

BRISTOL ROYAL INFIRMARY INQUIRY

THE INQUIRY'S APPROACH TO THE ASSESSMENT OF THE ADEQUACY OF PAEDIATRIC CARDIAC SURGICAL SERVICES

1. Introduction

1.1 Under its terms of reference, the BRI Inquiry is required, amongst other things, to make findings as to the adequacy of care delivered at Bristol to children who received cardiac surgical services between 1984 and 1995. The terms of reference of the Inquiry are:

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

1.2 The purpose of this note is:

- to set out the Inquiry's approach to assessing the adequacy of the services provided;
- to explain how the various sources of evidence and information available to the Inquiry contribute to that assessment;
- and specifically, to explain, in detail, the work in hand to consider one of those sources, the clinical case notes;
- to invite comment upon the approach set out.

The note is in two parts: Part One - an overview of all the sources on adequacy available to the Inquiry; and Part Two - an explanation of how one of those sources, the clinical notes, is to be examined by expert review.

This note is written for parents, families and their legal representatives; present and former hospital staff and their legal representatives; and for organisations and others with an interest in the Inquiry. Comments on the Inquiry's approach are welcome. They should be addressed to Una O'Brien, Secretary, Bristol Royal Infirmary Inquiry, 2-10 Temple Way, BRISTOL BS2 0BY. Email: inquiry@doh.gov.uk.

PART ONE – AN OVERVIEW OF THE SOURCES ON ADEQUACY

2. The task of assessing the adequacy of paediatric cardiac services

2.1 The Inquiry is taking a very wide ranging approach to assessing the adequacy of paediatric cardiac surgical services, as demonstrated by the Inquiry Issues List, published after consultation in March 1999. Work is already well under way, in oral hearings and through the gathering of documents and written evidence, to examine the management and the funding of the service, (Block 2 and 3 evidence); the way in which clinical care was organised (Block 4 evidence); how families were treated, and the specific matters of pre-operative, surgical and post-operative care (Blocks 1 and 5 evidence).

3. Sources of information on adequacy

3.1 Unfortunately, there is no template against which the adequacy of the service can readily be assessed. The Inquiry, therefore, has to build its understanding from a variety of sources. No single source on its own will provide all the answers. Nonetheless, the sources of evidence and information listed below, taken together, should enable the Inquiry Panel to make findings. Three sources are already being explored, and will be familiar to those following the Inquiry:

Written and oral evidence on individual children's cases

3.2 The Inquiry has, as of mid-July, received 94 statements from families and expects at least another 140, and maybe more if more families come forward. In addition, 14 parents have already given oral evidence, and more will be invited to do so as the Inquiry progresses.

Written and oral evidence on systems and approaches

3.3 So far the Inquiry has received 106 statements on how paediatric cardiac services were established and financed, as well as on how the service at Bristol was set up, organised and managed. In addition, 45 witnesses have given oral evidence on these matters. The Inquiry will continue to seek additional statements where further evidence is necessary.

Documents requested by the Inquiry, and submitted to the Inquiry by organisations and individuals within by the Inquiry's remit

3.4 Many thousands of documents have been submitted to the Inquiry as potentially relevant to events at Bristol. Main sources are the United Bristol Healthcare NHS Trust; Avon Health Authority; the Department of Health, and other national organisations, such as medical and nursing Royal Colleges. Of the many thousands of documents handed over to the Inquiry, and not including clinical records, around 6,200 documents, consisting of around 34,000 pages, have so far been assessed as potentially relevant, and many are being presented to the Panel in oral hearings. All of the relevant documents will eventually be published; many will contribute to the Inquiry's understanding of the adequacy of the service.

4. Other important sources

4. Other sources of evidence and information are also being explored. The contribution of these sources will have been less evident in the Inquiry thus far, but they will come to play an increasing part as the Inquiry progresses.

Expert evidence

4.1 The Inquiry has established an Expert Group consisting of 35 independent experts with a wide range of clinical, academic and managerial experience. Additional Experts will be invited to join the Group, should the need arise. Experts bring wide knowledge and understanding of the standards and received practice at the time under review. Their evidence will be valuable to the Inquiry in helping to provide a context within which the adequacy of the Bristol service can be assessed. Increasingly, members of the Expert Group will be called to participate in oral hearings and to give formal opinions as necessary. Those opinions will be made public.

