clinical negligence litigation would be a major step in changing the climate and the incentive for reporting when things go wrong and, we believe, encourage the openness essential for improving safety. Although our view on what needs to happen is clear, we recognise that such a radical change is likely to have wide implications, not least in terms of any new system of compensation. We recognise, therefore, that the way forward lies in a review by an expert group of the entire system of clinical negligence litigation, with clear terms of reference to consider alternatives to the current arrangements. The review must also address needs arising from harm, both financial and emotional, and how they should be compensated.

Reporting systems

36 Within the NHS itself, a policy of reporting sentinel events which is both open and non-punitive should be pursued. (By a non-punitive policy we mean a policy which expressly indicates that the NHS prizes information and it will not punish those who report errors, including their own, except in circumstances of criminal behaviour.) The adoption of such a policy need not await the outcome of the examination of clinical negligence litigation, although any system of reporting will remain imperfect until that wider issue is tackled.

37 What we envisage through this policy is the creation of a new compact of trust between the hospital and the workforce, made in the cause of patients' safety. Healthcare professionals must be able to know that they can come forward. They must feel safe to do so. The hospital must continually reassure them by its actions that this is so. Of course, patients also must come to understand and accept this process. They will first need to be persuaded that lessons are, in fact, learned and that, where they have been harmed, they can and will receive their due, whether it be an apology or compensation, without the need for clinical negligence litigation. But, according to Professor Leape, the public will accept it. He points out that the public's principal interest lies in what is being done about a problem. They do not expect perfection,

³¹ Lord Pearson. *The Royal Commission on Civil Liability and Compensation for Personal Injury Reports*. HMSO, 1978

they accept that things can go wrong, but they do expect honesty and action.³² To bring about this change of policy, indeed of philosophy, will represent a major challenge of leadership. The NHS and trusts must make it clear that they will not criticise but, indeed, prize those who report errors. Only where there is criminal behaviour (which thankfully is very rare), will there be a place for blame.

Making reporting as easy as possible

38 We now turn to the challenge of making policy become reality. We focus on the local level because that is where any system of reporting succeeds or fails. We begin by making two general points. Reporting must be made as easy as possible, using all available means of communication (including a confidential telephone reporting line). The policy on reporting and an explanation of how to report and, crucially, to whom, should be integrated into all elements of a trust's internal communications activities, induction training and other staff training. Staff must know what is expected of them and what systems are in place to enable them to report.

Incentives to report

39 We propose a system of measures to encourage healthcare professionals to report sentinel events. The incentives, which should be reflected in healthcare professionals' contracts and in the rules of professional bodies, should include:

- Immunity from disciplinary action by the employer for healthcare professionals who report a sentinel event within 48 hours, except where they themselves have committed a criminal offence.
- Immunity from disciplinary action by professional bodies for healthcare professionals who report a sentinel event within 48 hours, except where they themselves have committed a criminal offence.
- An option to report on a confidential basis, unless the public interest demands otherwise.
- The possibility of disciplinary action against a healthcare professional by the employer or the relevant professional body if a sentinel event is covered up or not reported.

Confidentiality

40 There may be circumstances in which healthcare professionals will only report a sentinel event if guaranteed confidentiality, specifically that they will not be identified or identifiable as the source of the report. Fear of recrimination from colleagues may be one such circumstance. For this reason, the option of reporting in confidence must exist. Clearly, once a sentinel event is reported, it will then be the job of the relevant executive director of the trust and the chief executive to take appropriate action.

41 Confidentiality can be a valuable device in reassuring employees and encouraging the reporting of sentinel events. Moreover, if attempts were made to abuse confidentiality by using it as a cloak to hide wrongdoing, other healthcare professionals could (and would) speak up. The trust chief executive in the exercise of their statutory duty to ensure the quality of care, would have to investigate and act. In this context we would add that, were any healthcare professional to seek to prevent the employer from taking any action by consistently reporting their own errors within the required time, thereby avoiding disciplinary action, the employer would have the option of referring the professional to, in the case of doctors, the National Clinical Assessment Authority. Similar systems, providing the opportunity for professional assessment and, where necessary, retraining should be put in place for all other healthcare professionals. This would not constitute disciplinary action; it would, however, protect the safety of patients.

Acting on reports

42 The trust, in receipt of reports from staff, must act. All sentinel events should be subject to a form of structured analysis which takes into account the wider factors within the organisation which may have given rise to the event, as well as the conduct of individuals. This analysis is best done within the organisation in which the event occurs and as close as possible to the time of the event. We have in mind and commend something akin to the process of 'root cause analysis'. Borrowed from the world of engineering, this process allows all of the factors which might have contributed to an event to be identified and analysed. It was recently advocated by the DoH³³ and has been used successfully for some years in the USA by the Joint Commission for the Accreditation of Healthcare Organisations. The analysis in turn forms the raw material for a plan of action designed to address the failures or omissions which have been identified.

Learning from what is already working in the NHS

43 In developing such a system there is much that can be learned from the emerging experience within the NHS. It is encouraging to see evidence of a move towards open reporting as revealed in the inspection reports of the Commission for Health Improvement (CHI). For example, in relation to Southampton University Hospitals NHS Trust, CHI stated: 'A new process for reporting adverse incidents was introduced in early 2000. An important feature is that reporting of non-clinical and clinical incidents is combined'. Yet it also noted: 'In common with staff in most other health organisations though, some staff in the Trust feel reticent about raising concerns about colleagues – especially doctors about other doctors and other staff about doctors'. In relation to North West Wales NHS Trust, CHI wrote: 'The Trust states that its approach to managing risk is to ensure that it develops a culture of "no blame" ... The evidence clearly indicates that the Trust has made significant progress in achieving this.'³⁴

³³ 'Building a Safer NHS for Patients', April 2001, p. 38, Department of Health. www.nhs.org.uk

³⁴ See Commission for Health Improvement. 'Clinical Governance Reviews'. 2000/01. www.chi.nhs.uk/eng/report/index

Learning from other industries and other healthcare systems

- 44 There are also lessons to be gained from the experience of other industries and other countries. A non-punitive approach to reporting possible breaches of safety has long been part of the culture of the aviation industry. In this country and in the United States, programmes for safety in aviation encourage pilots to report incidents to their companies, allowing immediate corrective action (see Box A below). In this way, airlines learn. Safety is protected. Passengers travel safely.

Box A: Examples of aviation safety reporting systems

British Airways

- The British Airways Safety Information System (BASIS) is a tool for safety management, developed and introduced by British Airways in 1990 and now used by 150 organisations around the world.
- It supports the process of investigating possible breaches in safety and is predicated upon a philosophy that puts safety at the centre of the organisation.
- An open reporting culture is a key to the success: ‘... the fundamental principle behind BASIS is that an open, penalty-free reporting culture be developed and supported. This encourages staff to contribute high quality safety information without fear of recrimination.’ To support the culture, letters are sent to staff thanking them for their report and giving them details of the investigation.
- BASIS produced a database of over 43,000 incidents for 1999. Through the analysis of trends, BASIS helps airlines and other related organisations to adopt strategies to prevent adverse events and to promote safety.

Source: Seminar 6 report, and website of the BA Safety Information System: www.basishelp.com

Aviation safety reporting system – the US federal system

- Eligibility for limited immunity from disciplinary action for non-criminal offences is a powerful incentive to report. No immunity is given if the event is deemed intentional; where there is a question of qualifications; or, if the report is filed after 10 days.
- The number of reports of events is around 30,000 a year. Data have been used to redesign aircraft, air traffic control systems, airports, and for the training of pilots.
- Management of the system is contracted out to an independent third party.

Source: Barach P, Small SP. ‘Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems’. *BMJ* 2000; **320**: 759–63; www.bmj.com

- 45 A number of hospitals in the USA have also successfully implemented open reporting systems (see Box B below). That some hospitals in the USA have been able to do so while clinical negligence litigation flourishes may suggest that such litigation is not a barrier to openness, despite our previously expressed views. The response is complex. The crucial difference, apart from any structural differences between the law and practice in England as compared with the various states in the USA, may lie in the source of the funds for compensation. In the USA, the hospital claims from its insurer which passes on the cost in increased premiums for healthcare insurance, which the hospitals pass on to the patients in increased healthcare costs. In the UK it is the service provider, the NHS, which pays the cost and, short of increasing taxes, or taking funds from elsewhere in the public sector, money spent on meeting claims is money

not spent on care. Thus, the financial impact and incentives in the USA and the UK are different.

Box B Safety reporting systems in US hospitals

The Luther-Middleford Hospital in Eau Claire, Wisconsin

- In 1997, a team under a clinician, Roger Resar, undertook an assessment of errors in medication and found that patients were probably at risk of two to three drug errors during a stay.
- A non-punitive system of reporting was established, first in just one department but now throughout the hospital.
- Reports of errors from nurses and technicians rose by up to sevenfold in the first month after the system was introduced in spring 1998. The number of errors reported levelled off in time as changes to systems were put in place to tackle some of the underlying factors leading to the errors reported.
- The hospital has, as one of its stated objectives, ‘to provide safe care’. There is a commitment to safety within the hospital, and a determination to apply thinking about safety to everything it does.
- The hospital’s president and CEO (Chief Executive Officer) says, ‘We have worked hard at changing the cultural fear of punishment. Now we tell people they’ll get in trouble if they don’t report an error – and they have a 48 hour period to let us know if something has gone wrong’.

Source: Findlay S (Ed) *Reducing medical errors and improving patient safety; success stories from the front lines of medicine*. Washington, DC: The National Coalition of Health Care and the Institute for Healthcare Improvement, February 2000. www.nchc.org

The Veteran’s Administration – the healthcare system for US veterans and their families

- The VA includes 172 hospitals and employs 200,000 people. Features of the patient safety system include a safety events registry to which staff are encouraged to report all incidents that caused significant harm to a patient.
- Reported errors are subject to analysis leading to corrective action and preventive measures, rather than punitive action (the sole exception being a criminal or a deliberately unsafe act).
- Individuals who suggest broadly applicable safety improvements qualify for bonuses of up to \$5,000; institutions can receive up to \$25,000.
- The head of the VA’s National Center for Patient Safety, James Bagian, an engineer and former astronaut, says ‘The old model was, you stressed who was at fault. The new model is that we understand you do not come to work to make errors and we want to minimize the risk that you will do so.’

Source: Findlay S (Ed) *Reducing medical errors and improving patient safety; success stories from the front lines of medicine*. Washington, DC: The National Coalition of Health Care and the Institute for Healthcare Improvement, February 2000. www.nchc.org

Designing safer systems, buildings, equipment and pharmaceuticals

- 46** By bringing more information about sentinel events into the open, it becomes possible to understand their causes and to act accordingly. Very often the causes can be minimised by designing safer systems and equipment. This approach of looking at systems is exemplified by the reports into an incident in Nottingham in 2001 when a young patient was mistakenly given the drug vincristine by spinal injection.³⁵ This was a catastrophic clinical error; the patient died two weeks later. The reports considered how the human systems (of staff induction and training) and the equipment used for giving injections, should all be changed across the NHS to reduce substantially the risk of a similar error occurring elsewhere again.
- 47** In terms of occupational health and safety, the Health and Safety Executive (HSE) has a well-developed system for collecting, analysing and acting on information about unsafe materials or practices. Under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995, all employers are required to report relevant incidents. The incidents are analysed and where patterns emerge, action is taken to improve guidance and to seek changes. One among many examples is the recently produced guidance to safeguard flat-belt conveyors in the food and drink industries. An analysis of accidents caused by machinery in these industries over a ten-year period showed conveyors to be the cause of 30% of injuries investigated by the HSE. The new guidance covers legal requirements for, and safe design of, new conveyors as well as guidance on maintenance for old as well as new machines.³⁶
- 48** During the Inquiry's seminars, we were impressed by the extensive experience of anaesthetists in applying a 'systems approach' to safety. The work of the Royal College of Anaesthetists and the Association of Anaesthetists of Great Britain and Ireland deserves to be commended. Through their emphasis on protocols and guidelines, and in their influence on the design of equipment, they have helped to make remarkable advances in the safety of anaesthesia over the past 30 years. The field of anaesthetics (and of anaesthesiology in the USA) has led the way in the use of 'engineered safety devices', meaning devices that physically prevent errors. One example, quoted in a recent article in the *'British Medical Journal'*, is the system in the operating theatre of gas connectors that are designed so as prevent a gas hose or cylinder from being installed in the wrong site.³⁷ In healthcare as a whole, however, it is well recognised that the adoption of an approach to solving or addressing specific hazards by designing equipment differently is under-explored.³⁸ This is to be regretted, given the

³⁵ Toft B. 'External Inquiry into the adverse incident at Queen's Medical Centre Nottingham on 4th January 2001'; and Woods K. 'The Prevention of Intrathecal Medication Errors'. NHS Executive, April 2001. Both reports available at www.doh.gov.uk

³⁶ See HSE Press Release E072:01, 23 April 2001. www.hse.gov.uk/press. The original RIDDOR regulations were made in 1985 and themselves expanded on a form of reporting accidents obligatory in factories before that

³⁷ Gaba DM. 'Anaesthesiology as a model for patient safety in health care'. *'BMJ'* 2000; **320**: 785–8. www.bmj.com

³⁸ See 'An Organisation With a Memory', p. 78

great pool of knowledge and skill amongst the medical profession and within the NHS. Organisations within the DoH, such as the Medicines Control Agency, the Medical Devices Agency and NHS Estates also have a wide range of experience of the effect of design-led solutions on improving safety and on changing the conditions which give rise to unsafe practices. For the future, therefore, we regard it as of great importance to develop this area of research and development. We take the view that the new National Patient Safety Agency should, as a matter of urgency, bring together managers in the NHS, representatives of the pharmaceutical companies and of the manufacturers of medical equipment, members of the healthcare professions and the public to tackle what are some of the more fundamental and persistent underlying causes of unsafe practices. The aim should be to seek to apply approaches based on engineering and design so as to reduce (and eliminate to the extent possible) the incidence of sentinel events. In this context, we commend in particular the example of the Australian Incident Monitoring Study (AIMS) in anaesthesia, which, since 1998, has held ten national consensus conferences bringing together all interested parties to discuss ways of reducing the rate of adverse incidents in anaesthesia.

Incorporating a concern for safety into systems and policies

- 49** We argued at the outset of this chapter that a concern for the safety of patients must be visible at every level of the NHS. But it must be more than a concern. The systems and policies of the NHS and of individual trusts must incorporate that concern, reflect it and thereby promote the safety of patients. Commitment to safety is not a separate, autonomous, 'self-contained' policy. It must be embedded in everything which the NHS does, from, for example, the education and training of healthcare professionals, to the design of buildings and equipment, to protocols for treatment, care and the administration of drugs, to the systems for responding when things go wrong.
- 50** We believe that one development in particular is called for. At the level of individual trusts, we take the view that an executive member of the board should have the responsibility for putting into operation the trust's strategy and policy on safety in clinical care, so as to protect the safety of patients. Further, a non-executive director should be given specific responsibility for leading the strategy and policy aimed at securing safety in clinical care. This concern for safety should be linked to existing systems for clinical governance, by ensuring that this non-executive director also serves as the Chair of the board's clinical governance committee. Through this leadership, the attention of *all* healthcare professionals will be directed towards safety. It will be the responsibility of *all*. It may also be helpful to note here, in the light of what we learned from the events of Bristol, that it must be made clear that, should it ever arise, the chief executive has the duty and the authority to close down even on a

temporary basis a particular service if it poses too great a threat to the safety of patients. We describe in the next chapter a process by which trusts should be validated, rather than inspected, by CHI. It should always be open to trust chief executives, in pursuit of their duty to protect patient safety, to call in CHI to advise on whether a service or a facility is unsafe.

Chapter 27: Care of an Appropriate Standard

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

Messages from Bristol

- The absence of explicit agreed clinical standards of care for patients who received paediatric cardiac surgical (PCS) services, whether in Bristol or elsewhere, made it very difficult, either at the time or subsequently, to assess the quality of care.
- Standards of care in Bristol, as elsewhere, were regarded as a matter for individual clinicians to determine, doing the best for their patient, based on their professional skills and the knowledge they could acquire over time.
- As regards the monitoring of the PCS service, a good deal of data was available at the time in Bristol about the PCS service. Yet the nature of the data coupled with the prevailing mindset were such that no real understanding of performance emerged, whether of Bristol or of other hospitals, for the purpose of comparison. To the extent that the clinicians at the time understood and reflected on their performance, they only had to satisfy *themselves* that the service was of sufficient quality. There was no systematic mechanism for monitoring clinical performance. Explanations of poor performance could be advanced which were plausible but lacked evidence, in the absence of sound data.
- As regards the absence of both explicit standards and any rigorous monitoring of outcomes, the Bristol PCS service as a specialty was little different from other areas of clinical practice at the time.
- From the perspective of parents whose children were cared for in Bristol, it was assumed by many that because the UBH/T was designated as a 'supra regional centre', its standards of care and treatment were amongst the best in the country.
- Few parents whose children were cared for in Bristol had any idea that there was no real way of knowing this: that there were no agreed standards of care and not only no external monitoring of clinical performance but no real mechanism for doing so.

Introduction

- 1 The term standard is in essence a neutral term. What we import into it here is an element of quality. Any level of performance can meet some standard. But the standard which we are concerned with is that which properly serves the interests of the patient. Thus we take the term 'standard of care' to mean an agreement on what a patient is entitled to expect as good practice in a particular context, based on the best available evidence. A standard of care, therefore, sets the boundaries of what is good practice. It also, however, needs to be sufficiently flexible to allow for minimum standards and standards of exemplary practice to which a service can aspire. In this chapter we examine briefly the approach to standards of clinical care in the past, and we consider the impact of recent policy changes. We argue that the systems for setting and monitoring standards of clinical care can and should be further improved. We advocate a new approach to setting of standards for hospitals, and we set out proposals for a more rigorous and better co-ordinated system to monitor the performance of the NHS as a whole.

The past: an absence of standards and of monitoring

- 2 Clearly, patients wish for a good outcome¹ (where this is possible). But this disarmingly simple proposition is easier to state than to define. It contemplates agreement on what amounts to a good outcome, and sometimes patient and professional may disagree. It further contemplates ways of assessing, measuring, recording and comparing outcomes, so as to produce information which would allow the patient and the professional to come to a view as to what is 'good'. It also calls for an understanding of the relationship between outcome on the one hand, and treatment and care on the other, bearing in mind that there can be many variables which affect a person's health, whatever treatment and care they may receive. The link may be more obvious and visible in some areas of medicine (such as therapy with drugs), than in other areas of treatment. Until recently, apart from a few exceptions, this information and understanding have barely existed in any significant way. Thus perhaps the most essential tool in achieving, sustaining and improving quality of care for the patient was lacking. Hospitals and the NHS could tell you about throughput (number of patients treated), bed occupancy (the proportion of beds occupied in the

¹ We take as our definition of a health outcome one cited by the Royal College of Physicians in its paper for Seminar 6: 'A change in health, health related status, or risk factors affecting health. A health outcome may be the result of the natural history of the disease or may be the effect of interventions designed to prevent or to treat it.' (Derived from Pearson M et al. (Eds). 'Outcome Indicators for Asthma'; report of a Working Group to the Department of Health, London. Royal College of Physicians Research Unit and Oxford Unit of Health Care Epidemiology. London: NHSE, 1999)

hospital), and, latterly, the costs involved. But, generally speaking, quality of outcome was a closed book.

- 3 The explanation is complex. One powerful factor lies in the historical origins of the NHS. As we have already said, until at least the early 1980s, the Department of Health (DoH) regarded quality of care as essentially an issue for healthcare professionals: something the Department should not interfere in. Thus there was no imperative from the centre to generate information about the quality of care as we understand the term today, and consequently, there was no reliable national picture of the quality of care. For their part, healthcare professionals often monitored their own work at a local level, reviewing, for example, deaths and complications. But with very little or no comparative data from other units or hospitals, based on agreed criteria and subject to rigorous analysis, all they really had to go on in judging how well they were doing was little more than anecdote. Furthermore, there were no systems, either within the hospital or elsewhere, to identify poor clinical outcomes or take action, unless or until some scandal broke, or a pattern of performance was so poor as to attract attention. Papers were presented at conferences, articles were written in journals, and colleagues met and discussed their work. But all of this was piecemeal and of varying value.²
- 4 Until well into the 1990s, the notion that there should be explicit standards of care which all healthcare professionals and hospitals should seek to meet, and which would apply to patients across the NHS, simply did not exist. We heard evidence in both Phases of the Inquiry, for example, that clinical standards were regarded as a matter for individual doctors to address within their own practice. The Royal College of Physicians, for example, told us that 'Quality of care was simply left as a matter for individual doctors to supervise within their own practice until the 1980s.'³ Such an approach, in which individual professionals were responsible for all stages of their own work, was the norm in healthcare (as it was in other areas of professional practice such as the law). Its weakness lay in the lack of anything against which professionals could test their performance. At its worst, it led to complacency and an erosion of self-questioning. Reliance on experience became a substitute for continuing self-appraisal. Variations in practice were seen as the proper exercise of professional choice rather than as evidence of differing standards. A further weakness lay in the assumption that the presence or absence of decent equipment and decent facilities made little or no difference to the quality of care: that all that was needed was to rely on well-trained professionals to do their best. That was not fair to professionals. One of the crucial insights from Bristol is that leadership and management of a hospital, the organisation of patients' care, and the state of a hospital's buildings and equipment, are as relevant as, and interact with, the competence of healthcare professionals in influencing the standard of care. The conclusion must be that the standards and quality of healthcare are not, and cannot be, a matter solely for healthcare professionals.

² For information about how paediatric cardiac surgeons kept up to date in the 1980s and 1990s see Annex B

³ Seminar 6. Royal College of Physicians. Position Paper. Also see Summary Report of Seminar 6 at Annex B

The gradual shift towards an interest in standards and in monitoring

- 5 The Royal Colleges and various specialist associations of healthcare professionals, sometimes allied to Royal Colleges and sometimes not, issued, and indeed continue to issue, suggested standards of care (as distinct from standards of professional practice), guidelines and guidance to their members. Other organisations also contributed and contribute from time to time, such as the British Medical Association (BMA). The DoH, through the Clinical Standards Advisory Group,⁴ also played a role. But all of this guidance was advisory. It was seen as an exhortation to best practice. There was no assumption that it should normally be followed. Indeed, none of the various bodies had any authority to cause their guidance to be followed. What such guidance constituted was an extension of the notion that standards were for the individual professional, to the idea that they could be for the profession as a group. There was rarely, if ever, any involvement of non-professionals in the development of the guidelines, nor any coherence necessarily between the various guidelines.
- 6 As regards information on performance which could help clinicians to reflect on and to improve the quality of care, there were exceptions to the general lack of data, most notably in the case of four national Confidential Enquiries.⁵ The reports of these Confidential Enquiries covered only certain specified areas of healthcare. They depended on the co-operation of clinicians to submit data. Not all did so. The data were then aggregated and anonymised. This process encouraged the participation of professionals who were otherwise anxious at comparisons being made which might not be informed. It inevitably meant that comparisons could not be easily made. In particular, the prospect of patients gaining any information on the performance of Dr X in Unit Y in Hospital Z was lost. A similar process was evident in Bristol. The Society of Cardiothoracic Surgeons collected and distributed in aggregated form data about mortality rates in paediatric cardiac surgery (from the UK Cardiac Surgical Register). While ahead of other specialties in this regard, participation was voluntary. The data were made available only to those surgeons who were members of the Society, though they in turn could decide to make the data more widely available. The Society itself did not make the data known to the various hospitals nor to the public.
- 7 As regards the role of learned journals (and other literature) as a source of reliable information on practice whereby professionals could compare their performance with that of others, it was accepted wisdom that bad results were less likely to be written up in the literature. The data on performance were assumed to be skewed. The picture presented in the literature and the reality of everyday treatment were, consequently, regarded as some distance apart. It followed that all healthcare professionals whose performance did not meet the standards achieved in the literature were able to persuade themselves that it was the literature not they who were out of line. Thus, until recently, the patient and the doctor were steering their way towards quality of care with only the crudest of maps.

⁴ The Clinical Standards Advisory Group existed between 1991 and 1999. Its function was to advise the Secretary of State, as requested, on standards of clinical care in the NHS and on access to and availability of services to NHS patients

⁵ They are the Confidential Enquiries into (1) Maternal Deaths (since 1952) (2) Stillbirths and Deaths in Infancy (since 1992) (3) Peri-operative Deaths (since 1987) and (4) Suicide and Homicide by people with Mental Illness (since 1992)

Clinical audit: the policy and the practice

- 8 The shortcomings of this approach have increasingly come to be realised. Relying on each individual to maintain his knowledge of the latest literature, research and best practice has become an unrealistic proposition with, on the one hand, the increasing complexity and variety of information, and, on the other, the growing demands on professionals' time to care for patients. Meanwhile, the variations in the outcome of healthcare which exist across the country today (to the extent that they are understood), serve as an indictment of the old way of doing things. In a patient-centred healthcare system, the standard of care patients can expect should be determined by something more than the capabilities of individual healthcare professionals and the vagaries of individual hospitals.
- 9 In 1989 the first attempt was made to introduce a more systematic approach to improving the quality of clinical care in the NHS. The DoH formally adopted a policy of requiring hospitals, and later trusts, to undertake medical, later extended to clinical, audit. The idea that clinicians should take time to reflect on their practice and make any necessary change to it was well accepted (if not widely practised or supported). The new policy introduced an element of formality. It was accompanied by ring-fenced funding, and local co-ordinating committees were established. At the time this was a significant step, but with the benefit of hindsight and experience we can now see how limited a step it was.
- 10 The story of the initiative to introduce a national system of clinical audit has not been a happy one. The ring-fenced resources were not always used effectively, and were sometimes deployed for other pressing needs, given the extremely tight financial constraints in the NHS generally at the time. Furthermore, the whole initiative was suspected by healthcare professionals of being a tool of managerial control. And, because participation was voluntary, the implementation of audit in any given hospital was fragmentary, with some clinicians participating and others not. The practice of clinical audit, if not the policy, came to be regarded by many as at worst a failure, at best, not a signal success.⁶ Thus if clinical audit was the tool whereby performance and outcome were to be measured, both locally and nationally, its relative failure meant that, by the late 1990s, the NHS was almost as ill-equipped as ever to address the issue of quality. Patients have not been well served.

Recent developments

- 11 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. To adopt the words of the White Paper '*A First Class Service*':

⁶ See the Expert paper prepared for the Inquiry: Walshe K and Offen N. '*An evaluative commentary on systems for review and audit at the United Bristol Hospitals/NHS Trust 1984–1995*'. See Annex B 10m

‘High quality services should be available to all patients. At present, there are unacceptable variations in the quality of care available to different NHS patients in different parts of the country. This has to change’.⁷

- 12** A number of recent developments suggest room for guarded optimism for the future. The first is that, with an injection of funds into the NHS, attention can begin to move beyond issues of cost and efficiency to embrace more fully the issues of the quality of care. We say again, however, that without a continued increase in funding, progress along the lines which we propose will simply not be sustainable. Second, to signal the importance of quality and standards, the Government, for the first time in 1999, placed on trusts and health authorities a statutory duty to establish and maintain arrangements for monitoring and improving the quality of healthcare. Clearly, if the chief executive of a trust is legally responsible, and publicly accountable for making something happen, the odds of its happening improve. Third, Government has made it clear that it will set national standards for clinical care in the form of clinical guidelines developed by the National Institute for Clinical Excellence (NICE), and through National Service Frameworks (NSFs) developed by the DoH. Fourth, initiatives are in hand to monitor performance. The Commission for Health Improvement (CHI) is required to inspect each trust every four years to review clinical governance arrangements.⁸ In addition, part of CHI’s work will be to undertake a programme of reviews to see how well the guidelines developed by NICE and the NSFs are being implemented. Further, CHI with the Audit Commission will jointly publish information annually on the performance of the NHS, including performance against a selected number of clinical indicators, such as rates of survival from different forms of cancer. Such initiatives represent a start, albeit belated, on the road to understanding and then improving quality of care.

⁷ Department of Health. *A First Class Service; Quality in the New NHS*. London: The Stationery Office, 1998

⁸ According to CHI: ‘Clinical governance comprises the clinical and managerial systems, procedures and working practices that NHS organisations should have in place to ensure that patients receive the best possible care.’ For background to clinical governance reviews see: www.chi.nhs.uk. Examples of systems which form part of clinical governance arrangements include clinical audit, risk management and the arrangements for staffing and staff management

Box A – Current arrangements for setting national standards of care

Clinical Guidelines from the National Institute for Clinical Excellence (NICE)

- NICE is a Special Health Authority for England and Wales. It is part of the NHS. Its role is to provide patients, healthcare professionals and the public with authoritative, robust and reliable guidance on current 'best practice'.
- Its guidance refers both to particular technologies in healthcare (medicines, medical devices, diagnostic techniques and procedures) and the clinical management of specific conditions.
- One of the four main strands of NICE's work is to set 'clinical guidelines for clinicians and patients'. Around 20 topics are addressed annually. A list of topics is set and agreed annually by the Secretary of State for Health and by the Welsh Assembly. A long-term objective identified by NICE is to achieve a full description of clinical practice.

Source: www.nice.org.uk

National Service Frameworks (NSFs) from the Department of Health

- NSFs were first announced by the Government in the White Paper '*The New NHS*' (1997). NSFs set national standards and define service models for a specific service or care group. They aim to put in place programmes to support implementation of the standards and to establish performance measures against which progress within an agreed timescale can be measured.
- The first two 'Frameworks' were the Paediatric Intensive Care Framework and the Calman-Hine report on Cancer Services. Three more are in place: Mental Health (1999); Coronary Heart Disease (2000); and Care of Older People (2001). Others, in preparation, include: Care of People with Diabetes, to be published later this year (2001); and one for Children's Health Services. When NSFs are written they include some clinical performance indicators which can be used to monitor implementation of the framework.
- The Department of Health develops each NSF with assistance of an expert group of health professionals, service users and carers, health service managers, and other relevant bodies.

Sources: NHS Plan 2000, www.doh.gov.uk

Scope for building on recent developments

- 13** To point to the potential for improvement and to possible shortcomings in the arrangements currently being established or proposed is not to criticise for its own sake. It is really to recall our central concern: can we be sure that events similar to those which happened in Bristol are not happening now or will not happen in the future? If we cannot be sure, and we do not think that we can be, we must highlight shortcomings in the various current proposals which prevent us from being so. We believe that more attention needs to be given to co-ordinating the setting of standards; addressing uncertainty where there are no standards; ensuring that standards are sufficiently comprehensive; and improving the ways in which standards are monitored. We deal with each of these in turn.

Insufficient co-ordination in setting standards

- 14** As we mentioned previously, many of the Royal Colleges and specialist professional organisations since the late 1980s, have issued, intermittently, standards and guidance for the treatment of a range of conditions. In the last two to three years, probably in

response to the widely acknowledged vacuum in this area, this work has intensified. We list here a few examples. The Royal College of Nursing told us that its current work '... includes setting national standards and clinical guidelines ...'.⁹ The Royal College of Physicians, through what is now its Clinical Effectiveness and Evaluation Unit, has since 1990 produced guidelines for the care and treatment of over 90 conditions. In the particular clinical areas which are of interest to this Inquiry, the Royal College of Surgeons of England recently issued guidance on children's surgery;¹⁰ and, with regard to the removal and retention of human material, the Royal College of Pathologists issued guidance in 2000, only to be followed by the BMA and the DoH, each with its own guidance on the same topic.

- 15** There is much to be welcomed here, not least the preparedness of the Royal Colleges and other bodies to seek to fill the previous vacuum. But there are also disadvantages in the appearance of a host of guidelines from different bodies, some, indeed, on the same subject. Trusts and healthcare professionals may not know which standards should be followed, or what status or authority the standards have. Furthermore, patients do not know what to expect or what they are entitled to. Indeed, if patients with a particular condition were to seek to refer to the guidelines which relate to the care of their condition they might find several, aimed at different specialists, emanating from different Royal Colleges and professional associations. Equally, they might also find standards developed by local clinicians, or by the DoH, or possibly by NICE. Or, they might find none at all. It has to be said also that there is frustration on the part of the Royal Colleges and professional associations, as we heard during Phase One that, where they have developed standards, they have no means of ensuring compliance. The written evidence of Dr Michael Godman, then President of the British Paediatric Cardiac Association, was typical: 'It is clear, however, that there is at present a vacuum in relation to the enforcement of standards. The Royal Colleges are primarily concerned with training and neither the Department of Health nor Purchasers/Commissioners for Services have set clearly defined standards by which centres can be judged.'¹¹
- 16** There is also the potential for confusion if NSFs are written so as to include particular clinical standards other than those developed under the auspices of NICE. NSFs are laid down by the DoH. We have already referred to what we regard as an essential role of the DoH: to be the headquarters of the NHS. It is entirely compatible with this role that the DoH should seek to lay down NSFs, if Frameworks mean addressing broad issues concerning priorities, the effective use of resources, and the organisation of care. But it should not be part of the DoH's role also to seek to set standards for clinical care, whether as part of NSFs or not. If it does so, it goes beyond what we regard as its proper role. It adds to the confusion as to which standards apply if they should appear in an NSF and be issued by NICE. It also undermines the role of NICE as the body charged with setting standards. We recognise that the new arrangements introduced in 1999 are still, to a degree, bedding down. But, in relation to NSFs,

⁹ Seminar 6. The Royal College of Nursing. Position Paper

¹⁰ The Royal College of Surgeons of England. 'Children's Surgery – A First Class Service'. London, May 2000

¹¹ WIT 0047 0005 Dr Godman

we take the view that it should be the role of NICE to establish the detailed clinical standards which patients are entitled to expect, and thereby lend substance to these Frameworks.

Confusion as to the availability of standards

- 17 Although the task of setting national standards has begun, uncertainty is created in those areas of healthcare for which, currently, there are no national standards. The public are left uncertain as to whether there are any standards for the care and treatment of their particular condition, or whether such standards as may have been produced by a Royal College, or on some local initiative, are appropriate. There is a danger that conditions which are not categorised as 'national priorities' may be given too little attention. And, of course, where there is no standard, there is no agreed benchmark against which to monitor performance and learn lessons.
- 18 Hence, we consider that a timetable over the short, medium and long term should be published, and revised periodically, for the development of national clinical standards, so that the public may be consulted and kept aware of those areas of healthcare which are covered by such standards and those which will be covered in the future. Target dates should be set by which clinical standards will have been prepared for all major conditions and illnesses.

Comprehensive standards

- 19 Standards relating to the quality of clinical care must not be seen solely in relation to care at the bedside. One of the significant lessons of Bristol is the effect which the organisation and management of a service has on the quality of clinical care. Thus standards must also relate to all the relevant aspects of management of care. This is clearly recognised in the *'Manual of Cancer Services Standards'*.¹²

Problems with regard to monitoring standards

- 20 Local monitoring: the responsibility for delivering care of good quality to patients must be a matter for individual trusts, and for the healthcare professionals within those trusts. The arrangements for clinical governance in the NHS now recognise this. As part of the process of providing care of good quality, there must be systems in place to enable trusts and healthcare professionals to monitor and assess their performance against agreed standards, and to compare or 'benchmark' their performance against that of other units in similar circumstances offering similar services. The process of clinical audit, which is now widely practised within trusts, should be at the core of a system of local monitoring. Yet, in order to undertake audit effectively, clinical teams need time. They need to generate and have access to data of good quality about their own performance and about that of other teams in similar trusts. Further, they need to know how to analyse and to interpret such data, or to have access to the necessary expertise to help them to do so. And they need to have the necessary support, in terms

¹² NHS Executive. *'Manual of Cancer Services Standards'*. December 2000. The manual includes standards for the way in which multi-disciplinary clinical teams should work and standards for the organisation and management of cancer networks and cancer units

of administrators and information technology, to be able to do this. Currently, throughout the NHS, there is considerable scope for improvement on all of these fronts. On the matter of data, for example, there continue to be a plethora of systems, of varying quality, for collecting, coding, validating and analysing clinical information.

- 21** National monitoring: it remains very difficult for a particular trust to compare itself with another equivalent trust, or for a given unit or specialty within a trust to be compared with one in other trusts. We acknowledge the further development, since 1999, of clinical performance indicators, and the DoH's proposals for extending the range and type of these indicators.¹³ But we are also mindful of the scepticism with which clinicians continue to view much of the data used for such national clinical indicators. Many are based on Hospital Episode Statistics (HES) data which are collected and collated by the DoH from the various patient administration systems of trusts. This Inquiry's extensive investigations into the HES data have confirmed that their quality and reliability improved steadily in the 1990s. But the data are still not highly trusted by clinicians for a variety of reasons, not least the conventions which are used to code clinical information and the fact that the data are coded in hospitals by non-clinician coding staff.¹⁴
- 22** With regard to those clinical audits which are organised on a national basis (which differ from national clinical indicators in that they take a detailed view of the care of patients with a given condition), the few such audits as exist cover only a small proportion of the total of care in the NHS. This itself reflects the shortage of national standards. Yet such audits are an important tool in assessing the quality of care because of the type of comparative data they can produce. The Royal College of Physicians told us that its Sentinel Audit of Stroke considered over 7,000 cases drawn from 80% of the hospitals treating patients who had suffered a stroke. By drawing on such a large number of cases it was possible to identify patterns and make comparisons on a wide scale and thus to separate the best performing from the worst performing units with considerable confidence.¹⁵ Such national audits are vital for the future; they will only come to have real meaning when there are standards to which such audits relate.
- 23** Currently, the future for national comparative audits appears to be unclear. NICE provides some funding to various Royal Colleges for the audit of certain specialties on a national scale. NICE is also responsible for the four national Confidential Enquiries. It is CHI, however, which has been set the task of monitoring whether the standards set by NICE have in fact been implemented. CHI is also responsible for monitoring the National Service Frameworks and, with the Audit Commission, has already commenced its first review (of the Cancer Framework). A third body, the National

¹³ We note in particular a recent document '*NHS performance indicators: A consultation*'. Department of Health, May 2001. www.doh.gov.uk/piconsultation

¹⁴ See Annex A Chapter 19 and Annex B (Sections 7 and 8) for the disagreements about the quality of HES data between clinicians in Bristol and the Inquiry's experts on statistics

¹⁵ Rudd A, et al. 'The national sentinel audit of stroke; a tool for raising standards of care'. '*J Roy College Physicians*'. London: 1999; **33**: 460–5. Other examples of national audits include those led by the Royal College of Surgeons of England on liver transplantation and on sino-nasal surgery

Specialist Commissioning Group, commissions and, intermittently, conducts national audits of those services it funds, one example being the UK national audit of intrathoracic transplantation. All of this is important work, undertaken with the intention of developing and improving clinical care. All of it is work which has implications for trusts. It is trusts, at the sharp end of the delivery of healthcare, which must deal with the various apparently unconnected and uncoordinated collections of data and respond to whatever analysis or report emerges subsequently. Looked at from the perspective of the patient, the various collections of information, whether national clinical indicators, national audits or reviews into particular standards, appear to be fragmented, with no proper co-ordination, with variable feedback to trusts and healthcare professionals, let alone to patients themselves.

