

## **Key Issues in Retrospective Evaluation of Morbidity Outcomes Following Paediatric Cardiac Surgery**

### **Executive summary**

*Of the possible long-term complications of heart disease, brain damage has the most impact on child and family. Many open-heart operations for complex disease cannot be accomplished with current techniques without putting the brain at some risk. Late learning difficulties may be a reflection of brain damage, related for example to a period of circulatory arrest that the surgeon needed to achieve the cardiac repair.*

*There are many short-term complications of open-heart surgery in children; most complications increase the length of stay in ICU/hospital.*

*Retrospective short and long-term morbidity data are extremely time-consuming to collect from unstructured, paper-based records. Good quality morbidity studies require prospective planning and co-operation with specialists outside the field of paediatric cardiology/surgery; few exist.*

*Doctors do not see organisation of the collection of morbidity data as a priority task and may question its relevance to decision-making, especially when the early death of a child is the only alternative to surgery.*

*Two parallel universes have evolved for collecting diagnostic, procedural and mortality data. One provides 'process' data helpful to contracting and hospital administration; diagnoses and procedures are entered by coding clerks with virtually no clinical input. The other is administered by individual departments and specialist bodies and in principle is aimed at providing data by which professional standards can be scrutinised and to advance understanding of the risk factors for surgery by aggregating data. Neither collects morbidity data in a usable form.*

*As mortality rates fall, it becomes harder to discriminate the 'signal' of an outlier from the 'noise' of chance variation and the additional collection of short-term morbidity information would offer much to the process of monitoring standards.*

*Research is needed both to document the range of late problems postoperative children experience and to understand how and when best to inform parents about these.*

## **Introduction**

This report was commissioned to provide expert clinical advice to the BRI Inquiry about retrospective evaluation of morbidity outcomes. It is based on my personal knowledge and expertise. I am Dr Catherine Bull FRCP and I trained in cardiology at the Brompton, Hammersmith and Great Ormond St hospitals. From 1984-1999, I was Senior Lecturer and Honorary Consultant in Paediatric Cardiology at Great Ormond St Hospital. For the past year I have left paediatric cardiology but work as 'Medical Advisor to Family Services' at the same hospital. I have a clinical and academic interest in long-term follow-up studies and their implications for contemporary decision-making.

### **1. Morbidity: what it means and why some perspective on morbidity is needed.**

#### 1.1 Terminology

Doctors use the term 'morbidity' to contrast with a complication-free recovery to a normal state. Cardiac surgery has cardiac outcomes with effects on longevity and quality of life that vary from trivial to severe; very few heart operations are 'corrective'. The long-term non-cardiac complications of open heart surgery in children include a variety of problems under the heading of 'brain damage' or 'learning difficulties', problems with the mechanics of breathing (diaphragm palsy, tracheal and chest wall problems) and the psychological consequences of the disease and its treatment on child, siblings and parents. There are also many short-term complications, which may increase length of stay in intensive care or in hospital including infection and respiratory problems; often these are not associated with long-term sequelae. As in natural language, the medical use of a term does not necessarily mean that it has been unambiguously defined.

#### 1.2 Reasons why perspective on morbidity is needed

The Inquiry may require some context information about the morbidity of open-heart surgery for several reasons:

- It may wish to consider how morbidity data, if available, could be used for statistical monitoring.
- Some context about prevalent morbidity rates should also inform consideration of the issues surrounding the discussions of operative risk. Doctors, parents, the BRI Panel and the legal profession will all have views on what should be included in such a discussion and this might reasonably depend on both dreadfulness of the complication and the estimate of the risk of it happening. The estimate of the risk of a complication might itself be a guess or based on local or national audit data, or published data.
- The paucity of discussion about morbidity in the statistical material does not imply a lack of recognition of or respect for the experience of parents bringing up a disabled child, but it does reflect a lack of a certain formal sort of data. The Inquiry may also consider whether the dearth of information is meaningful in terms of how the specialty of paediatric cardiology/surgery operates.

*1.3 For a variety of reasons, the Inquiry needs some more information about morbidity after cardiac surgery in children.*

## **2. The published literature**

### 2.1 Long-term sequelae: Information in the published literature

There follows a very brief review of the issue of brain damage after open-heart surgery in young children; this is not a comprehensive or tightly researched section.