An examination of existing data sources and their respective value

4.2 In March 1999, the Inquiry set out its strategy on making use of relevant data sources about paediatric cardiac surgery at Bristol and elsewhere. Since then the Inquiry has been busy acquiring data sources. On 8th July 1999, the Inquiry published a preliminary assessment of the value of data sources; and on 13th and 14th July, the Panel heard oral evidence on this subject. The paper and a transcript of the oral hearings are available on the Inquiry's website, and copies can be obtained from the Inquiry's Bristol office. The Inquiry has identified six key data sources and analysis is underway to assess what, singly and together, these sources reveal about the level of activity and performance of paediatric cardiac surgery, and thus throw light on the adequacy of the Bristol service. The Inquiry is making extensive efforts to ensure that information about every child within the terms of reference is included within the data sources analysed for these purposes.

Externally Commissioned work

4.3 As well as the use of independent analysts to examine relevant data sources, other externally commissioned work will include reviews of relevant research and literature. Some work will be commissioned on a timeframe to meet the needs of Phase Two and of preparing the final report. A progress note on the externally commissioned work will be published in the early autumn.

4.4 The Inquiry is also investigating the feasibility of undertaking, within the Inquiry's remit and timetable, other studies which could contribute to an understanding of adequacy. For example, the Inquiry intends to explore the possibility of a "blind" study of clinical records, where experts would review anonymised records from Bristol as well as from other centres. Also, the Inquiry intends to examine the feasibility of a review of the performance of Bristol paediatric cardiac surgery, along broadly similar lines to the external study commissioned by the United Bristol Healthcare NHS Trust into adult cardiac surgery in 1995. The Inquiry does not underestimate the substantial methodological difficulties of such studies, but nevertheless, their feasibility will be fully explored.

Clinical records and an Expert Review of selected clinical records

4.5 The Chairman and the Panel have decided that, in so far as clinical notes of children who received cardiac surgery at Bristol can contribute to the Inquiry's understanding of the adequacy of services, it would be appropriate both statistically and generally to submit to expert review a fair and representative sample of them.

4.6 Part Two of this paper provides information about the clinical records available to the Inquiry; sets out how the clinical case review exercise is intended to work, and gives details on the sampling technique. Although the Inquiry is subjecting a sample of cases to expert review, every child's case will play its part. The Inquiry has created a new database with information drawn from the clinical records of over 1,800 children who received paediatric cardiac surgery in Bristol between 1984 and 1995. Analysis of this will provide a complete picture of the whole of the work in paediatric cardiac surgery performed between 1984 and 1995. It is important, however, to re-state here that it is not part of the Inquiry's remit to undertake a detailed case review of the care of each child; the Inquiry's role, rather, is to investigate the adequacy of care delivered by an institution.

Conclusion

5. Given the breadth of the Inquiry's approach to understanding the adequacy of the Bristol paediatric cardiac service it is inevitable that many sources of information and evidence will need to be examined. Each source brings a distinct perspective and no single source will provide a definitive answer on adequacy. The Chairman and Panel will evaluate the evidence from all of these sources in reaching their conclusions as to the adequacy of services.

PART TWO – THE CLINICAL CASE NOTE REVIEW EXERCISE

1. Introduction

1.1 The Inquiry Chairman and Panel have decided that they wish clinical experts to review a sample of the clinical case notes of children who received paediatric cardiac surgical services at Bristol. Such a review will make an important contribution to the Inquiry's understanding of the adequacy of the services at Bristol. The purpose is to provide the Panel with a qualitative perspective on the overall *pattern* of care, and to highlight areas where services were adequate or less than adequate; the exercise is not designed to reach specific conclusions about individual cases.

1.2 The Inquiry recognises at the outset that its approach has strengths and weaknesses which set the context for any conclusions. In terms of strengths, the exercise is unique in scale and depth. Never before has a sample of cases, drawn from virtually all the paediatric cardiac activity at Bristol over 12 years, been reviewed. Nor has such an extensive team of clinical experts been assembled to conduct such a review. Alongside these strengths, the Inquiry acknowledges possible weaknesses. Since this is overtly an exercise to review what are known by the experts to be *Bristol* notes, the reviewers could, unconsciously, bring some subjective views into play. Being aware of this is one way of guarding against it. In addition, the absence, for most of the period, of formal, published standards for paediatric cardiac surgical care makes interpretation of adequacy a difficult challenge for the review teams. The Inquiry intends to present findings in a full and open way, so as to air strengths and shortcomings. No more will be claimed for the review than can reasonably stand up to appropriate scrutiny.

