Chapter 1: Introduction

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]

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[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.

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[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 new-born 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.

Chapter 2: The Conduct of the Inquiry

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 statute[1] 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

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[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]

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[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 report[5] 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.

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[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 a 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.'

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[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 B[8] 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.

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[8] Annex A, Chapter 1 and Annex B, Section One

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 unintimidating 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 paper[10] 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

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[9] We use the term 'UBH/T' to refer to that group of hospitals in Bristol which, prior to 1991, comprised the United Bristol Hosptials, 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

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[12] Chairman's Preliminary Statement, 27 October 1998. See Annex B, 1b

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;

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[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 inquisitiorial 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

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

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

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[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

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[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.

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[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 encouragement[6] 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 directorates[7] 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

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[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.

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[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

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[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,

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[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 *under*-funded 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.

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[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.

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[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.

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[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

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]

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[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

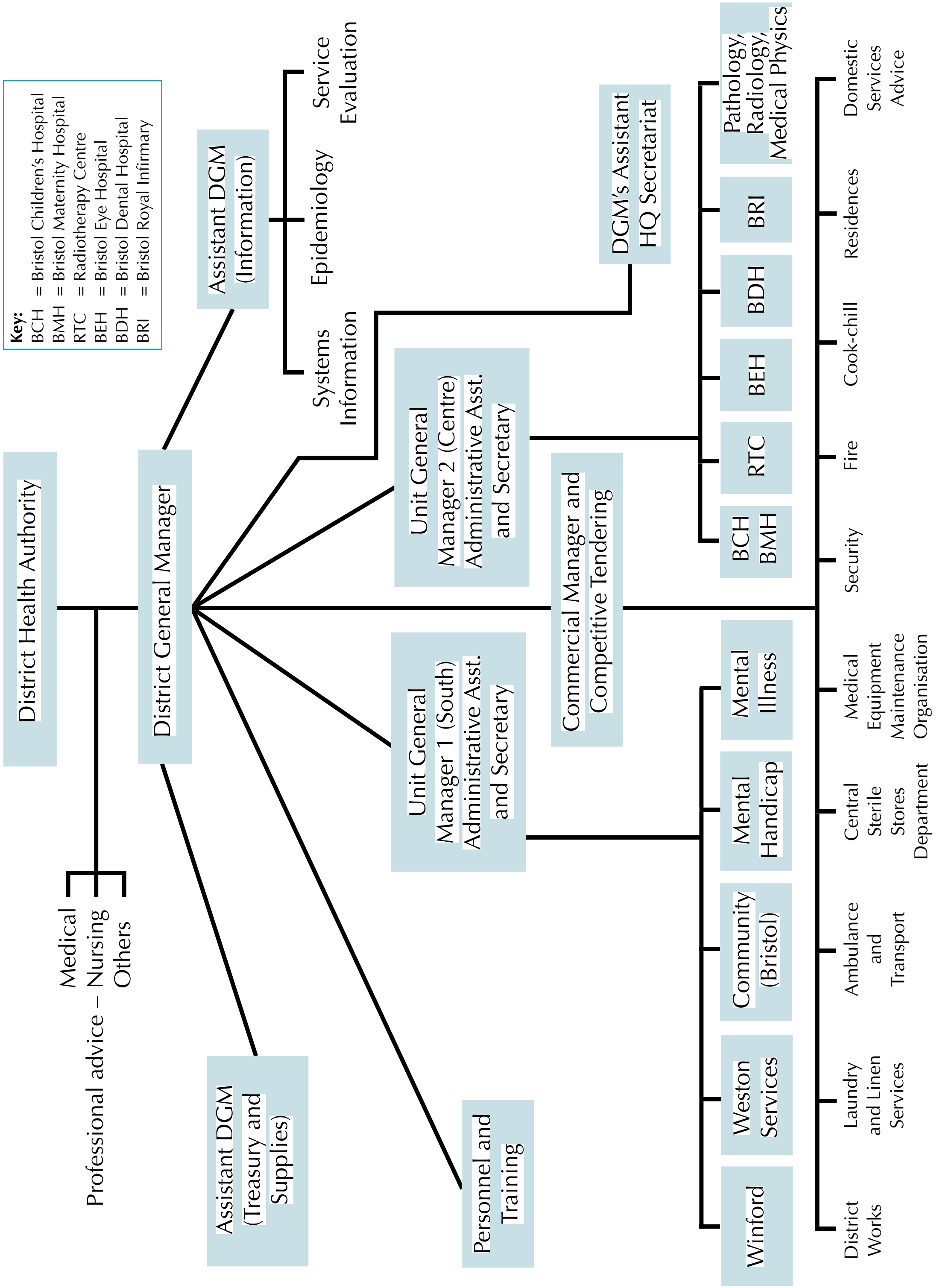
[2] WIT 0074 0425; from correspondence from Dr Roylance to the Regional Health Authority dated 1 May 1985

