

BRISTOL ROYAL INFIRMARY INQUIRY

REPORT ON THE CLINICAL CASE NOTE REVIEW

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EXECUTIVE SUMMARY

1. This is the final report of the Clinical Case Note Review; it builds on the preliminary findings which were published by the Inquiry in November 1999.
2. The purpose of the Clinical Case Note Review was to assist the Inquiry's Panel in meeting its terms of reference "to make findings as to the adequacy of the service". The Review is only one of a number of sources of evidence and information available to the Inquiry on the matter of adequacy.
3. The Bristol Royal Infirmary Inquiry commissioned clinical experts to review a sample of cases of children who received paediatric cardiac surgery in Bristol between 1984 and 1995. The sample consisted of 80 cases of children who between them, underwent 98 procedures.
4. The sample of 80 cases was selected at random from over 1800 children who underwent either open or closed cardiac surgery at Bristol. The sample was deliberately structured to reflect the concerns which had led to the Inquiry. It included children who had died as well as those who were alive, but was weighted towards those who were younger, and those who had had open heart surgery. When due account is taken of this weighting, it is possible to generalise to the full group of paediatric cardiac patients in Bristol, from the results of the 80 cases reviewed.
5. Each set of notes case was reviewed by a multi-disciplinary team of clinical experts who were asked to assess, first, the adequacy of pre-operative, surgical and post-operative care and, second, the adequacy of the care overall.
6. Reports were prepared according to a standard form. The expert reviewers were asked to indicate whether care had been adequate, or less than adequate. Where care was thought to have been less than adequate, reviewers were asked to indicate whether the care might have had an impact on the outcome for the child. Reviewers were not asked to indicate if care was more than adequate – the focus was deliberately on identifying less than adequate care and understanding the possible reasons for it.
7. Families of the children included in the Review, and Bristol clinicians, were given the opportunity to comment on individual reviews in which they had an interest. These comments, plus a small number of further reviews at the request of parents or Bristol clinicians, were taken into account in the conclusions.
8. The results of the Review must be treated with caution. Clinical case notes do not contain all the relevant information about the care given to a child, albeit that they describe a great deal of what took place. Further, it is difficult to be confident about the relationship between less than adequate care, when it occurred, and the impact such care might have had on the outcome for the child.
9. In general terms, the review suggests that:
 - the care received by 70% of the children was adequate;

- the care received by 30% of the children was less than adequate to different degrees. For just over 5% of all the children, it was considered that different management would reasonably be expected to have made a difference to outcome
11. Where care was considered by the review teams to be less than adequate, to whatever degree, certain key themes emerged consistently. These were:
- shortcomings in the organisation of care;
 - delays between diagnosis and treatment;
 - shortcomings in the cardiological contribution to both pre-operative and post-operative care;
 - weaknesses in the conduct of surgery;
 - shortcomings in the organisation of the intensive care for children who had open heart surgery;
 - difficulties arising from delivering care across two sites;
 - shortage of resources in terms of personnel and equipment.
12. The Clinical Case Note Review suggests shortcomings in the overall organisation of paediatric cardiac surgical care in Bristol. It focuses criticism on the functioning of the clinical team and the infrastructure of the organisation, rather than on individual clinicians.

Part I Introduction

1. This is the final report of the Clinical Case Note Review (referred to as the CCNR) to the Inquiry Panel. **It is written, not as an academic paper, but as a general summary, intended to be accessible to a wide range of audiences.** The purpose of the report is to place before the Inquiry Panel the results of the CCNR; to identify the strengths and weaknesses of the exercise, and to suggest what conclusions may be drawn from this work. It will ultimately be for the Inquiry Panel to determine what weight they attach to the CCNR in reaching their overall conclusions, in the light of all the other evidence presented to the Inquiry.
2. The purpose of the CCNR exercise is to provide the Inquiry Panel with a qualitative perspective on the adequacy of care in the Bristol paediatric cardiac surgical service between 1984 and 1995. The focus of the exercise is to consider a range of care across pre-operative, surgical and post-operative services, and to highlight the patterns of adequate and less than adequate care. The exercise was not designed to reach specific conclusions about individual cases.
3. It is important to re-emphasise that a wide range of evidence on the adequacy of care at Bristol is before the Inquiry Panel; the CCNR is but one source. Other sources include written and oral evidence; documents submitted to the Inquiry; expert evidence; examination of existing data sources and other externally commissioned work. The clinical experts undertaking the CCNR were aware of the purpose and context of the exercise.
4. Table 1 identifies the phases of the CCNR review and the work produced at each stage, all of which form the source materials for this report.

Table 1. Stages of the CCNR Exercise

Stage of the CCNR review process	Activity	Outputs
Stage 1: July - October 1999	Review, by multi-disciplinary teams of expert clinicians, of eighty sets of case notes, selected as a stratified random sample. Completion of CCNR report forms by expert teams.	Eighty CCNR report forms
Stage 2: September-October 1999	Second review of fifteen sets of case notes within the original eighty, to help assess the methodology. Completion of CCNR report forms by expert teams.	Fifteen CCNR report forms (referred to in this report as “repeat reviews”)
Stage 3: October – December 1999	Circulation of CCNR report forms, and invitation to submit formal written comments, to (a) Parents who wished to see report form (b) Bristol clinicians mentioned on report forms.	Formal written comments
Stage 4: November 1999	Publication of CCNR Preliminary Report and oral evidence before the Inquiry Panel.	Preliminary Report and oral evidence
Stage 5: December 1999-February 2000	Invitation to Parents and Clinicians to request a further review against a set of criteria. Consequential further review of thirteen sets of case notes and completion of CCNR report forms by expert teams.	Thirteen CCNR report forms (referred to in this report as “requested reviews”)

Table 1. Stages of the CCNR Exercise

Stage of the CCNR review process	Activity	Outputs
Stage 6: March 2000	Repeat of stage 3 for the thirteen requested review report forms.	Formal written comments
At various stages during the process	Invitation to expert clinical review team leaders and to team members to comment on their overall findings and the particular clinical considerations involved in assessing adequacy of care.	Written comments from expert clinicians

5. The report starts with an explanation of the methodology and the approach adopted. Then we deal separately with each of the categories of source material identified above. It is particularly important to take this approach with the various categories of CCNR report form. The eighty selected for the initial review carry a special significance because they are the product of a sampling process. We consider first, and in some detail, the results of the eighty reviews. Later, we look at the Repeat Review Exercise used to test the methodology of the overall process. We also examine the Requested Review Exercise, the stage at which additional reviews were undertaken at the request of Bristol clinicians or of parents. We also consider the themes arising from all the formal written comments. We then draw conclusions from the eighty reviews and consider whether the findings from these further sources strengthen or weaken the conclusions which may be drawn from the initial eighty reviews.

Part II

The Review Process and Methodology

Clinical Background

6. In developing a methodology for the review of clinical case notes to inform an assessment of adequacy of care, the BRI Inquiry faced a unique challenge. There was no pre-existing methodology for such a major, retrospective review of the case notes of children who had been treated for congenital (meaning “born with”) heart disease.
7. Certain features of the care process associated with paediatric heart surgery had to be allowed for within the methodology:
 - children who are born with heart disease need and receive care from many different nurses and doctors at any one time and over the years;
 - cardiologists and surgeons have a significant role in the care of children who have congenital heart disease. Many other clinicians and health-workers are also likely to be involved in a hospital care “episode”, not least nurses, anaesthetists, perfusionists, pharmacists and probably physiotherapists. Sadly, if the child dies, a pathologist is also likely to be directly involved;
 - for a few children, a heart problem can be diagnosed, treated and indeed cured in one episode of care in hospital;
 - for many children though, the care process is complicated and may involve an initial diagnosis followed by a series of surgical procedures and other treatment over a period of years. A first operation may only be an initial operation in a plan of treatment;
 - children with heart defects who need heart surgery may have either “closed” heart surgery, (meaning that the heart or major arteries are operated on whilst the heart is still beating) or, “open” heart surgery, (meaning that the heart is stopped whilst the surgery takes place, and the child is supported by a heart-lung bypass machine);
 - heart defects represent a spectrum of heart abnormalities. Even though diagnostic labels are given to individual children, no two children’s hearts are identical. Thus the best operative management is not always clear, and surgeons and cardiologists always come together to discuss and agree a plan of treatment. There may be several options – both for the type of surgery and for its timing.
8. In addition, although children with heart disease may be seen by GPs and locally based paediatricians before and after surgery at a specialist centre, the Inquiry’s terms of reference covered only the treatment at the Bristol Royal Infirmary (where open heart surgery took place) and the Bristol Royal Hospital for Sick Children (where closed heart surgery took place, and paediatric cardiology services were located). Thus the case review could concentrate only on the care given at Bristol and not that given to a child by the NHS as a whole.

9. These considerations led the Inquiry to reject the conventional case review approach used in clinical negligence cases, where a single specialist reviews the entire case notes and writes an expert opinion usually concentrating upon the allegations of failure at a particular stage of the process. Instead, the Inquiry sought to develop an approach which would reflect the involvement of a range of clinical specialists and the care pathway which includes diagnosis, pre-operative care, surgery itself and post-operative care.
10. The approach adopted by the Confidential Enquiry into Still Births and Infant Deaths (CESDI), which involves multi-disciplinary team review, consideration of a range of care aspects, and a standard report form proved a good starting point, and was the basis of the process for the pilot of the CCNR review in May 1999. Other strategies considered included a “blind” review; providing copies of the notes which did not reveal the outcome of each case; having only one member of the review teams aware of the outcome; providing information gradually so that one aspect of care could be discussed at a time; and mixing in casenotes from other units without revealing the source of any of the notes. For a variety of reasons, the Inquiry concluded that none of these approaches was practical or feasible. The CCNR methodology was based on what was required to assist the Inquiry meet its terms of reference and on what was feasible and practical given the availability of high level clinical expertise to undertake such an exercise.

The CCNR review methodology

11. The review methodology¹ was developed by a multi-disciplinary group of clinical experts to the Inquiry. Its key features were:
 - each case of a child in the sample was reviewed by a multi-disciplinary team of clinicians drawn from the Inquiry’s Expert Group, rather than by a single expert, and the experts met together to discuss each child’s case;
 - the review teams were asked to make assessments as to the adequacy of care delivered in Bristol, based on their interpretation of standards at the time, using a selection of Bristol clinical records. The teams were not asked to consider the care given by GPs, or by other NHS hospitals, to children in the sample.
 - the experts on each team comprised a paediatric cardiac surgeon, a paediatric cardiologist, a paediatric anaesthetist, a paediatric pathologist, and either a paediatric intensive care nurse or a paediatric nurse;
 - the teams were asked to give a grade for overall adequacy of care, as well as grades for thirteen individual aspects of care grouped under pre-operative care (six aspects), surgical care (three aspects), post-operative care (three aspects) and post-mortem if one took place;

¹ See Annex A “Methodology” for further details

- four possible grades could be assigned to care overall and to individual aspects of care:
 - 4 – Adequate;*
 - 3 – Less than adequate, but different management would have made no difference to outcome;*
 - 2 – Less than adequate; but different management might have made a difference;*
 - 1 – Less than adequate; but different management would reasonably be expected to have made a difference to outcome.*

In addition, the reviewers could assign an “X” if they decided there was insufficient information on which to base a view.

- no CCNR report form was to be made public without the consent of the family whose child’s case note were reviewed. Every effort was made to contact the families of children in the sample, to explain the process, and to seek families’ views on and consent for publication of CCNR report forms.

Selection of cases for review

12. Eighty cases were selected for review comprising forty children who had died within thirty days of their last surgical procedure (of whom six had closed heart surgery, and thirty four open heart surgery) and forty children who were alive at thirty days after their last surgical procedure (again, of whom six had closed heart surgery and thirty four open heart surgery).²
13. The case notes reviewed were selected from amongst the notes of the 1827 children known to the Inquiry to have had open or closed heart surgery in Bristol between 1984 and 1995. The case notes of all these children were eligible for inclusion in the CCNR³.
14. The Inquiry decided to select a stratified random sample so that those who had open-heart surgery, those who were younger and those who died where more likely to be included in the sample. This decision was taken to reflect the concerns which had led to the Inquiry. Full details of the sample are given in Annex B. Tables 2a and 2b provide a summary of the types of case in the dataset, and the types of case in the sample.

² Three children who were alive thirty days after their last surgical procedure, died much later. For the purposes of this report, we take the child’s status 30 days after surgery; thus these three children are included in the “alive” group.

³ See Annex B “Selection of Cases for Clinical Review” for further details.

Table 2a - Number of cases in the CCNR, as derived from the 1827 records of Bristol paediatric cardiac surgery children

	Type of Surgery: Open (total 1290)				Type of Surgery: Closed (total 537)				TOTAL
	Age: under 1 Year		1 - 15 years		Age: under 1 year		1 - 15 years		
	Status 30 days after surgery:				Status 30 days after surgery:				
	Died	Alive	Died	Alive	Died	Alive	Died	Alive	
Number in Sample:	27	27	7	7	5	5	1	1	80
Number of patients overall:	147	504	49	590	44	260	3	230	1827
Sample as a % of patients in each category:	18%	5%	14%	1%	11%	2%	33%	0.4%	4%

Table 2b - How the sample was weighted from three perspectives: (1) for type of surgery, (2) for outcome (in terms of mortality) and (3) for age.

(1)	Bristol Paediatric Cardiac Surgery cases - 1827 = 100%	CCNR Sample cases - 80 = 100%
<i>Type of surgery:</i>		
Open heart	1290 (71%)	68 (85%)
Closed heart	537 (29%)	12 (15%)
(2)	Bristol Paediatric Cardiac Surgery cases - 1827 = 100%	CCNR Sample cases - 80 = 100%
<i>Outcome 30 days after surgery:</i>		
Child had died	243 (13%)	40 (50%)
Child was alive	1584 (87%)	40 (50%)
(3)	Bristol Paediatric Cardiac Surgery cases - 1827 = 100%	CCNR Sample cases - 80 = 100%
<i>Age of child at time of main (ie most complex) procedure:</i>		
Under 1 year	955 (52%)	64 (80%)
Between 1 and 15 years	872 (48%)	16 (20%)

15. Fifteen cases were reviewed twice, at the time of the original exercise, to help assess the methodology. All reviewers were aware this would be part of the process; the exact cases reviewed twice were and remain unknown to the reviewers.
16. Thirteen cases⁴ were subject to a review in response to applications to the Panel from parents or clinicians. The reviewers who undertook these reviews were aware that they were conducting a further review, but they were and remain unaware of the arguments put to the Panel for the further review.

Interpreting the adequacy of care

17. In the paper entitled “The Inquiry’s Approach to the Assessment of the Adequacy of Paediatric Cardiac Surgical Services”, published in July 1999, the Inquiry set out a description of the CCNR exercise. The Inquiry’s approach to the review of clinical notes has been deliberately qualitative and acknowledges that, for most of the years 1984-1995, there were no clearly set down, nationally agreed standards for paediatric cardiac surgical services. Therefore, the members of each review team were asked, as far as possible, to apply their best clinical judgement drawing on their understanding and knowledge of professional standards at the time at which the care was delivered. The teams were made aware that, although consensus was desirable, there was no need, nor any requirement, for consensus in every case. It is striking that, in the event, in only four out of eighty cases were review teams unable to come down firmly with a single grade for the overall adequacy of care (four cases were given an overall grade of 2/3).
18. After the initial report on the CCNR in November 1999, the Inquiry sought more information from the clinical experts who had undertaken the reviews on the considerations they had brought to bear during their review meetings in determining whether care was adequate or less than adequate. Initially, one clinician from each specialty was asked to give a written view which was subsequently circulated to other clinicians in that specialty for comment and additional contributions. A synthesis of responses, by specialty, is at Annex E.

Discussion of methodology

19. From the outset, the Inquiry has been open about the strengths and weaknesses of the exercise. Its strengths lie in the scope and depth and the level of expertise brought to bear. This is the first time that clinical experts have reviewed a sample of cases, drawn from virtually all the paediatric cardiac activity at Bristol over a twelve year period. It is also the first time, to our knowledge, that such an exercise has been undertaken by multi-disciplinary teams of clinicians, rather than by individual specialists, and looking across a range of care, rather than at particular specialties.

⁴ The thirteen cases approved for requested review did not include any of those cases which had been the subject of a repeat review.

20. The possible weaknesses acknowledged thus far still apply. The CCNR was, overtly, an exercise to review what were known by the experts to be *Bristol* notes, and it must be recognised that reviewers could, unconsciously, bring some subjective bias and hindsight into play. Being aware of such influences is one way of guarding against them. Also, the notes did not conceal the eventual outcome for the child. It would have been impractical, in the time available, to conceal the origin of the notes or the outcome for the child. In addition, the absence, for most of the period, of formal, published standards for paediatric cardiac surgical care made interpretation of adequacy a difficult challenge for the review teams.

