

PAEDIATRIC CARDIAC SURGERY INQUIRY

OUTLINE CLOSING SUBMISSIONS

ON BEHALF OF THE UNITED BRISTOL HEALTHCARE TRUST

1. INTRODUCTION

- 1.1 Before the Inquiry opened in October 1998 UBHT made it clear that it was committed to assisting the Inquiry team in obtaining the necessary documentation and to making available members of staff past and present to give oral evidence. Over the intervening 15 months, UBHT has given its support and co-operation unstintingly. It has supplied tens of thousands of pages of records, memoranda, minutes and correspondence from which to obtain a historical perspective on the various issues. It has also provided some 130 witness statements from those who have been asked or have volunteered to give oral evidence. The Trust's witnesses were encouraged to express their honest views, rather than merely what their employers might wish to hear. It has been a noteworthy feature of the evidence that a number of those witnesses were not afraid to criticise what they perceived to be failings in the organisation and the unsatisfactory performance of other members of staff. The Trust wishes to emphasise that whatever may have been the failings in management structure and communication during the period covered by the Inquiry, UBHT is a much healthier, more efficient and well-balanced organisation now than it was at that time.

1.2 However the Trust's participation in this Inquiry has involved significant cost. It must be remembered that UBHT exists to provide healthcare, teaching and research, and is funded for those purposes. It has no other course of funding. At the outside a decision was taken to make sensible and selective use of legal advice and assistance to prepare the evidence and help Trust employees, but not to maintain a routine presence in the Chamber during the oral hearings. This was not intended to be discourteous to the Inquiry; nor did it suggest indifference to the evidence or the outcome. It merely reflected the view that the Trust's resources would be better employed in running its hospitals. Credit should also be given to the Internet coverage, which made it a simple task to follow the detailed and the general aspects of the Inquiry on a daily basis. In addition, the Trust has reviewed and commented on over 250 witness statements provided by parents and others.

1.3 These closing submissions do not even approach an analysis of all, or even a majority, of the Issues with which the Inquiry has to deal. The format that was adopted for the obtaining and giving of evidence lent itself to a much less confrontational proceeding that might have been anticipated, given the subject-matter. Thus, on the major issues interested parties have been able to get their views across in those witness statements and, where appropriate, in oral evidence in a way which does not demand selection between examination in chief and cross-examination.

- 1.4 There are, however, discrete issues which UBHT wishes to address in short closing submissions in order to summarise its case as far as the past is concerned and to emphasise its aspirations for the present and future.
- 1.5 There is one final and important introductory point. The Trust has been dismayed at the consistently hostile and critical reporting of events in the media throughout the Inquiry. Good and beneficial aspects of treatment and care, past and present, have been largely ignored. While, of course, neither the Panel nor the Inquiry team can have any control over what is or has been written, it must be recognised that to destroy or seriously to undermine the confidence of the community in its local hospitals is in nobody's interests. Nor should the impact of negative and critical comment over many months on the morale of hospital staff be underestimated.

2. STRUCTURE

(a) Formal management structure

- 2.1 The Inquiry covers the period from 1984 to 1995. During that period there were obviously critical changes which affected not only Bristol and its various health authorities, but also the whole of the NHS. Looking back to the early 1990s nobody could foresee how the Health Service reforms would work out and one can sense the feeling of distrust amongst a substantial body of the medical staff at the BRI at the prospect of Trust status; [Nix Day 23 and Baird Wit 75 008/9].

- 2.2 Whether or not it was necessary or appropriate for the health authorities to obtain Trust status when they did is no longer really an issue. It is likely that it would have happened at some time in any case. However, it is clear that had it not been for the strong personality of Dr John Roylance and his commitment to medical management of the hospitals, there would have been a great deal more opposition to the changes.
- 2.3 Hugh Ross inherited the original Trust structure (with some modifications introduced by successive chairmen, Peter Durie and Robert McKinlay). Necessary changes were made to reflect the clear need for involvement of the Trust Board and the efficient use of the management expertise which it possessed [See Ross Day 19]. Secondly, a start was made on the redefinition of the pivotal role of Medical Director. Initially it had only been considered necessary to devote 2 sessions a week to the task (which was clearly insufficient). When Mr Baird took over the position of Medical Director, it was increased to 4 sessions. The current position is that the Medical Director devotes 7 sessions a week; the majority of his time, which is a true recognition of the importance of his function, and he is now assisted by 4 Associate Medical Directors, each of whom devotes 2 sessions each to the task [See Baird Wit 75 0002].
- 2.4 The Trust believes that all of the changes which have been instituted over the last 5 years have improved its efficiency and performance and have brought with them significant benefits for its patients and a greater awareness of their needs. However, the Panel may feel that the problems

which UBHT encountered in its early years were not unique to this particular Trust. If any similar organisation were to be put under the microscope for 9 months of sustained investigation it is likely that a range of similar (although not identical) problems and difficulties would be thrown up.

3. PAEDIATRIC CARDIAC SURGERY

(a) Supra-regional designation

3.1 The historical background to the provision in Bristol of paediatric cardiac surgical services is important, since there has been a natural tendency to concentrate on the later period to identify the circumstances in which things may have gone wrong.

