The BRI inquiry into paediatric cardiac surgery in Bristol (1984-1995)

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Introduction

1. This statement is made in response to the Inquiry's request for information relating to evidence to be heard in "Block 4". It supplements my earlier witness statement dated 8th June 1999. My comments are confined to the period I was employed at the BRI until 1993.

2. For ease of reference I repeat here the introductory paragraphs to my first statement, setting out my career history.

Background

3. After obtaining a BA (Hons) in French I joined the NHS in 1981 as a Health Centre Administrator in Bristol employed by the Bristol and Weston Health Authority. I subsequently undertook a 3 year course to qualify as a member of the Institute of Health Service Management. In 1983, I became Administrator at the Bristol Dental Hospital. In 1986, I was appointed General Manager of the Bristol Eye Hospital. In 1989/90, I was seconded to work with the team, led by Dr John Roylance, which was preparing the application for Trust status. In essence my role was to support the team and to turn their deliberations into the application document. I completed the work on the application and was then appointed Assistant Director of Planning

when Trust status was granted. In 1991, I was appointed as the General Manager of the Directorate of Surgery. I held this post until 1993.

4. From February to October 1993 I was seconded to work on improving Trust relationships with general practitioners and to preparing the Trust to work effectively with GP Fundholders. After the secondment I then moved to Avon Health Authority where I was appointed Director of Operations for the FHSA in 1994. In April 1996 I became Assistant Director of Development for the Avon Health Authority following the merger with the FHSA. On 1 April 1999, I was appointed Senior Manager, North Somerset Directorate of Avon Health Authority.

5. Whilst I was General Manager of the Directorate of Surgery from March 1991 to February 1993, my responsibilities were to manage the resources available to the Directorate in order to ensure the provision of the best quality surgical services for the local population. Within this Directorate there were 800 staff and we had a £20 million annual budget. The Directorate included 5 major specialities, which were A&E, general surgery, trauma and orthopaedics, cardiac surgery, and urology. The Directorate was the largest in the Trust at that time.

Issue C: The Service Provided: Nature and Outcomes

6. My role as General Manager was to manage all the resources to support the clinical work of the Directorate. Clinical matters were dealt with by the Clinical Directors, who set clinical standards and a strategy having regard to the views of the Associate Clinical Directors and other clinicians. Once a strategy had been decided it was then up to me as General Manager to deploy the Directorate's resources to ensure the strategy was implemented as effectively as possible. We were all trying to use resources to treat as many patients as possible. I have no knowledge of the procedures or information set out in Issue C which are clinical matters outside the remit or scope of my own role.

Issue D: Referrals

Issue D1: The identity and the distribution of hospitals (and/or general practices, if appropriate), from which children were referred to:

a. the paediatric cardiologists; or

b. the paediatric cardiac surgeons based at the BRI

7. As far as I was aware children were referred from the South West and Wales region. I cannot state the individual hospitals from which they were referred.

Issue D2: The judgement or impression formed by referring paediatricians or other clinicians of the paediatric cardiac surgical services provided by the BRI

8. I have no information to offer on this issue.

Issue D3: The sources of information available to such referring clinicians upon the standards of treatment and care attained at the BRI

9. I am speaking for surgery at the BRI as a whole, not specifically for cardiac surgery. As far as I am aware there was no marketing information as such. My understanding was that generally the surgeons did not provide any data, but they did give lectures on the services provided, for example to GP's. I cannot say whether this happened in paediatric cardiac surgery. I was never involved in setting up such lectures. In general, I understood that GPs built up a picture of each surgeon by information supplied by other GPs and also by referring their patients to particular surgeons. It was quite often the case that they had favourite surgeons they used for the majority of matters. This meant that some surgeons had larger waiting lists than others. During my time as Eye Hospital Manager, to address this, I suggested that we pool the lists for the more standard operations, eg cataracts. Some surgeons were not keen to do this, as it would have gone against the GP's original request. As a compromise, we decided to begin informing GPs of the waiting list situation, for each surgeon, and the GP could then, if they wished, select the surgeon who had

the shorter waiting list. As far as I know, this was never considered for cardiac surgery.