Three sections follow:

- how the clinical case note review exercise will work;
- how the output of the clinical case note review exercise will be handled by the inquiry;
- the method for selecting a sample of cases.

2. How the clinical case note review exercise will work

2.1 The exercise will be undertaken by teams of clinicians drawn from the Inquiry's Expert Group. The teams will review a sample, initially, of 80 sets of clinical case notes, to include both children who died within 30 days of surgery and children who were alive at that time. The review teams' reports will be on a standard form, and, where possible, the teams will be asked to make assessments as to the adequacy of key aspects of pre-operative, surgical and post-operative care, as well as of adequacy of care overall, in cases of both mortality and survival.

Expert Review Teams

2.2 The clinicians on the Inquiry's Expert Group have been formed, for the purposes of this exercise, into multi-disciplinary Review Teams, and each team will be asked to review a set of clinical case notes.

Each review team consists of five members:

- paediatric cardiac surgeon;
- paediatric cardiologist;
- paediatric anaesthetist/intensivist;
- paediatric pathologist, and;
- paediatric nurse or intensive care nurse.

2.3 Available for advice and assistance as necessary are the general paediatricians and paediatric nurses on the Expert Group. Should any team feel it needs to call on further specialist expertise, the Inquiry will endeavour to make that expertise available.

Review Methodology

2.4 The Inquiry's approach to the review of clinical notes is 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 are asked, as far as possible, to apply their best clinical judgement drawing on their understanding and knowledge of received professional standards at the time at which the care was delivered. Although consensus is desirable, there is no need, nor any requirement, for the review team to reach consensus in every case.

2.5 In determining the most appropriate method for the review, the Inquiry took the advice of members of the Inquiry's Expert Group and then tested that advice in a pilot exercise.

2.6 Experts advised that the most sensible approach would be to adapt an existing review methodology, rather than to devise a completely new approach. The methodology suggested was that used to review cases in the Confidential Enquiry into Still Births and Infant Deaths, (CESDI). In CESDI, multi-disciplinary teams of clinicians review the circumstances surrounding a still birth or an infant death. They make assessments of aspects of care which are recorded on a standard form. CESDI review teams are asked to decide whether or not care was "sub-optimal" in any respect, and, if so, to reach a view as to whether different care could have resulted in a different outcome for the child.

2.7 During May, a pilot was undertaken to develop and test an approach for a review of Bristol clinical notes, including records of children who were alive after surgery as well records of those who died. The pilot team, comprising clinicians from the Inquiry Expert Group, were also asked to advise on practical aspects of the review, such as range of expertise needed on a team, and the availability to team members of clinical records.

2.8 The pilot exercise confirmed that, with some adjustments, an overall approach based on multi-disciplinary teams and an adapted CESDI reporting form was feasible. As a result, the

Chairman and Panel have decided to proceed with the first stage of the review along the lines described below.

Review Meetings

2.9 The Review consists of four stages: reading; reaching a tentative independent view; discussing those views at a multi-disciplinary meeting, and reporting on the outcome of the discussions.

2.10 All members of a review team are given access to the clinical notes. To the extent they can be located, relevant perfusion and ITU charts, echocardiograms and angiograms, and X-rays will be made available to the clinicians on each team as necessary. Each expert can read the notes and develop a tentative view of what they show, from the perspective of his or her own clinical expertise.

2.11 Each team will hold review meetings, where case histories will be discussed, following a short case history introduction. Each member of the team will contribute from his or her own expertise, drawing on an understanding and knowledge of professional practice at the time. The team together will try to reach a view about adequacy in relation to specific aspects of care as well as in relation to the overall management of the case, even where two or three operations took place.

Review Report Forms

2.12 A blank copy of the review report form is attached at Annex A for information. The form is designed to help structure the case review discussions, and to capture the output of those discussions in a consistent format. The form also allows for the fact that *some* children had more than one operative procedure in separate episodes of care. For each child's case reviewed, the report 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 within different episodes of care.

2.13 The Inquiry does not require conclusions where none can reasonably be drawn; therefore, it has been made clear to review teams that it is acceptable not to reach a conclusion about a particular aspect of care, or a particular operative procedure, or about the overall adequacy of care, if the review team feel there is insufficient information on which to base a conclusion. The review report forms will form the basis of a single summary report from the Review Exercise, to be presented to the Panel during the autumn hearings.