#### **2.1.1 Background**

It is astonishing, considering that much open-heart surgery in infants requires that the child's entire circulation is stopped completely or grossly slowed down for as much as an hour at a time, that the majority of children seem to emerge with no adverse neurological consequences. However, depending on *how* you look (by detailed scans and tests or by simple parental or medical observation) and *when* (in the early aftermath of surgery or much later when things have stabilised) a varying proportion of children *do* suffer from temporary or permanent neurological injury (seizures or movement disorders) or disorders of higher cortical functioning such as mental retardation or learning disabilities.

To assess how commonly brain damage occurs and understand the range of severity involved, ideally we need to identify a large cohort of children, unselected as having a particular problem and follow them up for a long time. In the nature of a fast-changing medical environment, by the time long-term studies are complete they may be rendered less relevant by changes in patient population and in surgical procedure. This may go some way to explaining why such studies do not currently exist. From a scientific point of view, assessing a cohort of operated children fairly early after surgery has the advantage of relevance (eg to assessing alternative techniques for cerebral protection during surgery) but the disadvantage that the findings may have limited predictive validity for understanding how the deficits will impact on a child's prospects for future education and independence. There is also an issue of specialism; the preoperative and early postoperative assessment is the domain of paediatric neurologists and neuro-physiologists. Later assessment is also the domain of educational psychologists, physiotherapists and other allied professions. Paediatric cardiologists and surgeons have few of the relevant skills themselves.

#### **2.1.2 Co-morbidity**

The incidence and severity of brain damage around the time of surgery is not completely haphazard and not all children with heart disease even approach surgery with good prospects for normal brain function later. Some are very sick during labour and after delivery. For some children, their heart disease is only one manifestation of a bigger problem that may have been genetically programmed (e.g. the situation in Down's syndrome with atrio-ventricular septal defect). When a syndrome is recognised, it is also more difficult confidently to attribute late abnormality to peri-operative events, partly because so many started off with

some neurological abnormalities and partly because knowledge of the developmental milestones of children with syndromes is more sketchy.

There are also cardiac diagnoses (for instance, coarctation, interrupted aortic arch and hypoplastic left heart, Fallon 1995) which are not related to syndromes but which seem particularly prone to postoperative neurological complications. Some of these complications may not be avoidable with current techniques and understanding. In 'left heart syndromes', the fetal brain arteries do not develop in a normal pressure and flow environment and later may not accommodate stress well. Also managing surgery when blood flow to the brain and lower body cannot both be optimal at the same time is very challenging.

### **2.1.3 Cerebral protection.**

To open a very small heart and operate inside requires it to be clear of tubes and empty of blood. For the duration of this part of the operation, a heart-lung machine circulates cooled blood around the rest of the body to protect it from the consequences of lack of heart-beat. However for parts of many of the operations carried out in infancy, even the blood flow that the machine delivers has to be cut down drastically to stop the operative field inside the heart flooding with blood. Though methods of cerebral protection during this no-flow (circulatory arrest) or low-flow time are evolving, there is an undoubted cerebral insult that will generally increase the longer the brain is without blood. If the heart is to be repaired, there seems no current way out of this impasse. We can only seek to understand and perhaps extend the limits of recovery of the brain and hope to work within them. The sort of studies that have been done in animals to ascertain the duration of circulatory arrest that is safe (the period during which no irreversible brain damage occurs) cannot be performed in humans. However, cohort studies (eg. Bellinger 1995) are consistent with the hypothesis that a period shorter than 35 minutes (at 18°C) has a minimal effect on a child's developmental indices one year later. The science of 'damage limitation' is evolving but may not be perfectible. Almost all studies of neurological outcome are able to demonstrate that the longer the period of circulatory arrest the higher the proportion of children with long-term discernible brain damage (Bellinger 1995). The duration of circulatory arrest will depend mainly on the anatomy to be 'fixed' but also the speed of the surgeon. Not all infant heart operations can be completed in under 35 minutes of circulatory arrest time.

### **2.1.4 Useful studies**

Some useful studies exist: A UK paper (Fallon 1995) reviewed 523 cardiac surgical discharge summaries. The authors found that some adverse neurological event (seizure, abnormal stiffness, involuntary movements, coma or visual deficits) was recorded in 31/523 (6%) of the records. Eight of the patients with neurological problems died and 4 of the 23 survivors were lost to long-term follow-up. Of the 19 affected survivors, 4 seemed to have recovered completely with no discernible late problem but 15 (3% of the survivors of open-heart surgery) had persisting neurological problems. In 9 of the 19 patients, neuro-developmental abnormalities documented *pre-operatively* probably contributed to the ongoing neurological deficit, as well as *peri-operative* events. The main correlates of adverse neurological outcome were longer circulatory arrest time during operation and experiencing a period of very low

blood pressure (mean arterial pressure < 40 mm Hg) either during operation or postoperatively. Because of the nature of study (retrospective examination of notes), the authors believe that the picture they paint is of the *minimum* incidence of neurological events in patients undergoing cardiac surgery.