10. From February 1993, my role as the Trust's Liaison Officer with GPs was very much concerned with the issue of GP Fundholding. Initially, Fundholding did not extend to cardiac surgery, though CABGs were included subsequently. Because Fundholders were purchasing individual procedures, they needed to know how much each operation would cost. They relied on their own knowledge about outcomes of surgery. My role also had a PR aspect to it. As the BRI was in the centre of the city, there tended not to be a close personal relationship between the hospital staff and the GPs across Avon. I also acted as a trouble shooter for GP problems with BRI services. For instance, it was often the case that GP's did not receive speedy replies from surgeons following referral, and I would address these concerns. GPs did not discuss any clinical concerns with me.

Issue D4: The factors influencing clinicians, in deciding to refer children to the BRI rather than to other centres performing paediatric cardiac surgery

11. I can add no more than I have above (D3 paragraph 9).

Issue D5: Whether there is evidence to suggest that clinicians based outside the BRI but within its "catchment area" were deciding to refer children to centres other than the BRI, and if so, why

12. I have no information to offer on this issue.

Issue D6: Whether any of the paediatric cardiologists based at the BRI decided to refer a child to a paediatric cardiac surgeon outside the BRI; and if so, why

13. I have no information to contribute on this issue.

Issue D7: The extent of and reasons for tertiary referral from the BRI to other centres of paediatric cardiac surgery

14. I have no information to contribute to this issue.

Issue D8: The information (if any) given to parents or guardians at the time of referral to the BRI, upon the services and care to be expected at the BRI and/or at other centres; and the information (if any) given concerning the possibility of referral to other centres

15. Information would be given during the consultation, I assume some of this would have been oral and some written, in the form of leaflets. However, I have no personal knowledge of this.

16. My impression during my period with UBHT was that there were counsellors employed through the Heart Circle who gave information to parents on the services and care to be expected at the BRI. In general, I believe that parents of children who were patients would probably receive more detailed support and information than adult patients.

Issue E: Pre-Operative Management of Cases

Issue E1: The arrangements and services available to manage the transfer of sick children from referring hospitals to the BRI

17. I was not aware of the arrangements and therefore I can offer no information on this issue.

Issue E2: Where children were managed, pre-operatively, and under which clinical speciality

18. I was aware that some children were treated at the BRHSC and some on ward 5 at the BRI. I can add no further information.

Issue E3: The re-assessment of the clinical condition of children admitted for elective surgery, following admission

19. I have no information to offer on this issue, which is a medical matter.

Issue E4: The manner in which decisions to recommend surgery for a child were discussed between paediatric cardiologists and paediatric cardiac surgeons, and other members in the cardiac surgery team; and the means by which such decisions were taken

20. I have no information to offer on this issue, which is for the medical staff to answer.

Issue E5: Who bore the ultimate responsibility of deciding whether and what surgery was appropriate for a child, who should perform it, and when it should take place

21. I have no information to offer on this issue, which will be answered by the medical staff.

Issue E6: the organisation and management of theatre lists

22. Organisation and management of theatre lists was dealt with by the surgeons and theatre team, under the guidance of the General Manager in the speciality who was Lesley Salmon. My own role was more on the performance management side, ensuring that every month we were carrying out the target number of operations to comply with the contracts with our purchasers. If we were falling behind I would look for reasons for that. For example, there could be a high number of emergencies, no ITU beds or, something like an epidemic of flu. Such issues would be discussed in the monthly Directorate meetings. For example, if there was an outbreak of flu, leading to staff shortages, all we could do would be to employ extra bank or agency staff, if any were available. However, this would involve additional costs.

Issue E7: The mechanisms in place in order to ensure that surgery (whether elective, urgent or emergency) took place at a time regarded by the clinicians at the time as clinically optimal or appropriate

23. Ultimately the responsibility for deciding when was the optimal or appropriate time for an operation could only be that of the consultant caring for the patient. From a General Manager's perspective, the only way of ensuring that operations took place at appropriate times was ensuring that lists were planned using performance data. A Theatre Manager would need to know approximately how long it took Mr X to carry out each procedure. In my time a theatre computer system was implemented which was called the "FIP theatre system". One of the aims of this system was to ensure that theatre time was planned more effectively. Data in respect of how long it took each surgeon to do each procedure was fed into the computer over a period of time. It would then be possible to pull off a list so that one could see exactly how long each surgeon took, on average, to do each particular procedure. It was often the case that surgeons took much longer than they predicted. Often surgeons were over-optimistic about the number of cases they could operate on because they were reluctant to have any spare time on their lists at the end of the day which could be

used for the benefit of patients. A consequence of this was that sometimes a scheduled operation had to be cancelled and put back on the list at a future date. It was a balancing act and some surgeons were better at it than others. Equally, an emergency procedure could result in a whole elective list being cancelled.