- 24** One area in which there remains a serious gap is the absence of a mechanism, outside trusts or individual clinical teams, for taking a view of the whole range of clinical performance, drawing on clinical indicators, the results of national audits, and on other relevant data. We would describe this process as surveillance. Such a mechanism of surveillance would contemplate a body or organisation with the responsibility and the expertise actively to analyse data and other evidence, to spot trends over time and to identify patterns of poor (and good) performance, either in a particular hospital, or in a particular specialty across a number of hospitals. Such patterns would not necessarily be evident to those who provide a service, or, though evident, they may be ignored or overlooked for whatever reason. The DoH acknowledged this gap in April 2001 when it stated: 'The NHS does not have a systematic way of monitoring the occurrence of poor clinical outcomes of care unless they are manifest as serious events.'¹⁶ The purpose of such surveillance must be: to identify those whose performance lies outside the ordinary pattern of overall performance; to draw attention to this; to see that questions are asked; to ensure that the reasons for the performance are identified and understood; and to take action if it is needed. Until such a form of surveillance exists, there remains the possibility that patterns of poor performance will continue to go unaddressed or unrecognised. We also have in mind that such surveillance could identify those whose performance is consistently good. Such information could help to prompt improvements elsewhere. Thus, although much important progress is under way, lack of clarity, lack of co-ordination, the continuing possibility that important matters are ultimately not dealt with by any organisation, since each thinks the other is doing it, or because no one has the responsibility to act, all mean that problems remain to be solved.
- 25** The recent progress to which we have referred in developing standards of care, whatever its drawbacks, begins to point to the way forward which the NHS needs to follow if it is to take standards of care seriously so that patients consistently receive an appropriate quality of care. But they are only a beginning: the magnitude of the task should not be underestimated. It will need to be properly resourced. The development of standards and the production of good guidance takes time and expertise. But without them, there will be no way to evaluate and improve the quality of care. We set

¹⁶ 'Building a safer NHS for Patients; implementing *An organisation with a memory*'; para 52. Department of Health, April 2001. www.doh.gov.uk

out now a number of steps that we regard as essential to future thinking about standards of care, and to future arrangements for monitoring their implementation.

Setting standards for clinical care

- 26** We have already argued that the emergence of a variety of standards of clinical care from a variety of organisations, while it shows a willingness to become involved, may produce more confusion than clarity. One of the themes of Bristol was that, while a large number of organisations were involved in one way or another in paediatric cardiac surgery, each thought the other was looking after the matter of standards (and, to a degree, performance in relation to those standards), such that the concern for quality fell through the cracks between the various organisations.¹⁷ That lesson from Bristol leaves us in no doubt that there must be some body or organisation which takes overarching responsibility for the setting of standards. This does not mean that this body itself should necessarily draft the standards, only that it is there to see that they are developed, agreed and kept up to date.
- 27** The organisation best suited to do this is NICE. It already has authority from the Secretary of State to develop clinical guidelines which can form the basis of, and embrace, standards. If required, it would have to be given any necessary additional statutory authority to develop and manage a programme of setting standards, along with the necessary additional resources. In turn, NICE must engage and make full use of the expertise of relevant organisations such as the Royal Colleges and the specialist professional associations. It must draw on the expertise of senior management in the NHS. It must also fully engage the public, patients and carers, as indeed it is seeking to do. The principle would be that of the hub and spokes. The hub would be NICE. It would have overall responsibility and be accountable. The spokes would be the contributing elements: the Royal Colleges, the specialist professional associations, the public and the NHS. In this way, standards would be co-ordinated and managed across the whole of healthcare. It would spell the end to the cottage industry of various bodies developing standards for the NHS and issuing them independently. There will be one authoritative organisation, NICE, under whose aegis all standards for the care provided by the NHS would be issued. All such standards should be made public.

Patient-centred standards

- 28** It follows from all that we have said about the need for care to be organised around the needs and interests of the patient, that the standards must be built around patients and their conditions. While this appears obvious, it has two significant implications. It means first that, ordinarily, standards will not be drawn up by, and solely addressed

¹⁷ See Annex A Chapters 4 and 20–31

to, one group of professionals. Patients, particularly those in hospital, are seen by, and need the care of, professionals in different disciplines, often working in teams. Patients are also seen within NHS facilities, and the quality of those facilities and the way in which care is organised, as we have learned, affect the standards of care. Patients also need timely access to care. Thus the standards must address, reflect and incorporate the roles and responsibilities of those in the team who from time to time will care for the patient and the physical facilities in which care is provided. They must include guidance as to how promptly patients should get access to care. They must also address such matters as the way in which care for people with a given illness or condition is organised as between primary, community and hospital care. This conclusion adds further strength to the view that the setting of standards must be the responsibility of an organisation, NICE, which can co-ordinate the activities of the different professional bodies involved and ensure that the patient's perspective and the patient's journey are taken into account. The second implication is that patients and the public must themselves be involved in the setting of standards, so that their interests and concerns are fully taken into account.

The authority of standards of clinical care

- 29** What authority should the standards have and what should follow if they are not observed? We have said that NICE must have the legal authority to take the lead in developing and issuing standards. But that does not address the matter of what authority the standards themselves may have. Should some standards be obligatory? Care is needed here. To describe standards as obligatory means for us that they must be followed and that, if they are not, some action will follow. We accept that some standards should be obligatory. We also accept that other standards will serve as aspirations to be achieved over time. When we use the term obligatory we do not mean that failure to observe the standards would bring legal sanction. This would create a nightmare situation in which legalistic arguments would intrude into the care of patients. Further, in the case of standards addressed to healthcare professionals, it would deny the professionals the proper exercise of discretion to tailor care to the needs of the individual patient. It would bring an undesirable element of rigidity, where flexibility and responsiveness to the requirements of individual patients are essential.
- 30** Thus, in the case of the healthcare professional, where standards are not followed we look to the professional's contract. We see the obligation to observe the standards which are issued by NICE as being necessarily incorporated into the contract of employment between a healthcare professional and his employer. Failure to comply with the standards, without acceptable justification,¹⁸ would then entitle the employer to take whatever action was deemed appropriate. Initially it could involve retraining. It need not, indeed it should not, result in some automatic response of suspension or

¹⁸ Guidelines and standards must cover the majority of patients, but we accept that they have to be applied flexibly. We agree with the view of the Royal College of Physicians that there will be times when it is right for clinicians to deviate from a guideline as long as there is a justification for the change in plan, and it is recorded in the patient's notes. See Seminar 6. Royal College of Physicians. Position Paper

disciplinary action save where warranted.¹⁹ To the extent that the standards constitute good practice, professionals who observe them can rebut any allegation of poor quality of care. Professionals who do not observe them would be required to justify their conduct.

Generic standards for healthcare organisations

- 31** We note that in Scotland the standards set by the Clinical Standards Board include what are described as generic standards, that is, standards which are addressed to the hospital as a whole. These are distinct from standards which focus on the care and treatment of patients with a particular illness or condition. We have already observed that, in relation to Bristol, the standard of care was significantly influenced by factors which were not specific to the healthcare professionals, were generic to the hospital as a whole. For example, the state of the buildings and of equipment, the quality of the leadership, and the Trust's policies and procedures all had an impact on the adequacy of care for children with congenital heart disease. It was the healthcare organisation, as much as (or more than) the healthcare professionals, which caused the problems. This leads us to the view that there needs to be increasing rigour in preventing trusts from continuing to offer a clinical service (or services) when the service falls below the agreed standards and is consistently less than adequate. Professor Mike Richards, the Government's National Cancer Director, addressed this very point when launching the *'Manual of Cancer Services'* in 2001. He said: 'The public want to know that the service they are getting is a good one. If a hospital is way off the standard we want, should we be having patients dealt with by that sort of service? The answer must be no ...'²⁰ We believe this is fundamentally the right approach. We would add that, in practice, should matters so deteriorate and not be capable of rapid improvement, this would mean the suspension or closure of services, and the re-provision of the service in another hospital. Clearly such drastic action and all the consequent upheaval it would produce would be very much the last straw. In particular, it must not mean that a poor service is starved of resources so that it gradually 'withers on the vine' and patients suffer ever diminishing standards. Support, not sanctions, is the preferred approach. We explain, later on, the wider system which we believe should be put in place to give effect to this approach.
- 32** We have made it clear earlier (Chapter 25 – The Competence of Healthcare Professionals) that the process of validating and revalidating healthcare professionals as being competent to do their job is an important component of ensuring the safety and quality of healthcare. In the future all healthcare professionals will be expected to participate in such a process. In our view, it is equally important that trusts, including

¹⁹ We found the approach adopted in the DoH's publication *'Supporting Doctors, Protecting Patients'* to the balance between support and discipline too heavily weighted in favour of the latter, particularly with regard to too-ready recourse to suspension

²⁰ Charter, D. 'Red Tape row over cancer treatment'. *The Times*, 19 Jan 2001

primary care trusts, also participate in a formal process of validation and revalidation, a process which is of a different order from, but in parallel with, that which healthcare professionals will undergo. We choose the term 'validation' not only to mirror the process recommended for healthcare professionals but also to indicate that while akin to licensing it contemplates more. Licensing tends to be thought of as a 'one-off' event, whereas to us validation is a process. What makes validation akin to licensing is the element of permission to continue.

- 33** The analogy of the airline industry is instructive. It provides a service of potentially high risk. All elements of the industry are subject to standards for safety and quality which are monitored. While the competence of individual airline employees is regularly checked and revalidated, and the airworthiness of aeroplanes is frequently checked, the airline company itself must also seek certification from the regulatory body to entitle it to operate an air service. Thus the individuals who operate the service, the equipment they use, and the organisation which provides the service are all subject to a form of external regulation.

A system for validating healthcare organisations

- 34** We see the need for a shift from the current notion of inspection of healthcare organisations in England towards one of validation. Inspection is a single event. It implies a 'checking' mentality, and carries negative and punitive overtones. Validation, on the other hand, implies a constructive approach and a continuous process. We see it as a process with a clear aim: to help in the improvement of the quality of healthcare. It would include, but not be confined to, external assessment. The organisation itself would evaluate its own performance in the light of established standards, and be subject to external validation checks and visits. In what follows we set out how a system of validation of trusts would work.
- 35** The first stage in the process of validation is the setting of generic standards which will form an objective basis for assessment, and which all trusts must meet in order to be validated and thereby be entitled to provide NHS services. These standards will focus on matters such as the patient's experience and whether the trust is responsive to patients' needs. They will also address the trust's systems for ensuring that care is safe and of good quality (corporate management, clinical governance, risk management, clinical audit, the management and support of staff, and the management of resources). The basis for many of these standards in fact already exists, in one form or another, whether as legal requirements imposed on the trust, or in the form of guidance from the DoH and other bodies. Once translated into standards, we believe they should be obligatory. By this we mean that, unless the standards are met, the trust would not have the necessary validation. Periodically, each healthcare organisation in the country would receive a visit from external assessors to ensure that the standards were being complied with. (Sometimes, we believe, visits should be unannounced.) Thus, for example, the current routine visits by CHI would no longer be 'inspections' but would become visits to validate a trust as suitable to offer NHS services. The

system should be flexible. It would be a matter for CHI to determine how frequently it should visit a trust.

- 36** Compliance with the standards laid down on systems, facilities and staff, would mean that the trust would be granted validation and thus be entitled to offer NHS services. Ways might be explored to recognise circumstances where a trust exceeded the obligatory standards, or offered particularly good or exemplary service. The standards themselves, and the results of external assessment, will be made public and be easily accessible and visible throughout the trust and in the local community.
- 37** The validating body should adopt an approach which is flexible and seeks to support organisations. Its aim must be to promote continued improvements in the quality of care in the NHS. That said, however, it should have powers to act if standards fall such as to threaten the quality of care or the safety of patients. If any area of practice were to fall below the required standard, the organisation would be put on ‘validation watch’. An action plan and a timescale would be agreed for any problems to be remedied. If certain key areas of practice failed to improve, or fell significantly below the required standard, such as seriously to threaten the quality of care received by patients, it would remain open to the validating body to withhold, suspend, or even withdraw, validation.
- 38** We believe that the switch from a system of inspection to one of validation would further the overall direction of current policy. It would be achievable within the existing structure of CHI, but would take a change in emphasis and approach which we believe would be welcomed within the NHS and by the public.

Rationalising the ‘inspection industry’: a single body to validate healthcare organisations

- 39** Currently there is no effective co-ordination of the various external inspections and assessments that trusts are required undergo, or of the generic standards they are required to follow. Apart from putting an unnecessary administrative burden on trusts in dealing with these activities, there is inconsistency and an inevitable fragmentation of the process, with the consequent danger that matters are overlooked. Thus instead of the National Health Service Litigation Authority (NHSLA), the Royal Colleges, the Health and Safety Executive, the Audit Commission and numerous other bodies issuing standards independently and considering separate aspects of the trust’s management, in the future these various standards and forms of external inspection must be integrated into a single validation process. There must be a single, coherent, co-ordinated set of standards with which NHS organisations have to comply, overseen by a single validation process and a single validating body. By a single validating body, we do not mean that one body should itself set all the standards and or undertake all aspects of the process.²¹ What we mean is that one body should be in overall charge, ensuring that the generic standards exist, that they are consistent and coherent, and

²¹ We see scope for collaboration between a programme of validation led by CHI and the many voluntary accreditation programmes currently available and used by many trusts

capable of implementation within an organisational setting. Further, that a single body should take a view as to how well the trust meets all the generic standards. CHI, suitably structured so as to give it the necessary authority and independence, is well placed to adopt this role.

- 40** The place and role of the Audit Commission is a specific example of the case for rationalisation. In terms of its role of ensuring the proper stewardship of public finances, which is carried out through the Commission's District Audit Service, we see no overlap with other bodies. Indeed this activity must continue. But in terms of its other role of helping those responsible for the NHS to achieve economy, efficiency and effectiveness, there is now a degree of overlap with the role and functions of CHI. We recognise that during the 1990s the Audit Commission helped to fill a vacuum in addressing issues to do with clinical effectiveness and comparative performance. Our concern, however, is that notwithstanding the high quality of their work they continue to provide reports on such matters, even though other bodies, in particular NICE and CHI, are now established. In proposing a single validating body and the rationalisation of the inspection industry, therefore, we see the need for reappraising the future of this second role of the Audit Commission.

Validation in the private sector

- 41** These generic standards must apply wherever patients receive healthcare services paid for by the NHS. This would include all trusts within the NHS and those organisations in the voluntary or the private sector which treat patients paid for by the NHS. It is plainly not acceptable for a patient to receive care paid for by the NHS in a private hospital if the standards of care are below those which apply to NHS hospitals. Thus there must be a system whereby, if private hospitals are to provide care to NHS patients, they must first achieve validation against the obligatory standards established within the NHS. Currently, the Government's intention is that private hospitals which provide acute care will be inspected, not by CHI, but by a new body, the National Care Standards Commission.²² There must be a serious question as to whether it is in patients' interests for there to be two separate systems of inspection, applying different standards, one set for the private sector and another for the public sector. Patients are entitled to expect that, wherever they are treated as an NHS patient, the standards stipulated by the NHS will apply. Thus we would urge that, with regard to patients treated in the private sector and funded by the NHS, the approach adopted by the National Care Standards Commission replicates that which applies to patients treated within the NHS.

Validation of services or facilities within a trust

- 42** We also see considerable benefit to patients in taking a further step, by extending the process of validation of trusts to cover discrete, identifiable services within a trust. This

²² The National Care Standards Commission, established under the Care Standards Act 2000 and due to be fully operational in 2002, is a non-departmental public body with a remit to regulate residential care homes and private and voluntary healthcare in England. It will set national minimum standards, inspect, investigate complaints against registered services, and report to the Secretary of State on the range and quality of regulated services

will involve setting or developing existing standards for those services. In some circumstances it would be appropriate for the standards to focus on a particular set of clinical conditions, for example, services for people with cancer, or services for children with congenital heart disease. In other circumstances, the standards could focus on a particular facility within the hospital, such as the accident and emergency service, or the day surgery service. Thus, a local hospital or a primary care trust might be granted validation to provide day surgery, but not major acute surgery. It might be granted validation to run a minor injuries unit but not a major accident and emergency department. A large acute hospital might be granted validation to provide services designated as specialist services. One crucial consequence of this approach is that a hospital would not be able to offer a new service unless it met the standards necessary for validation. It would not be acceptable for a trust to aim to develop the service so as to be able to meet the standards at some point in the future. Moreover, by offering a service to the public which was not validated, chief executives would be in breach of their duty to ensure the quality of the services offered.

- 43** This process of validation would have very significant consequences for patients and their carers and families. To take the example of children's acute hospital services, parents in the future would know that a given hospital had received national validation to provide inpatient facilities for children, and thus that the hospital met the national standards on staff trained in paediatric care; suitable facilities for children; and child- and family-centred care. Thus they would know that the hospital had been validated to undertake paediatric surgery. They would know that the hospital had been validated to provide paediatric intensive care. Moreover, since the standards would be a matter of public knowledge, the public would know the standards to be expected. The public nature of the standards and the link to validation, which would be known to all those who work in and use the service, will act as a powerful and continuing incentive to maintain the standards. Validation of healthcare organisations would also be significant for the healthcare professionals. It would constitute an independent and public affirmation of the service of which they were a part.
- 44** We recognise that, in this as in any form of regulation, there will be costs as well as benefits. The costs of extending the process of validation to specific services are difficult to determine in the abstract. They will depend on the way the system is implemented. We believe that in time the benefits, in terms of the quality of care for patients, of there being nationally stipulated standards and a system of validation, will outweigh any direct costs. And there could be savings from better co-ordination and a rationalisation of the various inspections which trusts currently undergo. We recognise, however, that there is a case for proceeding carefully. We do not therefore suggest that a system of validating particular services be introduced all at once across the country. This would be to invite the sort of chaos which has dogged numerous other initiatives. Rather we urge that approaches to the validation of specific services be developed, piloted and evaluated, prior to their implementation on a national scale. Children's acute hospital services in general, and paediatric cardiac surgery in particular, should, we believe, be included in any pilot. Should the pilot be successful, the category of discrete service which should be a priority for this form of validation

are those specialist services which are currently funded by, or meet the criteria for funding, set by the National Specialist Commissioning Advisory Group (NSCAG), the successor body to the Supra Regional Services Advisory Group (SRSAG).

Monitoring of performance

- 45** Monitoring performance is a crucially important activity which warrants careful analysis. Fundamentally, its role must be to help to improve the quality of care, not to point the finger or to blame. It is important for two reasons. First, it enables clinical teams, through the process of clinical audit, to review and improve the quality of the care they provide to patients. Both local audit and national audit have a role in achieving this. Second, by the publication of information on performance, the public are included and informed about how well their NHS is performing and how well standards are being met. Thus information on performance and its publication are crucial elements in the accountability of the NHS to the public. Monitoring performance entails a number of phases which we consider here in turn.

Information and clinical audit

- 46** Here we refer to the need to be able to collect information about performance, to assess it, to change and improve it where necessary, and, just as importantly, to revisit the standards with a view to changing or developing them. Information is the basic building block of any system of standards and quality. In the past, there have been great difficulties in collecting information, based not only on the technical problems associated with establishing proper systems for doing so, but also on differing approaches as to what should be recorded, and then how it should be classified and grouped for analysis.
- 47** It is a truism that central to any process of reporting and recording information is agreement on what is being reported. Regrettably, lack of agreement, as to how, for example, to categorise a particular procedure, or what period of time should be used to measure the outcome of a procedure, has bedevilled initiatives in the fields of audit and performance assessment. We heard from Professor de Leval, Professor of Cardiothoracic Surgery, Great Ormond Street Hospital, in the course of a Phase Two Seminar²³ that, even in the relatively small and cohesive world of paediatric cardiac surgery, three ways of categorising procedures exist at an international level, and it is extremely difficult for those involved to agree on which one to adopt. Indeed, Professor de Leval went so far as to urge that, in the absence of agreement, a solution should be imposed. Otherwise, he argued, progress would be impossible and the loser would be the patient. We agree that standardised methods of reporting and classification of information are crucial, both in paediatric cardiac surgery, and

generally. We are persuaded that, in the case of paediatric cardiac surgery, with the active engagement of the Royal Colleges, the DoH and other interested bodies, agreement can be reached. But, if it cannot, the issue is sufficiently important to warrant the imposition of standardised categories by the NHS Information Authority.

- 48** We have seen that there have been sections of the medical profession in the past who have been suspicious of data collection and audit. It is important to understand the basis for this suspicion. Fundamentally, it arises from an anxiety that data would be either inaccurate, or that, when analysed, complexities such as case mix will not be adequately explained or understood. There are concerns that data will be interpreted and used in an uncritical way, to support criticism or invidious comparison. We note and welcome the point made to the Inquiry by the Royal College of Physicians on this matter: ‘physicians are not frightened or worried about having data to judge ... their performance, as long as those data are seen to be an accurate and fair representation of best care. Most in fact welcome the opportunity to have reliable data to monitor and improve the service they offer. The chance to do this jointly with management could be a huge opportunity for the NHS to make major improvements that would benefit patients.’²⁴
- 49** We believe it important for the future that these anxieties and aspirations are acknowledged. In practical terms this should not mean that information about performance should be hidden. What it does mean is that serious attention must be paid to the development of robust methodologies which can be applied to data so as to give as fair and accurate a picture as is possible. Variables such as case mix and where possible, in the case of surgery, operative risk must be allowed for, so that, wherever feasible, it is possible to compare like with like. It also means that data must be properly analysed with appropriate expertise. We referred in an earlier chapter (Chapter 25 – The Competence of Healthcare Professionals) to the need for a higher priority to be given to educating healthcare professionals about clinical audit and the use and interpretation of data. In addition to this, we consider that clinical teams need to be able to have access to support and guidance in the process of analysis, and that such support and guidance should be available either in, or through, a central clinical audit office which should exist within each trust.
- 50** Clearly, for progress to be made in this vital area, some rapprochement is essential between the various healthcare professionals: the managers, the doctors, the nurses and others. A crucial first step is to make the process easier for the clinicians. They complain with justification that they do not have the necessary time or resources to collect and classify information properly, and that they work with multiple and incompatible clinical IT systems. At the same time, because they are not involved, clinicians are sceptical of the value of information collected and coded by non-clinicians, principally the information which is collected in hospitals’ Patient Administration Systems, and which, in turn forms the basis of the national Hospital Episode Statistics (HES) and numerous national clinical indicators.

²⁴ Seminar 6. Royal College of Physicians. Position Paper

- 51** We have seen in Bristol in all too graphic detail, in what was in reality a small PCS service, how the surgeons, cardiologists and anaesthetists compiled separate sets of data, for similar purposes but without reference to each other. Looking back this now seems tragic. We have seen how the surgeons in Bristol and elsewhere had confidence in general in their 'own' data recorded in their personal logs or through their departmental systems, but distrusted the data in hospital administrative systems, and in the UK Cardiac Surgical Register. And we have seen that the tendency was to criticise or explain away the statistics, rather than to ask questions or do something about what the data may imply. We have also seen that data existed at a national level, in the form of the HES database. We have discovered that (at least from 1991), when cross-matched with other sources of data, it is reliable. But, we have discovered that at the time covered by our Terms of Reference the use of HES as a means of learning about mortality rates, for example, was not properly recognised.
- 52** For the future, we are persuaded of the conclusion reached by our Experts: '... the current "dual" data collection in separate administrative and clinical systems is wasteful and anachronistic.' We also agree with their suggestion as to the way forward: 'A vital aim should be two-way linkage between administrative and clinical systems.'²⁵ We do not advocate abandonment of current systems, far from it. What is needed is much greater attention to improving and streamlining the processes of data collection, coding and validation and to ensuring that respective systems can communicate with each other. The aim must be to collect data as a by-product of clinical practice and to reduce the multiplicity of methods and systems for collecting data. Collecting similar data on different occasions, in slightly different ways, for different purposes, is the discredited way of the past. The contribution that audit can make to improving the quality of care is simply so important that it must be given the priority it needs. It must be underpinned by systematic and reliable systems for collecting and analysing information which have the confidence of healthcare professionals, of those who manage the healthcare system, and the public. It must also be properly resourced, both in terms of funding and of dedicated support staff.
- 53** Second, as part of the culture of openness which we referred to earlier, and for the benefit of patient and professional alike, information and the results of audit must be shared within the hospital. The corollary is, of course, that, as we have said, healthcare professionals must feel that it is 'safe' to share such information. They must be able to work in an environment of mutual understanding and support, in which the overriding purpose is to put patients first. Thus professionals must be entitled to add explanations and caveats to data, so as better to inform those who might study the results made available. Each trust should have, as we have said earlier, a central clinical audit office, which, apart from supporting the process of audit within the trust by providing advice and expertise, can ensure that audit is undertaken and that the results are brought together for the trust as a whole. We note that this is already taking place in most trusts as part of their arrangements for clinical governance. We would add one final point. Healthcare professionals are now coming to see audit as central

to their role of caring for patients. We believe that in a patient-centred healthcare service, this recognition should be reinforced by making participation in clinical audit an explicit element in a healthcare professional's contract with the employer.

54 At the national level, we are convinced that it would be of benefit to the quality of healthcare if the monitoring of clinical performance were brought together and co-ordinated by one body. This would include the co-ordination of national audits and the validation and presentation to the public of information about performance in relation to national standards. It would also include filling the gap which we referred to earlier, the absence currently of a mechanism for surveillance, to review trends in performance over time and between trusts. We propose that all of these activities should be brought together under an independent Office for Monitoring Healthcare Performance which should be part of CHI. Its role could include:

- taking the lead in validating and publishing data, collected from within the NHS, on performance in relation to national clinical indicators and nationally agreed standards (this is already undertaken by CHI and the Audit Commission);
- guiding and funding the audit activities of the Royal Colleges and of the various medical organisations (such as, for example, the Society of Cardiothoracic Surgeons), so as to ensure that such activities are part of a wider strategy for auditing clinical performance;
- incorporating the audit functions currently performed by NICE (the funding of national audits by Royal Colleges and the Confidential Enquiries), and the multi-centre specialty audits necessary to monitor the implementation of standards;
- providing guidance on good practice in the analysis of data on performance, at both national and local levels, in particular, on the application of statistical techniques and methods; and
- providing a mechanism for the surveillance of data about performance (clinical indicators, the results of national audits and other relevant information) with a view to identifying patterns of poor (and good) performance.

The Office for Monitoring Healthcare Performance should be part of a reconstituted CHI, which itself must be fully independent of government and the DoH. It would play a key role in supplying rigorous and robust information about the performance of each trust. This in turn could be passed back to individual trusts and would be used in the process of validating trusts.

Informing the public and the professional

55 Information arising from audit and review must be disseminated so that those in a position to do so may take appropriate action. This clearly includes the relevant healthcare professionals and the trust chief executive. Does this mean that the

information should also be made public? We recall that our central concern here, as elsewhere, is with the creation of a culture within the hospital and beyond which is patient-centred. If this is the aim, then the question of publication admits of only one answer. The public, who are patients in another guise, should have access to the analysed data. We believe that the data which are put into the public domain should relate not only to the performance of the trust as a whole, but should also describe the performance at the level of a specialty and of the consultant unit.²⁶ Performance at the level of a specialty or a department is important. It is an intermediate point between the trust as a whole and a consultant unit. Further, it offers an opportunity to address the performance of a service from the *patient's perspective*, and should include the contribution to care not only of doctors but also a cross-section of healthcare professionals.

- 56** It will be objected that audit data are complex and hard to understand. The public will be misled and draw unwarranted conclusions. Healthcare professionals will be unfairly criticised. All of these are, of course, real risks. But they are risks that must be faced and resolved. The alternative, of continued secrecy and anonymity, is no longer a real option. A new compact between the community and its hospitals must be forged in which the public must accept that the price of information is a considered and responsible reaction to it.
- 57** This new compact is much more likely to be forged when the next stage in improving quality through information is taken. Systems must be put in place within the hospital to take account of and, crucially, to respond to what the data describe. In a flexible organisation, all those involved in the hospital, at whatever level, should have a part to play in determining the appropriate responses. But also patients and the general public must be involved. (We will consider later how best this can be achieved.) By involving the public, not only does the hospital show that it is listening, but the public gains a degree of ownership and understanding of what can and should be done.
- 58** We said earlier that a concern for safety must be embedded in the organisation. We repeat this in relation to quality. It must be seen as the concern of all, not merely the responsibility of the chief executive. We are seeking in our approach to create a continuing and continuous interaction between on the one hand safety, the standards of clinical care and the standards of professional competence, and, on the other, the validation of hospitals to provide healthcare services. And, by involving patients and the public, a network of support is created as well as a collective will to sustain and improve the quality of care.

Chapter 28: Public Involvement Through Empowerment

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

Messages from Bristol

- The absence of any system for consulting parents and learning from them denied the hospital a valuable source of information about the care and service it provided.
- The absence of mechanisms for involving parents and families effectively in the care of their children led many to feel excluded.
- The absence of a clearly identified person and a place to turn to, led to a sense of bewilderment in many parents.

The issue

- 1 For a healthcare service to be truly patient-centred it must be infused with the views and values of the public (as patients past, present or future). The public must be involved. To be involved, the public must be empowered in the sense in which the word is used in the evidence of the NHS Primary Care Group Alliance. It suggested that public empowerment means: ‘a public that is sufficiently informed as to be able to formulate meaningful views about quality and direction in the planning and delivery of health care; which views are listened to and acted on by commissioners and providers of NHS health care at the core of their decision making.’¹ We gratefully adopt this view.
- 2 In Chapter 23 (Respect and Honesty), we considered the entitlement of individual patients to more and better information and a greater degree of involvement in their care and treatment. In this chapter, we take a wider view. Here we consider how to empower and involve patients and carers in improving the quality of healthcare services generally. We explore how to involve the public as citizens in decision-making about the NHS, their NHS. The problem, while simple to state remains intractable: it concerns how, in a modern democracy, a public service such as the NHS can have embedded within it not only the principle that it exists to serve the public, but also mechanisms to ensure that this aspiration is translated into reality.

Past experience

- 3 There has been no shortage of efforts and initiatives aimed at involving patients and the public in the NHS. But we detected a widely felt unease that too much of this effort has been of token value and has not succeeded in empowering patients. Indeed, *'The NHS Plan'* states clearly: 'Patients are the most important people in the health service. It doesn't always appear that way. Too many patients feel talked at, rather than listened to. This has to change.'²
- 4 Over the years, institutions, such as community health councils, have been created; 'lay'³ people have been taken onto regulatory bodies (e.g. the General Medical Council and the United Kingdom Central Council) and onto hospital management committees and then trust boards as non-executive directors; and procedures have been adopted to consult the public, in such cases as the proposed closure of a hospital.
- 5 The result, however, has not been a sense of growing empowerment, such that the public, as patients or as taxpayers, after all these years of supposed involvement, feel truly in partnership with the professionals who run and provide our healthcare service. Indeed, the evidence from Bristol is the opposite: a sense, among many parents, of disempowerment, of inability to get the healthcare service to address their needs, and of bewilderment about where or to whom they could turn for help.
- 6 The reasons for this state of affairs are complex. To the extent that they can be identified, they allow us to suggest alternative approaches. A principal reason must be the lack of real power enjoyed by the bodies set up within the NHS to give the public their voice. Without power, such bodies swiftly become 'talking shops', attractive to those who like to talk but ineffective in terms of translating talk into action. The involvement of the public and patients – if it is always heavily outweighed by that of professionals on, for example, regulatory bodies, or if the role which the public are expected to play is not clear, for example on trust boards – gives the appearance of public involvement without any real substance. Public 'consultation', whereby the public are presented with a 'fait accompli', or their views are ignored, leads to disengagement and cynicism. The net effect is frustration, loss of trust and an increasing lack of interest amongst the public in the bodies and structures that are supposed to promote their interest.
- 7 At the same time, healthcare professionals in the NHS have increasingly tended to regard public involvement as at best a token, not to be taken too seriously, and at worst troublesome, challenging well-laid plans, and raising what are perceived to be awkward questions. The barriers to effective public involvement were mentioned by many participants at a Seminar on this topic (see Box A) and were summed up well by the NHS Primary Care Group Alliance in its paper to the Inquiry. We agree with the

² *'The NHS Plan'*. London: Department of Health, 2000. Para 10.1

³ In this chapter we do not use the term 'lay' to describe members of the public, since the term itself sets up a barrier between the 'professional' and the so-called 'lay' person. This, in turn, serves to exclude members of the public from making an effective contribution

Alliance's view on the need for a shift in culture towards the involvement of patients and the public. It wrote: 'Being sincere about involving patients and the public in making decisions about their own care or about local health services involves a shift of power. Until individuals working in the NHS are ready for that, any user or public involvement in decision making will be a token event.'⁴ We believe that the time is overdue for that 'shift of power'.

Box A

Barriers to effective involvement of patients and the public in the NHS include:

From within the NHS –

- a negative culture towards empowering the public that pervades the NHS;
- a lack of awareness of the benefits of an empowered public;
- a lack of clarity about how to get public representation;
- the difficulties in reaching a cross-section of the public.

From amongst the public –

- a feeling that public engagement exercises are just exercises in public relations;
- a sense that there is no commitment to act on any views obtained from them;
- practical difficulties, such as lack of time, skills or confidence;
- a sense of being a lone voice amongst professional experts.

Source: Adapted from the NHS Primary Care Group Alliance's Paper and other Seminar 7 papers

The changing direction of policy

- 8 Since the mid-1990s, successive governments have signalled a shift in policy towards a greater emphasis on the involvement of the public and patients in healthcare. Recent initiatives have placed this involvement in the NHS of the future at centre stage.⁵ This represents a major development. We agree strongly with *'The NHS Plan'* when it states: 'NHS care has to be shaped around the convenience and concerns of patients ... patients must have more say in their own treatment and more influence over the way the NHS works.'⁶ This matters not only because, as citizens who 'own' the NHS, we have a moral and political right to be involved, but also because greater involvement will bring greater feedback from the public and this in turn will help to improve the quality of healthcare. We would add, however, that the measures adopted must be fit to do the job. Public confidence in the NHS cannot afford another period of rhetorical flourish not matched by real action.

⁴ Seminar 7. The NHS Primary Care Group Alliance. Position Paper

⁵ See *'Patient and public involvement in the new NHS'*. London: Department of Health, 1999; and *'The NHS Plan'*. London: Department of Health, 2000

⁶ *'The NHS Plan'*. London: Department of Health, 2000. Para 10.1

What is needed

- 9 If the NHS is properly to recognise and reflect the public interest, we have to ask what is needed, both at the level of principle and of practice, in the day-to-day affairs of such a large and complex organisation. Historically, the views and wishes of the public have been articulated indirectly, through politicians and healthcare professionals. The Secretary of State, as an elected politician, answers to Parliament and the people for all aspects of policy within the NHS. Healthcare professionals on the ground have daily contact with patients and a strong sense of what patients want. Yet society is changing and involvement by proxy is no longer seen to be enough. The public are no longer prepared to be passive, trusting and grateful recipients of what is made available. They are no longer prepared to hope that their views will be fully reflected by the professionals. That is not a criticism of professionals; it is just a reflection of the way the world has changed. Increasingly, with public services as with commercial services, the public are ready to challenge, prepared to question, and have come to expect that services will be responsive to their needs.
- 10 Thus the starting point for a consideration of how the public's interests may effectively be reflected and safeguarded, is that the public itself, in some shape or form, must be directly involved. The public must be included. In the world of professional services, this is still a problematic proposition. The challenge is to find new ways of involving the public which will work and which are embedded in the fabric of the system. There must also be ways which take account of changes in society, whereby *representative* democracy appears to be less trusted than a democracy which is *participatory*: 'leave it to others' being supplemented or even supplanted by 'do it yourself'. Moreover, the public who must be engaged is not some, largely notional, 'general public', conceived as a homogeneous entity with common views and needs. Such an entity may be relevant when truly national health issues arise, affecting, for example, the identification of national priorities or the introduction of a highly specialised service. But there are other, disparate publics, divided or grouped according to such criteria as where they live, their age, their gender, their ethnic background or their particular healthcare needs. These many sections and groups also need to be involved.
- 11 Two questions warrant consideration. First, what are the most pressing matters on which these various publics should be heard: essentially, what is the agenda for public involvement? Secondly, how, for the future, can we ensure that the involvement of the public and patients is effective: essentially what principles should underlie and inform any decisions about the mechanisms for involvement?

What is the agenda for public involvement?

- 12 There are, perhaps, four principal areas in which the involvement of the public is most pressing, arising from a commitment to a patient-centred NHS. They are: the

development and planning of services; the operation and delivery of services; the competence of healthcare professionals; and the protection of vulnerable groups. In each case the public must be involved at all levels from the national to the local.

The planning and development of services

- 13** The aim of a patient-centred service is that it be designed and planned to address the needs of the particular sectors of the public it exists to serve. Thus strategic planning at national level, including the priorities set by government, must have input from the public. Equally, at local level, the particular needs of the communities served by the NHS must also be acknowledged through involvement of these communities. This means involvement in the initial development of options for change as well as consultation on those options. Too often in the past, when major changes in service are needed, local communities have been excluded from the process of developing ideas and options. As a result, consultation has often been perceived by the public as a gesture or a sham. There are genuine and difficult problems involved in the re-organisation of local services, and the only way to gain public acceptance is to let in the public much earlier in the process.