An important American study funded by the National Institute of Health (Bellinger 1995) studied 155 babies one year after an arterial switch operation for transposition with or without ventricular septal defect. Of the cohort, 6% had had obvious seizures in the post-operative period but none had had any since discharge. Paediatric neurologists examining the children carefully at one year, found that 34% had a discernible abnormality, all judged to be mild. Most commonly observed were abnormalities of tone (floppy or stiff); 5% had cerebral palsy and 1% had abnormalities of vision or hearing. At least 15% of the children had abnormalities on a brain MRI scan, mainly mild. Developmental assessment of one-year old babies relies on specialist experience and can obviously only test a limited range of intellectual and motor functions; the results are expressed as scores. Since the characteristics of the corresponding normal population of one-year olds is known, a score can be defined below which you would expect to find only 2% of normal babies (2SD below the mean). When psychomotor scores of operated patients were assessed, it was found that 20% of the transposition babies were performing at a level worse than 2 SD below the normal mean. Mental Development indices at this age are also available and 6% of babies tested had scores worse than 2SD below the below the normal mean. More complicated operations (TGA+VSD), longer circulatory arrest time and early post-operative seizures were predictive of worse scores later. Assessment at one year of age may have limited predictive value and retesting of these children as they approach school age may give a better idea of how well the children will function academically, but we can presume that though many will be indistinguishable from normal, that the 'average' of the group as a whole will be shifted below normal.

Another American study (Miller 1996) *has* performed neurological and psychometric examinations on 104 consecutive children who had all sorts of open-heart surgery 1987-9 when they were old enough for IQ testing. Cerebral palsy of some degree occurred in 22%. The mean IQ for the group was 90 and 22% had scores below 70. A lower IQ was associated with more behavioural and emotional problems in children and adolescents with congenital heart disease in a study of 323 Dutch children late after 'correction' of congenital heart disease. Some appraisal of cognitive development is becoming a more common feature of long-term follow up studies of children with particular diagnoses or operations. For instance of 133 patients studied after a Fontan procedure, the mean IQ was 95 ( $p < 0.006$  versus normal) with 8% having IQ < 70 (Wernovsky G 2000).

Without open-heart surgery, children can still have schooling problems, related mainly to their uncorrected heart disease but sometimes to palliative surgery. Among other studies documenting the developmental and educational handicap associated with uncorrected heart disease is a N Ireland study by Casey et al 1996. These authors contrasted the behavioural adjustment at school of 26 cyanotic children with palliated complex congenital heart disease

with 26 children with innocent murmurs. Only 62% of the children with complex heart disease were attending school full-time and both teachers and parents rated the children with heart disease as being more withdrawn than children with innocent murmurs.

There are no studies associating particular profiles of learning difficulties with previous heart operations. There are no studies explicitly discriminating 'avoidable' from 'unavoidable' brain damage but the implication of much of the literature is that, even with best practice, there is inevitably some trade-off between repairing a complex heart problem and inflicting some damage on the brain. The children with profound motor and cognitive disabilities are only the tip of an iceberg of children with more minor difficulties.

### **2.1.5 Other long-term sequelae**

There is extensive information from long-term studies about longevity and cardiac well-being after surgery for a variety of lesions. These are difficult studies to undertake because patients may be lost to follow-up, especially as historically their care was often dispersed at adolescence. The management of some conditions has changed radically in the past 20 years, so these studies often do not reflect the outlook for current patients.

### 2.2 Short term complications: information in the published literature

Children emerging from a cardiac operation are vulnerable to countless possible complications. They arrive in an intensive care unit with varying magnitudes of trauma to their hearts, brains, lungs and kidneys and the whole goal of intensive care medicine is to manipulate conditions so that the body can recover without further complications arising. Often treatment aimed at supporting one organ can leave another organ vulnerable to problems –e.g. ventilatory support relieves the heart and chest-wall of much of the work of breathing but makes the lungs vulnerable to infection.

