
BRISTOL ROYAL INFIRMARY INQUIRY

Issues List, for Part I of the Inquiry

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Explanatory Note

Background

This is the Issues List for Phase 1 of the Bristol Royal Infirmary Public Inquiry.

The Inquiry's terms of reference are:

“To inquire into the management of the care of children receiving complex cardiac surgical services at the Bristol Royal Infirmary between 1984 and 1995 and relevant related issues; to make findings as to the adequacy of the services provided; to establish what action was taken both within and outside the hospital to deal with concerns raised about the surgery and to identify any failure to take appropriate action promptly; to reach conclusions from these events and to make recommendations which could help to secure high quality care across the NHS.”

Phase 1 of the Inquiry, which will start in Bristol during March 1999, will examine the delivery of complex paediatric cardiac surgical services at the Bristol Royal Infirmary and Children's Hospital from 1984-1995. Phase 2 will examine relevant wider issues, so as to ensure that the Inquiry fulfils the requirement to identify matters that would “help secure high-quality care across the NHS”. Fuller details of the two stages are set out in the Chairman's Opening Statement.

This List aims to set out the central matters with which the Inquiry will be concerned during the first phase. We hope it will help to explain the aims of the Inquiry. But we recognise that new issues may arise during the course of the Inquiry, as information is provided to us. The Inquiry will review the Issues List periodically, to see whether it requires alteration. So, if there are further issues which any reader believes should be included, please write to us and let us know, as the Inquiry progresses.

Purpose of the Issues List

1. The list of issues is intended to be broad and inclusive. It aims to examine the whole system responsible for the management of children needing heart surgery services. The Issues List should assist the process of investigation and enquiry. It does not seek to pre-judge any issue before that process has taken place. The Inquiry is not a trial or a law-suit in which one person wins and another loses, and there are no parties or sides.
2. The breadth of the Inquiry also means that we will look at a number of comparators, when seeking to set the service at Bristol in its proper national context. In looking at the quality of care, we are interested in the range of outcomes, or results, experienced across the NHS. The Inquiry will seek to investigate minimum acceptable standards or levels and the “best practice”, as well as reasonable or “average” standards.

3. When reading the Issues List, please also bear in mind the following:
- This is a list of issues and not a statement of the methods that will be used to investigate each issue. The Inquiry aims to publish further details of its proposed methods of investigating certain matters (eg, issue C: further details are at page 8 of this list). Again, comments and suggestions for improvement will be welcome at that stage.
 - The weight that will be given by the Inquiry to different issues may vary. The length of the treatment of an issue in this List is not an indication of its importance to the Inquiry. Some of the most central issues can be very shortly stated; they will still require extensive examination. This list does not attempt to set out the various issues in an order of priorities; nor do we believe that it would be helpful to do so.

Evidence on the Issues will be commissioned by the Inquiry by the means of formal written statements and oral hearings. Given the variety and number of issues to be examined, there is a need to break up the hearings into “blocks” or tranches. A document setting out the likely blocks of evidence and the order of evidence at public hearings has been published which gives further details.

Notes on the text

- a. At all times, unless otherwise indicated, the questions set out below relate to the period 1984 – 1995.
- b. We recognise that standards and conditions changed considerably across that 11 year period. We seek to explore, evaluate and recognise those developments; and to set services within the appropriate time frame. But for ease of reading, the Issues List refers to "1984 - 1995" without repeating the point that changes within this period will be explored.
- c. The abbreviation “BRI” stands for both the Bristol Royal Infirmary and the Bristol Royal Hospital for Sick Children (“the BCH”), unless otherwise indicated.
- d. “Clinicians” is used to mean doctors, nurses and other health care professionals.
- e. “The Department of Health” also means the NHS Management Executive and NHS Executive.
- f. Complex paediatric cardiac surgical services: the view of the Inquiry is that all operative or invasive cardiac procedures fall, potentially, within the terms of reference, whether the condition diagnosed is classified as simple, intermediate or complex. If the Inquiry takes the view that specific invasive procedures should be excluded from its scope, this will be because these procedures were demonstrably simple and straightforward, and not accompanied by any significant risks. Any such decision will be made public, and comments and criticisms invited.

