

**THE BRISTOL ROYAL INFIRMARY INQUIRY****COMMENTS ABOUT EVALUATION OF SURGICAL ASPECTS OF CARE**

**Prepared by J Stark, The Institute of Child Health, London**

Before I discuss how I have approached the assessment of care from a surgical point of view, I would like to repeat some of the comments I made before we started to review the case notes. I was concerned that

- a) No similar review had been undertaken by paediatric cardiac surgeons previously.
- b) A different approach is required for assessment of adequacy of care to that used for assessment of negligence in medical-legal cases.
- c) Selection of patients was heavily biased towards the young patients and those who died.
- d) The management of an individual patient could be interpreted differently if the patient survived or died.

The proposal that each child should be reviewed by a team of experts who represented various specialties involved in the management of children with congenital heart disease (CHD) was, in my view, very helpful. Treatment of CHD requires the cooperation of several specialties who often share the responsibility for care of the patient. To separate their roles in many circumstances may be arbitrary.

To illustrate advantages of the teamwork, I would like to describe briefly how the notes of twenty patients were evaluated by our group. First, each member studied the notes of all patients allocated to the group. During the meeting either the surgeon or the cardiologist presented the case of each child and initiated a discussion about the adequacy of different aspects of care. The "chairman" of the group then completed the report form with the assistance of all members of the group. It is important to stress that all members contributed to the assessment of all aspects of care, but the cardiologist formulated the "final" opinion about investigations, the anaesthetist/intensivist about anaesthesia and intensive care, etc. As a surgeon I was mainly concerned with surgery, although I also contributed to the evaluation of other aspects of care.

The thirteen elements of patient care have been grouped into three sections; pre-operative care, surgical care and post-operative care and assessment. With hindsight, I wonder whether a separate section should have been assigned to organisational aspects. On several occasions we came across the situation where "less than adequate care" was the consequence of poor organisation rather than an action of an individual clinician. We could comment, but were unable to assign it an appropriate grading.

In my comments I shall follow the same sequence of the review process as used in the review forms.

**PRE-OPERATIVE CARE (A-F)**

Includes six elements of 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

In general, the surgical contribution to a patient's care during the pre-operative period is either small or none. However, in many departments, including the Bristol department, surgeons are involved in discussion about clinical assessment and management (B), accuracy and completeness of diagnosis (C) appropriateness of treatment strategy (D) and timing of operation (E).

I would therefore consider the surgeon's responsibility for his/her part in formulating decisions during pre-operative care. For example, if the patient was not presented to the surgeon early enough and the operation was performed "too late", this would have been the cardiologist's responsibility. If on the other hand the patient was discussed with the surgeon and a joint decision was made to postpone surgery, then I would assign the responsibility for "less than adequate care" to both the cardiologist and the surgeon, probably on a 50:50 basis. The third possibility is that the patient was presented and the operation recommended by the cardiologist, but the surgeon decided to postpone surgery. In this case, the delay would have been the responsibility of the surgeon. The last scenario could be that both the cardiologist and surgeon agreed that the patient should be operated, but the operation was seriously delayed by the lack of intensive care beds, nurses, theatre time, etc. In this case, in my view the delay could be the responsibility of the overall organisation/management.

Occasionally the surgeon may be involved in the care of a patient who requires resuscitation on admission and urgent/immediate operation. However, in the notes that I evaluated I did not come across this scenario.

**SURGICAL CARE (G - I)****G Surgical Procedure**

The assessment of surgical procedures is based almost entirely on operative reports. The disadvantages of this approach are obvious. Fortunately, operative reports prepared by the Bristol surgeons were generally very detailed and most information I sought could be found. Before I start to discuss the individual points, I would like to stress that each step of the surgical procedure should be seen in relation to other factors and each operation needs to be evaluated in the whole complexity, not only as single steps. Contributions of other members of the team should also be considered.

The following questions illustrate how I approached the assessment:

- a) Was this an optimal procedure for the particular defect or the combination of defects?
- b) Was the operation performed satisfactorily?

- c) Was the contribution/interaction of other members of the team (perfusionist, anaesthetist, assistants, nurses) during the operation "good enough"?
- d) Could organisational/management aspects influence the outcome of the operation?

Often more than one type of procedure could be considered for any particular defect. The choice of the procedure must be evaluated in the context of the period of time when the operation was performed. Some procedures performed routinely in 1984 could still be considered appropriate in 1995 only under certain circumstances. (Pulmonary artery banding for ventricular septal defect in infants under the age of six months was performed in many departments in 1984, while in 1995 it would be selected only for multiple ventricular septal defects in infants in the first few weeks of life). Other operations used in 1984 would be considered inappropriate in 1995 (Waterston shunt).