The operation and delivery of services

- 14** As regards public involvement in the *operation* of the NHS, two concerns are central: safety in the care of patients and high quality in the delivery of the service. What we contemplate here is effective involvement of the public, at national and local levels, both in setting and reviewing the standards to be met regarding the safety and quality of care, and in monitoring the observance of those standards. In the past, these have been seen as matters solely for healthcare professionals on which, given the technical nature of the issues, the 'lay' public were thought to have little to offer. The issues are not only technical. Indeed, if the quality of the care given to patients is to be taken seriously, there are some matters on which only patients are qualified to speak, for example, the extent to which any particular service accords with the needs of the patient. It was the NHS's current weakness in this regard, its unresponsiveness to the interests and needs of the public, which contributed towards the NHS being ranked below a number of European countries in the World Health Organisation's recent analysis of national healthcare services.⁷ The views of patients and the public are relevant not only to the standards to be observed by healthcare professionals; but also to the standards and performance of hospitals. We have already proposed, in Chapter 27, a system of validation of trusts. Clearly, as elsewhere, the public must be involved in this process.

Assuring the competence of healthcare professionals

- 15** We are concerned here with the network of measures designed to assure the competence of healthcare professionals. This is the other side of the coin of concern for safety and quality. The public are entitled to be involved at all levels and stages:

⁷ 'World Health Report 2000. Health Systems: Improving Performance'. The UK healthcare system was ranked number 19, compared on a range of factors with the healthcare systems of 191 countries worldwide. www.who.int

in both setting and agreeing the systems for assuring competence and in their operation.⁸ As regards individual healthcare professionals, assuring competence embraces initial registration, the continuing monitoring of performance through continuing professional development (CPD), appraisal and revalidation, and the application of disciplinary measures when necessary. Historically, the public has only been involved in the last of these. However, we see them all as an interrelated whole in which the involvement of the public is essential if a truly patient-centred service is to emerge.

- 16** In particular, we would expect the public to have a role in those bodies charged with setting standards for education and training and with controlling access to the professional register. Involvement of the public in these activities serves at least two valuable functions. First, the public can participate in the process of setting and reviewing the criteria for admission to the profession.⁹ After all, the professional is going to be caring for the public as patients. Secondly, public participation in this process serves as a warranty that the public's interests are being safeguarded and as a reminder that the profession exists for the public.

The protection of vulnerable groups

- 17** Bristol was about the treatment of infants and children. It has been the unhappy history of the NHS that the interests of children have not commanded the importance which they deserve. Indeed, such has been the neglect of these interests that we propose significant changes in Chapter 29 (Children) to the way in which children's healthcare is managed and delivered in the future. Children are a part of the public. Because of their youth and immaturity, however, they are largely excluded from having a say in what happens to them. The involvement of the public, therefore, in the case of children, so as to safeguard children's healthcare services, must largely be achieved through those who can speak on behalf of children. But this does not mean that children's views are to be ignored nor that they should not be sought. We agree with the Royal College of Nursing (RCN), when it wrote in one of its papers for Phase Two:

'Until recently children were rarely asked to comment upon the services they receive. Instead it was assumed that adults could represent children's views ... We believe more emphasis needs to be placed on the development of methodologies which could be used to gather children's views and perceptions of their care.'¹⁰

- 18** For this reason, in Chapter 29, we advocate for children a children-centred healthcare service. To achieve this, we propose measures aimed at ensuring that both children and their parents are involved in the planning, organisation and delivery of their care.

⁸ We note the initiatives of various Royal Colleges in involving the public in their activities: The Royal College of General Practitioners (RCGP) has had a patient liaison group since 1983, the Royal College of Surgeons of England (RCSE) since 1999. Equally proposals are under consideration for expansion of the representation of the public on the General Medical Council (GMC)

⁹ This would be in addition to involvement in the selection of those admitted to university to study to become healthcare professionals, which we referred to earlier

¹⁰ Seminar 7. The Royal College of Nursing. Position Paper

In this way, children's needs and interests, and those of their parents, will be properly taken into account. Of course, children are not the only vulnerable group in our society. The elderly and infirm, people with disabilities and those with learning disabilities are among other groups which must be included rather than excluded. The point we wish to stress is that the agenda for involving the public must take account of the needs and contribution of vulnerable and hitherto excluded groups.

- 19 We now turn to consider what are the proper mechanisms for empowering and involving the public.

Involvement at a national level in the formation of health policy

- 20 The recent and growing recognition that the public must have more opportunity to be involved in the NHS is beginning to take effect. There have been a number of initiatives to involve the public and patients at national level, some examples of which are shown in Box B.

Box B

Examples of recent initiatives to involve patients and the public in the formation of national policy on healthcare:

- *'The NHS Plan'*: groups representing patients and carers were involved in the process of developing the Plan and are represented on the 12 working groups charged with implementing the Plan.
- The Commission for Health Improvement (CHI), amongst its 'project boards', has one devoted to patients and the public. CHI inspection teams include 'citizen and lay' inspectors.
- The National Institute for Clinical Excellence (NICE) is seeking to ensure that arrangements are in place for the participation of patients and the public in all areas of its work.
- The NHS Research and Development Strategy is committed to involving the public as active participants in setting priorities and commissioning research.
- Since 1998 the Department of Health has undertaken a national annual survey of patients' views.

- 21 In terms of the quality of care, the first and most obvious method of ensuring that the public's interests are served is to involve the public adequately and appropriately in those bodies concerned with establishing and monitoring standards. This means that the involvement of the public must be embedded at every level in the structures of the National Institute for Clinical Excellence (NICE), the Commission for Health Improvement (CHI), and the soon to be established National Patient Safety Agency. The public must also be involved in the development of National Service Frameworks. What must be made clear is the crucial role played by involving the public. Not only does it ensure that the standards of care meet the needs and expectations of the public, it also serves to ensure that the public can trust in the system.

- 22 We note particularly the efforts of NICE to involve the public. A recent paper on the patient’s voice states:

‘In the past, patient representatives in guidelines working groups have sometimes been expected to provide little more than passive co-operation within a clinically dominated process. The Institute’s aims for patient participation in guideline development should be much bolder.’¹¹

We agree. We would add that while NICE perhaps understandably talks of being ‘bolder’, to us it is not a question of boldness, but of doing what is right. There must be, in short, an unstinting commitment on the part of organisations in the NHS to engage with the public and patients, to involve them, to listen, to maintain a dialogue and to be responsive to what they have to say.

Involvement in local health services

- 23 In one sense there is nothing particularly new in saying that the public should be involved in their local health service. This was acknowledged as long ago as 1974 when community health councils were first established, and there has long been a requirement on local health services to hold public consultation exercises on proposals to close a hospital. Thus the principle of involving the public in some form is well established. It is the practice that has come to be seen as poor.
- 24 A sense of frustration with the mechanisms for involvement at a local level contributed, in 2000, to a series of proposals from government to increase the extent of that involvement and to seek to make it more closely engaged with the delivery of healthcare services. A summary of the proposals is at Box C.

Box C

Summary of recent proposals to involve patients and the public in the formation of policy and the operation of the NHS at a local level:

- There should be a statutory duty on NHS trusts and health authorities to consult and involve the public concerning the planning of services, the development of proposals for change, and decisions about the operation of services.
- Each trust should have a Patients’ Forum, to provide direct input into how NHS services should be run.
- Each trust should have a representative of patients on its board.
- In each locality there should continue to be a body to represent patients’ views.
- Local authorities should have powers to scrutinise proposals for making significant changes to local health services.
- There should be a national body to represent patients’ views.
- Patients leaving hospital should be invited to give their views and each trust, in its annual report, should be required to publish a summary of the views expressed.

Sources: Department of Health. *The NHS Plan*, 2000 and The Health and Social Care Act, 2001

¹¹ *Patients’ voices: Achieving a patient and carer focus for the Institute’s work*. National Institute for Clinical Excellence, 2000. www.nice.org.uk

- 25 These proposals represent a significant agenda for change. They have not received universal support, not least as regards the proposed abolition of community health councils (CHCs) and their replacement by Patients' Forums and Patients' Councils. The fear is that the forums and councils will not have sufficient independence and distance from the trust and local health services to inspire confidence and challenge decisions. It is fair to say, however, that CHCs were open to criticism not because they lacked independence but because they lacked power. In a sense, they were a tolerated mechanism for venting public concern, because ultimately they could do nothing.
- 26 It is of crucial importance that the central goal is kept in sight: that of embedding the involvement of the public in the mainstream of a trust's activities. The involvement of the public must not be some side-show, off to one side. As the NHS White Paper '*A First Class Service*' stated, the involvement of patients and the public '... should not be a discrete, "add-on" task but part of the way all NHS organisations work.'¹² We agree. What is important now is not to allow the process of involving the public to become overtaken by debates about the precise mechanisms to be used: what groups there should be or how they should relate to each other. That is to lose sight of the central challenge which is how to engage and involve the public and patients so that the quality of care which the NHS and each trust deliver can continuously improve. That is the only agenda. Thus, rather than commenting in detail on current proposals, which may, of course, change, we think it more important to draw out certain general principles to guide decision-making in the future about the mechanisms or structures which are necessary. They are principles which in our view apply to the involvement of the public at both national and local levels.

Principles to inform future decision-making about how to involve the public and patients in the NHS

- 27 We should say that in drawing up these principles, we have been greatly assisted by the papers submitted for our seminars. Of particular assistance was the paper from the RCN.¹³

■ Patients and the public are entitled to be involved wherever decisions are taken about care in their NHS

The contribution which patients and the public can make to the organisation and to the delivery of healthcare should be sought and valued. The NHS was created as a service to serve the public. Thus the involvement of the public in its future direction is both proper and necessary. The perspectives of patients and of the public must be

¹² Department of Health. '*A First Class Service; Quality in the New NHS*'. London: The Stationery Office, 1998

¹³ Seminar 7. The Royal College of Nursing. Position Paper

heard and taken account of wherever decisions affecting healthcare are made, including by professional organisations such as the Royal Colleges.

■ **The involvement of patients and the public must be embedded in the structures of the NHS and permeate all aspects of healthcare in the NHS**

All aspects of strategy, policy-making, and the delivery of healthcare, can benefit from the involvement of patients and the public. Thus mechanisms are needed to include them in the formal structures of organisations. Arrangements must also be made to ensure that the advice and views of patients and the public are heard. Bodies such as Patients' Forums and Patients' Councils undoubtedly have a role, but they must not become devices for ghettoising the public and patients. Thus they are not a substitute for the involvement of patients and the public in the mainstream of activity.

■ **Information**

Without information, patients and the public will remain disempowered. It is essential that they receive and can gain access to the information they need to participate fully at whatever level their contribution is sought.

■ **Healthcare professionals must be involved in the process**

While our concern here is to empower patients to be involved in the organisation and delivery of healthcare, we recognise the importance of striking a partnership in this endeavour with healthcare professionals. This will be of enormous lasting value in taking the process forward. Thus there must also be a recognition of the need to educate and train healthcare professionals so as to develop an understanding and appreciation of the role which patients and the public can play.

■ **Honesty about the scope of involvement**

Some decisions can and should be made by the public. Others cannot. Between these two extremes there is scope for a wide range of public involvement. The guiding principle should always be to ensure the greatest possible involvement of the public and patients, unless there are good reasons for acting otherwise. To ensure that confidence is retained and trust not put at risk, whatever the context, the *scope* of involvement of the public should be identified and made explicit at the outset.

■ **Transparency**

It is important that the processes by which patients and the public become more actively involved in the healthcare process are open to scrutiny, and are transparent in the way that they work.

■ Effectiveness

The mechanisms for public involvement should be evaluated. Changes to these mechanisms and structures should draw on the evidence of what works. The NHS Modernisation Agency could play an important role here. We need to learn and understand the most effective forms of involvement in terms of helping to improve the quality of healthcare. The goal must be the widest possible involvement of patients and the public in the NHS at local level.

■ Training, development and preparation

A high degree of participation from some individuals will be required. It is important, therefore, that such individuals are properly prepared and supported through, for example, the provision of training and guidance.

■ Funding

To be effective the involvement of the public and patients requires proper funding. This particularly includes the provision of sufficient resources for those involved, such as payments for childcare or loss of earnings or time spent preparing for and attending meetings. The various bodies should have an appropriate budgetary allocation to meet such costs. It is on such apparently minor issues, but matters of great importance to the individuals concerned, that the involvement of the public often founders. Without financial support, many, with the best will in the world, cannot take part.

■ Involving different groups

It is important that all patients and members of the public have the opportunity to become involved. But such involvement should not be limited to 'patients' groups' or those representing the interests of patients with a particular illness or condition. The net must be cast widely, not least to ensure that the broad range of experience of the NHS is captured. That said, it is unlikely that, through representation alone, the full range of the public's views will be obtained. Thus it is important to encourage the use of professionally conducted surveys, at a local and national level. The surveys should be seen as part of a strategy for public empowerment.

- 28** It is important to mention here the particular role which primary care trusts (and groups) can play. With their power to place contracts with hospitals, primary care trusts (PCG/T) are in a strong position to exert an external influence on the quality of care. In a PCG/T of 200,000 patients and 100 GPs there will be in the order of at least one million consultations a year. PCG/Ts, therefore, should be especially vigilant to ensure that they have in place arrangements to discover and take account of patients' and the public's views. This should include seeking patients' views about the care which they have received in hospital and on matters which they consider could be improved. One mechanism for achieving this could be through the PCG/T's Patient and Advocacy Liaison Service. The views of patients can then inform the process of

contracting with hospitals. Clearly, there will need to be a much greater degree of involvement and empowerment of patients and the public than simply to have a single 'representative' on the PCG/T board.

- 29** On a separate matter, there is an argument as to whether there is a need for government to establish some body at a national level to represent the public's interest but which stands *outside* the organisational structure of the NHS. There is some force in the idea of some form of permanent watchdog: a national, publicly funded body to represent and promote the patient's perspective. There are, however, counter-arguments. First, by being outside the system, the scene may be set for the development of confrontational attitudes between the patients' watchdog and the NHS which serve the interests of neither. Secondly, without formal powers to challenge or change, the body may soon lose credibility and be seen as 'toothless', a gesture towards public engagement rather than a reality. If, on the other hand, the body were given formal powers, it would, perhaps, endanger the creation of that partnership between professional and public which we regard as the essential building block for the future, by appearing to endorse the sovereignty of patient power. This would be to go too far. A patient-centred service is not a patient-dominated service.
- 30** Accordingly, we are of the view that, on balance, the priority should be that the public's interests are embedded into all the organisations and institutions concerned with quality of performance within the NHS. In this way the public is 'on the inside', rather than 'on the outside'. Moreover, in wider constitutional terms, it leaves the field clear to democratically elected politicians to be, as they must be, the final arbiters of the wider public interest, able to weigh both competing priorities within the NHS, and the relative claim of the NHS as against those of other sectors of public service.

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Children are entitled to healthcare which is specifically designed to meet their needs as children. Parents are entitled to be involved in and informed about the care of their children, save in exceptional circumstances.

Messages from Bristol

- The specific healthcare needs of babies and young children undergoing open-heart surgery were too readily subordinated to the need to care for adult cardiac patients.
- There was no system to establish and indicate who had responsibility for the management and care of these children and their families during the various phases of care.
- In the absence of effective planning or service frameworks for children's acute healthcare at national or local level, the particular needs of children were not effectively met.
- The relative lack of concern for the particular needs of a group of highly vulnerable individuals, whatever the degree of dedication of particular individuals, meant that for this among other reasons, the quality of care for children who received open-heart surgery at the Bristol Royal Infirmary was less than it should have been.

Introduction

- 1 We argue that children and their healthcare needs should be given greater recognition and higher priority in the health service. We suggest that a National Service Framework (NSF) for children is urgently needed and welcome the Government's recent recognition of this. We make proposals for improving the leadership of children's healthcare services at every level. Finally, we address two areas of particular concern arising from the events in Bristol: staffing and communication.
- 2 All of the principles and recommendations in this report, though not intended specifically to address healthcare services for children, will, once implemented, have a marked effect on children's services. In addition, however, there are a number of issues which are particular to the provision of healthcare services for children and which we believe demand special attention.
- 3 The relatively low status in the overall scheme of things which was given to healthcare services for children undergoing open-heart surgery in Bristol is all the more poignant

given that there existed within the Bristol group of hospitals a dedicated children's hospital, with expertise in looking after sick children. Sadly, that expertise was not linked effectively to the BRI. The comment of Dr Peter Martin, consultant paediatrician, who worked as a senior house officer at the Bristol Royal Hospital for Sick Children between 1988 and 1989, is telling:

'... myself and colleagues thought it was rather bizarre that the sickest children post-operatively were managed in a unit where the resident staff were generally not paediatrically trained and the nursing staff were also not paediatrically trained. This was in stark contrast to the children requiring less intensive surgery who were looked after on a paediatric intensive care unit with paediatric anaesthetists, resident and paediatric medical staff, as well as of course, nursing staff who only looked after ill children.'¹

- 4 National and professional organisations concerned with the provision of children's healthcare services contributed to the first Seminar in Phase Two of the Inquiry. The clear message from their submissions was that shortcomings in acute healthcare services for children were by no means unique to Bristol. More disturbing, they told us that, while there has undoubtedly been improvement since 1995, notably in the fields of paediatric intensive care and in a number of specialist services for children with specific conditions such as cleft lip and palate, children's healthcare services as a whole still remain a low priority. This was borne out in evidence throughout the Inquiry. We were told, for example, that healthcare services for children are still, generally, fragmented and poorly co-ordinated. Furthermore, we were told that although well-established guidance exists, the extent to which it is implemented varies across the country. There is no system for ensuring that the guidance is put into operation, nor are there any sanctions against those trusts which persistently fail to implement it. The particular performance of those services connected with children's healthcare, as distinct from the quality of services in general, is not systematically monitored. Thus it is not surprising that very little information is available locally or nationally about the quality of such services.
- 5 We welcome the decision of the Department of Health (DoH) to begin to develop a National Service Framework for children (March 2001). Such a framework should help to overcome the reluctance of some of those responsible for planning and managing healthcare services to recognise the particular requirements of children and families. In our view, one of the central priorities for the Framework must be acute care for children, including that which takes place in district general hospitals as well as in the more well-known specialist hospitals for children. It is in the general, non-specialist hospitals that constant vigilance is especially needed to ensure that the particular needs of children are not overlooked. The Framework must address this.

¹ See Annex A Chapter 9 for further evidence about the split site and split service

The priority given to children's healthcare services

- 6 Children and young people up to the age of 16 make up about 20% of the population. They enjoy better overall health than ever before. Nevertheless, they make significant use of acute healthcare services. We were told by the Royal College of Paediatrics and Child Health that the number of children admitted to hospital albeit for short periods has been steadily increasing: 'By the age of 2 years, about 25% [1 in 4] of children will have experienced one or more hospital admissions.'² We were also informed by the DoH that: 'After the age of 5 approximately 1 in 12 children are admitted [to hospital] each year with over half of such care being provided by the surgical specialties'... futhermore: 'In each year 1 in 5 children attend an Accident and Emergency Department ...'.³
- 7 This degree of recourse to healthcare services has not been adequately matched by any measures aimed specifically at meeting children's needs. This has not been for want of trying by those who have addressed the issues. Indeed, it is a remarkable feature of children's healthcare services that, over a period of 40 years, successive independent reports have made the same or similar recommendations. All, in their different ways, have called for a greater priority to be given to children's healthcare services:

'Greater attention needs to be paid to the emotional and mental needs of the child in hospital, against the background of changes in attitudes towards children, in the hospital's place in the community, and in medical and surgical practice. The authority and responsibility of parents, the individuality of the child and the importance of mitigating the effects of the break with home should all be more fully recognised.' (Platt Report, 1959)⁴

'The special needs of children which arise from the fact that they are growing developing persons should be reflected in the facilities that are provided for them and, perhaps more important, in the training of those who care for them. We want to see a service which is child-centred and we believe that this must be a service in which the professional staff are adequately trained and experienced in the special needs of children.' (Court Report, 1976)⁵

'Children have special health care needs because they are physically and emotionally different from adults ... The root cause of hospitals failing to apply the principles is often a lack of attention of many clinicians, managers and other staff

² Seminar 1. The Royal College of Paediatrics and Child Health. Position Paper

³ Seminar 1. NHS Executive, Department of Health. Position Paper

⁴ 'The welfare of children in hospital'. The Platt Report. Ministry of Health, Central Health Services Council. London: HMSO, 1959

⁵ 'Fit for the Future: The Report of the Committee on Child Health Services'. Volume One. London: HMSO, 1976

to these special needs and the needs of children’s families.’ (*Children First: A Study of Hospital Services*. Audit Commission, 1993)⁶

‘At present health services for children do not always consider the specific need of children. Children’s health services ... are too often based on traditional custom and practice or indeed on professional self-interest. Children’s health services must be needs led, not based on historical patterns or the self-interest of provider groups.’⁷ (*Hospital Services for Children and Young People*, Health Select Committee, 1997)

- 8 All of these reports urged that the needs of children and their parents should be the central principle informing arrangements for children’s healthcare services. Remarkably, some would say scandalously, despite the consistency of these recommendations over such a long period of time, there has been an equally consistent failure fully to implement these fundamental principles, a failure which continues to this day.
- 9 Sue Burr, Paediatric Nurse Adviser at the Royal College of Nursing (RCN), reflected the frustration of many healthcare professionals when she told the Inquiry:

‘... I think we probably have the best guidance in the world in relation to the welfare of children and young people in hospital – if only that was implemented ...’⁸
- 10 Despite our censure, we recognise that there has been some improvement over the years in services and guidance. The proposed NSF must take these improvements further. We were also reminded by the DoH of its current guidance: *The Welfare of Children and Young People in Hospital*⁹ which states that service for children which is of good quality:
 - ‘provides for the child as a whole, for his or her complete physical and emotional well being and not simply for the condition for which treatment is required;
 - ‘is child and family centred with children, their siblings and their parents or carers experiencing a “seamless web” of care, treatment and support, as they move through the constituent parts of the NHS;
 - ‘admits children to hospital only if the care they require cannot be as well provided at home, in a day clinic or on a day care basis.’¹⁰

⁶ *Children First: A Study of Hospital Services*. Audit Commission. London: HMSO, 1993

⁷ *Hospital Services for Children and Young People*. House of Commons Health Select Committee (Session 1996–97) Fifth Report. London: HMSO, 1997

⁸ T34 p. 46 Miss Burr

⁹ DoH. *The Welfare of Children and Young People in Hospital*, HMSO, 1991

¹⁰ Seminar 1. NHS Executive, Department of Health. Position Paper

These principles are right, but it must be remembered that as we write this Report it is ten years since they appeared. Words must become action.

- 11 The DoH referred us to developments such as the standards set out in the *'Patient's Charter'*. It also pointed to the marked improvement in the quality and availability of paediatric intensive care services, in response, among other things, to the tragic events surrounding the death of Nicholas Geldard.¹¹ Other developments include a significant increase in the number of trained children's nurses working with children in local district hospitals, and the establishment of Diana nurses to care for sick children at home. There has also been a fundamental shift towards the greater involvement of parents or carers during a child's stay in hospital. The RCN and the relatively recently created Royal College of Paediatrics and Child Health have been particularly energetic in seeking to raise professional standards, and in exerting pressure on government to consider child-centred care in its widest sense.
- 12 All of these developments have tended to concentrate on standards which have to be reached. Important as these are, we are also concerned with the action which has been taken. As the Audit Commission and the Health Select Committee made clear, it is not so much that good ideas and good guidance are lacking. Indeed, as we have found, there is a remarkable consensus across the professions caring for children in hospital about the standards which should apply in the provision of children's healthcare. The problem lies in action, in translating the words into deeds. The difficulty appears to be systemic: the absence thus far of any overall framework of care, of management systems and, above all, of leadership and political will, all of which are needed to ensure that good practice is indeed implemented.
- 13 In this chapter, therefore, we have not sought to revisit or rewrite the already very comprehensive guidance and principles set down by the Royal Colleges and others. The principles set down by the Audit Commission in 1993 strike us as robust and we endorse them. These six principles state that children and young people's health services should be built around:
 - child- and family-centred care;
 - specialist skilled staff;
 - separate facilities;
 - effective treatments;
 - appropriate hospitalisation; and
 - strategic commissioning.

¹¹ A major effort to improve the availability of facilities for paediatric intensive care followed the death from a brain haemorrhage in December 1995 of 10-year-old Nicholas Geldard. No paediatric intensive care bed was available in his home city of Manchester, and he had to be taken by ambulance to Leeds, where he died

- 14** What we focus on is action. Indeed, had the principles set out in the DoH's 1991 guidelines and the Audit Commission's report been implemented in Bristol, a good number of the shortcomings in care would have been addressed much earlier. Forty years have elapsed since inadequacies in children's services in the NHS were first identified and proposals for improvement were articulated. In the light of the pressing need for improvement, the questions which guide us are: why is action so slow in coming; why do children's health services continue to be undervalued? We are in no doubt that there must be a fundamental shift in attitude and approach, so that action to improve children's healthcare services is taken at every level of policy-making and of management. Without such a shift, exhortations to good practice will continue to be uttered. But there will be no guarantee that a neglect of children's needs, similar to that which we saw in Bristol, is not happening now and will not happen again.

The healthcare needs of children and young people are different from those of adults

- 15** We start with what seems to be a difficulty on the part of policy-makers and health service managers fully and consistently to accept or acknowledge that the healthcare needs of children and young people are different from those of adults. It seems so obvious that it hardly needs to be said: just as children differ from adults in terms of their physiological, psychological, intellectual and emotional development, so they differ in their healthcare needs. They experience and see the world differently. Children are in a constant state of growth and development which creates particular needs and demands which are of a different order from those affecting adult patients. Their relative physical and emotional immaturity, in comparison with adults, has implications for both the treatment which they receive and the physical environment in which they are cared for. Children communicate their thoughts and feelings in a very different way from adults. Effective communication with children as patients (often through a combination of play, one-to-one interaction, and by communication with parents) is seen by professionals involved in paediatric healthcare as crucial to the child's physical and psychological wellbeing. Thus the ability of staff to care appropriately for children is crucial. Skills, understanding and knowledge are required which are different from those of staff who mostly care for adults.
- 16** There is still a continuing lack of recognition of the need for the holistic, child-centred approach to the care and treatment of children which has been advocated for the past 40 years. Liz Jenkins, Assistant General Secretary of the RCN, told the Inquiry:
- '... 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. They do not see them as a client group that have wholly different needs.'¹²
- 17** Children's needs are ordinarily expressed through their parents, who are usually the primary providers of their care. But there are also important differences between children and their families. Their interests do not always coincide. Equally, children

¹² T34 p. 33 Mrs Jenkins

are different at various stages of development: infancy, childhood and adolescence. Thus, although as a group they are different from adults, children and young people cannot be seen as a homogeneous group. In short, a child-centred approach to healthcare is complex.

- 18** Of the many examples of the complexities of caring for children with their parents we mention just one here: the issue of obtaining consent to treatment. As is well known, the role of a child who is to be treated in the process of gaining consent to that treatment is problematic. As children grow towards maturity, they achieve greater control over what can be done. But until the child reaches adulthood at 18, the law places certain limits, at least on what can be refused, if a parent decides otherwise. We do not wish to review this exceedingly complex area here. We do, however, wish to make some observations. In the case of a baby or young child, there is no question of the child giving or withholding consent. It is the parent who must do so. This is a very heavy burden to bear, particularly when the child is seriously ill. Asking parents' to give their consent on behalf of their child is of a different order than asking them to give their consent for themselves. There will always be agonies of doubt and, if events turn out badly, of self-recrimination. For this reason, the principles which we set down earlier, in Chapter 23 on Respect and Honesty, must be scrupulously observed. Consent by a parent is quintessentially a process. It has little to do with putting a signature on a form, and everything to do with being taken along a journey of information, advice and support which equips the parent as much as possible to make the necessary decision. Nor can there be any justification for holding information back, however well intentioned the motive. This is because it is the parent's responsibility to make a decision which is in the child's best interests. That responsibility falls (and weighs heavily) on the parent, not the doctor, the nurse, or anyone else. To carry out this responsibility the parent therefore needs the fullest possible account of what is proposed, the alternatives, the risks and the possible outcomes. Once informed, of course, the parent may ask for help and should be supported. This is what is meant by the principles of respect and honesty which we referred to earlier. And on this theme of respect, we add one final point. A child may not be sufficiently mature to give consent, but may be able to participate to a degree in the process. All those caring for the child must be alert to this and must involve the child to the extent compatible with the child's capacity to comprehend what is involved.

A framework for the future of children's healthcare services

- 19** We state at the outset that we recognise that the health of children depends on a variety of factors, of which healthcare is only one. Thus we welcome the efforts under way on a broader social front to improve education and to tackle child poverty,

particularly for more vulnerable families. These will have lasting benefits for the general health of children. In parallel with these efforts, we insist that the quality of children's healthcare services must also be improved.

- 20** The need to agree and issue the National Service Framework (NSF) for children, on which work has recently begun, is urgent. The DoH's 1991 guidance needs to be updated and brought into line with other developments in the NHS. Furthermore, changes are taking place within the NHS, such as the rapid development of primary care groups and trusts, which will have a direct impact on children's health services. In the absence of a strategic planning framework to provide guidance on models of good practice, and to set minimum standards, important decisions on the future of healthcare delivery are still being taken in a vacuum.
- 21** It is evident to us that the new framework must provide an overall strategy to enable trusts and health authorities to focus on the whole range of services which, taken together, constitute children's healthcare services. The following are amongst the key issues that need to be addressed: how to achieve greater integration of hospital and community healthcare services for children; the future arrangements for acute care and for specialised services for children; how to improve the commissioning of children's healthcare services so that it is based on children's needs rather than on providers' convenience; and the need for sufficient paediatrically trained staff.

Greater integration of healthcare services for children

- 22** Healthcare services for children are currently provided at every level of the NHS: primary care, in the community, and in hospitals (Accident & Emergency, secondary care and specialist tertiary care). As we have said already, historically, it is a feature of the provision of healthcare in hospitals that the care is organised around the needs of the organisation or the healthcare professionals. Children's healthcare services are no exception. This must change. Child-centred care must be care centred around the child. Strategic guidance is needed, based on evidence from the UK and abroad, as to which type of organisational model would best achieve the optimal integration of all the relevant services so that they are organised around the needs of children and their families, rather than around the needs of providers.
- 23** We were told of emerging models of service in England such as that in Newham, London, where a community trust manages the whole range of healthcare for children, including the acute ward in the local acute hospital trust. The Royal Liverpool Children's NHS Trust runs a 'hospital at home' service for children with long-term needs. Efforts are also being made around the country to establish paediatric clinical networks to share good practice. One example is the Partners in Paediatrics Network, a partnership of acute and community trusts in Staffordshire, which work together on matters such as manpower planning, professional education and planning paediatric care. Outside the UK, we were particularly impressed by the high level of integration achieved in Philadelphia in the USA, where the Philadelphia Children's Hospital runs the paediatric wards in a number of local district hospitals, as

well as the community health clinics for children and some primary care centres. While all aspects of this model may not be transferable here, given the well-established strengths of our primary care system, we take the view that there is much to learn from the Philadelphia experience. We see scope for a pilot project where a large children's hospital, with its experience in paediatric care and leadership in children's healthcare, could take responsibility for the management of children's acute healthcare and community services in a number of related general acute hospital trusts in a specific geographical area. Thus, for example, in the future there could be Birmingham Children's Hospital 'at' Walsall Hospitals NHS Trust; or Great Ormond Street Hospital 'at' the Greenwich Healthcare NHS Trust. These are just illustrations of what might develop into a hub and spoke model, where the hub is the specialist paediatric hospital, and the spokes are district general hospitals which include paediatric care amongst many other services. Equally, the development of primary care trusts offers significant opportunities for the closer integration of primary care, community care and general paediatric secondary care, always provided that the system created is informed by a comprehensive view of children's needs. This is the crucial message of the experience in Philadelphia. Not only must the services be more closely integrated, they must also all be imbued with the philosophy of child-centred care.

The future of acute and of specialised services for children

- 24** The NSF must address the complex question of the location of acute and specialised healthcare services for children, and the extent to which they should be close to healthcare services for adults. Where rebuilding programmes are already under way, local services are facing fundamental questions about where to locate children's acute services in relation to general acute services. We are convinced that the optimal arrangement for children's acute hospital services is that they be located in a children's hospital. Ideally, the children's hospital should be physically as close as possible to, but separate from, an acute general hospital. Such an arrangement means that children can be cared for in a paediatric environment, whilst giving easy access to specialist help from the acute hospital, *if* it is needed. This is the arrangement now achieved in Bristol with the new children's hospital, opened in 2001. In the past, open-heart surgery and post-operative intensive care for children took place in the BRI, away from the children's hospital, in a setting which was primarily for the care of adults. The proximity of a children's hospital was not enough to influence the quality of care for the children once they were taken into an environment intended for the care of adults.
- 25** It is possible to achieve care of high quality within children's hospitals which are at some physical distance from an acute general hospital. Indeed, there are several very successful examples of such hospitals in the UK. The difficulties lie in access to certain facilities which may not routinely be found in a children's hospital. Equally, there may not be access to certain specialists, the appointment of whom could not be justified in a children's hospital given the infrequent call on their services. Clearly, these

difficulties can be overcome to a degree by good management and organisation of care.

- 26** As regards specialist or tertiary services for very sick children, we have already touched on the general issues involved in Chapter 27 (Standards). It is important here to make clear some points of principle. We do not presume to indicate, not least because we do not have the relevant information, what services should be where, or how many centres there should be which specialise in any particular specialty. Instead, we confine ourselves to the factors which should guide such decisions. We take the view that in the case of specialist services, the premise must be that the quality of the care received by children will depend on the level of skills and competence of the healthcare professionals. Given the comparative variety of the conditions treated through specialist services, the necessary level of skill and competence will only be acquired if the number of centres is limited. The continuum can be expressed: fewer centres, greater competence, the greater the possibility of better outcomes for the children. It is also crucial to add that there must be a sufficient volume of work in any one centre to enable the clinicians to achieve a good level of success in outcome.¹³ Advice should be sought from the experts on the appropriate number of patients to be treated to achieve good outcomes.
- 27** If this is the proper way forward, it is crucial that there should be a mechanism which can make it happen. This involves not only the designation of the particular centre as an approved centre, but also, and this is a crucial lesson from Bristol, the power to *prevent* other centres from carrying out the particular specialist service. We note that in their submissions to our Seminar, both the DoH and the Royal College of Paediatrics and Child Health (RCPCH) used the expression 'if' specialist services were to be concentrated in a limited number of centres. Clearly, somebody has to decide about such concentration, and equally clearly (and perhaps more urgently) somebody has to decide who will make such a decision. We take the view that this issue, the location of specialist services for children, must be addressed in some proper degree of detail in the proposed NSF.
- 28** We add a further point. We are taxed by the relevance, in making decisions on the location of specialist services, of geography. We are conscious that equality of access to care would seem to be threatened if care is concentrated in a small number of centres of excellence. This was one of the dilemmas of Bristol's designation as a supra regional centre. Moreover, we recognise that for children with complex health problems and their families, we are not merely talking of one episode of surgery or of treatment, but a long-standing relationship with the centre concerned. For parents and children regularly to have to travel long distances is a hardship in many ways, not least in terms of the financial cost. On balance, however, we regard the most important consideration to be the quality of the care which the child is entitled to. If this can only be provided at some distance from the child's home, then this must be accepted. The alternative of providing sub-standard care closer to the child's home is not an

¹³ Spiegelhalter D, 'An investigation into the relationship between mortality and volume of cases in surgery for congenital heart disease from 1984 to 1995', May 2000. See Annex B 7d

option we should any longer be prepared to accept. We are reinforced in our view by the fact that a clear message from Bristol was that parents were prepared to travel long distances if this meant that their child would get good care. We only add that, if our view is accepted, parents must not be left without assistance. Easily accessible financial help, probably through new Family Support Funds held by the specialist centres themselves, should be available, as should suitable accommodation provided at or very close to the hospital. We think it essential that necessary financial assistance be made available promptly to meet costs incurred when a family is a great distance from home, caring for a sick child. This assistance must be administered flexibly and be available to a wider group of people than is the existing Hospital Travel Costs Scheme, which is very restricted and in any case offers only the most basic support. Thought should also be given to the use of modern technology, e.g. the use of video telephones, to enable children to remain in touch with their families.

How to improve the commissioning of children's healthcare services so that it is based on children's needs rather than on providers' convenience

29 The new NSF must state that arrangements should be put in place to ensure that children's healthcare services are commissioned locally in an integrated way. Attention should be drawn to examples of good practice. What this means is both deceptively obvious yet radical. It contemplates that, in planning healthcare services for children, the starting point is the needs of children in that particular locality, rather than, and this is the important point, what those providing a variety of services have hitherto been in the habit of providing. The services are planned around the children, rather than the children taking whatever is on offer and not receiving what is not on offer. The work of the East London and City Health Authority, which has set up a system of locality-based commissioning for children's services, is a good example of integrated commissioning.

The need for sufficient, paediatrically trained staff

30 Until the proposed NSF appears, the future direction of children's healthcare services will remain unclear. Thus, identifying the number of paediatrically trained nurses and doctors which will be required in the future is currently problematic. It is imperative, therefore, that the professionals who care for children should be fully involved in the development of the NSF, and engaged in analysing the implications for levels of staffing. Equally, it is imperative that the NSF be agreed and implemented as a matter of urgency. We deal with staffing issues in more detail later on.