To establish the national, regional and local contexts in which the complex paediatric cardiac surgical services provided at the BRI were made available.

The Central Government context

- A1 The national framework established by the DOH, and the Supra-Regional Services Advisory Group, during the years 1984 - 1995, including the:
- a. policy aims, purposes and guidance;
 - b. legal and contractual structure;
 - c. financial provision, incentives and constraints;
 - d. supervisory, accountability or monitoring mechanisms and controls (relating to costs, outcomes and quality).
- A2 The policy aims behind the designation of certain institutions as supra-regional centres for the delivery of neonatal and infant cardiac surgery.
- A3 The process and criteria by which such centres (including the BRI) were selected, and the selection bodies.
- A4 The methods and criteria for monitoring standards, outcomes and costs at such centres.
- A5 The reasons for the de-designation of all supra-regional centres for neonatal and infant cardiac surgery, from 1 April 1994.
- A6 The implications of de-designation, in April 1994, for the BRI; and the funding and monitoring arrangements that replaced the system of supra-regional designation.
- A7 The information collected by the DOH and the Supra-Regional Services Advisory Group in respect of neonatal and infant cardiac surgical services at the BRI; and its availability.
- A8 The nature, extent and availability of data gathered by the national government upon standards and outcomes in paediatric cardiac surgery, by such means as the Confidential Enquiry into Peri-Operative Deaths.

The Regional and Local Context

- A9 The regional and district framework in which the delivery of paediatric cardiac services at the BRI was set during the years 1984 - 1995, including:
- a. policy aims, purposes and guidance;
 - b. contractual structure;
 - c. financial provision, incentives and constraints;
 - d. supervisory, accountability or monitoring mechanisms and controls (if any) provided by the various Health Authorities during this period.
- A10 The role of the District and Regional Health Authorities in setting and/or monitoring safety and quality standards (whether by involvement in audit processes or structures, or by any other means).
- A11 The role of the District and Regional Health Authorities in defining, monitoring and maintaining professional standards and competence (whether as a product of the health authorities' status of employer of hospital consultants until April 1991, or by any other means).

Professional Associations and Statutory Bodies

- A12 The role of professional associations, such as the Royal Colleges (medical and nursing), the BMA, the Society of Cardiothoracic Surgeons and trade unions, or statutory bodies such as the GMC and the UKCC, in defining and maintaining professional and quality standards, and in responding to complaints or concerns from health professionals or members of the public.
- A13 The information collected by professional associations (such as the Society of Cardiothoracic Surgeons), in respect of paediatric cardiac surgical services, both nationally and at the BRI; and its availability.

National Standards in Paediatric Cardiac Surgical Services

- A14 The national standards or guidance that existed, in 1984 - 1995, upon the organisation, management and delivery of :
- a. Care for children in hospitals;
 - b. Paediatric cardiac surgical services.

Issue B. The BRI and its Paediatric Cardiac Surgery Unit

The structure, management, organisation and staffing of the paediatric cardiac surgical services unit; and its place within the hospital as a whole.

- B1 The structure of paediatric cardiac surgical services at the respective sites at the BRI and BRHSC, including:
- a. the services offered;
 - b. funding of services, and the incentives created thereby;
 - c. organisational set-up: lines of authority, chains of command, communication and accountability, both professionally and managerially;
 - d. the extent to which medical and nursing staff were involved in management and managerial issues;
 - e. facilities available at each site, including their use by other services, eg adult cardiac surgery;
 - f. staffing: numbers, natures of posts held, criteria for appointment and employing body, training and experience, job plans or descriptions and their review, and patterns of deployment (such as the use of shared appointments and the rotation of skilled staff);
 - g. regulatory and disciplinary structures;
 - h. counselling and support for staff;
 - i. relationship with the University of Bristol and other academic centres;
 - j. key managers and clinicians: identities, powers and functions, collaboration between disciplines;
 - k. nature and scope of “outreach” clinics and other services offered by the paediatric cardiac team to local hospitals.
- B2 The implications and effect of designation, and de-designation, as a supra-regional centre upon the financing, organisation, management and delivery of paediatric cardiac services at Bristol.
- B3 The effect of the creation of the UBHT in April 1991 on the financing, organisation, management and delivery of paediatric cardiac services at the BRI.
- B4 The implications of, and incentives created by, the means by which paediatric cardiac surgical services or staff members were financed or paid.

