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". I also make reference to my earlier statement provided to the Inquiry dated 19 June 1999. My comments are, again, confined to my period of employment relevant to this Inquiry, namely October 1983 to June 1989 at the BRHSC (also referred to as the Children's Hospital/BCH), not the BRI.

2. To assist the Inquiry, and to avoid repetition, I refer to my first statement dated 19 June 1999 where I have previously made comments covering a particular issue. My first statement dealt with issue B and issue H. There may be some overlap with the remaining issues being addressed in this statement. I make this statement first by considering my personal involvement, and secondly by commenting upon the structures and procedures in place at that time. At the end of the statement I comment on particular documents drawn to my attention by the public inquiry.

Issue C: The Service Provided: Nature and Outcomes

3. I had no involvement in clinical or nursing matters relating to the BRI and can therefore make no comment on this issue.

Issue D: Referrals

4. I have no direct knowledge or involvement relating to the referral of children to the BRI in terms of the clinical assessment of the need for that referral and the direction of that referral, as these were matters for the clinicians.

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

5. There were transfers of paediatric cardiology patients between BRHSC and the BRI, this was often by way of referral from the Intensive Care Unit at the Children's Hospital to the BRI for catheterisation in the earlier years, and for surgery. The transfer process occurred once the child was stable enough for surgery and the child was then escorted from BRHSC to the BRI. Once ready to return the child was again collected, from my memory, by a nurse from PICU and at that stage received a detailed handover from the nurse at the BRI. I believe (although at this stage I cannot be sure) that there was continuity of medical notes throughout this transfer period, and with nursing notes following the child to both areas. I do not recall any problems in relation to the transfer of the patients between the Children's Hospital and the BRI. In my role as Senior Nursing Officer, I am sure I would have heard of any major difficulties arising from these transfers from the nursing officer or unit staff, on my frequent visits to PICU. I have no recollection of any being brought to my attention.

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

6. The majority of children were managed at BRHSC pre-operatively and then transferred to the BRI for open cardiac procedures. Pre-operatively these children would be under the care of the cardiologists and then once stable enough for surgery, would be transferred to the care of the cardiac surgeons at the BRI. Some closed cardiac procedures were carried out at the Children's Hospital.

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

7. The paediatric cardiologists at the BRHSC were in communication with the paediatric cardiac surgeons prior to surgery for assessment of the child's condition. I expect that this sort of communication took place. I recall a general picture of much co-operation and collaboration between the cardiologists and the cardiac surgeons, as this was obviously vital to the plan of treatment for these children. The nursing assessments of the child's physiological and psychosocial state were also part of this process.

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

8. This was not a nursing issue. I am unaware of the process by which these decisions were made. I believe that much communication occurred between the paediatric cardiologists and the paediatric cardiac surgeons.

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

9. I am unable to provide any information, as this is a clinical issue.

Issue E6: the organisation and management of theatre lists

10. I am unable to provide any information or comment on this issue as this will relate to the BRI and/or to the surgical team. It is a clinical issue and not one in which I would have had any routine involvement. I do not recall there having been any serious problems with listing closed cardiac surgical procedures at the BRHSC, such

as might have been drawn to my attention if there had been insoluble difficulties in resourcing a theatre list.

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

11. This was a clinical issue and as such I can make no comment on it.

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

12. This again is predominantly a clinical matter and as such I can make no real comment, save for confirming that if there were significant nurse staffing problems or difficulties with regard to availability of beds on PICU at the BRHSC, it may have affected the post-operative transfer back from the BRI and therefore the timing of the surgery. As a nation-wide issue, there were frequent limitations on bed availability in PICU's and the BRHSC was no exception. Once capacity was reached in terms of bed availability and staff, we closed to admissions until further capacity appeared. We would not compromise the level of care given to the children under our care.

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

13. If there had been a significant effect for a child from the BRHSC, for whatever reason, I believe the night sister would have made me aware of this during the formal handover. This handover each morning identified the condition of critical

patients and new admissions. I cannot remember any significant difficulties in relation to paediatric cardiology during the relevant time.