31 We believe that the proposed NSF must also:

- set standards which must be observed, as well as those to which services should aspire, while leaving appropriate room for innovation and adaptation to local needs. Too often in the past, the failure to stipulate standards which are mandatory has undermined efforts to ensure that proper standards of care are delivered;

- establish incentives (including but not limited to financial incentives) for the improvement of children’s healthcare services, with particular help for those trusts which most need it; and
 - set out plans for the publication of information about the quality and performance of children’s healthcare services at national level, at the level of the individual trust, of the specialty, and of individual consultant units.
- 32** We have said earlier in our Report that we believe the inspection of trusts by the Commission for Health Improvement (CHI) should be developed so that it becomes a system whereby hospitals are validated to provide services. Once the system is established, we believe that, in the case of children’s healthcare services, there should be a specific process of validation, such that trusts would only be permitted to provide healthcare services for children if they meet the appropriate standards in a range of relevant areas, including numbers of paediatrically trained staff, a proper level of paediatric facilities and an environment imbued with the values of paediatric care. In this regard, we note the proposal of the Royal College of Surgeons in a recent report from its Paediatric Forum.¹⁴ It recommends that inpatient surgery on children should only be undertaken in those hospitals which provide comprehensive paediatric facilities. It then lists proposed minimum requirements which any district acute hospital must meet if it includes surgery on children amongst its services. This is precisely the type of requirement we have in mind. By contrast, it is currently still the case that there is no mechanism to ensure that hospitals which do not meet such standards refrain from undertaking surgery on children.

Leadership of children’s healthcare services

- 33** Children are a vulnerable group. They lack the means to speak up for themselves in the complex world of healthcare. It falls to adults, therefore, to protect their interests. If adults fail to do so, they fail the children to whom they owe a duty of care and who have rights which demand protection.
- 34** We come back to the question, who provides leadership for children’s healthcare services? Currently, there is no single, influential, unifying voice, with political influence or power, which serves as an advocate for children’s needs. Rather, at best, there is a loose network of institutions, voluntary organisations and individuals, often from within the healthcare professions specialising in children’s health, which put the case for greater value to be accorded to children’s healthcare services. Sadly, these have little or no power systematically to bring about change. We comment on the need for this to change, on the need to take up the cause of children’s healthcare, in the paragraphs which follow.

¹⁴ The Royal College of Surgeons of England. *Children’s Surgery – A First Class Service*. London, May 2000

Leadership in government

35 The lack of clear leadership at the level of national government was demonstrated until recently by allocation of ministerial responsibility for children's health and healthcare services amongst Ministers in the DoH. A Minister of State had responsibility for 'child and adolescent mental health services', and for 'family issues'. A Parliamentary Under-Secretary had responsibility for 'maternity and child health'. There was no Minister, of whatever status, charged with responsibility for all aspects of 'health and healthcare services for children and young people'. Frankly, this is well nigh a national scandal. We note and welcome the shift in policy reflected in the unification of issues relating to children's health under the auspices of a single Minister responsible for 'children's health, including Children's Task Force.' This development must now be reflected in a more integrated approach to children's healthcare throughout the NHS.

Leadership in the NHS

36 Few English health authorities have a senior officer with specific responsibility for commissioning children's healthcare services. Apart from free-standing children's hospital trusts, there is scant evidence within trusts which care for children as well as adults that any senior, board-level manager, or non-executive director, is responsible for taking an overall view of the entirety of healthcare services for children and young people within the trust. This may reflect a historical reality that services have tended to be managed by reference to specialty (for example, cardiac surgery) rather than by reference to patients. A way must be found within healthcare organisations to allow the voice and needs of those who use the service to be heard, as well as that of the specialists (it is not a case of 'either/or'). In our view, it is this absence of a significant voice for children, at any level of policy-making or management within the NHS, which both signals and reinforces the low priority given to children's healthcare services. Thus all acute care trusts which care for children as well as adults should have a designated executive member of the board whose responsibility it is to ensure that the interests of children are protected and that they are cared for in a paediatric environment by paediatrically trained staff.

37 Speaking up for children's healthcare services also calls for clinical leadership. Despite the efforts of many individuals, there are considerable barriers in the way of progress. Paediatrics, as a specialty, historically has had a low status. This can be seen in those acute hospital trusts which are not exclusively devoted to the care of children, where the importance of children as a distinct group of patients, and of those who provide children's healthcare services, is not systematically recognised at a senior level. We were told, for example, by the RCN, that, according to a comprehensive survey which it undertook in 1998, few acute hospital trusts have a paediatrically qualified nurse working at a level of seniority above ward level. Thus, nurses with specialist training in the care of children are not routinely involved in the development of policy within a trust. They struggle to influence the development of appropriate child-centred policies, especially in areas where children receive care alongside adults, such as in general surgery, outpatient departments, and in accident and emergency.

38 We have already noted and commended the efforts of two of the Royal Colleges in taking a lead on developing standards for children’s healthcare services. This has taken place, however, in a wider context in which, as we have said, paediatrics as a specialty, historically, has been undervalued within the clinical professions. This was a strong theme in the evidence from the RCN. The late Professor David Baum, then President of the Royal College of Paediatrics and Child Health (a Royal College since 1996), told us:

‘Across the world, the independent voice of paediatrics has been later than physicians and surgeons as an identifying group in the world of medicine ...’¹⁵

In the light of the evidence which we heard and read, we believe that a very substantial effort is required to change the way in which children’s healthcare services are thought about, led and managed.

A new voice for children

39 It was suggested to us that the only real way to secure a sustained improvement in the priority accorded to children’s healthcare services is to develop new institutional arrangements. These would be designed to ensure that some organisation or body takes specific responsibility for raising the quality of children’s healthcare and for ensuring that any guidance is consistently implemented. We agree. We recognise, however, that there are different schools of thought as to what such an institutional arrangement should be. One approach is to promote improvements in children’s healthcare services in the context of children’s rights generally and alongside other children’s services, such as education and social care. This could be achieved by the office of an independent Children’s Commissioner. It could also be achieved by a greater integration of the working of the various government departments involved. Another suggested approach is to maintain the focus on healthcare and, within the existing organisational structures, find ways of elevating the leadership of and priority given to children’s healthcare services. These approaches are not mutually exclusive. We consider each in turn.

A broad-based approach

40 In the course of the Inquiry it became apparent that the picture presented to us of children’s healthcare services, that of fragmentation, patchy implementation of guidance, a variable regard for the particular needs of children, and the absence of information about and monitoring of performance, is a picture which is not unfamiliar to other areas of children’s services, most notably the services for children in the care of local authorities. It was put to us that there is a wider systemic weakness in the formation of policy in government, in that the particular needs and the voice of children and young people are generally given a low priority. This is despite the recognition in the UK of the UN Convention on the Rights of the Child, such that this recognition may appear to some to be a triumph of gesture over action.

¹⁵ T18 p. 21 Professor Baum, then President of the Royal College of Paediatrics and Child Health

- 41** We have been deeply touched by the evidence that, in terms of public policy, the interests of children have for far too long been neglected. Although it is beyond our remit, we consider there to be merit in the arguments we have heard for the creation of an office of Children's Commissioner. Various arrangements are emerging in the UK with regard to the status and authority of such an office as well as to the range of issues which could fall within its jurisdiction. Understandably, since there is as yet little experience of such an office, the evidence as to its relative effectiveness has yet to emerge. The Welsh Assembly has appointed a Children's Commissioner for Wales with a remit, under the Care Standards Act 2000, to review and monitor all social care services for children, including, for example, children's homes and fostering and adoption services. The Scottish Parliament is also considering the creation of a similar office with a wider remit: to monitor the implementation of the UN Convention on the Rights of the Child. Recently, the Welsh Assembly initiated a public consultation exercise on proposals to widen the role and powers of its Children's Commissioner so that he could review the effect on children in Wales of the exercise or proposed exercise by the Assembly of any of its functions.¹⁶ The Scottish proposal, if it goes ahead, would seem to embrace the advocacy of children's rights to healthcare, that being one of the wide range of services provided by the state on which the Convention touches. We note also here the joint initiative of the Save the Children Fund and Oxfordshire County Council. They state that they have established the first Children's Rights Commissioner in a local authority in the UK. The aim of the initiative is to establish standards on children's rights, which can be incorporated across the local authority's agencies into all policy documents, planning proposals, initiatives, funding applications and monitoring.
- 42** A range of other approaches with the aim of raising the quality of children's services is emerging. For instance, in the case of standards of care in local authority homes, the new National Care Standards Commission in England will have a Children's Rights Director with the responsibility to inspect and regulate homes where children are in care. At the same time, and arising from the Government's policy to address the social exclusion of children and young people, the Prime Minister in June 2000 announced the establishment of a new Cabinet Committee on Children and Young People's Services. The Committee is charged with ensuring the coherence and success of the Government's policies on preventing poverty and underachievement among children and young people. Healthcare and health services are not specifically mentioned as falling within the responsibility of the Committee, although a Health Minister is amongst its members. This must change. The Cabinet Committee should specifically include in its remit matters to do with healthcare and health services for children and young people.

A focus on healthcare

- 43** As we have made clear, the issues involved in improving the quality of children's healthcare services warrant particular and urgent attention. We see real value in

¹⁶ The Children's Commissioner for Wales, Mr Peter Clarke, was appointed in March 2001. In the same month the National Assembly for Wales published a consultation paper on proposals for new and extended functions under the Children's Commissioner for Wales Act 2001

including healthcare services within the remit of broader-based initiatives, such as that of the office of a Children's Commissioner, designed to promote the rights of children and to improve the ways in which the needs of children are properly met. Indeed, there could be positive advantage in terms of the better integration of a whole range of services intended for children. There is, however, a danger that the specific improvements needed in the field of healthcare could easily be swamped by other needs in other areas. For this reason it is important to examine another approach to raising the priority of children's healthcare services: the development of institutional mechanisms which are designed for this, and only this, task.

- 44** We take as a starting point, by way of analogy, the approach which has been adopted to improve health services for older people. There is now within the NHS a National Director for Services for Older People whose role it is to lead a programme of change and reform in four areas earmarked for improvement: assuring standards of care, extending access to services, promoting independence in old age, and ensuring fairness in funding. We are impressed by this approach.¹⁷ A parallel initiative for children's healthcare services in the form of a National Director for Children's Healthcare Services would be of real and lasting benefit, always provided that it was combined with a strong commitment by government at ministerial level and a strong national framework for children's healthcare services, both of which we have referred to earlier.

Specific issues

- 45** It is not our intention, as we have said, to rewrite the principles and (long-standing) guidance relating to children's healthcare services. There are, however, two matters of such importance that we wish to single them out for special mention. They are the staffing of children's healthcare services, and communication between healthcare staff, children and their parents or carers.

The staffing of children's healthcare services

- 46** It is worth recalling the words of the late Professor Baum:

'... it is manifestly the case that children should be looked after by children-trained staff ... we have to break through barriers of small people needing fewer staff to the understanding that these are whole-time people, these children and babies, who require whole-time staff and the sicker they are, the more complex the health care techniques, the more dedicated completely preoccupied attention [is needed] from the nursing staff attending, therefore the more are needed in the whole staff of the hospital and that produces tremendous difficulties, both in having the budget to

¹⁷ One of the Panel would go further and also recommend the appointment of a Children's Commissioner, as discussed earlier

employ the staff, but downstream or upstream to have enough nurses coming through that training.’¹⁸

- 47** The acceptance that children are distinct from adults requires, in turn, the acceptance of the need for the care of children to be provided by appropriately trained staff. We have said this already. What this means is that all healthcare staff who treat children must have training in caring for children. This is especially so in relation to paediatric intensive care. For nursing in acute hospitals, there are very clear standards as to the number of nurses trained in the care of children who should be available: they are set down by the DoH in its 1991 guidance. The standards require that at least two Registered Sick Children’s Nurses (RSCNs) (or nurses who have completed the child branch of Project 2000) be on duty 24 hours a day in all children’s departments and wards in the hospital and that there be an RSCN available 24 hours a day to advise on the nursing of children in other departments. These standards should serve as the minimum standards and should apply where children are treated (save in emergencies) to take account of changing patterns in the provision of acute healthcare services. We also believe, however, that the standards should be reviewed as a matter of urgency.
- 48** According to a recent RCN survey of acute healthcare provision for children, around seven in ten trusts met the DoH’s standard for the level of paediatric nursing.¹⁹ Those trusts which did not meet the standard mentioned cover for night duty as a particular difficulty. We were told that, although there is no shortage of people applying to qualify as children’s nurses, there *is* a pressing need for well-trained and highly-skilled nurses to cope with the growth in paediatric sub-specialties, which are amongst the most technologically advanced and labour intensive areas of nursing. We were also told that turnover among staff often leads to a lack of continuity of staff with the appropriate level of knowledge and expertise.
- 49** As with nursing so with medicine and surgery, there is no place in the NHS of today for occasional paediatric practice. Children deserve better. We are convinced from the experience of Bristol that all doctors who treat children, both in hospital and in primary care, should receive appropriate training and continuing professional development in paediatrics.
- 50** In terms of surgery, in the light of what we have previously said about the particular characteristics and needs of children, we believe that surgery, of whatever type, on children should be a sub-specialty, carried out by designated surgeons who have undergone appropriate training. This is not to say that there is no scope for mixed adult-paediatric practice. To argue this would be impractical and, in any event, there is no strong evidence to suggest that a mixed practice in itself is unsafe. Moreover, it ignores the fact that children grow up and, to the extent that they need further surgery, the paediatric cardiac surgeon, for example, familiar with responding to congenital heart defects must be able to care for them. What matters is that surgeons who operate

¹⁸ T18 p. 36 and T18 p. 39 Professor Baum

¹⁹ Royal College of Nursing. ‘*Children’s Services: Acute Health Care Provision*’. London: RCN, June 1999

on children, no matter that they also operate on adults, must be trained to care for children, and they must undertake sufficient operations on children to maintain their skills. The report of the Paediatric Forum of the Royal College of Surgeons of England recommends specific paediatric training for all surgeons who operate on children. It suggests that a minimum of one paediatric operating session²⁰ a fortnight be performed. We endorse the principle underlying this proposal: that there must be a minimum level of regular operating sessions. We doubt, however, that it is advisable to have a generic minimum level: the minimum level is likely to vary according to the particular paediatric surgical specialty. As a matter of priority, the GMC, the body responsible for the revalidation of doctors, should agree with the Royal College of Surgeons of England the appropriate number and range of procedures which surgeons who operate on children must undertake to retain their validation. Some areas of expertise may require more sessions than others. In the case of PCS, based on our experience of events in Bristol, we believe that one session a fortnight is probably too infrequent an engagement with children to maintain competence. While we do not stipulate the required number of sessions we are persuaded that an average of four sessions a week should be the minimum number required. Clearly this must be agreed as part of the process of revalidation as a matter of urgency. We express no view as to whether this should also apply to other paediatric surgical specialties. We recognise, however, that, over time, implementing this approach is likely to have consequences for the way in which general surgery on children is organised.

- 51** As regards medical care, clearly what was said about the surgeon applies also to the anaesthetist and others: if they are to care for children they must be trained to do so and periodically demonstrate that they have maintained their skills. And there must be enough of them. It may also be appropriate here to point out that with the growing influence of primary care groups and trusts, there is a strong case for saying that the expertise of GPs in paediatric care could be improved. A number (two or three) of GPs on a primary care trust (PCT) should be required to undergo additional professional training (with appropriate support) in paediatrics and then become the 'children's experts' within the PCT. This would take us a step further towards integrating children's healthcare into all aspects of the health service. A still further step which we recommend is that each health authority and primary care group/trust should designate a senior member of staff to have responsibility for commissioning children's healthcare services locally.

Communication between healthcare professionals, children and their parents or carers

- 52** Children, once they grow out of infancy, are acute observers of the mood and body language of others. It is impossible to avoid communicating with them. For this reason, good practice is now founded on the principles of truthfulness, clarity and awareness of the child's age.²¹ In practice, this means that healthcare professionals

²⁰ We take the term 'session' to mean half of a working day

²¹ We have been greatly assisted in this section by expert advice from Jean Simons. See her paper at 10k in Annex B: 'Giving information to parents with an unwell child; an expert opinion'

who care for children must be able to listen to children, to respect their needs for information and to be prepared and able to give such information in the right amount and in a way which is suitable for the child's age. Clearly, this is not necessarily a straightforward or easy matter. It causes us again to reinforce our view that those who care for children must be trained in paediatrics and in the special skills of communicating with children about illness and treatment.

- 53** In the case of children still in infancy, communication is with their parents. We were left in no doubt that one of the principal lessons from Bristol is that parents wish to be treated with respect. They want their particular knowledge of their child to be valued, and they wish to be included in the process of caring for their child. Parents are entitled to nothing less, and good practice now reflects this. Our experience of receiving the evidence of parents, 238 of whom gave formal written statements to the Inquiry, is that they do not, for the most part, expect healthcare professionals to have all the answers. What they do expect is that their concerns as parents will be addressed. As Jean Simons, Head of Bereavement Services, Great Ormond Street Hospital for Children, points out, parents become angry or frustrated when a healthcare professional unilaterally decides which topics are 'too difficult' for them to deal with. Making such assumptions, or avoiding certain issues altogether, are not good practice. Healthcare professionals caring for children should be trained in the particular skills necessary to communicate with parents. There needs to be a willingness on the part of the healthcare professional to be more open with parents about difficult issues, and to assess to what degree the parents want to discuss them.
- 54** Of particular difficulty is the issue of false hope. Parents in Bristol, as would any parent, wanted only the best possible for their children, not least the chance of life-saving treatment. Having heard from so many parents as to how they felt the doctors at Bristol led them to believe their children would get better, or would not necessarily have permanent side effects after surgery, we were struck by Jean Simons' comment:
- '... the reliance and trust most patients place in doctors to give them cause for hope, can lead doctors to concentrate on discussing the aspects of treatment which can give cause for hope at the expense of realistic information about what the treatment may do to the patient's quality of life, or indeed what truly realistically the treatment could be expected to achieve.'
- 55** This is a real human dilemma. Healthcare professionals, especially those caring for children, share this hope for the future. But all have to guard against allowing this natural human instinct to get in the way of being straightforward with parents. There is no single or easy solution to this. What is called for is constant awareness and vigilance amongst those involved in supporting the parents of sick children in hospital to ensure that they are not inadvertently avoiding the difficult issues. One very practical step which we recommend is, systematically, to seek feedback from parents several weeks after their child has been in hospital about their perceptions of the experience. Such feedback could then be regularly reviewed in clinical team audit meetings and appropriate lessons learned.

Recommendations

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Introduction

- The issues addressed in Section Two of our Report are complex and have challenged every developed country.
- There are no right answers; just, perhaps, less wrong answers.
- Cultural and institutional change takes time and can be slow, requiring patience and forbearance.
- Nothing can be achieved 'on the cheap': not only must funding for the NHS continue to grow in a sustained manner, but ways must be found to protect it as far as possible from the ordinary turbulence of economic cycles.
- There are no quick fixes, but progress is possible and can be achieved. We reject both the 'magic wand' and 'nothing can be done' schools of policy.
- Change can only be brought about with the willing and active participation of those involved in healthcare: the public, patients, healthcare professionals, trusts and health authorities, and government.

Purpose of the Recommendations

- To meet our Terms of Reference.
- To advance the central notion of a patient-centred healthcare service committed to continuous improvement. We adopt as our starting point that the NHS exists to serve patients.
- To promote a new culture within the NHS: a three-way partnership of respect, honesty and openness between:
 - NHS and public;
 - professionals and patients; and
 - professionals and professionals.

- To give effect to the following:
 - The patient must be at the centre of everything which the NHS does.
 - The commitment and the dedication of staff in the NHS must be valued and acknowledged: those caring for patients must themselves be supported and cared for.
 - There must be openness and transparency in everything which the NHS does.
 - The impact of the way in which services are organised on the quality of care which patients receive must be recognised: the quality of care depends on systems and on facilities, as well as on individual healthcare professionals.
 - All those involved in healthcare – doctors, nurses, other healthcare professionals, and managers – are collectively healthcare professionals: each group must recognise and acknowledge the contribution of others in the service of patients.
 - The safety of patients must be the foundation of the NHS’s commitment to the quality of its services.
 - Sentinel events, that is, errors, other adverse events, and near misses, which occur during the care of patients, must be seen as opportunities to learn, not just as reasons to blame.
 - There must be clear and understood systems of responsibility and accountability: a culture of blame is no substitute for such systems.
 - The quality of healthcare must be guided by agreed standards, compliance with which is regularly monitored.
 - The role of central government in relation to the NHS should be:
 - a) to act as its headquarters in terms of management; and
 - b) to create independent mechanisms for regulating the quality of healthcare and the competence of healthcare professionals.
 - The various independent bodies must themselves be co-ordinated so as to avoid the fragmentation of responsibility which arose in the past. Existing bodies, suitably shaped, must be used. We recommend the creation of only one new body.

The nature of the Recommendations

- Our Recommendations are grouped together under various headings reflecting the themes highlighted in our Report. We identify those Recommendations which we consider sufficiently important to merit early implementation. Other Recommendations we recognise will take some time to implement, either because further debate is required, or because they require other changes to be in place.
- The Recommendations are interlocked and interrelated. They are parts of a jigsaw: each needs the other to complete the picture. We believe that action needs to move forward in relation to all the themes simultaneously. We do not place a priority on one theme over another.
- We have deliberately chosen not to cost the Recommendations we make. This is not least because, with many of our Recommendations, change can be achieved by doing things differently within existing resources. We estimate that around half of our Recommendations could be implemented with no or relatively modest expenditure. A significant number relate to changes already underway. Furthermore, many of the fundamental changes needed in the way in which the NHS currently works concern attitudes and culture. The resources needed for these changes are not necessarily financial. That said, the NHS continues to confront the consequences of long-term underinvestment. We make it clear that, to achieve that which patients are entitled to expect of the NHS, will require sustained additional funding. To fail to provide it would be to fail the NHS and thus to fail the public.
- Whether, how and over what time frame these Recommendations are implemented will be a matter for government and for others. We are conscious of the fact that the NHS has only recently begun to digest and respond to '*The NHS Plan*'. The Department of Health (DoH) is setting a series of targets to be achieved to implement the Plan. A further report, such as this one, with many Recommendations might seem like the last straw. But this would be to misunderstand this Inquiry and the nature of our Recommendations. First, we make no apology that there are a large number. It would be a surprise if it were otherwise, given the nature of our task. Secondly, our Recommendations are not in the form of performance targets: tasks which must be achieved in a certain way by a certain date. Thirdly, they are not addressed specifically or exclusively to trusts or to professional bodies or Royal Colleges or even to the NHS. They include all and go beyond them. And fourthly, while there are some which call for urgent action, many of the Recommendations are about a process of change over time. They build on each other and can be organised accordingly.

The structure of the Recommendations

- The story of Bristol was about children. There are a number of issues particular to the provision of acute healthcare services for children which demand special attention. As a consequence, we make a series of Recommendations which focus specifically on healthcare services for children.
- We also include Recommendations addressed to the care and treatment of children with congenital heart disease, including paediatric cardiac surgery.
- Because the focus of the Inquiry was on services provided within the acute hospital sector of the NHS, our Recommendations are addressed principally to that sector. Throughout we use the word 'trust' to refer to an NHS acute hospital or healthcare trust. We do not intend to refer to any other type of trust. Whenever we wish also to include primary care trusts we specifically say so.
- Throughout the Recommendations we use the term patients. In the case of young children and those otherwise unable to decide for themselves this should be taken to include parents and carers.
- Perhaps the most significant change we call for is one which does not attract a specific Recommendation. This is the change which is needed in the culture of the NHS. We see changes to that culture as being a product of the Recommendations as a whole. If the Recommendations are implemented, changes in the culture will follow.
- To reflect the patient's journey, the Recommendations are divided into categories as follows:
 - respect and honesty;
 - a Health Service which is well led;
 - competent healthcare professionals;
 - the safety of care;
 - care of an appropriate standard;
 - public involvement through empowerment; and
 - the care of children.

The Recommendations

Respect and honesty

Partnership: involving patients

- 1 In a patient-centred healthcare service patients must be involved, wherever possible, in decisions about their treatment and care.
- 2 The education and training of all healthcare professionals should be imbued with the idea of partnership between the healthcare professional and the patient.
- 3 The notion of partnership between the healthcare professional and the patient, whereby the patient and the professional meet as equals with different expertise, must be adopted by healthcare professionals in all parts of the NHS, including healthcare professionals in hospitals.

Keeping patients informed about treatment and care

- 4 Information about treatment and care should be given in a variety of forms, be given in stages and be reinforced over time.
- 5 Information should be tailored to the needs, circumstances and wishes of the individual.
- 6 Information should be based on the current available evidence and include a summary of the evidence and data, in a form which is comprehensible to patients.
- 7 Various modes of conveying information, whether leaflets, tapes, videos or CDs, should be regularly updated, and developed and piloted with the help of patients.
- 8 The NHS Modernisation Agency should make the improvement of the quality of information for patients a priority. In relation to the content and the dissemination of information for patients, the Agency should identify and promote good practice throughout the NHS. It should establish a system for accrediting materials intended to inform patients.
- 9 The public should receive guidance on those sources of information about health and healthcare on the Internet which are reliable and of good quality: a kitemarking system should be developed.

Communicating with patients¹

- 10 Tape-recording facilities should be provided by the NHS to enable patients, should they so wish, to make a tape recording of a discussion with a healthcare professional when a diagnosis, course of treatment, or prognosis is being discussed.
- 11 Patients should always be given the opportunity and time to ask questions about what they are told, to seek clarification and to ask for more information. It must be the responsibility of employers in the NHS to ensure that the working arrangements of healthcare professionals allow for this, not least that they have the necessary time.
- 12 Patients must be given such information as enables them to participate in their care.
- 13 Before embarking on any procedure, patients should be given an explanation of what is going to happen and, after the procedure, should have the opportunity to review what has happened.
- 14 Patients should be supported in dealing with the additional anxiety sometimes created by greater knowledge.
- 15 Patients should be told that they may have another person of their choosing present when receiving information about a diagnosis or a procedure.
- 16 Patients should be given the sense of freedom to indicate when they do not want any (or more) information: this requires skill and understanding from healthcare professionals.
- 17 Patients should receive a copy of any letter written about their care or treatment by one healthcare professional to another.
- 18 Parents of those too young to take decisions for themselves should receive a copy of any letter written by one healthcare professional to another about their child's treatment or care.
- 19 Healthcare professionals responsible for the care of any particular patient must communicate effectively with each other. The aim must be to avoid giving the patient conflicting advice and information.

Support services for patients

- 20 The provision of counselling and support should be regarded as an integral part of a patient's care. All hospital trusts should have a well-developed system and a well-trained group of professionals whose task it is to provide this type of support and to make links to the various other forms of support (such as that provided by voluntary or social services) which patients may need.

¹ See also Recommendations 59 and 60 which focus on the communication skills of healthcare professionals and Recommendations 187–191 concerning communication between healthcare professionals and children and their parents

- 21 Every trust should have a professional bereavement service. (We also reiterate what was recommended in the Inquiry's Interim Report: 'Recommendation 13: As hospitals develop websites, a domain should be created concerned with bereavement in which all the relevant information concerning post-mortems can be set out in an appropriate manner.')
- 22 Voluntary organisations which provide care and support to patients and carers in the NHS (such as through telephone helplines, the provision of information and the organisation of self-help groups) play a very important role. Groups which meet the appropriate standards as laid down by the NHS should receive appropriate funding from the state for the contribution they make to the NHS.

Consent to treatment

(In relation to post-mortems and the removal and retention of human material, we restate here those Recommendations from the Inquiry's Interim Report which related to consent: 'Recommendation 26: Obtaining parents' consent should be seen as a process, and not just the signing of a form. As part of that process, parents should be allowed proper time to reflect and be informed that they may change their minds until such time as they sign a form indicating their consent.' 'Recommendation 27: As part of that process, parents should have access to: advice and information which is comprehensible, accessible, and in a form which allows it to be taken home if desired.')

- 23 We note and endorse the recent statement on consent produced by the DoH: '*Reference guide to consent for examination or treatment*', 2001. It should inform the practice of all healthcare professionals in the NHS and be introduced into practice in all trusts.
- 24 The process of informing the patient, and obtaining consent to a course of treatment, should be regarded as a process and not a one-off event consisting of obtaining a patient's signature on a form.
- 25 The process of consent should apply not only to surgical procedures but to all clinical procedures and examinations which involve any form of touching. This must not mean more forms: it means more communication.
- 26 As part of the process of obtaining consent, except when they have indicated otherwise, patients should be given sufficient information about what is to take place, the risks, uncertainties, and possible negative consequences of the proposed treatment, about any alternatives and about the likely outcome, to enable them to make a choice about how to proceed.

- 27** Patients should be referred to information relating to the performance of the trust, of the specialty and of the consultant unit (a consultant and the team of doctors who work under his or her supervision). (See further the Recommendations on care of an appropriate standard.)

Feedback from patients

- 28** Patients must be given the opportunity to pass on views on the service which they have received: all parts of the NHS should routinely seek and act on feedback from patients as to their views of the service. In addition, formal, systematic structured surveys of patients' experience of their care (not merely satisfaction surveys) should be routinely conducted across the NHS and the results made public.
- 29** NHS trusts and primary care trusts must have systems which ensure that patients know where and to whom to go when they need further information or explanation.
- 30** We endorse the initiative in *'The NHS Plan'* to establish a Patient Advocacy and Liaison Service in every NHS trust and primary care trust. The establishment of this service should be implemented in full as quickly as possible. Once established, patient advocacy and liaison services must be given secure funding to enable them to provide an effective service to patients.
- 31** Trusts and primary care trusts must have systems for publishing periodic reports on patients' views and suggestions, including information about the action taken in the light of them. (See further the Recommendations on care of an appropriate standard.)
- 32** So as to provide for patients an effective, efficient and seamless information and advocacy service, consideration should be given to how the various patient advocacy and liaison services in a given geographical area could most effectively collaborate, including in relation to the provision of information for patients and the public.

Responding to the patient when things go wrong

- 33** A duty of candour, meaning a duty to tell a patient if adverse events² have occurred, must be recognised as owed by all those working in the NHS to patients.
- 34** When things go wrong, patients are entitled to receive an acknowledgement, an explanation and an apology.
- 35** There should be a clear system, in the form of a 'one-stop shop' in every trust, for addressing the concerns of a patient about the care provided by, or the conduct of, a healthcare professional.

² An adverse event is an unplanned event which results in harm to a patient. We use the term 'adverse event' rather than 'sentinel event' in this instance so as to exclude 'near misses'

- 36 Complaints should be dealt with swiftly and thoroughly, keeping the patient (and carer) informed. There should be a strong independent element, not part of the trust's management or board, in any body considering serious complaints which require formal investigation. An independent advocacy service should be established to assist patients (and carers).
- 37 There should be an urgent review of the system for providing compensation to those who suffer harm arising out of medical care. The review should be concerned with the introduction of an administrative system for responding promptly to patients' needs in place of the current system of clinical negligence and should take account of other administrative systems for meeting the financial needs of the public. (See further the Recommendations on the safety of care.)

A Health Service which is well led

- 38 The DoH's roles in relation to the NHS must in future be made explicit. The DoH should have two roles. It should be the headquarters of the NHS. It should also establish an independent framework of regulation which will assure the quality of the care provided in and funded by the NHS, and the competence of healthcare professionals.

The regulation of the quality and safety of healthcare

- 39 The framework of regulation must consist of two overarching organisations, independent of government, which bring together the various bodies which regulate healthcare. A Council for the Quality of Healthcare should be created to bring together those bodies which regulate healthcare standards and institutions (including, for example, the Commission for Health Improvement (CHI), the National Institute for Clinical Excellence (NICE) and the proposed National Patient Safety Agency). A Council for the Regulation of Healthcare Professionals should be created to bring together those bodies which regulate healthcare professionals (including, for example, the General Medical Council (GMC) and the Nursing and Midwifery Council); in effect, this is the body currently referred to in *'The NHS Plan'* as the Council of Healthcare Regulators. These overarching organisations must ensure that there is an integrated and co-ordinated approach to setting standards, monitoring performance, and inspection and validation. Issues of overlap and of gaps between the various bodies must be addressed and resolved.
- 40 The two Councils should be independent of government and report both to the DoH and to Parliament. There should be close collaboration between the two Councils. The DoH should establish and fund the Councils and set their strategic framework, and thereafter periodically review them.

- 41 The various bodies whose purpose it is to assure the quality of care in the NHS (for example, CHI and NICE) and the competence of healthcare professionals (for example, the GMC and the Nursing and Midwifery Council) must themselves be independent of and at arm's-length from the DoH.
- 42 All the various bodies and organisations concerned with regulation, besides being independent of government, must involve and reflect the interests of patients, the public and healthcare professionals, as well as the NHS and government.

The management of the NHS at the local level

Contractual relations between trusts and employees

- 43 The contractual relationship between trusts and consultants should be redefined. The trust must provide the consultant with the time, space and the necessary tools to do the job. Consultants must accept that the time spent in the hospital and what they do in that time must be explicitly set out.
- 44 The system of Distinction Awards for hospital consultants should be examined to determine whether it could be used to provide greater incentives than exist at present for providing good quality of care to patients. The possibility of its extension to include junior hospital doctors should be explored.
- 45 The doctors' Code of Professional Practice, as set down in the GMC's *'Good Medical Practice'*, should be incorporated into the contract of employment between doctors and trusts. In the case of GPs, the terms of service should be amended to incorporate the Code.
- 46 The relevant codes of practice for nurses, for professions allied to medicine and for managers should be incorporated into their contracts of employment with hospital trusts or primary care trusts.
- 47 Trusts should be able to deal as employers with breaches of the relevant professional code by a healthcare professional, independently of any action which the relevant professional body may take.

The chief executive and senior management

- 48 The security of tenure of the chief executive and senior managers of trusts should be on a par with that of other senior professionals in the NHS.

The trust board

- 49 The criteria and process for selection of the executive directors of a trust board must be open and transparent. Appointments should be made on the basis of ability and not on the basis of seniority.

- 50 The NHS Leadership Centre, in conjunction with trusts, should develop programmes of training and support for clinicians and others who seek to become executive directors.
- 51 As recommended in *'The NHS Plan'*, there should be an NHS Appointments Commission responsible for the appointment of non-executive directors of NHS trusts, health authorities and primary care trusts.
- 52 Newly appointed non-executive directors of trusts, health authorities and primary care trusts should receive a programme of induction: this should refer to the principles and values of the NHS and their duties and responsibilities with regard to the quality of care provided by the trust. This programme should be provided through the NHS Leadership Centre.
- 53 A standard job description should be developed by the NHS for non-executive directors, as proposed in *'The NHS Plan'*.
- 54 Throughout their period of tenure, non-executive directors should be provided with training, support and advice organised and co-ordinated through the NHS Leadership Centre.
- 55 The Chairs of trust boards should have a source of independent advice (or mentor) during their period of office, drawn from a pool of experts assembled by the NHS Leadership Centre.
- 56 Arrangements should be in place in the standing orders of trust boards to provide for proper continuity in the management of the trust's affairs in the period between the cessation of the Chair's term of office and the commencement of that of a successor.

Competent healthcare professionals

Broadening the notion of professional competence

- 57 Greater priority than at present should be given to non-clinical aspects of care in six key areas in the education, training and continuing professional development of healthcare professionals:
 - skills in communicating with patients and with colleagues;
 - education about the principles and organisation of the NHS, and about how care is managed, and the skills required for management;
 - the development of teamwork;

- shared learning across professional boundaries;
 - clinical audit and reflective practice; and
 - leadership.
- 58** Competence in non-clinical aspects of caring for patients should be formally assessed as part of the process of obtaining an initial professional qualification, whether as a doctor, a nurse or some other healthcare professional.
- 59** Education in communication skills must be an essential part of the education of all healthcare professionals. Communication skills include the ability to engage with patients on an emotional level, to listen, to assess how much information a patient wants to know, and to convey information with clarity and sympathy.
- 60** Communication skills must also include the ability to engage with and respect the views of fellow healthcare professionals.
- 61** The education, training and Continuing Professional Development (CPD) of all healthcare professionals should include joint courses between the professions.
- 62** There should be more opportunities than at present for multi-professional teams to learn, train and develop together.
- 63** All those preparing for a career in clinical care should receive some education in the management of healthcare, the health service and the skills required for management.
- 64** Greater opportunities should be created for managers and clinicians to ‘shadow’ one another for short periods to learn about their respective roles and work pressures.

Leadership: skills and capacity

- 65** An early priority for the new NHS Leadership Centre should be to offer guidelines as to leadership styles and practices which are acceptable and to be encouraged within the NHS, and those which are not.
- 66** Steps should be taken to identify and train those within the NHS who have the potential to exercise leadership. There needs to be a sustained investment in developing leadership skills at all levels in the NHS.
- 67** The NHS’s investment in developing and funding programmes in leadership skills should be focused on supporting joint education and multi-professional training, open to nurses, doctors, managers and other healthcare professionals.
- 68** The NHS Leadership Centre should be involved in all stages of the education, training and continuing development of all healthcare professionals.

The systems for assuring competence

- 69 Regulation of healthcare professionals is not just about disciplinary matters. It should be understood as encapsulating all of the systems which combine to assure the competence of healthcare professionals: education, registration, training, CPD and revalidation as well as disciplinary matters.
- 70 For *each* group of healthcare professionals (doctors, nurses and midwives, the professions allied to medicine, and managers) there should be one body charged with overseeing *all* aspects relating to the regulation of professional life: education, registration, training, CPD, revalidation and discipline. The bodies should be: for doctors, the GMC; for nurses and midwives, the new Nursing and Midwifery Council; for the professions allied to medicine, the re-formed professional body for those professions; and for senior healthcare managers, a new professional body.
- 71 In addition, a single body should be charged with the overall co-ordination of the various professional bodies and with integrating the various systems of regulation. It should be called the Council for the Regulation of Healthcare Professionals. (In effect, this is the body currently proposed in *'The NHS Plan'*, and referred to as the Council of Healthcare Regulators.) (See Recommendation 39.)
- 72 The Council for the Regulation of Healthcare Professionals should be established as a matter of priority. It should have a statutory basis. It should report to Parliament. It should have a broadly-based membership, consisting of representatives of the bodies which regulate the various groups of healthcare professionals, of the NHS, and of the general public.
- 73 The Council for the Regulation of Healthcare Professionals should have formal powers to require bodies which regulate the separate groups of healthcare professionals to conform to principles of good regulation. It should act as a source of guidance and of good practice. It should seek to ensure that in practice the bodies which regulate healthcare professionals behave in a consistent and broadly similar manner.
- 74 It should be a priority for the Council for the Regulation of Healthcare Professionals to promote common curricula and shared learning across the professions.