24. There was also in place a ward "FIP" system. These computer systems were introduced on a regional basis at a time when computer systems were seen to be a way of monitoring activity and resources more accurately. However, they initially involved the employment of additional clerks to input data, as this was not seen as an appropriate nursing or medical task.

Issue E8: Whether operations (particularly elective ones) were carried out at a time regarded by the clinicians in charge of the child's care as appropriate; or whether the timing of the operations was affected by matters such as limitations in the number of beds available in the ICU, availability of nursing staff or other staff, or the requirements of adult cardiac surgery

25. I cannot comment on the times that operations took place. The availability of an ICU bed was an essential pre-requisite when planning a cardiac operation. It was certainly the case, particularly with cardiac surgery, that because of its complex nature, if an operation became unexpectedly difficult, the operation would go on beyond the time predicted by the surgeon when the lists had been drawn up. This would have a knock on effect on the following listed operation. The greatest effect was on the last operation of the day, which would be dealt with late or cancelled. Surgeons tried not to cancel operations wherever possible, because patients for open heart surgery were very keyed up. However, cancellations did occur. Patients would have to be put back onto the waiting list and this could take some weeks.

Issue E9: If there were delays in surgery, the effect (if any) of such delays upon the outcome for the children affected

26. I have no information to offer on this issue, which is a clinical matter.

Issue E10: The qualifications, training, experience and skills of the paediatric cardiologists

27. I have no information to offer on this issue.

Issue E11: The service provided by paediatric cardiologists in diagnosing or describing:

a. the structure and anatomy of the child's heart and lungs;

b. the clinical condition of the child;

c. the nature of the surgical procedure required, and any complications that might be encountered by the surgeon;

d. the speed or urgency with which any intervention was required

28. I have no information to offer on this issue.

Issue E12: The protocols or clinical guidelines, machinery, equipment or technical services (eg radiological interpretation) available to the cardiologists to assist them in this task

29. I have no information to offer on this issue.

Issue E13: Pre-operative assessment and preparation procedures, including meetings at which treatment and operations were discussed and planned

30. I have no information to offer on this issue.

Issue E14: Pre-operative observation, assessment and care by the nursing staff and other professions (such as physiotherapists)

31. I have no information to offer on this issue.

Issue E15: Liaison of staff with parents; and the participation of parents in the assessment and care of their child

32. When I visited the cardiac ward, my impression was that liaison of staff with parents was very good. I was aware that the surgeons spent a lot of time with parents, especially Mr James Wisheart. There were also specialist counsellors available for parents to consult. Careful provision was made for parents to be able to stay with their child and help with care.

Issue F: Management of Surgery

Issue F1: The qualifications, training, experience and skills of the paediatric cardiac surgeons at the BRI

33. I can make no comments in relation to the qualifications, experience and skills of the paediatric cardiac surgeons at the BRI. The only general comments I can make are in relation to training. As General Manager I was responsible for a training budget, but this did not cover medical staff training which was entirely separate. All surgeons are given a number of weeks of time per year for training. Nurses were also sent on various courses. It was the personal responsibility of the consultant surgeons to ensure that they were up-to-date and that their junior staff training programmes were completed. It was part of the ward manager/theatre sister's managerial responsibility to ensure that nurses received the training they needed. Such needs of individuals would be discussed at nursing staff appraisals.