- B5 The nature, scope and use of mechanisms and procedures (whether formal or informal) for establishing, monitoring and maintaining (a) safe treatment and care; (b) high-quality treatment and care; (c) professional competence and (d) managing costs; and/or for monitoring clinical outcomes and adverse events.
- B6 Protocols and guidelines to assist clinical decision-making and practice.
- B7 Documentation and the maintenance of high-quality clinical records.
- B8 The location of responsibility for (a) staffing levels and staff training; and (b) management and co-ordination of the staff team.
- B9 The information made available to referring clinicians, and to members of the public, on the standards of treatment and care attained at the BRI.
- B10 Complaints procedures available to members of the public, their use and the responses to such complaints by the hospital, Trust or health authority leadership;
- B11 Mechanisms and structures available to staff members to raise, and to secure action upon, clinical or managerial issues of concern to them; and the limitations of such methods.
- B12 The culture of the BRI, as expressed in such matters as:
- a. the relative power and status of key individuals, or groups such as managers, surgeons, cardiologists, anaesthetists, nurses, or professions allied to medicine;
 - b. the self-image and morale of such groups;
 - c. identity and loyalties amongst staff members, whether towards other staff groupings, or to outside professional associations or other societies;
 - d. leadership, team-working and communication between members of staff;
 - e. the responses towards poor performance by a member of a staff;
 - f. the attitudes towards patients who complained of poor service or care;
 - g. the attitudes towards staff who complained of poor standards of care and/or towards “whistleblowers”.
- B13 The extent to which the structures and attitudes described under this Issue, B, differ from those commonly adopted by large organisations involved in risky activities; and the nature of any such differences.

Issue C. The Service Provided: Nature and Outcomes

- a. *The number and nature of complex paediatric cardiac surgical procedures performed at the BRI from 1984 - 1995; and their outcomes;*
- b. *The extent to which those outcomes differed from the range of outcomes to be observed across similar units (in particular, other institutions designated as supra-regional centres for neonatal and infant cardiac surgery), at the relevant times;*
- c. *The limitations of the data available to determine (a) and (b); and the effect of such limitations.*

C1 The BRI data: the number and nature of the complex paediatric cardiac surgical procedures performed at the BRI from 1984 - 1995; and the outcomes achieved by such intervention.

C2 The national context:

- a. The written data or information gathered or published, whether in the years 1984 – 1995 or subsequently, that would help to establish the range of outcomes obtained by, and/or to be expected of, similar units in the UK (and in particular, other institutions designated as supra-regional centres for neonatal and infant cardiac surgery), at the relevant times;
- b. the availability of such data or information, at the time (both nationally, and within the BRI)

C3 The nature and content of any further information available to members of the paediatric cardiac surgery team at the BRI at the time, that may have assisted them to assess and improve the standard of performance of the Unit, for example:

- a. discussions with colleagues at other centres performing paediatric cardiac surgery, or attendance at conferences;
- b. sharing of data or joint working with other units or centres of excellence.

C4 The limitations upon the reliability and validity of the available data and information.

C5 Whether the sources listed above, and/or expert opinion available to the Inquiry, demonstrate that the mortality and morbidity rates for any type of surgical procedure performed (or any statistically significant portion of the series), fell outside the range of outcomes to be expected of, and acceptable for, a supra-regional centre (or other relevant comparator) within the UK at the relevant time.

Note: the Inquiry will be concerned to identify procedures where the results were better than average, as well as those in which results were poor or bad.

C6 Whether the answers to question (5) alter, and if so how, if the work of individual surgeons is analysed.

C7 Whether the limitations of the data available on mortality or morbidity make it difficult, or impossible, to form satisfactory judgements or conclusions upon questions (5) and (6); and, if so, why.