The education of healthcare professionals

- 75 Pilot schemes should be established to develop and evaluate the feasibility of making the first year's course of undergraduate education common to all those wishing to become healthcare professionals.
- 76 Universities should develop closer links between medical schools and schools of nursing education with a view to providing more joint education between medical and nursing students.

- 77** Universities should develop closer links between medical and nursing schools and centres for education and training in health service and public sector management, with a view to enabling all healthcare professionals to learn about management.
- 78** Access to medical schools should be widened to include people from diverse academic and socio-economic backgrounds. Those with qualifications in other areas of healthcare and those with an educational background in subjects other than science, who have the ability and wish to do so, should have greater opportunities than is presently the case, to enter medical schools.
- 79** The attributes of a good doctor, as set down in the GMC's *'Good Medical Practice'*, must inform every aspect of the selection criteria and curricula of medical schools.
- 80** The NHS and the public should be involved in (a) establishing the criteria for selection and (b) the selection of those to be educated as doctors, nurses and as other healthcare professionals.

Post-qualification training and continuing professional development

- 81** In relation to doctors, we endorse the proposal to establish a Medical Education Standards Board (MESB), to co-ordinate postgraduate medical training. The MESB should be part of and answerable to the GMC which should have a wider role. (See Recommendation 70.)
- 82** CPD, being fundamental to the quality of care provided to patients, should be compulsory for all healthcare professionals.
- 83** Trusts and primary care trusts should provide incentives to encourage healthcare professionals to maintain and develop their skills. The contract (or, in the case of GPs, other relevant mechanism) between the trust and the healthcare professional should provide for the funding of CPD and should stipulate the time which the trust will make available for CPD.
- 84** Trusts and primary care trusts must take overall responsibility through an agreed plan for their employees' use of the time allocated to CPD. They must seek to ensure that the resources deployed for CPD contribute towards meeting the needs of the trust and of its patients, as well as meeting the professional aspirations of individual healthcare professionals.

Appraisal

- 85** Periodic appraisal should be compulsory for all healthcare professionals. The requirement to participate in appraisal should be included in the contract of employment.
- 86** The commitment in *'The NHS Plan'* to introduce regular appraisal for hospital consultants must be implemented as soon as possible.

- 87** The requirement to undergo periodic appraisal should also be incorporated into GPs' terms of service.

Revalidation

- 88** Periodic revalidation, whereby healthcare professionals demonstrate that they remain fit to practise in their chosen profession, should be compulsory for all healthcare professionals. The requirement to participate in periodic revalidation should be included in the contract of employment.
- 89** The public, as well as the employer and the relevant professional group, must be involved in the processes of revalidation.
- 90** The new Council for the Regulation of Healthcare Professionals should take as a further priority an early review of the various systems of revalidation and re-registration to ensure that they are sufficiently rigorous, and in alignment both with each other and with other initiatives to protect the public. The Council should also seek ways to incorporate managers (as healthcare professionals) into the systems of CPD, appraisal and revalidation.

Managers

- 91** Managers as healthcare professionals should be subject to the same obligations as other healthcare professionals, including being subject to a regulatory body and professional code of practice. (See Recommendation 70.)

Clinicians who hold managerial positions

- 92** Where clinicians hold managerial roles which extend beyond their immediate clinical practice, sufficient protected time in the form of allocated sessions must be made available for them to carry out that managerial role.
- 93** Any clinician, before appointment to a managerial role, must demonstrate the managerial competence to undertake what is required in that role: training and support should be made available by trusts and primary care trusts.
- 94** Clinicians should not be required or expected to hold managerial roles on bases other than competence for the job. For example, seniority or being next in turn are not appropriate criteria for the appointment of clinicians to managerial roles.
- 95** The professional and financial incentives for senior clinicians to undertake full-time senior managerial roles should be reviewed: the aim should be to enable senior clinicians to move into a full-time managerial role, and subsequently, if they so wish, to move back into clinical practice after appropriate retraining and revalidation.
- 96** To protect patients, in the case of clinicians who take on managerial roles but wish to continue to practise as clinicians, experts together with managers from the NHS should issue advice as to the minimum level of regular clinical practice necessary to

enable a clinician to provide care of a good quality. Clinicians not maintaining this level of practice should not be entitled to offer clinical care. This rule should also apply to all other clinicians who, for whatever reason, are not in full-time practice, and not only to those in part-time managerial roles.

- 97** To facilitate the movement of clinicians in and out of managerial positions, the proposed systems for the revalidation (and re-registration) of doctors, nurses and professions allied to medicine should distinguish between professionals who are managers and also maintaining a clinical practice and those who are not. Those who are not maintaining a clinical practice should be entitled to obtain the appropriate revalidation (and re-registration) to restart a clinical practice, after retraining, and should be assisted in doing so. (See Recommendation 95.)
- 98** The relevant professional regulatory bodies should make rules varying the professional duties of those professionals, whose registration they hold, who are in full-time managerial roles, so as to take account of the fact that, while occupying such roles, they do not undertake responsibility for the care of patients.

The acquisition and development of new clinical skills

- 99** Any clinician carrying out any clinical procedure for the first time must be directly supervised by colleagues who have the necessary skill, competence and experience until such time as the relevant degree of expertise has been acquired.
- 100** Before any *new* and hitherto untried invasive clinical procedure can be undertaken for the first time, the clinician involved should have to satisfy the relevant local research ethics committee that the procedure is justified and it is in the patient's interests to proceed. Each trust should have in place a system for ensuring that this process is complied with.
- 101** Local research ethics committees should be re-formed as necessary so that they are capable of considering applications to undertake new and hitherto untried invasive clinical procedures.
- 102** Patients are always entitled to know the extent to which a procedure which they are about to undergo is innovative or experimental. They are also entitled to be informed about the experience of the clinician who is to carry out the procedure.
- 103** The Royal College of Surgeons of England should, in partnership with university medical schools and the NHS, be enabled to develop its unit for the training of surgeons, particularly in new techniques. It should also explore the question of whether there is an age beyond which surgeons, specifically in areas such as paediatric cardiac surgery, should not attempt new procedures or even should not continue in a particular field of surgery.

Discipline

- 104** In the exercise of their disciplinary function the professional regulatory bodies must adopt a more flexible approach towards what constitutes misconduct. They must deal with cases, as far as possible, at a local level and must have available a range of actions which both serve the interests of the public and the needs of the professional.
- 105** The need to involve the public in the various professional regulatory bodies applies as much to discipline as to all the other activities of these bodies (see Recommendation 42).

The safety of care

- 106** We support and endorse the broad framework of recommendations advocated in the report '*An Organisation with a Memory*' by the Chief Medical Officer's expert group on learning from adverse events in the NHS. The National Patient Safety Agency proposed as a consequence of that report should, like all other such bodies which contribute to the regulation of the safety and quality of healthcare, be independent of the NHS and the DoH.
- 107** Every effort should be made to create in the NHS an open and non-punitive environment in which it is safe to report and admit sentinel events.³
- 108** Major studies should, as a matter of priority, be carried out to investigate the extent and type of sentinel events in the NHS to establish a baseline against which improvements can be made and measured.

A national reporting system

- 109** There should a single, unified, accessible system for reporting and analysing sentinel events, with clear protocols indicating the categories of information which must be reported to a national database.
- 110** The national database of sentinel events should be managed by the National Patient Safety Agency, so as to ensure that a high degree of confidence is placed in the system by the public.
- 111** The National Patient Safety Agency, in the exercise of its function of surveillance of sentinel events, should be required to inform all trusts of the need for immediate action, in the light of occurrences reported to it. The Agency should also be required to publish regular reports on patterns of sentinel events and proposed remedial actions.

- 112** *All* sentinel events should be subject to a form of structured analysis in the trust where they occur, which takes into account not only the conduct of individuals, but also the wider contributing factors within the organisation which may have given rise to the event.

Incentives to encourage the reporting of sentinel events

- 113** The reporting of sentinel events must be made as easy as possible, using all available means of communication (including a confidential telephone reporting line).
- 114** Members of staff in the NHS should receive immunity from disciplinary action by the employer or by a professional body if they report a sentinel event to the trust or to the national database within 48 hours, except where they themselves have committed a criminal offence.
- 115** Members of staff in the NHS who cover up or do not report a sentinel event may be subject to disciplinary action by their employer or by their professional body.
- 116** The opportunity should exist to report a sentinel event in confidence.
- 117** There should be a stipulation in every healthcare professional's contract that sentinel events must be reported, that reporting can be confidential, and that reporting within a specified time period will not attract disciplinary action.
- 118** The process of reporting of sentinel events should be integrated into every trust's internal communications, induction training and other staff training. Staff must know what is expected of them, to whom to report and what systems are in place to enable them to report.

The system of clinical negligence

- 119** In order to remove the disincentive to open reporting and the discussion of sentinel events represented by the clinical negligence system, this system should be abolished. It should be replaced by an alternative system for compensating those patients who suffer harm arising out of treatment from the NHS. An expert group should be established to advise on the appropriate method of compensation to be adopted.

Designing for safety

- 120** The proposed National Patient Safety Agency should, as a matter of urgency, bring together managers in the NHS, representatives of the pharmaceutical companies and manufacturers of medical equipment, members of the healthcare professions and the public, to seek to apply approaches based on engineering and design so as to reduce (and eliminate to the extent possible) the incidence of sentinel events.

Incorporating a concern for safety into systems and policies

- 121** At the level of individual trusts, an executive member of the board should have the responsibility for putting into operation the trust's strategy and policy on safety in clinical care. Further, a non-executive director should be given specific responsibility for providing leadership to the strategy and policy aimed at securing safety in clinical care.

Care of an appropriate standard

- 122** One body should be responsible for co-ordinating *all* action relating to the setting, issuing and keeping under review of national clinical standards: this should be NICE, suitably structured so as to give it the necessary independence and authority.
- 123** Once the recommended system is in place, only NICE should be permitted to issue national clinical standards to the NHS. The DoH (as the headquarters of the NHS) while issuing, for example, National Service Frameworks and supplementary guidance, should not be able to rescind or detract from the standards issued by NICE.
- 124** NICE should pursue vigorously its current policy of involving as wide a community as possible, including the public, patients and carers, in the work to develop and keep under review clinical standards. In particular, the special expertise of the Royal Colleges and specialist professional associations should be harnessed and supported. Account should also be taken of the expertise of the senior management of the NHS.
- 125** National standards of clinical care should reflect the commitment to patient-centred care and thus in future be formulated from the perspective of the patient. The standards should address the quality of care that a patient with a given illness or condition is entitled to expect to receive from the NHS. The standards should take account of the best available evidence. The standards should include guidance on how promptly patients should get access to care. They should address the roles and responsibilities of the various healthcare professionals who will care for the patient. They should take account of the patient's journey from primary care, into the hospital system (if necessary), and back to primary and community care, and of the necessary facilities and equipment.
- 126** Such standards for clinical care as are established should distinguish clearly between those which are obligatory and must be observed, and those to which the NHS should aspire over time.

- 127** A timetable over the short, medium and long term should be published, and revised periodically, for the development of national clinical standards, so that the public may be consulted and kept aware of those areas of healthcare which are covered by such standards and those which will be covered in the future. Target dates should be set by which clinical standards will have been prepared for all major conditions and illnesses.
- 128** Resources, and any necessary statutory authority, must be made available to NICE to allow it to perform its role of developing, issuing and keeping under review national clinical standards.
- 129** Standards of clinical care which patients are entitled to expect to receive in the NHS should be made public.

Standards of care: NHS organisations

- 130** There must be a single, coherent, co-ordinated set of generic standards: that is, standards relating to the patient's experience and the systems for ensuring that care is safe and of good quality (for example corporate management, clinical governance, risk management, clinical audit, the management and support of staff, and the management of resources). Trusts must comply with these standards.
- 131** The current system of inspection of trusts and primary care trusts should be changed to become a system of validation⁴ and periodic revalidation of these trusts. The system should be supportive and flexible. Its aim should be to promote continued improvement in the quality of care.
- 132** One body should be responsible for validating and re-validating NHS trusts and primary care trusts. This body should be CHI, suitably structured so as to give it the necessary independence and authority. Other bodies (for example the NHS Litigation Authority) which are currently concerned with setting and requiring compliance with those generic standards which should fall within the authority of CHI, should carry out their role in this respect under the authority of and answerable to CHI.
- 133** Validation and revalidation of trusts should be based upon compliance with the generic standards which relate to the patient's experience and the systems for ensuring that care is safe and of good quality.
- 134** The standards against which trusts are to be validated, and the results of the process of validation or revalidation, should be made public.

⁴ We choose the term 'validation' not only to mirror the process which healthcare professionals will have to undergo, but also to indicate that, while akin to licensing it contemplates more. Licensing tends to be thought of as a 'one-off event', whereas to us validation is a process. What makes validation akin to licensing is the element of permission to continue

- 135** Any organisation in the voluntary or private sector which provides services to NHS patients should be required to meet the standards for systems, facilities and staff which organisations in the NHS must meet. The aim should be that, wherever care is funded by the NHS, there is a single system of validation which indicates to the public that the organisation meets the necessary standards.
- 136** The validating body should have the power to withdraw, withhold or suspend a trust's validation if standards fall such as to threaten the quality of care or the safety of patients. Any trust or organisation whose validation may be affected in this way must be given the opportunity to take appropriate remedial action. It must then satisfy CHI that it has taken remedial action before its continued validation can be confirmed.
- 137** CHI should consider how it might work with the providers of those programmes of accreditation already adopted by a significant number of trusts. In the future, where required standards are met, CHI should accept as part of its validation process the accreditation obtained through these programmes.
- 138** The process of validation of trusts should, in time, be extended to cover discrete, identifiable services within trusts. This extension of validation should first be piloted and evaluated.
- 139** The pilot exercise for this form of validation should include children's acute hospital services and paediatric cardiac surgery.
- 140** Should the pilot exercise be successful, the category of discrete services which should be a priority for this form of validation are those specialist services which are currently funded or meet the criteria for funding by the National Specialist Commissioning Group (the successor to the Supra Regional Services Advisory Group).
- 141** For discrete services, whether specialist services or otherwise, to be validated trusts they must be able to demonstrate that all relevant aspects of the service can *currently* be met, rather than that the trust *aims* to develop so as to be able to do so at some point in the future. Trusts which do not meet the necessary standards to ensure the safety of patients and a good quality of care should not be permitted to offer, or continue to offer, the relevant service.
- 142** Where the interests of securing quality of care and the safety of patients require that there be only a small number of centres offering a specialist service, the requirements of quality and safety should prevail over considerations of ease of access. It is and should be the responsibility of the NHS to assist patients, and their families or carers, with the cost of transport and accommodation when they have to travel away from home to receive specialist services. Such support should not be the subject of a means test. (See further Recommendations 181 and 182 on specialist services for children.)

Monitoring standards and performance

Local monitoring

- 143** The process of clinical audit, which is now widely practised within trusts, should be at the core of a system of local monitoring of performance. Clinical audit should be multidisciplinary.
- 144** Clinical audit must be fully supported by trusts. They should ensure that healthcare professionals have access to the necessary time, facilities, advice and expertise in order to conduct audit effectively. All trusts should have a central clinical audit office which co-ordinates audit activity, provides advice and support for the audit process, and brings together the results of audit for the trust as a whole.
- 145** Clinical audit should be compulsory for all healthcare professionals providing clinical care and the requirement to participate in it should be included as part of the contract of employment.

National monitoring

- 146** The monitoring of clinical performance at a national level should be brought together and co-ordinated in one body: an independent Office for Information on Healthcare Performance. This Office should be part of CHI.
- 147** The Office for Information on Healthcare Performance should supplant the current fragmentation of approach through a programme of activities involving the co-ordination of the various national audits. In addition to its other responsibilities, the new system should provide a mechanism for surveillance whereby patterns of performance in the NHS which may warrant further scrutiny can be identified as early as possible.

Information systems

- 148** The current 'dual' system of collecting data in the NHS in separate administrative and multiple clinical systems is wasteful and anachronistic. A single approach to collecting data should be adopted, which clinicians can trust and use and from which information about both clinical and administrative performance can be derived.
- 149** Steps should be taken nationally and locally to build the confidence of clinicians in the data recorded in the Patient Administration Systems in trusts (which is subsequently aggregated nationally to form the Hospital Episode Statistics). Such steps should include the establishment by trusts of closer working arrangements between clinicians and clinical coding staff.
- 150** The Hospital Episode Statistics database should be supported as a major national resource which can be used reliably, with care, to undertake the monitoring of a range of healthcare outcomes.

- 151** Systems for clinical audit and for monitoring performance rely on accurate and complete data. Competent staff, trained in clinical coding, and supported in their work are required: the status, training and professional qualifications of clinical coding staff should be improved.
- 152** The system of incentives and penalties to encourage trusts to provide complete and validated data of a high quality to the national database should be reviewed. Any new system must include reports of each trust's performance in terms of the quality and timeliness of the submission of data. The systems within a trust for producing data of a high quality, and its performance in returning such data in a timely manner to the national database, should be taken into account in the process of validating and revalidating the trust.
- 153** At national level, the indicators of performance should be comprehensible to the public as well as to healthcare professionals. They should be fewer and of high quality, rather than numerous but of questionable or variable quality.
- 154** The need to invest in world-class IT systems must be recognised so that the fundamental principles of data collection, validation and management can be observed: that data be collected only once; that the data be part and parcel of systems used to support healthcare professionals in their care of patients; and that trusts and teams of healthcare professionals receive feedback when data on their services are aggregated.

Publication of information about performance and standards

- 155** Patients and the public must be able to obtain information as to the relative performance of the trust and the services and consultant units within the trust.
- 156** As part of their Annual Reports trust boards should be required to report on the extent of their compliance with the national clinical standards. These reports should be made public and be made available to CHI.

Public involvement through empowerment

- 157** The involvement of the public in the NHS must be embedded in its structures: the perspectives of patients and of the public must be heard and taken into account wherever decisions affecting the provision of healthcare are made.
- 158** Organisations which are not part of the NHS but have an impact on it, such as Royal Colleges, the GMC, the Nursing and Midwifery Council and the body responsible for regulating the professions allied to medicine, must involve the public in their decision-making processes, as they affect the provision of healthcare by the NHS.

- 159** The processes for involving patients and the public in organisations in the NHS must be transparent and open to scrutiny: the annual report of every organisation in the NHS should include a section setting out how the public has been involved, and the effect of that involvement.
- 160** The public's involvement in the NHS should particularly be focused on the development and planning of healthcare services and on the operation and delivery of healthcare services, including the regulation of safety and quality, the competence of healthcare professionals, and the protection of vulnerable groups.
- 161** Proposals to establish Patients' Forums and Patients' Councils must allow for the involvement of the wider public and not be limited only to patients or to patients' groups. They must be seen as an addition to the process of involving patients and the public in the activities of the NHS, rather than as a substitute for it.
- 162** The mechanisms for the involvement of the public in the NHS should be routinely evaluated. These mechanisms should draw on the evidence of what works.
- 163** The process of public involvement must be properly supported, through for example, the provision of training and guidance.
- 164** Financial resources must be made available to enable members of the public to become involved in NHS organisations: this should include provision for payments to cover, for example, the costs of childcare, or loss of earnings.
- 165** The involvement of the public, particularly of patients, should not be limited to the representatives of patients' groups, or to those representing the interests of patients with a particular illness or condition: the NHS Modernisation Agency should advise the NHS on how to achieve the widest possible involvement of patients and the public in the NHS at local level.
- 166** Primary care trusts (and groups), given their capacity to influence the quality of care in hospitals, must involve patients and the public, for example through each PCG/T's Patient and Advocacy Liaison Service. They must make efforts systematically to gather views and feedback from patients. They must pay particular attention to involving their local community in decision-making about the commissioning of hospital services.

The care of children

Responsibility for children's services

- 167** A National Director for Children's Healthcare Services should be appointed to promote improvements in healthcare services provided for children.

- 168** Consideration should be given to the creation of an office of Children’s Commissioner in England, with the role of promoting the rights of children in all areas of public policy and seeking improvements to the ways in which the needs of children are met. Healthcare would be one of the areas covered by such a commissioner. Were such an office to be created, we would see it as being in addition to, rather than in place of, our other recommendations about the need to improve the quality of leadership in children’s healthcare services.⁵
- 169** The Cabinet Committee on Children and Young People’s Services should specifically include in its remit matters to do with healthcare and health services for children and young people.
- 170** Each health authority and each primary care group or primary care trust should designate a senior member of staff who should have responsibility for commissioning children’s healthcare services locally.
- 171** All trusts which provide services for children as well as adults, should have a designated executive member of the board whose responsibility it is to ensure that the interests of children are protected and that they are cared for in a paediatric environment by paediatrically trained staff.

Setting standards for children’s healthcare services

- 172** The proposed National Service Framework (NSF) for children’s healthcare services must be agreed and implemented as a matter of urgency.
- 173** The NSF should include a programme for the establishment of standards in all areas of children’s acute hospital and healthcare services.
- 174** The NSF should set obligatory standards which must be observed, as well as standards to which children’s services should aspire over time.
- 175** The NSF should include incentives for the improvement of children’s healthcare services, with particular help being given to those trusts most in need.
- 176** The NSF must include plans for the regular publication of information about the quality and performance of children’s healthcare services at national level, at the level of individual trusts, and of individual consultant units.

Planning the future of children’s healthcare services

- 177** There must be much greater integration of primary, community, acute and specialist healthcare for children. The NSF should include strategic guidance to health authorities and trusts so that services in the future are better integrated and organised around the needs of children and their families.

⁵ One Panel member was of the definite opinion that an office of Children’s Commissioner in England should be established to deal with any matter affecting the rights or welfare of children

- 178** Children’s acute hospital services should ideally be located in a children’s hospital, which should be physically as close as possible to an acute general hospital. This should be the preferred model for the future.
- 179** In the case of existing free-standing children’s hospitals, particular attention must be given to ensuring that, through good management and organisation of care, children have access when needed to (a) facilities which may not routinely be found in a children’s hospital and (b) specialists, the appointment of whom in a children’s hospital could not be justified given the infrequent call on their services.
- 180** Consideration should be given to piloting the introduction of a system whereby children’s hospitals take over the running of the children’s acute and community services throughout a geographical area, building on the example of the Philadelphia Children’s Hospital in the USA.
- 181** *Specialist* services for children should be organised so as to provide the best available staff and facilities, thus providing the best possible opportunity for good outcomes. Advice should be sought from experts on the appropriate number of patients to be treated to achieve good outcomes. In planning and organising specialist services, the requirements of quality and safety should prevail over considerations of ease of access.
- 182** Where *specialist* services for children are concentrated in a small number of trusts spread throughout England, these trusts should establish Family Support Funds to help families to meet the costs arising from travelling and staying away from home. The Funds should be administered flexibly and should not be limited to those on income support or with low incomes.
- 183** After completion of a pilot exercise, all trusts which provide acute hospital services for children should be subject to a process of validation to ensure that they have appropriate child- and family-centred policies, staff, and facilities to provide a good standard of care for children. Trusts which are not so validated should not, save in emergencies, provide acute hospital services for children.

The staffing of children’s healthcare services

- 184** Children should always (save in exceptional circumstances, such as emergencies) be cared for in a paediatric environment, and always by healthcare professionals who hold a recognised qualification in caring for children. This is especially so in relation to paediatric intensive care.
- 185** The 1991 standards for the numbers of paediatrically qualified nurses required at any given time should serve as the minimum standard and should apply where children are treated (save in emergencies). The standards should be reviewed as a matter of urgency to take account of changing patterns in the provision of acute healthcare services.

186 All surgeons who operate on children, including those who also operate on adults, must undergo training in the care of children and obtain a recognised professional qualification in the care of children. As matter of priority, the GMC, the body responsible for the revalidation of doctors, should agree with the Royal College of Surgeons of England the appropriate number and range of procedures which surgeons who operate on children must undertake in order to retain their validation. This will have consequences for the way in which general surgery for children is organised.

Communication between healthcare professionals, children and their parents or carers

187 Parents should ordinarily be recognised as experts in the care of their children, and when their children are in need of healthcare, parents should ordinarily be fully involved in that care.

188 Parents of very young children have particular knowledge of their child. This knowledge must be valued and taken into account in the process of caring for the child, unless there is good reason to do otherwise.

189 Children's questions about their care must be answered truthfully and clearly.

190 Healthcare professionals intending to care for children should be trained in the particular skills necessary to communicate with parents and with children.

191 Healthcare professionals should be honest and truthful with parents in discussing their child's condition, possible treatment and the possible outcome.

Healthcare services and treatment for children with congenital heart disease

192 National standards should be developed, as a matter of priority, for all aspects of the care and treatment of children with congenital heart disease (CHD). The standards should address diagnosis, surgical and other treatments, and continuing care. They should include standards for primary and social care, as well as for hospital care. The standards should also address the needs of those with CHD who grow into adulthood.

193 With regard to paediatric cardiac surgery, the standards should stipulate the minimum number of procedures which must be performed in a hospital over a given period of time in order to have the best opportunity of achieving good outcomes for children. PCS must not be undertaken in hospitals which do not meet the minimum number of procedures. Considerations of ease of access to a hospital should not be taken into account in determining whether PCS should be undertaken at that hospital.

- 194** With regard to those surgeons who undertake paediatric cardiac surgery, although not stipulating the number of operating sessions sufficient to maintain competence, it may be that four sessions a week should be the minimum number required. Agreement on this should be reached as a matter of urgency after appropriate consultation.
- 195** With regard to the very particular circumstances of open-heart surgery on very young children (including neo-nates and infants), we stipulate that the following standard should apply unless, within six months of the publication of this Report, this standard is varied by the DoH having taken the advice of relevant experts: there must, in any unit providing open-heart surgery on very young children, be two surgeons trained in paediatric surgery who must each undertake between 40 and 50 open-heart operations a year.
- 196** The national standards should stipulate that children with CHD who undergo any form of interventional procedure must be cared for in a paediatric environment. This means that all healthcare professionals who care for these children must be trained and qualified in paediatric care. It also means that children must be cared for in a setting with facilities and equipment designed for children. There must also be access on the same site as where any surgery is performed to a paediatric intensive care unit, supported by trained intensivists.
- 197** Surgical services for children with very rare congenital heart conditions, such as Truncus Arteriosus, or involving procedures undertaken very rarely, should only be performed in a maximum of two units, validated as such on the advice of experts. Such arrangements should be subject to periodic review.
- 198** An investigation should be conducted as a matter of urgency to ensure that PCS is not currently being carried out where the low volume of patients or other factors make it unsafe to perform such surgery.

Appendix 1: List of Acronyms used in the Report and Annexes

1946 Act	National Health Service Act 1946
1973 Act	National Health Service Reorganisation Act 1973
1977 Act	National Health Service Act 1977
1980 Act	National Health Service Act 1980
1990 Act	National Health Service and Community Care Act 1990
1995 Act	Medical (Professional Performances) Act 1995
AA	Association of Anaesthetists of Great Britain and Ireland
AAGBI	Association of Anaesthetists of Great Britain and Ireland
ACTA	Association of Cardiothoracic Anaesthetists of Great Britain and Ireland
ADGM	Assistant District General Manager
AGMETS	Advisory Group for Medical Education, Training and Staffing
AHA	Area Health Authority
AIMS	Australian Incident Monitoring Study
AIP	Approval in Principle document
APAGBI	Association of Paediatric Anaesthetists of Great Britain and Northern Ireland
ASD	Atrial Septal Defect
Avon HA	Avon Health Authority. The Avon HA came into existence formally on 1 April 1996 following the merger of the former District Health Authority and Family Health Services Authority. It inherited the planning and purchasing roles
AVSD	Atrio-Ventricular Septal Defect
B&DHA	Bristol & District Health Authority. This formally came into existence on 1 October 1991 as the purchasing authority for the Bristol area, and remained until 1 April 1996, when it merged with the Avon Family Health Services Authority to become the Avon Health Authority
B&DPC	Bristol and District Paediatric Committee
B&WDHA	Bristol & Weston District Health Authority. This was formed on 1 April 1982, following the abolition of the Avon Health Authority (Teaching), from the old Bristol Health District (Teaching) and the Weston Health District, which had merged in 1978. B&WDHA continued in existence until the purchaser-provider split took place on 1 October 1991
BAPS	British Association of Paediatric Surgeons
BCAU	Bristol Clinical Audit Unit
BCH	Bristol Children's Hospital. See BRHSC below
BCS	British Cardiac Society
BDH	Bristol Dental Hospital
BEH	Bristol Eye Hospital
BHCAG	Bristol Heart Children Action Group. This group was initially a group of parents who met to provide comfort and support to each other. They called for a Public Inquiry as early as June 1996. However, the BHCAG was not formally convened until March 1998
BMA	British Medical Association

BMH	Bristol Maternity Hospital
BMJ	British Medical Journal
BPA	British Paediatric Association
BPCA	British Paediatric Cardiac Association
BRHC	Bristol Royal Hospital for Children (opened April 2001)
BRHSC	Bristol Royal Hospital for Sick Children (formerly known as the Bristol Royal Children's Hospital (the BRCH); also referred to in evidence as the Bristol Children's Hospital
BRI	Bristol Royal Infirmary, part of the UBH/T, located in central Bristol
BSSG	Bristol Surgeons Support Group. A group largely comprising former patients of Mr Wisheart and Mr Dhasmana, but including parents of children on whom the surgeons had performed paediatric cardiac surgery, and set up following the General Medical Council Hearings in relation to charges against Mr Wisheart, Mr Dhasmana and Dr John Roylance
CABG	Coronary Artery Bypass Graft
CAC	Clinical Audit Committee
CASPE	Clinical Accountability, Service Planning and Evaluation
CAVSD	Complete Atrio-Ventricular Septal Defect
CCNR	Clinical Case Note Review
CCR	Coded Clinical Records
CEP	Continuing Education Points
CEPOD	Confidential Enquiry into Peri-Operative Deaths
CHC	Community Health Council
CHD	Congenital Heart Disease
CHI	Commission for Health Improvement
CHSC	Central Health Services Council
CICU	Cardiac Intensive Care Unit
CME	Continuing Medical Education
CMO	Chief Medical Officer
CNO	Chief Nursing Officer
COG	Clinical Outcomes Group
CPD	Continuing Professional Development
CQI	Continuous Quality Improvement
CSB	Cardiac Surgery Board
CSJWP	Cardiac Surgery Joint Working Party
CSMB	Cardiac Services Management Board
CSR	Cardiac Surgical Register
CSWP	Cardiac Surgery Working Party
CV	Coefficient of Variation: the standard deviation divided by the mean
DAC	District Audit Committee
DGH	District General Hospital
DGM	District General Manager

DHA	District Health Authority
DHSS	Department of Health and Social Security. Established on 1 November 1968 when the two separate Ministries of Health and Social Security were amalgamated
DMO	District Medical Officer
DMT	District Management Team
DNAC	District Nurse Advisory Committee
DoH	Department of Health. Established in July 1988 following the decision to split the DHSS into two Ministries ¹
DSS	Department of Social Security. See also DHSS
DySSSy	Dynamic Standard Setting System
ECG	Electrocardiogram
EFL	External Financing Limit
EL	Executive Letter
ENB	English National Board for Nursing, Midwifery and Health Visiting
ENT	Ear, Nose and Throat
ERA	Employment Rights Act 1996
FHSA	Family Health Service Authority
FPC	Family Practitioner Committee
FPCC	Finance, Property and Computing Committee of B&WDHA (q.v.)
GMC	General Medical Council
GOS	Great Ormond Street Hospital for Children NHS Trust
GP	General Practitioner
GPFH	General Practitioner Fundholder
HA	Health Authority
HC	Health Circular
HCA	Health Care Assistant
HCHS	Hospital and Community Health Services
HDU	High Dependency Unit
HES	Hospital Episode Statistics
HMC	Hospital Medical Committee
HRC	Hospital Recognition Committee
HRG	Health Resource Group
HSE	Health and Safety Executive
ICD	International Classification of Diseases
ICS	Intensive Care Society
ICU	Intensive Care Unit. Also referred to in evidence as ITU. See also CICU and PICU
ITU	See ICU
IV	Intravenous
JCC	Joint Consultants' Committees

JCHMT	Joint Committee on Higher Medical Training
JCHST	Joint Committee on Higher Surgical Training
JCSAC	Joint Consultants Specialist Advisory Committee
JPAG	Joint Planning Advisory Group
LHAC	Local Hospital Audit Committee
LVOTO	Left Ventricular Outflow Tract Obstruction
MAAG	Medical Audit Advisory Group
MAC	Medical Audit Committee
MACSOM	Medical Audit and Clinical Standards Outcome Measurement
MDA	Medical Devices Agency
MDI	Medical Database Index
MDU	Medical Defence Union
MDUS	Medical and Dental Defence Union of Scotland
MEC	Medical Ethics Committee of the BMA (q.v.)
MESB	Medical Education Standards Board
MIWG	Medication Information Working Group
MPD	Medical Policy Division of the DoH
MPS	Medical Protection Society
MRC	Medical Research Council
NBNI	National Board for Nursing, Midwifery and Health Visiting for Northern Ireland
NBS	National Board for Nursing, Midwifery and Health Visiting for Scotland
NCEPOD	National Confidential Enquiry into Peri-operative Deaths
NEQAS	National External Quality Assessment Scheme
NHS	National Health Service
NHS Trust	We use this generic term to refer to any trust which provides acute hospital care
NHSE	NHS Executive (in existence from April 1 1995)
NHSLA	National Health Service Litigation Authority
NHSME	NHS Management Executive (in existence from May 1989 to March 31 1995)
NICE	National Institute for Clinical Excellence
NICS	Neonatal and Infant Cardiac Surgery
NMC	Nursing and Midwifery Council
NNEB	National Nursery Examination Board
NSCAG	National Specialised Commissioning Advisory Group
NSF	National Service Framework
NVQ	National Vocational Qualification
OBD	Occupied Bed Day
OPCS	Office of Population Censuses and Surveys
OPCS4	OPCS Classification of Operations and Procedures, Fourth Revision
OPD	Outpatient Department

PAC	Performance Assessment Committee
PAD	Patient Administration Database
PAMs	Professions Allied to Medicine
PAS	Patient Administration System
PATS	Patient Analysis and Tracing System
PCC	Professional Conduct Committee
PCG/T	Primary Care Group/Trust
PCS	Paediatric Cardiac Surgery / Paediatric Cardiac (Surgical) Service
PICS	Paediatric Intensive Care Society
PICU	Paediatric Intensive Care Unit
PIDA	Public Interest Disclosure Act 1998
PL	Perfusionist's Log
PMSW(T)	Principal Medical Social Worker (Teaching)
PPC	Preliminary Proceedings Committee of the GMC
PPRC	Policy Planning and Resources Committee
PREP	Post-registration Education and Practice
PS	Pulmonary Stenosis
PTA	Persistent Truncus Arteriosus
RAWP	Resource Allocation Working Party
RCA	Royal College of Anaesthetists
RCCHP	Royal College of Child Health Practitioners
RCGP	Royal College of General Practitioners
RCM	Royal College of Midwives
RCN	Royal College of Nursing
RCP	Royal College of Physicians of London
RCPCH	Royal College of Paediatrics and Child Health
RCSE	Royal College of Surgeons of England
RDPH	Regional Director of Public Health
RGM	Regional General Manager
RGN	Registered General Nurse
RHA	Regional Health Authority
RHMAC	Regional Hospital Medical Advisory Committee
RIDDOR	Reporting on Inquiries, Diseases and Dangerous Occurrences Regulations
RIS	Regional Information System
RMC	Regional Medical Committee
RMO	Regional Medical Officer
RPCMAC	Regional Primary Care Medical Advisory Committee
RR	Relative Risk
RSCN	Registered Sick Children's Nurse

RTC	Radiotherapy Centre
S&WRHA	South and West Regional Health Authority
SAC	Specialist Advisory Committee
SCS	Society of Cardiothoracic Surgeons of Great Britain and Ireland
SEN	State Enrolled Nurse
SERNIP	Safety and Efficacy Register of New Interventional Procedures
SFI	Standing Financial Instruction
SGHA	South Glamorgan Health Authority
SHA	Special Health Authority
SHO	Senior House Officer
SHSC	Scottish Health Services Council
SI	Statutory Instrument
SIFT	Service Increment for Teaching
SIFTR	Service Increment for Teaching and Research
SL	Surgeon's Log
SMAC	Standing Medical Advisory Committee
SMR	Standardised Mortality Ratio
SNMAC	Standing Nursing and Midwifery Advisory Committee
SR	Senior Registrar
SRC	Supra Regional Centre
SRS	Supra Regional Service
SRSAG	Supra Regional Services Advisory Group
STCVS-UK	Society of Thoracic and Cardiovascular Surgeons of Great Britain and Ireland
SWAANS	South West Audit Assistants Network Services
SWCHR	South West Congenital Heart Register
SWRHA	South Western Regional Health Authority. This became operational from 1 April 1974 and continued until it merged with part of the Wessex Regional Health Authority in 1994, to become the South and West Regional Health Authority. It continued in this form until 1 April 1996
TAPVD	Total Anomalous Pulmonary Venous Drainage
TGA	Transposition of Great Arteries
TNAC	Trust Nurse Advisory Committee
TQM	Total Quality Management
UBH	United Bristol Hospitals. A group of hospitals servicing Bristol prior to the formation of the UBHT (q.v.) on 1 April 1991 ²
UBH/T	The term used by the Inquiry to refer to the hospitals comprising the UBH (q.v.) and the UBHT, both before and after Trust status

UBHT	United Bristol Healthcare NHS Trust. A teaching trust formed on 1 April 1991, comprising nine hospitals and community centres, providing a comprehensive range of healthcare services both in hospitals and the community. The majority of UBHT hospitals are in central Bristol, whilst community care is provided by staff based in health centres and clinics in central and south Bristol, and parts of Bath and North East Somerset and North Somerset
UHW	University Hospital Wales, Cardiff
UKCC	United Kingdom Central Council for Nursing, Midwifery and Health Visiting
UKCSR	UK Cardiac Surgical Register
VSD	Ventricular Septal Defect
WL	Wisheart's Log
WNB	Welsh National Board for Nursing, Midwifery and Health Visiting
WTE	Whole-time Equivalent

1. Edwards B. *The National Health Service 1946–1994: A Manager's Tale*, The Nuffield Provincial Hospitals Trust 1995, p. 145
2. The Bristol Royal Infirmary, Bristol Royal Hospital for Sick Children, Bristol Eye Hospital, Bristol Maternity Hospital, Bristol General Hospital, and University of Bristol Dental Hospital. Between 1960 and 1974 they were joined by Bristol Homeopathic Hospital and Farleigh Hospital

Appendix 2: Details of Individuals who Gave Oral and Written Evidence¹ to the Inquiry and Individuals who are Mentioned in the Report or Annex A

The following Appendix contains a list of those who gave evidence to the Inquiry (in the form of a Formal Written Statement or at the Oral Hearing) and others who are mentioned in the Report and Annexes.²

Every attempt has been made to ensure the accuracy of the information as at July 2001.