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

14. I have no knowledge or information in relation to 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

15. I have no knowledge or information in relation to 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

16. I have no knowledge or information in relation to this issue.

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

17. Paediatric cardiac surgeons would invariably come to the BRHSC to specifically address treatment proposals and planning. This would include liaison with the paediatric cardiologists and the nursing team. As far as I was aware, at the appropriate stage of these discussion, they included the parents and informed them of the procedure, progress expectations, possible complications and prognosis. A

nurse was usually present during this process in a supporting role, both as support for the clinician and also for the family. From memory, these meetings were usually held in the PICU interview room. I cannot say how frequently they were held or how they were structured, as I was not personally involved.

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

18. The children were closely monitored pre-operatively. The majority of the cardiology cases would be on PICU at BRHSC. Therefore, I would have anticipated that the patient/nurse ratio would have been either, 1 to 1 or 1 to 2 if there were 2 less dependent ICU patients. I cannot now recall the exact staffing establishment for that area to substantiate the ratios. On site there would have been all other necessary professionals, for example physiotherapists and dietitians. The BRHSC was often used as a stabilising unit for BRI referral, in essence treating the child until ready for surgery.

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

19. The ethos at BRHSC, as in other children's hospitals, was always to regard parents as a part of the caring team. A child was never seen as a single entity; all clinical staff regarded the family and the child as one unit. I believe this was reflected in the way that staff liaised with parents, and involved them in the assessment and care of the child. This was certainly the approach at BRHSC during my time there, (which totalled some 16 years, in two episodes) and is absolutely vital to the success of any paediatric unit.

Issue F: Management of Surgery

20. Save for confirming my belief that the anaesthetists assisting at paediatric cardiac surgery at the BRI were all paediatric anaesthetists, I have no additional comment or information in respect of this issue.

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

21. I do not remember the names of specific guidance papers. I facilitated opportunities for staff to work towards and within such guidelines, for example through training programmes and planning meetings. I was aware that at that time there were audits undertaken in terms of the quality of service but I unable to remember detail. I believe that the lead consultant anaesthetist (I think Dr Hughes), along with Joyce Woodcraft (Clinical Manager of PICU), were involved in this auditing process. I have no other specific recollection in relation to this or any other documentation relevant to such standards.

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

22. The staffing levels at the Children's Hospital were set by the Chief Nurse (Mr Bennett) for the whole of the Authority. He was based at the BRI. My role was to ensure that funding allocated to each area was spent appropriately. In terms of staff recruitment within the PICU, I was involved in selecting senior staff (ie Sisters). The nurses within PICU at BRHSC were, from my recollection, children's trained nurses, the majority with ICU experience too. At lower grades the staff may have been paediatric nurses but not ICU experienced, and were gaining that experience in the unit.

23. My recollection was that at that time Ms Beckingsale was the Authority's post- basic Training Officer based at the BRI. Training needs were identified through the individual appraisal process and at specific unit meetings; these I prioritised and discussed with the Central Training Officer. The Training Officer would then consider the requests and the training needs would be, on the whole, satisfied.

Central training opportunities were available. There were occasions when individuals were seconded elsewhere for specific training, e.g. the Intensive Care Course. Some specific paediatric training programmes were delivered at BRHSC to meet the local need at that time.

24. In terms of the staffing levels, the Chief Nurse set the ratios, with some discussion with the managers. If there was a shortage of staff, we would assess whether this was a long or short-term issue, and how that difficulty would be managed; for example, by means of temporary bed closures.

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

25. As far as I was aware, the skill-mix and expertise of the staff within PICU were acceptable and within the guidelines of the day. Care was given and procedures were carried out by safe practitioners. I cannot now recall how we measured against published guidelines at that time.

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

26. Efforts were made to staff the unit to meet the activity across the 24-hour period and to meet the standards set for establishments throughout the period. I cannot recall any detail, so long after I was working at the BRHSC.