Interpretation of Results

21. As with any exercise of this type, it is very important to interpret the results within the context of the methodology and its limitations.
22. The results of the CCNR can be viewed from two perspectives. First, the eighty case reviews reveal a range of qualitative insights about specific aspects of the adequacy of care given to a cross section of children with a range of conditions over a twelve year period. Second, because the sample is fair and statistically valid, it is possible to draw some wider conclusions about the adequacy of care given to all 1827 children. But any such conclusions must take full account of the weighting in the sample. As those at highest risk and those who died were included preferentially, then it is important to realise that it leads to distortion if this is not taken into account.⁵
23. The Review was designed to assess whether care had been "adequate" or "less than adequate", with grades of "less than adequate" care assigned according to the perceived impact of the care on outcome.⁶ For the cases of children who were alive at thirty days, one would expect a tendency to grade the care as adequate, as different management could not have improved on outcome. It is equally self-evident that in a case of death or disability, scrutiny of adequacy of care is likely to be more critical. Given these tendencies, it must be of particular interest to note from this exercise those aspects of care which were graded as less than adequate for children who had a good outcome; and, those aspects of care graded as adequate for those children who were not alive thirty days or who experienced disability after surgery.
24. Reviewers knew from the outset that each CCNR report form would be treated as expert evidence to the Inquiry, and eventually be made public, subject to the permission of the family concerned. They were also informed that report forms would be shown to those with a direct interest in the care of a child, for formal written comment. The finished review report forms were completed according to guidance issued to review teams. In all, ninety-eight procedures on eighty children were considered separately. In a very small number of cases, the reviewers gave a single report on several procedures. For the purposes of this overview, we have treated the grades and comments as though they are reports on single procedures.

⁵ See Tables 2a and 2b

⁶ See Page 9

25. Review groups did not always provide comments to explain their reasoning as to why care was less than adequate. With hindsight, additional comments might have helped to give a more full understanding of the reasons behind a given overall grade, particularly in those few cases where there seemed on first sight to be a discordance between the overall grade and the grades given to individual aspects of care. Clearly, this is not simply a mathematical relationship; groups were making judgements about whether management of the care of the child, overall, would have made a difference to outcome. In some cases reviewers may have considered that only one aspect of care, given its importance to the eventual outcome, determined the overall grade. It is suggested that in any future studies of this type, review groups should be encouraged to make full use of the comments sections.

Part III
Review of Results from the Review of 80 cases

The analysis of results is in four parts:

- A. Results overall
- B. Summary of results from the sample of 80 cases
- C. Results from the sample by overall grade 1-4
- D. Results from the sample by aspect of care

A. Results overall

Distribution of overall grades for adequacy of care, (a) for the sample (b) extrapolated to all patients known to the Inquiry to have received paediatric heart surgery between 1984 and 1995

Table 3a. for the sample of 80 cases

Adequacy (Overall Grade for Adequacy)	Frequency (No. of children in sample assigned this grade)	Percent (% of children assigned this grade)	Cumulative %
1	13	16	16
2	11	14	30
2/3	4	5	35
3	13	16	51
4	39	49	100
Total	80	100	

Table 3b. Extrapolated to the Bristol paediatric heart patients as a whole

Adequacy (Overall Grade for Adequacy)	Frequency	Percent	Cumulative %
1	101	5.5	5.5
2	69	4	9.5
2/3	20	1	10.5
3	345	19	29.5
4	1294	70.5	100
Total	1829	100	

Note to Table 3b: The numbers in the column entitled "frequency" should not be taken as precise values, but as estimates. They have been calculated by re-weighting each of the eighty cases individually according to the original probability of that case being selected. Annex B, Note 1, makes it clear how this was done. This process can result in an estimate not being a whole number. For presentation, the numbers are rounded to the nearest whole number, hence the total of 1829 is an approximation to the original total of 1827.

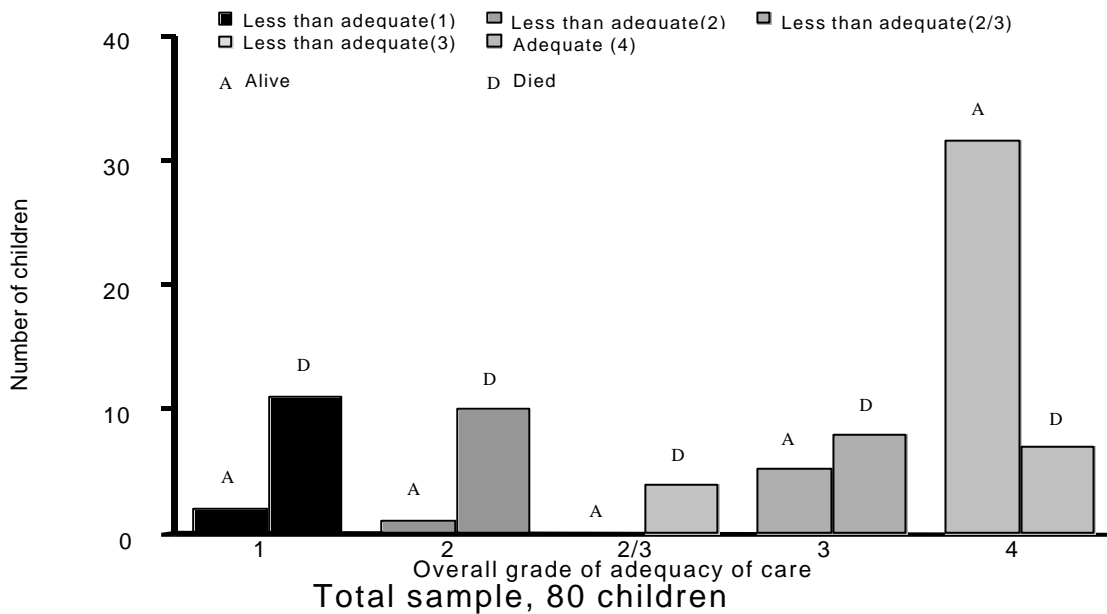
26. Table 3a shows the distribution of results for the sample of 80 cases. The sample was deliberately structured to include a larger number of children who died, children who had surgery under one, and children who had open heart surgery. The pattern of results from the sample can only properly be understood when set in the context of all the children who are known to have had paediatric heart surgery at Bristol. Table 3b, shows the results of the sample, re-weighted and extrapolated to the Bristol paediatric heart surgery patients as a whole. From this table, it can be estimated that the care given to just over 70% of all children was adequate, and that given to around 30% was less than adequate to varying degrees (grades 1-3). On a raw interpretation, the results would seem to suggest that the care given to just over 9% of the children was such that different care might have or would reasonably be expected to make a difference to outcome (grades 1 and 2). The text which follows in this report seeks to set these initial results in the context of the strengths and weaknesses of the review exercise as a whole.

B. Summary of results from the sample of 80 cases

Table 4. Overall grade for adequacy of care by outcome thirty days after last surgical procedure

Overall grade	Outcome 30 days after surgery		
	Died	Alive	Total
1	11	2	13
2	10	1	11
2/3	4	0	4
3	8	5	13
4	7	32	39
Total children	40	40	80

Figure 1. Graph of overall grade for adequacy of care by outcome 30 days after last surgical procedure



27. Table 4 and Figure 1 show that the care given to 39 children in the sample was assessed by review teams to be adequate. Review teams considered that in twenty-four cases out of eighty, overall, different management might have or would reasonably be expected to have made a difference to outcome (grades 1 and 2).

28. The CCNR exercise reported on 98 procedures performed on 80 children. The table below shows the distribution of overall grades for adequacy by the number of procedures per child.

Table 5. Overall grade for adequacy of care by number of procedures per child individually assessed by review teams

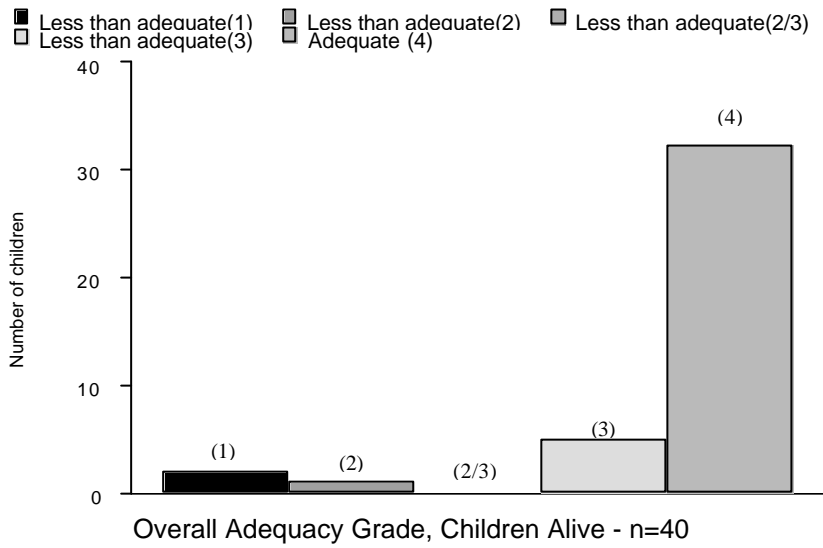
Overall grade	Number of procedures per child			
	1 procedure	2 procedures	3 procedures	Total
1	10	3	0	13
2	9	2	0	11
2/3	3	1	0	4
3	10	3	0	13
4	31	7	1	39
Total children	63	16	1	80

29. In seventeen case reviews, the reviewers reported separately on more than one procedure. The information in this table shows overall grades for multiple procedure case reports. There appears to be no immediately obvious difference between the overall grades assigned to multiple procedure cases and those assigned to single procedure cases.

30. The following four graphs are self explanatory and provide an overall summary of the results of the review of eighty cases, according to the main features (operation type/outcome) of each case.

Figure 2. Distribution of overall adequacy grades, separately for those alive 30 days after their last operation and those who died within 30 days of their last operation. Numbers of children shown for each adequacy grade in that category of vital status.

a) Those alive at thirty days



b) Those who died within thirty days of their last operation

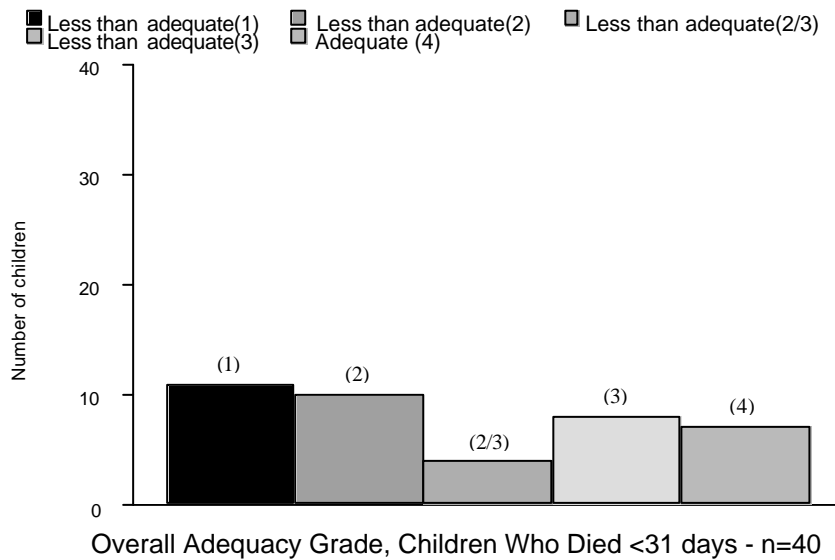
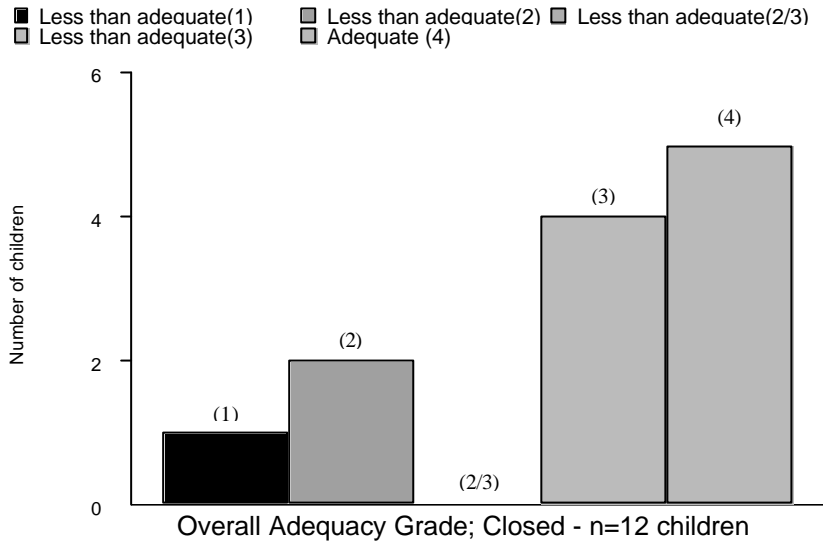


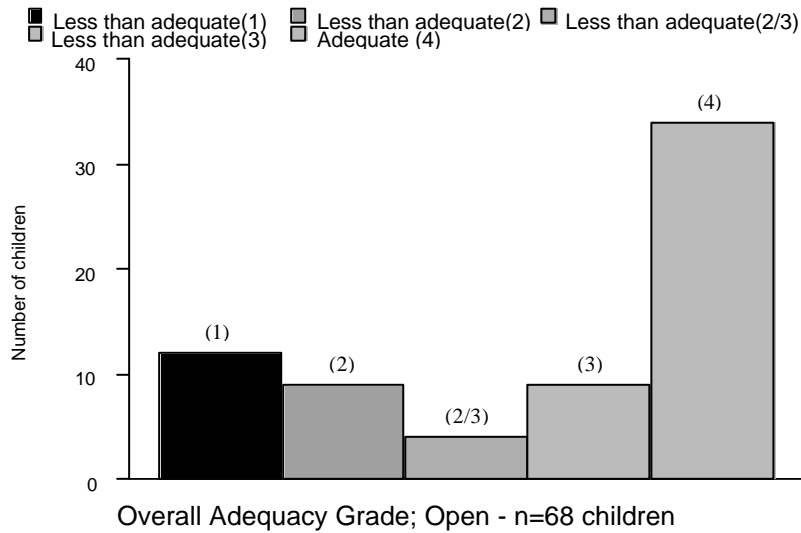
Figure 3. Distribution of overall adequacy grades for closed and open type of operation. Numbers of children shown for each adequacy grade in that category of operation.

Note: the vertical scales on the following graphs are different

a) Children who only had a closed operation



b) Children who had an open operation at some stage, not necessarily their last operation.



C. Results from the sample by overall grade 1-4

31. This part of the report deals in turn with each category of overall grade, and identifies the key aspects of care which appear to have contributed to the overall grade given to the case⁷.
32. The review teams considered thirteen aspects of care in all, grouped according to three broad headings: pre-operative care, surgical care, and post-operative care. They were also asked to assess the adequacy of the post-mortem where one took place. When care was "less than adequate," a comment usually accompanied the grading. In the tables that follow, each aspect of care is identified by a letter, A-M. The letters are assigned to each aspect of care as follows:

Pre Operative Care

A	Timing and appropriateness of initial referral/condition on arrival
B	Clinical assessment and management
C	Accuracy and completeness of diagnosis
D	Appropriateness of initial treatment strategy
E	Timing of planned treatment
F	Immediate pre-operative management including nursing

Surgical Care

G	Surgical Procedure
H	Perfusion
I	Anaesthetic

Post Operative Care and Assessment

J	Post operative - medical/ICU care
K	Post operative – surgical care
L	Post operative – paediatric cardiological care

Post-mortem

M	Post-mortem
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Clinical Responsibility for Aspects of Care

33. *Pre – operative care.* Clinical responsibility for the first aspect of care, the timing and appropriateness of initial referral and the condition of a child on arrival (A) is usually with the referring doctor, who could have been a neonatologist, paediatrician or GP. It is included here as an aspect of care because it was thought important to note the condition of the child on arrival. The responsibility for pre-operative aspects of care covered in the CCNR (B – F) lay mainly with the consultant cardiologist. In general, the surgical contribution to a patient's care during the pre-operative period is relatively minor. However, in most departments, during the 1980s and early 1990s, surgeons were involved in discussions about clinical assessment and management (B), accuracy and completeness of diagnosis (C), appropriateness of treatment strategy and timing of operation (D). The reviewers also considered immediate pre-operative management including nursing (F) and noted that responsibility was mostly a nursing one, but could include the cardiologist and anaesthetist/intensivist if the child was admitted as an emergency.
34. *Surgical care.* Clinical responsibility for surgical procedure (G) is with the surgeon. The surgeon is responsible for obtaining consent and recording the discussion with the parents in the notes.

⁷ See Annex D for details of the adequacy grades assigned to each case reviewed, grouped according to the overall grade given in each case.

35. Perfusion (H) : it became apparent during the review that the practice and perception as to which consultant (as between the surgeon and the anaesthetist) had overall responsibility for perfusion, varied from centre to centre and over time. The reasons for this may lie in the involvement of different players in the perfusion process:
- the perfusionist is responsible for assembling the heart/lung machine and priming and preparing it for the procedure. The perfusionist advises the surgeon on size of cannulae, (which should be large enough to provide adequate flow for the size of the patient), and runs and monitors the machine during the case;
 - the anaesthetist prescribes the priming fluid and all the drugs to be added to the circuit, both initially and during the case. The anaesthetist receives the monitoring information and tests from the perfusionist and controls the blood pressure during perfusion, using drugs. The anaesthetist also decides, in conjunction with the surgeon, the overall management strategy for perfusion (alpha stat or pH stat);
 - the surgeon inserts the cannulae for bypass, and ensures their optimum position to give best flow. The surgeon decides on the temperature for cooling, depending on the length and complexity of the operation and may ask for periods of reduced flow to allow better visibility in the operative field. If these periods are too prolonged, the surgeon will be reminded by the perfusionist and/or the anaesthetist as long periods of reduced flow can cause acidosis.
36. Thus good perfusion, an essential aspect of any open heart surgery, is very much a team effort and each member of the team relies on the experience and skills of the others in the team. It was not always apparent from the Bristol clinical notes which consultant specialist was responsible for perfusion; formal written comments from Bristol anaesthetists and perfusionists suggest that perfusion was an activity for which the surgeon had overall responsibility.
37. Conduct of anaesthesia (I) is the responsibility of the anaesthetist, but close cooperation between the anaesthetist and the surgeon is essential for the successful outcome of an operation. They each rely on each other's experience and skills.
38. *Post – operative care.* The responsibility for various aspects of post-operative care (J – L) depends very much on the organisation of the Intensive Care Unit. In some units between 1984 and 1995, surgeons took the lead responsibility; in others it was cardiologists, and in others, anaesthetists. In Bristol, responsibility for care in the ICU developed during the period 1984 – 1995 in similar fashion to that of many other departments during this time. Early in the period, in most units, most aspects of post-operative care were the responsibility of and dealt with by the surgical team helped by the anaesthetists (ventilation, and extubation) and cardiologists (diagnosis of post-operative problems). This changed towards the end of the period under review, when specialist “intensivists”, (usually anaesthetists) who had chosen to specialise in intensive care, were appointed in many places to be the lead clinicians on the Intensive Care Unit.