Abbott, Dr Tom	Consultant Anaesthetist, Southampton University Trust Hospitals (c. 1991)
Acheson, Professor Sir Donald	Chief Medical Officer for England (1983–1991)
Adamson, Mrs Helen ‡	Mother of Martyn
Addicott, Mr Graham	Financial Management Unit, NHS Management Executive, Department of Health
Agarwal, Dr NK	Consultant Paediatrician, Singleton Hospital, Swansea. Clinician who referred children to Bristol
Alberti, Professor Sir Kirk George *‡	President, Royal College of Physicians of London (since 1997)
Anderson, Professor Robert *‡	Professor of Paediatric Cardiac Morphology, Great Ormond Street Hospital for Children NHS Trust (since 1999); Member of the Inquiry's Expert Group
Angelini, Professor Gianni *‡	British Heart Foundation Professor of Cardiac Surgery, University of Bristol (since October 1992)
Angilley, Mr Alan ‡	Administrative Secretary to the SRSAG (1987–January 1992); Branch Head, Finance Directorate, NHS Executive, Department of Health
Appleton, Ms Sarah ‡	Social Worker responsible for Ward 5 UBH/T (January 1989–1994)
Armstrong, Dr Ernest *‡	Secretary, British Medical Association (1993–2000)
Armstrong, Ms Kay *‡	Staff Nurse, latterly Sister in Cardiac Theatres UBH/T ³ (October 1984–1994); Anaesthetic Sister and Surgeon's Assistant, UBHT (1994–1995)
Armstrong, Professor Peter ‡	President, Royal College of Radiologists (1998–September 2001)

¹ 577 Formal Written Statements were received by the Inquiry. Details of other papers submitted to and commissioned by the Inquiry can be found in Annex B

² The information about individuals (other than parents) concentrates on the role or position they held between 1984–1995

³ We use the term 'UBH/T' to refer to that group of hospitals in Bristol which, prior to 1991, comprised the United Bristol Hospitals, and, since 1991, have been known as the United Bristol Healthcare (NHS) Trust. Included within this group of hospitals are the BRI and the BRHSC

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Arnold, Dr Robert	Consultant Paediatric Cardiologist at the Alder Hey Children's Hospital; Member of the Inquiry's Expert Group
Ashwell, Dr Jane *‡	Senior Medical Officer, Department of Health (1991–1995); Senior Medical Officer at the National Assembly for Wales (since 1995)
Ashworth, Dr Michael *‡	Consultant Paediatric Pathologist, St Michael's Hospital, UBHT (since 1993)
Aylin, Dr Paul *	Clinical Senior Lecturer in Epidemiology and Public Health, Imperial College School of Medicine, London
Baber, Mr Michael ‡	Father of Timothy
Bagnall, Mr Guy and Mrs Angela ‡	Parents of Georgina
Baird, Mr Roger *‡	Consultant General Surgeon; Shadow Clinical Director for Surgery, UBHT (February 1990–March 1991); Clinical Director for Surgery, UBHT (April 1991–November 1993); Chairman Elect, Hospital Medical Committee, UBHT (April 1994–March 1996); Chairman, Hospital Medical Committee, UBHT (April 1996–March 1997); Acting Medical Director, UBHT (November 1996–March 1997); Medical Director, UBHT (April 1997–March 1999)
Baker, Mrs Cynthia ‡	Mother of Sarah
Baker, Dr Ian *‡	Specialist in Community Medicine, Avon Area HA (1980-1982); Specialist in Community Medicine, B&WDHA (1982–1984); District Medical Officer, B&WDHA (1984–1988); Director of Public Health and Assistant General Manager (Planning), B&WDHA (1988-1991); Director of Public Health and District General Manager (Acting), B&WDHA (1991); Consultant in Public Health Medicine, Department of Public Health Medicine, B&DHA (from 1991)
Baker, Mrs Janet ‡	Mother of James
Baldwin, Mrs Bette ‡	Project Assistant to Patient Survey Project, UBHT (1991–1992); Research Officer, Patient Survey Unit/Patient Survey & Information Unit, UBHT (1992–1999); Head of Consumer Involvement & Information Unit, UBHT (1999–to date)
Ball, Ms Marjorie ‡	PA to Chief Executive, UBHT; Patient Support Manager and Office Manager, Chief Executive's Office/Complaints Manager (1996–1998); Clinical Governance Support Manager (since 1998)
Barker, Mr Paul ‡	Administrator of the Central Unit, BRI (1979–1985)
Barrington, Mr Ian *‡	Administrative Assistant, BRI (1983–1985); Deputy Commissioning Officer/ Assistant Administrator, Bristol Eye Hospital (1985–1988) Assistant General Manager, Children's and Obstetric Services, B&WDHA (1988–1991); General Manager, Children's Services, UBHT (since 1991)
Bascombe, Ms Linda ‡	Mother of Danielle
Baskett, Mr Peter ‡	Consultant Anaesthetist, BRI and Frenchay Hospital (1966–1996); President of the Association of Anaesthetists of Great Britain and Ireland (1990–1992)

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Baum, Professor David*‡	Former President, Royal College of Paediatrics and Child Health (1985–September 1999); Professor of Child Health, University of Bristol
Beacham, Ms Tessa ‡	Assistant Director of Personnel (Staff Development), UBHT (1991–1997)
Bell, Mr Nigel ‡	Chief Executive, NHS Information Authority (from 1999)
Belsey, Mr R	Cardiothoracic Surgeon, Frenchay Hospital, BRHSC and BRI (1950s and 1960s)
Belson, Ms Peg ‡	Advisor to Action for Sick Children
Berry, Ms Nicola *‡	Mother of Matthew
Berry, Professor Peter Jeremy ‡	Professor of Paediatric Pathology, University of Bristol; Consultant Paediatric Pathologist, UBH/T (since November 1983)
Berwin, Ms Onyx	Cardiac Theatre Nurse, UBH/T
Bevan, Mr Gwyn	Reader in Policy Analysis, London School of Economics and Political Science
Bidgood, Mrs Jennifer ‡	Mother of Michael
Binding, Ms J	Administrator, Corporate Affairs Intelligence Unit, NHS Management Executive, Department of Health
Bisgrove, Mrs Brenda ‡	Mother of David
Black, Dr Andrew ‡	Senior Lecturer in Anaesthesia, Sir Humphrey Davy Department of Anaesthesia, University of Bristol (since 1982)
Blight, Mr Mark ‡	Father of Jake
Boardman, Mr Stephen *‡	Management Consultant; Manager of District Planning Department, latterly Director of Planning and Estates, B&WDHA (1987–April 1991); Director of Corporate Development, UBHT (April 1991–July 1992)
Bolsin, Dr Stephen *‡	Consultant Cardiac Anaesthetist, BRI, Consultant Anaesthetist Bristol Eye Hospital and St Michael’s Hospital, Bristol (Sept 1988–1995)
Bond, Mr Douglas ‡	Father of Timothy
Booth, Mr William *‡	Grade G Charge Nurse, BRHSC (1990–1993); Clinical Nurse Co-ordinator, Royal Hospital for Sick Children, Glasgow (1993); Grade G Charge Nurse, Paediatric Intensive Care Unit, BRHSC (1993–1995); Clinical Nurse Manager, Paediatric Intensive Care Unit, BRHSC (since 1995)
Booth, Mrs Leonora ‡	Mother of Daniel
Booth, Ms Gail ‡	Mother of Elisa Marie
Bottomley, Rt Hon Virginia	MP; Minister for Health (1989–1992); Secretary of State for Health (1992–1995)
Boundy, Reverend Canon Neville ‡	Vicar (Canon) of Cotham Parish Church, retired 2000
Boyce, Mr Jonathan ‡	Director of Health Studies, Audit Commission (since 1994)
Boyland, Ms Amanda ‡	Mother of James

*‡ Those who gave oral evidence in addition to written evidence

† Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Bradley, Mr Paul *‡	Father of Bethan
Brain, Mrs Diane ‡	Mother of Ellie
Brant, Mr Graham ‡	Staff Nurse/Senior Staff Nurse, Ward 5B, BRI (March 1991–May 1993); Charge Nurse, Ward 5B, BRI (May 1993– January 2001)
Brawn, Mr William	Consultant Paediatric Cardiac Surgeon, Diana, Princess of Wales Hospital, Birmingham
Briggs, Mr Robert *‡	Father of Laura
Brokenshaw, Mr David ‡	Former Secretary, Children’s Heart Circle in Wales
Brooker, Ms Sally ‡	Mother of Richard
Brown, Mr Christopher ‡	Regional Principal, Regional Liaison Division, Department of Health (1990–1991); Corporate Affairs Unit (1991–1992); Deputy Head, Corporate Affairs Intelligence Unit (since 1992)
Browne, Reverend Peter ‡	Hospital Chaplain, BRI and Co-ordinator of Chaplaincy Volunteers (1996–1998)
Brownhill, Ms Josephine ‡	Mother of Daniel
Browse, Professor Sir Norman	President of Royal College of Surgeons of England (July 1992– 1995)
Bryan, Mr Alan *‡	Senior Lecturer in Cardiac Surgery, University of Bristol and Consultant Cardiac Surgeon, BRI (since July 1993)
Bryant, Mr Julian ‡	Father of Lee
Bull, Dr Kate	Medical Advisor to the Department of Nursing & Family Services, previously Honorary Consultant Paediatric Cardiologist, Great Ormond Street Hospital for Children NHS Trust
Bullimore, Dr Jill ‡	Consultant Clinical Oncologist, UBH/T (since 1978); Chair of Clinical Audit Committee (Jan 1995–1996)
Burgess, Mr Michael *‡	Honorary Secretary, Coroner’s Society of England and Wales (since 1993); HM Coroner for Surrey (since 1986)
Burman, Dr David	Chairman, Hospital Medical Committee Administrative Medical Officer, SWRHA
Burn, Father Leonard ‡	Chaplain to Bristol Central Hospitals (1981–1983)
Burr, Miss Sue *‡	Paediatric Nurse Adviser, Royal College of Nursing
Burroughs, Mr Paul	Child Psychotherapist, UBH/T
Burton, Dr Geoffrey ‡	Anaesthetist, BRI and BRHSC (1960–1991)
Burton, Mrs Linda *‡	Mother of David
Butchart, Mr Eric	Consultant Cardiothoracic Surgeon, University Hospital of Wales, Cardiff (c. 1986)
Bwye, Mr Douglas *‡	Father of Jason
Caddy, Mr Edward Donald	Chief Clinical Perfusionist, BRI (retired June 1994)

*‡ Those who gave oral evidence in addition to written evidence

† Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Cain, Dr ARR	Consultant Paediatrician, Royal United Hospital, Bath. Clinician who referred children to Bristol
Calman, Professor Sir Kenneth *‡	Chief Medical Officer for England (1991–1998)
Cameron, Mr Ewan ‡	Senior Assistant Director of Finance, UBHT (since 1992)
Campbell, Professor Michael *	Professor of Medical Statistics, The Northern General Hospital, University of Sheffield; Member of the Inquiry's Expert Group
Carlisle, Sir Michael *‡	Chairman, SRSAG (April 1989–October 1994)
Carroll, Mrs Jill‡	Mother of Sean
Carter, Mr Alan ‡	Information Technologist, Management Consultant; Manager of Information Technology, B&WDHA (1986–1991); Director of Information Technology and Assistant Director of Operations, UBHT (1991–1995)
Cawdrey, Dr JE	Consultant Paediatrician, Royal Gwent Hospital, Newport
Cermakova, Reverend Helena *‡	Anglican Hospital Chaplain (full-time), BRHSC and St Michael's Hospital, Bristol (since 1995)
Challacombe, Dr David	Consultant Paediatrician, Taunton and Somerset Hospital. Clinician who referred children to Bristol
Chamberlain, Dr D	Consultant Cardiologist; Chairman of the Cardiology Committee, Royal College of Physicians
Chambers, Dr TL	Consultant Physician, Southmead Hospital, Bristol (since 1990)
Chantler, Sir Cyril	Former Dean, United Medical and Dental Schools of Guy's and St Thomas's Hospitals; Chairman, Great Ormond Street Hospital for Children NHS Trust
Chapman, Mr Robert ‡	Father of Paolo
Chapple, Mrs Jane ‡	Mother of Laura
Charles, Father Bernard Michael ‡	Catholic Hospital Chaplain (part-time), BRI and BRHSC (1991–1996)
Charlton, Mr David ‡	Father of Hannah
Charlwood, Ms Pamela	Regional General Manager, SWRHA (1993-1994); Chief Executive, Avon Health Commission and Avon Health Authority (since 1994)
Chiarito, Mr Antonio ‡	Father of Maria
Chinnick, Ms Pauline ‡	Theatre Nurse, BRHSC (1983–1984); Junior Staff Nurse, Ward 5, BRI (1984–1985); Senior Staff Nurse, Ward 33, BRHSC (1986–1987); Paediatric ICU, BRHSC (1987); Sister Ward 33 (1987–1990); Senior Staff Nurse, Baby Unit, BRHSC (1990–1991); Night Sister, BRHSC (1991–2000)
Churchill, Mr John	National Health Service Executive South and West
Clarke, Mrs Caroline ‡	Mother of Joshua
Clarke, Lord Justice	Chair, Thames Safety Inquiry

*‡ Those who gave oral evidence in addition to written evidence

† Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Clarke, Rt Hon Kenneth	MP; Minister for Health, DHSS (1982–1985); Secretary of State for Health (1988–1990)
Clarke, Mr Peter	The Children’s Commissioner for Wales
Clarke, Mrs Tracey *‡	Mother of Melissa
Clement, Dr Alan ‡	Consultant in Anaesthesia, BRI (1968–1993)
Clifford, Mr Robert *‡	Head of the Coroners Section of the Animals, Bye-Laws and Coroners Unit, Constitutional and Community Policy Directorate, Home Office (since August 1995)
Coates, Dr David	BMA Place of Work Accredited Representative, UBHT
Colclough, Mr Peter ‡	District General Manager, Gloucestershire Health Authority (1990–1992); Chief Executive of Gloucestershire Health Authority (1992–1995)
Colclough, Mrs Carol ‡	Mother of Andrew
Cole, Mrs Jane ‡	Mother of Tanya
Coleman, Dr Eric ‡	President, Society of Cardiological Science & Technology
Collins, Father Francis	Catholic Hospital Chaplain (part-time), BRI and BRHSC (1981–1987)
Collins, Mr Tony *‡	Father of Alan
Cordery, Mrs Susan ‡	Mother of Louise
Coulter, Dr Angela	Chief Executive, Picker Institute Europe
Counsel to the Inquiry	Brian Langstaff QC, Eleanor Grey and Alan Maclean
Cowie, Ms Nicola ‡	Regional Clinical Audit Administrator, University of Bristol (1993–1994)
Crompton, Professor Gareth *‡	Chief Medical Officer for Wales (January 1978–August 1989)
Cronin, Dr AJ	Consultant Paediatrician, Scott Hospital, Plymouth. Clinician who referred children to Bristol
Crookes, Ms Stella ‡	Mother of Angus
Cross, Mr Andrew ‡	Industrial Relations Officer, British Medical Association (1993–1994)
Crowley, Ms Julie	See Julie Vass
Culverhouse, Mrs Edna ‡	Medical Social Worker responsible for Ward 5, BRI (1974-1983)
Cummings, Mrs Michelle *‡	Mother of Charlotte
Curnow, Mr Malcolm *‡	Father of Verity
Curnow, Mr Robert ‡	Emeritus Professor of Statistics, Department of Applied Sciences, University of Reading (from 1996); Member of the Inquiry’s Expert Group
Curnow, Mrs Sandra ‡	Mother of Laura and Rebecca
Currie, Mrs Edwina	Parliamentary Under Secretary of State (Health), DHSS/DoH (1986–1988)

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Cutter, Mrs Rowena ‡	Mother of Scott
Darbyshire, Mr Andrew *	Advanced Nurse Practitioner, Royal Liverpool Children's Hospital (since 1996); Member of the Inquiry's Expert Group
Darbyshire, Mr Kenneth and Mrs Susan *‡	Parents of Oliver
Darzi, Professor A	Professor of Surgery, School of Medicine, Imperial College, London
Davies, Dr Leslie G	Cardiologist, University Hospital Wales, Cardiff
Davies, Dr Ian ‡	Consultant Anaesthetist, BRI (since 1993)
Davies, Mr Philip ‡	Father of Aaron
Davies, Mrs Tanya ‡	Mother of Jonathan
Davies, Mr Timothy ‡	Father of Richard
Davis, Karlene	General Secretary, Royal College of Midwives (since 1997)
Davis, Mrs Phillipa ‡	Mother of Luke
Day, Dr Alan	Consultant Paediatrician, Cheltenham General Hospital, East Gloucestershire NHS Trust. Clinician who referred children to Bristol
de Leval, Professor Marc *‡	Professor of Cardiothoracic Surgery, Great Ormond Street Hospital for Children NHS Trust (since 1974)
Dean Hart, Mr John Christopher ‡	Consultant Ophthalmologist, UBHT (since 1970); Chairman, Hospital Medical Committee, B&WDHA/B&DHA (1990–1992); Medical Director, UBHT (1991–1992)
Deanfield, Professor John	Professor of Cardiology, Great Ormond Street Hospital for Children NHS Trust
Deverall, Mr Phillip	Consultant Paediatric Cardiothoracic Surgeon formerly Director and Head of the Department of Cardiothoracic Surgery at Guy's Hospital
Dhasmana, Mr Janardan *‡	Senior Surgical Registrar, UBH (1978–1985); Consultant in Cardiothoracic Surgery, BRI and BRHSC (1 January 1986–8 September 1998); Associate Clinical Director in Cardiac Surgery, UBHT (January 1993–October 1995)
Dieppe, Professor Paul	Dean, Faculty of Medicine, University of Bristol (1995–1997)
Dingwall, Professor Robert	Professor of Sociology, University of Nottingham
Disley, Ms Sheena *‡	Ward Sister, Ward 5B, BRI (1984–to date)
Dopson, Dr Sue	University Lecturer in Management Studies and a Fellow in Organisational Behaviour, Templeton College, Oxford (from 1994)
Dowling, Mrs Julie ‡	Mother of Laurie
Down, Mrs Samantha ‡	Mother of Daniel
Downes, Mr Richard ‡	Perfusionist, BRI (1992–1994), Chief Perfusionist, BRI (since 1994)
Downing, Mrs Caroline Anne ‡	Mother of Samantha

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Doyle, Dr Peter *‡	General Surgeon; Senior Medical Officer, Department of Health (from 1985); Medical Secretary, SRSAG/National Specialist Commissioning Advisory Group (from 1994)
Doyle, Dr RF	Chief Administrative Medical Officer, Pembrokeshire Health Authority
Duddridge, Mr Leonard	Hospital Porter, BRHSC (1983–1993)
Dunford, Mr Robin (Rhett) ‡	Childcare Social Worker, BRHSC (April 1990–April 1994); Social Worker responsible for Ward 5, BRI
Dunham, Ms Madeline	Principal Psychologist, UBH/T
Dunman, Ms Penny	Patient’s Advocate, Brighton Healthcare NHS Trust
Dunn, Professor Peter ‡	Emeritus Professor and Senior Research Fellow, University of Bristol
Durie, Mr Peter *‡	Chairman of UBHT (April 1991–June 1994)
Dussek, Mr Julien E ‡	Consultant Cardiothoracic Surgeon, Guy’s Hospital, President, Society of Cardiothoracic Surgeons of Great Britain and Ireland
Dymond, Ms Christine ‡	Mother of Paul
Dymond, Mr Nigel ‡	Father of Naomi
Eastwood, Mrs Justine *‡	Mother of Oliver
Eaton, Mrs Patricia ‡	Mother of Lian
Edwards, Mrs Janet ‡	Mother of Sophie
Edwards, Ms Marie *‡	Mother of Jazmine
Edwards, Dr P	Consultant Paediatrician, Clinical Director, Princess of Wales Hospital Bridgend. Clinician who referred children to Bristol
Elliott, Mrs Joyce ‡	Mother of Ben
Elliott, Mr Martin ‡	Consultant Cardiothoracic Surgeon, Great Ormond Street Hospital for Children NHS Trust (1985–2000)
Ellis, Mrs Christine ‡	Mother of Richard
Ellis (formerly Forrester), Ms Julia ‡	Mother of Richard
English, Sir Terence *‡	Consultant Cardiothoracic Surgeon; President, Royal College of Surgeons of England (1989–1992); Member of SRSAG (1990–1992)
Evans, Miss Amanda Jayne ‡	Mother of Joshua
Evans, Miss Deborah *‡	Inpatients Services Manager, BRI (1987–1989); Contracts and Quality Development Manager, B&WDHA (1990–1991); Director of Contract Management, B&DHA (1991–1996); Director of Commissioning, Avon HA (1996–1999); Geographical Director (Bristol), Avon HA (since 1999)
Evans, Dr Dewi R	Consultant Paediatrician, Singleton Hospital, Swansea. Clinician who referred children to Bristol
Evans, Mr J	Association of Welsh Community Health Councils
Evans, Dr R	Consultant Community Paediatrician, Scott Hospital, Plymouth. Clinician who referred children to Bristol.

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Evans, Professor Stephen *	Specialist in Epidemiology, Medicine Control Agency
Everest, Mr Graham	Project Co-ordinator/Administrator, SWRHA (1983–1986); Project Manager, SWRHA (1987–1989)
Fairhurst, Father John	Catholic Hospital Chaplain (part-time), BRI and BRHSC (1989–1990)
Falcone, Mrs Margaret ‡	Mother of Louie
Farndon, Professor John *‡	Professor and Head of Division of Surgery, University of Bristol, and Honorary Consultant Surgeon, UBH/T (since 1988)
Feloy, Mrs Josephine ‡	Mother of Jessica
Fenton, Dr Theo	Senior Registrar in Paediatric Nephrology, Southmead Hospital (1992–1994)
Ferguson, Dr SD	Consultant Paediatrician, Royal Gwent Hospital, Newport. Clinician who referred children to Bristol
Ferris, Mrs Rachel *‡	Associate General Manager, Rheumatology, Genito-urinary Medicine and Dermatology Directorate of Medicine, UBHT (1992–1993); Associate General Manager, Trauma & Orthopaedics and Accident & Emergency, UBHT (1993–1994); General Manager, Directorate of Cardiac Services, latterly General Manager of the Directorate of Cardiothoracic Services, UBHT (since 1994)
Fields, Mrs Patricia ‡	Nursing Officer, BRI (1977–1986); Operational Nurse (1990–1993); Directorate Nurse Advisory for Surgery (1992–1993); General Manager Anaesthetics (1993–1998); Professional Head of Nursing, BRI, Bristol General Hospital and Keynsham Hospital (1998–date)
Fitzgerald, Mrs Lisa ‡	Mother of Ben
Fleming, Professor Peter ‡	Consultant Paediatrician, BRHSC (1982–1996); Head of Division of Child Health, Department of Clinical Medicine, University of Bristol (since 1996)
Flook, Ms Shirley ‡	Mother of Oliver
Flynn, Mr Billy	National Health Service Executive
Forbes, Dr WR	Consultant Paediatrician, retired, Swansea
Ford, Mr Simon ‡	Father of Samuel
Forrest, Mr Paul *‡	HM Coroner for the District of Avon (since 1992)
Forrester-Wood, Mr Christopher	Consultant Thoracic Surgeon, Frenchay Hospital, Bristol
Forsythe, Mrs Sheila *‡	Mother of Andrew
Fowler, Rt Hon Sir Norman	Former Secretary of State for Health and Social Security 1981–1987
Fox, Mrs Lorraine ‡	Mother of Darryl
France, Sir Christopher ‡	Second Permanent Secretary, DHSS (May 1986–March 1987); Permanent Secretary, DHSS (March 1987–July 1988); Permanent Secretary, DoH (July 1988–February 1992)

*‡ Those who gave oral evidence in addition to written evidence

† Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Francombe, Mrs Susan *‡	Mother of Rebecca
Freeman, Dr Marie ‡	Acting Regional Medical Officer, Director of Service Planning and Assistant General Manager, SWRHA (1986–1988)
French, Dr TJ	Consultant Paediatrician, Taunton & Somerset Hospital, Taunton, formerly of Yeovil District Hospital. Clinician who referred children to Bristol
Fritchie, Dame Rennie	Chair of SWRHA/S&WRHA (1992–1996)
Frowen, Mr John ‡	Father of Michael
Fyfe-Williams, Mrs Susan ‡	Staff Nurse, BRI (1985); Ward Manager, The Glen, Bristol (1986–1991); Customer Relations & Employment Trainer/Staff Development Officer, UBHT (1991–1994); Staff Development Officer, UBHT (since 1995)
Gallivan, Professor Stephen	Director of Clinical Operational Research Unit, University College London; Member of the Inquiry's Expert Group
Gardner, Dr Freda ‡	Consultant Clinical Psychologist; British Heart Foundation Clinical Research Fellow, University of Bristol, (since 1993)
Garrett, Mr JA ‡	Director, Medical Equipment Management Organisation, UBHT (1995–to date)
Gear, Mrs Patricia ‡	Mother of John
Gerrish, Miss Janet ‡	Senior Nursing Officer, BRI (1975–1982); Director of Nursing Services, Central Unit (1982–1986); Hospital Manager, BRI (1986–1989); Planning Department, BRI (1989–1991)
Gibbons, Mr Jonathan ‡	Father of Jessica
Gibbs, Ms Carla ‡	Mother of Jamielee
Gibson, Dr Ronald	Consultant Cardiologist, Royal Brompton Hospital, London
Gilbertson, Dr N	Consultant Paediatrician, Royal Cornwall Hospital, Truro. Referring Clinician
Gillard, Mrs Deborah ‡	Mother of Christy
Godman, Dr Michael *‡	President, British Paediatric Cardiac Association (1997–2000)
Good, Mrs Angela ‡	Mother of Joseph
Goodwin, Dr A	Consultant Paediatrician and Neonatologist, Princess of Wales Hospital, Bridgend. Clinician who referred children to Bristol
Goodwin, Ms Mary	Cardiac Liaison Nurse, Great Ormond Street Hospital for Children NHS Trust
Gould, Dr Stephen *	Consultant Paediatric Pathologist, The John Radcliffe Hospital, Oxford; Member of the Inquiry's Expert Group
Gray, Sir Denis Pereira	President, Royal College of General Practitioners (1997–2000)
Gray, Mr John ‡	Manager of Legal Services, UBHT (since 1991); previously Administrator, Legal Services, B&WDHA

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Green, Professor Michael Alan *‡	Consultant Pathologist to the Home Office since 1965; Professor of Forensic Pathology, University of Sheffield (1980–1999)
Greenaway, Mrs Anthea ‡	Mother of Louise
Greenslade, Mr Ralph and Mrs Marilyn‡	Parents of Meirion
Gregory, Mr Peter *‡	Head of the Health Policy Division, the Housing, Health and Social Work Policy Group (1982–1986); Head of the Health Services Planning Division in the NHS Directorate in Wales (1986–1990), Director of the NHS in Wales (March 1994–1999)
Griffiths, Mr Colin and Mrs Gaynor ‡	Parents of Zara
Griffiths, Dr AD	Consultant Paediatrician, Nevill Hall Hospital, Abergavenny. Clinician who referred children to Bristol
Haggerty, Mrs Moira ‡	Mother of Matthew
Hale, Ms Kathryn ‡	Senior Nurse, BRHSC (October 1983–June 1989)
Hall, Mr Andrew ‡	Father of Laurence
Hall, Ms Alisa ‡	Staff Nurse, BRI (1986–1988); Staff Nurse, ICU, Royal United Hospital, Bath (1988–1989); Senior Staff Nurse, BRI (1990–1992); Staff Nurse, PICU, BCH (1994–1997); Senior Staff Nurse, PICU, BCH (since 1997)
Hall, Mr Michael ‡	Registrar of the Council of Professions Supplementary to Medicine
Hall, Mr Neil	Children's Heart Circle of Wales
Halliday, Dr Norman *‡	Head of Medical Policy Division, DoH (1984–1992); part time Senior Medical Officer, DoH (1992–1994); Medical Secretary, SRSAG (1983–1994)
Hallidie-Smith, Dr K	Cardiologist, retired, Hammersmith Hospital
Hallworth, Dr David	Consultant Anaesthetist, Royal Hospital for Sick Children, Glasgow; Member of the Inquiry's Expert Group
Ham, Professor Chris	Professor of Health Policy and Management, University of Birmingham (since 1992); Member of the Inquiry's Expert Group
Hamilton, Professor David ‡	Chairman, Executive Committee of SCS, University Department of Clinical Surgery, Edinburgh; Chairman of RCSE Working Party 1992
Hamilton, Mr Leslie *	Consultant Paediatric Cardiac Surgeon, The Freeman Hospital, Newcastle; Member of the Inquiry's Expert Group
Hammond, Dr Phillip *‡	GP; Columnist for the 'Express' and 'Private Eye'
Hancock, Miss Christine	General Secretary, Royal College of Nursing (1989–May 2001)
Harding, Ms Ann *	Acting Director, NHS Information Authority June–October 1999
Hargreaves, Dr Thomas ‡	Member of Regional Hospital Medical Advisory Committee (1987–1991)
Harral, Mr Vincent ‡	District Administrator, B&WDHA (c. 1976–March 1986)
Harrett, Dr D	Chief Administrative Medical Officer, Gwent Health Authority
Harris, Mrs Mary ‡	Mother of Sarah

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Harris, Samantha ‡	Mother of Kimberley
Harrison, Mr David ‡	Father of Andrew
Hart, Sir Graham *‡	Permanent Secretary, DoH (March 1992–November 1997)
Harvey, Mr Nicholas	MP for North Devon (since 1992)
Havenhand, Mrs Alison ‡	Mother of Victoria
Hawkins, Miss Catherine (CBE) *‡	Regional Nursing Officer, SWRHA (March 1984–December 1992); Regional General Manager, SWRHA (August 1984–December 1992)
Hawkins, Mr Donald ‡	HM Coroner for the District of Avon (1978–1992)
Hawkins, Mrs Janet *‡	Mother of Paul
Hayes, Dr Alison ‡	Consultant Paediatric Cardiologist, BRHSC (October 1993 – to date)
Healing, Mr Bill ‡	Principle Assistant Treasurer, Avon Health Authority (1975–1982); Finance Director, Frenchay Health Authority (1982–1991); Finance Director, B&DHA (1991–1996); Finance Director, Avon Health Authority (since 1996)
Henderson, Professor Andrew ‡	Professor Emeritus, Honorary Consultant Cardiologist, University of Wales, College of Medicine, Cardiff
Herborn, Mrs Mona ‡	Theatre Nurse, BRI (1980–1988); Sister in Cardiac Theatres (1988–1998)
Hill, Mrs Debra ‡	Mother of Thomas
Hill, Mrs Diana *‡	Mother of Jessica and James
Hill, Ms Joanne ‡	Mother of Ashleigh Rees
Hill, Mrs Marie ‡	Mother of Kate
Hine, Dame Deirdre ‡	Principal Medical Officer, then Deputy Chief Medical Officer, Welsh Office (1985–1988); Chief Medical Officer, Welsh Office (March 1990– 1997) Chair of the Commission for Health Improvement
Hine, Mr William and Mrs Phillipa ‡	Parents of Thomas
Hobden, Mr Paul ‡	Father of Ruth
Hodges, Dr IGC	Consultant Paediatrician, East Glamorgan General Hospital, Mid- Glamorgan. Clinician who referred children to Bristol
Hooper, Mr Andrew *‡	PAS Manager (April 1988–1991); Health Records Manager, BRI (1991–to date)
Hopla, Mrs Janet ‡	Mother of John
Hopla, John ‡	Son of Janet
Horner, Mr Richard ‡	Father of Gareth
Hosker, Mrs Barbara ‡	Mother of David
House, Mrs Belinda *‡	Mother of Ryan
Houston, Dr Alan *	Consultant Paediatric Cardiologist, Royal Hospital for Sick Children, Glasgow; Member of the Inquiry's Expert Group

*‡ Those who gave oral evidence in addition to written evidence

† Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Howard, Rebecca	Inquiry Panel Member, Director of Nursing, Alder Hey Children's Hospital, Liverpool
Howe, Rt Hon Lord Howe of Aberavon	Former Chancellor of the Exchequer (1979–1983), Foreign Secretary (1983–1989), Deputy Prime Minister (1989–1990)
Howell, Reverend A	Free Church Hospital Chaplain (part-time), BRHSC and St Michael's Hospital (1983–1993)
Hoyle, Mr Roger ‡	District General Manager, Exeter Health Authority (1989-1993); District General Manager, Exeter & North Devon Health Authority (1993-1994); Chief Executive, Liverpool Health Authority (since 1994)
Hoyle, Ms Sarah ‡	Assistant to Chief Nurse (1988–1991) UBH; General Manager of St Michael's Hospital (1991–1994) UBHT
Hughes, Dr David ‡	Consultant Paediatric Anaesthetist, UBH/T (since 1981)
Hughes, Professor IA	Professor of Paediatrics, Cambridge; formerly at the Department of Child Health, Cardiff
Hughes, Dr JNP	Chief Administrative Medical Officer, Mid-Glamorgan Health Authority
Humphrey, Professor Charlotte	Professor of Health Care Evaluation, Florence Nightingale School of Nursing and Midwifery, King's College London; formerly Senior Lecturer in Sociology, Royal Free and University College Medical School, University College London
Hunt, Mrs Paula ‡	Mother of Sara
Hunter, KR	Regional Advisor of the Royal College of Physicians
Hunter, Dr Stewart *‡	Consultant in Paediatric Cardiology, Academic Department of Cardiology, Freeman Hospital, Newcastle upon Tyne
Hurst, Mr Antony	Administrative Secretary of SRSAG (1983–1987)
Hutchinson, Ms Susie	Cardiac Liaison Nurse, Birmingham Children's Hospital
Hutchinson, Dr T	Consultant Community Paediatrician, Bath West Community NHS Trust. Clinician who referred children to Bristol
Hutter, Mr Jonathan ‡	Senior Registrar (1986–1989); Consultant Surgeon (since 1989)
Hutton, Dr Peter	Clinical Lecturer and Honorary Senior Registrar, Department of Anaesthesia, University of Bristol (1982–1986)
Irvine, Sir Donald *‡	President, GMC (since 1995)
Jackson, Mr Barry *‡	President, Royal College of Surgeons of England (since 1998)
Jackson, Mrs Louise ‡	Mother of Shaun
Jackson, Mr Peter ‡	Executive Director, Regional Outpost, NHS Management Executive (1990–1994)
Jacobs, Mr Leonard ‡	Father of Mark
James, Mrs Gail ‡	Mother of Craig
Jarman, Professor Sir Brian	Inquiry Panel Member and Emeritus Professor at Imperial College School of Medicine at St Mary's Hospital, London

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Jarvie, Reverend Michael (deceased)	Spiritual Advisor, UBH/T and Anglican Hospital Chaplain (full-time), BRI (c. 1992)
Jefferis, Mrs Helen ‡	Mother of Phillip
Jenkins, Mrs Liz *‡	Assistant General Secretary, Royal College of Nursing
Jenkins, Ms Susan ‡	Mother of Nathan
Jerrard, Ms	Medical Personnel Department, B&WDHA
Joffe, Dr Hyam *‡	Consultant Paediatric Cardiologist, BRHSC and BRI (since 1980); Clinical Director, Children's Services, UBHT (1990–1994)
Johnson, Mr Gerald ‡	Chief Executive, B&DHA (1992–1994)
Johnson, Mrs Helen *‡	Mother of Jessica
Johnson, Mrs Julie *‡	Mother of Max
Johnson, Dr Robert ‡	Consultant Anaesthetist, UBH/T (since 1975); Chairman of Division of Anaesthesia, BRI (1987–1990); Honorary Senior Clinical Lecturer, University of Bristol (since 1994)
Jones, Mrs Carol ‡	Mother of Lewis
Jones, Mrs Caroline ‡	Mother of Matthew
Jones, Mrs Jacqueline ‡	Mother of Damien
Jones, Ms Melanie ‡	Research Assistant, B&WDHA (1989–1990); Project Leader, Patient Survey Unit (1990–1994); Self-Employed Healer (since 1994)
Jones, Dr RH	Consultant Paediatrician, Medical Director, Princess of Wales Hospital, Bridgend. Clinician who referred children to Bristol
Jones, Dr RWA	Consultant Paediatrician, Derriford Hospital, Plymouth. Clinician who referred children to Bristol.
Jones, Dr Susan *‡	President, Association of Paediatric Anaesthetists of Great Britain and Ireland (until 1999)
Jones, Mr Trevor ‡	Father of Bethany
Jones, Ms Sue ‡	Staff Nurse, BRI (1984–1987); Registered Sick Children's Nurse (1988–1991); Night Sister, BCH (1991–1993); Sister, BCH (1993–1994); G Grade Nurse, BCH (1994–1995); Sister, BCH (1996–1998); Practice Development Nurse, UBHT (since 1998)
Jooman, Mr	District Statistical Officer, B&WDHA (1985–1991); Trust Information Manager, UBHT (1991–to date)
Jordan, Mrs Paula *‡	Mother of Joe
Jordan, Dr Stephen *‡	Consultant Paediatric Cardiologist, UBH/T (1969–May 1993)
Joyce, Mr Robert ‡	Father of Thomas
Kammerling, Dr RM	Public Health Physician, B&WDHA
Kapila, Miss Leela	President, British Association of Paediatric Surgeons
Keen, Mr Gerald ‡	Consultant Cardiothoracic Surgeon (until 1991)