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

27. Immediate post-operative care was undertaken at the BRI. I can provide no comment with regard to that care. Once the child was stable following the surgery,

they were transferred to the BRHSC for the remainder of the post-operative care, unless discharged home directly.

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

28. The anaesthetist and consultant surgeon led the care at both the BRI and BRHSC. The nursing teams were obviously different as between the two hospitals. However, as already mentioned in paragraph 5, continuity of nursing care was ensured if at all possible, acknowledging the limitations of shift patterns. There was also a nurse to nurse handover at the point of transfer. This handover would have been similar to that of a shift handover, detailing current clinical status, planned care and treatment required. I was never made aware of any specific problems with regard to continuity of care between the two hospitals or the various professionals involved in paediatric cardiac surgery.

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

29. I was unaware of any particular impact or difficulties.

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

30. There are clearly different demands on nurses in relation to the management of adults as compared with paediatric cases. These include physiological/biological variances and, in particular, the psychosocial aspect of care in respect of the management of the child and their family. I am unsure of the skill-mix within the ICU at the BRI in terms of nursing care. I refer to paragraph 22 of my first statement with regard to the PICU at the Children's Hospital.

31. I am unsure how to respond adequately to the issue that children were receiving treatment in an adult area. It was accepted there were different demands on nurses when caring for patients of diverse age ranges. Opportunities were created for nurses from the cardiac unit at the BRI to gain experience on PICU at BRHSC in order to enhance their skills and knowledge base. However, it was acknowledged and accepted at that time, that the Children's Hospital did not have the facilities to undertake that workload. At this time it was accepted that the physiological needs and the availability of surgeons, equipment and support staff (e.g. for bypass surgery, equipment) had to take precedence over the psycho/social or developmental needs of the child.

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

32. My memory is very scanty on these issues. I believe there was a hospital maintenance contract for medical equipment. In terms of supply, the lead consultant anaesthetist and clinical manager identified equipment requirements, in consultation with other clinical colleagues. I cannot remember the funding arrangements or how frequently this consultation occurred, although I recall that the General Manager managed the purchasing process, including how this was funded.

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)

33. There were certainly guidance documents covering post-operative infection rates and there were audits covering this area too, although I do not recall the details. I do not recall any issues raised with regard to hygiene and cleanliness at the PICU. I have no recollection, for example, of any closures due to cross-infection issues. Infection control procedures were strictly adhered to in the PICU. There were 2 isolation cubicles used for children with infectious diseases. I do not recollect a particular problem with hospital acquired infection rates.

Issue G11: The management of discharge and future care

34. A percentage of our children would be discharged from PICU at BRHSC to their local hospital for further care. Some children were transferred from PICU onto other wards at the Children's Hospital, for example Ward 33 (a surgical ward). As with any PICU there were a limited number of beds available. Once the child's condition had sufficiently improved and no longer required high dependency care, transfer from PICU was clinically safe and appropriate. From memory, it was often pre-planned that children living outside of the Bristol boundary would be discharged back to their local hospital, if continuing hospital care was deemed necessary. This was planned in conjunction and collaboration with the parents and the local hospital team.

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

35. See paragraph 19 above. My role was to support the nursing staff only if issues with parents arose that they were unable to resolve at unit level, and these were very rare. A specific example may have arisen in response to the transfer of a child from PICU to the wards and the anxieties relating to a reduced nursing input. Ward staff took steps to introduce themselves to the family prior to transfer and aimed to show them around the ward. PICU medical and nursing staff would explain in detail the changes to care to be given in response to the child's improved condition.

Issue H: The Split Site

36. Addressed in paragraphs 59 to 61 of my first statement.

Issue I: Treatment of Families, including the Bereaved

Issue I1: The nature, extent and adequacy of the services that were established to inform, support and counsel families with children receiving surgical cardiac care at the BRI, whether before, during and after surgery

37. At BRHSC we used the Authority's core training programmes for counselling and bereavement to ensure that the nurses and clinicians were competent to support and counsel families. The Heart Circle was a local charitable organisation, whose expertise included counselling, practical support, shared personal experience gained through a similar situation and fund raising. The members of the Heart Circle worked closely with the clinical teams on PICU, Ward 3 and any area where children with cardiac conditions were managed. The Heart Circle also supported the PICU staff. They were regular visitors to the Children's Hospital and were part of the caring team.