Note: the Inquiry will need to take account of limitations arising out of the scope of the data collected; its reliability; and the assurances as to confidentiality or anonymity given when it was collected.

C8 Whether any factors suggest, or require the conclusion to be drawn, that the children presenting for cardiac surgery in Bristol were not representative of national trends or norms. Such factors might, for instance, include:

- a. The age of the child at the date of referral for surgery;
 - b. The clinical condition of the children presenting;
 - c. The age of the child at the date of surgery;
 - d. Assessment of the merits or desirability of surgery in “high-risk” cases.
- C9 If so, the extent to which children presenting for surgery differed from such national trends or norms, and the reasons for these divergences.

Explanatory Note to Issue C: Methodology

Mortality

The Inquiry is undertaking an analysis of all paediatric cardiac surgical cases handled by the BRI between 1984 and 1995. The Inquiry expects to analyse a number of factors including diagnosis or nature of defect, nature of operative procedure, age of child at date of procedure, surgeons or other medical staff involved, and outcome, in terms of mortality rates.

Various data sources will be drawn upon, such as: the clinical records of all children treated; the hospital admissions statistics created by the BRI; the Hospital In-Patient Enquiry and Hospital Episode Statistics held by the Department of Health; the Surgeons’ logs; and the Register of the Society of Cardiothoracic Surgeons. By drawing on sources such as the national statistical data held by the Department of Health, the Inquiry will explore the extent of possible comparisons with national results, and, in particular, with the performance of other supra-regional centres for infant and neonatal and, generally, paediatric cardiac surgery. This process may suggest procedures and/or time periods, during which the outcomes at the BRI and/or by individual surgeons differed materially from the range of outcomes obtained elsewhere. If so, it will serve to guide further, more detailed exploration of the reasons for such divergences. Factors for further exploration are included at C8 – C9, and in the remainder of the Issues List. The Inquiry is aware of the fact that information held nationally is unlikely to answer questions about the reasons for any divergences in outcomes, as opposed to their presence.

Morbidity

The Inquiry also intends to scrutinise a sample of the total number of paediatric cases operated upon during the period 1984 - 1995, to examine (to the extent possible) whether morbidity rates significantly exceeded those achieved in other centres. The means by which such a sample is selected (its size, its members, and whether particular focus should be placed on certain types of heart defect or procedure) is a matter for further consultation.

Issue D. Referrals

To establish the information upon which decisions to send children to the BRI were based, whether by parents or by referring clinicians.

- 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.
- D2 The judgement or impression formed by referring paediatricians or other clinicians of the paediatric cardiac surgical services provided by the BRI.
- D3 The sources of information available to such referring clinicians upon the standards of treatment and care attained at the BRI.
- D4 The factors influencing clinicians, in deciding to refer children to the BRI rather than to other centres performing paediatric cardiac surgery.
- 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.
- 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.
- D7 The extent of and reasons for tertiary referral from the BRI to other centres of paediatric cardiac surgery.
- 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.

Issue E. Pre-Operative Management of Cases

To examine the adequacy of the services provided prior to surgery.

- E1 The arrangements and services available to manage the transfer of sick children from referring hospitals to the BRI.
- E2 Where children were managed, pre-operatively; and under which clinical speciality.
- E3 The re-assessment of the clinical condition of children admitted for elective surgery, following admission.
- 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.
- Note: for the related issue of discussions with parents, please see Issue L*
- 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.
- E6 The organisation and management of theatre lists.
- 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.
- 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 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.
- E9 If there were delays in surgery, the effect (if any) of such delays upon the outcome for the children affected.
- E10 The qualifications, training, experience and skills of the paediatric cardiologists.
- 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.
- E12 The protocols or clinical guidelines, machinery, equipment or technical services (eg radiological interpretation) available to the cardiologists to assist them in this task.
- E13 Pre-operative assessment and preparation procedures, including meetings at which treatment and operations were discussed and planned.
- E14 Pre-operative observation, assessment and care by the nursing staff and other professions (such as

physiotherapists).