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Keen, Professor Peter ‡	Dean, Faculty of Medicine, Bristol University (1993–1995)
Keeton, Dr Barry *	Consultant Paediatric Cardiologist, Southampton General Hospital; Member of the Inquiry's Expert Group
Kenealy, Mrs Dilys ‡	Mother of Gareth
Kennaird, Dr DL	Consultant Paediatrician, Torbay Hospital, Torquay. Clinician who referred children to Bristol
Kennedy, Professor Ian	Chairman of the Inquiry and Professor of Health Law, Ethics and Policy, School of Public Policy, University College London
Kennington, Mrs Diane *‡	Patient Affairs Officer, BRI (since 1983)
Keogh, Mr Bruce *‡	Consultant Cardiothoracic Surgeon, Queen Elizabeth Medical Centre, Birmingham; Secretary, Society of Cardiothoracic Surgeons of Great Britain and Ireland
Kesby, Ms Mary ‡	Staff Nurse, BRI (1987–2000)
Kift, Mrs Carol ‡	Mother of Steven
Laband, Dr John	Junior Doctor, BRHSC (Nov 1994–Jan 1995)
Langlands, Sir Alan *‡	Deputy Chief Executive, NHS Executive (1993–1994); Chief Executive, NHS Executive (1 April 1994–2000) Principal and Vice-Chancellor of Dundee University
Langston, Mr Robert ‡	Father of Oliver
Laszlo, Dr Gabriel ‡	Consultant in General and Respiratory Medicine, BRI; Chairman Elect, Hospital Medical Committee, UBHT (April 1992–1993); Deputy Chairman, HMC (April 1993–1994); Chairman, HMC (April 1994–April 1996)
Laurance, Mr Tony ‡	Regional Director, NHS Executive South and West
Lavin, Ms Mandie *‡	Director of Professional Conduct, UK Central Council for Nursing, Midwifery and Health Visiting
Lawler, Dr Paul *‡	Consultant Intensivist, South Keeble Hospital, Middlesborough; President, Intensive Care Society
Lawrence, Ms Audrey	Research Management Consultant, Lawrence Research
Le Var, Mrs Rita *‡	Director for Educational Policy, and Assistant Chief Executive, English National Board for Nursing, Midwifery and Health Visiting
Leape, Professor Lucian	Adjunct Professor, Harvard School of Public Health
Leeming, Mrs Alison ‡	Mother of Jamie
Lenton, Dr S	Consultant Community Paediatrician, Bath. Referring Clinician
Leonard, Mr Richard and Mrs Jayne ‡	Parents of Katherine (known as Katie)
Lewis, Mr Aubry	Father of Kirsty
Lightman, Mr Ivor	Deputy Secretary to the Welsh Office with responsibility for Health and Social Care (1981–1988)

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Littlepage, Dr BNC	Chief Administrative Medical Officer, West Glamorgan Health Authority
Lloyd, Dr Jennifer	Senior Medical Officer, Welsh Office
Lloyd, Mrs Lynne ‡	Mother of Kate
Lloyd, Mrs Mollie ‡	Foster Carer of Jackson Powell
Long, Mr Frank ‡	Kitchen Porter, Relief Porter, Auxiliary Nurse BRHSC, (c. 1984–1991); Head Porter/Portering Manager, St Michael’s Hospital, Bristol (1991–1994)
Loveday, Mr Robert and Amanda Evans	Parents of Joshua
Lunniss, Mr Richard *‡	Father of William
Lupini, Dr	Bristol General Practitioner. Clinician who referred children to Bristol
Lye, Mr David ‡	NHS Trust Unit, DoH (1989-1993)
Macfarlane, Ms Alison	Medical Statistician, National Perinatal Epidemiology Unit, Institute of Health Sciences, University of Oxford
MacIntosh, Mr Graham ‡	Social Worker, BRI (since 1984); Acting Team Manager, Social Work Department (1997–1998)
Maclean, Mavis	Inquiry Panel Member and Director of the Oxford Centre for Family Law and Policy, Oxford University
Macrae, Dr Duncan *	Consultant in Paediatric Intensive Care; Director of Paediatric Intensive Care, Royal Brompton Hospital; Member of the Inquiry’s Expert Group
MacSween, Professor Roderick ‡	Former President of the Royal College of Pathologists (1996–1999)
Maguire, Mrs Mary ‡	Mother of Rebekah
Maguire, Dr SA	Consultant Paediatrician, Royal Gwent Hospital, Newport. Clinician who referred children to Bristol
Maher, Mrs Janet‡	Shadow General Manager, Shadow Directorate of Medicine, UBHT (1989–1991); General Manager, Directorate of Medicine, UBHT (1991–April 1993); General Manager, Directorate of Surgery (April 1993–March 1998); General Manager, UBHT (March 1998–March 1999)
Maisey, Mrs Margaret *‡	South Unit General Manager and Nurse Adviser, B&WDHA (1986–1989); Central and South Unit General Manager and Nurse Adviser, B&WDHA (1989–1991); Director of Operations and Nurse Adviser UBHT (1991–1996); Director of Nursing (1996-1997) UBHT
Major, Rt Hon John	MP; Parliamentary Under Secretary of State for Social Security, DHSS (1985–1986); Minister of State for Social Security, DHSS (1986–1987); Prime Minister (1990-1997)
Mallone, Mr John *‡	Father of Josina (Josie)
Mandelson, Mrs Valerie *	Manager and Senior Counsellor, Alder Centre, Alder Hey Children’s Hospital, Liverpool; Member of the Inquiry’s Expert Group
Manfield, Ms Jennifer ‡	Mother of Brad

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Mann, Canon Charmion ‡	Anglican Hospital Chaplain, BRHSC and St Michael's Hospital UBHT (1985–1994)
Marr, Mrs Susan *‡	Director for Adult and Children's Nursing, English National Board for Nursing, Midwifery and Health Visiting
Marshall, Mr Paul ‡	Regional Principal for West Midlands & South Western Region, Regional Liaison Division, DoH (1988–1991)
Martin, Ms Geraldine ‡	Unit Administrator, Bristol Children's & Obstetrics Unit UBH (1984–1985)
Martin, Dr Peter	Consultant Paediatrician, (SHO, BRHSC 1988/89)
Martin, Dr Robin *‡	Consultant Paediatric Cardiologist, BRHSC (since 1989)
Martyr, Mrs Eileen ‡	Mother of Aaron
Mascie-Taylor, Dr Hugo	Medical Director, Leeds Teaching Hospitals NHS Trust
Masey, Dr Sally *‡	Consultant Anaesthetist, BRI (since May 1984)
Mason, Dr Alastair ‡	Regional Medical Officer / Regional Director of Public Health, SWRHA (April 1988–June 1994)
Matthes, Dr J	Clinical Director, Paediatrics, Singleton Hospital, Swansea. Clinician who referred children to Bristol
McClelland, Mr John	Forward Planning Officer, SWRHA (until 1990)
McCoy, Mr David ‡	Chairman of the Regional Hospital Medical Advisory Committee (1990–March 1994)
McKinlay, Mr Robert *‡	Chairman, UBHT (July 1994–November 1996)
McLorinan, Mr John *‡	Father of Joseph
McMullen, Dr S	Principal Medical Social Worker (Teaching), BRI (1975–1987); Social Work Team Manager, BRI (1987–1992)
McNinch, Dr AW	Consultant Paediatrician, Royal Devon & Exeter Hospital, Exeter. Clinician who referred children to Bristol
McNulty, Dr Terry	Leeds University Business School
McPherson, Professor Klim	Professor of Public Health Epidemiology, London School of Hygiene and Tropical Medicine; Member of the Inquiry's Expert Group
Meadows, Ms Karen ‡	Mother of Sarah
Milkins, Mr Graham ‡	Hospital Porter, BRHSC (1993–1994); Acting Head Porter, BRHSC (1994–1995); Head Porter, BRHSC (1995–1999)
Minnis, Reverend Will ‡	Free Church Hospital Chaplain (part time), BRI (1976–1995)
Monk, Dr Christopher *‡	Consultant Anaesthetist, BRI, Honorary Senior Lecturer, University of Bristol (January 1989–to date); Clinical Director of Anaesthesia (January 1993–December 1995)
Moore, Dr Roger ‡	Branch Head, NHS Executive (since 1997)
Moores, Dame Yvonne ‡	Chief Nursing Officer, DoH and Director of Nursing, NHS Executive (1992–1999)

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Morgan, Dr J	Consultant Paediatrician, East Glamorgan General Hospital, Mid Glamorgan. Clinician who referred children to Bristol
Morgan, Dr Keiran ‡	District Medical Officer, Southmead Health Authority (1985–1991); Director of Public Health, B&DHA (1992–1995); Director of Public Health, Avon Health Authority
Morgan, Mr Terence ‡	Father of Kelly
Morgan, Ms Tracey ‡	Mother of Daniel
Mortimer, Mr Geoffrey	Chairman of B&DHA ; Chairman of HMC
Mott, Dr Martin	Chairman of B&WDHA, Division of Children's Services
Muirhead, Dame Lorna	President, Royal College of Midwives (since 1997)
Murray, Professor Gordon *	Professor of Medical Statistics, University of Edinburgh
Nichol, Sir Duncan ‡	Chief Executive, NHS Management Executive (January 1989–March 1994)
Nicholson, Mr Eamonn ‡	Senior Clinical Perfusionist, BRI (1988–1994); Chief Clinical Perfusionist, BRI (1994– to date)
Nisbet, Ms Isabel	Head of Branch, Performance Management NHS Executive Directorate, Department of Health 1991–1994
Nix, Mr Graham *‡	Senior Assistant Treasurer / Associate Financial Manager (Acute), B&WDHA (1984–1987); Principal Assistant Treasurer / Financial Manager (Acute), B&WDHA (1987–1990); Treasurer, B&WDHA (1990–1991); Director of Finance, UBHT (since January 1991); Deputy Chief Executive, UBHT (since March 1993)
Noblett, Miss	Consultant Paediatric Surgeon, BRHSC
Norman, Mrs Alison	President, UKCC
Norman, Professor John	Department of Anaesthesia, University of Southampton
O'Donnell, Dr Michael ‡	General Practitioner and member of GMC 1971–1996
O'Keefe, Mr John ‡	Father of Daniel
Orchard, Ms Kathleen ‡	Administrator, Bristol Dental Hospital (1983–1986); General Manager, Bristol Eye Hospital (1986–1989); General Manager, Directorate of Surgery, UBHT (March 1991–February 1993); Director of Operations, FHSA (1994–1996)
Orme, Dr RL'E	Consultant Paediatrician, Exeter, Devon. Clinician who referred children to Bristol
Osborne, Professor J P	Consultant Paediatrician, Royal United Hospital, Bath. Clinician who referred children to Bristol
Owen, Mr John	Director, NHS in Wales (1985–1994)
Owen, Mr Steven *‡	Administrative Secretary, SRSAG (January 1992–February 1996)
Paget, Ms Susan ‡	Mother of Louise

*‡ Those who gave oral evidence in addition to written evidence

† Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Palit, Dr A	Consultant Paediatrician, Withybush General Hospital, Haverfordwest. Clinician who referred children to Bristol
Parker, Dr John	President, British Cardiac Society 1993–1995
Parr, Mr Anthony ‡	Deputy Treasurer, B&WDHA (1985–1987); Director of Finance B&WDHA (1987–1991)
Parsons, Mr Eric ‡	Regional Liaison Division – Yorkshire Region (1986–1989); Yorkshire Regional Health Authority (1989–1991); Desk Officer, Regional Liaison Division – South Western Region and Region Group Head for West Midlands, Oxford & Trent (1991–1993); Joint Health Care Directorate, Public Health
Parsons, Mr Michael *‡	Father of Mia
Passfield, Ms Helen	Hospital Play Therapist, BRHSC (1986–1994)
Pawade, Mr Ashwinikumar ‡	Consultant Paediatric Cardiac Surgeon, UBHT May 1995–2001 (since 1 May 1995)
Peach, Sir Leonard ‡	Director of Personnel, NHS Management Board (1985–1986); Acting Chairman, NHS Management Board (1986); Chief Executive, NHS Management Board (1986–1989)
Peacock, Ms Margaret	General Manager In-Patient Services, BRI
Peacock, Mrs Sharon ‡	Mother of Andrew
Pearson, Lord	Author of <i>The Royal Commission on Civil Liability and Compensation for Personal Report</i> . 1978
Penfold, Mrs Jennifer ‡	Mother of John
Pentecost, Mrs Lorraine *‡	Mother of Luke
Perham, Dr TGM	Consultant Paediatrician, Derriford Hospital, Plymouth. Clinician who referred children to Bristol
Perry, Mrs Susan ‡	Mother of Martin
Pheby, Dr D	Lecturer in clinical computing, Department of Public Health, Bristol University
Phillips, Mrs Fay ‡	Mother of Ryan
Pickering, Professor Brian ‡	Deputy Vice Chancellor, University of Bristol; Non-Executive Director, UBHT (1990–1998); Member of Bristol & Weston Health Authority (1988–1990)
Pike, Mrs Jaqui ‡	Mother of Michael
Pitman, Dr Marianne *‡	Specialist in Community Medicine / Consultant in Public Health Medicine, SWRHA (1980–1994); Consultant in Public Health Medicine, S&WRHA (April 1994–1996)
Plackett, Mrs Penelope *‡	Mother of Sophie
Player, Mrs Josephine ‡	Mother of Scott
Poloniek, Dr Jan	Lecturer in Statistics, St George's Hospital Medical School

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Porter, Mrs Alison ‡	Mother of Amy
Pottage, Mrs Erica *‡	Mother of Thomas
Powel, Mr Timothy ‡	Father of Jay
Powell, Mrs Bernadette ‡	Mother of Jessica
Pratten, Mrs Jean *‡	Justice of the Peace; founder Bristol & South West Children's Heart Circle, Secretary (1972–1989), Chairman (1989–1997)
Priestley, Mrs Kate ‡	Chief Executive, NHS Estates (since 1998)
Prince, Mr Leigh Kieran ‡	Patient who received surgery
Prophet, Dr	A Senior Medical Officer in Dr Halliday's division, Department of Health
Prosser, Dr R	Consultant Paediatrician, Royal Gwent Hospital, Newport. Clinician who referred children to Bristol
Pryn, Dr Stephen *‡	Consultant in Anaesthesia and Intensive Care, UBHT (since August 1993)
Prys-Roberts, Professor Cedric *‡	Professor of Anaesthesia, University of Bristol, and Honorary Consultant Anaesthetist, UBH/T (1976–1999); President, Royal College of Anaesthetists (June 1994–June 1997)
Pullan, Reverend M	Free Church Hospital Chaplain (part time), BRHSC and St Michael's Hospital (since 1993)
Purnell, Ms Jennifer ‡	Mother of Robert
Purvis, Mrs Marion ‡	Mother of Oliver
Pye, Reverend J	Free Church Hospital Chaplain (part time), BRHSC and St. Michael's Hospital (1988–1993)
Quinn, Dr M	Consultant Paediatrician, Royal Devon & Exeter Hospital, Exeter. Clinician who referred children to Bristol
Rainbow, Ms Carole ‡	Senior Sister, ITU (1981–1992); Staff Development Department (1992); Secondment to Director of Nursing/Operations, Trust Headquarters (1992–1997); Assistant Director of Nursing (1997–date)
Ratcliffe, Dr Jane *‡	Consultant in Paediatric Intensive Care; Honorary Secretary, Paediatric Intensive Care Society (1991–1998)
Rathbone, Mrs Jacqueline ‡	Mother of Brydie
Ravey, Mr David ‡	Chief Executive, Welsh National Board for Nursing, Midwifery and Health Visiting (since 1987)
Rayner, Sir Derek	Director, Marks & Spencer plc. The Prime Ministers Efficiency Adviser (early 1980s)
Reason, Professor James	Professor of Psychology, University of Manchester
Reith, Dr Bill *	Honorary Secretary of Council, Royal College of General Practitioners
Reed, Ms Alison	Cardiac Theatre Nurse, BRI
Rees, Dr Russell	Consultant Cardiologist, BRI
Rex, Mrs Brenda *‡	Mother of Steven

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Reynolds, Dr GM	Chief Administrative Medical Officer, East Dyfed Health Authority
Reynolds, Dr Martin ‡	Regional Medical Officer, SWRHA (1980–May 1984); Chief Medical Advisor / Assistant General Manager, SWRHA (May 1984–July 1986)
Richards, Professor Mike	Government’s National Cancer Director, Consultant Oncologist, Guy’s and St Thomas’ NHS Trust
Richardson, Ms Susan ‡	Mother of Ella
Rickard, Ms Helen *‡	Mother of Samantha
Riddette-Jones, Mrs Rosemary ‡	Mother of Luisa
Riddiford, Mrs Alison ‡	Nurse; Theatre Manager, BRI (1983–1986); Surgical Service Manager (General) (1986–1987)
Rizza, Ms Anna ‡	Mother of Marianna
Roberts, Mrs Carol ‡	Mother of Steven
Roberts, Dr Gareth ‡	Consultant Paediatrician (Community Child Health); Chairman, Avon Paediatric Committee
Roberts, Mr Paul *‡	Father of Andrew
Robinson, Ms Penelope ‡	Director of Professional Affairs, Chartered Society of Physiotherapists
Robinson, Mrs Susan ‡	Mother of Amanda (known as Mandy)
Ross, Mr Hugh *‡	Chief Executive, UBHT (since October 1995)
Ross, Sir Keith ‡	Consultant Cardiac Surgeon, founded Society of Cardiothoracic Surgeons of Great Britain and Ireland (1988–1989), Fellow of Royal College of Surgeons of Edinburgh, retired 1990
Rossi, Father Claudio	Catholic Hospital Chaplain (part time), BRI and BRHSC (1989–1990)
Rowlandson, Dr P	Consultant Paediatrician, Princess Margaret Hospital, Swindon. Clinician who referred children to Bristol
Roylance, Dr John *‡	Clinical Lecturer in Radiology, University of Bristol (1964–October 1995); Consultant Radiologist, BRI (1964–January 1985); District General Manager, B&WDHA (1985–March 1991); Chief Executive, UBHT (1 April 1991–October 1995)
Rudd, Dr PT	Consultant Paediatrician, Royal United Hospital, Bath. Clinician who referred children to Bristol
Rudge, Mrs Linda ‡	Mother of Danyeale
Rundle, Mrs Sandra ‡	Mother of Matthew
Russell, Dr Graham ‡	Senior Registrar, Bristol Histopathology Rotation (including Bristol Maternity Hospital, Southmead Hospital, BRI & Frenchay Hospital) (1986–1991); Consultant in Histopathology and Cytology, Kent & Wessex Trust (1991–1994); Head of Histology, Pemby Hospital (since 1994)
Sadler, Mrs Helen ‡	Mother of Edward

*‡ Those who gave oral evidence in addition to written evidence

† Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Sainsbury, Dr C	Consultant Paediatrician, Torbay Hospital, Torquay. Clinician who referred children to Bristol
Salisbury, Dr AJ	Consultant Paediatrician, Princess Margaret Hospital, Swindon. Clinician who referred children to Bristol
Salmon, Miss Lesley *‡	Associate General Manager, Cardiac Services (September 1991–1993); General Manager, Cardiac Services (October 1993–October 1994); General Manager of Obstetrics, Gynaecology and ENT, St Michael’s Hospital, Bristol (since October 1994)
Samuel, Mr Patrick ‡	Father of Elizabeth
Saunders, Mrs Barbara ‡	Mother of David
Savage, Mrs Yvonne ‡	Scrub/Theatre Nurse, BRHSC (since 1981)
Scallan, Dr Michael	Consultant Anaesthetist, Royal Brompton Hospital; Member of the Inquiry’s Expert Group
Sally, Dr Gabriel	Director of Public Health, South & West NHS Executive (since 1996)
Scott, Mr Finlay	Chief Executive and Registrar, GMC (since July 1994)
Scott, Ms Lindsay	Director of Nursing, UBHT (since 1997)
Selway, Kathy	Successor to the conflated posts of Miss Stratton and Mrs Vegoda – Cardiac Liaison Nurse (since 1996)
Sethia, Mr Babulal	Consultant Paediatric Cardiac Surgeon, Birmingham Children’s Hospital and Royal Brompton and Harefield Hospitals NHS Trust; Member of the Inquiry’s Expert Group
Shaw, Dr Charles ‡	Member, Medical Audit Committee, BRI (January 1993–1996)
Sheridan, Mrs Ellen *‡	Mother of John
Sherriff, Ms Barbara ‡	Nursing Officer / Clinical Nurse Manager / Unit Manager, BRHSC (1981–1991); Service Development Manager, BRHSC (1991–1992); Assistant General Manager BRHSC (since 1992)
Sherwood, Mr Louis ‡	Non-Executive Director, UBHT (1 April 1991–November 1998)
Shinebourne, Dr Elliott	Paediatric Cardiologist, Royal Brompton Hospital, London
Shipley, Mrs Phillipa *‡	Mother of Amalie
Short, Dr Donald ‡	Consultant Anaesthetist UBH/T, retired (1969–1993); Chairman, Department of Anaesthesia (1981–1983)
Shortis, Mrs Maria *‡	Mother of Jacinta
Silcox, Mrs Lisa ‡	Mother of Hannah
Silverton, Louise ‡	Royal College of Midwives
Silove, Dr Eric *	Consultant Paediatric Cardiologist, Diana, Princess of Wales Hospital, Birmingham (retired 2001); Member of the Inquiry’s Expert Group
Simmonds, Mr Philip ‡	Father of Christopher
Simons, Jean	Head of Bereavement Services, Great Ormond Street Hospital for Children NHS Trust

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Simpson, Dr Jenny ‡	Chief Executive, British Association of Medical Managers
Skelton, Mrs Janet ‡	Mother of Justin
Skinnard, Mrs Janet ‡	Mother of Samuel
Skone, Dr JF	Chief Administrative Medical Officer, South Glamorgan Health Authority
Smith, Dr Anthony ‡	Chief Executive of the English National Board for Nursing Midwifery and Health Visiting
Smith, Mrs Gillian ‡	Mother of Andrew
Smith, Judith	Fellow at the Health Services Management Centre, University of Birmingham
Smith, Dr LDR	Consultant Cardiologist, Royal Devon & Exeter Hospital, Exeter. Clinician who referred children to Bristol
Smith, Mrs Lesley ‡	Mother of Katherine
Smith, Mr Patrick ‡	Social Worker responsible for Ward 5, BRI (February 1987–November 1988)
Spicer, Mrs Brenda *‡	Mother of Gary
Spiegelhalter, Dr David *	Senior Scientist, MRC Biostatistics Unit, University of Cambridge and Member of the Inquiry's Expert Group
Stacey, Mrs Janet ‡	Mother of Lisa
Stansbie, Dr David ‡	Consultant Chemical Pathologist, B&WDHA/BRI (since 1988); Vice Chairman, UBHT Medical Audit Committee (1990–1994)
Staples, Ms Joanna ‡	Mother of Amy
Stark, Mr Jaroslav *	Consultant Cardiothoracic Surgeon, Great Ormond Street Hospital for Children NHS Trust; Member of the Inquiry's Expert Group
Steel, Mrs Clare ‡	Mother of Jonathan
Stevens, Dr D	Consultant Paediatrician, Gloucestershire Royal Hospital. Clinician who referred children to Bristol
Stirrat, Professor Gordon ‡	Professor of Obstetrics and Gynaecology, University of Bristol, and Honorary Consultant in Obstetrics and Gynaecology, UBHT (1982–2000); Chairman, Division of Obstetrics and Gynaecology, UBHT (1988–1990)
Stokes, Ms Penelope ‡	Mother of Adam
Stone, Mr Ian ‡	District Personnel Manager, B&WDHA (1982–1985); District Manpower Manager, B&WDHA (1986–1991); Director of Personnel, UBHT (since 1 April 1991)
Stone, Ms Vivian ‡	Non-Executive Director, UBHT (1991–1996)
Stoneham, Miss Marion ‡	Acting General Manager, South Unit, B&WDHA (October 1985–February 1986); Manager, Children's and Obstetric Sub Unit, B&WDHA (February 1986–1990)
Stratton, Miss Helen *‡	Cardiac Liaison Nurse, UBH/T (November 1990–February 1994)

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Stribling, Mr Kenneth ‡	Father of Kelly
Strunin, Professor Leo *‡	President, Royal College of Anaesthetists, since 1997
Sturdy, Mr John ‡	Father of Reuben
Sturman, Mrs Heather ‡	Mother of Rebecca
Suckling, Mrs Sandra ‡	Mother of Jason
Sullivan, Ms Jean ‡	Mother of Lee
Sullivan, Mr Tony ‡	Hotel Services Manager, St Michael's Hospital and BRHSC (since 1996)
Sumner, Dr Ted	Consultant Anaesthetist, Great Ormond Street Hospital for Children NHS Trust, NHS Trust member of the Inquiry's Expert Group
Sutherland, Professor George	Cardiologist, Southampton General Hospital (1983–1987)
Swanton, Dr Howard *‡	President, British Cardiac Society
Tarantino, Mrs Sharon *‡	Mother of Corinna
Taylor, Dr GP	Consultant Paediatrician, Royal Cornwall Hospital, Trillick, Truro. Clinician who referred children to Bristol
Taylor, Professor K	Consultant Cardiothoracic Surgeon, Hammersmith Hospital
Thomas, Mrs Alison *‡	Mother of Dafydd
Thomas, Mrs Fiona *‡	Senior Staff Nurse, Ward 5, BRI (May 1986–May 1988); Sister, Ward 5B, BRI (May 1988–October 1992); Acting Clinical Nurse Manager (November 1992–October 1993) UBHT; Clinical Nurse Manager of Cardiac Surgery (November 1993–December 1996) UBHT
Thomas, Sister Julia ‡	Sister in charge of Cardiac Surgery ICU UBH (1982–1988); Clinical Nurse Manager of Cardiac Unit UBH/T (1988–1992)
Thomas, Dr Trevor *‡	Chairman of District Audit Committee, B&WDHA/Chairman of Medical Audit Committee UBHT (1991–1993); Consultant Anaesthetist, UBH/T (1972 to date); Associate Director of Obstetric Anaesthesia, UBHT (1991–1998)
Thompson, Ms Linda ‡	Mother of Jody
Thorn, Mrs Mary ‡	Mother of Richard
Thorne, Dr Marie *‡	Head of the School of Organisational Behaviour, Bristol Business School, University of the West of England
Thorp, Mr Jeremy ‡	NHS Executive South West Regional Office
Tilley, Mrs Kathleen ‡	Mother of Lauren
Todd, Lord AR	Author of the Todd Report 1968 on medical education
Treasure, Professor Tom	Consultant Cardiothoracic Surgeon, St George's Hospital, London
Tripp, Dr John H	Consultant Paediatrician and Senior Lecturer in Child Health, Royal Devon & Exeter Hospital NHS Trust. Clinician who referred children to Bristol
Turvey, Mrs Jennifer ‡	Mother of Kate

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Tyrrell, Dr J	Consultant Paediatrician, Royal United Hospital, Bath. Clinician who referred children to Bristol
Underwood, Ms Betty	Representative, Joint Trade Union Committee, B&WDHA
Underwood, Dr Susan *‡	Consultant Anaesthetist, UBHT (October 1991–to date)
Vann Jones, Professor John *‡	Consultant Cardiologist, BRI (1982–to date); Clinical Director for General Medicine (1989–October 1993); Clinical Director of Cardiac Services (October 1993- Spring 1996) Honorary Professor, University of Bristol (1993–to date)
Vardulaki, Ms Katerina	Research Fellow, Health Services Research Unit, London School of Hygiene and Tropical Medicine
Vas Falcao, Dr G	Consultant Paediatrician, Withybush General Hospital, Haverfordwest. Clinician who referred children to Bristol
Vass, Mrs Julie (formerly Crowley)	Assistant General Manager, BRHSC (1994–to date); Line Manager to Helen Vegoda
Vegoda, Mrs Helen *‡	Counsellor in Paediatric Cardiology, UBH/T (January 1988– September 1996); Counsellor in Child and Family Support, BRHSC (1996–to date)
Verrier Jones, Dr R	Consultant Paediatrician (retired), Llandough Hospital, Penarth, South Glamorgan. Clinician who referred children to Bristol
Vickery, Mr John	Representative, Joint Trade Union Committee, B&WDHA
Vincent, Professor Charles	Director, Clinical Risk Unit, University College London member of the Inquiry's Expert Group
Vulliamy, Dr CB	Consultant Paediatrician, Breconshire War Memorial Hospital, Powys. Clinician who referred children to Bristol
Wagstaff, Mr Phillip *‡	Father of Amy
Waite, Mrs Anne *‡	Mother of Caroline
Wakley, Sister Constance †	Sister, Cardiac Catheter Unit, BRHSC (1987 to date)
Waldegrave, William	MP for Bristol West (1979–1997); Secretary of State for Health (1990–1992)
Walker, Professor Frederick †	Chairman, Pathological Society of Great Britain & Ireland (1992–2000)
Walker, Mr Paul	Consultant Physician and Adult Cardiologist, UBHT
Walker, Mrs Rosemary †	Mother of Ryan
Wallace, Ms Diane †	Mother of Arron
Walshe, Dr Keiran *‡	Senior Research Fellow, Health Services Management Centre, University of Birmingham; Member of the Inquiry's Expert Group
Warburton, Mrs Susan †	Mother of Sam
Ward, Dr P	Consultant Paediatrician, Derriford Hospital, Plymouth. Clinician who referred children to Bristol
Warr, Mr	Maintenance Manager, UBH/T

*‡ Those who gave oral evidence in addition to written evidence

† Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Warren, Ms Catherine ‡	Nurse, Ward 5B, BRI, (1984–1995); now Senior Staff Nurse, Paediatric ICU, BRHSC
Watson, Christine	President, Royal College of Nursing October 1998–October 2000
Watson, Mr John ‡	General Manager, Central Unit, B&WDHA (1986–1989); Chief Executive Avon Family Health Service Authority (1990–1996)
Weaver, Dr C	Consultant Paediatrician (retired), University Hospital of Wales, Cardiff. Clinician who referred children to Bristol
Webb, Anthony John	Senior Research Fellow, Department of Surgery, University of Bristol, Consultant Surgeon UBH 1967–1994
Webb, Dr MSC	Consultant Paediatrician, Gloucestershire Royal Hospital. Clinician who referred children to Bristol
Webb, Mrs Sylvia ‡	Mother of Jamie, Katie and Martin
Webb, Father William	Catholic Hospital Chaplain (part time), BRI and BRHSC (1988)
Webber, Mrs Clare ‡	Mother of Zack
Webster, Dr M	Consultant Paediatrician, Taunton & Somerset Hospital, Taunton. Clinician who referred children to Bristol
Welby, Ms Karen *‡	Mother of Jade
Welch, Reverend Bill	Free Church Hospital Chaplain (part time), BRI (1995–1997)
Wells, Mrs Caroline ‡	Deputy Administrator, BRI (1979–1985)
Whitfield, Dr M	GP Representative, UBHT's Medical Audit Committee (1991–1993)
Whiting, Ms Alison	ITU/Theatre Service Manager, BRI
Whiting, Ms Belinda ‡	Mother of Sophie
Whitney, Faerlyn ‡	Staff Nurse at BRHSC 1976–1991
Whitmore, Mrs Sandra ‡	Mother of Mark
Wigley, Mrs Janice ‡	Mother of Cassian
Wilcox, Mrs Janice ‡	Mother of Lewis
Wilde, Dr Peter ‡	Consultant Cardiac Radiologist, BRI (1982 and current); Associate Clinical Director of Cardiology, BRI (December 1995–May 1996); Joint Clinical Director of Cardiac Services (June 1996–August 1996); Clinical Director of Cardiac Services (September 1996–2000)
Wilkins, Ms Sheila ‡	Audit Assistant, Directorate of Surgery, BRI (1991–1993)
Wilkinson, Mrs Mary ‡	Mother of Sara Jane
Willatts, Dr Sheila ‡	Consultant in Anaesthesia and Intensive Care Medicine, BRI, and Consultant in Charge of ICU, UBH/T (since 1985)
Williams, Ms Carol *	Clinical Nurse Specialist, Guy's and St Thomas's NHS Trust member of the Inquiry's Expert Group
Williams, Mr Clive ‡	Father of Jamie
Williams, Mr John ‡	Father of Melanie

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Williams, Dr N Brian ‡	Consultant Anaesthetist, BRI (since 1977); Chairman of Division of Anaesthesia, UBH/T (1990–1992); Shadow Clinical Director, Department of Anaesthesia, UBH (1990–1991) Clinical Director, Department of Anaesthesia UBHT (1991–1992)
Williams, Mr RC	Assistant Director, Health Services Division, Welsh Office
Williams, Dr T	Consultant Paediatrician, Nevill Hall Hospital, Abergavenny. Clinician who referred children to Bristol
Williamson, Ms Linda	Contract Manager, B&DWHA
Willis, Mr Stephen and Mrs Michaela *‡	Parents of Daniel
Willmer, Mr Richard *‡	Head of Branch and a Chief Statistician in the Statistics Division, DoH (since 1991)
Wilson, Mr Arthur	Regional Treasurer, SWRHA (1984–August 1993); Acting Regional General Manager, SWRHA (December 1992–1993)
Wiltshire, Ms Lorna ‡	Nursing Officer, BRI (January 1979–April 1981); Night Nursing Officer, BRI (April 1981–April 1990); Nurse Manager, Cardiac Unit (1990); Assistant Manager in General Surgery (1990–1993)
Wingfield, Mrs Anne ‡	Mother of Benjamin
Winyard, Dr Graham ‡	Regional Director of Public Health, Wessex Regional Health Authority, and Senior Principal Medical Officer, DoH (1990–1993); Medical Director, NHS Executive, and Deputy Chief Medical Officer (1993–1998)
Wisheart, Mr James *‡	Cardiac Consultant, retired, UBH/T 1975–1995; Associate Clinical Director for Cardiac Surgery (October 1990–1992); Chairman, HMC (1992–1994); Medical Director, UBHT (April 1992–1994)
Witts, Miss Jacqueline ‡	Mother of Daniel
Wolf, Dr Andrew ‡	Paediatric Anaesthetist, UBHT
Wong, Mrs Stephanie ‡	Mother of Kin-Fei
Wood, Mrs Theo	Public Relations Officer, B&WDHA/UBHT (1987–1996)
Woodcraft, Ms Joyce Marian *‡	Nurse, BRHSC (1977–1994); Senior Sister, ICU, BRHSC (1985–1994)
Woolley, Mr John Moger ‡	Non-Executive Director, UBHT (1 April 1991–October 1993)
Yacoub, Professor Sir Magdi	British Heart Foundation Professor of Cardiothoracic Surgery, National Heart and Lung Institute, Royal Brompton Hospital, London (since 1986); Consultant Cardiothoracic Surgeon, Harefield Hospital, Middlesex (since 1969)
Yates, Professor John	Director of Inter-Authority Compendium & Consultancy, Health Services Management, University of Birmingham
Yeomans, Reverend Robert ‡	Spiritual Advisor, UBHT and Anglican Hospital Chaplain (full time), BRI (since 1993)
Zorab, Dr John ‡	Consultant Anaesthetist, Frenchay Hospital, Bristol (1966–1996); Medical Director, Frenchay Hospital, Bristol (retired)

*‡ Those who gave oral evidence in addition to written evidence

‡ Those who gave written evidence, in the form of a formal written statement, only

* Those who gave oral evidence only

Appendix 3: Guide to the Annexes of the Final Report

There are four Annexes to the Final Report. They are included on the CDs which accompany the Report. This is a selective guide to the contents of each of the Annexes

Annex A

Chapter 1: Background to and Conduct of the Public Inquiry

- The Terms of Reference
- The powers of the Inquiry
- The Inquiry Panel
- Secretary to the Inquiry and Secretariat
- The Solicitor to the Inquiry
- Counsel to the Inquiry
- The Preliminary Hearing and the call for evidence
- Early contact with participants
- The Issues List
- The Bristol office and the hearing chamber
- Design of the hearing chamber
- Public facilities
- The media
- Documentary evidence
- Witness statements
- Other possible witnesses
- The Expert Group

The information technology systems:

- Background
- Office systems
- Hearing chamber
- Transmission of proceedings to other locations

Commissioned work:

- The Clinical Case Note Review (CCNR)

Phase One hearings:

- Oral evidence
- The Panel's visit to the BRI and BRHSC

Phase Two Seminars

Preparation of the Final Report:

Structure of Annex A

Structure of Annex B

Annex C

Annex D

Chapter 2: A Historical Introduction

The creation of the National Health Service

The NHS from 1948 to 1974

The NHS 1974–1984

Main events, 1984–1996

Conclusion

Chapter 3: Developments in the UK in the Diagnosis and Treatment of Congenital Heart Abnormalities in Children, 1984–1995

The perspective of children with congenital heart disease

Diagnosis and initial assessment:

Echocardiography

Doppler echocardiography

Colour-flow mapping of Doppler echocardiography

Transoesophageal echocardiography

Cardiac catheterisation

Management strategies

Post-operative care:

The cardiac nurse

Long-term post-operative management

The specific heart abnormalities and procedures referred to in the Inquiry:

The normal heart

The heart with a congenital abnormality

Coarctation of the Aorta

Atrial Septal Defect (ASD)

Ventricular Septal Defect (VSD)

Complete Atrio-Ventricular Septal Defect (CAVSD)

Truncus Arteriosus

Tetralogy of Fallot

Transposition of the Great Arteries (TGA)

Total Anomalous Pulmonary Venous Drainage (TAPVD)

The Fontan procedure

Chapter 4: National Accountabilities and Roles

The National Framework: responsibilities for healthcare:

- Lines of reporting
- The CMO and the NHS Executive
- The role of the CMO (Wales)
- The role of the Welsh Medical Committee
- Links between the Welsh Office and the DoH
- The influence of DoH policy on the Welsh Office
- Perceptions and responsibility
- The Performance Management Directorate
- The Clinical Outcomes Group
- Changes since the period of the Inquiry's Terms of Reference