Issue I2: The nature, extent and adequacy of the services that were established to inform, support and counsel families with children who died or suffered permanent disability after receiving cardiac care at the BRI, including liaison with community and social services

38. From my recollection there was a file available to nursing staff within PICU detailing procedures to follow and information to give to parents following a child's death. Advice was given in terms of the practicalities, such as the certification of the death and release of their child's body, as well as advice about support groups and counselling services. This was by way of leaflets and contact details for voluntary organisations. Where children suffered permanent disability following surgery, my understanding was that a referral was made to the appropriate professional teams who would be providing the ongoing care to the child and family. There was not, as far I can remember, a patients' affairs officer.

Issue I3: The financing of the support and counselling services

39. I was unaware of a specific budget that supported a counselling service. The Heart Circle was a voluntary organisation reliant upon charitable donations, which was available to provide valuable support for families. See paragraph 37.

Issue I4: The priority afforded to support and counselling work by hospital management and clinical staff

40. Counselling and support within BRHSC was given a high priority and was regarded as part of the case management. In this sense it did not present as a separate discipline, but was seen as an integral part of the entire care process for each child in which all members of the clinical team had a part to play. This meant that, whilst from a financial point of view, counselling itself did not feature particularly highly in specific fund allocation, it was given high priority in respect to the ongoing training given to nursing staff "on the job", in order that they felt competent to support and counsel the families in their care.

Issue I5: Whether staff coming into contact with parents who were under stress because of the nature and severity of their child's condition, or who had lost children, showed appropriate sensitivity in their dealings with such parents; and, if not, the importance and effect of any such failures

41. At the BRHSC, the H grade clinical manager and the Nursing Officer had, as part of their roles, responsibility for supporting and counselling staff. Any stress related issues affecting either an individual or the team was dealt with at unit level.

42. If there were any issues of inappropriate response or lack of sensitivity from the staff to parents, this would have come to my attention, usually through a letter of complaint. The nursing staff at BRHSC were all specifically recruited to deal with paediatric cases, to ensure that the ethos of sensitivity and approaching each case as a family unit was maintained throughout the hospital. In addition the BRHSC was a

relatively small hospital and as such the staff all knew each other fairly well. It had quite a family feel to it and the staff on the whole supported each other. This small community culture enabled me to have a real awareness of 'live' personnel or operational issues. The closeness of the staff in the hospital meant that if there were any particular problem with a member of staff it would come to my attention quickly. The PICU clinical manager and I worked very closely. I certainly believe I would have been aware if any problems had existed within the unit at that time. I can confirm that, to the best of my recollection, there were no major issues at the BRHSC, PICU in the relevant period.

43. From my recollection, there was no formal complaints procedure in place during this period. However, if parents raised concerns regarding the sensitivity of staff to their situation and they wished the matter to be addressed, they were advised to write to the Hospital Manager. The issue would then be addressed by the appropriate professional i.e. me, if the complaint was a nursing one, or the Consultant, if a member of medical staff was involved. Following an investigation an action plan would be formulated, if required, and implemented by the PICU team.

44. I cannot make any particular comment with regard to the BRI staff and how they dealt with patients. I believe that any inappropriate responses, particularly in dealing with patients transferred from the BRHSC, would have been brought to my attention.

Issue J: Post-Mortems and Inquests

Issue J1: The nature and extent of the responsibilities of (a) hospital staff; (b) hospital pathologist; and (c) H M Coroner to report and investigate deaths

45. The reporting of deaths to the Coroner would have been the responsibility of the clinicians, albeit that the nursing staff would have been aware of when this need arose.