[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 1985[5]



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[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.

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[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

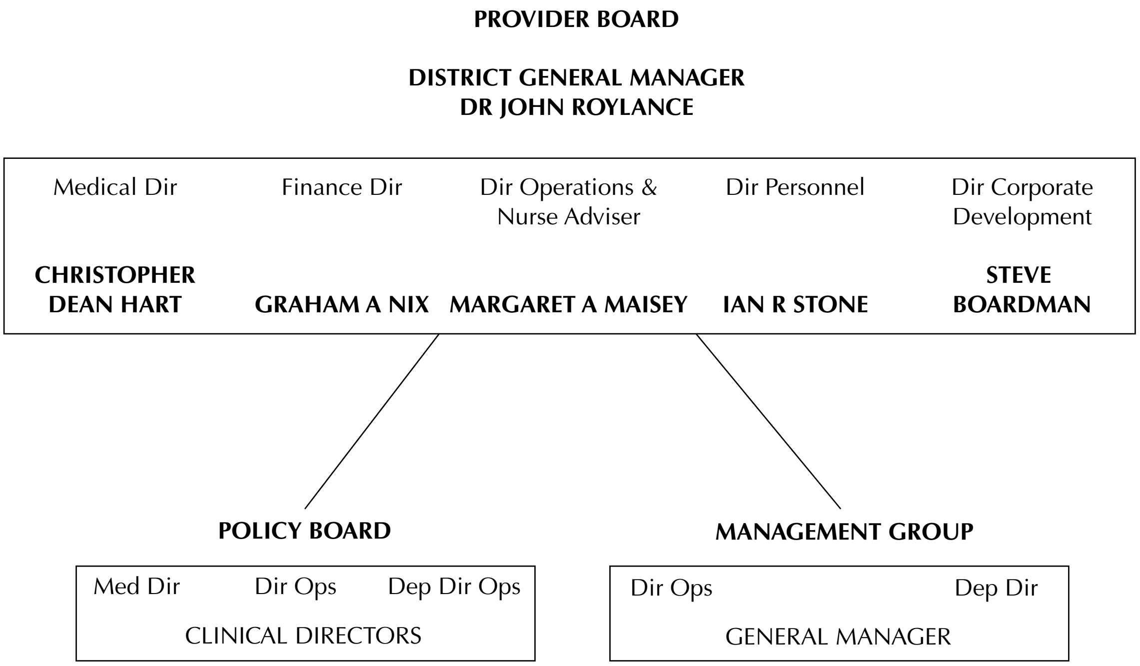
[9] WIT 0108 0006 Dr Roylance

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. 1990[11]



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[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.

