

Section One INTRODUCTION AND METHODOLOGY

Introduction

1.1 This report is an initial overview of the Clinical Case Note Review (referred to as the CCNR). **It is essentially a first, factual report-back to the Inquiry. Full and final interpretation of the results will require further consideration. This is not written as an academic research report, but rather, as a general summary intended to be accessible to a wide range of audiences.**

1.2 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 adequacy and less than adequate care*. The exercise was not designed to reach specific conclusions about individual cases.

1.3 It is important to emphasise that the CCNR is only one of a number of sources of information and evidence available to enable the Inquiry to assess the adequacy. 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 this CCNR were informed of these considerations in advance.

1.4 It is also important to state that this preliminary report has been prepared within a few weeks of completion of the clinical case note review exercise. While the authors are confident of the overall analysis and pattern of results, they are mindful that this paper may contain minor errors of detail. Any such shortcomings will be identified and amended in the final report of the exercise.

Methodology

1.5 Two supplementary notes are attached. Note A on the methodology of the review exercise, and Note B on the selection of cases for the sample. Key points to note about the methodology and selection of cases are as follows:

- The approach employed was developed and tested in a pilot study in May 1999.
- The CCNR used a standard report form, adapted from the reporting process used in the Confidential Enquiry into Still Births and Infant Deaths (known as CESDI).
- 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 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 review teams were asked to make assessments as to the adequacy of care delivered in Bristol, using Bristol clinical records. They were not asked to consider the care given by GPs or by other NHS hospitals, to children in the sample.
- 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.
- Four possible grades could be assigned:

4 – Adequate;

3 – Less than adequate, but different management would have made no difference to outcome;

2 – Less than adequate; different management might have made a difference;

1 – Less than adequate; different management would reasonably be expected to have made a difference to outcome.

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

- The cases reviewed were selected from the cases of all children known to have had heart surgery in Bristol between 1984 and 1995. The sample consisted of 80 cases, comprising forty children who had died within 30 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 30 days after their last surgical procedure (again, of whom six had closed heart surgery and thirty four open heart surgery).¹
- The sample of cases was random and **weighted towards younger children who had open heart surgery.**
- Fifteen cases were reviewed twice to validate 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.

Discussion of methodology

1.6 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. From the outset, the Inquiry has been open about the strengths and weaknesses of the exercise. Its strengths lie in the scope and depth of the exercise 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 12 years. 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.

1.7 The possible weaknesses acknowledged in July still apply. This has been, 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 into play. Being aware of this is one way of guarding against it.

¹ 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.

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.

1.8 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 score for the overall adequacy of care (four cases were given an overall score of 2/3).

The Process of the Case Reviews

1.9 The scale of work involved is significant and amounts to about 1,500 hours of clinical time, thus far. Eighty cases were reviewed, fifteen of which were subjected to a second review, making a total of ninety five case reviews. Taking account of the five cases reviewed for the pilot, one hundred sets of case notes were considered in all by six expert review teams.

1.10 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.

1.11 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. The duration of each case review discussion ranged from between 45 minutes and nearly 2 hours. On average, we estimate that each case review, including all preparation and meeting time, took about 15 hours of clinical time, making a total of around 1,500 hours of clinical time in all. 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.

Difficulties in the review process

1.12 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.

Interpretation of Results

1.13 As with any exercise of this type, it is very important to interpret the results within the context of the methodology and its limitations.

1.14 The Review was designed to assess whether care had been "adequate" or "less than adequate". Within the category "less than adequate", grades were assigned depending on the review team's judgement as to whether different management might have or would have made a difference to outcome. For the cases of children who were alive at 30 days, and not disabled, 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 30 days or who experienced disability after surgery.

1.15 The grading for adequacy of care is presented in this report for the whole sample, but it must be borne in mind that this sample emphasises younger children with more serious operations, and thus, it could be said, children who were more likely to have died than older children having less serious operations. Thus assessment of the adequacy of the overall pattern of care in Bristol must take this into account.

1.16 It is also important to emphasise that the reviewers in each case were aware that these were *Bristol* notes, with all that might imply about hindsight. 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 whether the child died or not. At the commencement of the exercise, the reviewers were informed that each CCNR report form would be treated as expert evidence to the Inquiry, and that each report form would be eventually be made public.

1.17 At this stage of reporting the results, we do so without age stratification, although we note that the sample was weighted towards younger children. The reviewers knew the age of each child at each procedure and took this into account in assessing the adequacy of care.

Review Report Forms

1.18 The finished review report forms were largely completed according to guidance issued to review teams. In eighteen cases, the reviewers reported separately on more than one procedure; of these, two procedures were separately considered in sixteen cases, and three procedures in two cases. Thus, in all, one hundred 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.

1.19 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 are there grades for post mortem where children are alive.

1.20 Initial validation checks of CCNR report forms has led to the identification of a very small number of errors which appear to be administrative in nature and are not untypical for an exercise of this type. Work is underway to check these apparent errors and any adjustments which have to be made, and which are expected to be minor, will be included in the final overview report.

Section Two
OVERVIEW OF INITIAL RESULTS

2.1 The following graphs and tables provide summary information of the overall results from the review of 80 sets of case notes.