Quality assurance

2.14 The Inquiry is mindful that differences of approach between the review teams could occur. In order to make any such differences transparent, and to help with the interpretation of the exercise overall, the Inquiry intends to distribute a number of the same case notes

across the teams; a team will not be aware when it is looking at case notes which have been considered by another team.

Timing

2.15 The aim is to complete the exercise early in the autumn.

3. How the clinical case note review report forms will be handled by the Inquiry

3.1 The clinical case note review report forms will be part of the evidence to the Inquiry on adequacy. A summary report of the conclusions which can be drawn from the exercise as a whole will be written by appointed experts, and presented to the Panel during the autumn oral hearings on Block 5. It is unlikely that the report forms of all cases will be referred to individually in oral hearings, but a number may be referred to in taking evidence from clinicians on the adequacy of care.

3.2 Completed clinical case note review report forms will be treated as though they were formal written statements from experts. Any individual criticised in a way considered relevant to the Inquiry will be sent a copy of the report form and given an opportunity to make a formal written comment. The report forms will also be sent to interested parties' legal representatives so that suggestions for general lines of questioning or further investigation can be put to Counsel to the Inquiry.

3.3 The Inquiry will make all reasonable efforts to contact families of those included in the sample. The families will be given an opportunity to see the completed clinical case note review form and, if they so wish, to make an informal comment or a formal written statement. Families' consent will be sought to personal medical information being made public by the Inquiry according to the procedure already set out on medical confidentiality.

3.4 In considering whether or not to make a formal written comment on a review group's findings, an individual, as set out in paragraph 3.2, may make a reasoned request to the Inquiry to see the actual clinical case notes which have informed the review group's conclusions. If the Inquiry considers the request to be justified, the clinical case notes will be made available for consultation, but only at the Inquiry's premises.

3.5 Full publication of the 80 sets of clinical case notes will not take place. If necessary, individual pages of clinical notes will be referred to in oral hearings on the adequacy of care. All appropriate efforts will be made to protect information which permits the ready personal identification of a child unless permission for release of medical confidentiality has been granted by the next of kin (where the child has died, or is still a minor) or by the former patient where s/he has reached adulthood.

3.6 If an individual with a direct interest in the Inquiry and in a specific case, disagrees with the review findings on a particular case, the matter may be referred to the Inquiry. A reasoned explanation for the disagreement should be made in writing. Each case will be considered on its merits, and where the Panel considers it proper, the case will be referred to another set of experts selected at random from the Inquiry's Expert Group. As far as

possible, the experts invited to sit on 2nd panels will be those who participated in the Review Exercise first time round, but not in respect of the case in question. However, for logistical and timing reasons, it may be necessary for the 2nd review panels to include additional experts not involved with the first review exercise.

3.7 Any interested individual, coming within paragraph 3.4 above, having gained permission to see the clinical case notes, could be accompanied by an advisor or a representative.

3.8 The Panel will maintain its practice of hearing expert evidence from those on the Inquiry's Expert Group and from others with expertise whom they consider it necessary to call. It will continue to be the Panel's practice not to call experts engaged by individuals or by organisations with an interest in the Inquiry. Membership of the Expert Group is based on nominations from a wide set of sources, and it remains open for individuals or organisations to put forward further nominations if they so wish.

3.9 The summary analysis of the clinical case note review will be based on the conclusions reached in the first review of cases. Should a second review reveal different conclusions from the first about a particular case, the conclusions of the first review will still be used in the summary. Any conclusions of the second review, however, will be taken fully into account and recognised as weakening the general conclusions of the summary.

3.10 The clinical case note review exercise is one of seven substantial sources of information and evidence on adequacy. As such it will not be the last word on adequacy. The Inquiry is not striving for a gold standard of research for this exercise – it cannot do so because of the inherent difficulties of reviewing clinical case notes after such a passage of time. Nor is the Inquiry seeking to try medical negligence trials. The Panel will receive the output of the exercise in the context of all of its strengths and shortcomings, and will not seek to make more from the exercise than is reasonable or justified.

4. The method for selecting a sample of cases

Purpose of the Sample

4.1 The clinical records case review exercise will constitute an important source of evidence on the adequacy of care received by children falling within the Inquiry's terms of reference. In view of the complexity of the clinical review process, it would be impracticable to review every case within the timescale of the Inquiry's oral hearings process. For this reason, the Inquiry has decided, as stated above, to proceed initially by selecting a fair and representative sample of cases to submit to in-depth, qualitative clinical review of adequacy of care.