39. *Post-mortem.* While the responsibility for the post-mortem (M) is with the pathologist, in order to get the maximum information, there would be follow up discussion with the surgeon, cardiologist and other members of the team.

Cases with an overall grade 1

Less than adequate care in which different management would reasonably be expected to have made a difference to outcome (i.e. an avoidable factor which probably contributed to death or disability).

Table 6 CCNR reports with grade 1 for overall care, showing the frequency of grades for individual aspects of care.

CHILDREN WITH OVERALL CARE Grade 1: 13 Children, 16 Procedures													
Grade	Aspect of Care												
	Pre Operative Care						Surgical Care			Post Operative Care			Post-mortem
	A	B	C	D	E	F	G	H	I	J	K	L	M
1		1	4	4	3		1		1	2	1		2
2	1	1	1	2			2		1	1	1	2	2
2/3													
3	1	2	2	2	4	1	3	2	1	2	1		1
3/4							1						
4	13	12	9	8	9	15	9	9	13	7	8	6	6
X								1		1	1	4	

Note to Table 6: This table is a summary of the detailed gradings given to the cases where there was an overall grade of 1. The figures are compiled from the CCNR report forms. See Annex D for detailed breakdown.

40. An overall grade of 1 was assigned by the reviewers to the care of thirteen patients (sixteen procedures), of whom twelve had open heart surgery and one had closed heart surgery. Two of the children were alive thirty days after their last procedure, one of whom had a moderate disability; the remaining eleven had died. The child who had closed heart surgery was amongst the eleven who died. One of the children survived open heart surgery but died the following year following interventional cardiac catheterisation.

41. For ten patients, pre-operative aspects of care were graded as less than adequate (mostly grade 1), and appear to have been the key determinants of poor outcome. It is notable that the accuracy and completeness of diagnosis (Aspect C); the appropriateness of initial treatment strategy (Aspect D) and the timing of planned treatment (Aspect E) all featured significantly as less than adequate.

42. The results suggest that operative care was not as significant a factor in contributing to poor outcome as pre-operative care, within this group of overall grade 1 cases. Surgical procedure (Aspect G) was considered probably to have contributed to a poor outcome in only one of the thirteen cases. Here, the initial strategy was cited rather than the technical aspects of surgery. In two further cases, the reviewers felt that the surgical technique in one of the child's three operations might have made a difference to outcome. The anaesthetic was considered probably to have contributed to a poor outcome in two cases. In one, there was a major problem with insertion of a central venous line and in the other anaesthetic management during cardiac catheterisation was criticised.

43. In four patients, aspects of intensive care management were given grades 1 or 2, thus, intensive care management may have contributed significantly to poor outcome. In two of these cases grades of 1 or 2 were also given for pre-operative aspects of care.
44. There is one case in this group where the reviewers were unable to identify as less than adequate (grades 1 or 2) any particular aspect of care. However, they appeared to take the view that the care overall, including delays, surgical treatment and the length of time on by-pass together warranted an overall grade of 1.
45. In summary, in those cases that were given an overall grade of 1, the reviewers were critical of both pre-operative and post-operative aspects of care. The reviewers commented on errors and delays in diagnosis and treatment strategy in these cases. They also questioned the organisation of post-operative care. In particular, they commented on a lack of cardiological input at this stage.

Patients with overall grade 2

Less than adequate care - different management might have made a difference to outcome.

Table 7. CCNR reports with grade 2 for overall care, showing the frequency of grades for individual aspects of care.

CHILDREN WITH OVERALL CARE Grade 2: 11 children, 13 Procedures													
Grade	Aspect of Care												
	Pre Operative Care						Surgical Care			Post Operative Care			Post-Mortem
	A	B	C	D	E	F	G	H	I	J	K	L	M
1							1			1			1
2		2	1	1	3		4	1	1	3	3		
2/3												1	
3	1	1	2	2	2				2			2	2
¾													
4	11	10	10	10	8	13	8	8	10	8	9	7	7
X								1				2	

46. An overall grade of 2 was assigned by the reviewers to the care of eleven patients (thirteen procedures), of whom nine had open heart surgery and two had closed heart surgery. Ten died within thirty days of their last surgical procedure. The eleventh child, who had received open heart surgery, was alive at thirty days after the last procedure without disability.
47. In contrast to those patients with an overall grade of 1, only four patients had been given grades of 2 for aspects of preoperative care. There were five patients with grades of 2 or 1 for the surgical procedure, three of whom had also been given grades of 2 or 1 for aspects of ICU care. Reviewers assigned grades of 2 or 1 for aspects of post-operative care in a total of six patients.

48. We noted that, in one patient in this group, only the postoperative cardiological care had been graded as less than adequate and then with a grade of 2/3. We must presume that the reviewers considered this to be such an important factor influencing overall care that they were unable to assign an overall grade 3 or 4.
49. The spectrum of aspects of care that were considered less than adequate was somewhat broader in this group compared with the group with an overall grade of 1, but the overall numbers are too small to draw any firm conclusions.
50. Thus, in those cases which were given an overall grade of 2, in the same way as cases which were given an overall grade of 1, the reviewers commented on errors and delays in diagnosis and treatment strategy as well as the organisation of post-operative care, particularly cardiological input at this stage. Reviewers also noted concerns about surgical procedure in some of these cases.

Patients with overall grade 2/3

Table 8. CCNR reports with grade 2/3 for overall care, showing the frequency of grades for individual aspects of care.

CHILDREN WITH OVERALL CARE Grade 2/3: 4 Children, 5 Procedures													
Grade	Aspect of Care												
	Pre Operative Care						Surgical Care			Post Operative Care			Post-mortem
	A	B	C	D	E	F	G	H	I	J	K	L	M
1													
2								1	1	1	1	1	
2/3							1						
3					1		2	2					
3/4													
4	5	5	5	5	4	5	2	1	4	1	1	1	3
X													1

51. The four patients in this group had a total of five procedures. All four died. The reviewers considered that care was less than adequate but appeared to be unable to decide whether different management would have made no difference to outcome (grade 3) or might have made a difference (grade 2). In one of these patients, no single aspect of care was graded as less than 3. All of the other three patients had been given a grade of 2 for at least one aspect of care. This problem illustrates the difficulty in deciding the influence of less than adequate care on the eventual outcome.

Patients with overall grade 3

Less than adequate but different management would have made no difference to outcome

Table 9. CCNR reports with grade 3 for overall care, showing the frequency of grades for individual aspects of care.

CHILDREN WITH OVERALL CARE Grade 3: 13 Children, 16 Procedures													
Grade	Aspect of Care												
	Pre Operative Care						Surgical Care			Post Operative Care			Post-mortem
	A	B	C	D	E	F	G	H	I	J	K	L	M
1													1
2		1	1	1			2			1	1		2
2/3													
3	1	1	1		5	2	5	4	4	4	3	3	1
3/4							1						
4	14	14	14	15	11	14	8	5	12	7	8	7	2
X										1	1	2	

52. An overall grade of 3 was given to the care of thirteen patients, (sixteen procedures), of whom nine had open heart surgery and four had closed heart surgery. Five of the children were alive thirty days after their last surgical procedure, one of whom had a moderate disability. Of the eight children who had died, two had closed heart surgery. In this group, "less than adequate" care was identified in a cross-section of aspects of care. In most of these cases, one or more aspects of care were given a grade of 3, but in a few aspects, gradings of 2 were assigned.
53. Pre-operatively, problems with the adequacy of care were identified in the cases of ten patients. The shortcomings mostly related to the timing of planned procedures, although cardiological assessment (Aspects B and C) was given a grade 2 for two procedures.
54. Operative issues were identified in the cases of seven patients as contributing to less than adequate care. Anaesthetic and perfusion were cited as a factor in six patients, and features of intensive care were cited in the cases of five patients.
55. In summary, in the cases that were given an overall grade of 3, the review teams comment on delays and intra-operative management and in some cases they also express concerns about perfusion and the length of surgery. By assigning an overall grade of 3, however, the reviewers consider that these aspects would not have made a difference to outcome. In many cases the reviewers comment that the cases are complex and high risk and would have challenged any unit.

Patients with overall grade 4

Care was adequate

Table 10. CCNR reports with grade 4 for overall care, showing the frequency of grades for individual aspects of care.

CHILDREN WITH OVERALL CARE Grade 4: 39 Children, 48 Procedures													
Grade	Aspect of Care												
	Pre Operative Care						Surgical Care			Post Operative Care			Post-mortem
	A	B	C	D	E	F	G	H	I	J	K	L	M
1													
2	1			1				1					
2/3													
3	1	1		1	3		1	1	5	3	1	2	1
3/4													
4	41	47	48	43	45	47	47	34	43	44	46	45	8
X						1		2					

56. The reviewers gave an overall grade of 4 to half of the cases, thirty-nine in all, encompassing forty-eight procedures. Seven children had died and thirty-two were alive within thirty days of their last surgical procedure.

57. In the CCNR reports of twenty-three children, all aspects of care were given a grade 4, and thus the total care was considered to have been adequate. A further sixteen CCNR reports contained a small number of grades less than 4. Timing of planned treatment (Aspect E); Anaesthetic (Aspect I), and post operative medical/anaesthetic intensive care (Aspect J) were cited more than twice as less than adequate.

58. In two cases, grades of 2 were given for aspects of care. One case cited two aspects of pre-operative care, and another cited perfusion. In this group there were very few comments accompanying the gradings, probably because there was little to be said in commenting where care was adequate. Some reviewers made complimentary comments about good outcomes in difficult cases.

**Children alive whose care was ascribed with a less than adequate grade;
Children who died whose care was ascribed an “adequate” grade**

59. As mentioned in paragraph 23 above, given a potential tendency to regard any care given to a child who died as less than adequate, it is important to focus on those cases where the grades would appear to go against this possible tendency. Of the forty children in the sample who died within 30 days of surgery, the care of seven was graded as adequate, ie given an overall grade of 4. All these children had complex congenital heart disease with surgical procedures carrying a significant mortality risk. In two cases, the reviewers specifically stated that the child would most probably have died in any unit in the UK. One child died after an arterial switch procedure from overwhelming infection, something that can happen in any unit. In the other four cases, the reviewers made no specific comments, but obviously considered overall care to have been adequate.

60. Again, as highlighted in paragraph 23, we asked whether there was anything to be learned from looking specifically at the cases of those children who were alive 30 days after surgery, but where the review teams had given a grade indicating that care was less than adequate. Out of the 40 children alive, eight received grades of less than 4. Five cases were given an overall grade of 3, but the teams did not feel different management would have made a difference. Most of the criticisms related to organisational issues within the unit, particularly related to timing of the operation. One case was given an overall grade of 2, suggesting different management might have made a difference. Here the criticism was of pre-operative assessment and timing of operation. In two cases, the teams were particularly critical and felt that different management would have made a difference to outcome (grade 1) - one of these children was left with disability. In both cases the criticisms were directed particularly at delays in investigation and surgery; there were also comments on poor continuity of care. Thus, in this group of children, the teams seemed principally to highlight issues concerning the organisation of care.

D. Results from the sample by aspect of care

61. For the purposes of preparing this report, the authors have had access to all CCNR review report forms. In this part of the report, we consider the themes emerging under each aspect of care in turn, taking into account the grades and comments given to all ninety-eight procedures within the eighty cases.

Table 11– Distribution of grades for all aspects of care, ninety-eight procedures

ALL 80 CHILDREN, 98 PROCEDURES													
Grade	Aspect of Care												
	Pre Operative Care						Surgical Care			Post Operative Care			Post-mortem
	A	B	C	D	E	F	G	H	I	J	K	L	
1		1	4	4	3		2		1	3	1		4
2	2	4	3	5	3		8	3	3	6	6	3	4
2/3							1					1	
3	4	5	5	5	15	3	11	9	12	9	5	7	5
3/4							2						
4	84	88	86	81	77	94	74	57	82	67	72	66	26
X						1		4		2	2	8	1

Note. For each of the 98 procedures assessed, reviewers did not always give a grade for each of the thirteen aspects of care.

62. This table shows the grades for each aspect of care in turn and captures information from all review forms.

63. We now highlight aspects of care in which a grade of "less than adequate" was assigned; we have drawn on the comments of the review teams in order to summarise the trends, bearing in mind that ninety-eight procedures were assessed in all. See paragraphs 33-39 for a breakdown of the clinical responsibility for each aspect of care.

PRE-OPERATIVE CARE (Aspects A-F)

64. The review teams were asked to consider six elements of pre-operative care: timing and appropriateness of initial referral/condition on arrival; clinical assessment and management; accuracy and completeness of diagnosis; appropriateness of initial treatment strategy; timing of planned treatment; and immediate pre-operative management, including nursing.

Note - the comments below apply to procedures – total number ninety-eight, as opposed to the total number of children whose case notes were reviewed, which was 80.

Timing and appropriateness of initial referral/condition on arrival (Aspect A)

65. In only six procedures was this aspect graded less than 4 and in only two was it considered to have affected the outcome.

Clinical assessment and management (Aspect B)

66. In ten procedures there was some concern about adequacy of care, but in only five instances was it considered to be of sufficient importance to have made a difference to outcome.

Accuracy and completeness of diagnosis (Aspect C)

67. In twelve instances, concerns were raised about diagnosis, but in only seven was a wrong or incomplete diagnosis thought to have made a difference to outcome.

Appropriateness of initial treatment strategy (Aspect D)

68. Grades of less than adequate were given for fourteen procedures; in nine the inappropriateness of initial treatment strategy was thought to have affected outcome. It appears that team decisions were made about surgical strategy which were considered by the case reviewers to be inappropriate.

Timing of planned treatment (Aspect E)

69. Delays in the timing of planned treatment were mentioned in relation to twenty-one procedures, but in only six cases were delays considered to have contributed adversely to outcome. There were delays both in the initial investigation (eg cardiac catheter), and between catheter and the actual time of surgery. In most cases, the reviewers were unable to ascertain from the medical notes the precise reasons for delay, but issues of resources and of co-ordination are recorded in some instances.

Immediate pre-operative management, including nursing (Aspect F)

70. Only three instances of "less than adequate" care were cited and in none was it considered likely to have made any difference to outcome.

CARE DURING SURGERY (Aspects G-I)

71. The reviewers were asked to consider three aspects of operative care: surgical procedure; perfusion and anaesthetic.

Surgical procedure (Aspect G)

72. Grades other than 4 were given for twenty-four procedures. Of these, for thirteen procedures, the reviewers did not consider that the surgical care affected outcome; whereas in eight procedures, i.e. those with a grade of 2, different management might have made a difference to outcome, and in only two, i.e. those with an grade of 1, was it considered that different care would reasonably be expected to have made a difference to outcome.

Perfusion [applies to open heart surgical procedures only] (Aspect H)

73. Perfusion was questioned in twelve procedures. In three of these, different management might have improved outcome. One of the most frequent comments concerned the incidence of acidosis.⁸ However, the factors which lead to acidosis can vary, and in the CCNR, expert reviewers were not able to draw out in any detail the series of events which might have led to the acidosis in individual cases.

Anaesthetic (Aspect I)

74. In sixteen cases there were grades less than 4; in four of these cases different anaesthetic care might have or would have made a difference to outcome.

POST OPERATIVE INTENSIVE CARE AND ASSESSMENT (Aspects J,K,L)

75. Reviewers were asked to consider three aspects of post-operative care and assessment: ICU/Medical care; surgical care and paediatric cardiological care.

76. During the review it transpired that the post-operative management in Bristol was undertaken primarily by surgeons with anaesthetists and that there was very little presence of paediatric cardiologists on the ICU. It was difficult for the reviewers to attribute specific responsibility and accountability for aspects of care other than ventilation, which is clearly the province of the anaesthetists. It was difficult to identify who was primarily responsible for taking the lead in the management, although it appeared for the most part to be the surgeon. (See also Para 38).

77. Although the format of the clinical case note review report form prompted reviewers to consider the anaesthetic, surgical and cardiological elements of post-operative management in intensive care, it was usually not possible to attribute primary responsibility for less than adequate care to specific members of the clinical team. It became apparent to the authors that reviewers had often graded "Medical" (or intensivist/anaesthetist) care as "Surgical", and vice-versa, because of difficulties in discerning separation of the roles of these respective disciplines in the ICU. However, we continue to comment on the grades as they were allocated and, with some reservation, separate them out as follows:

⁸ Acidosis is a condition which occurs when inadequate oxygen reaches the body tissues and, as a result, acid builds up in the blood stream. The oxygen needed by each patient will vary according to that individual's anatomy and size. It also depends on body temperature – during heart surgery the patient is deliberately cooled.