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

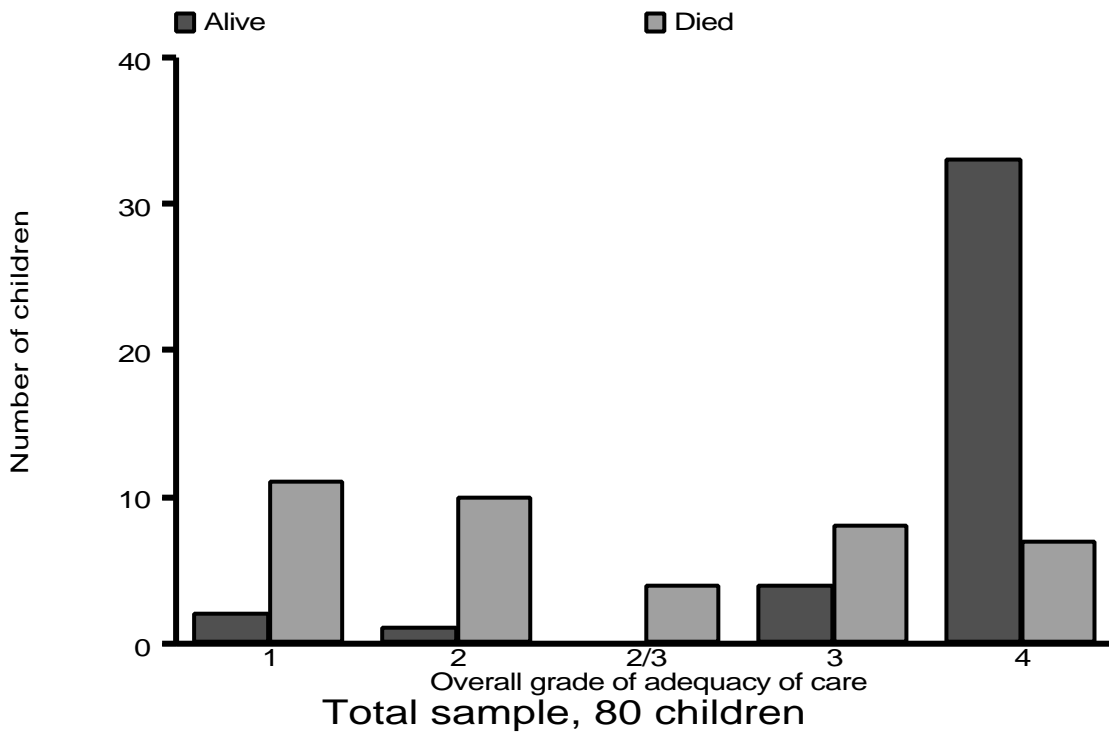


Figure 2
Overall grade for adequacy of care by outcome 30 days after last surgical procedure

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	4	12
4	7	33	40
Total children	40	40	80

2.2 The graph and table show that the care given to 50% of children in the sample was assessed by review teams to be adequate. Review teams considered that for 30% of children, (24 cases out of 80), overall, different management might have or would reasonably be expected to have made a difference to outcome.

2.3 As mentioned in the last section, the CCNR exercise reported on 100 procedures performed on 80 children. The table below shows the distribution of overall grades for adequacy by the number of procedures per child.

Figure 3 - 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	2	3	Total
1	10	3	0	13
2	9	2	0	11
2/3	1	3	0	4
3	10	2	0	12
4	32	6	2	40
Total children	62	16	2	80

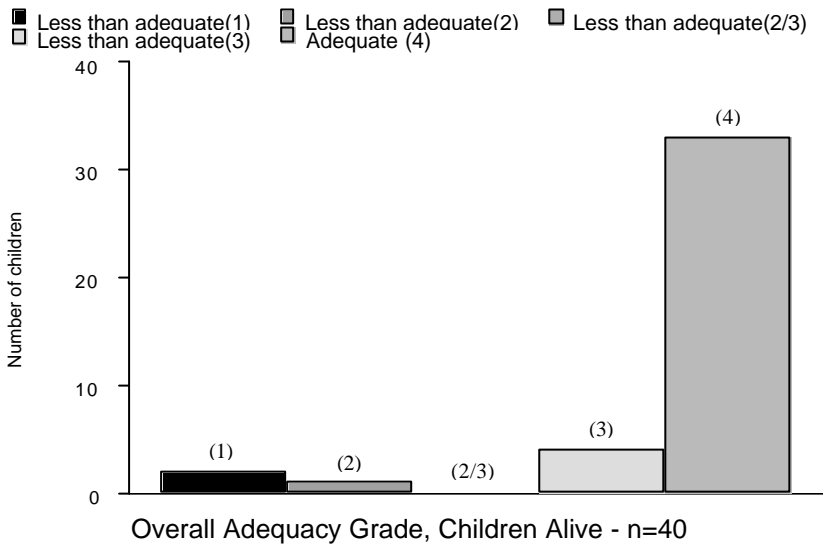
2.4 In eighteen case reviews, the reviewers reported separately on more than one procedure. The information in this table shows overall grades for multiple procedure case reports. There appears to be no immediately obvious difference between the overall grades assigned to multiple procedure cases and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

2.5 The following four graphs are self explanatory and provide an overall summary of the results of the review of 80 cases, according to the main features (operation type/outcome) of each case.