There is a large published literature on the incidence of particular complications observed in the ICU, mainly single-centre studies. Most complications have no long-term implications for the patients, but some do and a few follow-up studies are available. Because most complications impact on the duration of intubation or length of stay of the patient and because multiple complications very often summate, duration of intubation/ventilation/ICU/hospital stay have themselves become a sort of index of the smoothness of the postoperative course. These summary indices are useful for monitoring performance or cost rather than being of intrinsic interest to parents of children undergoing surgery.

Because the 'case-mix' admitted to paediatric ICUs is so varied, the Intensive Care community has approached the monitoring of standards using statistical models (e.g. PIM, PRISM, APACHE, Shann 1997, Jones 2000); these attempt to adjust mortality rates for the variability in the profile of admissions to the units. This is required to discriminate 'bad' units that handle straightforward patients poorly from 'good' units that may have worse mortalities and lengths of stay but sicker patients. This philosophy has required extensive work to prepare and maintain the statistical models but is beginning to pay dividends in terms of standard

setting. To date, these models have used adjusted mortality rates for between-centre comparisons, but length of stay data will be the next outcome to be addressed.

### 2.3 Causation

In the face of all this complexity involving pre, intra and postoperative factors, it is clear that seeking out a single cause of a complication is often not realistic. Even when an event like a post-operative cardiac arrest apparently accounts for a complication like brain damage, the arrest itself is only part of a chain of causation which may lead back to a whole set of conditions preceding it. The search for a cause has an agenda of its own; if an agenda requires a single cause then a 'best guess' single cause can often be found and argued. If the agenda is to understand 'causation' more generally, it will seek to understand the conditions more generally. Data can help to some extent with either exercise but the process of using it will be more transparent and appropriate if the question is clarified.

*2.4 There is quite a rich literature on short-term complications of open-heart surgery in children; most complications increase the length of stay in ICU/hospital. The literature on long-term mortality and cardiac well-being is rather more sparse. There is even less data on long-term non-cardiac morbidity.*

## **3. Why is there so little published morbidity information of use to parents, referring doctors or purchasers?**

Though an enormous amount is known about apparently abstruse details of ventricular diastolic function or the anatomy of the coronary arteries in transposition, it may seem surprising that the paediatric cardiology/surgery community do not know what proportion of their patients have learning difficulties after surgery. The absence of certain sorts of information may reflect something about the mechanics of the specialty or the doctor-patient relationship.

### 3.1 Prioritisation of research objectives

Firstly, morbidity information is very difficult to obtain. 'Death' is unambiguous but 'morbidity' terms have not always been unambiguously defined. Information is not collected according to a protocol and is recorded in paper notes that exist as a medium for doctors to communicate with each other, rather than as a resource for research or audit. The skills of someone doing retrospective research in this area are more akin to those of an historian or biographer than a scientist and the process is very tedious. As a generalisation, specialists-in-training would prefer to spend the time they have available for research on more 'scientifically sexy' topics. To some extent, this also reflects the kind of research that the specialist community rewards. Many medical journals mirror this attitude, prioritising 'new knowledge' over clinical information in their allocation of space. Research funding for large projects amassing and making sense of clinical information is very hard to obtain from charity-based funding bodies and centrally resourced research funds tend reasonably to prioritise fields of medicine used by large numbers of patients.

### 3.2 Who can research long term non-cardiac morbidity?

Secondly, none of the professionals caring for a child is ideally placed to answer many questions about risk of late sequelae. This is because of the way the specialty works. Surgeons' impressions of the incidence of brain damage after surgery are gained mainly from observing their own patients' course in hospital; they do not follow patients up long-term. Cardiologists follow up all the patients operated by the surgeons in their unit, but concentrate on their cardiac status. Neurologists based in the specialist hospital see patients in difficulty early after operation but do not see those that seem well. Because cardiac care is centralised, non-cardiac specialist care is usually based with a paediatrician nearer the families' homes. It is local General Paediatricians and general practitioners who organise most of the support that families of disabled children need and best understand the impact on the family - but no individual doctor sees many such patients. Though all these doctors will usually send copies of the letters about the children involved to all the other doctors, it would not be at all surprising if they each gave different answers to a question like 'what is the prevalence of learning difficulties in childhood survivors of open heart surgery?' Their guesses about many other complications of importance to the child's future quality of life will also vary.