In the case of children receiving open heart surgery, there are several possible reasons why blood flow may be inadequate for the body's needs and the child may develop acidosis. For example, a decision might be made deliberately to restrict blood flow so as to give the surgeon as clear as possible an area in which to conduct the operation. If the period of lower blood flow is prolonged, acidosis can occur. On occasions the circulation may have to be stopped completely (this can be done safely at very low temperatures and is a technique known as circulatory arrest) to give the surgeon a clear operating field. If this period is prolonged then acidosis may occur. Another reason for limitation of blood flow might be the way in which the heart by-pass machine is connected to the patient. This is a complex arrangement which needs to be adjusted to the particular patient's needs. If the connecting tubes between the child's blood vessels and the machine are too narrow for that child, blood flow will be restricted.

In recent years, the techniques for measuring an individual child's oxygen needs, and for assessing whether these are being met during the operation, have improved significantly. Thus it is easier in the current era to take more pro-active action to limit the incidence of acidosis.

78. There was a grading for less than adequate care in relation to medical care, which we take to mean anaesthetic care, (Aspect J) following eighteen procedures, including nine instances where care was graded as 1 or 2.
79. Surgical post-operative care (Aspect K) was graded as less than adequate in twelve instances, of which seven grades were 1 or 2, and paediatric cardiological post-operative care (Aspect L) was deemed less than adequate in eleven instances, of which three were grades 1 or 2.
80. Reviewers' comments on the intensive care touched on a range of issues including poor control of ventilation; early extubation; failure to undertake echocardiography; problems with fluid balance; failure to act when low blood oxygen presented post-operatively; and failure to assess reasons for poor cardiac output. Reviewers commented that they could find little evidence of the presence of paediatric cardiologists on the ICU at BRI.

POST-MORTEM (Aspect M)

81. It must be remembered that the reviewers were commenting only on the post-mortems as they were revealed in the post-mortem reports within the notes. The reviewers were not given access to retained human material – either tissue or organs. The reviewers regarded the post-mortems as an important aspect of the overall care because audit and the assessment of care depend on good pathological back up. The gradings reflect this approach.
82. Reviewers reported on thirty-nine post-mortems (including post-mortems on the three children who died more than thirty days after surgery). Grades 1 and 2 were assigned in the cases of eight children, all of whom had died within thirty days of their last cardiac surgical procedure. In commenting on post-mortems, the terms "inadequate" or "poor quality" appeared on four occasions but "adequate" appeared in many more.
83. The post-mortem reports were less helpful to clinicians reviewing the clinical records than they had expected; however, it was accepted that evidence from the post mortem and in particular from later histological examination would not always have been filed in the clinical records. Some of the post-mortem reports suggested to reviewers that the pathologist did not appear to have an appreciation of the technical details of the operation performed. The expert reviewers commented that there did not appear to be, or there was no record of, sufficient information exchanged between the clinical team and the pathologists either before or during the post-mortem. This led the expert reviewers to suggest that, if better information had been exchanged between the clinical team and the pathologists, more helpful pathological reports might have been produced.

Part IV
Results of the Repeat Review Exercise

Background and methodology for Repeat Reviews

84. As indicated in the Inquiry's July 1999 paper, mindful that differences of approach between review teams could occur, the Inquiry decided to distribute a number of the same sets of case notes across the teams. In all, fifteen sets of notes were reviewed twice, although none of the teams was told they were undertaking a repeat review, nor, by the same token, were they made aware of the grades assigned in the first review.

Here we compare the grades for overall care:

Table 12. Overall grade of care for fifteen cases, first review and repeat review

Repeat Review Case	OVERALL GRADE	
	First Review	Repeat Review
RR1	4	4
RR2	4	4
RR3	4	4
RR4	3	2
RR5	3	1
RR6	2/3	2
RR7	4	4
RR8	3	3
RR9	3	4
RR10	3	2
RR11	4	4
RR12	4	4
RR13	1	1
RR14	4	3
RR15	2	4

85. Of the fifteen cases selected for repeat review, eight children were alive and the other seven died within thirty days of their last cardiac surgical procedure.

86. In reviewing the grades, we separated those cases graded overall 3 or 4 (care was adequate or different treatment would have made no difference to the outcome), from those graded overall 1 or 2 (different treatment would reasonably have been expected to, or might have made a difference, to the outcome).⁹

87. In eight of the fifteen cases, there is complete agreement on overall grades between the teams. If the overall grades are grouped, grades 4 with 3, and grades 2 with 1, there is overall agreement in eleven, or about 70%, of cases.

88. Of the four cases where the teams disagreed significantly (as to whether different management might have or would have altered the outcome), there were two cases where there was only one grade difference i.e. 3 versus 2:

⁹ See Annex B for a note on CESDI by Dr Steve Gould. The approach of grouping similar grades was used by CESDI in an exercise to review a second time 113 sets of case notes, reported in the CESDI fifth annual report, May 1998.

- In one of these (RR4) the anatomy was very unusual and has only rarely been described before – this child died postoperatively. One team was critical of the inaccuracy in pre-operative diagnosis, while the other felt the rarity of the condition precluded accurate diagnosis. The decision as to whether this aspect of care might or might not have made a difference in a very rare condition is a moot one. This case reflects the difficulties that the reviewers faced when making judgements about unusual cases and suggests to some extent that, in reviewing such cases, the methodology is blunt.
 - In the second case (RR10), the child is alive but has moderate disability following a cerebrovascular accident (stroke). The groups identified the same aspects of care but differed in their judgement about the weight they attached to them. Both teams felt that an earlier operation should have been undertaken but differed as to whether this might or might not have changed the outcome. The case shows the fine judgements groups made when assigning grade 2 or 3 to a case.
89. The authors feel that the differing grades assigned to these two cases do not call into question the methodology of the CCNR. Both groups thought that the care had been less than adequate, but they differed about the impact of this care on outcome.
90. We were more concerned, however, about the two cases where there were two grades difference between the teams:
- In the first case (RR5) the child's case was given an overall grade 3 by the first team, and an overall grade 1 by the second team. The child was very ill with particularly small pulmonary (lung) arteries – this would have made the technical construction of a shunt very difficult. Even if a successful shunt had been constructed, it is possible that the pulmonary arteries might not have grown. One team was critical of the way the shunt was constructed and about the initial post-operative management. The other team felt the anatomy was so unfavourable that a different technique would not have made any difference. The child died. This case shows that there was some variation between the teams in the weighting they attached to the same aspect of care, not surprising in a retrospective review of care given to a child with a very serious condition. It is perhaps more surprising that such differences in weighting accorded by the review groups were relatively rare in this exercise as a whole.
 - In the second case (RR15), overall care was given a grade of 2 by the first review team and 4 by the second. This was described by both teams as a very difficult and complex case. One team felt it had been adequately managed, but the other believed a different approach by the anaesthetist at the first operation would have affected the outcome in the long term. This child survived the surgery but died some time later following an interventional cardiological procedure to dilate the pulmonary (lung) artery which was narrowed as a result of problems at the first operation. The review teams appeared to highlight different details in the case.

91. Both cases highlight our earlier observation (see paragraph 23) that, in any retrospective review where the child died, it could be argued that any different management might have or would probably have made a difference.

Implications of the Repeat Review Exercise

92. Taking into account the cases in which the review groups differed, the repeat review exercise showed a high degree of concordance between the teams suggesting that the expert team review methodology is valuable and capable of producing reliable results. We note that where groups differed, this occurred in very difficult cases, reflecting the normal reality of variation in clinical opinion. For example, in cases of unfavourable anatomy, groups may agree that the treatment strategy was wrong, but differed as to the impact of the child's anatomy on outcome. In only one case, (RR15), was the care considered adequate by one group and less than adequate by another group.

Part V
Results of the Requested Review Exercise

Background and methodology for Requested Reviews

93. Individuals with a direct interest in the Inquiry and in a specific case, such as parents and clinicians, who considered that all the matters in the case notes had not been taken into account, could make an application to the Inquiry Panel for the case to be subject to a further review. The Panel considered seventeen applications for a “requested review”, of which thirteen were justified. The methodology for the requested reviews was the same as that used for the review of the initial eighty cases. The expert review teams only considered the clinical case notes. They were aware that the case had been reviewed before, although they did not have access to the first CCNR report form. They did not have sight of, nor were they asked to take into account, the reasons surrounding the application for a further review. The experts invited to sit on further review teams were those who previously participated in the review exercise but not in respect of the case in question.

94. In this part of the report we consider what can be learned about the CCNR methodology and about adequacy of care at Bristol in the context of comparing the reviews of these self-selected cases.

Here we compare the grades for overall care:

Table 13. Overall grade of care for thirteen cases, first review and requested review

Requested Review Case	OVERALL GRADE	
	First Review	Requested Review
RQR1	2	1
RQR 2	1	1
RQR 3	1	2
RQR 4	1	2
RQR 5	4	2
RQR 6	2	2
RQR 7	4	1
RQR 8	1	3
RQR 9	1	1
RQR 10	2	2
RQR 11	1	4
RQR 12	1	1
RQR 13	1	2

95. Of the thirteen requested review cases, three children were alive and the other ten died within thirty days of their last cardiac surgical procedure.

Results of requested review exercise

96. As with the repeat review exercise¹⁰, in reviewing the pattern of grades overall, we grouped cases graded overall 3 or 4 (different treatment would have made no difference to the outcome or care was adequate), from those graded overall 1 or 2 (different management would reasonably be expected to, or might have, made a difference to the outcome).

97. On this basis, in nine of the thirteen cases we noted a close concordance between the overall grades. In only four cases was there a significant disagreement between the overall grades. Below, we draw out the significant issues in these cases and consider the implications for the methodology of the CCNR:

- In the first case, RQR 5, the child survived. The difference in grading between the review groups appears to rest on whether they felt the need to be critical of the adequacy of care in a case where the outcome was good. It is possible that the review groups may have had a tendency to give adequate grades where there was a good short-term outcome rather than consider the longer-term outcome. A timebanding was not put on outcome, a point illustrated by this case. Any future studies of this type may want to adjust instructions to the groups to ensure consistency of approach in defining the timing of outcome.
- In the second case, RQR 7, the abnormality was extremely difficult to treat and the condition of the child was associated with a high mortality rate in that era. The complication described in the post-mortem report is unusual. It appears that the groups differed in their interpretations of the post-mortem, leading one group to be more critical of the surgical procedure. This shows that the review groups have differed in their interpretation of the same information.
- In the third case, RQR 8, it is not obvious why there is a difference of judgement between the groups. Both groups agreed that care was less than adequate, but differed as to whether this had an impact on outcome. This difference highlights the problem of retrospective analysis and the differences when groups are considered long term or short time outcomes.
- The fourth case, RQR 11, reflects the rate at which standards of care were changing particularly in the late 80s and early 90s. Delay was a key issue, but the groups took a different view as to what standards of care were applied at the time. It is noticeable that this has arisen infrequently. We note that, in the first review, the case is given an overall grade of one and no aspect of care is given a grade of less than three. This, perhaps, highlights the need for more comprehensive guidance for any such review groups in the future.

98. These four cases illustrate a slight variation of approach between the review teams. The authors note that these were difficult cases and, in reviewing them, the groups differed about whether they looked at short term or long term outcomes and in the weight given to certain aspects of care. In nine of the thirteen cases,

¹⁰ The comparison of these requested reviews with the original cases must be considered in the context that these reviews were carried out in response to a request from either a parent or clinician. In these cases the review groups were aware that they were doing a second review; this was not the case in the repeat review exercise. The authors have analysed the results of the requested review exercise with this important caution in mind.

however, the requested review exercise showed a degree of concordance between the teams.

Implications of the Requested Review Exercise

99. The requested review exercise overall showed concordance between the grades. This is particularly significant because the review teams were aware that they were carrying out a second review as a result of a parental or clinician request (although they did not know the reason for the request or the first CCNR grades). Where variation in grades between the exercises did occur, it was interesting that requested review teams highlighted the same problems. Again, therefore, we see the different weighting which can be accorded to aspects of care in difficult cases. There may be implications here for the guidance given to review teams in any similar future exercise.

Part VI

Analysis of Formal Written Comments from Bristol Clinicians and Parents

100. Individuals with a direct interest in the Inquiry and in a specific case, such as parents and the Bristol clinicians, had the opportunity to see the completed review report form and submit a formal written comment on the case. 10 Bristol clinicians submitted formal written comments on 26 cases, while 5 parents also commented on their child's case. The majority of the comments relate to specific matters on individual cases, referring in some cases to a difference in interpretation of the clinical notes, and, in others, to events which the clinician or parent recalled but which were not recorded in the clinical notes. Here we summarise general points and themes arising from all the comments together and consider their implications for the review exercise. Formal written comments were submitted to the Inquiry in the knowledge that they would be made available in full to the Panel and published; thus we are able to refer here to the comments by name of author.¹¹

Surgeons

101. Mr Wisheart and Mr Dhasmana made formal written comments on the CCNR. Their comments highlight those cases in the requested review exercise in which review teams differed in their assessment of adequacy from the original CCNR reviewers. It is suggested that these cases demonstrate a lack of consistency between the review teams. It is also argued that review teams did not necessarily appreciate that certain actions had been taken by surgeons and that "team discussions", although not documented, had taken place. There is also disagreement with some criticisms of clinical decisions and explanation of their actions, suggesting misinterpretation by review teams of operation reports. Mr Wisheart's comments on several cases highlight the lapse of time between the completion of a catheter investigation and discussion of the child's case between the cardiologist and the surgeon, and the further time lapse between that discussion and the child attending a surgeon's outpatient clinic.

Anaesthetists

102. Two anaesthetists, Dr Burton and Dr O'Higgins¹² provided formal written comments on the CCNR. These comments offer explanation of the actions criticised by review teams. It is explained that specific clinical problems had to be managed in a certain way at the time. The comments refer to the persistent dilemmas in managing acidosis, (see paragraph 73). The anaesthetists point to dialogue and sharing of responsibility between anaesthetist and surgeon. There is also a firm assertion that perfusion is largely the responsibility of the surgeon, with the anaesthetist having a significant input.

103. Dr Burton also provided general comments on the anaesthetists' responsibilities at Bristol during his time in post. He states that the main responsibility for

¹¹ The formal written comments of Bristol clinicians and parents will be published alongside the relevant CCNR Report form, where parents have given their permission for the CCNR Report Form on their child's notes to be made public.

¹² Dr Burton: Anaesthetist, Bristol Royal Infirmary/Bristol Royal Hospital for Sick Children, 1959 - 1991; Dr O'Higgins, Anaesthetist, Bristol Royal Infirmary/Bristol Royal Hospital for Sick Children, 1971-1995.

postoperative medical care, was not that of the anaesthetist. Amongst the points he made were:

- anaesthetists did not have lead responsibility for perfusion. In the 1980s at least, perfusion was directed by the surgeon with the help and advice of the anaesthetist as required;
- blood samples were not analysed in theatre but sent to the pathology laboratory, which may have contributed to delays in obtaining and acting on pathology results;
- financial restrictions limited the availability of anaesthetic sessions on the BRI ICU;
- other resource problems, such as the limitations on equipment availability (in 1984 the BCH did not have a ventilator suitable for sick infants, and when Dr Burton visited other centres in the mid 1980's they appeared to have more equipment than Bristol);
- the problem of transferring sick babies from the Children's Hospital to the BRI.

104. Additional comment indicated that there was an organisational problem in terms of responsibility for patient care on the Intensive Care Unit.

Perfusionists

105. Three perfusionists, Mr Downes, Mr Nicholson and Mr Caddy provided formal written comments on the CCNR. These comments suggest that acidosis, which is remarked on in some review report forms, was due to long periods of bypass and could not be treated adequately by the perfusionist alone. It is explained that the use of sodium bicarbonate by the perfusionist, to help manage acidosis, could also have had undesirable consequences. (Mr Richard Downes, Chief Perfusionist at Bristol, for example, pointed out that repeated doses of sodium bicarbonate can lead to an overload of sodium in the body which, particularly in young children with undeveloped organs and structures, can cause renal failure). It is suggested that the comments on some report forms demonstrate lack of understanding about perfusion responsibilities; it is argued that there should have been a perfusionist on the panel of expert reviewers. Many of the comments on report forms are rejected in some detail; examples are acidosis, absence of urinary catheter, weight (fluid) gain during bypass, and hypovolaemia.

Pathologist

106. Professor Berry¹³ provided comments on a number of cases. He notes that most post-mortems were carried out for the Coroner. He explains that at regular clinico-pathological meetings clinicians could ask for details that had not appeared in post-mortem reports. He questions whether standards of the time had been applied in reviewing the cases. It is noted that there was no specialist

¹³ Consultant Paediatric Pathologist at Bristol since 1983 and Professor of Paediatric Pathology at the University of Bristol since 1990.

cardiac pathologist in Bristol. Improvements and developments in the pathology department are explained. Some errors of fact are pointed out and attributed to incomplete information being available to the review teams, i.e. histology said to be absent when it had been available. In his detailed comments about individual cases, Professor Berry rejects many of the reviewers' comments, supplying reasons; he also argues that most Bristol post mortem reports on children were better than those completed elsewhere, and offers material to support this argument.

Parents

107. Seventy families asked to see a copy of the CCNR report form on their child's notes and were invited to submit formal written comments; five families did so. The comments from parents highlight their experience that they had not been given complete or accurate information both before and after the operation. In one case, parents commented that the operation was delayed and they were not told of the potential risk of delay. There is mention of confusion about supportive equipment, alarms and monitors; apparently not fully explained. There appears to be some difficulty in understanding reasons for certain grades on the review report form and dismay at discovering that care, or post-mortem, may not have been adequate.