Figure 4

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 30 days



b) Those who died within 30 days of their last operation

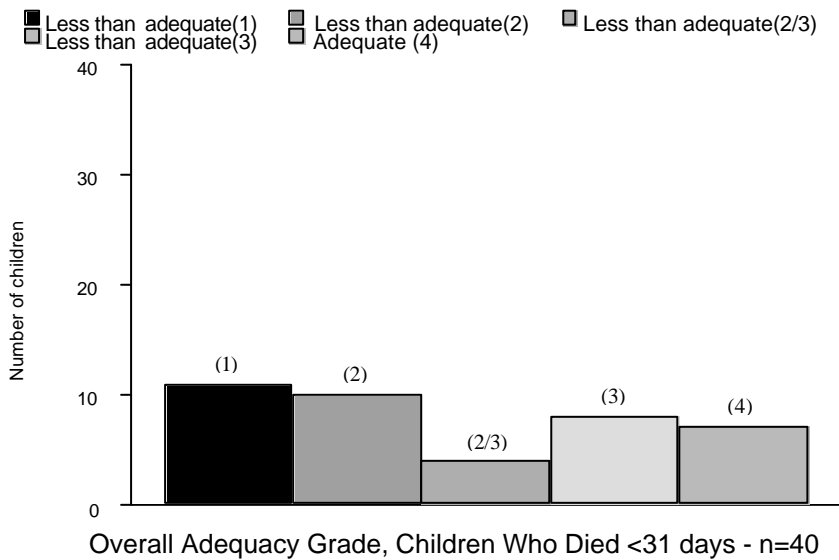
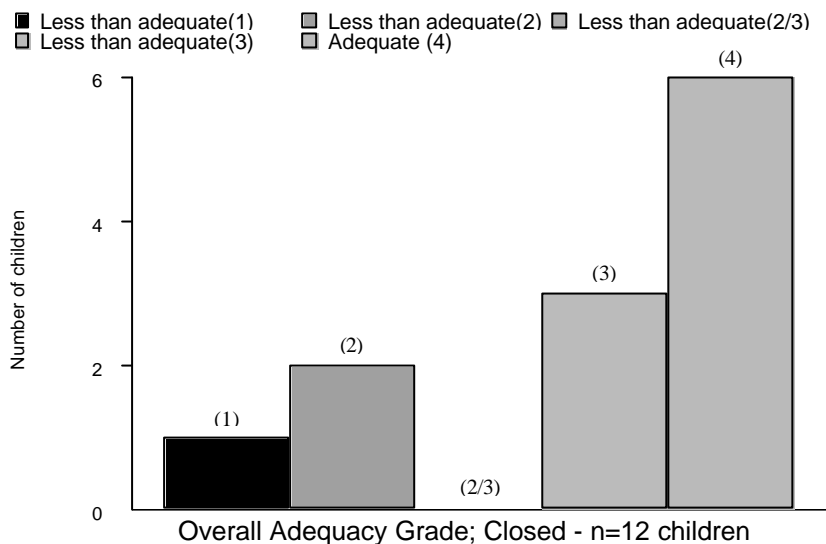


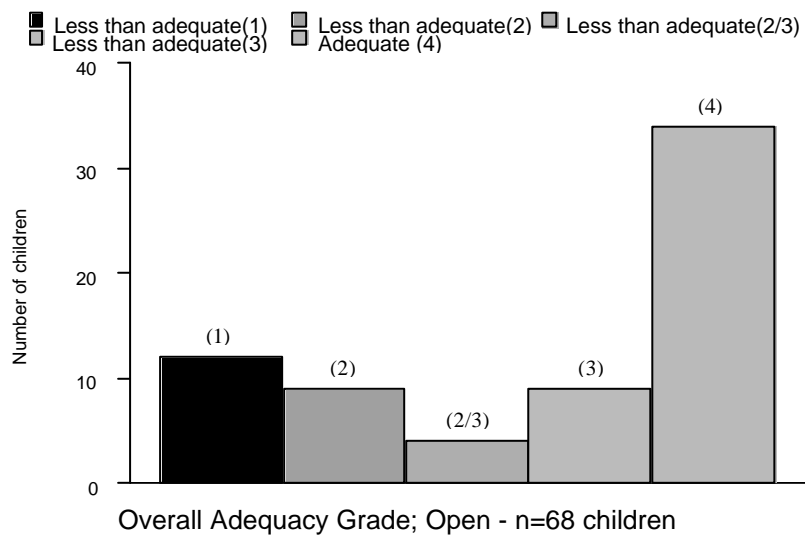
Figure 5 - Distribution of overall adequacy grades for closed and open type of operation. Numbers of children shown for each adequacy grade in that category of operation.

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.



Section Three ASPECTS OF CARE

3.1 For the purposes of preparing this report, the authors have had access to all CCNR review report forms. In this section 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 100 procedures within the 80 cases. The review teams considered thirteen aspects of care in all, grouped according to three broad headings: pre-operative care, surgical care, 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 which 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/ITU care
- K Post operative – surgical care
- L Post operative – paediatric cardiological care

Post Mortem

- M Post mortem

Figure 6 – Distribution of grades for all aspects of care, 100 procedures

ALL 80 CHILDREN, 100 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		2		1	3	1		4
2	2	4	3	5	3		7	3	3	6	6	3	4
2/3							1					1	
3	4	5	5	5	14	3	8	9	13	10	5	7	5
3/4					1		3						
4	86	90	88	83	79	96	79	58	83	69	75	69	26
X						1		4		2	2	8	7

n.b. For each of the 100 procedures assessed, reviewers did not always give a grade for each of the thirteen aspects of care.

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

3.2 We now highlight aspects of care in which "less than adequate" care was graded; we have drawn on the comments of the review teams in order to summarise the trends, bearing in mind that 100 procedures were assessed in all.

PRE-OPERATIVE CARE (Para A-F)

3.3 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 100, as opposed to the total number of children, which is 80.

A. Timing and appropriateness of initial referral/condition on arrival

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

B. Clinical assessment and management

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.

C. Accuracy and completeness of diagnosis

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.

D. Appropriateness of initial treatment strategy

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.

E. Timing of planned treatment

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.

F. Immediate pre-operative management, including nursing

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 (Para G-I)

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

G. Surgical procedure

Grades other than 4 (less than adequate care) were given for twenty-one procedures. Of these, for eleven procedures, the reviewers did not consider that the surgical care affected outcome; whereas in seven 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.