### *3.3 Morbidity studies require cooperation between parts of the medical profession*

## **4. Is guessing justified?**

### 4.1 Doctors have guessed at complication rates

Paediatric cardiologists and surgeons clearly have been reasonably comfortable with guessing about complication rates when questions have come up from parents or other professionals. Given the debate about what parents of children who are heading for cardiac surgery are told about complications, this may be rather surprising. All sorts of people, including 'risk managers' and the legal profession have views about the information content of these crucial conversations and may feel that detailed cataloguing of complications is the way to go. However, it is important to be realistic about what information parents facing a very emotionally-intensive decision need and can cope with. In practice, compared to the mortality estimate, the estimates of complication rates may seem of very secondary relevance.

### 4.2 Comparison with neonatology

Neonatology is a branch of paediatrics dealing with extremely premature babies. The EPICure study evaluated all UK babies born at 25 or fewer weeks of gestation in the UK for 10 months in 1995 (Wood 2000). Half of the children died and half the survivors had serious disability from cerebral palsy, chronic lung disease or blindness. Most parents facing the imminent delivery of a very premature infant are given this dismal information that is based on good quality data and most still ask that attempts be made to resuscitate the baby after delivery (Rennie 1996). This may surprise some people who have not themselves been faced with such a terrible decision.

Many decisions surrounding cardiac surgery in children have some similar qualities - often the cardiologists or surgeons can realistically say that the child will die without surgery. Very

few parents of babies with transposition will even think of declining a switch operation on the basis of a complication rate – whether this is guessed or based on local or national data. I believe - but cannot support with evidence - that it is because of a perception of the primacy of mortality information in influencing decision-making that paediatric cardiologists and surgeons feel less impelled to obtain detailed information on complication rates. They are also comfortable with terms like 'occasionally' or 'rare' or are prepared to guess at a number in discussion with parents.

It is fair to say that though some studies about communication of risk information are available in adult medical practice, there are few studies relevant to the decision-making tasks and their emotional context in paediatrics. This may be an area of research where collaboration from the commissioning stage between researchers and parents who have gone through the experience could be very useful. We also do not know the level of morbidity risk at which parents would reconsider the decision to go ahead with surgery. By analogy with extreme prematurity, this is probably much higher than the rates of morbidity seen after paediatric cardiac surgery.

*4.3 Short and long-term morbidity data are extremely time consuming to collect retrospectively. Doctors do not see this as a priority task. Negotiating with parents about an operation to avert the death of a child is very difficult and information-overload can confuse.*

## **5. Audit data.**

### 5.1 Local

Audit exercises tend to look at complications of surgery emerging in hospital (infection, phrenic nerve palsy, fits, length of intubation, ICU stay etc). They examine the frequency and profile of their occurrence and try to understand the determinants of the complications in local practice. To complete the audit loop, some change in practice follows and hopefully some decrease in incidence of the complication is observed. Some UK single-centre audit exercises doubtless exist, but there is no general mechanism for these to be disseminated outside their base-hospital. Such studies are rarely published in peer-review journals. Many hospitals have evolved paper-based or computer databases independent of their hospital PAS systems to use in these audit exercises.

### 5.2 National

National data collection about morbidity, conducted to a standard, has not happened in the UK, though it is emerging elsewhere in Europe. Definitions and standards are important if comparisons are to be made. Though 'Central Nervous System complications' were mentioned in 1.6% of admissions with an open procedure in UBHT (4 times more than elsewhere), the statistical experts to the BRI Inquiry were not able to unconfound this with UBHT's generally higher quality of ICD-9 diagnostic information input to HES than elsewhere.

### **5.2.1 HES: past and present**

Submissions to HES about morbidity are dependent on coding clerks who aim to work to rules and conventions with regard to coding; they do *not* code every single setback and inevitably vary in where they stop adding more complications. They have to use paper records that are not configured as documents amenable to retrospective standardisation. Long-term data (derived for instance from out-patient follow-up visits) is not captured. There is no method for automatically recording death outside a hospital. HES holds data using the ICD-10 coding system for diagnosis and OPCS-4 for cardiac surgery and both have the reputation for describing the detail of the modern paediatric cardiological specialty poorly. However, there has been no initiative (perhaps until the Inquiry) to simply dispense with the detail and 'lump' diagnoses under relatively few high-level ICD-9/10 or OPCS-4 codes. This would have required co-operation between administrative and clinical staff and probably also reflects the fact that the input data has never been put to any real use – a 'data graveyard'. Though the BRI Inquiry has been able to commission such an exercise, no statistical analysis of HES data useful to the specialty or its patients or referring doctors (and which could prove an incentive to facilitating good data entry) is usually offered. Essentially HES has been used as an arm of administration rather than a clinical tool. Because there is no record linkage across NHS hospitals nor linkage to national death records, electronic tracking of patients as they move out of the specialist centre is not available in England and Wales. It would be impossible to conceive a strategy for documenting through NHS records the outcome of a child who was admitted to hospital A where congenital heart disease was diagnosed, discharged to hospital B and who died at home.