Impact of Comments on CCNR Methodology and Results

108. Clearly, clinical opinion and assessment can vary and inevitably there are some differences between the review teams. Teams were aware that the only information that was available to them was in the case notes and that much conversation and decision-making may well not have been recorded. Review teams were hampered by not having all ICU and Perfusion charts available; it appears that many were destroyed because of lack of storage space. The comments of the Bristol clinicians serve to highlight the fact that opinions also varied between the review teams.

109. Review teams did not appear to consider that perfusionists would have had ultimate clinical responsibility. Bristol anaesthetists considered that perfusion was ultimately the responsibility of the surgeon. It is notable that a number of the review teams, which included surgeons and anaesthetists, must, by their comments, have implied or suggested that perfusion was the ultimate responsibility of the anaesthetist. This could be said to have revealed a contemporary confusion as to which specialty, surgery or anaesthesia, is responsible for perfusion.

110. The anaesthetists appear not to accept having had responsibility for a major part of postoperative intensive care, raising the question as to who was responsible. Major problems with equipment, logistics of blood tests and lack of staff are highlighted, as well as the difficulty of accepting and managing sick babies at the BRI.

111. Many of the comments from Bristol clinicians serve to confirm conclusions drawn by individual review teams, and by the authors of this report, concerning organisational aspects of care – namely, that where a number of specialists shared responsibility for aspects of care, such as pre-operative diagnosis and assessment,

perfusion, and post-operative intensive care, confusion existed as to who was responsible for caring for the patient at a given time.

112. The comments provided by Professor Berry do not significantly conflict with review teams' comments where the main thrust of criticism was directed towards an apparent lack of dialogue between clinicians and pathologists at the time of the post-mortem and consequently a lack of understanding by the pathologists of certain important clinical issues. Such discussions as might have taken place appear not to have been recorded in the notes, but we note that it would have been unusual for such discussion to have been recorded in an individual patient's notes.

113. The comments by parents do highlight problems in communication and understanding during a highly emotive time, which can happen in any hospital. Many of their comments are an understandable reaction to being included in the CCNR and having to go over what must be, for many, very painful details once more. That said, parents' comments taken together do not lead us to question the methodology or results overall.

Part VII
Post Review - comments from expert review team co-ordinators

114. At the end of the review exercise, each of the co-ordinators of the teams of expert reviewers was asked for a short note of overall impressions on the pattern of adequacy of care; all of the co-ordinators responded.¹⁴ As these impressions are those of clinicians who have studied Bristol clinical notes in considerable depth, they may be of assistance to the Inquiry. The expert teams, though different, identified very similar issues for comment. This may be thought to strengthen the weight that may be placed on their impressions.

Pre-operative assessment issues

115. The reviewers noted significant delays from primary referral to appropriate investigation. There were delays before cardiac catheterisations were planned, especially for patients who had previously had operations. It was not clear whether this was clinical policy or related to lack of resources.

116. There were delays between the time of the cardiac catheterisation and admission for an operation. Some of the outpatient letters indicated that the waiting list was “tight”. It was again not clear whether the delays related to the waiting list and to resources or whether some were actually clinical policy.

117. In general, investigations appeared to be adequate, providing the correct diagnosis, but many were considered to be incomplete in not providing all of the details that might have been ideal for a surgeon to know. This raised questions, such as whether the lines of communication between surgeons and cardiologists were adequate, and whether there was sufficient dialogue between specialists on clinical problems.

Pre-operative and Operative issues

118. There were some situations that should have been considered as urgent, in which an operation was significantly delayed; on occasion, the patient was even discharged from hospital while waiting for a very urgent operation. One team commented that from a nursing perspective it was difficult to determine the quality of pre-operative preparation which child and parents received. It appeared that these problems were probably related to the availability of resources.

119. Cardiopulmonary bypass procedures were done at BRI, which was remote from the Paediatric Cardiology expertise.

120. There were relatively long cross-clamp and circulatory arrest times; but a subjective interpretation was involved in making judgements.

121. Some of the teams made positive comments about good outcomes in difficult cases.

Post-operative Management issues

¹⁴ Team co-ordinators also commented on the practical arrangements for the CCNR. These comments are incorporated into Annex A.

122. There appeared to be a lack of paediatric nursing input at the BRI. It was not always apparent whether nurses or junior doctors had appropriate paediatric experience; some records suggested more familiarity with adults. On the ICU at the BRI, there was a noticeable absence of Paediatric Cardiological input. There appeared to be little evidence from the cases reviewed that echocardiograms were done on the BRI ICU.
123. It was difficult to determine who took either medical or nursing responsibility for directing the management of patients on the ICU, particularly as applied to the management of paediatric patients. In general, intensive care appeared to have been fragmented and insular in approach. There was failure to anticipate clinical problems, delayed response to post-operative problems and failure to involve other team members.
124. It appeared that the quality of nursing and physiotherapy at the Children's Hospital was excellent, whereas the reviewers considered that, had there been more obvious paediatric nursing involvement at the BRI, bereavement care could perhaps have been better.

Pathology issues

125. Some of the pathology reports did not appear to answer questions the reviewers were asking in relation to the death of a patient. The reviewers questioned whether there was sufficient exchange of information between the clinicians and the pathologists.
126. All of the above comments suggested that the whole group of Cardiologists, Cardiac Surgeons, Nurses, Technicians, Paramedical staff and Pathologists were not functioning adequately as a team. Most reviewers considered that the split site was a major contributing factor.

Part VIII

Assessment of results from the CCNR

The review

127. The Clinical Case Note Review is one of many pieces in the jigsaw of evidence available to the Inquiry to enable it to address two aspects of its terms of reference, namely to examine "the management of the care of children receiving complex cardiac surgical services", and to "make findings as to the adequacy of the services provided".
128. The purpose of the Clinical Case Note Review was to get a snapshot of adequacy of care during the period covered by the BRI Inquiry. This was achieved by selecting eighty cases from the 1827 children known to have undergone cardiac surgery in the period of the Inquiry, with the sample weighted towards younger age, higher risk, and those who died within thirty days.
129. The review was based on a study of clinical case notes; while these are often very rich sources of information, they do not include all the information relevant to the care of an individual and can vary in their quality. It must be remembered that clinical case notes are kept to assist clinicians care for a patient. They are not prepared as logs for later analysis by experts.
130. It was decided not to use the standard approach of review of case notes by experts that normally takes place in cases of litigation. Instead, a multidisciplinary team of experts reviewed the case notes at a meeting after each member of the team had obtained an overall view of the case and had, in particular, scrutinised their own area of expertise. The approach was novel but not entirely unfamiliar because the concept of team review is used by teams in cardiac departments for clinical audit. However, in this exercise the brief was different and the expert reviewers had formed new teams with colleagues from other hospitals. Nevertheless they perceived a real benefit to working together in this way.
131. There were no published results or standards against which the reviewers would be able to measure adequacy of care. It was acknowledged that in 1999 it would be difficult for any one individual to have a clear memory of standards of care that would have been expected, year by year, between 1984 and 1995, hence the value of teams of experts (rather than individual expert reviewers) and of ensuring that a number of cases were reviewed twice.
132. It must also be recognised that the complexity of congenital heart disease will always lead to different but equally valid opinions in managing individual cases.
133. In assessing individual cases, the reviewers developed a number of observations:
- in a review of this kind, which included children who were alive as well as those who died, it is important to be aware that there may have been a tendency to grade the care given to children who died as less than adequate, since there is always a possibility that different management would have made a difference. Equally, there may have been a tendency to grade the

care of those who survived as adequate, since, self-evidently, the outcome was good for the child;

- no similar review has ever been undertaken in the Paediatric Cardiac field. Therefore there are no set down protocols or standards against which this exercise can be judged. It is not known, for example, what proportion of cases would be judged as receiving less than adequate care in another centre.

Assessment of the exercise

The selected eighty cases – detailed insights

134. The grades for aspects of care that were less than adequate ranged across the whole spectrum of pre-operative, intra-operative and post-operative management. The comments supporting the gradings were more numerous and lengthy in the section related to ICU management where the apparent absence of paediatric medical and nursing care, the lines of responsibility and the lack of paediatric cardiological input were criticised.
135. In only two of the ninety-eight procedures was it considered that different conduct of the surgical procedure would **reasonably** have resulted in a better outcome and in eight procedures it **might** have done. The sample of cases was weighted towards very complex abnormalities, which would have placed considerable demands not only on the surgeons but also on the team as a whole. When care was considered to be less than adequate in any patient, there were a number of aspects that appeared to have an even greater influence on poor outcome than the actual operation. These involved all specialties in the service. It was of particular note that preoperative factors would often set the scene for a sequence of events that would lead to poor outcome, and that postoperative care on the ICU was a major determinant of outcome.
136. In our review, we considered there to be particular value in looking at those cases graded 1 or 2 for overall care. There were twenty four such cases. In thirteen graded 1 (different management would reasonably be expected to have made a difference) the teams highlighted issues of preoperative care and assessment. In the eleven graded 2 (different management might have made a difference), the reviewers referred to management issues in pre and post operative care and to the surgical procedure. In the nearest comparator, the studies carried out by the national Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI), findings vary as to the proportion of cases which involve sub-optimal care such that alternative management would reasonably be expected to have made a difference to outcome. In a 1995 study, while just over 66% of all cases involved a degree of sub-optimal care, in 40% of all cases, the care was such that alternative management would reasonably be expected to have made a difference to outcome. A further review in 1997, based on a one in ten sample of still births and infant deaths, found that the care in 22% of cases was such that alternative management would reasonably be expected to have made a difference to outcome. But it must be remembered that these studies consist only of cases where the baby died.¹⁵

¹⁵ See CESDI Annual Reports – No 4 1997; No 5 1998 and No 6 1999

137. Many of the reviewers' comments supporting their gradings of "less than adequate" care suggested that there were problems of communication within the team and that there appeared to be difficulties arising from the split site. There were several comments by reviewers that issues of resources and of the organisation and management of care might have been important factors.

138. It is inevitable that most of this report focuses on aspects of care that appeared to be "less than adequate". The whole issue of the Inquiry is focused on the question of adequacy. It should be noted that in this deliberately weighted sample of cases in which poor outcome featured highly, there were many examples of adequate care and in most instances, the reviewers would have been unlikely to have written comments in justifying those assessments. In some cases, even when death or disability occurred, the reviewers actually complimented the team on good management. We considered that it is likely that, in all centres, there will be examples of less than adequate care, which would only be revealed by a similar review, an exercise that we would consider to be beyond the resources, particularly the clinical expertise resource, available.

The impact of the repeat review exercise

139. In the repeat review exercise, cases were chosen at random for repeat review to help assess the reliability of the methodology. It showed a good degree of concordance on the broad pattern of grade, when cases are reviewed a second time. The degree of concordance, when grades are grouped 1 with 2, and 3 with 4, at around 70%, is very much in line with that found in a much bigger exercise in CESDI.

140. The repeat review exercise revealed a difficulty in some cases, of assessing the impact of less than adequate care on outcome, and the possible tendency to view care, where the outcome of death is known, as less than adequate.

141. For the CCNR as a whole, this finding suggests that the overall messages emerging on the relative balance between adequate and less than adequate care may be broadly reliable, but it is a reminder that this is an exercise involving subjective judgement where the outcomes were known, and thus the grades are liable to a degree of uncertainty.

The impact of the requested review exercise

142. Requested reviews were conducted, at the request of either a Bristol clinician or a parent, where the Panel accepted the argument put, that the full information in the clinical notes had not been taken into account.

143. To the extent that the notes were thought not to have been fully explored in the first review, one might have expected a significant number of these requested review cases to reveal different overall grades the second time around. This was not the case. Almost the same degree of concordance in overall grades (1 and 2 grouped, and 3 and 4 grouped) occurred in this exercise as in the repeat review exercise, 70%. Yet similar warning notes are struck by this exercise to those heard in the repeat review exercise. In very difficult cases, different clinical teams, although they highlight similar issues about care, do differ in their judgement as to the impact such care had on the outcome for the child. Thus,

caution must be exercised in interpreting the relationship between less than adequate care and the impact on outcome.

The impact of the formal written comments from parents and from Bristol clinicians

144. Formal written comments from Bristol clinicians cover a range of matters on specific cases, but taken as a whole some important themes emerge. The comments are a reminder that by no means all communication and interaction related to the care of a child is recorded in clinical notes. The comments also point to difficulties arising from the organisation of care across two sites, and from shortage of resources in terms of personnel and equipment.

145. Another theme of interest to emerge from Bristol clinicians' comments is that of the reviewers' uncertainty as to which clinical specialty, and which individuals, were responsible for perfusion and for post-operative intensive care. It could be said that the Bristol clinicians' comments have helped to bring to the surface a contemporary difference of opinion, and of practice, amongst the expert reviewers as to which clinical specialty was expected to have had overall clinical responsibility for care in these domains.

146. The comments from parents reveal quite strongly issues about lack of communication at the time their child was in hospital. Their comments are also an important reminder, that while the CCNR is deliberately a case note review, these are the case notes of much loved children.

Overall Conclusions

147. Bearing in mind all the cautions previously mentioned about the shortcomings of the methodology, and the lessons of the repeat and requested review exercises concerning the relative degree of reliability that may be applied to the gradings, it is still possible to draw some general and reasonably reliable conclusions from this exercise as a whole. When applied to all those patients known to have had open or closed heart surgery in Bristol between 1984 and 1995, and properly re-weighted to take account of the emphasis given to those who were young, had open heart surgery, and died, the findings of the clinical case note review indicate the following conclusions:

- overall, just over 70% of the children are estimated to have received adequate care. It is probable that some received more than adequate care, although the reviewers were deliberately not asked to assign grades which described how adequate the care was;
- overall, just under 30% of the children are estimated to have received less than adequate care. The degree to which such care had an impact on outcome must be interpreted with caution. A raw interpretation of the gradings would suggest that the care of around 5.5% of the children was such that different management would reasonably be expected to have made a difference to outcome; and for the care of a further 4%, different management might have made a difference to outcome. We know, however, from the repeat reviews that such a figure must be regarded with caution because of the difficulties in making subjective judgements about the relationship between care and outcome in very ill children, as well as the difficulties in relying on clinical notes alone.

148. What this degree of less than adequate care signifies will be a matter for the Panel to consider. It may be that, in such a complex field as paediatric cardiac care, the care in other centres in the UK during the same time period, if subject to a similar exercise, would also reveal a degree of less than adequate care.

149. Where care at Bristol was considered by the review teams to be less than adequate – to whatever degree – certain key themes emerged consistently. These were:

- shortcomings in the organisation of care;
- delays between diagnosis and treatment;
- shortcomings in the cardiological contribution to both pre-operative and post-operative care;
- weaknesses in surgery;
- shortcomings in the organisation of the intensive care for children who had open heart surgery;
- difficulties arising from delivering care across two sites;
- shortage of resources in terms of personnel and equipment.

In summary, the CCNR suggests shortcomings in the overall organisation of care and reveals deeper criticism of the functioning of the clinical team and of the infrastructure of the organisation, rather than of individual clinicians.

Leslie Hamilton
Eric Silove

METHODOLOGY

Introduction

1. This note aims to provide an outline of the Inquiry's approach to the methodology of the review exercise. The note is intended to supplement Part II of this report.

The Starting point – the Confidential Enquiry into Still Births and Infant Deaths (CESDI)

2. In early discussions on a possible methodology for the CCNR, several of the Inquiry's experts commended the CESDI model.¹ The strengths of the model from the Inquiry's perspective were that it offered:
 - a tried and tested approach to a retrospective review;
 - an approach to reviewing care where, historically, there have been aspects of care where formal guidance on standards did not exist;
 - a review process which allowed for the consideration of a range of aspects of care delivered by different specialties;
 - the prospect of bringing together experts from different specialties to discuss sets of case notes;
 - a structured approach to reporting, combining commentary with grading of a range of aspects of care;
 - a grading system which linked assessments of care with impact of care on outcome.
3. The Inquiry was also aware of the work undertaken in 1997 to test and review the CESDI methodology.² This revealed that while differences of opinion between review panels on individual cases are likely (and indeed to be expected in such a subjective process), when looked at overall, the level of agreement between panels is good, and it is greater where there are serious deficiencies in management of care.
4. A key difference between the CESDI and the CCNR methodology is the terminology used to describe care. CESDI uses the terms "optimal" and "sub-optimal", whereas the Inquiry used the terms "adequate" and "less than adequate". Dr Steve Gould explains that the term "sub-optimal" was deliberately used to apply a higher standard than alternative descriptions of care, such as "sub-standard" or "inadequate" might imply. The Inquiry chose to use the terms "adequate" and "less than adequate" for the primary reason that the Inquiry's terms of reference require it to "make findings as to the *adequacy* of care". In

¹ See Annex B for a fuller account of the CESDI methodology, prepared by Inquiry Expert Pathologist, Dr Steve Gould.

² CESDI 4th Annual Report 1997

applying these terms, the Inquiry was mindful that, to have used the terms “optimal” and “sub-optimal”, might have been to apply a higher standard than was required by the terms of reference.