Issue F2: The qualifications, training, experience and skills of anaesthetists assisting at paediatric cardiac surgery at the BRI

34. I can make no comment on this.

Issue F3:

(a) the qualifications, training, experience and skills of all other members of the surgical team (eg, nurses and perfusionists),

(b) the support and assistance given by such members of the surgical team

35. Responsibility for recruitment and training of staff was delegated to the Associate Directorates, ward and department managers (see F1 above). I was aware that it was always difficult to obtain theatre staff, for it is an incredibly demanding and technical job. There were numerous recruiting drives at various times, but I cannot actually remember any specific to cardiac surgery or paediatric cardiac surgery. It would certainly have been the case that recruiting nurses with paediatric cardiac

surgical experience was very difficult. I must stress again that I was not involved in the details of nursing recruitment. These were dealt with by Associate General Managers and Ward Managers.

36. One issue I do recall which affected all specialities was the effect of Project 2000 on staffing levels. This is referred to in document UBHT 0181 0353. This project meant that student nurses, who would in the past have been a part of the team, became full-time students, and only came to the hospital to do various placements. This meant that the student nurses were no longer part of the workforce. Therefore, not only did we have to re-organise staff and the way the wards worked, but we had to employ more staff to cover the gap made by withdrawal of the students from the workforce numbers.

37. When I took over as General Manager of the Surgical Directorate, there was an overspend of approximately £500,000. At this time cardiac surgery was under-spending.

38. As far as I recall, Roger Baird, as Clinical Director of Surgery, and I agreed with the Associate Directors, target savings for each of their specialities, taking into account their current levels of spending and their levels of activity. Costs in some areas would be increasing, eg in orthopaedic prostheses. We also made cases to the Trust Board for extra funding where we felt this was justified. The Board in turn would have had to make a case to the Health Authority. Ultimately, we pulled back a large proportion of the overspend by closing one general surgical ward and increasing day case work. We also maintained the number of cases by increasing throughput on other surgical wards, and reducing lengths of stay.

39. When I started my role as General Manager I went through nurse staffing issues with my nursing advisor, Mary Luhman, and took her advice as to what the big issues were. Apart from Project 2000, all I now recall is the issue of bank nurses. When I arrived it was clear that the BRI "bank" was run down and we instituted a recruitment drive to build it up.

40. If a fundamental change in staffing establishments were needed, I might be approached by the Ward Manager, the Associate General Manager or the Associate Clinical Director, or any clinician. I would then make inquiries with those persons, their peers, and the department to ascertain if it was a justifiable request. I would take the advice of my nurse advisor, Mary Luhman. If the request was justified I then had to assess whether the recruitment was possible within the budget. If the budget did not allow us to recruit more staff we would have had to go with our recommendations to the Trust Board and they would then have had to make a decision as to whether to fund the recruitment. If they refused, this might have affected throughput. It could have affected the number of operations and we might not have been able to comply with contracts. I cannot recall any specific requests in relation to cardiac surgery or paediatric cardiac surgery.

Issue F4: How the team in the operating theatre was constituted and co-ordinated, and its performance as an integrated team

41. I have no information to offer on this issue.

Issue F5: the factors affecting performance in the theatre. Such factors might include familiarity with tasks; design and performance of equipment; hours of work; error management; and so on

42. I believe there was a system for reporting issues to do with equipment failure and poor design. I do not recall any system relating to clinical "near misses". I assume this would now be part of audit and clinical governance but these are more recent developments.

Issue F6:

(a) the existence, extent and awareness of any material differences in the manner (including speed) of carrying out surgery at the BRI, when compared to surgical practices current at the time; and

(b) the impact (if any) of such factors upon mortality and morbidity rates

43. I have no information to offer on this issue, other than that it is important to minimise time on coronary bypass. "Speed" in cardiac surgery is therefore particularly important, provided always that the surgery is of high quality. Some surgeons will always be slower than others.

Issue G: Post-Operative Care

Issue G1: The national standards or guidance in existence, in 1984 -1995, to shape the organisation, the numbers and experience of staff within ICU's such as those of the BRI and the BCH

44. I was aware that there were national standards. A Consultant Anaesthetist, Dr Sheila Willatts, was responsible for the numbers and experience of staff within the general surgical ICU. She was a national authority on ICU issues. I believe the cardiac ICU was run separately by the cardiac consultants of the relevant specialties.