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[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

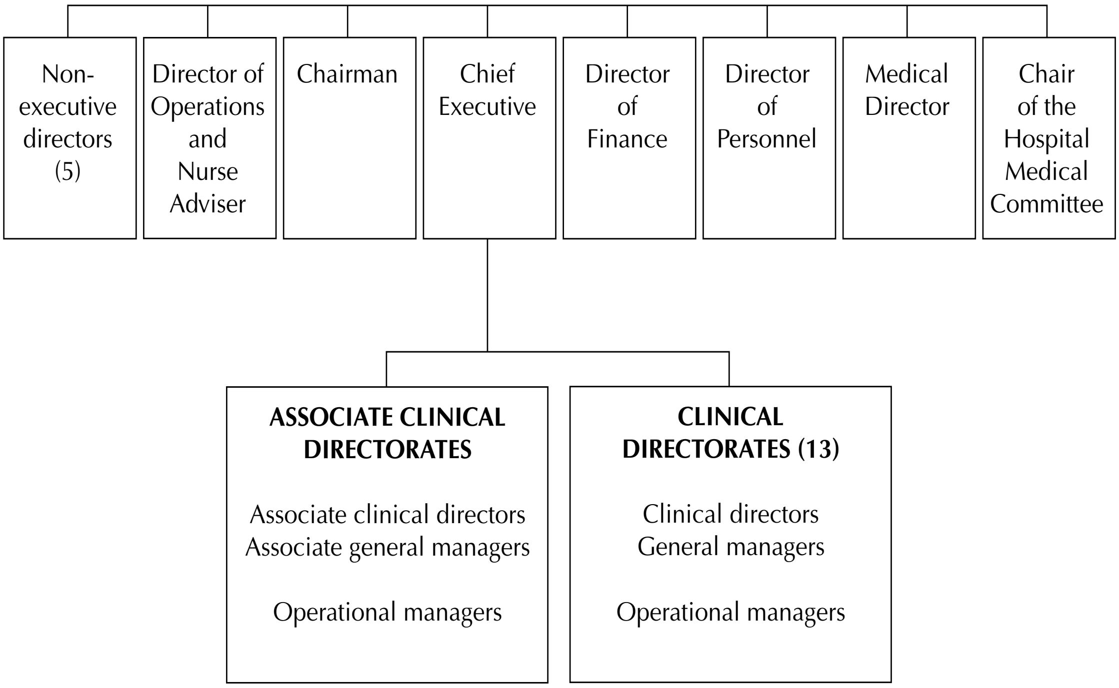
[13] Margaret Maisey, Director of Operations and Nurse Adviser 1991–1996, Director of Nursing 1996–1997 at UBHT

[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 1992[15]



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.

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[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]

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[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.

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[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]

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[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.

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[38] WIT 0084 0046 Mr Dhasmana

[39] T27 p. 115 Mrs Ferris

Setting the Scene

Chapter 6: Quality, Standards and Information

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.

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[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.

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[2] T52 p. 36 Sir Graham Hart

Audit[3]

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.

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[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 heath 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

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[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

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[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

[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.

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[11] T56 p. 54–5 Miss Hawkins

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]

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[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]

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[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.

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[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]

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[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.

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[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

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.

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[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 inquisitional 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

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[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.

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[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

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[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 this[13] … 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

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[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 Downs

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]

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[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

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[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 report[27] *'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:

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[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 Ashworth[32] 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 Fallot'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]

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[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

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

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[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.

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[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;

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[4] HN (83) 36 and DOH 0002 0022 – 0023

- 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

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[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

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[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

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[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]

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[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 1988[23] 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]

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[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]

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[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

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[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

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[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.