3.2 There can be no doubt that it was logical for Bristol originally to have been selected as one of the designated supra-regional centres. Not only did it obviously make logistical sense that there should have been a referral centre in the south west, but also, there was in place a distinguished teaching hospital with cardiac surgeons and cardiologists already doing work. There were also no realistic alternatives.

3.3 There have been criticisms of the small numbers of paediatric surgical operations performed during the period of supra-regional designation, but in common with other areas of medicine, a much more “generalist” approach was acceptable. At that time, cardiac surgeons, outside specialist children’s

hospitals, were expected, or would have expected, to operate on adults as well as children.

- 3.4 There should also be some acknowledgement of the fact that surgical techniques change with each generation and that those entering the surgical profession tend to find it easier to assimilate techniques than those having to adapt to techniques that change their practice.

(b) The split site

- 3.5 The split site was a theoretical problem, rather than a serious impediment to good and safe surgery. In retrospect, it was the cause of significant inconvenience and undoubtedly obliged parents to accustom themselves to different atmospheres in the Children's Hospital and the BRI, but nobody has suggested that patient safety was put at risk specifically as a result of the split site; or, if suggested, there is nothing to substantiate such suggestion.

- 3.6 Moreover, it is clear that the primary reason for the creation of a paediatric cardiac theatre at the Bristol Children's Hospital was not concerns about the split site but, rather, it was driven by the need to provide additional surgical facilities at the BRI for adult cardiac cases. [See Nix Day 23 p.164-6.]

(c) The current position

- 3.7 From May 1995 there was, for the first time, a dedicated paediatric cardiac surgeon in Bristol; a surgeon with an international reputation. There have been no criticisms of his performance (or his output).

3.8 Since July 1999 there have been two dedicated paediatric cardiac surgeons, which would now be the expected complement for a referral centre such as Bristol. It is clear that Bristol is now fulfilling its expected role.

4. **DEALINGS WITH PARENTS**

4.1 The Trust has always been aware of the importance of this issue. For many years there have been counsellors and liaison nurses available to support and advise parents whose children have come to Bristol for cardiac surgery. Although the staff directly involved with families, in both treating and counselling roles, tried to meet the needs of families, it is now clear that the Trust failed in some areas. The Trust's bereavement services are currently under review, to try to address the criticisms made and improve the service provided to families. The Trust would welcome any guidance and suggestions that the Inquiry may make for further improvement.

5. **RETAINED ORGANS AND TISSUE**

5.1 It has been acknowledged by the Trust that the removal of organs/tissue at post-mortem and their/its retention thereafter raises powerful emotions at a general and an individual level. The point hardly needs to be stressed that those who may have lost a child in tragic circumstances might feel that loss redoubled when discovering, in some cases many years later, that an organ or tissue from that child remains in existence, preserved in the pathology department of a hospital.

5.2 The efforts made by Mr Ross, Mr Barrington and Professor Berry to deal with the human aspects of this Issue are well documented [see Day 37 and Day 55] but require a little amplification. The Inquiry must have been impressed by the thorough, honest and sensitive way in which that difficult task was approached. A late attempt to suggest otherwise was grossly unfair and unwarranted. It is clear that the Trust adopted a policy of providing information to those parents who wished to be told and respected the feelings of those who simply did not wish to know. Moreover, great care (and an immeasurable amount of time) was taken in attempting correctly to ascertain the exact position, to try to ensure that accurate information was given. That a very small number of errors occurred is unsurprising, given the state of some of the earlier records at the Bristol Royal Infirmary, the time-scale involved, and the unprecedented level of detail requested by some parents. It is to be noted that hitherto no medical institution has had to carry out this retrospective "auditing" exercise (although one may be obliged to in the near future).

5.3 In terms of personal contact, in February 1999, Ian Barrington and his assistant Sarah Garrett, personally took on the responsibility of answering parents' questions and providing information and continued to do so until December 1999, to provide continuity and consistency of support and information. Professor Berry has gone to great lengths to discuss individual cases with parents and to help them to decide what to do with retained organs or tissue in a way which is both practical and lawful.

(a) The national picture

- 5.4 The national picture was graphically described by Professor Anderson, professor of paediatric cardiac morphology at Great Ormond Street [Day 45]. He spoke of substantial “collections” of organs at big teaching centres like Manchester, Leeds, Newcastle, Sheffield – particularly Liverpool, as well, of course, as in London and abroad.
- 5.5 It appears, undoubtedly, to have been a widespread practice and it was considered to have been a lawful one. Indeed, the government itself has confirmed, in answer to a parliamentary question, that UBHT did not break the law. In addition, the practice was considered to be ethically acceptable. That was the view in Bristol and the detailed report from Cameron McKenna seems to support that view.
- 5.6 Subject to obtaining the appropriate informed consent, there is no reason why the benefit of having pathology collections for future study and the support of improvements and advances in clinical practice should not endure. Nobody has seriously argued that retention per se of organs should be outlawed, since it is so obviously necessary to instruct those involved in ever more complicated surgery and to be able to carry out research in retrospect. What have to be established are clear guidelines which can be readily understood by practitioners and relatives alike and, where consent is required, the identification of the right person to obtain that consent at the appropriate time and in appropriate detail.