Issue G2: Staffing within the ICU's caring for children following cardiac surgery; numbers, training, experience and skills mix

45. The above comments apply. Again I would stress that I did not monitor staff levels on individual wards. This was the direct responsibility of the Associate General Managers and Associate Clinical Directors in the speciality. I would only have expected to hear if there were long term problems which could not be resolved locally.

Issue G3: How, if at all, the skills mix and expertise of the ICU staff differed from both published guidance and the standards and patterns to be observed across the country at the relevant time

46. I have no further information in relation to this issue (see above).

Issue G4: The availability of staff throughout the 24 hour day to assess and to meet, following such assessment, the needs of any child in ICU after paediatric cardiac surgery

47. I have no further information in relation to this issue.

Issue G5: The development and organisation of immediate post-operative care

48. I have no further information in relation to this issue.

Issue G6: Liaison between specialities, and steps taken to ensure continuity of care

49. I have no further information in relation to this issue.

Issue G7: The assistance provided by paediatric cardiologists. The impact (if any) of the fact that these cardiologists were based in the Children's Hospital, upon the availability of such assistance

50. I have no further information in relation to this issue.

Issue G8: The extent to which the demands or requirements placed upon ICU nurses and other staff by paediatric cardiac cases differed from those imposed by adult cardiac cases or other cases commonly encountered; and the steps taken to address any issues that might arise out of such differences

51. I have no further information in relation to this issue.

Issue G9: the supply and maintenance of proper and adequate equipment to the ICU

52. I have no further information in relation to this issue.

Issue G10: The standards of post-operative care delivered at the Infirmary and the Children's Hospital; (including such matters as post-infection rates, and the general standard of hygiene and cleanliness)

53. I have no further information in relation to this issue.

Issue G11: The management of discharge and future care

54. I have no further information in relation to this issue.

Issue G12: Liaison of staff with parents; and the participation of parents in the assessment and care of their child

55. As stated above I was not ward based. Whenever I did go onto the wards the parents seemed highly involved in the care of their children and helped with feeding, bathing, washing etc. As far as I remember there were no limits on visiting times, and parents could be there day and night. They were provided with accommodation and there were facilities such as play areas for the children.

Issue K: Training and Retraining

Issue K1: The support and assistance made available to all members of staff, to help them keep abreast with developments in clinical practice, and the use made of such facilities

56. As previously stated, my role in training issues was limited. The decisions were made by the Ward Manager or Associate General Manager, or for medical staff, by consultants. Detailed training requirements were assessed through individuals' appraisals and agreed with immediate supervisors/managers.

Issue K2: The process of appraisal and training required of a paediatric cardiac surgeon in 1984-1995, before embarking on an advanced operative procedure not previously performed by him

57. If a new procedure was to be introduced it was quite often the case that I did not know that this was occurring. Clinicians would ask their theatre managers for any new equipment and the first I would hear of it was when managers were concerned about costs or staff. This was something I would have to address, as it would affect the budget. Consultants would not however discuss clinical training issues with managers.

58. Sometimes the ward manager or the theatre sister would come to me and say that Dr X wanted a new procedure, particularly if it would require extra resources. If this was the case, the Clinical Director and I would meet with the clinician and find out what the implications of this new procedure were. For example, I recall clinicians wanting to use a new type of hip joint which was vastly more expensive. They believed it would last longer than previous types. If it was decided that new equipment was necessary, we would then review the budget to try to find money and resources for staff and/or equipment. I believe that in the case of the hip joints, this was found. If we could not see any obvious savings, we would have

approached the Trust Board and possibly the Health Authority. All of us were constantly trying to balance quality, cost and increasing throughput of patients.

59. I cannot recall any new procedures being assessed in cardiac surgery or paediatric cardiac surgery during the period I was General Manager of Surgery, though I seem to recall discussion about costs and effectiveness of different sorts of heart valves for adult cardiac surgical procedures.

K3: The extent to which those obligations were affected by the fact that:-

(a) the procedure was new, and now well-established elsewhere, or (conversely) that it was well-established elsewhere;

(b) there was an absence of "local" skill or advice, so that any assistance must necessarily have been obtained from outside the institution in question

60. I have no information to contribute on this issue.

K4: the professional or contractual obligations regarding such appraisal and training imposed upon a paediatric cardiac surgeon (both at the BRI, and generally within the UK)

61. There is a recognised Royal College programme for training of cardiac surgeons. I am not sure what a surgeon's contract states. I have never seen one. As previously stated, ensuring staff received training was not part of my day-to-day work, except as a very general overview.