H. Perfusion (applies to open heart surgical procedures only)

Perfusion, which is largely the responsibility of the anaesthetist, was questioned in twelve procedures. In three of these, different management might have improved outcome. One of the most frequent comments concerned acidosis, i.e. an unacceptable build up of acid in the bloodstream of the patient during the operation.

I. Anaesthetic

In eighteen 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)

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

3.6 Although the clinical case note review of post-operative management in intensive care was set up to be sub-divided between anaesthetists, surgeons and paediatric cardiologists, 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 ITU. However we continue to comment on the grades as they were allocated and, with some reservation, separate them out as follows:

3.7 There was a grading for less than adequate care in relation to medical care, which we take to mean anaesthetic care, (Aspect J) following nineteen procedures, including nine instances where care was graded as 1 or 2.

3.8 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.

3.9 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 ITU at BRI.

POST MORTEM (Aspect M)

3.10 If the guidelines on grading of “adequacy” had been strictly observed, none of the post mortems would have been graded less than 4 because the post mortem could obviously not have influenced outcome in any way. The reviewers did regard 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.

3.11 Reviewers reported on thirty nine post mortems (including post mortems on the three children who died more than 30 days after surgery). Grades 1 and 2 were assigned in the cases of eight children, all of whom had died within 30 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.

3.12 The post mortem reports were less helpful to clinicians reviewing the clinical records than they had expected. They commented that there did not appear to be sufficient information exchanged between the clinical team and the pathologists either before or during the post mortem and suggested in some cases that the pathologist did not appear to have had an appreciation of the operation or of the anatomy.

Section 4 OVERALL ASSESSMENT OF CARE

4.1 This section deals in turn with each category of overall grades, and identifies the key aspects of care which appear to have contributed to the overall grade given to the case.

Note - Supplementary Note C to this report gives all adequacy grades assigned to each case reviewed, grouped according to the overall grade given in each case.

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 (ie an avoidable factor which probably contributed to death or disability).

Figure 7

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

CHILDREN WITH OVERALL CARE, Grade 1. CHILDREN = 13; PROCEDURES = 16													
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			1		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	10	9	13	7	8	6	6
X								1		1	1	4	

4.2 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 30 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.

4.3 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.

4.4 The results suggest that surgical care was not as significant a factor in contributing to poor outcome as pre-operative care, within this group of overall grade 1 cases. In fact 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 one further case 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.

4.5 In the case of four patients, aspects of intensive care management were given grades 1 or 2 and thus may have contributed significantly to poor outcome; in two of these cases there were grades 1 or 2 were given for pre-operative.

4.6 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, the surgical treatment and the length of time on by-pass, together warranted an overall grade of 1.

4.7 The following quotations provide an insight into the issues of concern to reviewers. They represent a cross-section of the comments made on the CCNR report forms with an overall grade of 1:

Preoperative aspects (A-F):

Serious error in diagnosis; major deficiencies in postoperative care.

Failure to appreciate degree and significance of coarctation.

Clear evidence of delay in treatment strategy.

Incomplete diagnosis; serious error.

Unacceptable delays in referral and between diagnosis and surgery.

Should have had operation on same admission; not discharged with RV pressure 140.
Inadequate preoperative haemodynamic assessment.

(Some of these comments were repeated in several different case).

Surgical Procedure (G)

Decision to band PA was fatal.

Anaesthetic (I)

Subclavian venous line; inappropriate site; iatrogenic pleural effusion directly compromised shunt procedure.

Postoperative aspects (J-L)

Misleading post operative echocardiogram.

Intervention during this period would have been life saving.

Suspicion of tamponade; should have explored despite echo findings.

Patients with overall score 2

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

Figure 8

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

CHILDREN WITH OVERALL GRADE = 2 CHILDREN = 11; PROCEDURES = 13													
Aspect of Care													
Grade	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
3/4													
4	11	10	10	10	8	13	8	8	10	8	9	7	6
X								1				2	

4.8 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. One of the children, who had received open heart surgery, one was alive at 30 days after the last procedure without disability; the other ten died within 30 days of their last surgical procedure.

4.9 In contrast to those patients with an overall score 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 ITU care. Reviewers assigned grades of 2 or 1 for aspects of postoperative care in the cases of six patients.

4.10 We noticed 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 that this was such an important factor influencing overall care that they were unable to assign an overall grade 3 or 4.

4.11 It is interesting that 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 score of 1, but the overall numbers are too small to draw any firm conclusions. The following are a cross-section of quotations from the CCNR report forms with an overall grade of 2.

General comments:

Detailed postoperative cardiac assessment might have revealed correctable residual abnormality.

Organisational aspects of the Intensive Care Unit in terms of junior doctor cover, support, and overall leadership of the team.

Recurring theme of delayed surgical procedure, unnecessary cardiac catheterisation and prolonged surgical repair.

Unexplained delay in treatment of known coarctation.
Preoperative delays and postoperative ICU were potential factors in outcome.

Preoperative aspects (A-F)

Since this is a rare, high risk, surgical condition, additional opinion should have been sought and/or referral to another centre.

Delay between coarctation repair and subsequent care.

Gross delay in surgical treatment ("cardiology" implicated).

Surgical procedure (G)

Some surgeons would not have accepted suprasystemic RV pressure and would have attempted further measures.

Appeared not to understand nature of inflow obstruction...LV outflow obstruction not adequately relieved.

Bypass and ischaemic time were too long for straight forward surgery.