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[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 The PCS service was a split service provided over two sites until October 1995.[3]

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[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

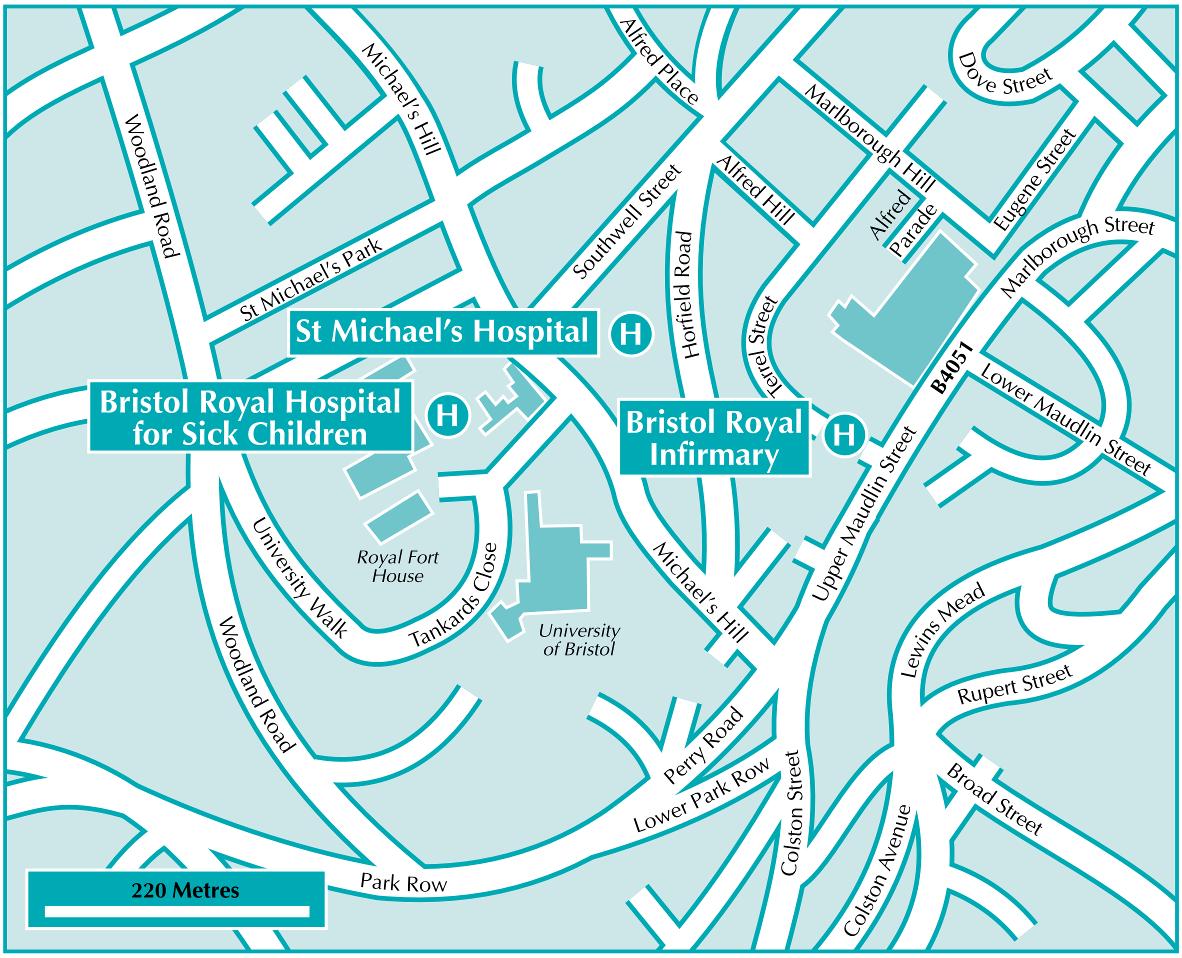

Figure 2: Services provided at the BRHSC and BRI from 1984 until October 1995

Services and facilities at the BRHSC	**Services and facilities at the BRI**
■ 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	■ 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 1992[5] 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 1994–1995[1]

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.

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[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 directorates[6]

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.)