K5: The professional obligations or duties (if any) placed upon the person or persons carrying out, or assisting with, the retraining of a professional colleague

62. I am not able to comment on this.

K6: The responsibility borne by:-

(a) a paediatric cardiac surgeon;

(b) an anaesthetist;

(c) other members of the surgical team (perfusionists, nurses, etc); or

(d) referring cardiologists

for ensuring that all members of the surgical team were properly trained to assist at new procedures not previously carried out at an institution

63. As previously stated, the senior surgeons had a duty to ensure that they and all junior surgeons were trained. Each surgeon had a professional duty to ensure that they kept up-to-date. Ward Managers and theatre staff were responsible for nurses being trained in new procedures and this was part of their managerial responsibilities.

Issue K7: the professional or contractual standards or obligations (if any) regarding the organising or undertaking of such further training imposed upon the individuals listed at (a) - (d) above.

64. I have no information to contribute on this issue.

Issue K8: the nature and extent of any further training undertaken by all members of the paediatric cardiac surgical team at the BRI, before embarking on any new surgical procedures

65. I have no information to contribute on this issue.

Issue K9: Whether such further training met the requirements of the professional or contractual standards or obligations

66. I have no information to contribute to this issue.

Issue K10: the steps to be taken by a paediatric cardiac surgeon to ensure that his surgical technique and/or clinical skills was and remained adequate to the task of performing procedures which he was accustomed to carrying out

67. I make no comment in respect of this issue, save to say that if a manager was concerned about a clinician, for example, because they were drinking or had marital problems affecting their ability to work, then they would go to that clinician's peers to ask them to deal with it. I do not recall this ever occurring in cardiac surgery or paediatric cardiac surgery. It was not part of a manager's role to review surgical skills or techniques.

Issue K11: In particular, the steps to be taken to:

(a) evaluate and assess his own performance;

(b) maintain competence; and

(c) embark on retraining (whether as a matter of routine, or in response to specific concerns about his ability to perform particular procedures)

68. As stated above, clinicians were given a certain number of weeks per year to train and this was funded by (I believe) a Regional budget. In respect of new procedures, I was aware that clinicians attended seminars at the centre of excellence where the procedure would be demonstrated. They could also spend time at that centre to develop their own skills.

Issue K12: The professional or contractual obligations (if any) regarding such evaluation and re-training imposed upon a paediatric cardiac surgeon (both at the BRI, and generally

69. I have no information to contribute on this issue.

Issue K13: The steps that were, in fact, taken by paediatric cardiac surgeons at Bristol to ensure that their surgical techniques and/or clinical skills were and remained adequate

70. Again I have no information to contribute on this issue. All surgeons were regarded as being individually responsible for assessing the adequacy of their clinical skills.

Issue K14: Whether such steps as were taken met the requirements of the professional or contractual standards or obligations current at the time and the extent to which those actions conformed to accepted practice

71. I have no information to contribute on this issue.

Issues K15-K27

72. I have no information to contribute on these matters.

Issue L: Informed Consent

Issue L1: How, and when parents guardians or (if appropriate) children should be informed of the risk associated with surgery

73. I cannot comment on when and how parents were told of risks associated with surgery. This is a clinical matter. In general terms, risks should be explained by the surgeon at the time of the initial consultation. I would only be involved in such issues if there were any written complaints, which were treated as a high priority. There were complaints procedures which were widely publicised and which set time limits for replying to complaints. Some complaints could take a lot of time to sort out because both facts and emotions would be involved. I also had informal discussions with other managers and clinicians, to encourage clinicians to spend more time when patients were unhappy. Often, when a clinician has tried his or her best, they can feel very aggrieved by criticism. They are not trained to deal with it. I wanted us to learn from complaints and it must be remembered there were only three to four complaints per month out of the thousands of operations done in the Directorate. I do not recall any specific complaints in relation to paediatric cardiac surgery.