Issue 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

46. I can make no comment on this issue.

Issue J3: The extent to which post-mortems and any inquests held upon children who died following complex cardiac surgery at the BRI performed such a function

47. I can make no comment on this issue.

J4: Whether consent (if required by law) to:

(a) hospital or coronial autopsies; and/or
(b) the retention of tissue and/or organs of the body

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

48. Discussions with parents about hospital and/or Coroners autopsies and organ donation were the responsibility of the clinicians. This was not a nursing role. Nurses would usually be in attendance during these discussions, again to support both family and doctors. This would be particularly so, where organ donation was

being discussed, as the family required a great deal of support. From vague recollections, nurses had written guidelines and information in respect of organ donation. I am unsure of the period when these were available.

49. If an individual nurse felt they had either a weakness in this area or a particular need to receive further training, then this request went to the PICU Clinical Manager or the Training Sister, when this post was introduced. I am unsure of the date this was introduced, but believe Bridget O'Reilly was the Training Sister. This then became a training issue which I would follow through with the Health Authority's Training Officer. I am unable to remember the specific content of the training programme. I am also unable to remember the uptake of the specific programme.

Issue K: Training and Retraining

50. The question of training and retraining was such an integral part of my role at BRHSC and in subsequent roles in other organisations, that my recollection of the specific details covering the relevant period is not particularly clear, as it is easy to become confused with present practice.

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

51. See paragraphs 6-9 inclusive of my first statement. There were clinical study days to ensure members of staff were up to date. The Training Sister facilitated all in-house training programmes, although I am unable to recall the precise details. I recall that the introduction of new cardiac procedures in particular, created a training need which had to be met. I remember that there was an informal rotation of nursing staff between the BRI and the BRHSC which provided opportunities to observe and practice alongside experienced nurses.

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

52. This is a clinical matter and as such I have no knowledge of it.

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

53. This is a clinical matter and as such I have no knowledge of it.

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)

54. This is a clinical matter and as such I have no knowledge of it.

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

55. This is a clinical matter and as such I have no knowledge of it.

K6: The responsibility borne by:-
(a) a paediatric cardiac surgeon;

56. This is a clinical matter and as such I have no knowledge of it.

(b) an anaesthetist;

57. This is a clinical matter and as such I have no knowledge of it.

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

58. See paragraph 50.

(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

59. I recall that the paediatric cardiologists (and indeed the paediatric cardiac surgeons) were excellent at appraising staff of the need to introduce new clinical procedures. They, along with the clinical manager, developed the written procedures. Unit meetings, open to all grades of staff, were fora at which staff would have the

opportunity to discuss new procedures and their possible implications on practice. Nursing Staff were involved in preparing documentation to support new care interventions. At the time in question, such meetings for PICU involved; Dr Joffe, Dr Hughes, Sheila Thompson and Joyce Woodcraft, and possibly Maggie Perrett (Nurse Manager).

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.

60. The School of Nursing ran certain post-registration courses. I have no other knowledge with regard to the professional or contractual standards or obligations imposed upon the relevant individuals.

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

61. This is a matter concerning the BRI, about which I have no knowledge.

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

62. This is a matter concerning the BRI, about which I have no knowledge.

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

63. These are clinical matters for the cardiac surgeon about which I have no knowledge.

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)

64. These are clinical matters for the cardiac surgeons to answer.

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

65. These are clinical matters for the cardiac surgeons to comment on, and I have no knowledge.

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

66. These are clinical matters for the cardiac surgeons to comment on, and I have no knowledge.

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

67. These are clinical matters for the cardiac surgeons to answer, and which I have no knowledge.

Issue K15: The responsibility borne by members of staff (such as the paediatric cardiac surgeons, the anaesthetists, other members of the surgical team, or managers) in ensuring that all members of the surgical team were, and remained, properly trained and skilled

68. See paragraph 60. Any relevant training was carried out within the unit. As a general comment, new surgical procedures rarely created a change in the nursing management of the case. If there were variations to the normal post-operative care of the child, these were clearly specified in the medical notes and verbally communicated to nursing staff by the attending doctor.