5. CESDI Panel members have expressed concern that knowledge of the outcome of a case might influence their opinions and make them overcritical, and some CESDI Panelists in certain cases now give a view on the notes unaware of the outcome. The Inquiry considered it inappropriate, for a variety of reasons, to seek to “blind” the Bristol notes as to outcome, not least because this would have involved the writing of case note summaries by experts, and this was judged to carry its own difficulty of introducing potentially another form of bias and inaccuracy. It was therefore decided to use original notes, but to take account of any potential bias arising from knowledge about outcome in drawing conclusions.
6. The Inquiry is aware that the CESDI methodology is developing all the time. It was possible to adopt one recent change, namely to include the records of children who were alive, as well as those of children who had died.

The Pilot exercise

7. A pilot exercise was undertaken by five members of the Expert Group in May 1999. The pilot found that it was feasible to assess the adequacy of care, and to grade those assessments. As a result of the pilot, the thirteen separate aspects of care, grouped under pre-operative, surgical and post-operative care, were determined. A further conclusion from the pilot was that all members of an expert review team should receive copies of clinical notes in advance of a review meeting.

Briefing and guidance to groups

8. The results of the pilot exercise were discussed at a briefing meeting with the clinical experts in June 1999. The Inquiry Secretariat also issued written guidelines for completing the reviews and the CCNR forms.

The Review Teams

9. The clinical experts who participated in the review exercise were drawn from the Inquiry’s Expert Group. The Inquiry established a single Expert Group to inform and support the Inquiry. Individuals who are members of the Expert Group are the Inquiry’s experts rather than experts for any individual or organisation that has an interest in the Inquiry’s work.
10. A multi-disciplinary team of clinicians drawn from the Inquiry’s Expert Group reviewed every case in the sample. The composition of the groups was, as far as possible, based on the location of the experts and the Inquiry also tried to ensure that each group had the benefit of the participation of one expert who had taken part in the pilot exercise. One expert on each team was appointed to the role of co-ordinator. The co-ordinators’ role was to liaise with the staff of the Secretariat; to ensure that their review team’s meetings were convened at a place and time convenient to team members; and to ensure that the CCNR reports were

completed and returned to the Inquiry office. Details of members of each of the review teams are to be found at the end of this Annex.

Selection and Distribution of Cases

11. The clinical case notes for the review exercise were selected using a stratified random sampling technique. The methodology for this is explained in greater detail in Annex C to this report. Of the 80 children whose case notes were selected, 78 families were traced and informed of the case review process. Despite extensive efforts, it has not proved possible to trace the two remaining families. Families were given extensive information about the Inquiry and the role of the CCNR; they were offered the opportunity to receive the completed review form and to comment upon it. They were also offered options on confidentiality, including, if they wished, for the CCNR report form on their child's care to remain confidential and not to be published. 12 CCNR report forms will not be published, either because the family requested full confidentiality, or the family could not be traced. Of those families who the Inquiry could trace 27 have given consent to the partial disclosure of the CCNR report form; 41 have given consent to the full disclosure of the form. Forms which the Inquiry makes public will have personally identifiable information removed to protect confidentiality.
12. When allocating cases to review teams, some care was taken so that groups reviewed a variety of types of cases in the sample. As far as possible, each group saw cases of children who had open and closed procedures, at a variety of different ages, and cases in which children had survived as well as cases where the child had died.
13. Each review team was asked to review between ten and twenty sets of notes. Within this, some teams reviewed the same sets of notes, although teams were not made aware that they were undertaking a repeat review. This was so that the Inquiry could assess the degree of consistency to be achieved by its approach.
14. Each member of the review team was provided with paper copies of the clinical notes. The Inquiry had previously scanned onto its database copies of the relevant clinical notes and, by virtue of that process, had assigned a unique number to each set of notes and to each page of those notes.
15. In addition to the main paper records, the Inquiry tried to obtain, where relevant, the following records from the United Bristol Healthcare NHS Trust:
 - perfusion charts;
 - ICU Charts;
 - echocardiograms and angiograms;
 - X Rays.
16. While the Inquiry made every effort with the UBHT to find these records, in some cases they no longer existed. The review teams were advised when the relevant charts could not be found for a particular child. All clinical records sent to expert reviewers had to be returned to the Inquiry office after each review meeting. All

members of the expert review teams were asked to sign confidentiality agreements.

The Review Meeting

17. The Inquiry suggested to the review teams that the presentation of the child's case history was most appropriately done by either the cardiologist or the cardiac surgeon, although all members of the team should have looked at the clinical notes and records before the meetings. The Inquiry asked that the surgeon and the cardiologist agreed in advance of the meeting on the allocation of cases between them, that is, on which cases each was going to take the lead in presenting.
18. In making the presentation, the Inquiry asked that the presenter should have in mind the results of the pilot exercise which suggested that a clinico-pathological approach should be taken rather than a medico-legal approach. The presenter was asked to cover diagnosis, pre-operative, surgical and post-operative care, referring as necessary to the operation note; to reports of catherisations, and to the post-mortem report where one existed.
19. At the meeting, each member of the review team was asked to contribute from his or her expertise, drawing on his or her sense of professional practice at the time in question. The review teams were asked to try and reach a view about the adequacy in relation to specific aspects of care as well as in relation to the overall management of the case, including where there were two or three operations. The pathologist was asked to be present at the full presentation of those cases where the child died in order to relate the post-mortem findings to the clinical problem.

Difficulties in the review process

20. The reviewers faced certain practical problems in undertaking the reviews. Clinical notes were sometimes not filed in date/time order and this made it difficult to establish the precise sequence of events, and contributed to a wider difficulty of identifying which doctor or nurse was responsible for care at a given time. Angiograms and echocardiograms were not always available; this occurred for some children who had had multiple procedures, and for a very few others where the test results could not be found. Some of the review teams experienced difficulties on occasion with poor quality photocopies. The authors, however, would like to note that they thought that the Bristol casenotes may have been better than those from other centres with which they are familiar.

The Scale of the Task

21. The scale of work involved was significant and amounts to over 1,700 hours of clinical time. Eighty cases were reviewed, fifteen of which were subjected to a repeat review, for validation purposes, and thirteen cases were subject to a further review as a result of a request to the Panel, making a total of 108 case reviews. Taking account of the five cases reviewed for the pilot, 113 sets of case notes were considered in all by nine expert review teams.

22. Each member of an expert review team was asked to read the clinical records of those cases assigned to a team. In over three quarters of the cases, this meant reviewing separate records from both the Bristol Royal Infirmary and the Bristol Royal Hospital for Sick Children. Depending on the complexity of the case and the number of hospital admissions, investigations and procedures, the records of any given patient could range between 200 and 1500 pages. Review team members devoted additional time to assessing aspects of care relating to their particular speciality. For example, the cardiac surgeon scrutinised the operation reports, perfusion details and postoperative care while the paediatric cardiologist studied the videotapes of echocardiograms and cine films of angiocardiograms, as well as other aspects of pre-operative and post-operative care. Some cases could be prepared within an hour, but a considerable number took longer, with the most complicated taking between three and four hours. The duration of each case review discussion ranged from between forty-five minutes and nearly two hours.
23. When a review team met, either the cardiologist or the surgeon took the lead in presenting the case. Each aspect of care was discussed by all the experts before agreeing and assigning a grade. It should perhaps be noted that nearly all of the clinicians involved with the review hold significant clinical responsibility for children's care within the NHS.

The Report Form

24. The Inquiry built upon the work of Confidential Enquiry into Still Births (CESDI) and adapted a standard reporting form³ that was tested and then refined following the pilot study in May 1999. The report form was designed to help structure the case review discussions and to capture the result of those discussions in a more consistent format. The form also allowed for the fact that some children had more than one operative procedure in separate episodes of care.

For each case reviewed, the report form consists of:

- a cover sheet which gives a view about the overall adequacy of care;
 - supporting sheets on pre-operative care, and on surgical and post-operative care, for each main surgical procedure with different episodes of care.
25. The review teams were asked to complete all boxes on the form. If they came to the view that there was insufficient information on which to comment then they were asked to put "x" in that section. If there were sections which did not apply to a particular case, they were advised to use the term "n/a".
26. On the right hand column of the form, the review teams were asked to indicate, where it was possible to discern from the clinical record, the name of the clinician responsible for a particular aspect of care. The Inquiry was mindful that there were a number of clinicians working in the relevant units. Therefore, wherever possible, the review teams were asked to enter a name, although the Inquiry accepted that in some cases it would not be possible to be certain of the identity of the responsible clinician.

³ A copy of the CCNR report form is at the end of this annex

27. The review teams were advised that it was acceptable not to reach a conclusion about a particular aspect of care, a particular operative procedure, or the overall adequacy of care, if the review team considered that there was insufficient information on which to base a conclusion.
28. Reviewers almost invariably assigned grades to aspects of care, where that aspect was relevant. Therefore, in the cases of children who received only closed heart surgery, there are no grades for perfusion, nor (obviously) are there grades for post-mortem where children are alive.
29. Initial validation checks of completed CCNR report forms led to the identification of a very small number of errors which appeared to be administrative in nature and are not untypical for an exercise of this type. The errors were checked and necessary amendments were made the agreement of review team co-ordinators.

Confidentiality and Publication

30. The Inquiry is committed to maintaining the confidentiality of personal medical information. The clinical experts who completed the review and received copies of the casenotes were asked to sign an undertaking to preserve the confidentiality of the information to which they were given access. The parents of the children in the sample of cases reviewed had the opportunity to see the completed form for their child and the Inquiry sought their permission to publish the review report form. In cases where the Inquiry was not given consent to publish personal medical information, the review report forms will not be published.
31. Where the Inquiry has been given consent to make public personal medical information about a child, the review form, any requested review form, and any formal written comments from clinicians and parents will be published. Nonetheless, the Inquiry Panel see no reason to reveal information which would lead to the identification of a child in the sample of cases reviewed. Therefore, the CCNR form, and any further review CCNR form, will have information such as initials, the day of birth and hospital numbers blanked out. CCNR forms will, therefore, be referred to by number and parents were advised of that number when they received their copy of the their child's form. Any formal written comments will also be published in a way that aims to prevent the disclosure of the family's identity.

COMPOSITION OF EXPERT REVIEW GROUPS

	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	Group 7	Group 8	Group 9
PAEDIATRIC CARDIAC SURGEON	Mr. James Pollock Royal Hospital for Sick Children Glasgow	Mr. Leslie Hamilton The Newcastle Upon Tyne NHS Trust (The Freeman Hospital) Newcastle	Mr. Jaroslav Stark Great Ormond Street Hospital for Children London	Mr Christopher Lincoln Royal Brompton Hospital London Mr. Philip Deverall Kent	Mr. Daryl Shore Royal Brompton Hospital London	Mr. Pankaj Mankad Edinburgh Royal Infirmary Edinburgh	Mr. Philip Deverall Kent	Mr. Pankaj Mankad Edinburgh Royal Infirmary Edinburgh	Mr. Jaroslav Stark Great Ormond Street Hospital for Children London
CARDIOLOGIST	Dr. David Dickinson Leeds General Infirmary Leeds	Dr. Alan Houston Royal Hospital for Sick Children Glasgow	Dr. Barry Keeton Southampton General Hospital Southampton	Dr. Eric Silove Birmingham Children's Hospital Birmingham	Prof. Andrew Redington Great Ormond Street Hospital for Children London Prof. John Deanfield Great Ormond Street Hospital for Children London	Dr. R Arnold Alder Hey Hospital Liverpool	Dr. David Dickinson Leeds General Infirmary Leeds	Dr. Alan Houston Royal Hospital for Sick Children Glasgow	Dr. Barry Keeton Southampton General Hospital Southampton
ANAESTHETIST	Dr. David Hallworth Royal Hospital for Sick Children Glasgow	Dr. Duncan Macrae Royal Brompton Hospital London	Dr. Edward Sumner Great Ormond Street Hospital for Children London	Dr Michael Scallan Royal Brompton Hospital London	Dr. Monica Stokes Birmingham Children's Hospital Birmingham	Dr. Neil S. Morton Royal Hospital for Sick Children Glasgow	Dr Michael Scallan Royal Brompton Hospital London	Dr. Duncan Macrae Royal Brompton Hospital London	Dr. Edward Sumner Great Ormond Street Hospital for Children London
NURSE – INTENSIVE CARE	Ms Carol Williams Guy's and St. Thomas's NHS Trust London	Mr. Andrew Darbyshire Alder Hey Hospital Liverpool	Ms. Fiona Smith Leicester Royal Infirmary Leicester	Ms Julie Gifford Guy's & St. Thomas' Hospital NHS Trust London	Miss. Barbara Shepherd Royal Manchester Children's Hospital Manchester	Ms. Brenda Harris Alder Hey Hospital Liverpool	Ms Julie Gifford Guy's & St. Thomas' Hospital NHS Trust London	Mr. Andrew Darbyshire Alder Hey Hospital Liverpool	Ms Carol Williams Guy's and St. Thomas's NHS Trust London
PATHOLOGIST or CARDIAC MORPHOLOGIST	Dr. Jean Keeling Royal Hospital for Sick Children Edinburgh	Professor Robert Anderson Great Ormond Street Hospital London	Dr. Isabella E Moore Southampton General Hospital Southampton	Dr. Stephen Gould The John Radcliffe Hospital Oxford	Prof. R.A. Risdon Great Ormond Street Hospital for Children London	Dr. Chris Wright Royal Victoria Infirmary Newcastle	Professor Robert Anderson Great Ormond Street Hospital London Dr. Jean Keeling Royal Hospital for Sick Children Edinburgh	Dr. Stephen Gould The John Radcliffe Hospital Oxford	Dr. Isabella E Moore Southampton General Hospital Southampton
Numbers of cases reviewed	15 reviews & 5 repeat reviews	20 reviews	20 reviews	9 reviews & 5 repeat reviews	11 reviews	5 reviews & 5 repeat reviews	3 requested reviews & 1 replacement	5 requested reviews	5 requested reviews

CONFIDENTIAL

**THE BRISTOL ROYAL INFIRMARY INQUIRY
REVIEW OF CLINICAL RECORDS**

COVER NOTE

Please complete all sections

Child's Initials: D.O.B: BRI number: BRHSC number:	Diagnosis:	Overall Outcome: Dead / Alive / Disability D1 = mild D2 = moderate D3 = severe
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Additional Comments: Overall grade for adequacy of care:

Date of Review: Team No: 1 / 2 / 3 / 4 / X Number of notes attached: (a) pre operative care - (b) surgical and post operative care -	Signed Team Co-ordinator
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<p>Please use the following summary grades for adequacy:</p> <p>Overall adequacy of care and relevance to outcome:</p> <p>4 = Adequate</p> <p>3 = Less than adequate care but different management would have made no difference to outcome.</p> <p>2 = Less than adequate care – different management MIGHT have made a difference to outcome (i.e. avoidable factor of uncertain influence on outcome).</p> <p>1 = Less than adequate care in which different management would reasonably be expected to have made a difference to outcome (i.e. an avoidable factor which probably contributed to death or disability)</p> <p>X = Insufficient information for comment.</p>
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Completed returns to: *Claire Bache, Bristol Royal Infirmary Inquiry, 2-10 Temple Way, Bristol , BS2 0BY*
Telephone: 0117 938 8727 Fax: 0117 938 8789/8790

CONFIDENTIAL

**THE BRISTOL ROYAL INFIRMARY INQUIRY
REVIEW OF CLINICAL RECORDS**

PRE- OPERATIVE CARE

Child's Initials:

D.O.B:

Date of Procedure:

Aspects of Care:	Adequacy of Care: 4, 3, 2, 1, or X	Comments – especially relevance of less than adequate care to outcome:	Specialty: GP, Cardiologist, Surgeon, Anaesthetist/Intensivist, Nursing, Technical, Pathologist
Timing and appropriateness of initial referral/ condition on arrival			
Clinical assessment and management			
Accuracy and completeness of diagnosis			
Appropriateness of initial treatment strategy			
Timing of planned treatment			
Immediate pre-operative management incl. Nursing			

Please use the following summary grades for adequacy:

Overall adequacy of care and relevance to outcome:

4 = Adequate

3 = Less than adequate care but different management would have made no difference to outcome.

2 = Less than adequate care – different management MIGHT have made a difference to outcome (i.e. avoidable factor of uncertain influence on outcome).

1 = Less than adequate care in which different management would reasonably be expected to have made a difference to outcome (i.e. an avoidable factor which probably contributed to death or disability)

X = Insufficient information for comment.

CONFIDENTIAL

**THE BRISTOL ROYAL INFIRMARY INQUIRY SURGICAL & POST OPERATIVE CARE
REVIEW OF CLINICAL RECORDS**

Child's Initials:

D.O.B:

Date of Procedure:

Aspects of Care:	Adequacy of Care: 4, 3, 2, 1, or X	Comments – especially relevance of less than adequate care to outcome:	Specialty: GP, Cardiologist, Surgeon, Anaesthetist/Intensivist, Nursing, Technical, Pathologist
Surgical Procedure			
Perfusion			
Anaesthetic			
Post operative care and assessment 1. ICU – Medical			
Post operative care and assessment 2. Surgical			
Post operative care and assessment 3. Paediatric cardiological			
Post Mortem			

Please use the following summary grades for adequacy:

Overall adequacy of care and relevance to outcome:

4 = Adequate

3 = Less than adequate care but different management would have made no difference to outcome.

2 = Less than adequate care – different management MIGHT have made a difference to outcome (i.e. avoidable factor of uncertain influence on outcome).

1 = Less than adequate care in which different management would reasonably be expected to have made a difference to outcome (i.e. an avoidable factor which probably contributed to death or disability)

X = Insufficient information for comment.

CESDI - Confidential Enquiries

This background note was prepared by Dr. Steve Gould, Consultant Paediatric Pathologist, The John Radcliffe Hospital, Oxford and member of the Inquiry's Expert Group.

