

The BRI Inquiry into paediatric cardiac surgical services in Bristol 1984-1995

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1. My qualifications are MD and FRCPath. I have been a Consultant Paediatric Pathologist since January 1993. Before that I was Senior Registrar in Histopathology in the Mersey Region Health Authority. My training was in adult pathology but I did undertake training in Paediatric Pathology in the department of Professor D van Velzen at the University of Liverpool in 1992. In addition I spent two years as Senior Registrar in Histopathology at Broadgreen Hospital, Liverpool, the site of the Regional Cardiothoracic Centre and so was very familiar with cardiac pathology in general.

2. When I was appointed to my present post in 1993 it was understood in discussions with Professor Berry that I would take a particular interest in paediatric cardiac pathology. He felt it would be good practice to have somebody in the department to take a primary interest in paediatric cardiac pathology. To this end and before taking up my post I spent some time with Dr Audrey Smith in the Institute of Child Health at the Royal Liverpool Children's Hospital at Alderhey. This took the form of direct instruction from Dr Smith in cardiac anatomy, both normal and abnormal, and direct inspection of the collection of congenitally malformed hearts at Alderhey. Following my appointment I kept my interest up-to-date by becoming a member of the British Paediatric Cardiac Association. I have attended regularly the annual meetings and also the study days organised by Dr Smith and Professor R Anderson at Alderhey. Taking an interest in cardiac pathology, I undertook the post-mortem examination of the majority of cases of children dying with congenital heart disease at the Bristol Royal Infirmary and the Bristol Children's Hospital from 1993. Most of these cases were examined under the direction of Her Majesty's Coroner.

3. I have been asked to comment on Issue J. I understand that the Inquiry has received written statements from the Royal College of Pathologists, The Coroner's Society and the Home Office regarding the legal, managerial and administrative aspects of the paediatric and cardiac pathology services generally and from Professor Berry, who was responsible for the cardiac pathology service up to 1993, on these issues locally.

J1 The nature and extent of the responsibilities of hospital staff, hospital pathologist and coroner to report and investigate deaths.

5. This task of reporting a death to the Coroner for investigation is almost always performed by a member of the medical team looking after the deceased patient. I have never reported a death directly to the Coroner but have on occasion been asked whether I thought a death was reportable and I can recall at least one occasion where I felt in retrospect that a death should have been reported when it was not. To the best of my knowledge all postoperative deaths in the period covered by the Inquiry were reported to the Coroner. In practice the only involvement I had was once the death had been reported and I was requested in the usual way by the Coroner's officer to perform an autopsy.

J2 The functions of post-mortems and inquests in helping to establish the cause of death of a child or the adequacy of the surgical or other services provided.

6. The principal function of the Coroner's post-mortem was to establish the cause of the death. In order to supply a cause of death I informed myself as best I could of the circumstances surrounding the death; I was usually in possession of the case notes and usually also the operation note. I performed the examination to the highest standard, to the best of my ability. As part of that thorough examination I removed and retained the heart for detailed analysis. I prepared my report and submitted it to H M Coroner and, with his permission, to the treating clinicians. I provided my opinion as to the cause of death. In many instances I was not certain of the exact mode of death but was satisfied that death was due to the presence of congenital heart disease. I found no case in which I suspected that death was the direct result of surgical or anaesthetic mishap. I recognised that I was not in possession of all the information and that a full understanding of the death required close clinico pathological correlation but I believe I excluded unnatural causes of death. I can recall only one post-operative cardiac case in which I was required to give evidence at an Inquest.

J3 The extent to which postmortems and any inquests held upon children who died following complex cardiac surgery at the BRI performed such a function.

7. The post mortems that I carried out in children who died following complex cardiac surgery were carried out in order to establish the cause of death. As I have said above, arriving at a cause of death was sometimes very difficult and involved clinicopathological correlation, a process in which the monthly meetings with the cardiologists and surgeons were important. I believe that the post-mortems did exclude technical surgical errors but post-mortems on their own do not provide the whole picture.

J4 Whether consent (if required by law) to autopsies and/or the retention of tissue was properly and sensitively sought: and, if consent was not required, whether proper and adequate information about this matter was given to parents, in an appropriate fashion.

8. In my autopsy practice I make, and have always made, a distinction between what is permissible in a Coroner's autopsy and what is permissible in a hospital autopsy. In a hospital autopsy the pathologist has the Consent Form as a guide to what one may or may not retain if the complexities of the case require it. In a Coroner's autopsy it has always been my understanding that the pathologist was obliged to retain any tissue that had a direct bearing on the cause of death if it was deemed necessary. This accords with the written Code of Practice of the Department of Paediatric Pathology at the Children's Hospital that was in place at the time of my taking up my appointment. I understand that a copy of that policy and its amendments has been furnished to the Inquiry by Professor Berry.

9. In conducting an autopsy on a child with congenital heart disease it was considered by Pathologists good practice to retain the heart, sometimes with the lungs attached. My primary purpose in retaining the heart was properly to examine it. The malformed and surgically operated heart in the fresh state does not easily lend itself to detailed dissection. The heart was fixed overnight by distension with formalin following which it was dissected. The dissection was often a very slow process and took in many instances several days, having to be fitted in around my other commitments in the Department. The dissection took so long because of the complexity of the anatomy and the necessity to record in as detailed a fashion as possible the disordered anatomy and to compare it with the pre-operative descriptions and the operative findings and descriptions. In some instances this was supplemented by drawings and photographs. I believed this to be good practice then and continue to believe it to be good practice.