The overall length of the operation depends mainly on the length of time needed by an anaesthetist to anaesthetise the patient and insert all the monitoring lines and on the length of time needed for the operation itself. The latter can be further separated into the time needed for opening the chest, the operation on the heart (length of cardiopulmonary bypass and length of aortic cross-clamping are also recorded), time to secure haemostasis and to close the chest. The length of each operation is influenced by many factors, some of which cannot be assessed from a patient's notes (inexperienced theatre nurse or surgical assistant, etc).

To judge whether the length of operation is reasonable or excessive is very difficult. There is no norm about how long an operation should take. It would be too simplistic to assume that the outcome of the operation would be better if it is performed faster. Some of the "fast" surgeons do not achieve the best results, while the results of some of the "slower" surgeons are consistently good. Certain operations require a very meticulous approach and even a "fast" surgeon may eventually prefer to perform them slowly. If, however, the surgeon is slow because he/she does not organise the operation well, loses time because he/she is not sure what to do or has to correct mistakes, then a long operation may reflect a lower standard of surgery.

Surgical time may be considerably prolonged by efforts to secure haemostasis. Bleeding is an ever-present risk of open heart surgery, as the patient on bypass must be given heparin to stop the blood clotting. At the end of the procedure the effect of heparin has to be "reversed" by the injection of another drug, protamine. Normal clotting mechanisms are not always restored immediately. Sometimes no clear cause for the excessive bleeding can be identified and a patient's related factors are suspected. Complex operations and re-operations are particularly prone to excessive bleeding. If several hours are needed to stop bleeding, a long operation does not indicate a lower standard of surgery. Operations performed at the beginning of the time period under consideration often lasted longer than operations performed at the end of this time period.

Length of aortic cross-clamping needs to be considered, together with the temperature at which the aorta was clamped and the technique of myocardial protection used. For some procedures the aorta is not cross-clamped. When cross-clamping is used, its duration varies from a few minutes for simple procedures to three or more hours for some complex operations. A long cross-clamp time without adequate myocardial protection could be considered "less than adequate care".

The temperature of the perfusate and the temperature of the myocardium have to be taken into consideration. Inadequate cooling or too deep or rapid cooling may be detrimental.

The technique of cardioplegia: Different techniques from intermittent aortic cross-clamping, through crystalloid cardioplegia to blood cardioplegia have been developed and used over the years. In

general, all the above-mentioned techniques would be considered adequate between 1984 and 1995 if administered properly.

With regard to the length of cardiopulmonary bypass (perfusion), there are no available standards for acceptable length of perfusion, but an "excessive" perfusion time may contribute to a sub-optimal outcome. The perfusion time can be influenced by several factors and will vary according to the complexity of the operation from a few minutes to several hours. Perfusion will be prolonged if extra time is required to cool/rewarm the patient.

One additional factor has to be taken into consideration. When perfusion is terminated, some hearts do not perform well and cannot support the circulation. The reason for this problem may be that the defect was not completely corrected or that there was an additional defect unknown from the pre-operative investigations. In this situation the surgeon may diagnose such defect by measuring pressures and oxygen saturations in various chambers of the heart, or the cardiologist by performing intra-operative echocardiogram. Under such circumstances, perfusion has to be restarted and the defects corrected. The presence of a residual defect may be considered "less than adequate surgery", while a newly diagnosed defect may be considered "less than adequate care" provided by the cardiologist.

Sometimes the "poor performance" of the heart cannot be explained. Some of these hearts may be resuscitated by a prolonged period of perfusion (cardiopulmonary bypass). If the long perfusion was partly due to resuscitation, the adequacy of surgical care would not be questioned. In this situation, the problem would be more likely be due to the severity/complexity of the defect.

Operative Technique: The assessment of the operative technique is difficult. One should consider whether the surgeon applied commonly accepted techniques for repair of the defect and performed the operation in a logical sequence. If the surgeon's technique was unusual, it is important to try to understand why that technique was used, whether it was a response to an unusual situation (discover of a previously unrecognised defect) or could it be explained in any other way. An unorthodox technique may be beneficial, but sometimes may be detrimental to a successful outcome.

## **H Perfusion**

The overall responsibility will be with the anaesthetist, surgeon or cardiologist. From the perfusion reports it is not clear which one of the personnel mentioned above had ultimate responsibility for perfusion in Bristol. Adequacy of perfusion can be assessed only by some indirect indices. For example, persistent acidosis during perfusion would indicate inadequate perfusion. To determine who was responsible for inadequate perfusion may be more difficult. Perfusion (cardiopulmonary bypass) is run by the perfusionist (heart-lung machine technician), who is responsible for the minute by minute conduct of perfusion. The perfusionist may not calculate/deliver adequate volume of perfusate from the heart-lung machine or appropriately manipulate arterial/venous pressures. The surgeon may use arterial/venous cannulae which are too small. Prolonged periods of reduced flow when the patient has not been adequately cooled may be another contributing factor. The anaesthetist may administer vasodilating drugs which may reduce arterial pressure excessively. Therefore, when assessing perfusion, one should look carefully into the possible contribution of all the individuals mentioned above.