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

Issue F. Management of Surgery

If analysis suggests that outcomes at the BRI were either poor or, equally, were good, the extent to which the management of cases within the operating theatre may be said to have caused or contributed to these outcomes and why.

Note: The Inquiry will be guided by the analyses carried out under Issue C in order to decide which cases or series of cases should be examined in detail to assist in resolution of this issue.

- F1 The qualifications, training, experience and skills of the paediatric cardiac surgeons at the BRI.
- F2 The qualifications, training, experience and skills of anaesthetists assisting at paediatric cardiac surgery at the BRI.
- 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
- F4 How the team in the operating theatre was constituted and co-ordinated, and its performance as an integrated team.
- 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.
- 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.

The Inquiry will seek to examine relevant factors such as (a) length of time on by-pass; (b) cross-clamping times; (c) the anaesthetic management, including drug régimes; (d) intra-operative monitoring and documentation; (e) returns to theatre.

Issue G. Post-Operative Care

To examine the adequacy of the management of post-operative care.

- G1 The national standards or guidance in existence, in 1984 - 1995, to shape the organisation, numbers and experience of staff within ICUs such as those of the BRI and the BCH.
- G2 Staffing within the ICUs caring for children following cardiac surgery: numbers, training, experience and skills mix.
- 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.
- 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.
- G5 The development and organisation of immediate post-operative care.
- G6 Liaison between specialities, and steps taken to ensure continuity of care.
- 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.
- 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.
- G9 The supply and maintenance of proper and adequate equipment to the ICU.
- 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).
- G11 The management of discharge and future care.
- G12 Liaison of staff with parents; and the participation of parents in the assessment and care of their child.

Issue H. The Split Site

The effect of the split site upon the care of children.

- a. H1 The extent to which (if at all) the quality of care offered was adversely affected by the fact that paediatric cardiac surgery and immediate post-operative care were carried out within a cardiac theatre and ICU catering for both adults and children.

- H2 Communication and collaboration between the ICU of the BRI and the paediatric ICU of the Children's Hospital; and transfer of children between the two sites.

- H3 The response of the clinicians and the management of the BRI to any problems created by the split site.

Issue I. Treatment of Families, including the Bereaved

- 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.
- 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.
- I3 The financing of the support and counselling services.
- I4 The priority afforded to support and counselling work by hospital management and clinical staff.
- 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.

Issue J. Post-Mortems and Inquests

- J1 The nature and extent of the responsibilities of (a) hospital staff; (b) hospital pathologist; and (c) HM Coroner to report and investigate deaths.
- 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.
- 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.
- 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.

Issue K. Training and Retraining

The adequacy of training and retraining of medical and nursing staff, for new and established surgical procedures.

- 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.

New Surgical Procedures

- 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.

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

- a. the procedure was new, and not 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.

- 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).

- 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.

Appraisal and Further Training of Other Staff Members

- 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.

- 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.

- 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.

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

Established Surgical Procedures

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.

In particular, the steps to be taken to:

K11

- 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).

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).

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.

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.

Other Staff Members

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.

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.

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

K18 Whether such continued education and training met the requirements of professional or contractual standards or obligations imposed at the time and the extent to which it conformed to accepted practice.

Learning Curves

K19 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 may fall below the standards achieved by a surgeon who has carried out a reasonable number of these procedures.

K20 The relationship between learning curves, and maintaining minimum acceptable levels of performance.

K21 The steps that can be taken to minimise the length of a learning curve, and to ensure that all relevant lessons are learnt as soon as possible.

K22 How an acceptable learning curve may be defined, prospectively.

- K23 The steps that can and should be taken to protect a patient, during the term of a learning curve.
- K24 The information, tools and professional guidance available to the medical profession, to assist in the task set out at (19) - (21).
- K25 The extent to which the profile of an acceptable learning curve (if such exists) may legitimately be affected by:
- a. the fact that the procedure is innovative and not well-established elsewhere;
 - b. the balance between the expected benefits of the new procedure, and the benefits likely to be obtained by the best alternative course of action;
 - c. the explanation of the risks given to the parents, guardian or child concerned.
- K26 The evaluation of the likely “learning curve” made by the paediatric cardiac surgical team at the BRI, before any new surgical procedure was embarked upon.
- K27 The steps (if any) taken, whether by such a surgeon or any other member of his unit, to monitor whether any adverse outcomes of a new surgical procedure were:
- a. a product of the process of acquiring sufficient experience at performing a new procedure; and/or
 - b. whether, if so, the process of acquiring such experience or skills was progressing at an acceptable rate.