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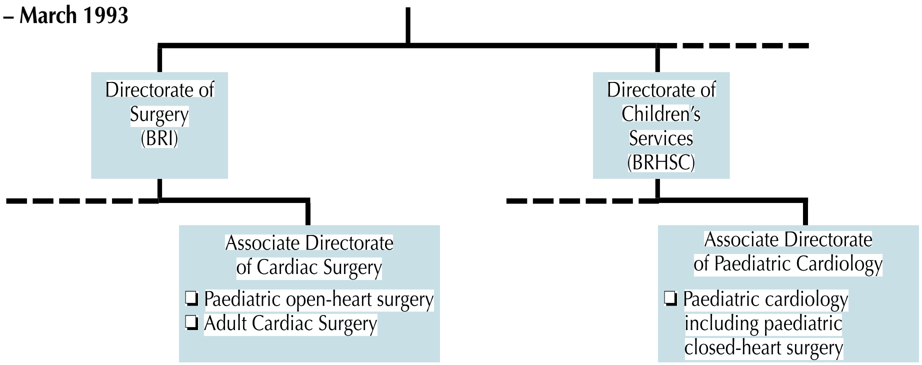
[6] See Figure 3: How the paediatric cardiac service fitted into the clinical directorate system

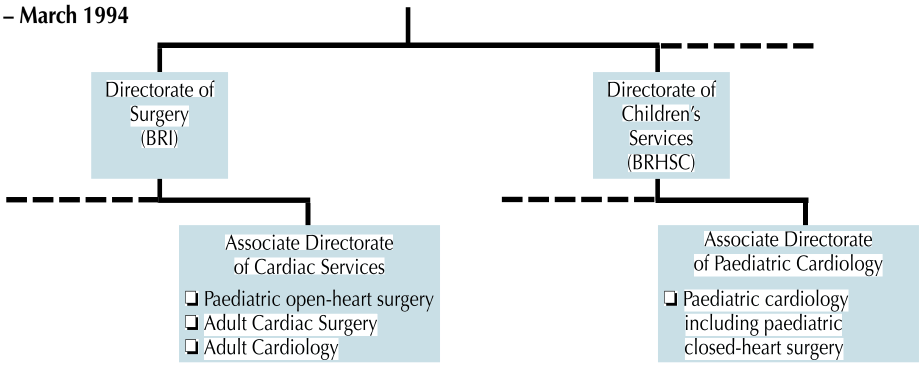
[7] See Figure 1: Location of relevant Bristol Hospitals during the period of the Inquiry's Terms of Reference