## I Anaesthetic

Although the conduct of anaesthesia is the responsibility of the anaesthetist, close cooperation between the anaesthetist and the surgeon is essential for the successful outcome of an operation. They rely on each others experience and skills. As the surgeon is usually perceived as the leader of the team, he/she could be held partially responsible for certain actions of other members of the team, including the anaesthetist. For example, the surgeon should be aware of the levels of arterial and venous pressures, temperatures, etc. If the surgeon doubts the reliability of any monitored parameters, he/she could check them by measuring them directly in the heart or the aorta. If the original reading was erroneous he/she should take measures to secure reliable monitoring for the remainder of the operation and ask the anaesthetist to replace the monitoring catheter for reliable post-operative monitoring. Thus, the division of responsibility for this aspect of care may be again somewhat arbitrary.

### Cardiology

The cardiologist's input to the surgical procedure is usually limited to advice in situation when either an unexpected defect is found during surgery or if the planned operation is not tolerated by the patient and alternative solutions are sought.

### POST-OPERATIVE CARE AND ASSESSMENT (J - L)

The assignment of individual responsibility to intensivists (J), surgeons (K) and paediatric cardiologists (L) during the post-operative period is also difficult. The responsibility for various aspects of intensive care depends very much on the organisation of the Intensive Care Unit. In Bristol this organisation developed during the period 1984-1995 in a similar fashion to that of many other departments treating children with CHD. Initially, most aspects of post-operative care were dealt with by the surgical team, helped by the anaesthetists (ventilation) and cardiologists (diagnosis of post-operative problems). This changed gradually when specialist intensivists started to take over the role of surgeons and anaesthetists. It was the impression of our review group that the organisation and coordination of post-operative care in Bristol was sometimes sub-optimal. The fact that some of the consultant anaesthetists were apparently not aware that the surgical team followed protocols for post-operative care illustrates this point. Under such circumstances less than optimal care could be considered due to the overall organisation/management, rather than to the actions of an individual.

In general, the overall care, including feeding or parenteral nutrition, fluid balance, treatment of kidney failure, neurological complications, etc, would be the responsibility of the intensivist. Ventilation, weaning of the patient from the ventilator or the insertion or change of indwelling catheters would be the responsibility of intensivists or anaesthetists, while surgeons would be responsible for the chest drains, reopening the chest for bleeding, chylothorax, tamponade or mediastinal infection. Paediatric cardiologists would be responsible for the day to day cardiological assessment, including the diagnosis of any residual/recurrent defects (echocardiography or cardiac catheterisation would be the two main diagnostic techniques used).

**CONCLUSION**

The assessment of surgical care depends on a surgeon's own experience, information from presentations and discussions at conferences, information from the literature (which may sometimes be controversial) and awareness of the changes that took place between 1984 and 1995. The evaluation of care by expert groups should be interpreted with some caution. The complexity of many congenital heart defects will always lead to different approaches and different opinions. These may however be equally valid for the management of individual patients. One should also remember that even "experts" may be wrong.



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# Royal Brompton & Harefield NHS Trust

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25<sup>th</sup> February 2000

RECEIVED  
20 FEB 2000

Ms Una O'Brien  
Secretary to the Inquiry  
Bristol Royal Infirmary Inquiry  
2-10 Temple Way  
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Dear Ms O'Brien

Thank you for your letter of 4<sup>th</sup> February. I have read Mr Stark's comments about the Evaluation of Surgical Aspects of Care.

I believe Mr Stark's document to be an excellent account of the difficulties of evaluating each of the six elements of care. I agreed with virtually every comment that Mr Stark made in his document.

I would just like to make two brief comments:

Under 'Surgical Procedure' Mr Stark refers to the contribution/interaction of other members of the team (perfusionists, anaesthetists, assistants, nurses) during the operation. I believe that in many instances the interaction of members of the team is very difficult or impossible to evaluate from a retrospective view of the case notes and operation notes.

Under the same heading 'Surgical Procedure' Mr Stark points out the difficulty in judging whether the length of an operation was reasonable or excessive. In many cases this is true, but there were some instances when routine surgery was performed without encountering any particular difficulty where the length of the operation was such that it could have, or did have, an adverse effect on the outcome.

These are the only two comments that I wish to make about what I believe is a very clear, concise and comprehensive account of the difficulties faced during this exercise.