Issue L. Informed Consent

- a. *Were the risks of surgery properly and adequately assessed?*
- b. *How was informed consent obtained?*

- L1 How, and when, parents, guardians or (if appropriate) children should be informed of the risks associated with surgery.
- 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
- 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
- L4 The professional guidance (if any) available to surgeons, or other advisors, upon the subject of informed consent and quoting for risk.
- L5 How the paediatric cardiac surgeons at the BRI, or other advisors, 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.
- L6 What parents and guardians attending at the BRI were told, and how were they informed, as to the risks associated with surgery, including the risks of:
 - a. mortality;

- b. morbidity, especially neurological deficit;
- c. likelihood of future surgery or protracted drug régimes being needed;
- d. other side effects or complications of surgery; and/or alternative treatment methods or the merits of non-intervention.

Issue M. Review of Cases and Medical and Clinical Audit

The nature and merits of the procedures and methods adopted to review the outcomes of paediatric cardiac surgery at the BRI.

- M1 The professional guidance available on the subjects of reviews of cases, and medical or clinical audit, from 1984 - 1995.
- M2 The requirements placed upon clinicians by (a) professional standards and (b) contractual obligations by way of review of cases, and medical or clinical audit, during these years.
- M3 The obligations (if any) placed on the BRI/UBHT, by the District or Regional Health Authorities and the DOH.
- M4 The proper role of the hospital management, and/or the District or Regional HA management, in:
- a. ensuring that systems of review or audit were in place, were adequately resourced and were functioning properly; and in
 - b. responding to the results of any audits.
- M5 The systems set up by those managing paediatric cardiac surgical services at the BRI, to ensure:
- a. review of the outcome of individual cases; and
 - b. review of the outcome of series of cases.
- M6 The use made of national or international information, whether from journals, research findings, registers or investigations such as the Confidential Enquiry into Peri-Operative Deaths (CEPOD).
- M7 The individuals to whom, or institutions to which, data or results were circulated as a result of such reviews or audits, and the purpose and regularity of such an information flow.
- M8 The constraints (if any) placed by confidentiality and/or the assurance of anonymity upon the use of audit data.
- M9 The advantages and disadvantages of the attitudes prevailing, at the time, to the use of audit data.
- M10 How well the systems of review and audit were maintained, and how they functioned in practice.
- M11 Whether (a) the structures set up; and (b) the manner in which they were, in practice, operated and run, met the professional and contractual standards and obligations imposed on the clinicians and upon the BRI, at the relevant time.
- M12 The success or otherwise of the systems of audit and review in place at the time, in:
- a. improving the quality of care or services;
 - b. detecting any areas or respects in which the services provided fell short of that which was acceptable, and devising and implementing solutions.

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Issue N. The Expression of Concerns

Note: In addressing this issue, the Inquiry bears in mind the distinction between expressing the opinion that the service at the BRI was capable of improvement but nevertheless acceptable; and the view that the service at the BRI (or aspects of it) was unacceptably poor. It is the latter which is meant by “an expression of concern”.

Parents

- 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.

Dr Bolsin

- N2 The concerns expressed about the quality or adequacy of paediatric cardiac surgical services by Dr Stephen Bolsin; the nature of those concerns; to whom they were expressed, and when.
- N3 The nature, scope and methodology of the “confidential audit” carried out by Dr Bolsin (with the assistance of others such as Dr Black), eg: the procedures examined; the data used, and the reasons why such sources were selected; the dates when the results were compiled, and by whom; the persons who were or were not informed that the data was being collected, and why; to whom, by what means, and when, the results were made available; and the merits of the methods adopted.
- N4 The response to any expression of concern made by Dr Bolsin (whether as a result of the audit data collected, or at any other time), from:
- a. colleagues (whether anaesthetists, cardiologists, cardiac surgeons, nurses or others);
 - b. the hospital or Trust management (or shadow management, prior to April 1991);
 - c. the Department of Health (see further below);
 - d. any others made aware of Dr. Bolsin’s views.