10. The hearts, once retained, were placed in labelled containers and stored in the department. Some hearts (anonymised for the purpose) were used for teaching of congenital malformations to trainee pathologists and other doctors and nurses, but no heart was retained, to the best of my knowledge, solely for its teaching value. In non-Coroners' cases involving congenitally malformed hearts, the heart was retained unless the section of the request form dealing with retention of tissue for teaching and research was struck out by the person signing the form. The heart was never retained if I was instructed not to retain it, or if I was made aware of objections to its retention. In addition to hearts held from local cases, I was regularly sent hearts for opinion by other pathologists in cases of congenital heart disease or in cases of sudden unexpected death where a cardiac cause was suspected. Following my examination of these hearts they were retained in the department unless the referring pathologist requested their return. The hearts, having been dissected, recorded and kept, were demonstrated by me at monthly

clinico-pathology meetings to the cardiologists and cardiac surgeons who were very keen to see the anatomy for themselves. I comment more fully on those meetings below. Once kept, it was not my policy to dispose of a heart, rather it was my practice to keep the heart indefinitely.

11. In retaining hearts where I felt it necessary I was I believed acting legally, ethically and in accordance with good practice. It was my understanding that the possibility of retention of hearts would be discussed in each case with the next of kin of the deceased by the person obtaining the consent to autopsy or explaining the necessity for a medicolegal examination. The process of taking consent for post-mortem examination was at one remove from the pathologist. In the period my statement covers, 1993-1995, it was my understanding that the task should fall to the senior clinician in charge of the case, ie. the consultant cardiac surgeon or cardiologist. I do not recall ever being asked to talk to parents before obtaining consent to autopsy in cardiac cases, although I have done so in other cases. I can recall at least one occasion when I have been asked to speak to parents after post-mortem in a cardiac case and I did so. I do not know if the parents found it helpful, but I hope that they did

12. I have considered whether it would have been or would now be possible to undertake a post-mortem examination in such a way that a sufficient examination of the congenitally malformed heart could take place in such a way that the heart could then be returned to the body in time for disposal with the body. Ideally the heart should be kept for several days to permit thorough examination and documentation. There is nothing then to prevent its return to the body. In preparing a post-mortem report it is frequently the case that the pathologist will want to check something and go back to the particular organ and re-examine it, photograph it and take further blocks for histology. This cannot be done if the heart is no longer available. And, of course, if the surgeon or cardiologist cannot come to see the heart in that time period, as is frequently the case, the opportunity for the closest clinico-pathological correlation is lost. I believe that it is desirable that there should be a collection of malformed hearts both operated and unoperated for the purposes of teaching, education and research but that should be with the knowledge and consent of the next of kin.

13. Since the adverse publicity in February 1999 about the retention of hearts in Bristol I do not keep hearts at post mortem unless there is specific written permission to do so. I understand that the Royal College of Pathologists is preparing guidelines on the retention of organs at necropsy and I await that report.

14. As part of my involvement in cardiac pathology it fell to me to organise the monthly clinico-pathological meetings with the cardiac surgeons and cardiologists. No radiologist attended (Dr Peter Wilde on several occasions expressed a wish to me to do so but he was precluded by attendance at another meeting at the same

time) and I do not recall an anaesthetist attending. The meetings pre-dated my appointment by several years. I cannot say when or by whom they were initiated. As far as I am aware no minutes had been kept of these meetings before my arrival. I attempted to do so and the first that I made a record of was in May 1993, the fifth such meeting that I attended. My notes consisted only of a list of those present and a list of the cases discussed. I kept these notes for my own sake and they were not circulated. I kept them because I believed that it was good practice to do so. The notes are not complete. I did not have a personal secretary and our department for many years had a shortage of good secretarial help, relying for several years on agency secretaries. Thus I had to make these minutes myself in my own time, and at busy periods they were left incomplete. The notes were presented to the GMC hearing last year and I believe that the Inquiry has a copy of them.

15. It was the practice to hold the clinico-pathological meetings once a month and to discuss all the deaths for the previous month. The meetings usually lasted between one hour and one and a half hours. There was usually at least one case. The cardiologist commenced by describing the clinical history and investigations, occasionally a catheter study would be shown. The surgeon then talked about the operation and any problems associated with it. I then demonstrated the fixed and dissected heart. Quite often one of the cardiologists or surgeons would also put on a pair of gloves and examine the heart closely themselves. Sometimes they made suggestions for further dissection. In cases of doubt or uncertainty I would sometimes be asked to seek a second opinion, usually from Professor Anderson, Professor of Paediatric Cardiac Morphology, at the Brompton Hospital. I do not recall any occasion when Professor Anderson's opinion differed in any significant way from my own.

16. The function of these meetings was educative for the cardiologists, cardiac surgeons and pathologists. The meetings were not used by me as a basis for published research/audit because they were case studies and I was not in possession of the other information necessary to audit the service (e.g. the number of operations performed). The information that I possessed and provided could have been used as part of audit but of itself was not sufficient for audit. For the same reason I could not comment on the results of cardiac surgery in Bristol. I can, however, say that at no time were concerns expressed to me, nor did I find anything in my own practice to cause me to feel concerned that the service might be other than satisfactory.

Signed



MICHAEL THOMAS ASHWORTH Dated 2nd July 1999