### **5.2.2 Hospital departments and specialist organisations: past and present**

Historically several hospitals prepared their own lists of diagnoses/operations for internal audit purposes, often borrowing parts of the lists of other hospitals or organisations and customising them. More recently there has been impetus for departments to cooperate under the umbrella of the various professional societies around the UK, Europe and the USA because these - working independently of HES and administrative data - have been preparing, piloting and trying to implement database-based monitoring systems. To appreciate the variety and relationships of these societies to each other, the Trusts and NHS bodies entails understanding a web of professional politics. All the organisations have to balance different professional objectives, different budgets and have varying degrees of support from the non-enthusiasts in their areas. They vary in how much they prioritise cooperation with other bodies working in this area against 'getting their own house in order'. However undoubtedly a momentum for improvement has been built up within the specialty.

No database that I am aware of uses *diagnosis* of congenital heart disease as the entry criterion; HES uses hospital admission and the specialist databases use an operation or other intervention as an indicator of which patients to capture. Thus, until they have an intervention, patients tend not to be admitted and to be invisible to the systems. Children who die preoperatively are hard to account for – though this may be important in some studies of outcomes (Bull 2000). For example it is not possible to use data from HES or any other database to establish the proportion of patients with Down's syndrome and congenital

heart disease who do *not* have surgery for comparison with those with similar heart disease but normal chromosomes.

No specialist organisation that I am aware of uses the ICD-10 or OPCS-4 lists and most have drawn up their own coded lists. These may be very long and able to capture rich detail or short, lumping similar diagnoses or operations together. Use of the coded data both at input and at extraction for analysis also requires a 'rule base' – e.g. if a child who has had three operations in quick succession dies, a rule may be used to attribute the death to the first operation – or the last! Some organisations e.g. EACTS (European Association of Cardio Thoracic Surgeons) have added some morbidity-related fields to the minimal dataset that is (in principle) collected on every child having a procedure done by a member of the respective organisations. These include duration of positive pressure ventilation and length of stay as well as fields for logging complications.

### **5.3 Advantage of monitoring with morbidity data.**

However, an advantage of collecting some sort of non-mortality data for monitoring purposes has been recognised. As mortality rates decrease, it is more difficult statistically to discern the 'signal' of an outlier from the 'noise' of chance variation. For instance, if 'average' long-run mortality rate for a class of operation is 2%, then a centre operating with a long-run average mortality of 4% will only be discernible if the number of patients in this class is enormous. This is not a feature of the field of paediatric cardiology/surgery. If we assume for monitoring purposes that low mortality and morbidity rates are both proxy for 'excellence', we could choose one or a combination of morbidity outcomes so that the incidence of 'death or complication' is around 20%. An example might be 'death OR ventilation for >3 days OR fits requiring anticonvulsants'. If average 'death or complication rates' are 20%, then an outlier with rates of twice the average will be confidently identified after a moderate number of operations. This tactic has already been incorporated in some studies under the 'keyword' of 'near-miss' (de Leval 2000). I believe that this is the best rationale for improving standard data collection in the area of morbidity.

*5.4 Two parallel universes have evolved. One provides 'process' data helpful to contracting and hospital administration; diagnoses and procedures are entered by coding clerks with virtually no clinical input. In principle, the other is aimed at providing data by which professional standards can be scrutinised and to advance understanding of the risk factors for surgery by aggregating data.*

## **6. What would have to be in place for the information to improve?**

The specialty cannot go back to an era when comparative monitoring of outcomes between centres was not available at all. *Some* information has to go into the public domain. Some scrutiny for poor performance *has* to occur on the basis of data. This could be either as 'league tables' which will pick up outliers *or* as some sort of accreditation system which allows parents, purchasers and referring doctors to conclude that a centre is 'at least as good' as

some standard. Because – thankfully – mortality rates are now low for many operations, either exercise will do its job better if some morbidity data is included.