1. Since its inception, CESDI has had two functions. The first is a count function in which a basic dataset about all deaths from twenty weeks of gestation to one year of age is collected. The second is a process of Confidential Enquiry in which a subset of deaths is selected and analysed by a multidisciplinary panel of experts.
2. In reviewing individual cases, panels are asked to assess management by a series of grades. Initial grading structure comprised:
 - 0 no sub-optimal care
 - I sub-optimal care; alternative management unlikely to affect outcome;
 - II sub-optimal care; different management *might* have given rise to a different outcome;
 - III sub-optimal care; different management would *reasonably have been expected* to alter the outcome.

Grades were given to individual aspects of management as well as a final 'overall' grade.

3. Central guidance of panels was limited. Assessment “..involved reference to agreed or perceived standards of care: where precise guidance did not exist, panels had the responsibility of identifying previously under emphasised or unappreciated problems in clinical management. The grading was thus essentially subjective, providing at most a consensus opinion on care that could have been improved¹.”
4. Grading was based on the identification of *sub-optimal* care. This was deliberately used to apply a higher standard than alternative descriptions of care such as ‘sub-standard’ or ‘inadequate’ might imply. The sub-optimal/optimal care grading system was intended to be very critical. The aim was to obtain as much information on clinical management as possible and identify any factors of clinical interest. For instance, management of a case considered grade 1, sub-optimal care, would generate a comment on management. However, because sub-optimal care might still be considered adequate care, say, no comment might be made if this alternative framework had been used (i.e. adequate care would probably not generate any comment).
5. While it has not been tested, in most areas of clinical management under consideration, it is likely that there would be reasonably close correlation between the ‘higher grades’ of sub-optimal care and other terms describing care such as ‘inadequate’ or ‘sub-standard’, especially when an overall grade is considered (see para 7 for caveat). It is probable that, for most panels, if care was sufficiently sub-optimal to compromise fetal outcome, then that care would also be classed as

¹ CESDI second annual report, para 3.4.1, p29.

inadequate or sub-standard. However, the choice of the optimal/sub-optimal system does emphasise CESDI's aim. *The aim of CESDI Confidential Enquiries is to identify areas of clinical care that tend to be deficient, and might be a focus for improvement and therefore of outcome.* Where a range of factors is identified, grading is an aid in highlighting those factors that might most usefully be tackled to improve outcome.

6. In this, the Confidential Enquiry process has been successful. Thus, in the first work programme, which focussed on intrapartum related deaths², the many different confidential enquiry panels consistently expressed concerns about the same broad areas of clinical management, despite the variation in the precise form of comments or criticism.
7. The second pass panel exercise³, in which the same case was reviewed by more than one panel, did emphasise some aspect of the working of the Enquiry and grading process. First, the grading system relates to outcome, not to the quality of care (although there is likely to be a relationship). Consequently, it is possible that relatively minor failures of care, if they occur at a relatively early stage in the management process, *once they are deemed sub-optimal (a high standard)*, almost inevitably acquires a high grade. Any variation in the management at an early stage *might* have led to a different train of events and therefore different outcome. Conversely, a low grade can be assigned to a poorly conducted aspect of management simply because it occurs at a time when death is already judged inevitable (e.g. resuscitation of a severely asphyxiated infant at birth).
8. Second, the second pass panel emphasised that, because the enquiry process is subjective and an expression of professional opinion, it needs to be acknowledged that differences of opinion are likely; some of these differences in grading and the focus of panel comment may simply reflect the unstructured panel approach. However, agreement between panels on an aspect of sub-optimal management is likely to be good evidence of the presence of sub-optimal management. There tends to more agreement on the higher grades of sub-optimal care.
9. The enquiry process has not remained static and there have been gradual series of modifications aimed at improving the process and consistency between panels. Thus, the current project, reviewing neonates who died at twenty-seven to twenty-eight weeks gestation, has accumulated a number of modifications:
 - panels are being asked to review infants who survived as well as infants those who died; these will act as a 'controls'. Panellists involved with the ante- or intrapartum management (obstetricians, midwives and GPs) have to express an opinion about the management of care unaware of the final outcome. (Panel members have always expressed concern that knowledge of the outcome might influence their opinions and make them overcritical. It is far easier to criticise and attribute a poor outcome to a perceived deficiency in management when that outcome is known);

² 4th Annual Report, 1997

³ 5th Annual Report, Chapter 3, p19, 1998

- the enquiry form is much more structured, with very specific questions on many areas of care (some questions are even in a Yes/No format). Comments are required if certain questions are answered in the negative;
- where standards exist for any aspect of management, they have been defined for panellists rather than relying entirely on panelists' interpretation or understanding of standards;
- where more subjective opinions are needed, panellists have been asked to grade them in terms of standard and substandard, major and minor. Initial grading of care standard has been separated from outcome;
- a separate question is asked about the relationship between the substandard care (major or minor), and outcome.

Summary

10. The CESDI confidential enquiry process has been under review consistently since its inception in 1992 and is continually being modified.
11. Panel conclusions are expressions of clinical opinion about complex areas of clinical management. Agreement between panels is more likely when there are serious deficiencies in management, but full uniformity of opinion between panels will always be difficult to achieve.
12. In judging the management of individual cases, caution needs to be exercised in accepting individual panel conclusions as definitive statements. However, cumulatively, enquiries do highlight areas of clinical management that tend to be deficient and where specific corrective strategies are most likely to improve outcome.

S.J.Gould
Consultant Paediatric Pathologist
2nd March, 2000

SELECTION OF CASES

Introduction

1. This note aims to provide a non-technical outline of the Inquiry's approach to selecting cases for clinical review as part of a wider investigation of the adequacy of care received by children within the terms of reference. It also seeks to respond to comments received by the Inquiry concerning the sampling approach and derivation of the sample numbers, as set out in July 1999¹.
2. The note outlines the Inquiry's approach to selecting cases for review; clarifies how sample cases have been derived; identifies the steps taken by the Inquiry to validate the sample; and sets the clinical review exercise in the context of wider evidence on adequacy of care.

The Inquiry's Approach to Selecting Cases for Clinical Review

3. The Inquiry's approach to selecting cases for expert clinical review is based on a set of key guiding principles which can be summarised as follows:
 - selected cases must be representative of all children falling within the Inquiry's terms of reference, as identified by the United Bristol Healthcare NHS Trust [UBHT] through a formal discovery process;
 - selected cases must reflect those concerns that led to the Inquiry;
 - cases must be selected in a way that is fair, transparent, rigorous, statistically valid, and feasible.
4. On the basis of these guiding principles and expert statistical advice, the Inquiry decided to select a stratified random sample of eighty cases, weighted preferentially towards children who:
 - were under one year at time of their first procedure;
 - received higher risk open heart procedures;
 - died within thirty days of their last procedure.
5. For comparative purposes, and to allow adequate investigation of morbidity as well as mortality, it was decided to select equal numbers of children who had died (forty) and children who were alive (forty).
6. The sampling approach and method have been devised to reflect the concerns that led to the Inquiry, and to ensure a balanced view of the care of all children falling within the terms of reference of the Inquiry. Statistical advice to the Inquiry confirms that all these aims are met by the achieved sample of 80 cases.

¹ An initial description of the case selection process was set out in the document *The Inquiry's Approach to the Assessment of the Adequacy of Paediatric Cardiac Surgical Services*, published in August 1999.

Comments on the Inquiry's Sampling Approach

7. Following publication of the consultation paper *The Inquiry's Approach to the Assessment of the Adequacy of Paediatric Cardiac Surgical Services* in August 1999, the Inquiry received a small number of comments on the sample figures set out at Annex B of that document. In particular, apparent discrepancies in numbers and types of procedures were noted between the Inquiry's sample figures and other data sources, including the surgeons' logs. Further comments concerned the rationale for the overall sample size and for selecting an equal number of children who had died and children who were alive; and the impact on representativeness of the sample of small sub-group sizes and absence of time-based stratification.
8. The Inquiry has looked carefully at the question of apparent discrepancies and taken statistical advice, and finds that these are explained by differences in (i) the data source used, and (ii) the ways cases are counted.

Derivation of Sample Cases

9. The Inquiry's sampling base is the coded clinical records dataset (CCR) derived from the clinical records of all children falling within the Inquiry's terms of reference, as identified by the UBHT following a formal discovery process. There will, inevitably, be discrepancies between figures extracted from the CCR dataset and other data sources - such as the surgeons' logs or the UK Cardiac Surgical Register - due to variations in data collection, data definition, and data items recorded.
10. The sample was drawn from 1827 cases. Of these 1290 had open heart surgery and 537 had closed heart surgery. The eighty cases in the sample are as anticipated from the sampling frame; that is to say the eighty cases consist of sixty-eight children who had received open heart surgery and twelve, closed heart surgery. Forty children were alive thirty days after their last cardiac surgical procedure and forty had died within that period.
11. Key points to note with regard to identification of the eighty cases in the sample are as follows:
 - the sample numbers represent children, rather than operations or procedures;
 - all children and all procedures were taken into account in selecting cases for inclusion in the sample. Sampling was not by surgeon;
 - a hierarchy of procedures was used to classify children: higher risk open procedures (arterial switch, repair of complete atrioventricular septal defect, correction of truncus arteriosus), other open procedures, and closed procedures. Thus, if at any time a child had a higher risk open procedure, this child was classed in this group;
 - classification of coded procedures as higher risk open, other open, or closed was based on clinical advice to the Inquiry, and inevitably reflects an element of clinical judgment;

- for sampling purposes, and to give emphasis to the whole child rather than to individual procedures, the age of the child was set as the age at first procedure (and not necessarily as the age at defining operation). One consequence of this is an apparent – but not real – exaggeration of the numbers of neonates in the sampling frame;
 - deaths are defined as deaths occurring within 30 days of the last operation received by the child;
 - the group of children who were alive 30 days after their last surgical procedure includes three children who died much later. For the purposes of this report, these children continue to be considered in the category of alive 30 days after last surgical procedure.
12. A table setting out the CCR sampling base figures in full is attached at Note 1 at the end of this Annex.
13. Statistical advice to the Inquiry confirms that apparent discrepancies with other data sources can be accounted for by differences in the ways cases are described, classified and counted, and that these in no way invalidate the sample.
14. The target sample size (eighty cases) is not statistically determined, but reflects the maximum number of cases that the Inquiry - in the light of clinical advice - considered feasible to submit to in-depth expert clinical review within the short timescale available.
15. The small sub-group sizes have no implications for the robustness of the clinical review exercise, as no analysis by detailed sub-group, is to be attempted. The Inquiry's sampling approach leaves distribution of cases by time to chance, since any other approach would result in sub-groups that were too small to be meaningfully analysed.

Sample Validation

16. The Inquiry has taken active steps to validate the sample, including the following:
- further detailed reconciliation of local UBHT data sources to ensure that the Inquiry has as complete a set of clinical records as possible for children falling within its terms of reference. Although a number of cases appear to be missing, statistical advice confirms that these do not invalidate the achieved sample;
 - a rigorous audit exercise to evaluate the quality and accuracy of clinical records coding and data entry for the CCR dataset. The audit exercise - based on a random sample of one hundred case records - has confirmed the high quality and accuracy of the clinically coded diagnoses and procedures recorded in the CCR dataset.

Reviewing Adequacy of Care: the Wider Context

17. The Inquiry has explored the feasibility of supplementing the clinical case note review exercise with a comparative evaluation of quality and outcomes based on audit of clinical records selected from a range of specialist provider units. In the light of accumulated evidence before the Inquiry, and taking into account legal and scientific advice, the Inquiry Panel concluded that pursuing major new comparative research to inform their assessment of the adequacy of care at Bristol is neither essential nor feasible. The Inquiry's experience confirms that a full-scale, comparative case note audit – based on blinding and a controlled design – would not be feasible to deliver within a reasonable timescale.

References

The following documents are available on the Inquiry's website: www.bristol-inquiry.org.uk

Bristol Royal Infirmary Inquiry - Issues List

The Inquiry's Approach to Making Use of Relevant Data Sources

Preliminary Overview of Existing Data Sources Relevant to the Inquiry's Remit

The Inquiry's Approach to the Assessment of the Adequacy of Paediatric Cardiac Surgical Services

**BRISTOL ROYAL INFIRMARY INQUIRY:
Children Receiving Heart Surgery at BRI and BCH, 1984 to 1995**

	<u>30 day mortality - CCR database</u>					<u>Samples and sampling ratios</u>			
	Total	Deaths	Non-deaths	% deaths		Sample deaths	Sampling ratio	Sample Non-deaths	Sampling ratio
<u>Age groups</u>									
<u>Open heart surgery (= 'ASTA')</u>									
<29 days	125	28	97	22%		6	21.4%	6	6.2%
29 days – 1yr	146	43	103	29%		6	14.0%	6	5.8%
1-15 yrs	104	21	83	20%		3	14.3%	3	3.6%
Total	375	92	283	25%		15	16.3%	15	5.3%
<u>Open heart surgery (= 'complex, not ASTA')</u>									
<29 days	99	34	65	34%		9	26.5%	9	13.8%
29 days – 1yr	281	42	239	15%		6	14.3%	6	2.5%
1- 15yrs	535	28	507	5%		4	14.3%	4	0.8%
Total	915	104	811	11%		19	18.3%	19	2.3%
<u>Closed heart surgery (= 'non-complex')</u>									
<29 days	128	36	92	28%		4	11.1%	4	4.3%
29 days – 1yr	176	8	168	5%		1	12.5%	1	0.6%
1-15 yrs	233	3	230	1%		1	33.3%	1	0.4%
Total	537	47	490	9%		6	12.8%	6	1.2%
					<u>Sample numbers</u>				
<u>Totals</u>						<u>Deaths</u>		<u>Non-deaths</u>	
Open	1290	196	1094	15%	<u>Open</u>	34		34	
Closed	537	47	490	9%	<u>Closed</u>	6		6	
Total cases	1827	243	1584		<u>Total</u>	40		40	
Sample cases available =		80			<u>Grand Total</u>	80			
and sample as % of total cases =		4% [which is 16% of deaths and 3% of non-deaths]							

Explanatory Notes:

- (1) The sampling base is the Clinical Coded Records (CCR) dataset
- (2) 'ASTA' refers to arterial switch, truncus and AVSD procedures
- (3) Numbers relate to children, not operations or procedures
- (4) The sampling method takes into account all recorded procedures
- (5) For sampling purposes, a hierarchy of procedures is used to classify children as follows:
 - (i) if a child received an ASTA procedure, it is classified as ASTA
 - (ii) if a child received an open procedure, it is classified as open
 - (iii) if a child received neither an ASTA nor an open procedure, it is classified as closed
- (6) 30 day mortality is defined as death within 30 days of last procedure
- (7) Age is taken as age of the child at time of first procedure

ADEQUACY GRADES FOR OVERALL CARE AND ASPECTS OF CARE, BY CASE REVIEWED

Table of grades for adequacy of care by individual aspects of care for those with Overall grade 1: 13 Children, 16 Procedures.

Some children had more than one procedure; the first is marked (a); the second (b) and so on.

Case No. ¹	Open/Closed ²	Died/Alive ³	A	B	C	D	E	F	G	H	I	J	K	L	M
1/1	O	D	4	4	4	4	4	4	2	4	1	1	.	2	4
1 /2	O	D	.	4	1	1	3	4	3	4	4	.	.	.	2
1/3	O	D	4	4	4	2	4	4	2	4	4	X	1	X	4
1 /4	O	D	4	4	1	4	4	4	3	4	4	2	2	2	4
1/5	O	D	4	4	1	2	4	4	4	3	4	3	3	.	2
1/6	O	D	4	4	4	4	1	4	4	4	4	4	4	4	4
1/7	C	D	4	3	3	1	3	3	1	.	4	4	4	4	4
1/8	O	D	4	4	4	4	4	4	4	4	4	1	X	X	1
1/9a	O	D	4	4	4	1	1	4	4	X	4	4	4	4	.
1/9b	O	D	4	4	4	3	4	4	4	.	2	.	.	.	4
1/10	O	A	4	1	4	4	3	4	4	4	4	4	4	4	.
1/11	O	A	3	3	4	3	3	4	3	4	4	3	4	X	.
1/12a	O	D	4	4	3	4	4	4	4	.	3	4	4	4	.
1/12b	O	D	4	4	1	4	4	4	3/4	3	4	.	.	.	1
1/13a	O	D	4	4	4	4	4	4	4	.	4	4	4	4	.
1/13b	O	D	2	2	2	1	1	4	4	4	4	4	4	X	3

Table of grades for adequacy of care by individual aspects of care for those with Overall grade 2: 11 Children, 13 Procedures.

Case No.	Open/Closed	Died/Alive	A	B	C	D	E	F	G	H	I	J	K	L	M
2/1a	O	D	4	4	4	4	4	4	4	4	4	4	4	2/3	4
2/1b	O	D	4	4	4	4	4	4	4	.	4	4	4	4	.
2/2	O	D	4	4	4	4	4	4	4	4	4	4	2	4	3
2/3	C	D	4	4	4	3	4	4	4	.	2	2	4	4	3
2/4	O	D	4	4	4	4	4	4	4	4	4	4	4	4	.
2/4b	O	D	3	4	3	2	4	4	4	X	4	4	4	4	4
2/5	O	D	4	4	3	3	3	4	2	2	4	2	2	3	4
2/6	O	D	4	2	4	4	2	4	1	4	4	4	4	X	4
2/7	O	D	4	3	4	4	3	4	2	4	4	1	4	4	4
2/8	O	A	.	2	2	4	2	4	4	4	4	4	4	3	.
2/9	C	D	4	4	4	4	4	4	2	.	3	4	2	4	4
2/10	O	D	4	4	4	4	4	4	2	4	3	.	.	.	1
2/11	O	D	4	4	4	4	2	4	4	4	4	2	4	X	4

¹ The numbers shown here are different from the actual CCNR report form numbers. This is to protect the identity of individual cases, in the event of second reviews.