Yours sincerely

Darryl Shore FRCS  
Consultant Cardiac Surgeon

22.SEP.2000 17:50

BRI INQUIRY

NO. 914 P.2/4

BRI INQUIRY

**Department of Paediatric Cardiology****Dr E D Silove  
Consultant Paediatric Cardiologist**

Our ref: EDS/JMM/bristol/adequacy

15<sup>th</sup> March 2000**Ms U O'Brien  
Secretary to the Bristol Royal Infirmary Inquiry  
2-10 Temple Way  
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Dear Una

**Re: Adequacy of Care**

Having read the folder of reports you sent me, I thought it would be appropriate if I were to set out my perception of the way in which the aspects of care were assessed by the review team which I chaired.

You will recall that I was closely involved in the original design of the CCNR forms. I then conducted the pilot study together with Jarda Stark, Duncan Macrae, Carol Williams and Isabella Moore. When the pilot group first sat down, we discussed in some detail how we would set about the review and it is no coincidence that I agree completely with everything that was written by Jarda Stark. In particular, I would change nothing in his introductory first page other than to add that one of our problems was that the medical records were written as a part of patient management rather than for the purpose of a subsequent Inquiry.

I will go on to deal with Aspects of Care and will not repeat any of the comments in "Introduction and Methodology" of the "Preliminary Report on the CCNR". Under each heading I will indicate the clinical area of responsibility.

**Preoperative Care****A) Timing and Appropriateness of Initial Referral/Condition on Arrival  
(Responsibility - Referring Doctor)**

We assessed whether the recognition of a heart problem by the referring Neonatologist, paediatrician or GP had been appropriate or delayed, whether necessary supportive treatment had been given prior to transfer and whether the condition on arrival in Bristol might have been the same, better or worse with different preliminary treatment.

Continued overleaf... ..

**Re: Adequacy of Care****- 2 -****B) Clinical Assessment and Management  
(Responsibility - Cardiology Consultant)**

This included the initial clinical assessment by junior medical staff, the time taken to involve consultant staff and the early immediate management by the consultant.

**C) Accuracy and Completeness of Diagnosis  
(Responsibility - Consultant Cardiologist)**

We assessed the accuracy of the clinical diagnosis and the confirmation where appropriate by echocardiography and/or cardiac catheterisation and angiography. We took into account the technological limitations of the day. There was difficulty for the review team in that video tapes of echocardiograms and cine films of angiograms were frequently not available.

**D) Appropriateness of Initial Treatment Strategy  
(Responsibility - Consultant Cardiologist with input from Cardiac Surgeon)**

We assessed the decision taken by the Cardiologist and the timing of discussion with the Cardiac Surgeon. We then assessed whether the initial treatment/strategy met the standards that then applied. We considered that both the Cardiologist and the Surgeon were closely involved in the initial treatment strategy.

**E) Timing of Planned Treatment  
(Responsibility - as D)**

Very similar considerations were taken into account as in D above. We took into account that a patient on the waiting list might appropriately have the operation either brought forward or delayed, depending on the circumstances. We also related the timing of the planned treatment to the date of the cardiac catheterisation. The timing of the cardiac catheterisation was also part of this Aspect of Care.

**F) Immediate Preoperative Management including Nursing  
(Responsibility - mostly Nursing, but included Cardiologist)**

For elective surgery this aspect of care was hardly relevant. In the case of emergency admissions we considered that preoperative management might well have a significant influence on subsequent surgical results.

**Surgical Care**

Aspects G, H and I have been adequately discussed by Mr Stark.

Continued overleaf... ..

- 3 -

Re: Adequacy of Care

Post-operative Care and Assessment (J, K and L)  
(Responsibility ill-defined between Surgeon, Anaesthetist, Cardiologist, and to some extent, Nursing)

Before we commenced the Clinical Casenote Review, we had been unaware of the process of management in the post-operative Intensive Care Unit. During the review it transpired that the management was undertaken primarily by the anaesthetists and surgeons and that there was very little presence of Paediatric Cardiologists on the ICU. It was difficult for the reviewers to attribute specific responsibility and accountability for aspects of care other than ventilation, which is clearly the province of the anaesthetists. It was difficult to identify who was primarily responsible for taking the lead in the management, although it appeared for the most part to be the surgeon.

There appeared to be lack of experience among the nursing staff in caring for paediatric patients. There was very limited involvement of paediatric cardiologists in helping with the diagnosis or management of clinical problems. Our group considered that the intensive care management suffered from poor organisation and lack of teamwork.

Post-Mortem (M)  
(Responsibility - Pathologist)

We were limited by the post-mortem report and recognised that the heart and lungs had often been retained but were not available for inspection by our group. This was a problem in assessing the adequacy of the post-mortem. However, there did appear to be a lack of dialogue between the pathologists and the clinicians in attempting to get maximum information from the post-mortem.

Most of these comments are a repetition of earlier discussions and of comments by others, but I thought it would be helpful to try to pull them together for the purpose of setting about the Final Report.

Kind regards

Yours sincerely

Dr E D Silove  
Consultant Paediatric Cardiologist