(b) The practice in the hospitals of UBHT

5.7 It is worth making the point that post-mortem work was only part of the work of the pathologists at the Bristol Children's Hospital and cardiac surgery post-mortems were an even smaller (although important) proportion of that workload. Post-mortems were only carried out with the signed consent or on the express authority of the Coroner, or with the written consent of the parents in the case of hospital post-mortems. No pathologist would have considered proceeding without such authorisation.

5.8 In fact, the practice in relation to tissue retention in the paediatric department at the Bristol Children's Hospital was entirely consistent with, if not better than, the practice in the country as a whole. It was accepted nationally that tissue samples should be retained and, where appropriate, whole organs. In Professor Berry's department during the period with which the Inquiry is concerned, microscope slides were prepared in almost every case, which compares favourably with the practice elsewhere. The fact that there have been criticisms to the effect that both too much and, in a few cases, too little tissue has been retained from post-mortem merely serves to emphasise the impossibility of pleasing everyone in this sensitive area, at least until there are clear national guidelines as to all the relevant aspects of good practice. It needs to be stressed that organs/tissue were only retained for good scientific reasons in the greater public interest and in the conviction that it was being done lawfully, for the reasons Professor Berry has explained.

- 5.9 At a more specific level, the paediatric pathology department at Bristol was forward-thinking in a number of respects: first there have been regular clinico-pathological meetings for many years aimed at identifying problems; although, over the years, the problems may have altered. Secondly, the paediatric pathologists audited their cardiac surgery post-mortems and published the results with the agreement of the surgeons [UBHT 0308 0076]. No other centre had done that before or has done it since; this is the only study of its type in the world. It has to be accepted that such a study cannot detect a higher than average mortality rate, but, nonetheless, its usefulness as an audit tool for pathology practice cannot be denied.
- 5.10 Professor Berry sought to raise the issue with colleagues of informing parents of tissue retention as early as 1987 [UBHT 0308 00129, 0017/18 and 0170]. He went on to institute changes in the consent forms on two occasions to reflect changes in public perceptions. Such changes could, of course, only be directed towards and implemented by the clinical staff – pathologists do not, themselves, obtain consent for post-mortem.
- 5.11 Professor Berry also raised the issue within the Royal College of Pathologists and in 1995 produced the first drafts of the College guidelines on tissue retention, before reluctantly withdrawing in recognition of the potential conflict of interest created by the setting up of this Inquiry.

(c) **The future**

5.12 The Royal College of Pathologists has recognised that things must change. That has been the view of Professor Berry for some years, as the documents disclose. Proper consent is necessary, although the timing of any discussion is always going to be problematical.

5.13 From the Trust's standpoint the current practice is to consult individual parents if there is a possibility of tissue retention and, as part of a Trust-wide review of bereavement services, there has been a detailed re-appraisal of what needs to be discussed, with whom and by whom. The Trust would obviously welcome any guidance which the Inquiry panel may feel able to give.

6. **EXPRESSIONS OF CONCERN**

6.1 The machinery was always in place for issues of clinical competence to be raised. The clinical directorate system effectively created departments with the clinical director a head of department. Concerns raised with clinical directors should have been capable of being shared at directorate level or, failing that, with the Medical Director or Chief Executive. This remains one of the available options for raising concerns.

6.2 There have to be reasons why recourse was not had to the mechanisms in place. The reasons may not have been unique to UBHT. First, since any suggested concern involved in this instance the Medical Director himself, it

might be argued that this cut out one potential line of complaint. Such a situation could not arise now, because there are alternative and well-publicised ways in which a problem could be brought to the attention of the Trust Board.

- 6.3 Secondly, the approach that Dr Bolsin actually took was not one which lent itself to sensible and objective debate. However good his intentions, he has to bear some responsibility for the climate of distrust between the anaesthetists and the cardiac surgeons which was obviously created.
- 6.4 Thirdly, on a more general basis, it has to be acknowledged that NHS institutions at the time were neither comfortable with dealing with issues of clinical competence, nor ready to deal with such issues whatever the mechanisms in place. Particularly when the concerns involved a senior surgeon. In the event, the setting up of the external investigation by de Leval and Hunter was a positive step, even if the evidence upon which they reported may not have been completely satisfactory. Equally, the Trust's response to the findings was a proper one, which clearly put the best interests of the patients first.
- 6.5 The position in 1999/2000 is very different. UBHT and the whole of the NHS will have learned from what happened in Bristol, whatever findings the Inquiry should make. At a local level, the role of the Medical Director has been strengthened, and improved by the addition of Associate Medical Directors; [see Baird Wit 75 0003]. The role of non-medical management in

issues of clinical competence appears to be accepted. On a broader basis the evidence seems to suggest that the emergence of clinical governance has pushed issues of actual competence (as opposed merely to qualification to perform a job) into the open. It is to be hoped that in future not only will the lines of reporting concerns be available, but also that no one will be deterred from using them.

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