² Open/Closed – defined as child’s main cardiac procedure.

³ Status relates to 30 days after last cardiac surgical procedure.

Table of grades for adequacy of care by individual aspects of care for those with overall grade 2/3: 4 Children, 5 Procedures

Case No.	Open/Closed	Died/Alive	A	B	C	D	E	F	G	H	I	J	K	L	M
3/1	O	D	4	4	4	4	3	4	3	3	4	.	.	.	4
3/2	O	D	4	4	4	4	4	4	3	3	2	.	.	.	4
3/3	O	D	4	4	4	4	4	4	4	4	4	2	2	2	X
3/4a	O	D	4	4	4	4	4	4	4	.	4	4	4	4	.
3/4b	O	D	4	4	4	4	4	4	2/3	2	4	.	.	.	4

Table of grades for adequacy of care by individual aspects of care for those with Overall grade 3: 13 Children, 16 Procedures.

Case No.	Open/Closed	Died/Alive	A	B	C	D	E	F	G	H	I	J	K	L	M
4/1	C	A	4	2	4	4	3	4	4	.	4	4	4	4	.
4/2a	C	A	4	4	4	4	4	4	3	.	4	4	4	4	.
4/2b	C	A	4	4	4	4	4	4	3	.	4	4	4	4	.
4/3	O	D	4	4	4	4	4	4	2	4	4	X	X	.	2
4/4	O	D	4	4	2	2	4	4	4	4	4	4	4	4	4
4/5	C	D	4	4	3	4	4	4	3/4	.	3	3	4	4	.
4/6a	C	D	4	4	4	4	4	4	3	.	3	3	3	3	.
4/6b	C	D	.	4	4	4	3	4	4	.	4	3	3	3	.
4/7	O	D	4	4	4	4	4	4	3	3	3	2	2	X	3
4/8	O	D	3	3	4	4	4	4	4	3	4	.	.	.	2
4/9	O	A	4	4	4	4	4	3	4	3	3	3	3	X	.
4/10	O	A	4	4	4	4	3	4	4	4	4	4	4	3	.
4/11a	O	D	4	4	4	4	4	4	4	.	4	4	4	4	.
4/11b	O	D	4	4	4	4	4	3	2	3	4	.	.	.	4
4/12	O	A	4	4	4	4	3	4	4	4	4	4	4	4	.
4/13	O	D	4	4	4	4	3	4	3	4	4	.	.	.	1

Table of grades for adequacy of care by individual aspects of care for those with Overall grade 4: 39 Children, 48 Procedures.

Case No.	Open/Closed	Died/Alive	A	B	C	D	E	F	G	H	I	J	K	L	M
5/1	O	A	4	4	4	4	4	4	4	4	4	4	4	4	4
5/2	O	D	4	4	4	4	4	4	4	4	4	4	4	4	3
5/3	O	A	4	4	4	4	4	4	4	X	4	4	4	4	.
5/4a	O	A	.	4	4	.	4	4	4	4	4	4	4	4	.
5/4b	O	A	4	4	4	4	4	4	4	.	4	4	4	4	.
5/5	C	A	4	4	4	4	4	4	4	.	4	4	4	4	.
5/6	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/7	O	D	4	4	4	4	4	4	4	4	4	4	4	4	4
5/8	O	A	4	4	4	4	4	4	4	4	4	4	4	3	.
5/9a	O	A	4	4	4	4	4	4	4	4	4	4	4	4	4
5/9b	O	A	4	4	4	3	3	4	4	4	4	4	4	4	.
5/10	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/11	C	A	3	4	4	4	4	4	4	.	4	4	4	4	.
5/12a	O	A	4	4	4	4	4	4	4	.	3	4	4	4	.
5/12b	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/13	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/14	O	A	4	4	4	4	4	4	4	4	3	4	4	4	.
5/15	O	A	4	4	4	4	4	4	4	3	4	3	3	4	.
5/16	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/17	O	A	4	4	4	4	4	4	4	4	3	4	4	3	.
5/18	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/19	O	A	.	4	4	4	4	4	4	4	4	4	4	4	.
5/20a	O	A	.	4	4	.	4	4	4	4	4	4	4	4	.
5/20b	O	A	4	4	4	4	4	4	4	.	3	4	4	4	.
5/21	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/22	O	D	4	4	4	4	4	4	4	2	4	4	4	4	4
5/23a	O	A	4	4	4	4	3	4	4	.	4	4	4	4	.
5/23b	O	A	.	4	4	.	4	4	4	4	4	4	4	4	.
5/24	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/25	C	A	4	4	4	4	4	4	4	.	4	4	4	4	.
5/26	O	A	4	3	4	4	4	4	4	4	4	4	4	4	.
5/27a	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/27b	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/28a	O	A	4	4	4	4	4	4	4	X	4	4	4	4	.
5/28b	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/28c	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/29	C	A	4	4	4	4	4	4	4	.	4	4	4	4	.
5/30	O	A	4	4	4	4	4	4	4	4	4	3	4	4	.
5/31	O	A	4	4	4	4	4	X	4	4	4	4	4	4	.
5/32	O	A	4	4	4	4	4	4	4	4	4	3	4	4	.
5/33	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/34	C	D	2	4	4	2	4	4	4	.	3	4	4	4	4
5/35	O	D	4	4	4	4	4	4	3	4	4	4	4	4	4
5/36	O	A	4	4	4	4	3	4	4	4	4	4	4	4	.
5/37	O	D	4	4	4	4	4	4	4	4	4	4	4	4	4
5/38a	O	D	4	4	4	4	4	4	4	.	4	4	4	4	.
5/38b	O	D	4	4	4	4	4	4	4	4	4	.	.	.	4
5/39	O	A	.	4	4	4	4	4	4	4	4	4	4	4	.

HOW THE CLINICAL EXPERTS ASSESSED ADEQUACY

1. During the clinical case note review, the experts from each specialty were asked to assess whether care had been adequate or less than adequate. However, standards of care for the period of the Inquiry's terms of reference were not clearly defined.
2. The Inquiry asked the experts to identify the key factors they used in assessing whether care was adequate or less than adequate for the case note review. The teams were specifically asked to assess the adequacy of care by their professional understanding of standards at the time of the surgical procedure, recognising that changes took place during the period covered by the Inquiry.
3. An explanatory letter was sent to a representative of each of the specialties involved in the Clinical Case Note Review teams – a surgeon, cardiologist, anaesthetist, pathologist and nurse. It contained the following paragraph:

“The Inquiry would find it helpful to see, in the final CCNR report, further insights from experts involved in this review, by specialty. Specifically they would like to know more about the key factors which experts from each specialty had in mind when assessing care was adequate or less than adequate to whatever degree and the extent to which the concepts of adequate/less than adequate changed over the period 1984-1995.”

4. Copies of the reply from these individual experts were then sent to other members of the review teams. In addition to the above paragraph, the covering letter also contained the following paragraph:

“In order to make this a manageable exercise, and to minimise duplication of effort, in December we asked five members of the Expert Group (a surgeon, a cardiologist, an anaesthetist, a pathologist and a nurse) each to set down their perspective of the essential elements of care which influenced their judgement as to whether paediatric surgical care, as reported in the clinical records, was adequate or less than adequate. We are now circulating these responses to each of the specialist groups within the Expert Group to seek further comments.”

Results

5. The replies from the initial representative and the other team members are summarised below for each specialty. Several experts prefaced their replies with the following comments:
 - the review was based on the medical records which were written as part of patient management rather than for the purpose of a subsequent Inquiry;
 - no similar review had been undertaken in any other unit in the UK or elsewhere;

- selection of patients for review was deliberately weighted towards very young patients, those undergoing open heart surgery and those who died;
 - the outcome of each case was known and this may well have affected the judgement as to whether care was adequate or less than adequate – if the patient died, then, by definition, different care might well have made a difference to outcome;
 - the division of the care process into thirteen aspects broadly reflected the pre, intra and post operative phases of care. However, a number of the aspects of care crossed specialty boundaries. Thus, there were a number of aspects of care where more than one specialist could have been said to have responsibility;
 - the review teams strived to evaluate whether the care given was appropriate for the year in which treatment was undertaken. There were changes in practice, to varying degrees, in all the specialties involved in paediatric cardiac surgery between 1984 and 1995.
6. The following are the key factors identified by the experts as the factors they considered in determining whether care was adequate or less than adequate, to whatever degree:

[Note Not all aspects of care are listed under each specialty – some aspects of care were the primary responsibility of one specialty alone while in others the responsibility was shared.]

Paediatric Cardiology

7. The paediatric cardiologist is responsible for the initial assessment and diagnosis and involved with the surgeon in planning the timing and strategy of management. The cardiologist is also involved in monitoring the recovery of a patient in the post-operative period.

The key elements which would have been noted when assessing adequacy of care in cardiological practice, by aspects of care:

- A. Timing and appropriateness of initial referral:
(actually the responsibility of the referring paediatrician); the reviewers noted any delay; whether prior treatment was appropriate and condition on arrival.
- B. Clinical assessment (including non-invasive investigations) and management:
the degree of consultant involvement and the early management plan.
- C. Accuracy and completeness of diagnosis:
the reviewers noted the accuracy of the clinical diagnosis and confirmation by appropriate investigation – echocardiography; repeat echocardiography; cardiac catheterisation and angiography; the adequacy of the information obtained and any comments if and when the child was discharged after these

investigations. (Review teams took into account the technological limitations of the day and were mindful of significant changes in practice and in echocardiography technology over the period of the Inquiry).

- D. Appropriateness of initial treatment strategy:
Reviewers noted the nature of the initial decision, and the timing of the discussion with the cardiac surgeon; the extent of involvement of the surgeon and timing of referral of the child to the surgeon.
- E. Timing of planned treatment in respect of prior investigations (particularly catheterisation) and the age of the child:
any significant or inappropriate delay.
- F. Immediate pre-operative management:
(mainly a nursing responsibility in elective cases, although reviewers did look for further cardiological assessment if there had been a significant delay between initial catheterisation and admission for surgery); for emergency admissions, the influence of pre-operative management on subsequent outcome was assessed.
- G; H; I. Surgical care: not relevant to paediatric cardiology.
- J; K; L. Postoperative care:
paediatric cardiologists have an important role in diagnosis and management of postoperative complications – key factors were the appropriate use of echocardiography and cardiac catheterisation.

Changes in Practice in Paediatric Cardiology, 1984-1995

8. Between 1984 and 1995 there was significant improvement in the technology of echocardiography and the development of colour flow Doppler – this allowed more accurate and definitive diagnoses by non-invasive means. It also allowed easier diagnosis of postoperative complications. There were trends towards earlier surgery for specific lesions (e.g. truncus arteriosus and complete AV septal defect) and towards primary correction rather than palliation (e.g. for ventricular septal defect). These trends created increased demands on the paediatric cardiologists in terms of diagnostic accuracy; intra-operative support by including echocardiography in theatre; and also in terms of the diagnostic assessment of the post-operative result.

Anaesthesia

9. The anaesthetist would not be involved in the early phase of care (i.e. aspects A – E) unless an emergency case required admission to intensive care. The key elements which would have been noted when assessing adequacy of anaesthetic practice, were, by aspects of care:

Anaesthetic for an operation:

- F. Immediate pre-operative management: evidence that a child was assessed pre-operatively and that the assessment was adequate to enable suitable choices of anaesthetic technique to be made. The degree and accuracy of pre-operative assessment. The use of suitable pre-medication drugs where appropriate. The time taken to anaesthetise and prepare for surgery. Appropriate monitoring of cardiovascular system.
- H;I. Intra-operative care (perfusion and anaesthetic):
The degree of consultant involvement. The appropriateness of anaesthetic technique. The appropriateness of intra-operative cardiovascular management. Management of unexpected complications. Evidence of inadequate perfusion and action taken. Whether a consultant anaesthetist was directly involved, or evidence that a case was appropriately delegated to a trainee. Whether the case was routine or out of hours.
- J;K;L. Postoperative care:
Evidence that anaesthetic support in intensive care was provided when required. Appropriate plans for analgesia and fluid management. Appropriate management of ventilation. Appropriate timing and management of extubation.
- Anaesthetic for cardiological investigation:
Evidence of appropriate assessment and use of anaesthetic. Evidence that the patient recovered in an appropriate environment. Evidence that suitable plans were made for analgesia, fluid management and general post-anaesthetic care.

Changes in practice in paediatric cardiac anaesthesia, 1984-1995

10. It was acknowledged by the reviewers that there was a change/improvement in the extent and detail of anaesthetic record keeping over the period of the Inquiry, stimulated by the medico-legal climate. Other changes related more to improvement in monitoring equipment rather than any significant changes in drugs or practice. There have been significant changes in intensive care, most notably an improved understanding of cardiovascular physiology in neonates and infants, which is presumed to have contributed to the significant improvement in mortality rates in this age group. In the early years covered by the Inquiry it would have been the practice in the majority of units for surgeons to take primary responsibility for postoperative care while the anaesthetist was chiefly involved in the management of ventilatory support. From the early 1990s onwards, some centres started to involve anaesthetists more fully in the management of the care of children in intensive care, with anaesthetists taking on clinical sessions dedicated to the intensive care unit. In some units this had, by 1995, evolved to the point where a full time intensivist (usually an anaesthetist) had been appointed to the ICU.

Surgery

11. Surgeon would not normally be involved in Aspects of Care A – C.

Key elements which would have been noted when assessing adequacy of surgical practice:

- D. Appropriateness of initial treatment strategy:
the degree of surgeon's involvement. The appropriateness of the decision to undertake surgery and the care plan.
- E. Timing of planned treatment:
Any significant or inappropriate delay in the timing of surgery. Whether consent was taken and the operation discussed with the parents.
- G. Surgical procedure:
Whether the procedure was commonly accepted and appropriate for the particular defect.
Where a technique was unconventional, whether it was a response to an unusual situation.
The sequence of the operation – whether it was performed logically.
Whether the operation was performed satisfactorily.
The management of cardiopulmonary bypass.
The time taken to perform the operation (cardiopulmonary bypass time, cross clamp time, circulatory arrest time).
The appropriateness and adequacy of myocardial protection.
The process of weaning from bypass.
Whether potential complications were anticipated.
Whether complications encountered were dealt with appropriately.

[Note: the teams acknowledged the importance of the printed operative record in reaching their judgements about the surgical procedure.]

- H. Perfusion:
management of cardiopulmonary bypass is a joint activity of the anaesthetist, surgeon and perfusionist. Whether the size and placement of cannulae for cardiopulmonary bypass was appropriate. Any evidence of inadequate perfusion; the length of time on perfusion and whether it was excessive given the circumstances of the surgery.
- K, also J and I Postoperative care:
Overall co-ordination of care involving other specialists as necessary. The management of cardiovascular stability. The management of surgical complications e.g. bleeding, pneumothoraces.

Changes in practice in paediatric cardiac surgery, 1984-1995

12. See comments under “paediatric cardiology” (paragraph 8). There were improvements in the accuracy of pre-operative diagnosis as a result of echocardiography. Surgical techniques are constantly evolving with new operations being introduced (e.g. arterial switch, the Fontan procedure); there were also trends towards earlier surgery for specific lesions (e.g. truncus arteriosus and complete AV septal defect) and towards primary correction rather than palliation (e.g. for ventricular septal defect). There were some improvements in the cannulae used for cardiopulmonary bypass and indeed improvements in cardiopulmonary bypass technology –specifically, in the oxygenator (artificial lung) and the smaller volume needed to prime the circuit. There were also significant improvements in control and correction of coagulation defects that made possible shorter operation times (less time stopping bleeding at the end of the procedure) and less bleeding post-operatively. In addition, improvements took place in illumination (surgical headlights) and magnification (surgical glasses).

Nursing

13. Nursing is obviously an activity involved in all aspects of care and so the key factors are summarised under pre-operative and postoperative care rather than for the individual aspects of care:

- Pre-operative care:
Evidence of use of checklist, nursing care plans and nursing notes.
Evidence of appropriate explanation to child and family, and evidence of preparation of the family – eg pre-op. visit to the ICU.
Documentation of family focussed information
- Postoperative care:
Evidence of child orientated care and evidence of involvement of parents in the child’s care.
Appropriate interpretation of observations for the age of the child.
Appropriate nurse action in response to changes in observations.
Appropriate pain assessment/management.
Frequency with which care plans were up-dated.
Evidence of communication with parents.
Evidence of continuity of care.
Discharge summary (nursing): particularly important when transfer from BCH to BRI and vice versa.
Bereavement care: appropriate care/support/counselling provision.

Changes in practice in paediatric cardiac nursing, 1994-1995

14. There was progressively more involvement of nurses with a paediatric training, particularly in postoperative care.

Pathology

14. The following factors were applied in assessing the adequacy of post-mortem reports:

- standards laid down in the “guidelines” of the Royal College of Pathologists;
- understanding of internal cardiac anatomy;
- understanding of procedure performed on the heart and the clinical history of the patient;
- evidence that the histology of lungs and heart had been assessed, and that the brain had been examined;
- evidence of communication between pathologist and clinical team.