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

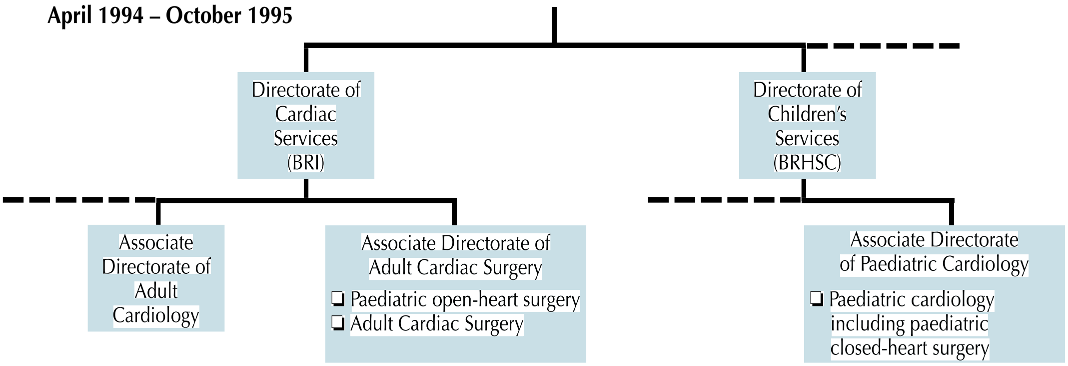
April 1991 – March 1993



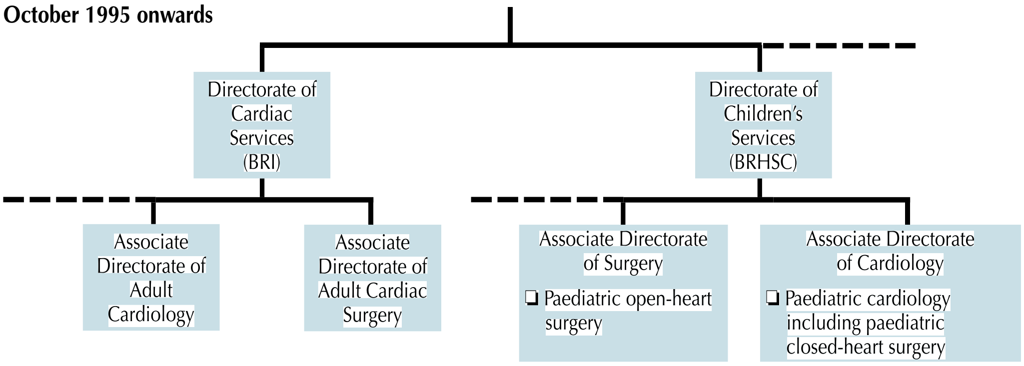
April 1993 – March 1994



April 1994 – October 1995



October 1995 onwards



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 clinics[9] with local consultant paediatricians were established throughout the South West Region. Dr Ian Baker[10] 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.

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[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

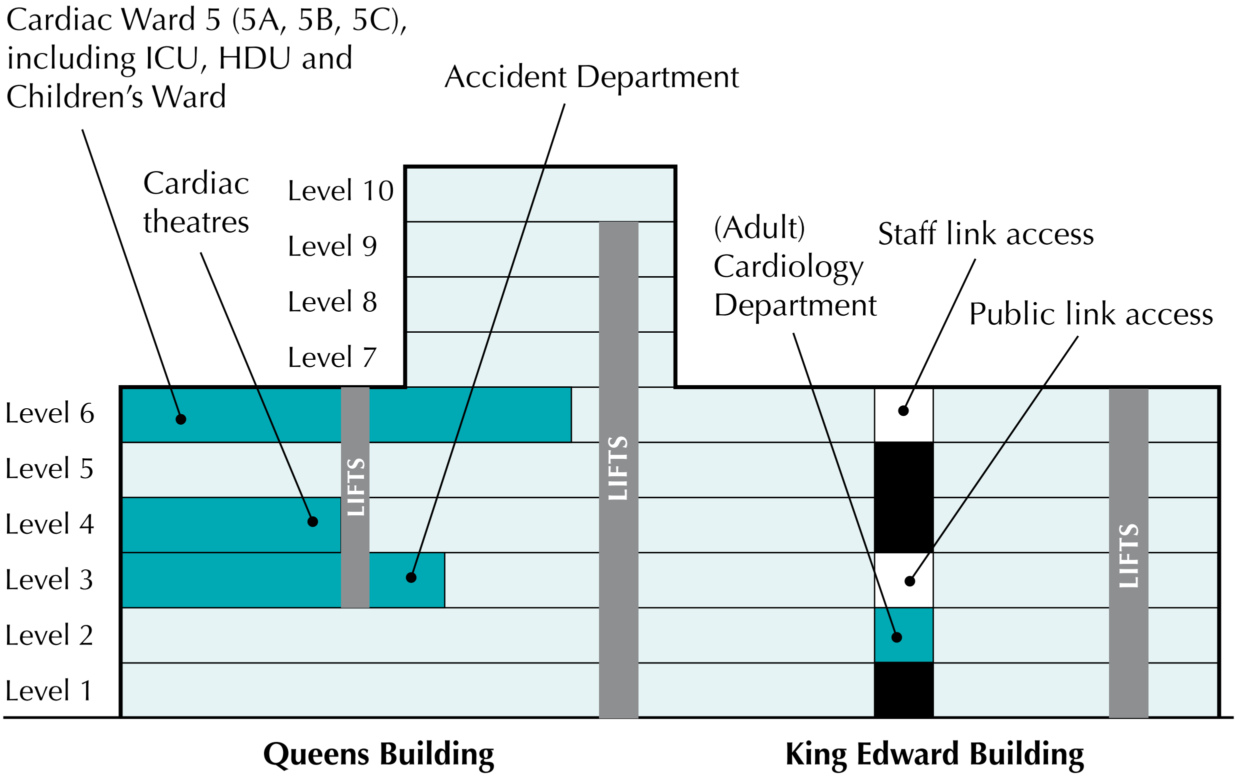
[12] BCS 0001 0017 and BCS 0001 0096; Chamberlain, et al. *'BMA report on staffing in cardiology in the UK in 1988'* and *'BMA report on staffing in cardiology in the UK in 1992'*