National regulatory and professional bodies:

- Professional regulation — medicine: the GMC
- Professional regulation — nursing: the UKCC
- Issues common to regulation of doctors and nurses (and others)
- Movement in attitudes and published guidance
- Nursing — National Boards for Nursing, Midwifery and Health Visiting: statutory basis and functions
- Royal Colleges
- Educational training standards — proposals for change
- The Colleges' role and responsibility for setting and monitoring standards of care
- Specialist associations

Trade unions of healthcare professionals:

- British Medical Association (BMA)
- Employment contracts

Summary of respective roles of bodies concerned with standards and their implementation

Continuing professional development (CPD):

- CPD as a professional obligation
- GMC
- Royal Colleges
- Revalidation

Chapter 5: Regional, District and Trust Management

Brief chronology of the main events

Statutory framework:

- Introduction
- Establishment of regional and district health authorities
- The regional health authority
- South Western Regional Health Authority 1981 — 31 March 1994
- South and West Regional Health Authority — 1 April 1994 to 31 March 1996

Avon Health Authority — 1 April 1996

The district health authority

Bristol & Weston District Health Authority — 2 April 1982 to 30 September 1991

Bristol & District Health Authority — 1 October 1991 to 31 March 1996

NHS trusts

Management structures throughout the period in question:

The South Western Regional Health Authority (SWRHA)

Managerial relationships with the Department of Health

Managerial relationships with the district health authorities

The Regional Hospital Medical Advisory Committee (RHMAC)

Other channels of communication within the Regional Health Authority

The Bristol & Weston District Health Authority (B&WDHA)

Transition of the Bristol & Weston District Health Authority (B&WDHA)
into the Bristol & District Health Authority (B&DHA)

Provider functions taken on by the UBHT

Targets

The relationship between district health authorities and the UBH and UBHT

Staffing and contracts of employment

Chapter 6: Funding and Resources

The allocation of resources:

The distribution of healthcare funds to the regional health authorities

'Top-sliced' funding

Revenue allocation

Capital allocations and capital charges

The pattern of funding in England

Allocations to the South Western Regional Health Authority

The distribution of funds by the Region to district health authorities

The supra regional and regional services: 1984–1990

Revenue allocations

Private funding

Management of funding by the District prior to 1991

UBHT's funding after 1991:

Capital funding after 1991

The budget-setting process after 1991

The delegation of budgetary control after 1991

Funding for paediatric cardiac services (PCS)

Contracts for cardiac services

Supra regional funding for the under-1s:

- The process of contracting
- The effect of the cessation of supra regional funding
- The financial management of the budget for paediatric cardiac surgical services, 1984–1990

Resources:

- The relation between funding and clinical services
- Cardiac surgery and cardiological services at the BRI
- The status of paediatric cardiac surgical services in Bristol
- Resources for neonatal work
- Strains on resources more generally
- Beds
- Nursing staff and sessions for cardiac surgery
- Equipment
- Disruptions in service
- Increasing the number of anaesthetists and surgeons

Chapter 7: Supra Regional Services

Summary and chronology

The national framework:

- Rationale for supra regional funding
- The administration of supra regional services: Supra Regional Services Advisory Group (SRSAG)

NICS as a supra regional service (SRS)

Developments in Wales until the designation of NICS as a supra regional service:

- The development of a paediatric cardiac service in Wales
- The Working Party report of 1981

The SRS system in operation:

- Bristol in the SRS system 1984/85
- Plans for the new Welsh Cardiac Unit and its effect on supra regional services (SRS)
- Continued designation of NICS
- De-designation of NICS

Monitoring of quality:

- The information collected by and available to the SRSAG
- The number of neonatal and infant open-heart operations at Bristol
- The encouragement/strengthening of the Bristol Unit
- The inability to control ‘proliferation’

Chapter 8: Management and Culture of the UBH and UBHT

- Dr Roylance's overview
- General management

The purchaser-provider split and the establishment of the UBHT:
Internal opposition to trust status

The development of the clinical directorate structure:

- The role of the clinical director
- The relationship between the clinical directors and the general manager — 'the managerial bubble'
- How did cardiac services fit into the management structure?
- Dr Roylance's key management concepts
- Bristol's management culture
- Oral culture
- Club culture
- Light touch from the centre
- The role of the UBHT Medical Director
- Mrs Margaret Maisey's dual role
- Mrs Maisey as Director of Operations
- Mrs Maisey's nursing responsibilities
- The role of the Trust Chairman
- The role of the non-executive directors
- Pathways for expressing concern
- The relationship between academics at the University of Bristol Medical School and the UBHT clinicians

The management of the UBHT under the leadership of Mr Ross

Chapter 9: The Split Service

- Location of relevant Bristol hospitals
- Bristol Royal Infirmary
- Comments by those outside the Bristol service
- Comments by referring paediatricians
- Comments by those providing support and counselling
- Comments by parents/patients
- Staffing levels
- Transfer of children between the BRI and the BRHSC
- Comments by the UBHT
- Comments by clinicians in Bristol
- Comments by those involved in management and finance on the split site
- Comments by the Trust Board

Chapter 10: Outreach Cardiology Clinics

- The concept of outreach clinics
- Clinics in the South West and South Wales
- Conduct of the clinics
- The involvement of local clinicians
- The involvement of surgeons

Chapter 11: Referrals

Referrals to Bristol – referral procedure, the catchment area and finance:

- Referrals to Bristol — information available to referring clinicians about standards at Bristol or elsewhere and factors influencing referral patterns
- Sources of information available to referring clinicians
- The role of the referring clinician
- Evidence of influence on referral patterns
- Relationships with the cardiologists
- Contracts
- Geographical convenience
- Supra regional status
- Established pattern
- Down's syndrome
- The split service/site
- Waiting lists
- Awareness of standards at Bristol
- Concerns about the standards at Bristol
- Information provided to parents/choice of treatment centres
- Referrals from Plymouth
- Referrals from Yeovil
- Referrals to Bristol from South Wales
- The catchment area
- Funding of referrals from Wales
- Evidence of influences on patterns of referral from South Wales
- Funding and resources pre-1991
- 1991 onwards
- Referral to cardiologists
- Evidence of the actual pattern of referrals from South Wales
- Concerns
- Parents' requests

Referrals to other centres by Bristol cardiologists and surgeons:

- Referral procedure and reasons for referral
- Evidence of referrals from Bristol to other centres
- Parents' request for a referral to another centre
- A second opinion
- Previous death of another child
- Previous operation at another hospital
- Waiting list

Chapter 12: Waiting Lists

- National guidelines
- Waiting lists at Bristol
- Explaining the waiting list
- Volume of cases
- Attempts to reduce the waiting list
- The impact of financial incentives/penalties on waiting lists
- Effect of the waiting list on patients

Chapter 13: Pre-operative Care

- The transfer of children from referring hospitals
- Pre-operative management of care:
 - Where children were managed pre-operatively
 - Under which specialty children were managed pre-operatively at the BRHSC
 - Under which specialty children were managed pre-operatively at the BRI
 - The management of pre-operative care at the BRHSC
 - Further assessment of the clinical condition of children admitted for elective surgery following admission to the BRHSC
 - The management of pre-operative care at the BRI
 - Further assessment of the clinical condition of children admitted for elective surgery following admission to the BRI
 - Further assessment of the clinical condition of children admitted for elective surgery following admission to the BRI
 - Shortage of cardiologists with paediatric experience
 - Further assessment by other specialties
- The decision to recommend surgery:
 - The decision on the timing of operations/the operating theatre list
 - Timing of emergency operations
 - Timing of urgent operations
 - Timing of elective operations
 - Delays in surgery

Chapter 14: Care in the Operating Theatre and the 'Learning Curve'

- The operating theatre team
- The role of the surgeons
- The role of the theatre nurses
- Performance of the team: a surgeon's perspective
- Management of the theatre nurses
- The role of the perfusionists
- The role of the anaesthetists
- The role of the cardiologists

The 'learning curve':

- Introduction
- New procedures
- The approach to a new procedure
- Defining the 'learning curve'
- Managing the 'learning curve'
- Retraining
- The Arterial Switch procedure
- The 'learning curve' and the Arterial Switch procedure
- The Arterial Switch programme at Bristol
- Mr Dhasmana's visit to Mr Brawn in Birmingham

Chapter 15: Post-operative Care

The management of post-operative care:

- Equipment and cleanliness in the ICU
- Role, training and number of nurses
- Staffing levels
- Skill mix

Involvement of clinical staff:

- Cardiologists
- Surgeons
- Anaesthetists
- Intensivists
- Consistency of approach
- Communication between specialties

Who was in charge of post-operative care?

- Involvement of parents
- Discharge
- Post-discharge care

Chapter 16: Support and Counselling

- Terminology
- The split site
- Priority
- Longer-term support and counselling

Role and responsibilities of UBH/T staff:

- Surgeons
- Cardiologists
- Nursing staff
- Support for nursing staff
- Staff generally

The Bristol and South West Children's Heart Circle:

- Financial and other support provided by the Heart Circle
- The posts of Helen Vegoda and Helen Stratton
- Comment on the service provided by the Heart Circle
- The Children's Heart Circle in Wales

UBH/T Chaplaincy:

- Organisation and role
- Funding and support for the Chaplaincy Service
- The effect of the split site
- Comment on the service provided by the Chaplaincy

Bristol City Council Social Services Department:

- Organisation, accountability and funding
- Role and training
- Support for the social work team
- Comment on the split site

UBH/T bereavement services:

- Comment on the service provided by the UBH/T bereavement service

Helen Vegoda:

- Background to the appointment
- Qualifications
- Funding
- Appointment
- Role
- Communication between Mrs Vegoda and others
- Support for Helen Vegoda
- Comment on the service provided by Helen Vegoda

Helen Stratton:

- Background to the appointment
- Qualifications
- Funding and employment status
- Appointment
- Role
- Development of Helen Stratton's role
- Communication between Helen Stratton and others
- Issues of 'territory' between Helen Vegoda and Helen Stratton
- Meeting on 9 January 1992
- Support for Helen Stratton
- Comment on the service provided by Helen Stratton
- Split site
- After the departure of Helen Stratton

Guidance and expert evidence on support and counselling:

1991 guidance — *'The Welfare of Children and Young People in Hospital'*

Non-governmental guidance

Expert evidence

Chapter 17: Communication Between Healthcare Professionals and Patients

Guidance from professional and related bodies:

The Medical Defence Union

The General Medical Council

The Royal College of Surgeons of England

The United Kingdom Central Council for Nursing, Midwifery and Health

Visiting (UKCC)

The *'Patient's Charter'*

Expert evidence

UBH/T clinician's evidence

The role of the junior staff

Calculating risks and informing parents about them:

The approach of the clinicians in Bristol

Mr Dhasmana

Mr Wisheart

Dr Martin

Dr Joffe

Dr Jordan

Dr Masey

Dr Pryn

Nurses:

Sister Woodcraft

Sister Disley

Counsellors:

Reverend Robert Yeomans

Mrs Vegoda and Miss Stratton

Parents' evidence on communication with clinicians and the process of obtaining their consent to surgery:

The Inquiry's Experts

Parents

Parents' evidence on the management of care and their encounters with other healthcare professionals at the UBH/T

Communication after the operation and when the child died:

The clinicians' evidence

Evidence from other members of staff at the UBH/T
Evidence from parents
Involvement of the GP, health visitor and social services after surgery

Parents' suggestions for improvements

Chapter 18: Medical and Clinical Audit

Introduction

Audit: the national perspective:

- Defining audit
- The development of definitions
- The national scene: a brief history of audit
- Key events
- Reactions to the Government's proposals
- Creation of the NHS market
- The introduction of clinical audit
- Changes in funding 1994/95
- Clinical effectiveness
- The setting of standards
- The nature of audit
- Types of audit
- The effectiveness of the national audit programme
- The constraints (if any) placed on confidentiality and/or the assurance of anonymity
- International comparisons
- Nursing audit
- The national context
- The Dynamic Standard Setting System (DySSSy)
- Evaluation of the nursing and therapy audit programmes
- The role of the coroner
- Records kept by the Home Office
- Reports sent to other organisations
- 'Unnatural death' and 'death by natural causes'
- Records kept by the Register of Births, Marriages and Deaths, and the Office of National Statistics
- The South West Region and audit
- 1988–1990 The Regional Hospital Medical Advisory Committee (RHMAC)
- The Bristol Clinical Audit Unit
- Effectiveness of the regional audit programme

Audit at district and unit level:

- 1985 – 1988 The B&WDHA Performance Assessment Committee
- The District Audit Committee
- The approach of the District to audit after April 1991
- Monitoring and review of performance by the District
- Involvement of the District in nursing audit

- Reporting of accidents/incidents
- The involvement of management in audit
- Devolution of responsibility
- Views expressed on the devolutionary approach
- Audit committees
- Audit co-ordinators and audit assistants
- Role of the clinical director
- The shift from medical to clinical audit
- Collation of audit material by the Audit Committee
- Summary of the annual Audit Committee reports
- Nursing audit in Bristol
- Attitudes towards the formal introduction of audit 1990–1993
- Views as to the relative responsibility for aspects of audit
- Audit of infant and neonatal cardiac surgical services: role and responsibility of the District

The audit and review of the paediatric cardiac surgical services in Bristol:

- Cardiac surgical audit meetings
- Audit meetings, paediatric cardiac surgery and paediatric cardiology
- Clinico-pathological meetings
- Evening meetings
- Other meetings

Chapter 19: Statistics Relating to the Clinical Performance of Paediatric Cardiac Surgical Services in Bristol Compared with Other Specialist Centres During the Period 1984–1995

Introduction: purpose and scope of the chapter

Section One: Statistics relating to clinical performance available to clinicians in Bristol during the period 1984 to 1995

Statistics relating to clinical performance by the clinicians in Bristol:

- Logs: Accessibility, availability and use of logs
- Annual statistical summaries
- The Annual Reports on paediatric cardiology and cardiac surgery
- Statistics produced for audit and other meetings
- The returns made to the UKCSR
- The South West Congenital Heart Register
- The METASA System and the Patient Analysis and Tracing System

Statistics relating to clinical performance at other specialist centres (for the purpose of comparison) available from external sources:

- The United Kingdom Cardiac Surgical Register (UKCSR)
- Working Party reports
- Statistics relating to clinical outcomes available from professional meetings, contacts and journals as a means of comparison
- Professional meetings, other professional contacts and professional journals

Other statistics relating to clinical performance:

- Patient Administration System
- The CHKS Report
- Hospital Episode Statistics

Section Two: The views of the Inquiry's Experts on the interpretation of statistics relating to clinical performance which were available to clinicians in Bristol during the period 1984–1995

Statistics relating to clinical performance produced by the clinicians in Bristol

Statistics relating to clinical performance at other specialist centres (for the purpose of comparison) available from external sources:

- The UKCSR
- Professional journals

Section Three: The principal conclusions of the Inquiry's Experts on statistics:

- The Experts' summary of their principal conclusions
- The principal conclusions in greater detail

Section Four: The evidence of the Inquiry's Experts relating to post-operative morbidity:

- Terminology
- Identifying morbidity in the form of brain damage following heart surgery in children
- The nature and extent of post-operative morbidity in Bristol
- Post-operative morbidity compared with other specialist centres
- The Experts' overall conclusions

Section Five: Views on the interpretation, reliability and validity of the evidence on statistics received by the Inquiry

Comments of the clinicians at Bristol (and others) on the evidence of the Experts on statistics received by the Inquiry, and the Experts' responses:

- The interpretation of the statistical evidence relating to clinical performance in Bristol
- The national sources of statistics used to compare clinical performance
- The statistical methods used by the Experts to analyse the data
- Differences in the data presented in the evidence of the Inquiry's Experts and the data submitted by the Bristol surgeons

The Bristol surgeons' formal written comments on the Expert's Overview Report and Experts' responses:

- Assessment of the Experts' Overview Report

Chapter 20: 1984 and 1985

- 1984
- 1985

Chapter 21: Concerns 1986

1986

The Unit's own report of its performance in 1986

Chapter 22: Concerns 1987

1987

Concerns expressed in Wales

Concerns expressed in Plymouth

Concerns expressed by South Western Regional Health Authority (SWRHA)

The Unit's own report of its performance in 1987

Chapter 23: Concerns 1988

1988

The Unit's own report of its performance in 1988

Chapter 24: Concerns 1989

1989

The Unit's own report of its performance in 1989

Chapter 25: Concerns 1990

1990

Concerns raised by Dr Stephen Bolsin

Concerns expressed by South Western Regional Health Authority (SWRHA)

The Unit's own report of its performance in 1990

Chapter 26: Concerns 1991

1991

Accreditation of a training post in cardiology by the Royal College of Physicians

Audit meeting 28 July 1991

Autumn 1991

Concerns expressed by South Western Regional Health Authority (SWRHA)

The Unit's own report of its performance in 1991

Chapter 27: Concerns 1992

1992

Concerns raised in relation to the position of Chair of Cardiac Surgery at the University of Bristol

Concerns raised by clinicians outside Bristol

Visit by the Supra Regional Services Advisory Group (SRSAG) in February 1992

Further concerns expressed at Bristol
'Private Eye'
Concerns raised with the SRSAG
Data collected by Dr Bolsin and Dr Black
The October article in *'Private Eye'*
Concerns of the theatre nurses

Further events in 1992
The Unit's own report of its performance in 1992

Chapter 28: Concerns 1993

1993

The data produced by Dr Bolsin and Dr Black
Concerns about the Arterial Switch procedure
Further concerns expressed at Bristol
Discussions with the Department of Health (DoH)
Late 1993

The Unit's own report of its performance in 1993

Chapter 29: Concerns 1994

1994

January
February
March
April
May
June
July
August
September
October
November
December

The Unit's own report of its performance in 1994

Chapter 30: Concerns 1995 and after

1995

January
Joshua Loveday's surgery
Further events in January
February
The first version of the Hunter/de Leval Report

March

The revised draft of the Hunter/de Leval report

Protocol for paediatric cardiac surgery

Public and press attention

April

Meeting between Dr Bolsin and Dr Roylance

The cardiac anaesthetic rota

Dr Bolsin's departure from Bristol

Andrew Peacock's surgery

Quoting risks

May onwards

Further clarification of the 'audit figures'

Mr Dhasmana's paediatric practice

Concerns 1996 and later

Professor de Leval's Report

The Hospital Medical Committee

Review of adult cardiac surgery

Chapter 31: Chronology of Key Events Relevant to and Including Expression of Concerns

Annex B

Introduction

Annex B contains a range of background papers, expert evidence and documents covering four broad areas: the conduct of the Inquiry (1,2,3); the statistical evidence to the Inquiry (4,5,6,7, 8); other expert papers (10, 11) and the Clinical Case Note Review (12)

1 The procedures of the Inquiry

- 1a The Secretary of State for Health's announcement of a Public Inquiry into Paediatric Cardiac Surgery Services at the Bristol Royal Infirmary (18 June 1998).
- 1b Opening statements from the Chairman of the Inquiry, Counsel and legal representatives made at the Inquiry's Preliminary Hearing (27 October 1998)
- 1c Issues List, for Phase One of the Inquiry (January 1999)
- 1d Opening statements from the Chairman of the Inquiry and Counsel made at the opening of the Inquiry's Oral Hearings (16 March 1999)
- 1e Key documents and comments relating to the Phase One of the Inquiry
 - Procedures for assessment of costs of participants at public expense
 - Formal Written Comment Protocol
 - Procedure to be followed in making an application for cross-examination
 - Clarification of re-examination of witnesses
 - Note on Material Relating to Matters Outside Terms of Reference
 - The Inquiry's approach to the assessment of the adequacy of paediatric cardiac services July 1999
 - Visit to the Bristol Royal Infirmary Inquiry and Bristol Royal Hospital for Sick Children on 22 July 1999 by the Panel of the Bristol Royal Infirmary Public Inquiry
 - Index to statements made by the Chairman of the Inquiry and Counsel relating to Inquiry procedures
 - The Conclusion of Phase One Oral Evidence
 - Inquiry's procedure on the disclosure of potential criticism
- 1f The Expert Group
 - Membership
 - Explanatory Note
- 1g Bibliography

2 Phase One of the Inquiry

2a Closing submissions from interested parties to the Inquiry for Phase One

(To read the transcript of the presentation of the Final Submissions to the Inquiry please see Transcript Day 96, February 9, 2000).

- Avon Health Authority
- Jordan, Joffe and Martin (Bristol Cardiologists)
- Dr John Roylance
- Bristol Surgeons Support Group (BSSG)
- Department of Health (DoH)
- Bristol Heart Children Action Group
- Mrs Margaret Maisey
- British Paediatric Cardiac Association (BPCA)
- Mr James D Wisheart
- Mr Janardan P Dhasmana
- United Bristol Healthcare NHS Trust (UBHT)
- Mr Hugh Ross

2b Formal Written Comments on Final Submissions

3 Phase Two of the Inquiry

Phase Two comprised a series of seven seminars. For each seminar, Annex B contains a Summary Report; a list of Seminar Participants and a list of organisations which submitted position papers.

3a Seminar One — Acute Healthcare Services for Children

3b Seminar Two — Determinants of performance: What factors determine the level of performance of organisations, especially in health care and the public sector generally?

3c Seminar Three — Culture: professional and managerial cultures and their impact on the quality of service

3d Seminar 4 — Leadership, Vision, Change and Learning from Experience

3e Seminar 5 — People: Education, Training, Development and Governance in the NHS

3f Seminar 6 — Systems: safety and risk management, quality and information

3g Seminar 7 — Service: Empowering the public in the health care process

4 Overview of statistical evidence (published 2000)

- 4a Spiegelhalter D et al. (2000): *'Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995'*.
- 4b Curnow, R (2000): *'Peer Review Advice on "Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry..."', Spiegelhalter D et al.*
- 4c Gallivan S (2000): *'Peer Review Report on "Overview of statistical evidence presented to the Bristol Royal Infirmary Inquiry..."', Spiegelhalter D et al.*

5 Background papers prepared by the Inquiry on statistics

- 5a 'The Inquiry's Approach to Making Use of Relevant Data Sources', March 1999
- 5b 'Preliminary Overview of Existing Data Sources Relevant to the Inquiry's Remit', July 1999
- 5c 'Synthesis of Statistical Sources: a Note on Expert Consultation on Key Analytical Issues', November 1999
- 5d 'Synthesis of Statistical Sources: Specialist Provider Centres by Identity and Anonymity Code', November 1999
- 5e 'A note on Supplementary Work to Inform the Inquiry's Assessment of the Adequacy of Paediatric Cardiac Surgical Services at Bristol', March 2000

6 Statistical reports (published 1999)

- 6a Evans SJW (1999): *'A report on local data relating to children who received cardiac surgery under the terms of reference of the Bristol Royal Infirmary Inquiry'*.
- 6b Aylin P, et al (1999): *'Analysis of Hospital Episode Statistics for the Bristol Royal Infirmary Inquiry'*.
- 6c Murray GD, Lawrence AE and Pollock J (1999): *'A Report on the UK Cardiac Surgical Register and the South West Congenital Heart Register for the Bristol Royal Infirmary Inquiry. A Statistical Analysis and Review of the Key Data Sources Relevant to the Inquiry's Remit'*.
- 6d Spiegelhalter DJ (1999): *'An initial synthesis of statistical sources concerning the nature and outcomes of paediatric cardiac surgical services at Bristol relative to other specialist centres from 1984 to 1995'*.

7 Further statistical reports (published 2000/2001)

- 7a Evans S (2000): *'Further Reports based on Local Sources of Data for the Bristol Royal Infirmary Inquiry'*.
- 7b Evans S (2000): *'Report on activity peaks in Local data'*.
- 7c Aylin P, Alves B, Cook A, Best N (2000): *'Supplementary Analysis of Hospital Episode Statistics for the Bristol Royal Infirmary Inquiry'*.
- 7d Spiegelhalter DJ (2000): *'An investigation into the relationship between mortality and volume of cases in surgery for congenital heart disease from 1984 to 1995'*.
- 7e Murray GD, Lawrence AE, Boyd J (2000): *'Linkage of Hospital Episode Statistics (HES) Data to Office for National Statistics (ONS) Mortality Records'*.
- 7f Lawrence AE and Murray GD (2000): *'The UK Cardiac Surgical Register: Assessment of Data Quality Issues for the Bristol Royal Infirmary Inquiry'*.
- 7g Lawrence AE and Murray GD (2000): *'Additional Explanatory Notes for the Bristol Royal Infirmary Inquiry: Clarification of UKCSR and HES/ONS Data Quality Issues'*.
- 7h Vardulaki K et al. (2000): *'A systematic review of the outcomes of open-heart paediatric surgery'*
- 7i Evans S (2001): *'A note on the statistical analysis of data classified in Group 6'*.
- 7j Campbell M (1999): *'Commentary on statistical analyses'*.
- 7k McPherson K (1999): *'Statistical Report for the BRI Enquiry'* [sic].
- 7l The UBHT documents relating to audit referred to by Professor Klim McPherson and Professor Michael Campbell in their expert statistical advice to the Inquiry

8 Formal written comments, other comments and responses relating to statistical reports

- 8a Formal written comments from various Bristol witnesses:
 - Janardan Prasad Dhasmana 'Response to Supplementary Statistical Evidence to the Inquiry'.
 - Janardan Prasad Dhasmana: Further submission in response to: 'Overview of Statistical Evidence...' (Spiegelhalter et al. September 2000)
 - Janardan Prasad Dhasmana: Statistics and Data Analysis
 - Janardan Prasad Dhasmana: Issue C — The Service Provided: Nature and Outcomes

- The Response of JD Wisheart to the ‘Overview of Statistical Evidence ...’ (Spiegelhalter et al. September 2000)
- Submission by James D Wisheart on The United Kingdom Cardiac Surgical Register as a Reliable Comparator
- Response of J D Wisheart to a group of statistical papers
- Statistics and Data Analysis: A review by James D Wisheart of the evidence offered by Professor SJW Evans, Dr P Aylin, Professor Murray, and Dr D Spiegelhalter, together with their oral evidence on Day 70, 3 November [1999]
- James D Wisheart’s review of data sources and statistical methods available to the Public Inquiry for discussion
- Response of James D Wisheart to the letters of Drs D Macrae, A Houston, Kate Bull and Mr JRL Hamilton

8b Spiegelhalter et al. (2000): ‘A Response to Submissions on behalf of Mr JD Wisheart’

8c Responses to formal written comments on the Overview Report and supplementary statistical reports

8d Other comments and responses relating to Statistical Reports:

- Comments on statistical analysis and review of outcomes of paediatric cardiac surgical services at Bristol and other specialist centres: Mr Jaroslav Stark
- Comments from Dr J Poloniecki
- Response to Dr J Poloniecki
- Papers from Professor John Yates
 - Examining variation in death rates: a Job for the Scientist not the Journalist
 - Early identification of poor performance and major performance failure
 - Analysis of HES Data for Cardio-thoracic work
 - A Case Study Exploring the Early Identification of Performance Failure in an Acute Hospital
- Peer review reports on papers submitted by Professor Yates

9 Papers on future improvements in monitoring performance (published 2001)

9a Stark J (2000): ‘*Future Improvements in the Routine Monitoring of Surgical Performance*’

9b Expert comment by clinicians on issues raised in Mr Stark’s paper and wider issues of clinical performance monitoring (2000)

[Professor Robert Anderson, Dr Stewart Hunter et al., Mr Leslie Hamilton, Dr Duncan Macrae, Mr Pankaj Mankad, Dr Eric Silove and details of the HeartSuite 2000 Cardiac Clinical Information System in use at Glasgow and Edinburgh)

- 9c Spiegelhalter D, Murray GD, McPherson K, Macfarlane A, Evans S, Curnow R, Campbell M and Aylin P (2000): *'Monitoring Clinical Performance: a Statistical Perspective'*
- 9d Macfarlane A (2000): *'Monitoring the outcome of care for children with specific problems in England'*
- 9e Gallivan S (2000): *'Key directions for the future in monitoring clinical performance'*.

10 Papers on a variety of topics

- 10a Bevan G (2000): *'National and Regional Resource Allocation Frameworks and Funding Availability for Acute Sector Health Services at Bristol'*
 - 10b Judge K (2000): *'Peer review advice for the Bristol Royal Infirmary Inquiry [on report by G Bevan on resource allocation]*
 - 10c Baldwin R, Hutter B and Rothstein H (2000): *'Risk Regulation, Management and Compliance'*
 - 10d Bull C (2000): *'Key Issues in Retrospective Evaluation of Morbidity Outcomes Following Paediatric Cardiac Surgery'*
 - 10e Gallivan S (2000): *'Report to the Bristol Royal Infirmary Inquiry: Learning curves in relation to surgery'*
 - 10f Hamilton L: *'Expert Comment on the Bristol PCS Annual Reports for 1987; 1988 and 1989/90'*
 - 10g Macrae D: *'Expert Comment on the Bristol PCS Annual Reports for 1987; 1988 and 1989/90'*
 - 10h Houston A: *'Expert Comment on the Bristol PCS Annual Reports for 1987; 1988 and 1989/90'*
 - 10i Bull C: *'Expert Comment on the Bristol PCS Annual Reports for 1987; 1988 and 1989/90'*
 - 10j Lincoln C et al. (1999): *'Typical knowledge base of a paediatric cardiac surgeon between 1984 and 1995'*
- Mr Christopher Lincoln, Honorary Consultant Cardiothoracic Surgeon (retired), Royal Brompton & Harefield NHS Trust

- Dr Robert Arnold, Consultant Paediatric Cardiologist, Royal Liverpool Children's Hospital NHS Trust
- Mr. Philip Deverall, Cardiac Surgeon (retired)
- Mr Leslie Hamilton, Consultant Cardiothoracic Surgeon, the Newcastle upon Tyne Hospitals NHS Trust
- Mr B Sethia, Consultant Cardiothoracic Surgeon, the Birmingham Children's Hospital NHS Trust
- Mr Jaroslav Stark, Honorary Senior Lecturer in Cardiothoracic Surgery, Great Ormond Street Hospital for Children NHS Trust

10k Simons J (2000): *'Giving Information to Parents with an Unwell Child'*

10l Smith J and Ham C (2000): *'An evaluative commentary on health services management at Bristol: setting key evidence in a wider normative context'* (including formal written comments from Bristol witnesses and authors' final note)

10m Walshe K and Offen N (2000): *'An evaluative commentary on systems for review and audit at the United Bristol Hospitals NHS Trust from 1984 to 1995'* (including formal written comments from Bristol witnesses and authors' final note)

10n Mandelson V: *'Comments on selected parents' experience of communication with clinicians in Bristol.'*

11 Papers on topics relevant to the context of the NHS 1984–1995

Prepared for the Inquiry by Professor Charlotte Humphrey, Professor of Health Evaluation at King's College, University of London, seconded part-time to the Inquiry Secretariat:

11a Reforming the NHS: policy changes and their impact on professional and managerial organisation and culture 1984–1995: June 2000

11b Commissioning, Purchasing, Contracting and Quality of Care in the NHS Internal Market: December 1999

11c Medical and Clinical Audit in the NHS: September 1999

11d Children's Services in the NHS: June 2000

11e Informed Consent: Concept, Guidelines and Practice with Reference to Children undergoing Complex Heart Surgery: December 1999

11f Support and Counselling for Parents of Children in Acute Health Care Settings: December 1999

12 The Clinical Case Note Review

- 12a Hamilton L and Silove E (2000): *'Report of the Clinical Case Note Review'*
- 12b Letters from Team Leaders of the Review on general observations arising from undertaking the CCNR: October 1999
- 12c Letters from Expert Review Team members as to how they assessed adequacy. December 1999–February 2000
- 12d The use of sample weights in the Clinical Case Note Review: A supplementary technical note. Professor Stephen Evans: October 2000
- 12e The CCNR report forms for which there is consent to publish and formal written comments of Bristol Clinicians on specific cases for which there is consent to publish
- 12f Formal written comments on the CCNR Final Report. September–November 2000

Formal written comments on specific CCNR forms were also submitted to the Inquiry, including, in October 2000 comments from the Bristol Cardiologists, Drs Jordan, Joffe and Martin which also make general points about the CCNR exercise. These additional comments are reproduced after the relevant CCNR forms at section 12e

- 12g A Final Note to the Inquiry Panel from the Clinical Case Note Review Report authors, further to consideration of the formal written comments on the Final Report. Mr Leslie Hamilton; Dr Eric Silove December 2000

ANNEX C

Interim Report: *'Removal and retention of human material'*, published May 2000

Part I: Introduction

Part II: Evidence

- The national scene

- The Bristol story

Part III: The background: law and relevant guidelines

- The law

- Relevant guidelines

Part IV: Recommendations

- General principles

- Option 1 – A Code of Practice

- Option 2 – New Law

Appendix:

- People

- Glossary

Annex A and Annex B (Interim Report)

Annex A

An account of the evidence to the Inquiry on the removal and retention of human material at post-mortem

Summary of evidence

Part I: The national context

Part II: The Bristol story

Part III: The parents' experience

Annex B

Law and guidelines

Introduction

Part I: The coroner and the coroner's post-mortem examination

Part II: The hospital post-mortem examination

Part III: The right to possession of the body and the duty to dispose

Part IV: Wrongful removal, retention and use

Part V: Other law and guidelines

ANNEX D

This is a verbatim transcript of the evidence heard during Phase One of the Inquiry (oral hearings between 16 March 1999 and 9 February 2000)

Appendix 4: Expenditure of the Bristol Royal Infirmary Inquiry: September 1998–July 2001

TYPE OF EXPENDITURE	1998/99 £k	1999/2000 £k	2000/01 £k	2001/02 (est) £k	TOTAL £k
Panel	55	487	414	96	1,052
Counsel	–	712	164	60	936
Legal fees: BHCAG counsel/solicitors	–	1,343	112	–	1,455
Legal fees: BSSG counsel/solicitors	–	119	14	–	133
Legal fees: other	–	32	10	–	42
Payments to parents' groups: BHCAG and BSSG	5	27	–	–	32
Expert contributors	2	565	382	10	959
Staff	231	1,259	1,012	255	2,757
Premises	1,322	814	679	67	2,882
Information technology and telecommunications	2,217	1,081	551	128	3,977
Other administrative (including publication) costs	126	445	233	390	1,194
	3,958	6,884	3,571	1,006	15,419
LESS VAT recovered	(7)	(596)	(227)	(75)	(905)
SUBTOTAL	3,951	6,288	3,344	931	14,514
LESS value of reusable assets (see notes 2 and 3)	–	–	–	–	466
TOTAL	–	–	–	–	14,048

These are the full provisional accounts up to the publication of the Report. Final accounts will be prepared in due course

NOTES

1. The financial year runs from 1 April to 31 March
2. Expenditure on premises included furniture which, after use by the Inquiry, was transferred to other public sector organisations with a valuation, after depreciation, of approximately £96,000
3. Expenditure on information technology includes equipment, which after use by the Inquiry, was transferred to other public sector organisations with a valuation, after depreciation, of approximately £370,000
4. BHCAG – Bristol Heart Children Action Group
5. BSSG – Bristol Surgeons Support Group

Appendix 5: Staff Employed on the Inquiry

The Inquiry team varied in size and composition according to the different phases of the Inquiry; some were direct employees of the Inquiry; others were employed on an agency basis. Nonetheless, they each made a valued contribution to the work of the Inquiry and were part of the team that supported the work of the Chairman and Panel.

Inquiry Secretary: Una O’Brien

Inquiry Solicitor: Peter Whitehurst

Assistant Secretary: Zena Muth

Assistant Solicitor: Charlotte Martin

Counsel

Brian Langstaff QC

Eleanor Grey

Alan Maclean

Legal Team

Theresa Abrefa

Marlo Baragwanath

Lisa Biddlecombe

Zane Denton

Vicky Hammond

Shelley Hecht

Linda Heufner

Jeremy Hodges

Anthony Kitson

Rosemary Lowe

Michelle Olsen

Adrian Phillips

Secretariat

Analysis team

Ruth Chadwick

Pat Annesley

Elizabeth Baldock

Val Tyler

Communications

Richard Green/Becky Jarvis

Rachel Gibbons

Phase Two

Melissa Simons

Leonie Horrocks

Charlotte Humphrey

Sue Kingswood

Administration and secretarial support

Roger Motton

Barry King

Claire Bache

Rosalyn Anderson

Adam Baker

Linda Bane

Claire Bennett

Paula Burton

Joanne Carter

Caroline Cunningham

Rachel Curtis

Pat Dadson

Helen Fawsett

Dan Goncalves

Saul Harris

David Hathaway

Lauran Heufner

Anna Kaye

Damien Middleditch

Lorraine Przyborowski

Jerry Robinson

Jenny Sandvold

Charlotte Stokes

Kathy Wiggan

Justin Worland

Contractors

ICL

Craig Cargill

Roger Davis

Mike Eaton

Geoff Elwell

Stuart Garland

Graham Northam

Legal Technologies Ltd

Mike Taylor

Tony Oluborode

Smith Bernal Ltd

Margaret Beaumont

Marie Brown

Donna Phelps

Clinical Coding Exercise

Christine Sweeting and clinical coding staff from the following hospitals:

Barts and the Royal London Hospitals NHS Trust

Barnet & Chase Farm Hospitals NHS Trust

Ealing Hospital NHS Trust

Great Ormond Street Hospital for Children NHS Trust

Ashford Hospital NHS Trust, Middlesex

Hammersmith Hospitals NHS Trust – including Charing Cross Hospital & Hammersmith Hospital

Redbridge Healthcare NHS Trust – King George's Hospital, Ilford

Royal Brompton & Harefield Hospitals NHS Trust

Royal Free Hospital NHS Trust

St. George's Hospital NHS Trust

West Middlesex University Hospital NHS Trust

The Inquiry would also like to thank the following companies and organisations for their support and help:

COI Communications: produced the Inquiry Report and Annexes

Knight Securities: provided Inquiry hearing chamber staff

Mentor Communications: produced the Information Video about The Inquiry

RS Live/Grayling: assisted with the launch of the Inquiry Report

Toptel: provided videoconference and voice services to the Inquiry hearing chamber