Guiding Principles

4.2 The guiding principles that the Inquiry has adopted for the selection of cases to be included in the clinical records review exercise are that the sample should aim to be:

- (i) representative of all children falling within the Inquiry's terms of reference, and must be statistically valid;
 - (ii) based on the clinical records identified by UBHT through a formal discovery process;
 - (iii) reflective of those concerns that led to the Inquiry;
- in addition:

- (iv) the sampling process must be fair and transparent, and the sample itself be feasible.

Sampling Base

4.3 The discovery process taken forward by the United Bristol Healthcare NHS Trust (UBHT) for identifying the clinical records of children receiving care within the terms of reference of the Inquiry has revealed a total of 1827 identifiable cases of children¹ who received open or closed heart procedures during the period 1984 to 1995.

4.4 During Spring 1999, the Inquiry undertook a substantial clinical coding exercise to extract summary information from all the clinical records - subsequently referred to as the Clinical Coded Records (CCR) dataset. The following information has been captured for each child: name, date of birth, gender, hospital record numbers, and clinical information including diagnoses, operative procedures with dates and surgeons' names, whether the child is alive or not according to the clinical record, the date of death, and whether or not a post-mortem took place. The CCR will be used as the sampling base from which cases for clinical review will be selected.

Target Sample Size

4.5. After careful consideration, the Chairman and Panel agreed that a target sample size of 80 cases will be a reasonable maximum number amenable to in-depth qualitative clinical case review within the timescale imposed by the Inquiry's oral hearings process. The Inquiry will hold open the option of reviewing further cases on a longer timescale, if this appears to be necessary and feasible.

Sampling Method

4.6 On the basis of the guiding principles outlined above and subsequent expert statistical advice, the Inquiry Chairman and Panel have agreed that a *stratified random sample* is appropriate, with varying sampling fractions. More specifically, it has been decided to stratify the sample on the basis of age, procedure and outcome, and to weight the sample preferentially towards neonates, higher risk open heart procedures, and deaths within 30 days of last procedure. (Thirty days is the commonly accepted post-surgery mortality standard). All cases will be eligible for inclusion in the sample and the selection will be at random. The sampling technique will involve selecting equal numbers of those who died within 30 days and those who did not in each of the age groups and each of the operation groups. The method chosen allows for a manageable number of records to be chosen without bias, but concentrating on the areas of concern which led to the Inquiry.

¹ This is the number of children thought to be within the terms of reference as at July 1999. The Inquiry is confident that this represents the vast majority of children, but recognises that the figure may grow marginally as further detailed reconciliation between different data sources is completed. The fact that it is not the final figure does not invalidate the sample.

4.7 Selecting a random sample is the best method of proceeding when it is not possible to scrutinise every record to the same detail. Each record of a particular type has the same chance of being selected as every other record of that type. The conclusions drawn from the expert review of the records will be able to be taken as a fair reflection of the whole set of records, to a statistically quantifiable extent.

4.8 In order to reflect the concerns that led to the Inquiry, the Chairman and Panel have decided to weight particular features of the sample. This will ensure that a higher proportion of some groups appear in the sample than would otherwise be the case. These groups are: (i) very young children; (ii) children who had open heart surgery; and (iii) children who died within 30 days of surgery. Within the “open” heart group, a further stratification is made for arterial switch operations, truncus operations and procedures to correct atrioventricular septal defects. This will ensure adequate coverage of those operations acknowledged to be more difficult.² It should be noted that although 50% of the records in the sample relate to children who died within 30 days of the procedure, the actual percentage of those who died within 30 days in the dataset as a whole, is 13%.

Sample Structure

4.9 On this basis, the sample will be stratified by age, procedure and outcome, as follows:

- | | | |
|-------|-------------------|--|
| (i) | Age: | Up to and including 28 days
29 days up to the first birthday
One year up to the 16 th birthday |
| (ii) | Procedure: | ‘Open’ heart procedures (i.e. requiring cardiopulmonary bypass) divided into 2 groups: (i) arterial switch and truncus operations, and procedures to correct atrioventricular septal defects, and (ii) all other operations

‘Closed’ heart procedures (i.e. not requiring cardiopulmonary bypass) |
| (iii) | Outcome: | Alive 30 days after last procedure
Died within 30 days of last procedure |

The table attached at Annex B provides a breakdown of the sample, with sample numbers and ratios.