Heparin should have been given at first operation to prevent shunt occlusion. Delay in reoperation for blocked shunt.

Cardioplegia given directly into aorta; anomalous left coronary would not have been perfused, probably contributing to poor myocardial preservation and poor contractile function of heart post-repair.

Anaesthetic (I)

Should one proceed with surgery after a major anaphylactic reaction?

Postoperative care and assesment - ITU (J-L)

Questionable management especially sequence of events...leading to reventilation and subsequently to severely compromised cardiorespiratory status.

Earlier dialysis should have been performed.

Delayed response to clinical evidence of sepsis.

Reoperation to close residual VSD and repair valvar regurgitation may have improved chances of survival.

Delayed sternal closure or reopening of chest might have helped.

Patients with overall score 2/3

Figure 9

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

CHILDREN WITH OVERALL GRADE = 2/3 CHILDREN = 4; PROCEDURES = 7													
Aspect of Care													
Grade	Pre Operative Care						Surgical Care			Post Operative Care			Post Mortem M
	A	B	C	D	E	F	G	H	I	J	K	L	
1													
2								1	1	1	1	1	
2/3							1						
3							1	2	1	1			
3/4					1		1						
4	7	7	7	7	6	7	4	1	5	3	4	4	3
X													2

4.12 There were four patients in this group having had a total of seven procedures, all of whom 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 or might have made a difference. 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.

Patients with overall score 3

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

Figure 10

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

CHILDREN WITH OVERALL GRADE = 3 CHILDREN = 12; PROCEDURES = 14													
Aspect of Care													
Grade	Pre Operative Care						Surgical Care			Post Operative Care			Post Mortem M
	A	B	C	D	E	F	G	H	I	J	K	L	
1													1
2		1	1	1			2			1	1		2
2/3													
3	1	1	1		5	2	3	4	4	4	3	3	1
3/4							1						
4	12	12	12	13	9	12	8	5	10	5	6	5	2
X										1	1	2	1

4.13 An overall grade of 3 was given to the care of twelve patients, (fourteen procedures), of whom nine had open heart surgery and three had closed heart surgery. Four of the children were alive 30 days after

their last surgical procedure, one of whom one with 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.

4.14 Pre-operatively, problems with the adequacy of care were identified in the cases of nine 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.

4.15 Surgical 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 eight patients, and features of intensive care in the cases of five patients.

4.16 The following are a cross-section of quotations taken from the comment sections of the CCNR report forms for cases given an overall grade of 3:

General comments:

Appropriate operation.....technically could have been better.

Very difficult anatomy. Possibly inoperable.

Very difficult anatomy with hypoplastic pulmonary arteries. Unsuccessful shunts because of small PA's.....Although child's father has expressed concern....- we could find no evidence that there had been any delay in the doctors attending the child.

Some evidence of lack of experience in dealing with children from ITU entries in case notes.

Less than adequate preoperative management. High risk case.

Long term excellent result.

Stroke was unfortunate, rare but unavoidable.....Definitely should have undergone surgery earlier.

Lack of insight concerning difficulty and complexity of surgical repair in child with this lesion

3 previous operations adequate. Delay in final "correction". Technical problems during surgery.

Very complex anatomy. Re-operation. High risk case

Preoperative aspects (A-F)

Preoperative pharmacological treatment. Could have received beta-blocker.

Delay from diagnosis to operation \pm 4 months despite severe failure to thrive.

Delay instituting proper treatment at BCH i.e. ventilation.

Incomplete assessment of left PA sling.

Failure of communication of importance of coarctation.

Long delay between acceptance for surgery and actual surgery.

Revision of shunt delayed...in spite of uncertainty of shunt function in early postop period.

Surgical valvotomy should have been undertaken earlier...suprasystemic pressure & low PO2.

Surgery delayed until 2 years of age.

Considerable delay in attempted corrective surgery.

Use of preprinted adult based care plan.

Surgical procedure (G)

Long cross clamp, long bypass

Shunt did not improve saturations. An alternative shunt should have been considered.

Long bypass & cross clamp times. Unwise to give propranolol during or immediately following bypass.

Difficult surgical case - apparent failure to anticipate potential problems.

Perfusion (H)

Persistent acidosis throughout perfusion.

Persistent acidosis with no attempted correction.

Very acidotic. Apparently cooled to 22 degrees prior to bypass.

Persistent acidosis not apparently corrected early in bypass.

Anaesthetic (I)

No central venous access - therefore inability to monitor CVP and give inotropes.

Arterial line in right brachial for right sided shunt is inappropriate.

PCV 50 shortly after bypass - far too high.

Postoperative care and assessment -ITU (J-L)

Extubation in very early postoperative period was inappropriate.

Earlier postoperative investigation should have been done.

Confusion in inotrope dose calculations.

High concentration of dextrose given requiring insulin infusion to control blood sugar.

Nursing comments....implies inexperience caring for children.

Greater paediatric cardiological input in postop care desirable.

Patients with overall grade 4

Care was adequate

Figure 11

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

CHILDREN WITH OVERALL GRADE = 4 CHILDREN = 40; PROCEDURES = 50													
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
¾													
4	43	49	50	45	47	49	49	35	45	46	48	47	9
X						1		2					4

4.17 The reviewers gave an overall grade of 4 to half of the cases, forty in all, encompassing fifty procedures. Seven children had died and thirty three were alive within 30 days of their last surgical procedure.

4.18 In the CCNR reports of twenty four 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. Aspect E, timing of planned treatment; Aspect I – anaesthetic, and Aspect J, post operative medical/anaesthetic intensive care were cited more than twice as less than adequate.

4.19 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.