N5 Whether such responses (or the lack of them) was adequate and appropriate; and, if not, the nature and importance of any inadequacies or deficiencies.

N6 If the response was inadequate or inappropriate, the reasons for these inadequacies or deficiencies.

Other Hospital Staff

N7 Whether other personnel employed within, or associated with, the BRI expressed concerns upon the performance of the paediatric cardiac surgery unit; and if so, to whom; as a result of what event or events; in

what terms; and when.

- N8 The response to any concern expressed by any staff employed within, or associated with, the BRI, from:
- a. colleagues;
 - b. the Regional or District Health Authorities;
 - c. the hospital or Trust management (or shadow management, prior to April 1991);
 - d. the Department of Health (see further below);
 - e. professional or statutory bodies (eg the Royal Colleges);
- to the extent that any of these bodies were contacted or approached.
- N9 Whether such responses (or the lack of them) were adequate and appropriate; and, if not, the nature and importance of any inadequacies or deficiencies.
- N10 If the responses were inadequate or inappropriate, the reasons for these inadequacies or faults.

The Trust Management

- N11 The nature of the concerns about paediatric cardiac surgery at the BRI (if any) relayed to:
- a. the Hospital Audit Committee;
 - b. the Hospital Medical Committee;
 - c. the Chief Executive of the Trust;
 - d. the Trust Board.
- N12 The other sources of information to which these bodies had access (eg, audit data, newspaper or magazine articles), that might reasonably have suggested cause for either concern about, or investigation of, paediatric cardiac surgical services.
- N13 The extent to which these potential sources of information were in fact considered.
- N14 How (if at all) the bodies described at 11(a) - (d) reacted to any concerns expressed to them.
- N15 Whether such responses (or the lack of them) were appropriate.
- N16 The formal or informal managerial, disciplinary, or regulatory structures existing within the BRI, through which issues of the adequacy of paediatric cardiac surgical services and/or issues of professional inadequacies or incompetence could have been raised and addressed; and the strengths and weaknesses of these systems.
- N17 Whether any of these mechanisms or structures were invoked; and, if not, why not.
- N18 Whether any of these mechanisms or structures should have been invoked.

The Department of Health and others

- N19 The concerns about paediatric cardiac surgery at the BRI (if any) relayed to the DOH and the Supra-Regional Services Advisory Group; the nature of those concerns, and the dates at which they were expressed.
- N20 The other sources of information to which these bodies had access (eg, contractual performance data, newspaper or magazine articles, DOH statistical data), that might reasonably have suggested cause for either concern about, or investigation of, paediatric cardiac surgical services.
- N21 The reaction of the DOH and/or the Supra-Regional Services Advisory Group to any such expression of concern; and whether it was adequate or appropriate.
- N22 The existence of any suggestion, prior to the decision to de-designate all centres in April 1994, that the BRI's neonatal and infant cardiac surgical services should be de-designated because of concerns that the centre no longer met the criteria for designation; and, if so, the grounds for consideration of such de-designation.
- N23 Whether in 1984 - 1995 the district or regional health authorities were, or should have been concerned, about the performance of the paediatric cardiac surgical unit at the BRI, as a result of the information held by such bodies and/or their powers and responsibilities.
- N24 Whether in 1984 – 1995, healthcare professionals in other hospitals or healthcare organisations had expressed concerns about the paediatric cardiac services at the BRI; and, if so, to whom had such concerns been expressed and with what results (if any).

N25 Whether in 1984 – 1995 other professional associations (such as the Royal Colleges) or statutory bodies, were, or should have been concerned, about the performance of the paediatric cardiac surgical unit at the BRI, as a result of the information held by such bodies and/or their powers and responsibilities.

ENDS

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