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



View from Upper Maudlin Street (not to scale)

ICU: Intensive Care Unit; HDU: High Dependency Unit

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]

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[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 RSCNs[17] 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 RCSN, 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]

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[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,

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[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

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[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,

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[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.

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[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.

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[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,

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[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]

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[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

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 padiatric 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]

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[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 visited[7] 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

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[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

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[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]

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[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

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[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 Masey[42] 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]

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[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

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[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

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[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 articles[69] 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.

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[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]

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[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]

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[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]

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[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

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[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

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[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 procedures[124] (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

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[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

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[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 service[147] 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 Inquiry[151] 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

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[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

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

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[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]

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[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 Medial 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

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[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

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[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

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[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

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[16] WIT 0352 0027 Dr Williams

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]

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[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 collect[22]). 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 stratification[23] 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.

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[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

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[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

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[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

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[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

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[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

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[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

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[37] A decision reported at [1999] AC 139

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-

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[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.

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[40] T87 p. 43 Mr Dhasmana

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

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[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.

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[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

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[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

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[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.

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[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 level[2] (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

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[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,

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[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.

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[4] Weinger MB, et al. 'Incorporating Human Factors into the Design of Medical Devices'. *'JAMA'*, 280(17); 1484, 1998

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

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

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[1] T65 p. 59 Sir Alan Langlands

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.

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[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 discussions[5] 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.

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[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 Authority[8]

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 Heath 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.'

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[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

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[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

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[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

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[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

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[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.

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[25] Indeed, we heard evidence that these powers were sometimes used in a draconian manner. T34 p. 114 Mrs Jenkins and T27 p. 91–2 Mrs Ferris

The Adequacy of Care

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

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

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[1] T56 p. 123 Miss Hawkins

[2] T36 p. 38 Dr Baker

[3] See Annex B, 10l 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

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[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.

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[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 Chidren'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 February[15] 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

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[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 Boardman[23] 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]

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[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 Dopson[25] 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.

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[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.