Sample Validation

² The Inquiry has given careful consideration to the option of further risk stratification of the sample. However, the Inquiry’s view is that any advantage to be gained would be outweighed by the ensuing disadvantage of serious delay in implementation of the clinical review exercise. Moreover, methodologies for pre-operative risk stratification in paediatric cardiac surgery are still at an early developmental stage, and would be unsuitable to apply retrospectively to the Bristol case notes.

4.10 Reconciliation of various data sources will continue over the summer to ensure that the Inquiry has as complete a set of clinical records as possible. If it becomes clear that the Inquiry has not yet received from the UBHT some relevant clinical records, these will be obtained, scanned and analysed and consideration given to a supplementary clinical records review exercise.

Strengths and Limitations of the Sample

4.11 The main strengths of the sample are as follows:

- (i) it meets all the requirements set out as guiding principles in section 4.2 above;
- (ii) it will ensure that the areas of concern which led to the Inquiry will be addressed as part of the clinical review exercise;
- (iii) it has been selected, within those areas, on a random basis so that selection into the sample is fair and no child could deliberately have been included or excluded on whim;
- (iv) it will enable the conclusions of the review to be representative of the entire dataset, taking stratification into account;
- (v) it includes children who had successful operations as well as those who did not;
- (vi) it can be used to provide a balanced view of the adequacy of cardiac surgical care of children within the terms of reference of the Inquiry;
- (vii) the sample size is such that it will allow clinical experts to conduct a detailed review of each case within the sample and to complete their task within a reasonable timescale.

4.12 Limiting the sample to 80 cases drawn only from patients treated at the Bristol Royal Infirmary and Bristol Children's Hospital means that potential for comparisons is inevitably limited. The Inquiry's considered view is that this sampling approach is necessary in order to deliver results within a reasonable timescale to inform the oral hearings process. The Inquiry will give careful consideration to the option of commissioning an extended clinical review exercise on a longer timescale.

5. Conclusion

5.1 The clinical records review exercise will constitute one of many sources of evidence on the adequacy of care. This note has set out in detail the Inquiry's approach to the clinical records review exercise and explains how the sample of cases for review was derived. The review will add to the Inquiry's understanding of the qualitative aspects of care, but any results and conclusions will need to be set in the context of the strengths and shortcomings of an exercise of this nature.

BRI Inquiry Secretariat
July 1999

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 scores 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.

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. ITU – Medical			
Post operative care and assessment 2. Surgical			
Post operative care and assessment 3. Paediatric cardiological			
Post Mortem			

Please use the following summary scores for adequacy:

<p>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.</p>
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ANNEX B

Sample of children who received heart surgery at the Bristol Royal Infirmary/Bristol Hospital for Sick Children between 1984 and 1995

Age Groups and Procedure Type	SAMPLE NUMBERS and RATIOS	
	Children who had died within 30 days of surgery	Children who were alive 30 days after surgery
<p><i>Note: the figures in brackets express the percentage of children in each category of the sample, based on the number of children in the same category of the clinically coded records dataset. For example, the 6 cases of children who died within 30 days of having open heart surgery (arterial switch, truncus and AVSD procedures) and were aged up to 28 days, comprise 21% of all such cases in the dataset. Percentages are rounded to the nearest whole number.</i></p>		
<u>Open Heart Surgery:</u> (Arterial Switch, Truncus and AVSD procedures)		
Up to and including 28 days	6 (21%)	6 (6%)
29 days up to the first birthday	6 (14%)	6 (6%)
One year up to the 16 th birthday	3 (14%)	3 (4%)
<u>SUB TOTAL</u>	15 (16%)	15 (5%)
<u>Open Heart Surgery</u> (other than Arterial Switch, Truncus and AVSD procedures)		
Up to and including 28 days		
29 days up to the first birthday		
One year up to the 16 th birthday	9 (27%)	9 (14%)
	6 (14%)	6 (3%)
<u>SUB TOTAL</u>	4 (14%)	4 (1%)
<u>Closed Heart Surgery</u>	19 (18%)	19 (2%)
Up to and including 28 days		
29 days up to the first birthday		
One year up to the 16 th birthday	4 (11%)	4 (4%)
	1 (13%)	1 (1%)
<u>SUB TOTAL</u>	1 (33%)	1 (>1%)
	6 (13%)	6 (1%)
TOTAL SAMPLE SIZE = 80 [comprising 40 deaths and 40 non-deaths]		