Issue L2: The use to be made of:

(a) national data;

(b) international data;

(c) the institutional record;

(d) the surgeon's own personal record;

(e) information upon the condition of the child;

(f) the opinion of the children's team;

(g) the opinion of any specialist nurses and/or family support services;

(h) any ethical advisory committee that may exist;

(i) written information or leaflets;

to the extent that these are or should be available to the surgeon or others advising on procedures and risks

74. I recall that some clinicians and some specialities did produce data, but essentially it was up to each surgeon as to what they provided. In the Eye Hospital I had been involved in producing leaflets providing information on certain common conditions, setting out what the condition was, the treatment options, and what was likely to be recommended. This was because it has been shown that patients recall only a tiny proportion of the information given to them in a consultation. I believe there were leaflets in cardiac surgery about after care, for example about diet etc., but I was not involved in drafting these.

Issue L3: The nature of the obligation of a surgeon, or other advisor, to refer to factors such as;

(a) the extent of the institution's experience in performing the procedure in question;

(b) the extent of the surgeon's personal experience in performing the procedure in question;

(c) the fact that other institutions within the UK are known to have higher or lower-risk records in the procedure in question than those that the surgeon would be obliged to quote as the risk if the procedure were carried out at his own place of work

75. I have no information to contribute on this issue.

Issue L4: The professional guidance (if any) available to surgeons, or other advisors, upon the subject of informed consent and quoting for risk

76. I understand that there was professional guidance for clinicians available from organisations such as the General Medical Council and the Royal Colleges and their Medical Defence bodies.

Issue L5: How the paediatric cardiac surgeons at BRI, or other advisers, treated the various factors referred to at (L2) and (L3) above, when giving estimates of risk. The factors that were used, and how, to arrive at any estimates given, and their adequacy.

77. I have no knowledge of this.

Issue L6: What parents and guardians attending at the BRI were told, and how they informed, as to the risks associated with surgery, including risks of:

(a) mortality;

(b) morbidity, especially neurological deficit;

(c) likelihood of future surgery or protracted drug regimes being needed;

(d) other side effects or complications or surgery, and/or alternative treatment methods or the merits of non-intervention

78. I have no information to contribute on this issue.

Issue M: Review of Cases and Medical and Clinical Audit

Issue M1: The professional guidance available on the subjects of reviews of cases, and medical or clinical audit from 1984-1995

79. I was not involved in medical or clinical audit in itself, as this was not within my remit. General Managers were responsible to ensure that a framework was in place and that every speciality met once a month to carry out audit. In other words, to organise the Directorate in such a way as to allow medical audit to take place. General Managers were not involved directly in the audit process itself. My perception was that audit was patchy in the Directorate of Surgery in the early years, although I understood cardiac surgery was one of the specialities which did undertake regular audit meetings.

80. I only went to audit meetings when invited. My impression was that clinicians wanted to audit interesting clinical conditions, whereas managers were more interested in auditing the features of the system, such as which procedures were the most effective, how long a patient waited, and how much day surgery could be carried out. There had to be a balance between the two. I did not attend any cardiac surgery audit meetings. As a manager, my knowledge of outcomes, or what was regarded as clinically acceptable, would come mainly via local clinicians in an informal way, although I did try to keep up with my specialties via British Medical Journal articles and "Medicine for Managers" conferences.

Issues M2 -M12:

81. I have no information to contribute to these issues, except that above.

82. In respect of UBHT 0006 0374 upon which I have been asked to comment, I do not recall receiving any critical incident reports in respect of clinical matters. The only reports I received were in respect of health and safety matters e.g such as a loose tile causing injury.

83. In respect of UBHT 0081 0240 and the introduction of the Associate Directorate of Cardiac Surgery (i.e. disease-based Directorates) I believed the purpose and effect of these were to establish systems of unified care for patients with cardiac disease and to encourage better use of staff and the resources which were currently split between cardiology (BRI Old Building) and cardiac surgery (Queens Building). The split between cardiology and cardiac surgery was becoming much less relevant with the advent of new procedures such as angioplasty.

SIGNED : ....
MS KATHLEEN MARY ORCHARD

DATED : ......19 August 1999

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