Issue K16: The professional or contractual standards or obligations (if any) regarding the organising or undertaking of such training imposed upon staff members, both at the BRI, and generally

69. I have no information on this issue.

Issue K17: The continued professional education and training undertaken by members of the paediatric cardiac surgical team at the BRI

70. This is a BRI issue and as such I have no knowledge of it.

Issue K18: Whether it is (a) inevitable; and (b) acceptable, that a surgeon carrying out a new procedure will experience a "learning curve" during which his competence or results mat fall below the standards achieved by a surgeon who has carried out a reasonable number of these procedures

71. This is a BRI issue and as such I have no knowledge of it.

Issues K19-K27

72. I do not feel that I can provide any information on these issues.

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. The medical and nursing team at BRHSC worked in collaboration with regard to the giving of information to parents. This included pre-operative information and assessment of risks. The nurse acted as a support to both the doctor and the parents, by reinforcing the information given by the doctor, as and when required.

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. Issues (a) to (d) and (h) to (i) are matters on which I have no information, much less any specific detail. I can confirm in relation to (f) and (g) that at the BRHSC the opinion of the children's team was definitely taken into consideration, and involved liaison between the Children's Hospital and the BRI clinicians.

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. This is a clinical matter and I have no information on it.

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

76. This is predominantly a clinical issue. The nurses would be trained to know what is expected during the consent process.

Issue L5: How the paediatric cardiac surgeons at the BRI. or other advisors, treated the various factors referred to at (L2) above 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 information on this issue, as it is a clinical matter.

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. This concerns the BRI, and I have no information to offer.

Issue M: Review of Cases and Medical and Clinical Audit

79. This issue relates to matters at the BRI and auditing processes in that institution. I have no knowledge or information on this issue. At the time I worked in Bristol, clinical audit had not been developed. Neither as a nurse, nor as a manager, was I involved in any form of medical audit, for it concerned and involved only the medical staff. If or to the extent medical audit was taking place at the BRHSC, I would not have known about it. Of course, this is very different from the more recent development of clinical audit involving all professional groups, and the principles of clinical governance.

Issue N: The Expression of Concerns

Issue N1: The parents' perceptions, both positive and negative, of the treatment and care received by their children, including:

(a) The nature and form of any concerns that may have been expressed
(b) The persons to whom they were conveyed; and
(c) The responses to any such concerns

80. Until this Inquiry and the publicity surrounding the paediatric cardiac unit became public knowledge, I was unaware of any expressions of concern by parents or by anyone else, in relation to the treatment received at the Bristol Royal Infirmary.

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81. These are matters concerning the BRI and I have no information on them.

Additional Comments on Documentation

82. I have been asked specifically to comment upon the following documentation:-

Report of a Working Party on Paediatric Intensive Care, BPA 1987 (RCPCH File 1, page 1);

Welfare of Children & Young People in Hospital DOH, 1991 (HOME 2, page 1);

Children First: A Study of Hospital Services, Audit Commission 1993 (WIT 46, p30);

The Care of Critically Ill Children, BPA 1993 (WIT 60, page 59)

Standards for Paediatric Intensive Care, Paediatric Intensive Care Society, 1993 (WIT 60, page 11);

Standards for Paediatric Care, RCN (RCN File 1, page 142).

The reports particularly address staffing levels for paediatric intensive care and are extremely helpful in auditing clinical standards. It particular they assist nurses and nurse managers endeavouring to develop and improve services, and addressing issues relating to the allocation of resources. In terms of the period in question, only the report of the Working Party on Paediatric Intensive Care had been published (1987) when I was in Bristol. Whilst I do not remember specific details following this report, I am aware that PICU at BRHSC were collecting information to audit their position against the criteria set. I recall Dr Hughes and Joyce Woodcraft led the audit process. Examples of information collected included bed occupancy, staffing, and dependency level figures. I was not involved in this process and I am unaware of the end result.

83. I have no other recollection in respect of that particular document. All the other documents were produced after the time I was at the BRHSC.

SIGNED : ......K. M. Hale.............
MISS KATHRYN HALE

DATED : ....13 Sept '99........

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