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[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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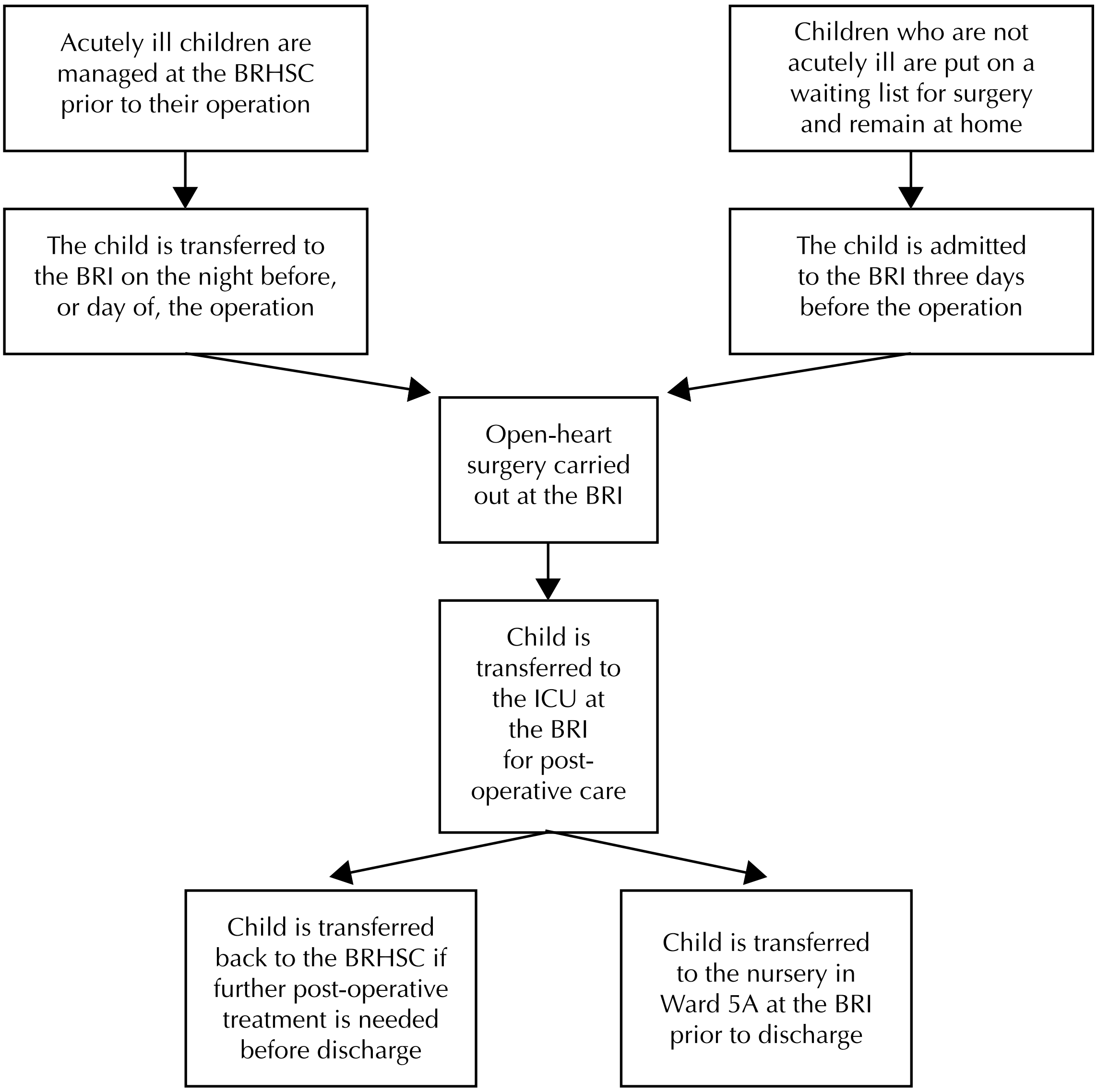
The patient's journey

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.

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[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.

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[4] T18 p. 370–4 Professor Baum

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 Cummings[7] 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]

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[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

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[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.

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[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]

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[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]

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[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

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[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

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[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 6.4[44] 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.

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[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

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

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[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 surgery[4] 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

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[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 Bwye, 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 about[12]. 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

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[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]

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[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 survey[24] conducted into the level of information and support being given to families attending for catheterisation at the BRHSC[25] 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.

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[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.

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[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.

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[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

The Adequacy of Care

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.

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[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.

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[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'

The Adequacy of Care

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 appointed[3] 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

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[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.

The Adequacy of Care

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

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 out[2] 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

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[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

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[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 tests[13] 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

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[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 reply[14] 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 Bull[15] 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 Macrae[16] 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]

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[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 coding[19] 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

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[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

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[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

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[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

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[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]

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[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

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[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

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[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.

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[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.

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[2] The Inquiry asked the UBHT to check all complaints made by patients (or carers) between 1984 and 1995. The UBH/T 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.