Undoubtedly if we were starting from scratch, the administrative and specialist monitoring ‘universes’ would be integrated. However, this does not necessarily mean that they should be immediately merged – it may be better to await progress on patient tracking and the electronic patient record. Meanwhile, each ‘universe’ could be put under pressure to deliver to its strengths.

## 6.1 HES and Hospital PAS systems

### **6.1.1 Improving the HES patient record**

Without tinkering much with the way things are done, the HES ‘system’ could be reengineered to feedback more useful data. Some collaboration with the specialty nationally would provide a small ‘minimum dataset’ on each patient. This would include ICD-10/OPCS-4 diagnoses/operations (probably ‘lumped’ into 4 – 12 categories and entered according to a hierarchical ‘rulebase’), morbidity data (with explicit definition of terms – eg ‘fits’, ventilation for more than 3 days) and length of stay (already available in principle). The ICD-10/OPCS-4 codes are not used to any great level of detail; the specialty could easily specify a very small subset of codes and a set of riders and rules for their use. The cardiac department and coding clerks of each Trust dealing with children with congenital heart disease would then have to agree how best to input to this standard – e.g. the medical staff might offer to fill in a paper proforma. In this way each Trust would be in a position to provide comparable data. Data coming from every patient across centres would then have to be aggregated, again using a rule-base agreed in advance with specialist knowledge so that an analysis appropriate to a report in some pre-agreed format could proceed. A professional body, some Public Health body or some other arm of the NHS could in principle, do the analysis. This is not an unreasonable goal.

### **6.1.2. Patient tracking**

The HES ‘system’ could improve the information returned to the specialty and its patients by organising patient tracking (by NHS number) and by linkage to national mortality data. In principle, this could then underwrite long-term follow up studies which would be much better than anything we have now. This functionality could then be used as a Registry for patients who have been admitted with congenital heart disease. This functionality has been achieved in Scotland for years.

## 6.2 Specialist databases

### **6.2.1. Role in monitoring professional standards**

Databases maintained by specialist bodies are in principle more versatile than the HES data, because they contain more fields and use codes that correspond better to the language of the modern specialty. As it organises itself under the scrutiny catalysed by events in Bristol, the specialty is, in principle, in a better position to define standards of adequacy and to address outliers – though their track record in this area is one of the subjects of the Inquiry. They could require that to be ‘accredited’ to look after children with congenital heart disease, a

centre should have organised access to its own data (specifying some minimum standard) and would submit specified data for central analysis and would cooperate with further scrutiny if the submitted data triggered anxiety.

#### **6.2.2. 'Benchmark' conditions**

In principle, for monitoring standards it is not absolutely necessary for every patient to be accounted for. Specified mortality and morbidity outcomes on a smaller subset of carefully defined 'benchmark conditions' chosen to range in severity may be adequate and would be much less time consuming to collect (Stark 2000). The professional bodies do not have budgets that can sustain collection, checking and analysis of huge datasets; I pay £25 per year to belong to 'my' professional body, the BPCA. The professional bodies cannot sustain a massive monitoring exercise on present budgets.

#### 6.3 Looking further forward: doctors and computers.

Radical improvement in the information environment awaits the creation of templates for electronic patient records and making changes in the way medical and non-medical hospital staff use records. If a well-configured electronic patient record is used prospectively in the process of care, capturing morbidity and 'process' information, many problems disappear. The concept of forwarding an anonymised subset of the EPR for central statistical analysis then becomes feasible. However, this will require that doctors do this aspect of their work in a formalised way and to a standard; in practice this means that they should be prepared to use a computer. This awaits a change in attitude. As a generalisation, doctors have not invested much effort in the EPR concept and many have poor keyboard skills and low 'computer literacy'. As hospitals come to rely more on electronic records, hospital computer and network infrastructures will have to improve and corresponding IT support be provided. Many clinicians have negative experiences of computing in hospitals; hopefully attitudes will change as systems are made to work.

#### 6.4 Future research: Generating and using outcome information helpful to non-specialists, including parents.

##### **6.4.1 Follow-up minimum dataset.**

The short-term morbidity outcomes that are useful for monitoring standards are not the outcomes of most interest to parents. Parents will be most concerned about the long-term impact of surgery on their child's life and perhaps on some short-term complications that might serve as predictors of late problems. In practice, parents would be most helped by statements of the probability of their child reaching certain 'milestones' by a certain age: e.g. the probability of the child being to walk independently by age 2 or read his name by age 5. Such indices were used in a study about quality of life in surgically palliated complex congenital heart disease from N Ireland (Casey 1994). An initiative in cooperation with the area of developmental paediatrics and with a focus on transparency to parents might fill this gap. A standard minimum dataset has already been suggested for the follow-up of prematurity (Johnson 1997). A 'snapshot' of the abilities of 5 and 10 year olds against which cohorts of children who had a difficult early history could be compared might be used by many paediatric specialties. Research money would be needed to close this gap.