Section Five

POST REVIEW - COMMENTS FROM EXPERT REVIEW TEAM CO-ORDINATORS

5.1 At the end of the review exercise, each of the co-ordinators of the six teams of expert reviewers was asked for a short note of overall impressions on the pattern of adequacy of care. 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

5.2 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.

5.3 There were delays between the time of the cardiac catheterisation and 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.

5.4 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 the 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?

5.5 It was difficult to determine who took medical or nursing responsibility for directing the management of patients on the ITU and particularly as applied to the management of paediatric patients.

Pre-operative and Operative issues

5.6 There were some situations which 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. It appeared that these problems were probably related to the availability of resources.

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

5.8 There were relatively long cross-clamp and circulatory arrest times. Such times would be unusual in the current era but not necessarily so in the past.

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

Post-operative Management issues

5.10 There appeared to be a lack of paediatric nursing input and probably junior medical staff input at BRI; and, on the ITU at the BRI, a noticeable absence of Paediatric Cardiological input. In particular, there appeared to be little evidence that echocardiograms were ever done on the BRI ITU.

5.11 It was difficult to determine who took either medical or nursing responsibility for directing the management of patients on the ITU and 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.

5.12 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

5.13 Some of the pathology reports did not appear to answer questions that 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.

5.14 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.

Section Six
PRELIMINARY RESULTS OF THE REPEAT REVIEW EXERCISE

6.1 As indicated in the Inquiry’s July 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.

6.2 Here we compare the grades for overall care; further work is needed to compare the grades on individual aspects of care.

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

Second Review Case	OVERALL GRADE	
	First Review	Second Review
SR1	4	4
SR2	4	4
SR3	4	4
SR4	3	2
SR5	3	1
SR6	2/3	2
SR7	4	4
SR8	3	3
SR9	3	4
SR10	3	2
SR11	4	4
SR12	4	4
SR13	1	1
SR14	4	3
SR15	2	4

6.3 Of the fifteen cases selected for repeat review eight children were alive and the other seven died within 30 days of their last cardiac surgical procedure.

6.4 In reviewing the scores we separated those cases scoring overall 3 or 4 (care was adequate or different treatment would have made **no** difference to the outcome), from those scoring overall 1 or 2 (different treatment might or would have made a difference to the outcome).²

6.5 In nine of the fifteen cases there is complete agreement on overall scores between the teams. When the overall grades are grouped into two (Grade 4 and 3, and Grade 2 and 1) there is agreement in eleven cases. We were particularly struck by the fact that one team which did a repeat review of five cases was in complete agreement with the original team.

² The approach of grouping similar grades follows that used by a second review exercise elsewhere - in its fifth annual report, May 1998, The Confidential Enquiry into Still Births and Infant Deaths reported on an exercise to review a second time 113 sets of case notes.

6.6 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 scoring grade difference i.e. 3 versus 2:

- In one of these (SR4) 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.
- In the second case (SR10) the child is alive but has moderate disability following a cerebrovascular accident (stroke). Both teams felt that earlier operation should have been undertaken but differed as to whether this might or might not have changed the outcome.

6.7 We were more concerned, however, about the two cases where there were two scoring grades difference between the teams.

- In the first case (SR5) 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 makes the technical construction of a shunt very difficult. Even if a successful shunt is constructed it is possible that the pulmonary arteries might not grow. One team was critical of the way the shunt was constructed and about the initial postoperative management. The other team felt the anatomy was so unfavourable that a different technique would not have made any difference. This child died.
- In the second case (SR15), overall care was given a grade of 2 by the first review team and 4 by the second. The child 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.

6.8 Both these cases highlight our earlier observation that in any retrospective review where the child died, it could be argued that any different management might or would have made a difference.

Emerging Implications of the Repeat Review Exercise

6.9 The repeat review exercise showed a degree of concordance between the teams suggesting that the expert team review methodology is valuable. Further analysis of the gradings and comments on each of the aspects of care, and, potentially further second reviews, might help to establish the extent to which this concordance is reliable or due to chance alone.

Section Seven
PRELIMINARY ASSESSMENT OF RESULTS FROM THE REVIEW OF 80 CASES

7.1 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".

7.2 In reaching preliminary conclusions, it is important to re-state the context of the exercise; the following points are relevant:

- a) 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.
- b) The review was based on a study of clinical case notes; while these are often very rich sources of information, they do not necessarily 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.
- c) The methodology involved weighting the selection of cases to be reviewed towards those patients who had died and those who were less than one year of age at the time of the operation. Eighty cases were selected 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 30 days.
- d) 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 it 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.
- e) There were no published results or standards against which the reviewers would be able to measure adequacy of care and it was acknowledged that in 1999 it would be very difficult to have a clear memory of standards of care that would have been expected between 1984 and 1995.
- f) 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.

7.3 In assessing individual cases, the Reviewers developed a number of observations:

1. For the most part it was accepted that survival of the patient without disability would have implied that care had been adequate. Expert review did reveal some cases within this group in which there was some criticism of adequacy of care.
2. A retrospective review of a case where the child has died is always likely to be critical of the management – by definition any different management might have made a difference.

3. 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.

Against this background, the following preliminary assessment can be drawn from the exercise thus far:

7.4 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 ITU management. The paediatric medical and nursing care, the lines of responsibility and the lack of paediatric cardiological input were criticised.

7.5 In only two of the 100 procedures was it considered that different conduct of the surgical procedure would **probably** have resulted in a better outcome and in seven 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 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 which would lead to poor outcome, and that postoperative care on the ITU was a major determinant of outcome.

7.6 In 30% of the cases (twenty four out of eighty) the review teams believed that different management might have or would have affected the outcome – three of the children were alive 30 days after surgery and the other twenty one had died. This type of review of surgery has never been undertaken before in the UK and therefore there is no benchmark standard against which to judge this proportion. In the nearest comparator, the national audit of stillbirths and infant deaths (CESDI), up to 40% of cases are criticised by the reviewers.

7.7 We considered there to be particular value in looking at these cases scoring 1 or 2 for overall care in the review. In the 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.

7.8 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 organisation might have been important factors.

7.9 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.

7.10 The second review exercise showed a degree of concordance between the teams suggesting that the expert team review methodology is valuable. Further analysis of the gradings for each of the aspects of care, and potentially further reviews, might help to establish the extent to which this concordance is reliable or due to chance alone.

7.11 We have made an initial assessment of this review of 80 cases, based on the 80 CCNR report forms. These conclusions may need to be supplemented in the light of the further work we have suggested, namely analysis taking account of the actual age of the children at each procedure, and further work on comparing second review reports with first review reports. The conclusions may also need to be adjusted in the light of any further second reviews. We are limited in our ability to assess the wider significance the outcome of this exercise, since we do not have, nor were we asked to apply, wider knowledge of the issues involved in providing paediatric cardiac care at Bristol.

Leslie Hamilton
Eric Silove

SUPPLEMENTARY NOTE A

1. Introduction

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 Section 1 of the *Preliminary Report on the Clinical Case Note Review*

2. The Pilot exercise

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 should receive copies of clinical notes in advance of a review meeting.

3. The Review Teams

A multi-disciplinary team of clinicians drawn from the Inquiry's Expert Group reviewed every case in the sample. 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 the 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 six review teams are to be found at the end of this note.

4. Selection and Distribution of Cases

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 *Supplementary Note B* to this report.

Each review team was asked to review between 10 and 20 sets; within this some teams reviewed the same sets of notes, although teams were not made aware that they were undertaking a second review. This was so that the Inquiry could assess the degree of consistency to be achieved by its approach.

Each member of the review team was provided with paper copies of the clinical records. The Inquiry had previously scanned onto its database copies of the relevant clinical records and by virtue of that process, had assigned a unique number to each set of notes and to each page of those notes.

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
- ITU Charts
- Echocardiograms and Angiograms
- X Rays

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.

5. The Review Meeting

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 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.

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 catheterisations, and to the post mortem report where one existed.

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.

6. The Report Form

The Inquiry built upon the work of Confidential Inquiry into Still Births (CESDI) and adapted a standard reporting form which 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.

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 then they were advised to use the term "n/a".

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 certain of the identity of the responsible clinician.

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.

COMPOSITION OF EXPERT REVIEW GROUPS

	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6
PAEDIATRIC CARDIAC SURGEON	Mr. James Pollock Royal Hospital for Sick Children GLASGOW	Mr. Leslie Hamilton The Newcastle Upon Tyne NHS Trust 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
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
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
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
PATHOLOGIST	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
NUMBER OF CASES REVIEWED	20	20	20	14	11	10

SUPPLEMENTARY NOTE B

1. Introduction

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.

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.

2. The Inquiry's Approach to Selecting Cases for Clinical Review

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.

On the basis of these guiding principles and expert statistical advice, the Inquiry decided to select a stratified random sample of 80 cases, weighted preferentially towards children who

- were under one year at time of their first procedure;
- received higher risk open heart procedures;
- died within 30 days of their last procedure.

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 (40) and children who were alive (40).

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.

3. Comments on the Inquiry's Sampling Approach

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.

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.

4. Derivation of Sample Cases

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 United Bristol Healthcare NHS Trust (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.

The sample was drawn from 1827 cases. The 80 cases in the sample are as anticipated from the sampling frame; that is to say the 80 cases consist of 68 children who had received open heart surgery and 12, closed heart surgery. 40 children were alive 30 days after their last cardiac surgical procedure and 40 had died within that period. Three of the children who are classified within the sample as being alive 30 days after surgery subsequently died six months or more after their last cardiac surgical procedure.

Key points to note with regard to identification of the 80 cases in the sample are as follows:

- (i) the sample numbers represent children, rather than operations or procedures;
- (ii) all children and all procedures were taken into account in selecting cases for inclusion in the sample; sampling was not by surgeon;
- (iii) a hierarchy of procedures was used to classify children: higher risk open procedures (switches, AVSDs and truncuses), 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;
- (iv) 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;

- (v) 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;
- (vi) deaths are defined as deaths occurring within 30 days of the last operation received by the child.

A table setting out the CCR sampling base figures in full is attached at Annex A.

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.

The target sample size (80 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.

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.

5. Sample Validation

The Inquiry has taken active steps to validate the sample, including the following:

- (i) 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;
- (ii) 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 100 case records - has confirmed the high quality and accuracy of the clinically coded diagnoses and procedures recorded in the CCR dataset.

6. Reviewing Adequacy of Care: the Wider Context

In order to allow findings on the adequacy of care provided at Bristol to be set against the context of data on activity and outcomes at other comparable specialist centres, the Inquiry is committed to exploring the feasibility of supplementing the Bristol clinical case review exercise with a comparative evaluation of quality and outcomes based on audit of clinical records selected from a range of specialist provider units.

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**

ANNEX A

	<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>Totals</u>					<u>Sample numbers</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

SUPPLEMENTARY NOTE C

**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

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

Case ¹ No.	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	4	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	.	4	4	4	.	4
1/9b	O	D	4	4	4	3	4	4	4	X	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	3/4	3	4	4	4	.	1
1/12b	O	D	4	4	1	4	4	4	4	.	3	.	.	4	.
1/13a	O	D	2	2	4	4	1	4	4	4	4	4	4	4	3
1/13b	O	D	4	4	2	1	4	4	4	.	4	4	4	X	.