#### **6.4.2 Risk conversations**

Doctors, lawyers and risk managers all have audiences for their views on the content of risk discussions but, at least until this Inquiry, it has been harder to know the breadth of views of parents. It is the parent's needs that are paramount. Many doctors will testify that the more urgent the conversation and the higher the stakes, the greater the proportion of parents who say something along the lines of 'do what ever you think...'. Risk information for childhood heart surgery is conveyed in a very emotive context. We know that parents appreciate time, empathy and clarity, but 'good practice' from the parents' perspective is not well documented, appreciated or honoured. The issue of information-overload by detailed morbidity data is part of this issue. The area is amenable to research.

*6.5 Short-term morbidity as well as mortality information must be collected, aggregated and understood by the specialty. The HES/administration data could be used to a standard of collection and analysis and the professional bodies could hope to demonstrate their ability to scrutinise professional standards on a smaller set of 'benchmark conditions'. Research is needed both to document the range of late problems the children experience and to understand how and when best to inform parents about these.*

Dr Catherine Bull

Medical Advisor to Family Services Department, Great Ormond St Children's Hospital Trust  
(1984-1999 Senior Lecturer and Honorary Consultant Cardiologist, Great Ormond St).

November 2000

## References.

- Bellinger DC, Jonas RA, Rappaport LA et al. *N Engl J Med* 1995; 332:549-55  
Developmental and neurologic status of children after heart surgery with hypothermic circulatory arrest or low-flow cardiopulmonary by-pass.
- Bull C, Yates R, Sarkar D, Deanfield J, de Leval M. *BMJ* 2000 320;1168-1173  
Scientific, Ethical and Logistical Considerations in Introducing a Novel Operation: a retrospective case study from paediatric cardiac surgery.
- Casey F, Craig BG, Mulholland HC. *Arch Dis Child* 1994 70: 382-386  
Quality of life in surgically palliated complex congenital heart disease
- de Leval MR, Carthey J, Wright DJ, Farewell VT, Reason JT. *J Thorac Cardiovasc Surg* 2000 119: 661-72  
Human factors and cardiac surgery: a multi centre study
- Fallon P, Aparacio JM, Elliott MJ, Kirkham FJ. *Arch Dis Child* 1995. 72: 418-422  
Incidence of neurological complications of surgery for congenital heart disease
- Johnson A. *Arch Dis Child* 1997 76:F61-63  
Follow up studies: a case for a standard minimum data set
- Jones GD, Thorburn K, Tigg A, Murdoch IA. *Intensive Care Med* 26: 145  
Preliminary data: PIM vs PRISM in infants and children post cardiac surgery in a UK PICU.
- Miller G, Tesman JR, Ramer JC, Baylen BG, Myers JL. *J Child Neurol* 1996 11; 49-53.  
Outcome after open-heart surgery in infants and children.
- Rennie J. *Arch Dis Child* 1996 74:F214-218  
Perinatal management at the lower margin of viability
- Shann F, Slater A, Wilkinson K. *Intensive Care Med* 1997 23:201-7  
Paediatric index of mortality (PIM): a mortality prediction model for children in intensive care.
- Stark J, Gallivan S, Lovegrove J, Hamilton JR, Monroe JL, Pollock JC, Watterson KG. *Lancet* 2000 355; 1004-1007  
Assessing mortality rates after operations for congenital heart defects and Surgeon's performances from five UK centres.
- Utens EM, Verhulst FC, Mijboom FJ et al. *Psychol Med* 1993 23:415-424  
Behavioural and emotional problems in children and adolescents with congenital heart
- Wernovsky G, Stiles KM, Gauvreau K et al. *Circulation* 2000 102:883-9  
Cognitive development after the Fontan procedure
- Wood NS, Marlow N, Costeloe K, Alan T, Wilkinson AR. *N Engl J Med* 2000, 343: 378-384  
Neurologic and Developmental Disability after Extremely Preterm birth.
- Wright M Nolan T. *Arch Dis Child* 1994 71:64-70  
Impact of cyanotic heart disease on school performance