Table of grades for adequacy of care by individual aspects of care for those with Overall grade 2

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	.
2/1b	O	D	4	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
2/3a	O	D	3	4	3	2	4	4	4	4	4	4	4	4	4
2/3b	O	D	4	4	4	4	4	4	4	X	4	4	4	4	.
2/4	O	D	4	4	3	3	3	4	2	2	4	2	2	3	4
2/5	O	D	4	2	4	4	2	4	1	4	4	4	4	X	4
2/6	O	D	4	3	4	4	3	4	2	4	4	1	4	4	4
2/7	O	A	.	2	2	4	2	4	4	4	4	4	4	3	.
2/8	C	D	4	4	4	4	4	4	2	.	3	4	2	4	4
2/9	O	D	4	4	4	4	4	4	2	4	3	.	.	.	1
2/10	O	D	4	4	4	4	2	4	4	4	4	2	4	X	.

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

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

Table of grades for adequacy of care by individual aspects of care for those with Overall grade 3

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	.
4/2	O	D	4	4	4	4	4	4	2	4	4	X	X	.	2
4/3	O	D	4	4	2	2	4	4	4	4	4	4	4	4	4
4/4	C	D	4	4	3	4	4	4	3/4	.	3	3	4	4	.
4/5a	C	D	.	4	4	4	3	4	4	.	3	3	3	3	.
4/5b	C	D	4	4	4	4	4	4	3	.	4	3	3	3	.
4/6	O	D	4	4	4	4	4	4	3	3	3	2	2	X	3
4/7	O	D	3	3	4	4	4	4	4	3	4	.	.	.	2
4/8	O	A	4	4	4	4	4	3	4	3	3	3	3	X	.
4/9	O	A	4	4	4	4	3	4	4	4	4	4	4	3	X
4/10a	O	D	4	4	4	4	4	4	4	3	4	4	4	.	4
4/10b	O	D	4	4	4	4	4	3	2	.	4	.	.	4	.
4/11	O	A	4	4	4	4	3	4	4	4	4	4	4	4	.
4/12	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

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	C	A	4	4	4	4	4	4	4	.	4	4	4	4	.
5/4	O	A	4	4	4	4	4	4	4	X	4	4	4	4	.
5/5a	O	A	4	4	4	4	4	4	4	.	4	4	4	4	.
5/5b	O	A	.	4	4	.	4	4	4	4	4	4	4	4	.
5/6	C	A	4	4	4	4	4	4	4	.	4	4	4	4	.
5/7	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/8	O	D	4	4	4	4	4	4	4	4	4	4	4	4	4
5/9	O	A	4	4	4	4	4	4	4	4	4	4	4	3	.
5/10a	O	A	4	4	4	4	3	4	4	4	4	4	4	4	4
5/10b	O	A	4	4	4	3	4	4	4	4	4	4	4	4	.
5/11	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/12	C	A	3	4	4	4	4	4	4	.	4	4	4	4	X
5/13a	O	A	4	4	4	4	4	4	4	.	4	4	4	4	.
5/13b	O	A	4	4	4	4	4	4	4	4	3	4	4	4	.
5/13c	O	A	4	4	4	4	4	4	4	4	4	4	4	4	4
5/14	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/15	O	A	4	4	4	4	4	4	4	4	3	4	4	4	.
5/16	O	A	4	4	4	4	4	4	4	3	4	3	3	4	.
5/17	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/18	O	A	4	4	4	4	4	4	4	4	3	4	4	3	X
5/19	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/20	O	A	.	4	4	4	4	4	4	4	4	4	4	4	.
5/21a	O	A	.	4	4	4	4	4	4	4	3	4	4	4	.
5/21b	O	A	4	4	4	.	4	4	4	.	4	4	4	4	.
5/22	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/23	O	D	4	4	4	4	4	4	4	2	4	4	4	4	4
5/24a	O	A	.	4	4	4	4	4	4	.	4	4	4	4	.
5/24b	O	A	4	4	4	.	3	4	4	4	4	4	4	4	.
5/25	O	A	4	4	4	4	4	4	4	4	4	4	4	4	X
5/26	C	A	4	4	4	4	4	4	4	.	4	4	4	4	.
5/27	O	A	4	3	4	4	4	4	4	4	4	4	4	4	.
5/28a	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/28b	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/29a	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/29b	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/29c	O	A	4	4	4	4	4	4	4	X	4	4	4	4	.
5/30	C	A	4	4	4	4	4	4	4	.	4	4	4	4	.
5/31	O	A	4	4	4	4	4	4	4	4	4	3	4	4	X
5/32	O	A	4	4	4	4	4	X	4	4	4	4	4	4	.
5/33	O	A	4	4	4	4	4	4	4	4	4	3	4	4	.
5/34	O	A	4	4	4	4	4	4	4	4	4	4	4	4	.
5/35	C	D	2	4	4	2	4	4	4	.	3	4	4	4	4
5/36	O	D	4	4	4	4	4	4	3	4	4	4	4	4	4
5/37	O	A	4	4	4	4	3	4	4	4	4	4	4	4	.
5/38	O	D	4	4	4	4	4	4	4	4	4	4	4	4	4
5/39a	O	D	4	4	4	4	4	4	4	4	4	4	4	4	.
5/39b	O	D	4	4	4	4	4	4	4	.	4	.	.	.	4
5/40	O	A	.	4	4	4	4	4	4	4	4	4	4	4	.

